Effective Health Care Program

Comparative Effectiveness Review
Number 88

Evaluation and Treatment of Cryptorchidism

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Evaluation and Treatment of Cryptorchidism

Structured Abstract

Objectives. We assessed the effectiveness of imaging for identifying and correctly locating testicles, the use of hormonal stimulation for treatment planning and hormones for achieving testicular descent, and choices among surgical treatments, including surgical approach (open vs. laparoscopic).

Data sources. We searched MEDLINE® via PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Embase, as well as reference lists of included studies.

Review methods. We included studies published in English from January 1980 to February 2012. We included studies of prepubescent males with cryptorchidism. For treatment planning studies, we included all designs except case reports. Imaging studies needed to have confirmatory surgical data. For treatment studies, we required an appropriate comparison arm. We excluded studies of disorders of sexual development or ambiguous genitalia. Two reviewers independently assessed the quality (risk of bias) for each study and the overall strength of the evidence, with discrepancies adjudicated by a third reviewer.

Results. We identified 60 unique studies meeting our review criteria; eight were of good, eight were of fair, and 44 were of poor quality. The accuracy of imaging to identify the presence or absence of testicles was 21 to 76 percent for ultrasonography (US), 42 to 92 percent for magnetic resonance imaging (MRI), 60 percent for computed tomography (CT) scan, and 100 percent for magnetic resonance angiography (MRA) and magnetic resonance venography (MRV). Both US and MRI failed to identify most cases of atrophied testicles. Two studies for a total of 44 boys accurately predicted anorchia using hormonal stimulation testing. Hormonal treatment is associated with testicular descent in some children, but rates generally do not exceed those seen with placebo by more than 10 percent. Surgical treatment for cryptorchidism is associated with success rates of testicular descent that range from 33 percent to 100 percent, depending on type of surgery. Weighted averages of success were 78.7 percent for one-stage Fowler-Stephens, 86 percent for two-stage Fowler-Stephens, and 96.4 percent for primary orchiopexy.

Conclusions. The body of the reviewed literature on cryptorchidism comprise primarily fair- and poor-quality studies, which limits our ability to draw definitive conclusions. No specific imaging technique is able to completely identify anorchia or position of the undescended testicles and thus eliminate the need for further surgical evaluation. Accuracy of imaging is related to location of the testicles, with less invasive methods demonstrating poor accuracy for abdominally located testicles and those that are atrophied. Hormonal stimulation testing may predict anorchia, but evidence is insufficient, with only two studies of fewer than 50 participants. Hormonal treatment is marginally effective relative to placebo, but it is successful in some children and has minimal side effects, suggesting that it may be an appropriate trial of care for some patients. Surgical options are effective, with high rates of testicular descent (moderate strength of evidence for Fowler-Stephens procedures, high for primary orchiopexy). Comparable outcomes occur with laparoscopic and open approaches.

Contents

Tables

Figures

Appendixes

Executive Summary

Background

Cryptorchidism is a congenital condition in which one or both testicles are not appropriately positioned in the scrotum at birth and cannot be moved into the proper position manually. The term "cryptorchidism" literally means "hidden testicle" and is often used interchangeably with the term "undescended testicle."[1] It affects an estimated 3 percent of full-term male neonates and up to 30 percent of premature male infants, making it the most common male genital anomaly identified at birth.[2,3] The etiology of cryptorchidism is not well understood, and the undescended testicles may be palpable or nonpalpable. The undescended testicles may be present in the abdomen, in the groin area, or misplaced in the scrotum. In some cases they are viable testicles, but in others they have atrophied and are no longer viable. Finally, in some individuals no testicle exists at all (anorchia).

Cryptorchidism is often apparent to parents, and examination for the condition is part of general pediatric care. Therefore, boys with cryptorchidism are usually identified early in life, often within the first year. Clinical decisionmaking about treatment is influenced by many factors, including whether or not the testicle is palpable, whether the condition is present unilaterally or bilaterally, the age at presentation, and coexisting medical conditions. In boys under 1 year of age whose testicle is palpable and is close to, but not quite inside, the scrotum, it may be difficult to distinguish between "true" cryptorchidism and a retractile testicle. In this case, health care providers often elect to observe the patient's condition until he is 1 year old.

Although about 70 percent of cryptorchid testicles spontaneously descend within the first year of life, the number of boys with persistent undescended testicles remains constant at approximately 1 percent.[4,5] Between 1992 and 2000, there were more than 600,000 physician office visits among males under age 18 for which cryptorchidism was the primary diagnosis (96 per 100,000 visits).[2] Once cryptorchidism is diagnosed, treatment choices may include watchful waiting, hormonal treatment, or surgery. Decisions about which clinical pathway to follow may be guided by results of hormonal stimulation testing and/or imaging, particularly when the testicle is nonpalpable.

The purpose of hormonal stimulation testing for bilateral nonpalpable cryptorchidism is to determine if viable testicular tissue is present. Specifically, if a boy has nonpalpable testicles, hormones such as human chorionic gonadotropin (hCG) are administered to stimulate the testicles. Increased levels of testosterone after administration of hCG suggest that there is at least one viable testicle somewhere in the body, while no hormone response suggests anorchia. The theoretical basis for using hormone stimulation to guide treatment is that, if there is no testicle present at all, then surgery is unnecessary and a child may be able to be spared the risks of exploratory surgery to find a missing testicle.

Imaging also is used to determine whether there is in fact a testicle and, if there is, to locate it in order to guide the optimal treatment approach. Imaging approaches include ultrasonography (US), computerized tomography (CT) scanning, routine magnetic resonance imaging (MRI), and magnetic resonance (MR) angiography and venography, some of which require sedation or anesthesia and are thus not without risks.

Medical options in the treatment of cryptorchidism consist of hormones intended to increase circulating androgens. This increase in circulating androgens, in turn, is thought to potentially promote testicular descent. The two hormones that are most commonly used for the treatment of cryptorchidism are luteinizing hormone-releasing hormone (abbreviated as LHRH and also

sometimes referred to as gonadotropin-releasing hormone [GnRH]) and hCG. Although used much less commonly, human menopausal gonadotropin (hMG) also is used occasionally and is thought to function in a manner similar to hCG. LHRH and its analogs and agonists can be administered intranasally, while hCG and hMG must be injected intramuscularly.

There are three primary surgical options for orchiopexy (surgery to move an undescended testicle into the scrotum), depending on the location and appearance of the undescended testicle. Primary orchiopexy is possible if the testicle is of normal size and appearance and if the testicular vessels are of adequate length. In this procedure, the testicle is surgically moved to the scrotum and fixed in place. Primary orchiopexy requires that the vessels be long enough to reach into the scrotum. If the vessels are so short that tension-free placement of the testicle in the scrotum is not possible, a Fowler-Stephens (FS) orchiopexy is performed. This procedure entails ligating the testicular vessels. The testicular blood supply then depends on collateral circulation from the deferential artery and the cremasteric system.[1]

The FS technique can take place in one of two ways: either (1) as a single-stage operation, in which the vessels are ligated and the testicle is then placed into the proper position in the scrotum, or (2) as a two-stage procedure, in which the vessels are ligated in the first operation, the testicle is allowed to develop presumably better collateral circulation in its abdominal position, and it is then moved to the proper position in the scrotum during a second procedure, usually 3–6 months later. Both primary orchiopexy and the FS procedure can be performed using laparoscopic or open surgical technique.

Finally, surgical orchiectomy (removal of the testicle) also can be performed, although this is usually reserved for cases where the testicle is not felt to be viable, as the primary goal of treatment is relocation of a viable testicle to a dependent position in the scrotum. Orchiectomy is not reviewed in this report, which focuses only on procedures to maintain testicular tissue and viability.

Clinical uncertainty and lack of guidance exist on the appropriate clinical pathway for treatment of cryptorchidism. Areas of uncertainty include selecting the optimal approach to treatment planning (imaging vs. no imaging, hormonal stimulation testing or not) and intervention (surgical vs. hormonal, one-stage vs. two-stage FS, various modifications of each of the surgical techniques, and open vs. laparoscopic approach). The immediate goal of most interventions for cryptorchidism is to reposition the undescended gonad in a “normal” position in the scrotum. Intermediate outcomes include psychological benefits in terms of body image, and long-term goals include preservation of fertility and prevention of testicular malignancy. All of these outcomes are important to patients.

Scope

This review focuses on the effectiveness of imaging for identifying and correctly locating testicles, on the use of hormonal stimulation for identifying anorchia in treatment planning, on hormones for achieving testicular descent, and on choices among surgical treatments, including surgical approach (open vs. laparoscopic).

Key Questions

We have synthesized evidence in the published literature to address the following Key Questions (KQs) and population, interventions, comparators, outcomes, timing, and settings (PICOTS).

KQ1a. For determining a course of treatment, is imaging equivalent to laparoscopy in determining the presence and location of a nonpalpable testicle?

KQ1b. In male children with bilateral nonpalpable testicles, does the use of hormonal stimulation testing reduce the need for surgery as part of a treatment plan?

KQ2. What is the effectiveness of initial hormonal therapy (human chorionic gonadotropin or luteinizing hormone-releasing hormone) for the treatment of cryptorchidism for outcomes, including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location, and function of the testicles

KQ3. What is the effectiveness of surgical therapies (one-stage vs. two-stage, laparoscopic vs. open approach) for the treatment of cryptorchidism for outcomes, including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location, and function of the testicles

KQ4. How do the age at presentation, physical presentation of cryptorchidism (unilateral vs. bilateral, palpable vs. nonpalpable, anatomic location), and occurrence of associated abnormalities (e.g., hernia) modify diagnosis, treatment, and outcomes?

KQ5. What are the nature and frequency of harms associated with workup or treatment for cryptorchidism?

Methods

Literature Search Strategy

We searched the following databases: MEDLINE® via the PubMed interface, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Embase. Details of the search strategy are available in the full report. The search strategy excluded studies not relevant to human populations and those that were not published in English. Based on input from the Technical Expert Panel and awareness of advances in surgical technique, including development of imaging techniques, we also excluded studies published before 1980. We required that study participants be prepubescent boys with cryptorchidism. For KQ1a and KQ1b, we accepted single-arm studies because the purpose of those questions was to assess treatment planning, which is based on the success of the approaches for identifying and locating testicles before and after surgical confirmation. For the treatment questions (KQ2 and KQ3), however, studies had to include an appropriate comparison group (i.e., comparison of different treatments, hormonal vs. surgical therapy, or treatment vs. no treatment). Studies of individuals with disorders of sexual development or ambiguous genitalia were excluded, because the clinical complexity of these patients means that they typically undergo multiple treatments for their conditions and results in this population would not be generalizable to the population typically presenting with cryptorchidism. In addition, for KQ1a we included only studies that evaluated the accuracy with which preoperative imaging techniques identified the presence and location of testicles, with confirmation by surgery. If a study had negative imaging for all subjects, if the imaging

techniques were not adequately described, or if relevant data to calculate diagnostic performance were not available, it was excluded. We required that the study report data on presence or absence of testicles along with identifying the position of testicles (abdominal, inguinal, or scrotal) as determined by imaging techniques and surgery.

Data were extracted into evidence tables for qualitative synthesis. All data extraction was done by an investigator on the team and verified by a second investigator. The data extracted included information on the study design, participant population, baseline and followup data on testicular position and other outcomes that were available, and harms experienced in the study.

Quality Assessment of Individual Studies

Quality was assessed using three published tools, depending on the study design. Two reviewers independently assessed the quality of each study, and then results were adjudicated. For randomized controlled trials (RCTs), we used the Cochrane Risk of Bias tool;[6] for cohort studies, the Newcastle-Ottawa Quality Assessment Scale;[7] and for prognostic studies of imaging, the Quality Assessment of Diagnostic Accuracy Studies-Revised (QUADAS-2) tool.[8] The results of these tools were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality designations using conversion thresholds developed by the team, as no explicit guidance exists. The conversion thresholds are presented in the main report.

Data Synthesis

Evidence tables were completed for all included studies, and data are presented in summary tables and analyzed qualitatively in the text. In addition, quantitative analysis was used for KQ1a (imaging compared with laparoscopy) and KQ3 (surgical therapies).

For KQ1a, the accuracy of imaging techniques was calculated for concordance with surgical results (open or laparoscopic), which were considered the gold standard. The performance characteristic data for each imaging technique compared with surgery was calculated, as was an overall accuracy rate. The ability of each imaging modality to correctly classify the position of the testicles also was calculated using the following categories, which refer to the location of the cryptorchid testicle: intra-abdominal (in the abdomen), inguino-scrotal (in the groin area or too high in the scrotum), or atrophied.

For KQ3, data on success of testicular descent were pooled and the weighted proportions (sum of all successfully treated testicles/total number of testicles in studies) were calculated for each treatment type. Similarly, weighted testicular atrophy rates were derived for each of the surgical techniques.

Strength of the Body of Evidence

We assessed the strength of the evidence for the main comparisons within the two primary treatment approaches (hormonal treatment and surgery) for the primary outcomes of testicular descent and atrophy. We used the approach to strength of evidence assessment described in the Effective Health Care Program Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[8]

We examined the following four major domains:

- Risk of bias (low, medium, or high)
- Consistency of findings (inconsistency not present, inconsistency present, or unknown or not applicable)

- Directness (direct comparison of influence on outcomes in RCT or indirect information from observational research)
- Precision (precise or imprecise based on outcome rates, size of the individual studies, and the total number of participants in the studies for the category of intervention)

The overall strength of evidence could be graded as "high" (indicating high confidence that the evidence reflects the true effect, and further research is very unlikely to change our confidence in the estimate of effect); "moderate" (indicating moderate confidence that the evidence reflects the true effect, and further research may change our confidence in the estimate of effect and may change the estimate); "low" (indicating low confidence that the evidence reflects the true effect, and further research is likely to change our confidence in the estimate of effect and is likely to change the estimate); or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect).

Applicability

The degree to which the findings in the review are likely to be applicable to clinical practice was assessed using a PICOTS framework according to the applicability chapter of the Methods Guide of the Effective Health Care Program.[9]

Results

We identified 3,448 nonduplicate titles or abstracts with potential relevance through the search process, with 830 proceeding to full-text review. Sixty-four, representing 60 distinct studies, were included in the review: 16 RCTs (2 good quality, 2 fair quality, 12 poor quality); 5 prospective cohort studies (1 good quality, 2 fair quality, 2 poor quality); 21 retrospective cohort studies (4 good quality, 17 poor quality); 16 prospective case series (1 good quality, 3 fair quality, 12 poor quality); and 2 retrospective case series (1 fair quality and 1 poor quality). Eighteen studies pertain to KQ1a, 2 studies to KQ1b, 14 studies to KQ2, 26 studies to KQ3, 23 studies to KQ4, and 11 studies to KQ5. See the full report for references to each study.

KQ1a. Utility of Imaging To Determine Course of Treatment

Eighteen unique studies met our inclusion criteria and addressed the performance of imaging techniques in identifying and localizing nonpalpable undescended testicles in prepubescent boys. Only four studies adequately described selection criteria for the participants, and three studies provided the time interval between imaging techniques and surgery. One study was of good quality, 4 of fair quality, and 13 of poor quality. More studies were conducted in Asia (N=9) than in the United States (N=4) or Europe (N=5). All of the studies were conducted in a hospital setting. The number of participants in the studies ranged from 11 to 135. The potential number of nonpalpable testicles to be localized ranged from 11 to 152. The boys' ages were between 1 month and 18 years.

Using surgery as a reference standard, the overall accuracy rate at identifying testicles using US ranged from 21 to 76 percent across the studies, compared with 42 to 92 percent for MRI and 60 percent in the one study on CT scan. The one good-quality study of US had an accuracy rate of 73 percent. Both magnetic resonance angiogram (MRA) and magnetic resonance venography (MRV) had 100-percent accuracy, but MRA was assessed in only two studies and MRV in one. There were no good-quality studies of MRA/MRV. Both techniques require anesthesia or sedation.

The accuracy of imaging techniques depended on the actual location of the testicles or whether they were atrophied. Neither US nor MRI demonstrated high accuracy at identifying atrophied testicles (16.7% and 32.3%, respectively), compared with 100-percent accuracy for MRA and MRV. When the testicles were located in the inguino-scrotal area, however, US demonstrated a 92-percent accuracy rate, compared with 83-percent accuracy for MRI. Performance was worse when the testicles were located intra-abdominally, with US demonstrating 33.7-percent accuracy and MRI 71.2-percent accuracy.

KQ1b. Utility of Hormone Stimulation Testing To Determine Course of Treatment

Two studies of a total of 44 boys examined the potential for hormonal stimulation testing to predict anorchia. One had fair quality and one had poor quality. Both were cohort studies in which hCG was used to stimulate testosterone secretion in order to diagnose any impairment in testicular endocrine function. Both used a similar study design, in which the participant was first given hCG to stimulate testosterone production and then underwent surgical exploration to confirm the absence or presence of viable testicular tissue.

Both studies reported 100-percent sensitivity, indicating that no nonviable testicles were missed. However, the studies were small and lacked a proper comparison of test characteristics between the two thresholds assessed (a greater than twofold increase in serum testosterone levels or a total testosterone of >5 ng/mmol after stimulation).

KQ2. Effectiveness of Hormone Therapy

Fourteen studies in 19 publications assessed hormonal therapy in treatment. Individual studies often included multiple arms. Six studies compared LHRH with placebo, one compared hCG with placebo, four compared LHRH with hCG, and six compared various doses or regimens. Of the 14 studies, 11 were RCTs, two were prospective cohort studies, and one was a retrospective cohort study. Three studies were of good quality, two were of fair quality, and nine were of poor quality.

Six studies specifically compared successful testicular descent rates following administration of either LHRH or placebo in boys with cryptorchidism (two fair quality and four poor quality). Four of five two-arm studies concluded that LHRH was more effective than placebo in inducing testicular descent, with variable reported effect sizes across studies (Table A). No harms of hormonal treatment were reported.

Table A. Short-term testicular descent in two-arm, randomized, placebo-controlled studies

Study N Length of Followup Quality	LHRH Dose	LHRH Frequency	LHRH Duration	LHRH Descent (%)	Placebo Descent (%)
Olsen et al., 1992 N = 123 4 weeks Fair	400 µg	3 times daily	4 weeks	9.7	1.6[a]
De Muinck Keizer-Schrama et al. and Hazebroek et al., 1986-87 N = 237 8 weeks Poor	200 µg	3 times daily	4 weeks	9.0	8.0
Hagberg and Westphal, 1982 N = 50 4 weeks Poor	100 µg	3 times daily	28 days	62.0	3.0
Karpe et al., 1983 N = 50 6 months Poor	100 µg	6 times daily	28 days	20.0	12.0
Wit et al., 1986 N = 49 8 weeks Poor	400 µg	3 times daily	28 days	37	18

CI = confidence interval; LHRH = luteinizing hormone-releasing hormone
[a]Statistical significance was reported only for this comparison—p=0.12 (95% CI, 0.1 to 16.6).

LHRH was compared with hCG and placebo in one study of fair quality. In that three-arm study, results comparing LHRH with placebo were equivocal, with LHRH being more effective than placebo in achieving testicular descent in patients with bilateral cryptorchidism, but being no better than placebo in patients with unilateral cryptorchidism. In this same study, hCG was better than placebo at achieving testicular descent in both bilateral and unilateral patients, but with only this one study of fair quality, the strength of evidence is insufficient. Four studies provided data on LHRH compared with hCG, with no clear indication of either being better than the other. The studies that compared doses and dosing schedules within hormone type were of poor quality and too heterogeneous to permit drawing useful conclusions.

Initial location of the testicle may influence success rates, but no study was adequately powered to assess this possibility. Studies of hCG have reported more frequent temporary virilizing side effects than those seen with LHRH or placebo, including increased penile length, erections, and testicular enlargement. All side effects were transitory.

KQ3. Effectiveness of Surgical Treatments

Twenty-six studies addressed surgical treatment. Four studies were judged to be of good quality, one of fair quality, and the remainder of poor quality. Eleven studies reported outcomes following either one-stage FS orchiopexy, two-stage FS orchiopexy, or primary orchiopexy. Five studies compared an open versus laparoscopic approach for the same procedure (one good quality, one fair, and three poor quality). Six studies compared minor surgical variations of primary orchiopexy (one good quality, five poor quality).

Three poor-quality studies reported long-term fertility outcomes in men who had undergone various surgical procedures for cryptorchidism in childhood. One good-quality study compared endocrine function in children with surgically treated or untreated cryptorchidism.

Surgical treatment for cryptorchidism was associated with success rates of testicular descent that ranged from 33 percent to 100 percent (Tables B–D), depending on type of surgery, with type of surgery depending on clinical presentation. No studies compared hormonal therapy alone to surgery. Only one study assessing testicular descent was rated as good quality. This study had a testicular descent rate of 63 percent for one-stage FS, 67.6 percent for two-stage FS, and 89.1 percent for primary orchiopexy, slightly lower in all types of surgery than the pooled estimate.

Table B. Success rates after one-stage Fowler-Stephens

Study Country	Quality	Total Participants	Total Testicles	% Success (N Testicles)
Stec et al., 2009 United States	Good	136	156	63 (27)
Baker et al., 2001 United States	Poor	226	263	74.1 (27)
Chang et al., 2001 United States	Poor	80	92	84 (19)
Chang et al., 2008 United States	Poor	48	48	94.3 (35)
Comploj et al., 2011 Austria	Poor	41	50	79 (33)
Denes et al., 2008 Brazil	Poor	46	54	33 (3)
Kim et al., 2010[a] South Korea	Poor	67	86	82 (11)
Total	NA	644	749	78.7[b]

NA = not applicable
[a]Controlled for location.
[b]Pooled percent.
Note: All studies were retrospective cohorts.

The weighted success rate for all three approaches exceeds 75 percent. The overall success rate for one-stage FS is 78.7 percent (Table B). The overall success rate for two-stage FS is 86 percent (Table C).

Table C. Success rates after two-stage Fowler-Stephens

Study Country	Quality	Total Participants	Total Testicles	% Success (N Testicles)
Stec et al., 2009 United States	Good	136	156	67.6 (37)
Baker et al., 2001 United States	Poor	226	263	87.9 (58)
Chang et al., 2001 United States	Poor	80	92	86 (7)
Chang et al., 2008 United States	Poor	48	48	80 (10)
Comploj et al., 2011 Austria	Poor	41	50	82 (17)
Denes et al., 2008 Brazil	Poor	46	54	88 (25)
Dhanani et al., 2004 United States	Poor	74	83	98 (49)
Kim et al., 2010[a] South Korea	Poor	67	86	67 (3)
Moursy et al., 2011 Egypt	Poor	66	76	88.8 (36)
Total	NA	784	908	86.0[b]

NA = not applicable
[a]Controlled for location.
[b]Pooled percent.
Note: All studies were retrospective cohorts.

The overall success rate of primary orchiopexy is 96.4 percent (Table D). Each type of surgery is used to address a different clinical presentation, so these success rates are not intended to be compared with one another.

Table D. Success rates after primary orchiopexy

Study Country	Quality	Total Participants	Total Testicles	% Success (N Testicles)
Stec et al., 2009 United States	Good	136	156	89.1 (92)
Baker et al., 2001 United States	Poor	226	263	97.2 (178)
Chang et al., 2001 United States	Poor	80	92	100 (66)
Denes et al., 2008 Brazil	Poor	46	54	96 (26)
Dhanani et al., 2004 United States	Poor	74	83	100 (28)
Kim et al., 2010[a] South Korea	Poor	67	86	98 (49)
Moursy et al., 2011 Egypt	Poor	66	76	100 (28)
Total	NA	695	810	96.4[b]

NA = not applicable
[a]Controlled for location.
[b]Pooled percent.
Note: All studies were retrospective cohorts.

The use of laparoscopy has increased across all surgical fields in the last decade. Laparoscopy in the treatment of cryptorchidism has two roles: (1) as an exploratory tool to locate a nonpalpable undescended testicle in the abdomen and (2) as a minimally invasive method of

orchiopexy. Two studies assessed laparoscopy for determining the location of the testicle and reported that it performed similarly to open exploration. Success of the ensuing surgeries was also similar, regardless of exploratory approach. Neither study addressed postoperative pain or time to return to normal activity. Neither study included a clinically relevant outcome, so we did not assess the strength of the evidence for this comparison.

Notably, all but one of the studies in our review published in the past 5 years that included assessment of the abdomen for a nonpalpable testicle used laparoscopy for this part of the procedure, even if they used an open technique to repair the cryptorchidism. This suggests that the results of the two studies comparing laparoscopic with open approaches are applicable to current practice.

One fair-quality and two poor-quality studies compared the use of a laparoscopic approach with open surgery for performance of orchiopexy. They reported similar clinical outcomes and less pain, shorter hospital stays, and a quicker return to normal activity with laparoscopy. No studies reported on the surgical learning curve, which is a potential modifier of effectiveness.

Few studies compared the effectiveness of different interventions associated with treatment for cryptorchidism on future fertility. Furthermore, in those studies (in which the participants are adults who had cryptorchidism in childhood), the primary outcome is usually semen analysis parameters, which are at best a proxy for fertility. One study examined ability to father children and focused on the addition of hormonal therapy to surgery; it found no advantage to the combination of hormones and surgery compared with surgery alone. No studies compared paternity rates between surgery and hormonal therapy in isolation. Therefore, no data are available to assess whether one approach is superior for fertility outcomes, although it is accepted that untreated cryptorchidism is associated negatively with later fertility.

KQ4. Modifiers of Treatment

Twenty-three studies reported modifier data, including 18 imaging studies (1 good quality, 3 fair, and 14 poor quality) and 3 studies of hormonal treatment (1 good quality and 2 poor quality). It has been suggested that in studies of hormonal treatment, age of the patient and initial position of the testicle affect outcomes. However, the reporting of data by age was inconsistent in two poor-quality studies (reported in four publications). Specifically, these two studies include patients with a wide range of ages, starting at birth and progressing through puberty. In addition, the two studies categorize age differently, making it impossible to consolidate the two studies and draw conclusions regarding the relationship between age and outcomes.

Most studies that provided data on pretreatment testicular position did not provide outcomes stratified on this measure, but those that did reported higher rates of descent if the testicle was initially lower. In one poor-quality study of LHRH that assessed the role of testicular position, 75 percent of testicles that descended could be manipulated at least to the scrotal entrance before treatment. A second poor-quality study, of hCG, reported success rates 2 to 3 times as high for initially inguinal testicles compared with those located intra-abdominally. Across the studies, the degree to which these lower testicles included in success rates are, in fact, retractile is unclear.

In one good-quality study of surgical repair specifically intended to examine factors associated with success, a retrospective review was performed of orchiopexies performed over 9 years at one institution. Multivariate analysis demonstrated that neither age nor patent processus vaginalis modified outcomes.

KQ5. Harms of Workup or Treatment

Eleven studies of hormonal and surgical interventions included harms. Two studies were of good quality, two were of fair quality, and seven were of poor quality. Theoretically, harms of imaging could include exposure to radiation or to contrast, but data on harms were not provided in any imaging studies included in the review. Reported harms of hormonal treatments were mild and transient. The most common outcomes were virilizing effects (e.g., hair, increase in penis size, and erections) and behavioral changes (e.g., aggression). In all studies, reported harms had receded by 6-month followup, if not before.

Rare cases of intestinal injury due to Veress needle puncture (one case) and to postoperative laparoscopic port site reducible hernia (three cases) and incarcerated hernia (two cases) were noted with laparoscopy. These adverse events are associated with the use of the laparoscopic approach and are not unexpected in this setting. They are not specific to cryptorchidism repair and can occur with any type of laparoscopy. Overall, adverse effects specifically associated with surgical repair for cryptorchidism were rare.

Discussion

Key Findings and Strength of Evidence

The goal of an intervention for cryptorchidism is to move the undescended testicle to a normal position in the scrotum in the safest and least invasive way possible. This report reviews the literature on treatment planning and therapeutic interventions to achieve these goals. Overall, only eight good-quality studies were available for analysis, and this lack of good-quality studies is reflected in the strength of evidence, which was generally low to moderate for any intervention and outcome. Strength of evidence was high only for the effect of primary orchiopexy on testicular descent, for which the most data are available.

Imaging approaches have a range of success rates at localizing cryptorchid testicles from 21 to 100 percent. The imaging literature provides mixed results for identifying cases of anorchia, with studies not pointing to a particular approach that provides adequate accuracy at identifying atrophy or complete absence of the testicle and thus could be used to avoid surgical intervention. The lack of good-quality studies affects our degree of confidence in establishing a rate of prediction of anorchia, but results do not seem to be directly related to study quality.

Applicability of the results on imaging depends on access and acceptability of the imaging approaches. Imaging approaches range from being readily available in the case of US to potentially less available for the approaches using MR. Some approaches require sedation, and reported success rates may reflect, in part, differences in the patient selection process, number of participants in each study, and the type of testicles present. Information on full physical exam, including obesity, condition of contralateral testicles, and prior hormonal or surgical treatment, which may all play a role in the performance of imaging, also was lacking. Only two studies (one fair quality and one poor) of hormonal stimulation testing for identifying viable testicular tissue were available, and more study is needed in this area. Most studies of hormonal treatment were of poor quality, precluding definitive conclusions as to a specific expected effect rate for any hormone or combination thereof. Nonetheless, studies report slightly higher rates of testicular descent for LHRH and hCG compared with placebo. End users of this report will need to balance this information with difficulties of administration in young children and potential side effects. Initial location of the testicle may influence success rates. Although no study was adequately

powered to assess this possibility, most studies that provide the data indicate higher success rates for testicles initially lower in position. Some studies have reported more frequent temporary virilizing side effects, including increased penile length, erections, and testicular enlargement, but all side effects were transitory.

We assessed the strength of evidence for our primary outcome of testicular descent (Table E). There is moderate strength of evidence for increased testicular descent with LHRH compared with placebo, low strength of evidence for increased testicular descent with hCG compared with placebo, and low strength of evidence for equivalence between LHRH and hCG.

Table E. Strength of evidence on testicular descent with hormonal treatments for cryptorchidism

Treatment Comparison Number of Studies; Total Subjects; Testes Treated	Study Design/ Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect
LHRH vs. placebo 6; 752; 935	RCT/ Moderate	Consistent	Direct	Imprecise	Moderate LHRH: 9%–62% Placebo: 0%–18%
hCG vs. placebo 1; 243; 280	RCT/ Moderate	Unknown	Direct	Unknown	Low Bilateral: 23% vs. 0% Unilateral: 15% vs. 0%
LHRH vs. hCG 3; 431; 465	RCT/ Low	Inconsistent	Direct	Imprecise	Low LHRH: 0%–18.8% hCG: 5.9%–23%
LHRH vs. hCG 1; 324; 198	Cohort/ High	Consistent	Direct	Imprecise	LowLHRH: 29.4% hCG: 34.5%

hCG = human chorionic gonadotropin; LHRH = luteinizing hormone-releasing hormone; RCT = randomized controlled trial

No studies provided cancer or fertility outcomes for the comparisons listed, so the strength of evidence is insufficient for these outcomes**.** Each surgical approach was assessed independently for ability to achieve testicular descent because, as described in the report, each approach is used under different clinical circumstances, and thus it is inappropriate to compare them with one another. We assessed the strength of evidence as our confidence in the weighted average of successful testicular descent associated with each surgical approach separately (Table F). Although retrospective studies typically have high risk of bias because of lack of a control group, in grading the overall strength of the evidence, we used an implicit comparator group, given the known natural history of disease. Given the low rate of spontaneous testicular descent, despite the high risk of bias of retrospective studies, strength of evidence might be considered high because of the high magnitude of effect when compared with an implicit control.

For the outcome of testicular descent, strength of evidence was moderate for one- and two-stage orchiopexy and high for primary orchiopexy. All studies were retrospective cohort studies and thus had high risk of bias, but we deemed this to be an appropriate study design for the question of the ability of orchiopexy to achieve testicular descent, and we considered the relative challenges of this design to be outweighed by the magnitude of effect. Primary orchiopexy had higher strength of evidence than one-stage and two-stage procedures based on the higher number of testicles (outcomes) reported in the literature.

We also assessed strength of evidence for the outcome of testicular atrophy, and on the same methodologic basis as was used for testicular descent, found the strength of evidence to be low for a 28.1-percent atrophy rate with one-stage FS, low for an 8.2-percent atrophy rate with two-stage FS, and moderate for a 1.83-percent atrophy rate for primary orchiopexy.

Table F. Strength of evidence of surgical treatments for cryptorchidism

Outcome Treatment Number of Studies; Total Subjects; Treated Testicles	Study Design/ Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect[a]
Testicular Descent					
1-stage FS 7; 644; 155	Retrospective cohort/ High	Consistent	Direct	Imprecise	Moderate 78.7% (range: 33%–94.3%)
2-stage FS 9; 784; 242	Retrospective cohort/ High	Consistent	Direct	Imprecise	Moderate 86.0% (range: 67%–98%)
Primary orchiopexy 7; 695; 467	Retrospective cohort/ High	Consistent	Direct	Precise	High 96.4% (range: 89.1%–100%)
Atrophy					
1-stage FS 3; 320;32	Retrospective cohort/ High	Consistent	Direct	Imprecise	Low 28.1% (range: 22%–67%)
2-stage FS 5; 470; 158	Retrospective cohort/ High	Consistent	Direct	Precise	Low 8.2% (range: 0%–12%)
Primary orchiopexy 5; 470; 273	Retrospective cohort/ High	Consistent	Direct	Precise	Moderate 1.83% (range: 0%–4%)

FS = Fowler-Stephens

[a]Pooled proportion (range).We assessed the strength of evidence for equivalence of laparoscopic and open approaches for achieving testicular descent to be low, with only one RCT of poor quality and two cohort studies of fair and poor quality, although the individual studies report that success rates are similar with both approaches. Similarly, strength of evidence was low for the effect of the approach on atrophy.

Contextual Information Not Covered in the Review

Although the comparative literature does not include long-term data on either fertility or cancer outcomes, there is a body of epidemiologic data and data from noncomparative studies to which we refer end users of this report. These studies did not meet the specific scope or inclusion criteria for our review, but they provide important information on long-term outcomes for individuals with cryptorchidism. Because we did not review these studies systematically as part of the scope of this review, we do not suggest that the references included here are comprehensive; rather they are representative and provide additional context for decisionmakers. Of particular note is a series of studies by Peter Lee and colleagues that describe long-term outcomes, including the ability to father children, among men treated surgically for cryptorchidism who have attempted paternity. These studies suggest that while men who were treated for unilateral cryptorchidism as children do not have substantially lower paternity rates than control subjects, men treated for bilateral cryptorchidism experience substantially lower paternity than both those with previous unilateral cryptorchidism and controls. These studies do not include untreated individuals with cryptorchidism; rather, the cryptorchid groups are "previously cryptorchid," having undergone surgery.

Applicability

The degree to which the data presented in this report are applicable to clinical care depends on the degree to which the population included in the studies represents the patient population in clinical care, as well as the availability of the interventions and the degree to which the study settings mirror those in usual clinical practice. Across all KQs, there is no indication that study populations are different from those in standard clinical practice. Indeed, many of the studies included are reports of clinical practice, including chart reviews. Study populations included children with undescended testicles, as required by our inclusion criteria. Data are provided across the studies on children with a range of initial testicular locations (e.g., intra-abdominal, inguinal, or scrotal) and unilateral or bilateral disease. The applicability of the imaging results depends on the availability of the specific imaging technologies in a given clinical setting, including the availability of trained and experienced operators. The applicability of the imaging results may also depend on patient age, with technologies requiring patient cooperation potentially more challenging to use in infants. With improvements in imaging techniques, it may also be the case that early studies underestimated the effectiveness of imaging technologies.

Hormonal approaches to treatment were assessed in children with both bilateral and unilateral cryptorchidism and at varying ages, providing data for the range of patients likely to be seen in clinical practice in the United States. Although most studies took place in Europe, the results should be applicable to a U.S. population, as the hormonal agents are readily available in the United States.

As with the hormonal treatment literature, the surgical literature applies to the range of patients likely to be seen in practice, and the surgical techniques assessed are those commonly used in U.S. clinical care. The most common outcome assessed was testicular position; this is typically the outcome targeted in clinical practice. In addition, most studies provided adequate followup data to assess later atrophy.

Research Gaps

Although a number of studies are available on US and MR approaches, very few studies are available on MRA and MRV, which could be useful for confirming findings after negative US and MRI. A study comparing multiple imaging modalities, such as US or MR, in the same patient, followed by diagnostic laparoscopy and appropriate treatment, would be of value in assessing the equivalence or superiority of any imaging approach.

Studies of hormonal treatment of cryptorchidism have focused primarily on LHRH and its agonists because it is easily administered intranasally. The wide range of success rates seen across studies is possibly due to heterogeneity in the study populations or potentially due to variability in drug absorption through the intranasal route. Some literature suggests that differences may be due to initial location of the testicle, but this is an area warranting more study, including conducting additional studies in which patients are carefully selected to assess efficacy by testicle location or analyses carefully controlled for this effect. Any side effects from hormonal therapy are temporary and not life threatening. It would be of some value to be able to accurately inform parents of the possibility of success with this treatment, as even a small likelihood of success coupled with avoidance of surgery may be appealing.

Current literature lacks assessment of whether a one-stage or two-stage method for the FS approach to surgery is superior or whether the two methods are similar. An appropriately designed RCT is needed of one-stage versus two-stage FS in children with nonpalpable,

presumably intra-abdominal testicles, who are determined not to be candidates for primary orchiopexy. In order for this comparison to be valid, the trial would also need to control for location within the abdomen at the time of presentation in order to avoid the shortfalls of the current observational literature. The primary outcome should be successful placement of a normal-sized testicle in the dependent portion of the scrotum. Ideally, outcomes would be measured both immediately and in the longer term (6 to 12 months later) to assess late complications, recurrences, and atrophy. Such a trial would be ethical, as primary orchiopexy would not be the focus of the study and would not be denied to patients in whom it could be performed.

The appropriate age for treatment remains unknown, with very little data available on the modifying effect of age on outcomes. Across all approaches to treatment planning and therapy, this important question has yet to be answered. Studies of long-term outcomes of treatment, both fertility and cancer, are notably missing. Development of a long-term cohort or a registry could provide broader and longer term data, and warrants consideration. When studies are published on fertility outcomes, the specific measures are inadequate, as they focus only on semen analysis (normal: >15 sperm per millimeter, >50 percent having normal motility and >4 percent having normal morphology). More appropriate measures should be included, such as the ability to achieve paternity when desired. Additional outcomes that warrant study are good measures of endocrine function, which is assessed by serum testosterone levels. (Normal values vary by patient age and laboratory but are generally 10–44 nmol/l.)

Conclusions

No specific imaging technique is able to completely identify anorchia or descent of the testicles and thus eliminate the need for further surgical evaluation. Accuracy varies by location of the testicles, with less invasive methods (9 studies of US, including 1 good, 2 fair, and 6 poor quality; 10 studies of MRI, including 3 fair and 7 poor quality) demonstrating poor accuracy for abdominally located testicles and those that are atrophied. Hormonal stimulation testing may predict anorchia, but more research is needed, with only two studies (one fair and one poor quality) of fewer than 50 participants. Hormonal treatment is somewhat more effective relative to placebo, with moderate strength of evidence, and is successful in some children with minimal side effects. Surgical options are effective, with rates of normal postoperative scrotal position above 75 percent. The strength of the evidence is moderate (low for atrophy) for the effects of either one-stage or two-stage FS procedures on testicular descent and high (moderate for atrophy) for primary orchiopexy. Comparable outcomes have been seen with laparoscopic and open approaches to surgical repair, with low strength of evidence overall.

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Introduction

Background

Condition

Cryptorchidism is a congenital condition in which one or both testicles are not appropriately positioned in the scrotum at birth and cannot be moved into the proper position manually. The term "cryptorchidism" literally means "hidden testicle" and is often used interchangeably with the term "undescended testicle."[1] It affects an estimated three percent of full-term male neonates and up to 30 percent of premature infants, making it the most common male genital anomaly identified at birth.[2, 3] Associated conditions and consequences of cryptorchidism include hypospadias, hernia, and testicular torsion. Bilateral, nonpalpable testicles associated with hypospadias or ambiguous genitalia may represent severe developmental abnormalities (including intersexuality) that can be life threatening, warranting specific testing and treatment.[1, 4] Ascertaining the correct treatment plan for cryptorchidism is therefore important and includes identifying associated conditions.

Cryptorchidism is often apparent to parents, and examination for the condition is part of general pediatric care. Therefore, boys with cryptorchidism are usually identified early in life, often within the first year. Clinical decision making about treatment is influenced by many factors, including whether or not the testicle is palpable, whether or not the condition is present unilaterally or bilaterally, the age at presentation, and coexisting medical conditions. In boys under 1 year of age whose testicle is palpable and is close to, but not quite inside, the scrotum, it may be difficult to distinguish between "true" cryptorchidism and a retractile testicle. In this case, health care providers often elect to observe the patient's condition until he is 1 year old.

Although about 70 percent of cryptorchid testicles spontaneously descend within the first year of life (most occurring in the first three months), the number of boys whose condition persists remains constant at approximately 1 percent.[5, 6] Between 1992 and 2000, there were more than 600,000 (96 per 100,000 visits in each year) physician office visits for males younger than age 18 for which cryptorchidism was the primary diagnosis.[2] The annualized rate of orchiopexy was constant at 18 per 100,000 from 1994 to 1996.[7] Given that the average submitted charges in 2008 for a level 3 in-office examination was $146 for new patients and $87 for established patients (according to physician payment information for value-driven health care data compiled by the Centers for Medicare & Medicaid Services) and that the charges for infant and postpubertal orchiopexy have been estimated to be $7,500 and $10,928, respectively, cryptorchidism incurs direct costs of millions of dollars annually, even by the most modest estimates.[8] Cryptorchidism is, therefore, both a significant and costly health problem in the United States.

Longer-term consequences of cryptorchidism include testicular malignancy and infertility/subfertility, with stronger evidence for the etiologic role of cryptorchidism in malignancy than in disordered fertility. With regard to testicular cancer, it has been clearly established that there is a strong positive correlation between cryptorchidism and testicular cancer. An estimated ten percent of all testicular tumors develop from an undescended testicle.[9] A commonly used estimate for cancer risk is that relative risk of incidence of a testicular tumor is about 40 times greater in men with cryptorchidism when compared to the general population.[10] This estimate, however, was based on studies from the 1940s, when the approach to diagnosis

and treatment of testicular cancer was quite different than current approaches. A more recent review of the literature estimates the relative risk of testicular cancer in men with cryptorchidism to be between two and eight times higher than men without cryptorchidism.[11]

Treatment Strategies

Cryptorchidism is diagnosed on physical examination and is usually fairly obvious to parents and providers when the testicle is not found in the "normal" position in the scrotum. The position of the cryptorchid testicle can vary and may be just above the scrotum, anywhere along the inguinal canal, or in the abdomen.[1] Sometimes the cryptorchid testicle can be palpated and sometimes it cannot. When testicles are located just above the scrotum, it is important to distinguish between truly cryptorchid testicles and retractile testicles. The key difference is that a retractile testicle can be manually milked into a normal position while a cryptorchid testicle cannot.[1] Retractile testicles are usually treated with observation, and they almost always descend into a normal position and remain there as the child grows. Some children with "low-lying" (defined as just above the scrotum) cryptorchid testes will experience spontaneous descent. In general, the further away the testicle is from the scrotum, the less likely it is to descend spontaneously into a normal position.[1]

Once cryptorchidism is diagnosed, treatment decisions may be guided by results of hormonal stimulation testing and/or imaging. Imaging is used to identify and locate the testicle in order to determine the optimal treatment approach. Imaging approaches include ultrasonography (US), computerized tomography (CT) scanning, routine magnetic resonance (MR) imaging and MR angiography and venography, some of which require sedation or anesthesia and are thus not without risks. The purpose of hormonal stimulation testing is to determine if viable testicular tissue is present in the setting of bilateral nonpalpable cryptorchidism. Specifically, if a boy has bilateral nonpalpable testicles, hormones such as human chorionic gonadotropin (hCG) are administered to stimulate the testicles. If increased levels of testosterone are noted after administration of human chorionic gonadotropins, it is assumed that there is at least one viable testicle somewhere in the body. If there is no testosterone response in the presence of elevated levels of follicle stimulating hormone (FSH), the boy is usually presumed to be anorchid. Imaging is often used to determine whether there is in fact a testicle and to locate it. In theory, absence of a testosterone increase in response to hormonal stimulation testing or inability to locate a testicle with imaging should preclude the need for surgery as it indicates a lack of a potentially functional testicle. However, the value and predictive power of these approaches for identifying the presence and location of a testicle is currently not well understood, and their ability to prevent unnecessary surgery is an area of clinical uncertainty.

Medical options in the treatment of cryptorchidism consist of hormones intended to increase circulating androgens. This increase in circulating androgens, in turn, is thought to potentially promote testicular descent. The two hormones that are most commonly used for the treatment of cryptorchidism are luteinizing hormone-releasing hormone (abbreviated as LHRH and also sometimes referred to as gonadotropin-releasing hormone [GnRH]) and hCG. Although used much less commonly, human menopausal gonadotropin (hMG) is also occasionally used and is thought to function in a manner similar to hCG. LHRH and its analogs and agonists can be administered intranasally, while hCG and hMG must be injected intramuscularly. This difference in mode of administration makes LHRH more acceptable in pediatric care.

The surgical options for the treatment of cryptorchidism are primarily dictated by the location and appearance of the undescended testicle. Primary orchiopexy (surgical mobilization

of the testicle with placement and fixation in the scrotum) is usually performed for palpable cryptorchid testicles that are of relatively normal size and appearance that are located in the inguinal canal. In cases in which the testicle is found to be atrophic with little or no viable germ cell tissue remaining, orchiectomy is often performed. For nonpalpable testicles located just inside the internal inguinal ring or in the abdomen, surgical management is more complicated and is dependent on location in the abdomen and the length of the gonadal vessels. If the testicle is of normal size and appearance and if the vessels are of adequate length, primary orchiopexy is usually performed. If the vessels are so short as to prohibit tension-free placement of the testicle in the scrotum, a Fowler-Stephens orchiopexy is performed. This procedure entails ligating the testicular vessels. The testicular blood supply then depends on collateral circulation from the deferential artery and the cremasteric system.[1]

This procedure can be performed one of two ways: either as a single-stage operation, in which the vessels are ligated and the testicle is then placed into the proper position in the scrotum, or as a two-stage procedure. In a two-stage procedure the vessels are ligated in the first operation, the testicle is allowed to develop presumably better collateral circulation in its abdominal position and is then moved to the proper position in the scrotum during a second procedure, usually 3–6 months later. Both primary orchiopexy and the Fowler-Stephens procedure can be performed using laparoscopic or open surgical technique.

There remains clinical uncertainty and lack of guidance on the appropriate clinical pathway for treatment of cryptorchidism. This uncertainty includes selecting the optimal approach to treatment planning (imaging vs. no imaging; hormonal stimulation testing or not) and intervention (surgical vs. hormonal, one-stage vs. two-stage Fowler Stephens, various modifications of each of the surgical techniques, and open vs. laparoscopic approach). The immediate goal of most interventions for cryptorchidism is to reposition the undescended gonad in a “normal” position in the scrotum. Intermediate outcomes include psychological benefits in terms of body image, and long term goals include preservation of fertility and prevention of testicular malignancy. All of these outcomes are important to patients. While there is some preliminary evidence that medical treatment with hormones, such as LHRH or hCG, may result in descent of the cryptorchid testicle into the scrotum, most children with cryptorchidism ultimately undergo surgical treatment for the condition. The standard urology textbook, Campbell-Walsh Urology, considers that “early surgical repositioning of the testicle into the scrotum before the onset of histopathological changes can reduce the risk of subfertility,” but this statement has not been systematically considered.[1] Although many clinicians advocate early orchiopexy to reduce the risk of testicular cancer associated with cryptorchidism, the published literature offers conflicting results.[10, 11] This topic was, therefore, nominated by a professional organization interested in developing guidelines for their clinical members on how to treat this condition.

Scope of the Review

This review focuses on the effectiveness of imaging for identifying and correctly locating testicles, on the use of hormonal stimulation for treatment planning and hormones for achieving testicular descent, and on choices among surgical treatments, including surgical approach (open vs. laparoscopic). We focus on treatment of pre-pubescent boys who have been diagnosed with cryptorchidism, and sought information on both short term outcomes (testicular descent) and longer-term outcomes (body image and quality of life, fertility and cancer). Orchiectomy is not

reviewed in this report because the report focuses only on procedures to maintain testicular tissue and viability.

Key Questions

We have synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ1a. For determining a course of treatment, is imaging equivalent to laparoscopy in determining the presence and location of a nonpalpable testicle?

KQ1b. In male children with bilateral, nonpalpable testicles, does the use of hormonal stimulation testing reduce the need for surgery as part of a treatment plan?

KQ2. What is the effectiveness of initial hormonal therapy (human chorionic gonadotropin or LHRH) for the treatment of cryptorchidism for outcomes, including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location, and function of the testicles

KQ3. What is the effectiveness of surgical therapies (one-stage vs. two-stage, laparoscopic vs. open approach) for the treatment of cryptorchidism for outcomes including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location and function of the testicles

KQ4. How does the age at presentation, physical presentation of cryptorchidism (unilateral vs. bilateral, palpable vs. nonpalpable, anatomic location) and occurrence of associated abnormalities (e.g., hernia) modify diagnosis, treatment, and outcomes?

KQ5. What is the nature and frequency of harms associated with workup or treatment for cryptorchidism?

The relevant population, interventions, comparators, outcomes, timing, and settings (PICOTS) are shown in Tables 1 and 2.

Table 1. PICOTS for KQs 1a and 1b

Category	Criteria
Study population	Prepubescent males presenting with cryptorchidism or suspected cryptorchidism
Interventions	Workup evaluation for treatment planning, including imaging (magnetic resonance imaging, computerized tomography, and ultrasonography), laparoscopy, and hormonal stimulation therapy; and hormones, including human chorionic gonadotropin or gonadotropin-releasing hormone
Comparators	Other workup evaluation approaches for treatment planning (imaging, laparoscopy, hormonal stimulation therapy), nontreatment, later treatment, hormones
Outcomes	• Ability to correctly identify the presence and/or location of the testicle • Need for further surgical intervention • Adverse effects, including but not limited to effects of sedation or anesthesia
Timing	Timeframe for reporting of outcomes will not be restricted
Setting	• All settings will be considered, including hospitals and university or academic medical centers. The effect of setting on diagnosis and therapy will be considered

PICOTS = population, intervention, comparator, outcomes, timing, setting

Table 2. PICOTS for KQs 2–5

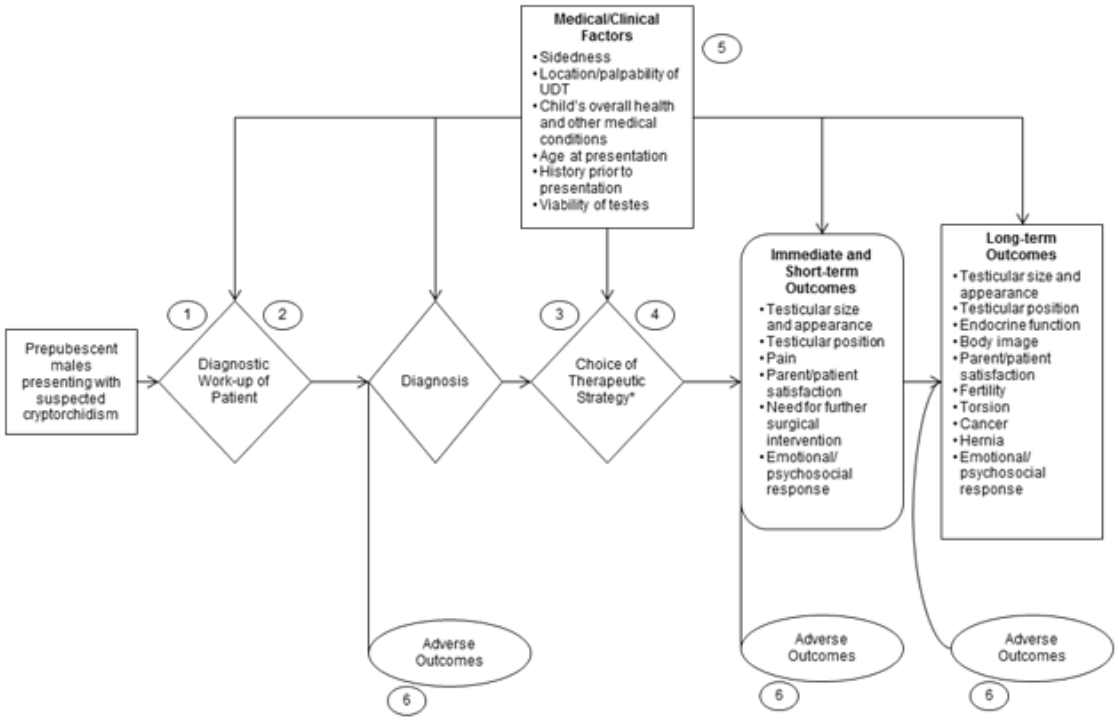
Category	Criteria
Study population	Prepubescent males presenting with cryptorchidism or suspected cryptorchidism
Interventions	Hormones including human chorionic gonadotropin or gonadotropin-releasing hormone; surgical therapy and specific surgical techniques (i.e., one-stage vs. two-stage orchiopexy, laparoscopic vs. open approach)
Comparators	Nontreatment, later treatment, hormones, and different surgical techniques
Outcomes	• Immediate (within 6 weeks of therapy) and short-term (6 weeks to 2 years of therapy) outcomes: o Testicular size and appearance o Testicular position o Pain o Parent/patient satisfaction o Need for further surgical intervention o Emotional/psychosocial response o Adverse effects, including but not limited to pain, infection, hematoma, and edema • Long-term (more than 2 years after therapy) outcomes: o Testicular size and appearance o Testicular position o Endocrine function o Body image o Parent/patient satisfaction o Infertility/subfertility o Torsion o Testicular malignancy and cancer o Hernia o Emotional/psychosocial response
Timing	Timeframe for reporting of outcomes will not be restricted
Setting	All settings will be considered, including hospitals and university or academic medical centers. The effect of setting on diagnosis and therapy will be considered

PICOTS = population, intervention, comparator, outcomes, timing, setting

Analytic Framework

We developed the analytic framework (Figure 1) based on clinical expertise and refined it with input from our key informants and technical expert panel members. It outlines potential areas in which to target a review of the effectiveness of treatments for cryptorchidism in children with cryptorchidism. The framework depicts how workup evaluations can affect the route of treatment in prepubescent males presenting with cryptorchidism. It also summarizes how treatments for cryptorchidism may result in intermediate outcomes such as change in testicular position, size, or appearance; pain; and need for further intervention, as well as long-term outcomes such as effects on fertility and endocrine function and the development of cancer. Also, adverse events may occur at any point after the workup of a patient.

Figure 1. Analytic framework of treatments for cryptorchidism



Organization of This Evidence Report

The Methods chapter describes our processes including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and methods for extraction of data into evidence tables, and compiling evidence. We also describe our approach to grading the quality of the literature and to describing the strength of the body of evidence.

The Results chapter presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies.

The final section of the report discusses the results and enlarges on the methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in the field.

The report includes a number of appendices to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A: Exact Search Strings and Results
- Appendix B: Sample Abstract and Full-Text Review Forms
- Appendix C: Excluded Studies
- Appendix D: Evidence Tables
- Appendix E: Quality of the Literature
- Appendix F: Applicability

We also include a list of abbreviations and acronyms at the end of the report.

Uses of This Evidence Report

We anticipate this report will be of primary value to organizations that develop guidelines for clinical practitioners and to health care providers who take care of male infants. Interested

organizations would include the American Academy of Pediatrics, the American Academy of Family Physicians; and the partner in this report, the American Urological Association. Treatment of cryptorchidism is generally provided by pediatric surgeons and urologists, but diagnosis and decisions about care trajectories may take place in general pediatrics and family practice. This report can bring providers up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of treatments for cryptorchidism. It will be of interest to parents concerned about the health of their infants and facing treatment choices around care for their children with cryptorchidism.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to advance research methods, understand risk factors, develop new treatment strategies, and optimize the effectiveness and safety of clinical care for boys with cryptorchidism.

Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center (EPC) used to produce a comparative effectiveness review (CER) on the approaches to treatment planning and treatment for cryptorchidism. These procedures follow the methods suggested in the Agency for Healthcare Research and Quality (ARHQ) Effective Health Care Program Methods Guide for Effectiveness and Comparative Effectiveness Reviews (available at http://www.effectivehealthcare.ahrq.gov/methodsguide.cfm)

We first describe the topic refinement process and the construction of the review protocol. We then present the Key Questions (KQs) and analytic framework. We also discuss our strategy for identifying articles relevant to our five KQs, our inclusion and exclusion criteria, and the process we used to extract pertinent information from the eligible articles and generate our evidence tables. In addition, we discuss our method for grading the quality of individual articles, rating the strength of the evidence and assessing the applicability of individual studies and the body of evidence for each KQ. Finally, we describe the peer review process.

Topic Development and Refinement

The topic for this report was nominated by a health care professional association in a public process using the Effective Health Care Web site (http://effectivehealthcare.ahrq.gov/). Working from the nomination, we drafted the initial KQs and analytic framework and refined them with input from key informants representing the fields of urology, pediatric care, primary care, and patient advocacy. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team have any conflicts.

After review from the AHRQ, the questions and framework were posted online for public comment. We made several changes in response to the AHRQ review. We reworded KQ1 and altered the analytic framework to clarify that the review would not address the diagnosis of cryptorchidism. We also developed separate population, interventions, outcomes, timing, and settings (PICOTS) criteria for the workup and intervention KQs. We received no comments during the public posting phase. We prepared final KQs and resubmitted them to AHRQ for review.

We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of pediatric urology, pediatric surgery, and pediatric endocrinology, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included five members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to review and provide comments as our work progressed. TEP members participated in conference calls and discussions through email to:

- Help to refine the analytic framework and KQs at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria
- Provide input on the information and domains included in evidence tables;
- Help to develop a hierarchy of participant characteristics and outcomes to assess systematically.

Literature Search Strategy

Search Methods

We conducted a PubMed/MEDLINE search including key Medical Subject Heading (MeSH) terms and keywords related to treatment of cryptorchidism.

The search strategy excluded studies not relevant to human populations and those that were not published in English; based on the input from the TEP and awareness of advances in surgical technique, we excluded studies published prior to 1980. We also used the search strategy to perform an initial exclusion of publications that lay beyond the scope of the review (letters, comments, case reports, reviews, news, editorials, historical articles, and meta-analyses), focusing on retaining items comprising primary data.

Additionally, we searched the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Embase to supplement the PubMed results. We used a combination of controlled vocabulary and keywords, limited to primary data, English-language reports, human subjects, and published from 1980 to the present. We also hand-searched references of included articles to identify additional studies.

Appendix A lists our search terms and strategies and the yield from each database. Searches were executed between May 2011 and February 2012.

Inclusion and Exclusion Criteria

Table 3 lists the inclusion/exclusion criteria we selected based on our understanding of the literature, key informant and public comment during the topic-refinement phase, input from the TEP, and established principles of systematic review methods.

Table 3. Inclusion and exclusion criteria

Category	Criteria
Study population	Prepubescent males presenting with cryptorchidism or suspected cryptorchidism
Time period	Studies published after 1980 due to changes in availability of interventions and imaging approaches around this time
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs • All study designs will be considered, except case reports • For KQ1a and KQ1b, single-arm studies may be included • For KQ2 and KQ3, studies must use a relevant comparison group (i.e., comparison of different treatments, hormonal vs. surgical therapy, treatment vs. no treatment) Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results • Studies detailing only the prevalence or etiology of cryptorchidism will not be included (i.e., an intervention for cryptorchidism must be included) • Studies that include individuals with disorders of sexual development or ambiguous genitalia will not be included, even if participants undergo treatment for cryptorchidism, as this treatment is likely to be in concert with treatment for associated conditions that may compound the difficulty in drawing meaningful conclusions • Studies must include at least one outcome measure of an outcome listed in the PICOTS Relevant outcomes must be extractable from data presented in the papers

KQ = Key Question; PICOTS= population, interventions, comparators, outcomes, timing, and settings

In addition to the overall criteria above, for KQ1a we only included studies that evaluated the accuracy with which pre-operative imaging techniques identified the presence and location of testicles, with confirmation by surgery. If a study had negative imaging for all subjects or if the imaging techniques were not adequately described or if relevant data to calculate diagnostic performance were not available, it was excluded. We required that the study report data on presence or absence of testicles along with identifying the position of testicles (abdominal, inguinal or scrotal) as determined by imaging techniques and surgery.

For KQ1a and KQ1b, we accepted single arm studies because the purpose of those questions was to assess treatment planning, which is based on the success of the approaches for identifying and locating testicles before and after surgical confirmation. For the treatment questions, however, (KQ2 and KQ3) studies had to include an appropriate comparison group (i.e., comparison of different treatments, hormonal vs. surgical therapy, treatment vs. no treatment).

Studies of individuals with disorders of sexual development or ambiguous genitalia were excluded, because the clinical complexity of these patients means that they are typically undergoing multiple treatments for their conditions and results in this population would not be generalizable to the population typically presenting with cryptorchidism.

Study Selection Process

Once we identified articles through the electronic database searches and hand searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form

(Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a third reviewer. All abstract and full text reviews were conducted using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Excluded studies and the reasons for exclusion are presented in Appendix C.

Development of Evidence Tables and Data Extraction Process

The staff members and clinical experts who conducted this review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our KQs. Three distinct evidence table templates were employed to facilitate the extraction of data most relevant to a specific KQ: one for KQ1a, one for KQ1b, and one for KQs 2 and 3. We based the format of our evidence tables on successful designs used for prior systematic reviews.

The team was trained to extract data by extracting several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two data extractors reconciled disagreements concerning the information reported in the evidence tables, the most common of which was study design. The full research team met regularly during the article extraction period and discussed global issues related to the data extraction process. In addition to outcomes related to intervention effectiveness, we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence tables are presented in their entirety in Appendix D. Studies are presented in the evidence tables alphabetically by the last name of the first author. Where possible, studies resulting from the same study population were grouped into a single evidence table. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

Data Synthesis

Evidence tables were completed for all included studies, and data are presented in summary tables and analyzed qualitatively in the text. In addition, quantitative analysis was used for KQ1a and KQ3 as follows. For KQ1a, the accuracy of imaging techniques was evaluated for concordance with surgical results (open or laparoscopic), which were considered the gold standard. Testicles were considered present if they were normal or atrophic including testicular nubbins (defined as a small wad of fibrotic tissue at the end of the spermatic vessels). Those testicles described as absent or vanishing were coded as absent testicles. The performance characteristic data for each imaging technique compared to surgery was arranged into a two-by-two table first and the sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV) and overall accuracy rate (OAC) were calculated (Table 4). Next, the

accuracy of each imaging modality at capturing the position of the testicles was compared to surgical results. Locations of the normal testicles have been categorized as intra-abdominal and inguino-scrotal. Normal testicles located in the inguinal/scrotal regions were grouped as inguino-scrotal. Both abdominal and inguino-scrotal atrophied testicles were classified as "Atrophy."

Table 4. Performance characteristic measures

Measure	Description
Overall accuracy rate (OAC)	The proportion of testicles correctly identified by imaging as present or absent among all the testicles subjected to both imaging and surgery. OAC = (TP+TN) / Total
Sensitivity (Se)	The proportion of testicles correctly identified as present by imaging among those identified as present by surgery. Se = TP / (TP + FN)
Specificity (Sp)	The proportion of testicles correctly identified as absent or vanishing by imaging among those considered absent by surgery. Sp = TN / (TN + FP)
Positive Predictive Value (PPV)	Among those testicles identified as present by imaging, what is the probability that it will actually be confirmed by surgery? PPV = TP / (TP + FP)
Negative Predictive Value (NPV)	Among those with a negative imaging result, what is the probability that the surgery also did not find them? NPV = TN / (TN + FN)

FP = false positive; FN = false negative; OAC=overall accuracy rate; TP = true positive; TN = true negative

For KQ3, data on proportions achieving testicular descent were pooled and the weighted proportions (sum of all success testicles/total number of testicles in studies) were calculated for each treatment type. Similarly, weighted testicular atrophy rates were derived for each of the surgical techniques.

Rating Quality of Individual Studies

Three existing, validated tools were used to assess quality of individual studies: the Cochrane Risk of Bias tool,[12] the Newcastle-Ottawa Quality Assessment Scale,[13] and the Quality Assessment of Diagnostic Accuracy Studies-Revised (QUADAS-2) tool.[14] The Cochrane Risk of Bias tool is designed for the assessment of studies with experimental designs and randomized participants. Fundamental domains include sequence generation, allocation concealment, blinding, completeness of outcome data, and selective reporting bias. The Newcastle-Ottawa Quality Assessment Scale was used to assess the quality of nonrandomized studies (e.g., cohort and case-control studies). This scale assesses three broad perspectives: the selection of study groups, the comparability of study groups, and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies, respectively. The QUADAS-2 tool was used to assess imaging studies (KQ1a) and includes items on the representativeness of patient spectrum, selection criteria, reference standard, verification bias, timing, and study withdrawals. All three tools are presented in Appendix E.

Quality assessment of each study was conducted by two team members independently using the forms presented in Appendix E. Any discrepancies were adjudicated by the two team members. Investigators did not rely on the study design as described by authors of individual papers; rather, the methods section of each paper was reviewed to determine which rating tool to employ. The results of these tools were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality designations using conversion

thresholds developed by the team, as no explicit guidance exists. The conversion thresholds are presented in Appendix E.

Strength of Evidence for Each KQ

We evaluated the overall strength of the evidence for the primary outcomes of treatment (testicular descent, atrophy, longer term fertility and cancer) (Tables 27–31). We used the approach to strength of evidence assessment described in the Effective Health Care Program Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[15]

We examined the following four major domains:

- Risk of bias (low, medium, or high),
- Consistency of findings (inconsistency not present, inconsistency present, or unknown or not applicable),
- Directness (direct comparison of influence on outcomes in RCT, or indirect information from observational research), and
- Precision (precise or imprecise based on outcomes rates, size of the individual studies and the total number of participants in the studies for the category of intervention).

For retrospective studies without a control group, we used an implicit comparator given the known natural history of disease.

The overall strength of evidence could be graded as "high" (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of effect); "moderate" (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate); "low" (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of effect and is likely to change the estimate); or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect). Strength of evidence was applied both to evidence of benefit and to evidence of lack of benefit. This means for instance that for a category of intervention in which there are multiple studies, with moderate bias and direct evidence showing no effect, and a single study reporting an insignificant reduction, the body of literature for the category of intervention could be scored as low evidence of lack of benefit.

Applicability

Finally, it is important to consider the ability of the findings to apply both to other populations and to other settings. Our assessment of applicability included determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category (Appendix F).

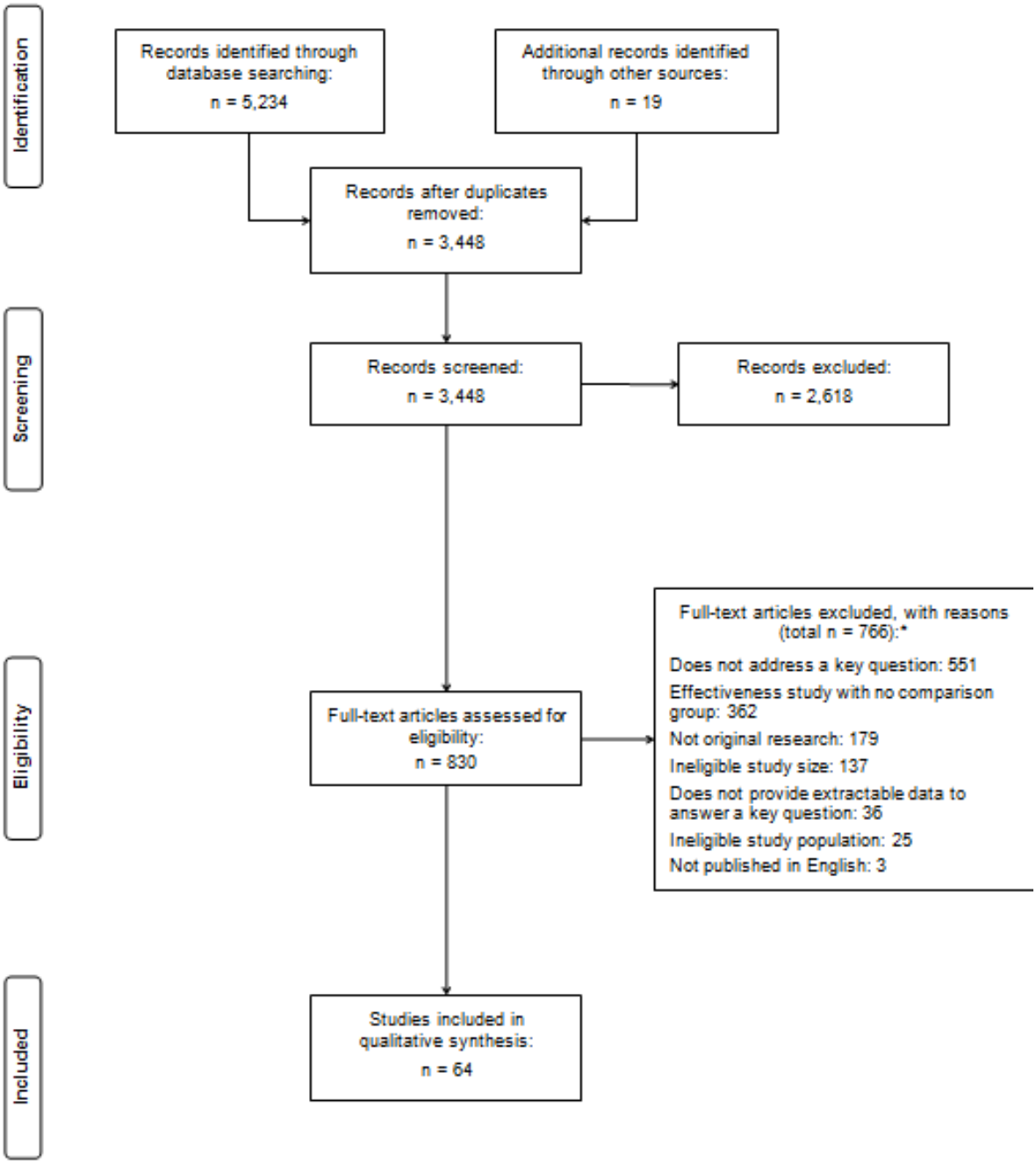
Peer Review

External experts in the fields of pediatrics, urology, and endocrinology as well as individuals representing stakeholders and patient/parent advocates were invited to contribute feedback of this review. Officers at AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment. All peer review and public comments were addressed and the text revised as appropriate. All comments and resulting edits were documented and synthesized into a disposition report, which will be made publicly available 3 months after the final version of the review is posted on the AHRQ Web site.

Results

We identified 3,448 nonduplicate titles or abstracts with potential relevance, with 830 proceeding to full-text review (Figure 2). Sixty-four were included in the review, representing 60 distinct studies: 16 randomized controlled trials (RCTs) (2 good quality,[16, 17] 2 fair quality,[18, 19], 12 poor quality[20-34]), 5 prospective cohort studies (1 good quality,[35] 2 fair quality,[36, 37] 2 poor quality[38, 39]), 21 retrospective cohort studies (4 good quality,[40-44] 17 poor quality[45-61]), 16 prospective case series (1 good quality,[62] 3 fair quality,[63-65] 12 poor quality[66-77]), and 2 retrospective case series (1 fair[78] and 1 poor quality[79]). Eighteen studies pertain to Key Question (KQ) 1a, 2 studies to KQ1b, 14 studies to KQ2, 26 studies to KQ3, 23 studies to KQ4, and 11 studies to KQ5.

Figure 2. Disposition of articles identified by the search strategy



*Articles may be excluded for multiple reasons.

KQ1a. Performance of Imaging Techniques

For determining a course of treatment, is imaging equivalent to laparoscopy in determining the presence and location of a nonpalpable testicle?

Key Points

- Eighteen studies (1 good quality,[62] 4 fair quality, [63-65, 78] and 13 poor quality[66-77, 79]) comprising 16 case series addressed imaging.
- Imaging approaches have a range of success rates at localizing cryptorchid testicles from 21 to 100 percent.
- The overall accuracy rate for identifying testicles ranged from 21 to 76 percent with ultrasound (US), 42 to 92 percent for magnetic resonance imaging (MRI) and was 60 percent in one study of computed tomography (CT) scan.
- Neither US nor MRI demonstrated high accuracy at identifying atrophied testicles (16.7 percent and 32.3 percent, respectively), compared to 100 percent accuracy for magnetic resonance angiography (MRA) and magnetic resonance venography (MRV).

Overview of the Literature

Eighteen unique studies met our inclusion criteria and addressed the performance of imaging techniques in identifying and locating nonpalpable undescended testicles in prepubescent boys. More studies were conducted in Asia (n=9) than in the United States (n=4) or Europe (n=5). All of the studies were conducted in a hospital setting. The number of participants in the studies ranged from 11 to 135; the potential number of nonpalpable testicles to be located ranged from 11 to 152. The boys' ages were between 1 month and 18 years (Table 5).

Table 5. Overview of studies addressing the performance of imaging techniques

Characteristic	US	MRI	CT	MRA	MRV	MRI & MRAr/V	Total Studies*
Total	9	10	1	2	1	1	18
Study Design							
Prospective case series	8	9	1	2	1	1	16
Retrospective case series	1	1	0	0	0	0	2
Confirmatory Diagnosis Category							
Open surgery	4	4	1	1	0	1	9
Laparoscopy	1	2	0	0	0	0	2
Surgery and/or laparoscopy	4	4	0	1	1	0	7
Included infants	3	4	0	0	0	1	7

Table 5. Overview of studies addressing the performance of imaging techniques (continued)

Characteristic	US	MRI	CT	MRA	MRV	MRI & MRAr/V	Total Studies*
Study Population							
United States	1	1	1	0	0	1	4
Europe	4	2	0	0	0	0	5
Asia	4	7	0	2	1	0	9
Total N participants	339	263	26	35	34	14	579
Total N testicles	391	294	30	40	44	14	658

CT = computed tomography; MRA = magnetic resonance angiography; MRI = magnetic resonance imaging; MRV = magnetic resonance venography; MRAr/v = MRI in combination with arteriography/venography; N = number; US = ultrasound
*Some studies include ≥ 1 imaging technique and number of subjects and testicles overlap.

Fourteen of the 18 studies (78 percent) assessed bilateral undescended testicles. Nine studies assessed the utility of US,[62-64, 68, 72, 73, 75, 77, 79] and 10 studies assessed MRI.[63, 65, 68-70, 72, 74, 76-78] Two studies of MRA[65, 77] and one study of CT scan[67] also met criteria for inclusion. MRV,[80] MRI in combination with arteriography/venography (MRAr/V),[66] and diffusion-weighted imaging (DWI) alone and in combination with conventional MRI[78] were the other techniques used to identify testicles. Sixteen studies were prospective case series[62-70, 72-77, 80] and 2 were retrospective case series.[78, 79]

Only four studies[62-65] adequately described selection criteria for the participants, and three studies provided the time interval between imaging techniques and surgery.[62, 78, 79] One study was of good quality,[62] 4 of fair quality, [63-65, 78] and 13 of poor quality.[66-70, 72-77, 79, 80] None of the studies reported any complication attributable to the imaging procedures.

Detailed Synthesis

Ultrasonography

Ultrasonography was used in nine of 18 studies to evaluate a total of 339 boys (391 testicles, 15.3 percent of boys with bilateral, nonpalpable testicles). One study was of good,[62] two of fair,[63, 64] and six were of poor quality.[68, 72, 73, 75, 77, 79] The participants ranged in age from 1 month to 17 years. Surgery confirmed the presence of 358 testicles (91.6 percent) with 33 (8.4 percent) absent or vanishing. Eighty-six (24.0 percent) of the testicles were found in the abdomen, 188 (52.5 percent) in the inguinal or scrotal region and 84 (23.5 percent) were found to be atrophied. Prior to surgery, 222 (56.8 percent) had been identified as present with US and 169 were indicated to be absent. The one good quality study [62] described selection criteria of participants, reported patient characteristics including previous surgeries, provided the time interval between imaging and surgery, and provided details on how imaging and surgery were conducted. The study reported only one intra-abdominal testis as identified by surgery.[62]

Of the 358 testicles found during surgery, US had identified 219 (61.2 percent), and correctly predicted that 30 testicles would be absent or vanishing (90.9 percent). Ultrasonography falsely identified three testicles as present when they were absent, and failed to identify 139 testicles that were found surgically. The sensitivity with which US identified the presence of surgically confirmed testicles ranged from 15 percent[73] to 80 percent across studies,[62] and the specificity was generally close to 100 percent except in two studies that reported substantially lower specificities of 67 percent[62] and 80 percent.[72]

The study-specific accuracy rate (using surgery as a reference standard) for US ranged from 21.4 percent[73] to 76 percent (Table 6).[72]The one good quality study had an accuracy rate of 73 percent [62]. In the three cases where US suggested the presence of testicles that turned out to be false positives, two were scar tissue[62] and one was a lymph node structure.[72]

Table 6. Studies assessing US for locating nonpalpable undescended testicles

Study N (N testicles) Quality	Reference Standard	Se (%)	Sp (%)	PPV (%)	NPV (%)	Accuracy (%)
Kullendorff et al. 1985[62] 11 (11) Good	Surgical exploration	80	67	67	80	73.0
Al-Shareef et al. 1996[63] 19 (24) Fair	Laparoscopy	19	100	100	15	29.2
Cain et al. 1996[64] 64 (74) Fair	Surgical exploration	65	NA	100	0	64.9
Guvenc et al. 2005[79] 15 (17) Poor	Laparoscopy / surgical exploration	62	100	100	44	70.6
Kanemoto et al. 2005[68] 46 (55) Poor	Laparoscopy / surgical exploration	57	100	100	15	60.0
Maghnie et al. 1994[72] 17 (21) Poor	Surgical exploration	75	80	92	50	76.0
Malone et al. 1985[73] 11 (14) Poor	Laparoscopy / surgical exploration	15	100	100	8	21.4
Nijs et al. 2007[75] 135 (152) Poor	Surgical exploration	72	100	100	18	73.7
Yeung et al. 1999[77] 21 (23) Poor	Laparoscopy / surgical exploration	41	100	100	7	43.5

N = number; NPV = negative predictive value; PPV = positive predictive value; Se = sensitivity; Sp = specificity; US = ultrasound

The degree to which US correctly identified testicles differed by location of the testicles (Table 7). For example, although there were 86 normal testicles found by surgery in the abdomen, US identified only 29 of these, missing more than 65 percent. On the other hand, US correctly predicted the presence of more than 90 percent of testicles found by surgery to be in the inguino-scrotal area. When testicles were atrophied, US was more likely to miss them altogether, failing to identify more than 80 percent of the 84 atrophied testicles across studies. Ultrasonography also "misplaced" three testicles, indicating that they were inguinally located when they were in fact in the abdomen.[75]

Table 7. Position and type of undescended testicles identified by surgery and US

Study N (N Testicles) Quality	Testicle Position & Type	Testicle Position by Surgery (N)	Testicle Position by Imaging (N)	Testicle Position Correctly Identified by Imaging N (%)
Kullendorff et al. 1985[62] 11 (11) Good	Intra-abdominal Inguino-scrotal Atrophy Total	1 4 0 5	2* 4 0 6	0 (0.0) 4 (100.0) NA 4 (80.0)
Al-Shareef et al. 1996[63] 19 (24) Fair	Intra-abdominal Inguino-scrotal Atrophy Total	16 0 5 21	4 0 0 4	4 (25.0) NA 0 (0.0) 4 (19.0)
Cain et al. 1996[64] 64 (74) Fair	Intra-abdominal Inguino-scrotal Atrophy Total	11 42 21 74	1 40 7 48	1 (9.1) 40 (95.2) 7 (33.3) 48 (64.9)
Guvenc et al. 2005[79] 15 (17) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	7 0 6 13	6 0 2 8	6 (85.7) NA 2 (33.3) 8 (61.5)
Kanemoto et al. 2005[68] 46 (55) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	3 35 13 51	0 29 0 29	0 (0.0) 29 (82.9) 0 (0.0) 29 (56.9)
Maghnie et al. 1994[72] 17 (21) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	4 6 6 16	2 6 5 13	1 (25.0) 6 (100.0) 5 (83.3) 12 (75.0)
Malone et al. 1985[73] 11 (14) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	7 5 1 13	1 1 0 2	1 (14.3) 1 (20.0) 0 (0.0) 2 (15.4)
Nijs et al. 2007[75] 135 (152) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	33 86 24 143	16 87 0 103	16 (48.5) 84 (97.7) 0 (0.0) 100 (69.9)
Yeung et al. 1999[77] 21 (23) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	4 10 8 22	0 9 0 9	0 (0.0) 9 (90.0) 0 (0.0) 9 (40.9)
Total 339 (391)	Intra-abdominal Inguino-scrotal Atrophy	86 188 84	32 176 14	29 (33.7) 173 (92.0) 14 (16.7)

NA = not applicable; N = number; US = ultrasonography
*Scar tissue..

Computed Tomography Scan

Computed tomography scan was used in one poor quality prospective case series of 26 boys, ranging in age from 2 to 18 years.[67] A total of 30 possible testicles were evaluated. Four boys had bilateral, nonpalpable testicles. Those boys in whom CT scan failed to locate the testicles were also assessed with spermatic venography. Due to technical difficulties or family refusals,

relevant data for spermatic venography could be extracted only for nine patients and are not discussed here.

Surgery determined that 28 testicles (93.3 percent) were present and 2 (6.7 percent) were absent. Nine (32.1 percent of 28) were found in the abdominal region and 19 (67.9 percent) in the inguino-scrotal region, including 17 at the internal ring, one each in the inguinal canal and in the canalicular region. Computed tomography scan identified 16 testicles as present (53.3 percent) and the proportion of absent testicles was 0.47 (46.7 percent). Computed tomography scan did not falsely predict any testicles to be present when they were not, but it did miss 12 testicles. Thus CT scan was able to identify testicles with a sensitivity of 57 percent, and specificity of 100 percent. Negative predictive value was 14.3 percent, with a 100 percent positive predictive value. Overall accuracy was 60 percent but the study was of poor quality (Table 8).

Table 8. Studies assessing CT scan for locating nonpalpable undescended testicles

Study N (N testicles) Quality	Reference Standard	Se (%)	Sp (%)	PPV (%)	NPV (%)	Accuracy (%)
Green 1995[67] 26 (30) Poor	Surgical exploration	57	100	100	14	60.0

CT = computed tomography; N = number; NPV = negative predictive value; PPV = positive predictive value; Se = sensitivity; Sp = specificity

CT scan correctly located 11 testicles in the inguino-scrotal region with 10 testicles at internal ring, 1 at inguinal canal and 5 in the abdominal region in 1 poor quality study (Table 9). However, it missed four intra-abdominal, one canalicular testicles and seven testicles at internal ring. Overall, CT scan located similar proportion of testicles at inguinal (57.9 percent) and in the abdominal regions (55.6 percent).

Table 9. Position and type of undescended testicles identified by surgery and CT scan

Study N (N Testicles) Quality	Testicle Position & Type	Testicle Position by Surgery (N)	Testicle Position by Imaging (N)	Testicle Position Correctly Identified by Imaging N (%)
Green 1995[67] 26 (30) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	9 19 0 28	5 11 0 16	5 (55.6) 11 (57.9) - 16 (57.1)

CT = computed tomography; N = number

Magnetic Resonance Imaging

Ten studies (3 of fair[63, 65, 78] and 7 of poor quality[68-70, 72, 74, 76, 77]) evaluated the accuracy of MRI for identifying nonpalpable testicles in a total of 263 boys with 294 testicles (31 boys with bilateral testicles). Seven of 10 studies were conducted in Asia. The boys were 8 months to 14.6 years in age. Both conventional and diffusion-weighted MRI (DWI) techniques were used (Table 10).

One fair quality case series used three types of MRI (conventional, DWI, and a combination of MRI and DWI) and two observers to read the pre-operative MRI images of 36 boys with 38 testicles.[78] Thirty-four testicles were found laparoscopically (89.5 percent) while 4 were not identified (10.5 percent). Using conventional MRI, observer 1 and observer 2, identified 29 and

30 testicles, respectively, as present. The overall accuracy rate (using surgery as a reference standard) for conventional MRI was 86 and 84 percent. Using DWI, observer 1 and observer 2 correctly identified the presence and absence of testicles with an accuracy rate of 86 percent and 81 percent, respectively. The diagnostic performance was superior when DWI and conventional MRI were used together. Both observers identified 31 testicles with a sensitivity of 0.88 and 0.91, specificity and PPV of 100 percent and an overall accuracy rates of 92 and 86 percent. The one false positive case identified with all the methods was confirmed to be an infected lymph node. Of the 34 testicles identified by laparoscopy, 19 (50 percent) were intracanalicular in position, while 11 were low intra-abdominal (29 percent) and 4 (10.5 percent) were high-intra-abdominal. Among the intra-abdominal testicles, one was reported to be atrophic (2.6 percent) which both observers failed to locate. Though both observers correctly located all 29 testicles by conventional MRI, details of the actual locations of these testicles were not reported.

Of the remaining nine studies, most of which were poor quality,[68-70, 72, 74, 76, 77] 256 testicles were evaluated with MRI (227 boys, 12.8 percent with bilateral, nonpalpable testicles). Surgery identified 214 testicles (83.6 percent) as present and 42 as absent, while MRI found 146 testicles (57 percent) as present and 110 (43 percent) as absent. MRI falsely identified 5 testicles as present including 4 lymph node structures[68] and failed to identify 73 testicles that were found surgically. Overall, MRI was able to correctly identify testicles with a sensitivity ranging from 0.33 to 0.82, specificity from 0.56 to 1.0, PPV of 0.83 to 1.0, and an overall accuracy rate of 42 to 83 percent. Overall accuracy ranged from 41.7 to 92 percent among fair studies and 43.5 to 88 percent in poor studies.

Table 10. Studies assessing MRI for locating nonpalpable undescended testicles

Study N (N testicles) Quality	Reference Standard	Se (%)	Sp (%)	PPV (%)	NPV (%)	Accuracy (%)
Al-Shareef et al. 1996[63] 19 (24) Fair	Laparoscopy	33	100	100	18	41.7
Kantarci et al. 2010[78] (by 2 raters) 36 (38) Fair	Laparoscopy	85 85	100 75	100 97	44 44	86 84
Kantarci et al. 2010[78] (by 2 raters) 36 (38)* Fair	Laparoscopy	88 82	75 75	97 97	43 33	86 81
Kantarci et al. 2010[78] (by 2 raters) 36 (38)† Fair	Laparoscopy	91 88	100 75	100 97	57 43	92 86
Lam et al. 1998[65] 14 (17) Fair	Surgical exploration	82	NA	100	0	82
Kanemoto et al. 2005[68] 46 (55) Poor	Surgical exploration / laparoscopy	63	56	86	26	61.7
Kato et al. 2011[69] 56 (63)† Poor	Laparoscopy / surgical exploration	80	100	100	39	82.5
Kier et al. 1988[70] 14 (15) Poor	Laparoscopy / surgical exploration	63	86	83	67	73.3
Maghnie et al. 1994[72] 17 (21) Poor	Surgical exploration	69	100	100	50	76
Miyano et al. 1991[74] 17 (17) Poor	Surgical exploration	82	100	100	75	88
Siemer et al. 2000[76] 29 (29) Poor	Surgical exploration	68	100	100	33	72.4
Yeung et al. 1999[77] 21 (23) Poor	Laparoscopy / surgical exploration	41	100	100	7	43.5

MRI = magnetic resonance imaging; N = number; NA = not applicable; NPV = negative predictive value; PPV = positive predictive value; Se = sensitivity; Sp = specificity
*Diffusion-weighted MRI.
†Conventional MRI and diffusion-weighted MRI.

Table 11 lists the location of testicles as identified by surgery and MRI. One study did not provide MRI results for the position or type of testicles and therefore does not contribute data to this table.[78] Surgery located 52 testicles in the intra-abdominal region and 100 in the inguino-scrotal region, while MRI located 38 (26 percent) testicles intra-abdominally and 88 (60.3

percent) in the inguino-scrotal region. Surgery and MRI also located 62 and 20 atrophic testicles respectively. MRI wrongly classified one testicular nubbin[69] as an intra-abdominal testicle. Overall, MRI was able to correctly locate 71.2 percent of the intra-abdominal testicles, 83 percent of the testicles in inguinal or scrotal region and only 32.3 percent of the atrophied testicles.

Table 11. Position and type of undescended testicles identified by surgery and MRI

Study N (N Testicles) Quality	Testicle Position & Type	Testicle Position by Surgery (N)	Testicle Position by Imaging (N)	Testicle Position Correctly Identified by Imaging N (%)
Al-Shareef et al. 1996[63] 19 (24) Fair	Intra-abdominal Inguino-scrotal Atrophy Total	16 0 5 21	6 0 1 7	6 (37.5) NA 1 (20.0) 7 (33.3)
Lam et al. 1998[65] 14 (17) Fair	Intra-abdominal Inguino-scrotal Atrophy Total	3 11 3 17	3 11 0 14	3 (100.0) 11 (100.0) 0 (0.00) 14 (82.3)
Kanemoto et al. 2005[68] 40 (47) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	2 26 10 38	2 26 0 28	2 (100.0) 22 (84.6) 0 (0.00) 24 (63.2)
Kato et al. 2011[69] 56 (63)[†] Poor	Intra-abdominal Inguino-scrotal Atrophy Total	13 13 30 56	14 13 18 45	13 (100.0) 13 (100.0) 18 (60.0) 44 (78.6)
Kier et al. 1988[70] 14 (15) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	1 7 0 8	0 6 0 6	0 (0.00) 5 (71.4) NA 5 (62.5)
Maghnie et al. 1994[72] 17 (21) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	4 6 6 16	4 6 1 11	4 (100.0) 6 (100.0) 1 (16.7) 11 (68.8)
Miyano et al. 1991[74] 17 (17) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	1 10 0 11	1 8 0 9	1 (100.0) 8 (80.0) NA 9 (81.8)
Siemer et al. 2000[76] 29 (29) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	8 17 0 25	7 10 0 17	7 (87.5) 10 (58.8) NA 17 (68.0)
Yeung et al. 1999[77] 21 (23) Poor	Intra-abdominal Inguino-scrotal Atrophy Total	4 10 8 22	1 8 0 9	1 (25.0) 8 (80.0) 0 (0.00) 9 (40.9)
Total 227 (256)	Intra-abdominal Inguino-scrotal Atrophy	52 100 62	38 88 20	37 (71.2) 83 (83.0) 20 (32.3)

N = number; MRI = magnetic resonance imaging

Magnetic Resonance Arteriography/Venography

Fourteen boys with a mean age of 28 months (range: 3–144) underwent MRI and MRAr/V as part of a larger, poor quality, prospective case series.[66] Imaging predicted that eight of the 14 testicles (57 percent) would be present, and that six (42.9 percent) were absent. No testicles were falsely predicted to be present by imaging, resulting in an overall accuracy rate for identifying testicles of 57 percent, and a positive predictive value of 100 percent (Table 12).

Table 12. Studies assessing other magnetic resonance techniques for locating nonpalpable undescended testicles

Study N (N testicles) Technique Quality	Reference Standard	Se (%)	Sp (%)	PPV (%)	NPV (%)	Accuracy (%)
Lam et al. 1998[65] 14 (17) MRA Fair	Surgical exploration	100	NA	100	NA	100
Desireddi et al. 2008[66] 14 (14) MRI & MRAr/V Poor	Surgical exploration	57	NA	100	0	57
Lam et al. 2001[71] 34 (44) MRV Poor	Laparoscopy / surgical exploration	100	100	100	100	100
Yeung et al. 1999[77] 21 (23) MRA Poor	Laparoscopy / surgical exploration	100	100	100	100	100

N = number; NPV = negative predictive value; MRA = magnetic resonance angiography; MRAr/V = MRI in combination with arteriography/venography; MRI = magnetic resonance imaging; MRV = magnetic resonance venography; PPV = positive predictive value; Se = sensitivity; Sp = specificity

Of the 14 testicles found surgically, five were located intra-abdominally, five were testicular nubbins, three were normal testicles in the inguinal canal and one was in the scrotum. MRI with MRAr/V correctly located 80 percent (4 of 5) of intra-abdominal testicles, 40 percent (2 of 5) of testicular nubbins, and 50 percent (2 of 4) of testicles in the inguino-scrotal region (Table 13). However it failed to correctly locate one of each scrotal, intra-abdominal, intracanalicular and three testicular nubbins.

Table 13. Position and type of undescended testicles identified by surgery and other magnetic resonance related techniques

Study N (N testicles) Technique Quality	Testicle Position & Type	Testicle Position by Surgery (N)	Testicle Position by Imaging (N)	Testicle Position Correctly Identified by Imaging N (%)
Lam et al. 1998[65] 14 (17) MRA Fair	Intra-abdominal Inguino-scrotal Atrophy Total	3 11 3 17	3 11 3 17	3 (100.0) 11 (100.0) 3 (100.0) 17 (100.0)
Desireddi et al. 2008[66] 14 (14) MRI & MRAr/V Poor	Intra-abdominal Inguino-scrotal Atrophy Total	5 4 5 14	4 2 2 8	4 (80.0) 2 (50.0) 2 (40.0) 8 (57.1)
Lam et al. 2001[71] 34 (44) MRV Poor	Intra-abdominal Inguino-scrotal Atrophy Total	5 28* 4 37	5 28 4 37	5 (100.0) 28 (100.0) 4 (100.0) 37 (100.0)
Yeung et al. 1999[77] 21 (23) MRA Poor	Intra-abdominal Inguino-scrotal Atrophy Total	4 10 8 22	4 10 8 22	4 (100.0) 10 (100.0) 8 (100.0) 22 (100.0)
Total 35 (40)	Intra-abdominal Inguino-scrotal Atrophy	7 21 11	7 21 11	7(100.0) 21 (100.0) 8 (100.0)

N = number; MRA = magnetic resonance angiography; MRAr/V = MRI in combination with arteriography/venography; MRI = magnetic resonance imaging; MRV = magnetic resonance venography
*2 testicles at pelvic skinfold.

Magnetic Resonance Venography

Magnetic resonance venography was assessed in 34 boys with a mean age of 6.4 years (range: 1–16 years), for a total of 44 testicles in one poor quality case series.[71] Ten of the boys had bilateral nonpalpable testicles. Patients younger than 5 years old received oral sedation while others received IV sedative. Magnetic resonance venography identified 37 of 44 testicles as present (84.1 percent) while identifying seven of 44 testicles as vanishing testicles (15.9 percent), all of which were confirmed surgically for 100 percent accuracy (Table 12). Magnetic resonance venography correctly located all 28 inguino-scrotal testicles (26 canalicular, and two testicles at pelvic skinfold), five intra-abdominal and four atrophic testicles, yielding a 100 percent accuracy rate in locating nonpalpable testicles (Table 13).

Magnetic Resonance Angiography

Two studies assessed gadolinium-infusion MRA in the identification of bilateral, nonpalpable undescended testicles in 35 boys (40 testicles), ages 1 to 16.[65, 77] Both studies were conducted in China and were prospective. One had fair quality,[65] and one was poor quality.[77] No adverse effects were reported with gadolinium infusions.

Surgery and MRA identified all 39 testicles as present (100 percent) and 1 as absent (Table 12).[77] MRA correctly located all the 7 intra-abdominal testicles, 21 inguino-scrotal testicles and 11 atrophied testicles confirmed by surgery, yielding an overall accuracy rate of 100 percent along with all the diagnostic performance indices at 100 percent (Table 13).

KQ1b. Hormonal Stimulation Testing

In male children with bilateral, nonpalpable testicles, does the use of hormonal stimulation testing reduce the need for surgery as part of a treatment plan?

Key Points

Only two studies (one fair and one poor quality) of hormonal stimulation testing were available; thus evidence is preliminary. Both included studies reported 100 percent sensitivity, indicating that no nonviable testicles were missed after hormonal stimulation treatment.

The studies were small and lacked a proper comparison of test characteristics between the thresholds assessed.

Overview of the Literature

Two studies assessed the utility of hormonal stimulation testing in identifying anorchia and avoiding the need for surgery in children with bilateral, nonpalpable cryptorchidism.[37, 39] Both were prospective cohort studies, one of fair quality[37] and one of poor quality.[39] One was conducted in the United Kingdom,[39] and the other in Hungary.[37] Both studies used human chorionic gonadotropin (hCG) to stimulate testicular testosterone production and confirm the presence of viable testicular tissue. A total of 44 children with bilateral nonpalpable cryptorchidism were enrolled in the two studies.

Detailed Synthesis

The fair quality study included 30 children total, but only 13 had bilateral, nonpalpable cryptorchidism.[37] The 30 participants were given three intramuscular injections of 1,500 IU of hCG over 3 consecutive days. Plasma testosterone was measured before initiation and after completion of the three injections by radioimmunoassay Of the 13 children with bilateral impalpable testicles, 9 had intra-abdominal testicles, 3 had bilateral anorchia, and 1 had unilateral aplastic testicle associated with contralateral intra-abdominal testicle at surgical exploration. In the nine children with bilateral intra-abdominal testicles, the mean testosterone level prior to hCG injection was 0.84 ng/mmol and increased to 5.45 ng/mmol after injection. In the three children with bilateral anorchia, the mean testosterone prior to hCG injection was 0.073 ng/mmol and 0.3ng/mmol after. None of the three patients with anorchia had a testosterone greater than 5 ng/mmol, although two did experience a greater than twofold rise from baseline.

In the poor-quality study, each of the 31 study participants with bilateral, nonpalpable cryptorchidism (age 1–12 years) was given an injection of 500, 1000, and 1500 IU of hCG for 3 consecutive days depending on their age.[39] Plasma testosterone was measured before and after these three injections using radioimmunoassay. Participants were judged to be anorchid if their plasma testosterone failed to double from baseline or, alternatively, to reach a peak of > 5 nmol/l after hCG stimulation. All patients then underwent surgical exploration. Eight were found to be anorchid. Of the remaining 23, 14 were found to have bilateral intra-abdominal testicles and 9 were noted to have either at least a unilateral intra-abdominal testicles or bilateral dysplastic testicles (which were usually excised). Among these 23 patients, 22 responded positively to the hCG stimulation test if a twofold rise in testosterone level from baseline was used as a threshold.

When a positive hCG test was defined as having a post-hCG testosterone of > 5ng/mmol, 15 of the 23 patients with viable testicular tissue had a positive response.

KQ2. Effectiveness of Hormone Therapy

What is the effectiveness of initial hormonal therapy (human chorionic gonadotropin or gonadotropin-releasing hormone) for the treatment of cryptorchidism for outcomes, including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location, and function of the testicles

Key Points

- Fourteen studies addressed hormonal therapy: 3 of good quality, [16, 35, 43, 44] 2 fair quality,[18, 19] and 9 of poor quality. [20-30, 38]
- Studies comparing hormonal treatment to placebo reported modestly higher rates of testicular descent for LHRH and hCG compared to placebo.
- Side effects were minimal and transient.
- Studies that compared doses and dosing schedules within hormone type were of poor quality and too heterogeneous to permit drawing any useful conclusions.
- There is moderate strength of evidence for increased testicular descent with LHRH compared to placebo, low strength of evidence for increased testicular descent with hCG compared to placebo and low strength of evidence for equivalence between LHRH and hCG.

Overview of the Literature

We found 19 publications from 14 distinct studies that addressed the effectiveness of initial hormonal therapy for the treatment of cryptorchidism (Table 14). Of the 14 studies, 11 were RCTs,[16, 18-30] 2 were prospective cohort studies,[35, 38] and 1 was a retrospective cohort study.[43, 44] Three studies were of good quality, [16, 35, 43, 44] two were of fair quality,[18, 19] and nine were of poor quality. [20-30, 38]

Although the literature is heterogeneous in terms of hormones used and outcomes assessed, most studies (n = 9) include LHRH or its analog/agonist in at least one arm.[16, 18-20, 23-25, 27, 29, 30, 38] Other agents assessed include hCG (n = 8),[16, 18, 20-22, 26, 28, 35, 38] hMG (n=2),[20, 38] and Buserelin (n = 2).[21, 22, 43, 44] Six studies included a placebo arm.[18, 19, 23-25, 27, 29, 30] One study examined long-term fertility outcomes associated with the use of hormonal treatment around surgery.[43, 44]

Table 14. Overview of cryptorchidism literature addressing outcomes of interest

Characteristic	RCTs	Prospective Cohort Studies	Retrospective Cohort Studies	Total
Total studies	11	2	1	14
Outcomes Reported				
Testicular descent	11	2	0	13
Long term fertility outcome	0	0	1	1
Interventions Used*				
LHRH	8	1	0	9
hCG	6	2	0	8
hMG	1	1	0	2
Buserelin	1	0	1	2
Dosing comparisons	2	1	0	3
Study Population				
United States	1	0	0	1
Europe	9	1	1	11
Other	1	1	0	2
Total participants with cryptorchidism	1,496	359	60	1,915

hCG = human chorionic gonadotropin; hMG = human menopausal gonadotropin; LHRH = luteinizing hormone releasing hormone; N = number; RCT = randomized controlled trial
*Studies may utilize multiple interventions.

Detailed Synthesis

Studies of LHRH and/or Its Analogs

Six studies used a placebo-controlled design to assess the effectiveness of LHRH in the treatment of cryptorchidism.[18, 19, 23-25, 27, 29, 30] All were double-blind RCTs, with the most common outcome testicular descent (Table 15). One fair-quality, three-arm study compared hCG, LHRH and placebo and found hCG to be more effective than placebo at inducing successful descent of the undescended testicle into the scrotum.[18] This study is discussed in greater detail in the section on studies comparing different hormonal regimens.

One fair-quality RCT compared LHRH to placebo.[19] This study randomized 141 boys with cryptorchidism age 2 to 12 years to receive either LHRH 0.4mg or placebo intranasal three times a day for 4 weeks. One hundred twenty-three (87 percent) participants had complete followup, including 62 (97 testicles) in the LHRH group and 61 (90 testicles) in the placebo group. Success was assessed immediately following treatment and was defined as having both testicles fully descended into the scrotum. In the LHRH arm, 9.7 percent of participants were considered successfully treated compared to 1.6 percent in the placebo arm, but the difference was not statistically significant.

Three papers were published from one poor-quality RCT of the effectiveness of LHRH in achieving complete testicular descent in children from 1 to 12 years old.[23-25] Of 252 participants,

237 (with 281 cryptorchid testicles) had complete followup. Neither the approach to random sequence generation, nor the allocation concealment was adequate or clear in this study. Participants randomized to LHRH received a total dose of 1.2mg/day (200µg inhaled in each nostril three times a day) for 4 weeks. Treatment was unblinded 8 weeks after randomization (4 weeks of study drug followed by 4 weeks off of treatment) and outcomes assessed. Nine percent of participants randomized to LHRH achieved complete testicular descent compared to eight percent in the placebo group. Although no differences were seen in the primary comparison, initial testicular location may have been associated with success in that no testicle initially located above the external inguinal ring descended.

The remainder of the RCTs comparing LHRH to placebo had slightly higher rates of descent in the treatment arms relative to placebo, but all were of poor quality. One assessed clinically acceptable descent into the scrotum following LHRH 100ug three times a day for 28 days in each nostril.[27] Fifty cryptorchid boys aged 1.5 to 10.5 years enrolled in the study. Outcomes were assessed immediately following the completion of treatment. Three participants dropped out of the study, leaving 23 (with 29 cryptorchid testicles) in the LHRH arm and 24 (with 32 cryptorchid testicles) in the placebo arm. Although 18 testicles (62 percent) had a "therapeutic effect" (defined as "significant move from the pretreatment location towards the bottom of the scrotum") with LHRH compared to one (3 percent) in the placebo arm, only eight (28 percent) testicles treated with LHRH had complete descent into the scrotum (number with complete descent not reported for placebo arm). Six of these successfully treated testicles were located at the scrotal neck at the start of treatment while two were located in the inguinal canal. Six to12 months later, these last two had re-ascended out of the scrotum and required surgical repair.

Another poor-quality double-blinded RCT enrolled 50 boys aged 3 to 8 years with unilateral undescended testicles to receive either LHRH 100ug in each nostril or placebo six times a day for 28 days.[29]The primary outcome of interest was complete descent into the scrotum, which was assessed immediately following the completion of treatment and 6 months after randomization. Immediately following completion of treatment, 20 percent (5 of 25) of the participants in the LHRH arm had responded to treatment. Of these, three were considered complete responses and two were "borderline." Twelve percent (3 of 25) of patients in the placebo group experienced testicular descent immediately following treatment. Response to treatment was not durable, with only eight percent (2 of 25) in the LHRH arm and four percent (1 of 25) in the placebo arm still descended after 6 months. Neither this study nor the one described above identified factors associated with testicular re-ascent.

A similar RCT of poor quality randomized 49 participants aged 1.2 to 11.9 years to either LHRH 400ug in each nostril or placebo three times a day for a period of 28 days.[30] Outcomes were assessed 8 weeks after randomization. The authors note that 37 percent of 35 testicles in the LHRH experience some degree of descent at 8 weeks compared to 18 percent of 34 in the placebo arm. However, no patients in the placebo group and only three (9 percent) in the LHRH group experienced complete descent.

Table 15. Short-term testicular descent in two-arm, randomized, placebo-controlled studies

Study N Length of Followup Quality	LHRH Dose	LHRH Frequency	LHRH Duration	LHRH Descent (%)	Placebo Descent (%)
Olsen et al., 1992[19] N = 123 4 weeks Fair	400µg	3 times daily	4 weeks	9.7	1.6[a]
De Muinck Keizer-Schrama and Hazebroek et al., 1986-1987[23, 24, 25] N = 237 8 weeks Poor	200µg	3 times daily	4 weeks	9.0	8.0
Hagberg and Westphal, 1982[27] N = 50 4 weeks Poor	100µg	3 times daily	28 days	62.0	3.0
Karpe et al., 1983[29] N = 50 6 months Poor	100µg	6 times daily	28 days	20.0	12.0
Wit et al., 1986[30] N=49 8 weeks Poor	400µg	3 times daily	28 days	37	18

CI = confidence interval; LHRH = luteinizing hormone releasing hormone; N = number
[a]Statistical significance was reported only for this comparison—p=0.12 (95% CI, 0.1 to 16.6).

Studies Focused on hCG and/or Its Analogs

One fair-quality, three-arm study compared hCG, LHRH and placebo and found hCG to be more effective than placebo at inducing successful descent of the undescended testicle into the scrotum.[18] This study is discussed in greater detail below in the section on studies comparing different hormonal regimens.

Three different studies (one of good[35] and two of poor[26, 28] quality) compared different dosing regimens of hCG (Table 16). These studies primarily focused on comparing higher vs. lower doses of the drug, with the intent to make the administration schedule easier and minimize side-effects. One poor-quality study randomized 183 cryptorchid boys to receive either hCG 1500 IU by intramuscular (IM) injection every other day for 14 days (88 participants) or four IM injections in a dose related to body weight (100 IU/kg) every 4–5 days to a maximal dose of 3000 IU (95 participants).[26] Successful outcome was defined as complete testicular descent into the scrotum and was assessed immediately following the conclusion of treatment. In children

with unilateral cryptorchidism, 50.8 percent and 50.9 percent of participants in each groups had successful outcomes. In children with bilateral cryptorchidism, 48.3 percent of participants in the lower dose group and 50 percent of those in the higher dose group had successful outcomes. Not surprisingly, children in whom the undescended testicle(s) was/were initially in the mid-inguinal canal or lower had higher success rates than those who had testicles located above that level.

The second study examining different dosing strategies of hCG primarily focused on schedule of administration as opposed to total dose received.[28] This poor-quality RCT randomized 332 boys with 435 cryptorchid testicles aged 1 to 13 years to receive either 2 lower dose hCG injections per week for 5 weeks or 1 higher dose hCG injection every 7–10 days for 3 weeks. The total dose received was effectively the same between the two arms and was determined by the age of the participant at the time of randomization. Complete success was defined as full descent of the testicle into the scrotum and was assessed between 8 weeks and 6 months after the conclusion of treatment. Restricting the analysis to cryptorchid testicles located above the high scrotum, the dosing schedule with more injections had a significantly higher complete success rate than the schedule with fewer injections (39.4 vs. 29.9 percent, $p<0.05$). However, children with abdominal testicles were significantly more likely to report complete success with more intensive injection regimen (31.5 vs. 13.5 percent, $p<0.05$). In addition, older children randomized to the more intensive dosing schedule (age 6–13) were more likely to report complete success than those assigned to the strategy with fewer injections (46.4 vs. 21.6 percent, $p<0.05$).

Similar to the study above that failed to show a difference between higher and lower doses of hCG, one good-quality prospective observational study comparing low-dose hCG (500 IU/week for 3 weeks) to a higher-dosing regimen (1,500 IU/m2 three times a week for 3 weeks) and found similar results.[35] Again, success was defined as complete descent into the scrotum and was assessed immediately following the conclusion of treatment. Twenty-one children were treated with the lower dose, which had a success rate of 66.7 percent, compared with 14 children treated with the higher dose, which had a success rate of 57.1 percent (p=NS)

Table 16. Testicular descent in studies comparing dosages of hCG

Study N Length of followup Quality	hCG Dose	hCG Frequency	hCG Duration	Descent, Side Unspecified (%)	Descent, Unilateral (%)	Descent, Bilateral (%)**
Aycan et al., 2006[35] N = 35 3 weeks Good	500 IU	Once a week	3 weeks	66.7	NR	NR
	1,500 IU/m^2	3 times a week	3 weeks	57.1	NR	NR
Forest et al., 1988[26] N = 183 2-3 weeks Poor	1,500 IU	Every other day	14 days	NA	50.8	48.3
	100 IU/Kg to a maximum of 3,000 IU	4 injections every 4-5 day interval	NR	NA	50.9	50.0
Hesse and Fischer, 1988[28] N = 332 8-24 weeks Poor	300-1,000 IU*	2 injections / week	5 weeks	NA	44.2	40.8
	1,000-5,000 IU†	1 injection every 7-10 days	3 weeks	NA	35.5	30.9

hCG = human chorionic gonadotropin; IU = international units; NA = not applicable; NR = not reported
*1-2 yrs old: 300 IU; 2-6 yrs old: 500 IU; 6-13 yrs old: 1,000 IU.
†1-3 yrs old: 1,000; 3-6 yrs old: 1,500; 6-10 yrs old: 3,000; 10-13 yrs old: 5,000.
**No comparisons were statistically significant.

Studies Comparing Hormonal Regimens

Four studies compared the effectiveness of hCG and LHRH therapy (Table 17).[16, 18, 20, 38] A good-quality randomized double-blind study compared the effectiveness of intranasal LHRH 100µg inhaled in each nostril six times a day for 4 weeks to parenteral hCG 1.2mg daily for 4 weeks.[16] In each arm, placebo injections or inhalations using the same administration schedule were also given to ensure blinding. Thirty-three boys with unilateral (29) or bilateral (4) cryptorchidism were enrolled in the study. The primary outcome was complete scrotal descent and was assessed immediately following treatment and then monthly for up to three months after the conclusion of treatment. One participant in the hCG (5.9 percent) had complete testicular descent into the scrotum as opposed to three in the LHRH arm (18.8 percent). The difference between the two arms was nonsignificant (p=0.23). The investigators conducted a parallel uncontrolled study of 13 boys with retractile testicle treated with the same hCG regimen which is presented in the same report. In this study, five of the 13 children (38.4 percent) had complete descent of the testicle into the scrotum[16]

One fair-quality RCT[18] that stratified by sidedness is not included in the table because it lacked pooled results, but is described here. The study describes a three-arm double-blind placebo controlled RCT assessing the effectiveness of hCG or LHRH. Children aged 1.8 to 13 years with unilateral or bilateral cryptorchidism were randomized to either hCG 100 IU/kg IM (maximum 1500 IU) twice weekly for 3 weeks, LHRH 200 µg intranasal in each nostril three times a day for 4 weeks, or inhaled placebo three times a day for 4 weeks. Although 330 participants were randomized, complete followup was available in only 243, of whom 155 had bilateral and 88 had unilateral cryptorchidism. After excluding 23 participants who were felt to have retractile testicles, the authors reported their results stratified by bilateral or unilateral disease. For participants with bilateral cryptorchidism, 23 percent treated with hCG reported complete descent of both testicles into the scrotum, as opposed to 9 percent in the LHRH group and 0 percent in the placebo group (Fisher's exact p=0.001). Among those with unilateral cryptorchidism, hCG was effective in inducing complete testicular descent in 15 percent of those treated with hCG, as opposed to 0 percent in either the LHRH or placebo groups (Fisher's exact p=0.02).

The remaining studies focused on combinations of hormonal therapy to determine if multidrug regimens worked better than single agents. One poor-quality RCT compared the effectiveness of four different hormonal regimens in 155 boys with unilateral palpable cryptorchidism age 10 to 48 months.[20] The four treatment regimens included: hCG 500-1000 IU intramuscular (IM) per week (depending upon age) for 6 weeks (n=37); hCG 500-1000 IU IM per week plus hMG 75 IU IM per week for 6 weeks; LHRH 1.2mg inhaled daily for 4 weeks and; LHRH 1.2 mg inhaled dialed for 4 weeks plus hCG 1500 IU IM per week for 3 weeks. Short-term testicular descent rates were similar among the four groups, with 22.5 percent of those in the LHRH-hCG group reporting complete testicular decent compared to 21.6 percent in the hCG alone group, 17.9 percent in the hCG-hMG group and 15.4 percent in the LHRH alone group. Roughly 5 percent of descended testicles had relapsed at 6 months with no differences noted among the groups. The overall long-term success rate in the study was 15 percent, with success rates within the four groups varying from 13 to 19 percent. The authors note that 74 percent of boys on hCG and 5 percent of those on LHRH initially reported signs of androgenization, such as erections and penis growth that receded at long-term followup.

Table 17. Testicular descent in studies comparing LHRH with hCG*

Study N Length of Followup Quality	hCG (%)	hCG + HMG (%)	LHRH (%)	LHRH + hCG (%)
Rajfer et al., 1986[16] N = 33 12 weeks Good	5.9	NA	18.8	NA
Bertelloni et al., 2001[20] N = 155 6 months Poor	18.9	12.8	12.8	15.0
Esposito et al., 2003[38] N = 324 4-6 weeks Poor	34.5	25.9	29.4	29.6

hCG = human chorionic gonadotropin; HMG = human menopausal gonadotropin; LHRH = luteinizing hormone releasing hormone; NA = not applicable
Christiansen et al., 1988[18] (reported in text) % descent reported for bilateral (hCG: 23%, LHRH: 9%, p=0.001) and unilateral (hCG: 15%, LHRH = 0%, p=0.02).
*No comparisons were significant.

Two papers from a single poor-quality RCT compared buserelin acetate (a gonadotropin-releasing hormone agonist which would function much like LHRH) 20 µg per day delivered in three inhaled doses for 4 weeks followed by hCG 1,500 IU IM per week for 3 weeks to inhaled placebo followed by hCG 1,500 IU IM per week for 3 weeks.[21, 22] Twenty-two participants with cryptorchidism were randomized to buserelin/hCG arm while 19 were randomized to the placebo/hCG arm. The primary outcome testicular descent assessed 3 months after the conclusion of hCG therapy. Thirty-six percent (8 of 22) of patients in the buserelin/hCG group were noted to have complete testicular descent at 3 months, as opposed to 11 percent (2 of 19) in the placebo/hCG group ($p<0.01$). It is worth noting that in both groups all but one of the testicles that responded to treatment was located in the prescrotal position at the time of randomization, indicating that cryptorchid testicle located closer to the scrotum are more likely to respond to hormonal treatment.

Finally, one poor-quality prospective cohort study examined 324 children with palpable unilateral or bilateral cryptorchidism aged 6 months to 13 years who were treated with one of five hormonal regimens: hCG 500 IU IM twice a week for 6 weeks (n=113); human menopausal gonadotropin (hMG) 150 IU IM twice a week for 4 weeks (n=35); LHRH 1.2mg inhaled daily for 4 weeks (n=85); hMG 150 IU IM twice a week for 4 weeks followed by hCG 500 IU IM twice a week for 6 weeks (n=27) and; LHRH 1.2mg inhaled daily for 4 weeks followed by hCG 500 IU IM twice a week for 6 weeks (n=64).[38] The authors reported that treatment was randomly assigned by 6-month period, whereby every six months a new treatment was randomly assigned and all participants enrolled during that time would receive that therapy. The primary outcome was complete descent into the scrotum (mid- or low scrotal position) after the completion of therapy although the exact timing of the assessment of the outcome is not reported, hCG alone was the most effective treatment, resulting in complete testicular descent in 34.5 percent of participants. The two next most effective therapies were LHRH alone and LHRH and hCG treatment resulting in testicular descent 29.4 and 29.6 percent of the time, respectively. Combined hCG and hMG resulted in testicular descent 25.9 percent of the time, while hMG

alone was completely ineffective with no participants reporting complete testicular descent. There were no significant differences in effectiveness between the four effective therapies. Successful outcomes were defined as complete descent into the scrotum and were assessed 1 week and 6 months after the conclusion of therapy.

Long-Term Fertility Outcomes Following Hormonal Therapy

No reports on long-term fertility outcomes following isolated hormonal therapy were found in our literature search. One good-quality study explored long-term fertility outcomes of hormonal therapy as an adjunct to surgical treatment in cryptorchidism.[43, 44] This study compared 15 young men who had cryptorchidism and were treated as children with orchiopexy followed by Buserelin 10ug intranasal every other day for 6 months to 15 age-matched controls who were treated by orchiopexy alone. The primary outcomes were semen analysis parameters measured in early adulthood (mean age=19 years). Those participants who received surgery and buserelin had significantly higher sperm counts (90 $x10^6$ sperm per ejaculate compared to $1x10^6$ in the surgery only group, $p<0.001$). In addition, 11 percent of those who received surgery and hormone therapy had normal morphology as opposed to none in the surgery alone group.

KQ3. Effectiveness of Surgical Therapy

What is the effectiveness of surgical therapies (one-stage vs. two-stage, laparoscopic vs. open approach) for the treatment of cryptorchidism for outcomes including but not limited to:

- Further surgical intervention
- The effect on infertility/subfertility
- The development of testicular malignancy
- The size, location and function of the testicles

Key Points

- Of 26 studies addressing surgical interventions, 4 were of good quality,[17, 40-42 1] of fair quality,[36] and the remainder of poor quality.[31-34, 45-61]
- Surgical treatment for cryptorchidism was associated with success rates of testicular descent that ranged from 33 percent to 100 percent. The type of surgery used depends on clinical presentation.
- Few studies compared the effectiveness of interventions on future fertility.
- There is moderate strength of evidence for a rate of descent of 84.2 percent (33 to 100 percent) among patients treated with one FS and for a rate of descent of 89 percent (67 to 98 percent) for patients treated with two-stage FS.
- There is high strength of evidence for a rate of descent of 96.8 percent (89.1 to 100 percent) associated with primary orchiopexy.

Overview of the Literature

Twenty-six studies provided outcomes of various surgical interventions for the treatment of cryptorchidism (Table 18). Five were RCTs,[17, 31-34] one was a prospective cohort,[36] and the remainder were retrospective cohorts.[40-42, 45-61] Ten were from North America,[36, 40, 41, 45, 46, 54, 56-58, 61] six from Europe,[17, 42, 47, 49, 52, 59] two studies were from Egypt,[31, 50] two studies from South Korea[33, 48] with one study from each of the following countries: Brazil,[60] Japan,[51] India,[55] Israel,[53] Iran[34] and Turkey.[32] Four studies were judged to be of good quality,[17, 40-42]one of fair quality,[36] and the remainder of poor quality.[31-34, 45-61]

Eleven studies reported on outcomes following either one-stage Fowler-Stephens (FS) orchiopexy, two-stage FS orchiopexy or primary orchiopexy in the same study.[40, 47, 48, 50, 52, 54, 56, 57, 59-61] Five studies primarily compared the same procedure performed through either a laparoscopic or open approach.[17, 31, 36, 49, 55] Six studies compared minor surgical variations of primary orchiopexy to one another.[32-34, 41, 45, 58] Three studies reported long-term fertility outcomes in men who underwent various surgical procedures for cryptorchidism in childhood,[46, 51, 53] while one compared endocrine function in children with surgically treated or untreated cryptorchidism.[42]

Table 18. Overview of surgical treatment studies addressing outcomes of interest

Characteristic	RCTs	Prospective Cohort Studies	Retrospective Cohort Studies	Total Literature
Total N studies	(n=5)	(n=1)	(n=20)	(n=26)
Outcomes Reported*				
Testicular descent	4	1	16	21
Atrophy	1	0	5	6
Fertility	0	0	3	3
Testosterone concentration	0	0	1	1
Interventions Used				
1 stage Fowler-Stephens	0	0	9	9
2 stage Fowler-Stephens	0	0	11	11
Primary orchiopexy	3	0	16	19
Laparoscopic exploration	1	0	1	2
Open exploration	1	0	1	2
Laparoscopic orchiopexy (primary or Fowler-Stephens)	1	1	1	3
Open orchiopexy (primary or Fowler-Stephens)	1	1	1	3
Study Population				
United States	0	0	7	7
Europe	1	0	5	6
Other	4	1	8	13
Total participants with cryptorchidism	685	66	1,950	2,701

N = number; RCT = randomized controlled trial
*Studies could report multiple outcomes.

Detailed Synthesis

Comparisons of Single-Stage, Two-Stage Fowler-Stephens and Primary Orchiopexy Procedures

The studies reporting results of surgical techniques were all retrospective, observational studies. Decisions about which method of surgical repair to use are made clinically, and not with the intent of comparing the effectiveness of the procedures in comparable groups of patients. The groups were therefore essentially different, and specific treatment choices were most likely made on the basis of where the affected testicle was located. Because these studies did not control for initial testicular location, the results can only be interpreted as providing noncomparative data on outcomes in groups with differing clinical presentations treated surgically. We identified 11 such studies, one of which was assessed as having good quality,[40] and the remainder poor quality.[47, 48, 50, 52, 54, 56, 57, 59-61] In all but one of these reports,[48] the authors failed to control for the location of the testicle in the abdomen. One study was of good quality and reported lower success rates across intervention types, but this study also did not control for testicular location.[40]

One Versus Two-Stage Fowler-Stephens Without Orchiopexy

Two studies reported outcomes for only one- and two-stage FS procedures and did not include primary orchiopexies.[57, 59] Neither reported the initial location of the testicle in the abdomen and the choice of one- versus two-stage approach was left to the operating surgeon, who decided at the time of the operation presumably based upon intra-operative findings. Comploj et al[59] noted no differences in success rates between 33 testicles treated with a one-stage FS procedure and 17 treated with a two-stage FS procedure. However, the exact definition of success is not clear, as at one point in the text, the authors note overall success rate of 79 percent in the one-stage FS group of and 82 percent in the two-stage FS group, yet in another part of the report, they report success rates of 64 percent and 76 percent, respectively. The paper also compares postoperative testicular volume measurements which presumably are more objective and may reflect testicular damage and atrophy related to both cryptorchidism and its treatment. Cryptorchid testicles treated with a one-stage FS procedure had lower mean post-operative volume compared to those treated with a two-stage FS procedure (0.38 cm^3 vs. 1.64 cm^3, respectively). The other study[57] that reported outcomes for only one- and two-stage FS procedures noted a higher success rate (defined as no atrophy) in the one-stage approach (94 percent, 33 of 35 testicles) than the two-stage approach (80 percent, 8 of 10).

Primary Orchiopexy Versus Two-Stage Fowler Stephens

Two studies compared primary orchiopexy to the two-stage FS procedure. Moursy et al[50] retrospectively compared outcomes in 36 nonpalpable testicles treated by two-stage FS orchiopexy to 28 treated with primary laparoscopy. Dhanani et al[61] compared outcomes in 28 nonpalpable testicles treated with primary orchiopexy and 55 testicles treated with a two-stage FS procedure. In both studies, the choice of procedure was left to the discretion of the operating surgeon who decided at the time of laparoscopic evaluation of the abdomen, presumably based on location of the cryptorchid testicle. In fact, the Moursy et al. study[50] specifically stated that high intra-abdominal testicles were treated with two-stage FS procedure, while low intra-abdominal testicles were treated by primary orchiopexy. In both studies, the success rate of primary orchiopexy was 100 percent, while the success rate following two-stage FS surgery was

89 percent in one study[50] and 98 percent in the other.[61] Neither study explicitly defined a "successful" outcome.

Primary Orchiopexy Versus One-Stage Fowler Stephens Versus Two-Stage Fowler Stephens

A single study controlled for location of the testicle by stratifying the analysis ("peeping" testicle vs. within 3 cm of the internal inguinal ring vs. beyond 3 cm of the internal inguinal ring).[48] The 3 cm cutoff was arbitrarily chosen by the study authors. The study compared laparoscopic primary orchiopexy to laparoscopy single and two-stage FS procedures. Eighty-six testicles were studied, but only 63 had more than 3 months of followup. One-stage FS orchiopexy was used to repair 11 testicles, of which three were located within 3 cm of the inguinal ring and eight were beyond 3cm from the inguinal ring. Nine (82 percent) of the testicles treated with a one-stage FS were viable 3-months post-operatively and both of the non-viable testicles were initially located beyond 3 cm from the inguinal ring.

The remaining 49 testicles were all treated with primary orchiopexy. Only one of these was initially located beyond 3 cm from the inguinal ring testicle and this one was viable 3 months after surgery. The remainder were all either within 3 cm of the inguinal ring or "peeping" and of these, 98 percent (47 of 48) were viable three months after surgery. Any direct comparison of surgical approaches in this study is limited by small sample size in the FS groups and the fact that location in the testicle influences both choice of approach and the underlying probability of post-operative viability.

Two studies comparing the three approaches reported intra-abdominal location of the nonpalpable testicle at the time of surgery, but neither stratified results by location. In one series of 101 nonpalpable cryptorchid testicles, 46 were "intra-abdominal," 14 were located at the iliac vessels, 22 were located at the inguinal ring, 12 were "peeping" through the ring, 3 were behind the bladder, and 4 were intracanicular.[56] Success rates (no specific definition given) were 92 percent for primary orchiopexy, 84 percent for one-stage FS, and 96 percent for two-stage FS orchiopexy. In a pooled series of 281 testicles, 65.2 percent of testicles treated by primary orchiopexy were either within 2 cm of the inguinal ring or peeping through the ring, in contrast to 6.9 percent of those repaired with one-stage FS orchiopexy and 21.1 percent with two-stage FS orchiopexy.[54] Among 19 "surgical failures," 13 were more than 2 cm from the internal ring, while only three were ectopic, two within 2 cm of the ring and two were "peeping."

Four studies[40, 47, 52, 60] did not report the distribution of intra-abdominal testicular location at the time of surgery, although three[40, 47, 60] specifically stated that when a testicle was located higher in the abdomen, one or two-stage FS procedure was performed, while when it was lower in the abdomen one-stage FS or primary orchiopexy was performed. Although post-operative atrophy and/or success rates for these studies are presented in Tables 19–24, it is impossible to determine if superior outcomes noted with one approach or another are due to the operation itself or to confounding by indication. Nine of the 11 studies provided success rates for primary orchiopexy, one-stage FS, or two-stage FS procedures. When the results of these nine studies are pooled, the overall success rate for primary orchiopexy is 96.4 percent (Table 19).

Table 19. Success rates after primary orchiopexy

Author Country	Quality	Total Participants	Total Testicles	% Success (N Testicles Treated)
Stec et al. 2009[40] United States	Good	136	156	89.1 (92)
Baker et al. 2001[54] United States	Poor	226	263	97.2 (178)
Chang et al. 2001[56] United States	Poor	80	92	100 (66)
Denes et al. 2008[60] Brazil	Poor	46	54	96 (26)
Dhanani et al. 2004[61] United States	Poor	74	83	100 (28)
Kim et al. 2010[48]* South Korea	Poor	67	86	98 (49)
Moursy et al. 2011[50] Egypt	Poor	66	76	100 (28)
Pooled %		**Total: 695**	**Total: 810**	**96.4**

N = number
*Controlled for location. All studies were retrospective cohorts.

The overall success rate for one-stage FS is 78.7 percent (Table 20).

Table 20. Success rates after one-stage Fowler-Stephens

Author Country	Quality	Total Participants	Total Testicles	% Success (N Testicles Treated)
Stec et al. 2009[40] United States	Good	136	156	63 (27)
Baker et al. 2001[54] United States	Poor	226	263	74.1 (27)
Chang et al. 2001[56] United States	Poor	80	92	84 (19)
Chang et al. 2008[57] United States	Poor	48	48	94.3 (35)
Comploj et al. 2011[59] Austria	Poor	41	50	79 (33)
Denes et al. 2008[60] Brazil	Poor	46	54	33 (3)
Kim et al. 2010[48]* South Korea	Poor	67	86	82 (11)
Pooled %		**Total: 644**	**Total: 749**	**78.7**

N = number
*Controlled for location. All studies were retrospective cohorts.

The overall success rate for two-stage FS is 86.0 percent (Table 21).

Table 21. Success rates after two-stage Fowler-Stephens

Author Country	Quality	Total Participants	Total Testicles	% Success (N Testicles Treated)
Stec et al. 2009[40] United States	Good	136	156	67.6 (37)
Baker et al. 2001[54] United States	Poor	226	263	87.9 (58)
Chang et al. 2001[56] United States	Poor	80	92	86 (7)
Chang et al. 2008[57] United States	Poor	48	48	80 (10)
Comploj et al. 2011[59] Austria	Poor	41	50	82 (17)
Denes et al. 2008[60] Brazil	Poor	46	54	88 (25)
Dhanani et al. 2004[61] United States	Poor	74	83	98 (49)
Kim et al. 2010[48]* South Korea	Poor	67	86	67 (3)
Moursy et al. 2011[50] Egypt	Poor	66	76	88.8 (36)
Pooled %		**Total: 784**	**Total: 908**	**86.0**

N = number
*Controlled for location. All studies were retrospective cohorts.

Five of the 11 studies provided atrophy rates for primary orchiopexy, one-stage FS, and two-stage FS procedures. When the results of these five studies are pooled, the overall atrophy rate for primary orchiopexy is 1.83 percent (Table 22).

Table 22. Atrophy rates after primary orchiopexy

Study Country	Quality	Total Participants	Total Testicles	% Atrophy (N Testicles Treated)
Baker et al. 2001[54] United States	Poor	226	263	2.2 (178)
Denes et al. 2008[60] Brazil	Poor	46	54	4 (26)
Humphrey et al. 1998[47] United Kingdom	Poor	48	20	0 (8)
Moursy et al. 2011[50] Egypt	Poor	66	76	0 (33)
Radmayr et al. 2003[52] Austria	Poor	84	57	0 (28)
Pooled %		**Total: 470**	**Total: 470**	**1.83**

N = number

The overall atrophy rate for one-stage FS is 28.1 percent (Table 23).

Table 23. Atrophy rates after one-stage Fowler-Stephens

Study Country	Quality	Total Participants	Total Testicles	% Atrophy (N Testicles Treated)
Baker et al. 2001[54] United States	Poor	226	263	22.2 (27)
Denes et al. 2008[60] Brazil	Poor	46	54	67 (3)
Humphrey et al. 1998[47] United Kingdom	Poor	48	20	50 (2)
Pooled %		**Total: 320**	**Total: 337**	**28.1**

N = number

The overall atrophy rate for two-stage FS is 8.2 percent (Table 24).

Table 24. Atrophy rates after two-stage Fowler-Stephens

Study Country	Quality	Total Participants	Total Testicles	% Atrophy (N Testicles Treated)
Baker et al. 2001[54] United States	Poor	226	263	10.3 (58)
Denes et al. 2008[60] Brazil	Poor	46	54	12 (25)
Humphrey et al. 1998[47] United Kingdom	Poor	48	20	0 (10)
Moursy et al. 2011[50] Egypt	Poor	66	76	5.6 (36)
Radmayr et al. 2003[52] Austria	Poor	84	57	6.9 (29)
Pooled %		**Total: 470**	**Total: 470**	**8.2**

N = number

While, on the surface, this may appear to favor primary orchiopexy over the two other approaches, all of these studies are observational cohort designs in which confounding by indication limits our ability to draw any conclusions regarding the superiority of primary orchiopexy to either the one- or two-stage FS approach. Nonetheless, these studies may provide some insight into surgical outcomes among these three clinically distinct groups.

Comparisons of the Same Procedure Performed Through Either an Open or Laparoscopic Approach

Given that the comparative effectiveness of the possible surgeries is unknown due to the confounding by indication noted above, the question of whether it might be possible to use a less invasive approach (laparoscopy rather than open surgery) becomes eminent. Five studies (one of good,[17] one of fair,[36] and three of poor quality[31, 49, 55]) compared laparoscopic versus open approaches of essentially the same procedure (Table 25). Two focused on approaches for exploration; three focused on surgical repair.

Two of the studies, one good[17] and one poor[55] quality, compared initial laparoscopic evaluation of the abdomen to open exploration in children with nonpalpable testicles. The good quality RCT reported randomizing 64 patients with 68 nonpalpable testicles to laparoscopic evaluation followed by open surgical repair depending upon laparoscopic findings to initial open exploration followed by appropriate treatment.[17] In 6 of 24 patients randomized to laparoscopy, intra-abdominal blind ending vessels and a closed inguinal ring was noted, and so open surgery was not performed. Twelve of 31 patients randomized to open exploration had a vanishing testicle. Mean operative time and cost were significantly higher in the laparoscopic group, but no differences were noted in recurrence rates. The second study was a poor-quality retrospective analysis to make a similar comparison of laparoscopic exploration followed by open repair to open exploration and repair.[55] Seven of 20 testicles in the laparoscopy arm were found to be non-viable, although the location of these vanishing testicles (intra-abdominal vs. canalicular) is not reported making it impossible to determine the number of patients that would have avoided open surgery with laparoscopic exploration. Rate of successful orchiopexy was similar between the two arms, although a specific definition of success was not given.

Table 25. Laparoscopic versus open exploratory approaches

Study N Design Quality	Nonpalpable / Palpable	Groups (N)	Outcomes
Ferro et al. 1999[17]* N = 64 RCT Good	Nonpalpable	Open surgical exploration (30) Laparoscopic exploration followed by open surgery (31)	• No differences in surgical approaches were noted. • No differences in post-operative recurrences were noted between the two groups.
Chandrasekharam et al. 2005[55] N = 27 Retrospective cohort Poor	Nonpalpable	Laparoscopic evaluation followed by appropriate surgical procedure (20) Open inguinal exploration followed by appropriate surgical procedure (20)	• Viable testicles were identified in 13/20 in the laparoscopic group and 14/20 in the open group. • Among viable testicles, 85% of patients in laparoscopic group had a "successful" orchiopexy compared to 86% in the open group.

N = number; RCT = randomized controlled trial
*Controlled for location.

The remaining three studies (one fair quality[36] and two poor[31, 49]) compared similar procedures using either a laparoscopic or an open approach (Table 26). One poor-quality RCT compared outcomes following various types of laparoscopic or open orchiopexies for nonpalpable testicles.[31] This study is one of the few reports in the literature that controlled for location of the testicle within the abdomen, allowing for comparisons between procedures. Specifically, the study design required that children who were found to have high abdominal testicles at the time of laparoscopic exploration underwent a two-stage FS procedure (with the second stage randomized to a open vs. laparoscopic approach) while those with low abdominal testicles underwent either open or laparoscopic primary orchiopexy. This greatly minimized the possibility of confounding by indication. The study was judged to be of poor quality because no information was given regarding the randomization process and the study was at high risk for both performance and detection biases. All patients in this study initially underwent laparoscopic evaluation of the abdomen to confirm the presence and location of a viable testicle. If the testicle

was noted to be high in the abdomen, the patient underwent a laparoscopic one-stage FS procedure (laparoscopic clipping of the testicular vessels). They were then randomized to receive either open or laparoscopic two-stage FS orchiopexy. Perioperative outcomes between participants undergoing laparoscopic or open second procedures were compared, with patients undergoing laparoscopic two-stage FS orchiopexy noted to have statistically significantly shorter operative times (p=0.000), time to oral feeding (p=0.004), hospital stays (p=0.008) and return to normal activities (p=0.000). While all testicles in both groups were noted to have satisfactory scrotal position after surgery, two of the 20 (10 percent) testicles in the laparoscopic arm and three of the 16 (19 percent) testicles in the open arm had atrophied after 1 year of follow-up. Patients in this study who had viable testicles located in the lower portion of the abdomen (closed to the inguinal ring) were randomized to undergo either laparoscopic or open primary orchiopexy. Like the high abdominal group, patients randomized to laparoscopic orchiopexy had statistically superior peri-operative outcomes. Of the 21 testicles randomized to laparoscopic orchiopexy and the 18 randomized to open orchiopexy, all were satisfactorily placed in the scrotum and no cases of atrophic testicles were noted after 1 year of follow-up.

The other two studies in this category were observational.[36, 49] One fair-quality cohort study included only palpable testicles and compared laparoscopic and open primary orchiopexy.[36] Despite having reasonable comparison groups, the results are difficult to interpret. The authors report that the participants undergoing the laparoscopic approach "had less pain when compared to the open technique in 80 percent of cases" using a visual analog scale, but how this comparison was made is unclear. Similarly, while the authors note that all patients had "satisfactory results in relation to size and location of testicle," details regarding these outcomes are lacking. Another poor quality cohort study included both palpable and nonpalpable testicles, failed to control for the location of the testicle in the analysis, and grouped both primary and FS orchiopexies into two heterogeneous groups based upon whether an open or laparoscopic approach was used, making it difficult to draw meaningful conclusions in terms of post-operative testicular position or viability.[49]

Table 26. Laparoscopic versus open surgical repair approaches

Study N Design Quality	Nonpalpable / Palpable	Groups (N)	Outcomes
Escarcega-Fujigaki et al. 2011[36] * N = 66 Prospective cohort Fair	Palpable	Laparoscopic orchiopexy (38 testicles)	• Laparoscopy caused less pain ("in 80% of cases"). • No differences in testicular position post-operatively.
		Open orchiopexy (37 testicles)	
Abolyosr 2006[31] * N = 75 RCT Poor	Nonpalpable	<u>High abdominal testicle</u> G1: Laparoscopic FSI followed by open FSII (20) G2: Laparoscopic FSI followed by laparoscopic FSII (21)	• Participants undergoing laparoscopic FSII had significantly shorter return to normal activity compared to open FSII (8.4 vs. 25 days, p<0.001). • While all patients in both groups had satisfactory scrotal position post-operatively, 0/21 in the laparoscopic FSII group had testicular atrophy compared to 2/20 in the open FSII group
		<u>Low abdominal and "peeping" testicle</u> G1: Laparoscopic primary orchiopexy (18) G2: Open primary orchiopexy (16)	• Participants undergoing laparoscopic orchiopexy had significantly shorter return to normal activity compared to open orchiopexy (9 vs. 28 days, p<0.001). • While all patients in both groups had satisfactory scrotal position post-operatively, 0/18 in the laparoscopic orchiopexy group had testicular atrophy compared to 3/16 in the open orchiopexy group
Lintula et al.2008[49] * N = 33 Retrospective cohort Poor	Nonpalpable	Laparoscopic orchiopexy (primary and FS) (16)	• No significant differences were noted in post-operative testicular position, size, complications or reoperation rates were noted between the two groups.
		Open primary orchiopexy (16)	

FS = Fowler Stephens; N = number; RCT = randomized controlled trial
*Controlled for location.

Comparisons of Various Surgical Modifications of Primary Orchiopexy

Six studies, one good[41] and five poor quality,[32-34, 45, 58] compared different modifications or techniques of orchiopexy. Three studies compared the type of incision used when performing primary orchiopexy.[33, 41, 58] The first study,[33] a poor-quality RCT, assigned 212 participants with low lying cryptorchid testes to undergo primary orchiopexy through either a single incision versus two incision approach. The study did not show a difference in success rates between the two procedures, with the single incision approach having a 92.5 percent success rate and the two incision approach having a 96.5 percent success rate. The only significant difference noted

between the two approaches was in operative time, with the single incision approach having shorter average operative times.

The good-quality retrospective cohort study compared 63 orchiopexies performed using a single prescrotal incision to 53 orchiopexies performed using the inguinal two-incision technique.[41] The two groups appeared comparable in terms of location and age at surgery. No differences were noted in testicular atrophy or re-ascent rates between the groups. The final poor quality retrospective cohort study reviewed 286 orchiopexy procedures clustered into three groups: (1) 125 performed through a low-scrotal incision; (2) 60 performed through a high scrotal incision and; (3) 101 performed using the inguinal two-incision technique.[58] Success rates between the three groups ranged from 98-100 percent and were not significantly different. It is worth noting that the two scrotal approaches were not attempted in any testicle that could not be milked down into the upper third of the scrotum under anesthesia, which may affect the comparability of the groups.

One poor-quality RCT randomized 104 participants to undergo either traditional primary orchiopexy, where the external oblique fascia is opened, or a "closed" technique, where the procedure is performed without opening the fascia.[34] The study did not report final location of the testicle in the scrotum but did report atrophy rates and found no significant differences between the two arms (2 percent vs. 4 percent). The primary outcome of the study was post-operative complication rates, with no differences noted between the two arms in terms of post-operative hematoma, infection or medial thigh sensory loss.

Another poor-quality RCT randomized boys with a total of 150 unilateral palpable undescended testicles undergoing scrotal pouch orchiopexy in three groups: (1) testicular fixation to the scrotal wall; (2) narrowing of the neck of the Dartos pouch and; (3) both testicular fixation to the scrotal wall and narrowing of the neck of the Dartos pouch.[32] Results were stratified by initial position of the testicle. No postoperative ascents were noted in the second or third group, but four of 50 testicles in the first group re-ascended out of the scrotum with a mean follow-up of 28 months. One testicle in the first group and one in the second group atrophied, while no atrophic testicles were noted in the third group. The authors conclude that only narrowing of the neck of the Dartos pouch is required to prevent re-ascent.

Finally, 1 poor-quality retrospective review compared 19 orchiopexies using a Jones approach (extensive retroperitoneal mobilization of the spermatic vessels without ligation through an incision medial to the superior anterior iliac spine) with 10 inguinal orchiopexies with testicular vessel ligation (effectively one-stage FS procedures).[45] Eighteen of the 19 orchiopexies performed using the Jones approach had a "satisfactory" outcome compared with 7 out of 10 in the inguinal orchiopexy group.

Fertility Indicators

Four retrospective cohort studies provided data on endocrine and fertility status and are discussed separately here.[42, 46, 51, 53] One good-quality study studied testicular endocrine function in children.[42] Three poor-quality studies focused on fertility and endocrine outcomes in adult men treated for cryptorchidism as children.[46, 51, 53]

One study of good quality compared plasma testosterone levels after hCG injection in 52 children with cryptorchidism and 10 age-matched controls.[42] Thirteen had untreated unilateral cryptorchidism, 10 had unilateral cryptorchidism and had previously undergone successful orchiopexy. The mean time between surgery and the study was 23 months. Seventeen had untreated bilateral cryptorchidism and 12 had bilateral cryptorchidism that had been successfully

treated with orchiopexy, generally about 24 months prior to the study. No significant differences were noted in post-hCG plasma testosterone levels between treated and untreated children with unilateral cryptorchidism (1.59 and 1.53 ng/ml respectively) and controls after hCG injection (1.67 ng/ml). In the bilateral group, however, untreated children had significantly lower testosterone levels when compared to treated children (0.94 vs. 1.58 ng/ml, $p<0.001$). Children who were treated for bilateral cryptorchidism had post-hCG testosterone levels that were not significantly different from controls.

Three poor-quality studies examined long-term fertility outcomes in men who were treated for cryptorchidism in childhood (Table 27).[46, 51, 53] One[46] reported actual paternity (ability to father children) rates, while the others[51, 53] reported semen analysis parameters. Men with unilateral cryptorchidism had higher paternity rates regardless of treatment when compared to men with bilateral cryptorchidism[46]. The addition of hCG treatment to orchiopexy was not associated with higher paternity rates than orchiopexy alone.

In the first study of semen parameters, no man with bilateral cryptorchidism treated with orchiopexy in childhood had a normal sperm density and only 7 percent had normal sperm motility.[51] These outcomes were considerably worse than those observed in the unilateral cryptorchid group, in which 72 percent of participants had normal sperm density and 70 percent had normal motility ($p<0.001$). Sperm density and motility were similar in men with unilateral cryptorchidism regardless of whether they were treated with orchiopexy or orchiectomy. Both groups had better semen parameters than men with untreated unilateral cryptorchidism, suggesting that surgical treatment of any type was associated with better semen parameters later in life, but that one surgical treatment was not more effective than another in this one poor quality study. The second study of semen parameters included four groups: patients with unilateral cryptorchidism who were successfully treated with hormonal therapy in childhood; patients with unilateral cryptorchidism treated with orchiopexy; patients with bilateral cryptorchidism treated with orchiopexy in childhood and; adult patients with untreated unilateral cryptorchidism.[53] Among the patients with unilateral cryptorchidism, the group treated with orchiopexy had similar sperm concentrations to untreated patients (17.0±2.9 vs. 16.6±4.6 millions ml^{-1} ± standard deviation, respectively) or those who were treated with hormonal therapy (15.1±5.8) but had a higher proportion of patients with normal sperm motility (57.2 percent ± 21.4, statistical comparisons not reported).

Table 27. Long-term endocrine and fertility outcomes in adult men with cryptorchidism treated in childhood

Study N Design Quality	Intervention(s) Lateral (N)	Semen Parameters			Paternity Rates			Testosterone levels (ng/ml)
		Normal Sperm Density (%)	Normal Sperm Motility (%)	Sperm Conc. (millions /ml)	Paternity Achieved (%)	Paternity Not attempted (%)	No Paternity (%)	
Gilhooly 1984[46] N = 145 Retrospective cohort Poor	hCG, orchiopexy Unilateral (70)	NR	NR	NR	80	10	10	NR
	Orchiopexy Unilateral (30)	NR	NR	NR	80	10	10	NR
	hCG, orchiopexy Bilateral (36)	NR	NR	NR	36	25	39	NR
	Orchiopexy Bilateral (9)	NR	NR	NR	33	33	33	NR

Table 27. Long-term endocrine and fertility outcomes in adult men with cryptorchidism treated in childhood (continued)

Study N Design Quality	Intervention(s) Lateral (N)	Semen Parameters			Paternity Rates			Testosterone levels (ng/ml)
		Normal Sperm Density (%)	Normal Sperm Motility (%)	Sperm Conc. (millions /ml)	Paternity Achieved (%)	Paternity Not attempted (%)	No Paternity (%)	
Okuyama 1989[51] N = 274 Retrospective cohort Poor	Orchiopexy Bilateral (61)	0	7	NR	NR	NR	NR	NR
	Orchiopexy Unilateral (149)	72	70	NR	NR	NR	NR	NR
	Orchiectomy Unilateral (26)	77	79	NR	NR	NR	NR	NR
	Untreated Unilateral (38)	42	58	NR	NR	NR	NR	NR
Yavetz 1992[53] N = 128 Retrospective cohort Poor	Orchiopexy Bilateral (40)	NR	8	0.3	NR	NR	NR	6.0
	Orchiopexy Unilateral (51)	NR	57	17	NR	NR	NR	5.5
	Successful hormone treatment Unspecified (24)	NR	27	15.1	NR	NR	NR	6.4
	Untreated Unilateral (13)	NR	24	16.6	NR	NR	NR	6.0

Conc = concentration; N = number; NR = not reported

KQ4. Modifiers of Treatment

How does the age at presentation, physical presentation of cryptorchidism (unilateral vs. bilateral, palpable vs. nonpalpable, anatomic location) and occurrence of associated abnormalities (e.g., hernia) modify treatment and outcomes?

Key Points

- Twenty-three studies reported modifier data, including 18 imaging studies (1 good,[62] 3 fair,[63, 65, 78] and 14 poor quality[64, 66-70, 72-77, 79, 80]) and 3 studies of hormonal treatment (1 good quality[40] and 2 poor quality[23-26]).
- Reported differences in outcomes by age and position were inconsistent and unclear.

Detailed Synthesis

The good and fair quality studies we reviewed demonstrate clear differences in accuracy of imaging approaches to treatment planning by location or presence of the testicle. These differences have been described in detail in KQ1a. Generally, however, while US was found to

locate most of the inguinal testicles, MRI was considerably better than US at locating intra-abdominal testicles, while US was marginally better than MRI in locating inguinal testicles (Table 28). Neither US nor MRI had high accuracy at identifying atrophied testicles. Both MRA and MRV could accurately determine location or condition (atrophy or not) of the testicles, but these approaches have been assessed in few studies and require a sedation or an anesthetic.

Table 28. Performance at locating the position and type of testicles

Imaging Technique (# Studies)	Quality of Studies	Correct Identification of Position of Testicles (%)		
		Normal Intra-Abdominal Testicles	Normal Inguino-Scrotal Testicles	Atrophied Testicles
Ultrasonography (9)	1 good[62] 2 fair[63, 64] 6 poor[68, 72, 73, 75, 77, 79]	33.7	92.0	16.7
MRI (10)	3 fair[63, 65, 78] 7 poor[68-70, 72, 74, 76, 77]	71.2	83	32.3
CT scan (1)	1 poor[67]	55.6	57.9	NA
MRA (2)	1 fair[65] 1 poor[77]	100.0	100.0	100.0
MRV (1)	1 poor[80]	100.0	100.0	100.0
MRI&MRAr/V (1)	1poor[66]	80.0	50.0	40.0

CT = computed tomography; MRA = magnetic resonance angiography; MRI = magnetic resonance imaging; MRAr/V = MRI in combination with arteriography/venography; MRV = magnetic resonance venography; NA = not applicable

In studies of hormonal treatment, age of the patient and initial position of the testicle have been suggested to affect outcomes. However, the reporting of data by age was inconsistent in two poor quality studies (reported in four publications).[23-26] Specifically, these two studies include patients with a wide range of ages, starting at birth and progressing through puberty. In addition, the two studies categorize age differently, making it impossible to consolidate the two studies and draw conclusions regarding the relationship between age and outcomes. Most studies that provided data on pretreatment testicular position did not provide outcomes stratified on position, but those that did reported greater success rates with a lower initial position. In one poor-quality RCT of LHRH[23] that did assess the role of testicular position, 75 percent of successes could be manipulated at least to the scrotal entrance before treatment. A second poor-quality RCT of hCG reported success rates two to three times higher for initially inguinal testicles compared to those located intra-abdominally.[26]

In one good-quality retrospective review examining factors associated with orchiopexy success over 9 years at one institution,[40] multivariate analysis demonstrated that neither age nor patent processus vaginalis was associated with observed outcomes.

KQ5. Harms Associated With Treatment

What is the nature and frequency of harms associated with workup or treatment for cryptorchidism?

Key Points

- Eleven studies included harms; 2 studies were of good quality,[16, 41] 2 were of fair quality,[18, 19] and 7 were of poor quality.[20, 27, 29, 30, 38, 50, 54]
- Reported harms of hormonal treatments were mild and included virilizing effects (e.g., hair, increase in penis size and erections) and behavioral changes (e.g., aggression). All harms were transient.
- Adverse events associated with surgery were rare and included Veress needle puncture, laparoscopic port site hernia, and incarcerated hernia.

Overview of the Literature

Eleven studies reported harms associated with treatments for cryptorchidism.[16, 18-20, 27, 29, 30, 38, 41, 50, 54] Seven were RCTs,[16, 18-20, 27, 29, 30] three were retrospective cohorts,[41, 50, 54] and one was a prospective cohort.[38] Eight studies reported harms associated with hormonal treatments,[16, 18-20, 27, 29, 30, 38] while three reported harms associated with laparoscopic surgery.[41, 50, 54] Two studies were of good quality,[16, 41] one was of fair quality,[18] and seven were of poor quality.[20, 27, 29, 30, 38, 50, 54]

Detailed Synthesis

Data on harms were not provided in any imaging studies included in the review. Reported harms of hormonal treatments were mild and transient. Eight[16, 18-20, 27, 29, 30, 38] of 14 studies reported harms of some sort. The most common outcomes were virilizing effects (e.g., hair, increase in penis size and erections), and behavioral changes (e.g., aggression). Of the eight studies reporting harms, two did not segregate data by study arm, and thus harms could have presented in either a treatment or placebo arm.[16, 38] One study reported that 74 percent of 116 boys receiving hCG had virilizing effects, compared to 5.1 percent of boys receiving only LHRH, but one of the hCG arms also included LHRH and another included hMG.[20] All side effects had receded by the 6-month followup. No other study reported side effects to be as common as virilization. One study that reported virilizing effects separately for hCG and LHRH reported that in the hCG group, 22.4 percent of boys experienced erections and 9.4 percent had penis growth, compared to 2.4 percent (two boys) having an erection in the LHRH group, and neither erections nor penile growth occurring in placebo.[18] Several studies reported that behavioral changes or aggression were reported after hormonal treatment. In one RCT,[18] the most common side effects included erection (which was reported in 14 percent of the hCG group, compared to 1 percent and 0 percent in the LHRH and placebo groups respectively), growth of the penis (which was reported in seven percent of the hCG group and not noted in the other groups), pain in the genital region site (which was reported in 7 percent of the LHRH group, 1 percent in the placebo group and 0 percent in the hCG group). Psychological changes (not further defined in the study) were seen in all three groups (7 percent in the hCG group, 12 percent in the LHRH group, and 10 percent in the placebo group).

Among studies reporting aggressive behavior as an adverse effect, one[30] noted aggression in 23 percent of boys treated with LHRH, compared to none with placebo, while a second study reported that one boy in each group was aggressive after treatment.[27]

One study of primary orchiopexy versus one and two-stage FS reported one case of Veress needle puncture into the sigmoid colon.[54] Another study comparing laparoscopic orchiopexy for low intra-abdominal testicles to two-stage FS or laparoscopic orchiectomy for high intra-abdominal testicles reported three laparoscopic port site hernias in the second group.[41] Finally, one study comparing a prescrotal versus inguinal approach reported two cases of incarcerated hernia in the prescrotal approach group.[50] These adverse events are associated with the use of the laparoscopic approach and are not unexpected in this setting. They are not specific to cryptorchidism repair and can occur with any type of laparoscopy.

Discussion

The association of undescended testicles with later adverse health outcomes, including testicular dysfunction, infertility and cancer compelled early identification and management of this condition. Establishing a treatment plan requires knowing whether a testicle exists, where it is, and to what degree it is likely to be functional. While surgical approaches can provide definitive answers, the use of either or both imaging and hormonal stimulation has the potential to provide clinicians and families with information in a non-invasive way to guide treatment. This includes the possibility of avoiding surgery altogether if no testicle is present. Imaging may also serve to provide clinicians with certainty about the location of the testicle when it is not palpable, ensuring that when surgery is performed, it can be done in a site-specific rather than exploratory way. If it is established that surgery is appropriate—that there is a testicle present in some form—the choice is what type of surgery to pursue, and whether to use an open or laparoscopic approach.

State of the Literature

We identified 3,448 nonduplicate titles or abstracts through the search process with potential relevance, with 830 proceeding to full text review (Figure 2). Sixty-four were included in the review, representing 60 distinct studies: 16 randomized controlled trials (RCTs) (2 good quality,[16, 17] 2 fair quality,[18, 19], 12 poor quality[20-34]), 5 prospective cohort studies (1 good quality,[35] 2 fair quality,[36, 37] 2 poor quality[38, 39]), 21 retrospective cohort studies (4 good quality,[40-44] 17 poor quality[45-61]), 16 prospective case series (1 good quality,[62] 3 fair quality,[63-65] 12 poor quality[66-77]), and 2 retrospective case series (1 fair[78] and 1 poor quality[79]). Eighteen studies pertain to Key Question (KQ) 1a, 2 studies to KQ1b, 14 studies to KQ2, 26 studies to KQ3, 23 studies to KQ4, and 11 studies to KQ5.

Principal Findings and Considerations

Discussion of Approaches to Treatment Planning

Reliable techniques are needed to differentiate intra-abdominal from inguinal testicles and discriminate testicles from other structures including lymph nodes and vessels in order to create appropriate plans once a diagnosis of cryptorchidism is made. We identified studies on a range of imaging techniques, including ultrasonography (US), magnetic resonance imaging (MRI, (conventional and diffusion-weighted), computed tomography (CT) scan, magnetic resonance venography (MRV), magnetic resonance angiography (MRA), magnetic resonance arteriography (MRAr), and combinations thereof. Overall, MRA and MRV demonstrated greater accuracy based on one fair[65] and two poor[66, 77] quality studies (Table 29). These last two imaging studies, however, usually require anesthesia or sedation.

Table 29. Performance of imaging techniques

Imaging Technique (# Studies)	Quality of Studies	Performance Characteristic Measures				
		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Overall Accuracy Rate (%)
Ultrasonography (9)	1 good[62] 2 fair[63, 64] 6 poor[68, 72, 73, 75, 77, 79]	15–80	67–100	67–100	0–80	21–76
MRI (10)	3 fair[63, 65, 78] 7 poor[68-70, 72, 74, 76, 77]	33–91	56–100	83–100	0–67	42–92
CT scan (1)	1 poor[67]	57	100	100	14	60
MRA (2)	1 fair[65] 1 poor[77]	100	NA-100	100	NA- 100	100
MRV (1)	1 poor[80]	100	100	100	100	100
MRI & MRAr/V (1)	1 poor[66]	57	NA	100	0	57.0

CT = computed tomography; MRA = magnetic resonance angiography; MRI = magnetic resonance imaging; MRV = magnetic resonance venography; MRAr/V = magnetic resonance arteriography/venography; NA = not applicable; NPV = negative predictive value; PPV = positive predictive value

Specifically, US (one good quality study[62]) had a sensitivity of 15 percent to 80 percent and a specificity of 100 percent for identifying testicles in most studies (Table 29). The false positive rate was very low, with a false negative rate of 39 percent. Overall accuracy ranged from 21 percent to 76 percent. Though US identified 92 percent of the testicles in the inguinal region (Table 28), it failed to identify two thirds of the intra-abdominal and more than 80 percent of the atrophied testicles. US also misidentified three abdominal testicles as inguinal. The true performance of US may be underestimated here due to higher number of abdominal testicles in these studies and due to the poor quality of most of the studies.

Studies using MRI (two fair[63, 78] and eight poor quality[65, 68-70, 72, 74, 76, 77]) reported a sensitivity of 33 percent to 91 percent and specificity of 56 percent to 100 percent (Table 29). Again, there were fewer false positive findings with MRI including one testicular nubbin identified as intra-abdominal and another absent testicle as inguinal. MRI was able to correctly locate a higher proportion (71 percent vs. 34 percent) of intra-abdominal testicles than US and was comparable in locating inguino-scrotal testicles (83 percent vs. 92 percent, Table 28). MRI failed to locate more than two thirds of atrophied testicles. The diagnostic performance was superior when conventional MRI was used with DWI for an overall accuracy rate of more than 85 percent.[78]

There is a suggestion that the diagnostic performance of imaging techniques improves when a combination of techniques are used.[63, 68, 72] Overall accuracy increased to 95 percent when US and MRI were used sequentially in one poor quality case series.[72]

The two studies, one of fair[65] and one of poor quality,[77] that evaluated the efficacy of MRA in identifying and locating nonpalpable testicles reported a perfect accuracy rate (100 percent), with correct identification of both normal and atrophied testicles as well as correct locations. MRI when used with MRAr/V[66] located 80 percent of intra-abdominal and 40 percent of testicular nubbins correctly in a poor quality study.

Only one study (of poor quality) assessed the use of CT scanning and reported a sensitivity of 57 percent and an overall accuracy rate of 60 percent, with correct identification of only 55 percent of the abdominal, inguinal and absent testicles.[67] The low accuracy rate may be

explained by the large number of children younger than 5 years of age in this study (~50 percent) as CT scan image quality suffers in this age group because of the diminished intraabdominal fat planes in young children and consequent difficulty in reading the images.

Other considerations are likely important in making a clinical decision about what practice to follow. Ultrasonography is readily available, relatively inexpensive, and requires no sedation. It does, however, require the patient's cooperation. Also, the ability to read and interpret US results is operator dependent. MRI is more expensive than either US or CT scan, and it requires a long scanning time with sedation in young patients. It may, however, be clinically preferable to US as it allows global, multiplanar depiction of the anatomy of the structures and can distinguish testicles from lymph nodes by using specific orientation and sequences in axial or coronal plane films. Diffusion-weighted MRI is another non-invasive technique that can identify highly cellular intra-abdominal testicles. MRV[71] shows great promise in correctly identifying and locating all nonpalpable testicles, but it is invasive, requires general anesthesia, and is difficult to perform.

The other pretreatment approach with potential to affect care is the use of hormonal stimulation testing to ascertain whether a viable testicle exists for surgical repair. Two studies (one fair[37] and one poor quality[39]) of a total of 44 boys examined the utility of hormonal stimulation testing in reducing the need for surgery in prepubescent males with bilateral impalpable testicles. Both were cohort studies in which human chorionic gonadotropin (hCG) was used to stimulate testosterone secretion to diagnose impairment in testicular endocrine function, in order to predict anorchia or testicular aplasia. Both used a similar study design in which the participant was first given hCG to stimulate testosterone production and then underwent surgical exploration to confirm the absence of presence of viable testicular tissue.

Both studies reported 100 percent sensitivity, suggesting that hormonal stimulation may have potential for identifying patients in whom surgery would be inappropriate. However, the studies are small, and lack a proper comparison of test characteristics between the two thresholds discussed (a greater than two-fold increase in serum testosterone levels or a total testosterone of > 5ng/mmol after stimulation).

Discussion of Approaches to Treatment

Treatment options for cryptorchidism may include an initial trial of hormone therapy to elicit testicular descent, or surgical repair. Fourteen studies (3 of good, [16, 35, 43, 44] 2 of fair,[18, 19] and 9 of poor quality [20-30, 38]) assessed hormonal therapy in treatment. Individual studies often included multiple arms. Six studies compared luteinizing hormone-releasing hormone (LHRH) with placebo; one compared hCG with placebo; four compared LHRH with hCG; and six compared various doses or regimens. Five studies were of poor[19, 23-25, 27, 29, 30] and one was of fair[18]quality, Four of five studies concluded that LHRH was more effective than placebo in inducing testicular descent with variable reported effect sizes across studies (Table 15).[18, 19, 27, 29, 30] Human chorionic gonadotropin is administered with multiple injections and was compared to placebo in one fair-quality study.[18] In that three-arm study (LHRH vs. hCG vs. placebo), hCG was superior to placebo, but with only one study of fair quality, the strength of evidence is insufficient. Four studies provided data on LHRH compared with hCG, with neither better than the other. The studies that compared doses and dosing schedules within hormone type were of poor quality and so heterogeneous as to preclude synthesis.

A small number of studies report that LHRH and hCG are somewhat more effective than placebo. Initial location of the testicle may influence success rates, and although no study was

adequately powered to assess this possibility, studies that do report stratified data consistently report that lower testicles have higher response rates to hormone treatment. Some studies have reported temporary virilizing side effects, including increased penile length, erections and testicular enlargement associated with hormonal treatment. All side effects were transitory.

We assessed the strength of evidence for our primary outcome of testicular descent. There is moderate strength of evidence for a superior effect of LHRH over placebo, low strength of evidence for the superior effect of hCG over placebo and low strength of evidence for equivalence between LHRH and hCG (Table 30). It is worth noting that followup in these studies of hormonal therapy was relatively short and likely did not capture cases of long-term re-ascent/failure, which may be a real concern in these patients.

Table 30. Strength of evidence of hormonal treatments for cryptorchidism

Number of Studies; Total Subjects; Testes Treated	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect
Testicular Descent					
LHRH vs. placebo 6; 752; 935	RCTs/ Moderate	Consistent	Direct	Imprecise	Moderate LHRH: 9%–62% Placebo: 0%–18%
hCG vs. placebo 1; 243; 280	RCT/ Moderate	Unknown	Direct	Unknown	Low Bilateral: 23% v 0% Unilateral: 15% v 0%
LHRH vs. hCG 3; 431;465	RCT/ Low	Inconsistent	Direct	Imprecise	Low LHRH: 0%–18.8% hCG: 5.9%–23%
LHRH vs. hCG 1; 324;198	Cohort/ High	Consistent	Direct	Imprecise	Low LHRH: 29.4% hCG: 34.5%

hCG = human chorionic gonadotropin; LHRH = luteinizing hormone releasing hormone ; RCT = randomized controlled trial

No studies provided cancer or fertility outcomes for the comparisons listed so the strength of evidence is insufficient for these outcomes.

Twenty-four studies provided outcomes of various surgical interventions for the treatment of cryptorchidism. Four studies were judged to be of good quality,[17, 40-42] one of fair quality,[36] and the remainder of poor quality.[31, 32, 45-61] Eleven studies compared outcomes following either one-stage Fowler-Stephens (FS) orchiopexy, two-stage FS orchiopexy or primary orchiopexy.[40, 47, 48, 50, 52, 54, 56, 57, 59-61] Five studies primarily compared the same procedure performed through either a laparoscopic or open approach.[17, 31, 36, 49, 55] Four studies compared minor surgical variations of primary orchiopexy to one another.[32, 41, 45, 58] Three studies compared long-term fertility outcomes in men who underwent various surgical procedures for cryptorchidism in childhood,[46, 51, 53] while one compared endocrine function in children with surgically treated or untreated cryptorchidism.[42]

Surgical treatment for cryptorchidism was associated with success rates of testicular descent that ranged in studies from 33 percent to 100 percent. No studies compare hormonal therapy alone to surgery. The three types of surgical repair are one-stage FS, two-stage FS and orchiopexy. If the testicular vessels are long enough to reach into the scrotum, then these structures should be spared and a primary orchiopexy is typically performed. The FS methods are used when the vessels are too short to allow mobilization of the testicle into the scrotum. In this approach, the gonadal vessels are divided and the testicular blood supply comes through collaterals, including the artery of the vas deferens. In the one-stage approach, the gonadal

vessels are ligated and the testicle is immediately moved down into the scrotum with great care taken not to injure any collateral circulation. In the two-stage approach, after ligation of the gonadal vessels, the first procedure is ended. The patient is then followed for 3 to 6 months, allowing presumably better collateral circulation to develop. At the end of this waiting period, a second procedure is performed to move the testicle into the scrotum. These FS approaches are usually reserved for patients with arguably more severe conditions. None of the studies in our review appropriately controlled for initial location of the testicle; thus it is unsurprising that studies report better outcomes among patients undergoing primary orchiopexy rather than FS surgery,[40, 47, 48, 50, 52, 54, 56, 60, 61] and the proportions achieving testicular descent should be looked at individually by surgery and not compared across surgical types.

The weighted success rate for all three approaches exceeds 75 percent, with an overall reported rate of 78.7 percent for one-stage FS, 86 percent for two-stage FS and 96.4 percent for primary orchiopexy. Each surgical approach was assessed independently for ability to achieve testicular descent because, as described in the report, each approach is used under different clinical circumstances, and thus it is inappropriate to compare them to one another. We assessed the strength of evidence as our confidence in the weighted average of successful testicular descent associated with each surgical approach separately (Table 31). Although retrospective studies typically had high risk of bias because of lack of a control group, in grading the overall strength of the evidence, we used an implicit comparator group given the known natural history of disease. Given the low rate of spontaneous testicular descent, despite the high risk of bias of retrospective studies, the strength of the evidence might be considered high because of the high magnitude of effect when compared with an implicit control.

For the outcome of testicular descent, strength of evidence was moderate for one and two-stage orchiopexy and high for primary orchiopexy. All studies were retrospective cohort studies, and thus had high risk of bias, but we deemed these to be an appropriate study design for the question of ability of orchiopexy to achieve testicular descent and considered the relative challenges of this design to be outweighed by the magnitude of effect. Primary orchiopexy had higher strength of evidence than one-stage and two-stage based on the higher number of testicles (outcomes) reported in the literature.

Table 31. Strength of evidence of surgical treatments for cryptorchidism, testicular descent

Number of Studies; Total Subjects; Treated Testicles	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect*
Testicular Descent					
1-stage FS 7; 644; 155	Retrospective cohorts/ High	Consistent	Direct	Imprecise	Moderate 78.7% (range: 33% – 94.3%)
2-stage FS 9; 784; 242	Retrospective cohorts/ High	Consistent	Direct	Imprecise	Moderate 86.0% (range: 67% – 98%)
Primary orchiopexy 7; 695; 467	Retrospective cohorts/ High	Consistent	Direct	Precise	High 96.4% (range: 89.1%–100%)

FS = Fowler Stephens
*Pooled proportion (range).

We also assessed strength of evidence for the outcome of testicular atrophy, and on the same methodologic basis as was used for testicular descent, found the strength of evidence to be low

for a 28.1 percent atrophy rate with one-stage FS, low for an 8.2 percent atrophy rate with two-stage FS and moderate for a 1.83 percent atrophy rate for primary orchiopexy (Table 32).

Table 32. Strength of evidence of surgical treatments for cryptorchidism, atrophy

Number of Studies; Total Subjects; Treated Testicles	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect*
Atrophy					
1-stage FS 3; 320;32	Retrospective cohorts/ High	Consistent	Direct	Imprecise	Low 28.1% (range: 22% – 67%)
2-stage FS 5; 470; 158	Retrospective cohorts/ High	Consistent	Direct	Precise	Low 8.2% (range: 0% – 12%)
Primary orchiopexy 5; 470; 273	Retrospective cohorts/ High	Consistent	Direct	Precise	Moderate 1.83% (range: 0% – 4%)

FS = Fowler Stephens
*Pooled proportion (range).

Laparoscopy in the treatment of cryptorchidism has two roles: (1) as an exploratory tool to locate a nonpalpable undescended testicle in the abdomen; and (2) as a minimally invasive method of orchiopexy. Two studies (one of good[17] and one of poor[55] quality) assessed laparoscopy for determining the location of the testicle, and reported that it was similar to open exploration. Success of the ensuing surgeries was also similar, regardless of exploratory approach. Neither study addressed postoperative pain or time to return to normal activity.

All but one of the studies in our review published in the past 5 years that included assessment of the abdomen for a nonpalpable testicle[31, 36, 48-50, 57, 59, 60] used laparoscopy for this part of the procedure, even if they used an open technique to repair the cryptorchidism, suggesting that the results of the two studies above are applicable to current practice. We assessed the strength of evidence for equivalence of laparoscopic and open approaches for achieving testicular descent to be low with one RCT of poor quality[31] and two cohort studies of poor[49] or fair quality[36] that provided consistent results (Table 33). While the strength of the evidence is low. the individual studies report that success rates are similar with both approaches. Studies reported similar clinical outcomes and less pain, shorter hospital stays and a quicker return to normal activity.[31, 36, 49] No studies reported on the surgical learning curve, which is a potential modifier of effectiveness.

Table 33. Strength of evidence of surgical approach for orchiopexy, testicular descent

Number of Studies; Total Subjects; Testes Treated	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect*
Testicular Descent					
Open vs. laparoscopic repair 1; 75; 75	RCT High	Unknown	Direct	Unknown	Low RCT: No difference in postoperative testicular position Cohorts: No difference in postoperative testicular position
Open vs. laparoscopic repair 2; 96; 110	Cohorts/ High	Consistent	Direct	Imprecise	

RCT = randomized controlled trial
*Pooled proportion (range).

Similarly, strength of evidence was low for the outcome of atrophy and the use of laparoscopic approach (Table 34).

Table 34. Strength of evidence of surgical approach for orchiopexy, atrophy

Number of Studies; Total Subjects; Testes Treated	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence and Magnitude of Effect
Atrophy					
Open vs. laparoscopic repair 1; 75; 75	RCT High	Unknown	Direct	Unknown	Low Laparoscopy: 10% Open: 19%

RCT = randomized controlled trial
*Atrophy rates for second stage orchiopexy; no atrophy reported with primary orchiopexy.

Few studies compare the effectiveness of interventions on later fertility. Furthermore, in those studies (where the participants are obviously adults who had cryptorchidism in childhood), the primary outcome is usually semen analysis parameters, which are at best a proxy for fertility. One poor quality study examined paternity (ability to father children) and focused on the addition of hormonal therapy to surgery, finding no advantage to the combination of hormones and surgery compared to surgery alone.[46] No studies compared paternity rates between surgery and hormonal therapy in isolation. To this end, it is difficult to comment on whether one approach is superior to another in terms of fertility outcomes, although the relationship of untreated cryptorchidism and later poor fertility outcomes has been reported.[81, 82]

Applicability

The degree to which the data presented in this report are applicable to clinical care depends on the degree to which the population included in the studies represents the patient population in clinical care, as well as the availability of the interventions and the degree to which the study settings mirror those in usual clinical practice. Across all KQs, there is no indication that study populations are different from those in standard clinical practice. Indeed, many of the studies included are reports of clinical practice, including chart reviews. Study populations included children with undescended testicles, as required by our inclusion criteria. Data are provided

across the studies on children with a range of initial testicular location (e.g., intra-abdominal, inguinal, or scrotal) and unilateral or bilateral disease.

Applicability of the imaging results depends on the availability of the specific imaging technologies in a given clinical setting, including the availability of trained and experienced operators. Ultrasonography is readily available, relatively inexpensive, and requires no sedation. It does, however, require the patient's cooperation. The ability to read and interpret US results is also operator dependent. MRI is more expensive than either US or CT scan and it requires a long scanning time with sedation in young patients. It does, however allow global, multiplanar depiction of the anatomy of the structures and can distinguish testicles from lymph nodes by using specific orientation and sequences in axial or coronal plane films.

The applicability of imaging may also depend on patient age, with technologies requiring patient cooperation potentially more challenging to use in infants. With improvements in imaging techniques, it may also be the case that early studies underestimated effectiveness of imaging technologies.

Hormonal approaches to treatment were assessed in children with both bilateral and unilateral cryptorchidism and at varying ages, providing data for the range of patients likely to be seen in clinical practice in the United States. Although most studies were done in Europe, the results should be applicable to a U.S. population as the hormonal agents studied are readily available in the United States.

As with the hormonal treatment literature, the surgical literature applies to the range of patients likely to be seen in practice, and the surgical techniques assessed are those commonly used in U.S. clinical care. The most common outcome assessed was testicular position; this is typically the outcome targeted in clinical practice. In addition, most studies provided adequate followup data to assess later atrophy.

Tables describing the PICOS elements as they can be used to assess applicability are provided in Appendix F.

Implications for Clinical and Policy Decisionmaking

The goal of any intervention for cryptorchidism is to move the undescended testicle to a normal position in the scrotum, in as safe and as least invasive a way as possible. This report has reviewed the literature on treatment planning and therapeutic interventions to achieve these goals.

Studies do not provide support that imaging has been shown to be helpful in guiding treatment decisions. Knowing where the testicle is (high or low intra-abdominal, inguinal or scrotal) could be helpful for planning a surgical approach, although there is no evidence that it can affect outcomes. The imaging literature provides mixed results, with studies not pointing to a particular approach that provides complete accuracy at identifying atrophy or absence of the testicle. Studies of hormonal stimulation testing suggest that this approach may be able to identify viable testicular tissue, but with only two studies (one of fair[37] and one of poor[39] quality) available, the literature is limited and much more information is needed.

Both open and laparoscopic approaches to the surgical repair techniques are viable. The question of which to use may be more clinically determined by issues such as desire for shorter recovery, tempered by provider skill at the particular approach. Providers adept at laparoscopy may choose this approach, and the evidence suggests that outcomes are similar to an open approach. Providers adept at the open surgical approach may also elect to do the surgery in an

open way. Again, the outcomes do not differ in the literature, but the strength of the evidence around this similarity is low.

Contextual Information Not Covered in the Review

Although the comparative literature does not include long term data on either fertility or cancer outcomes, there is a body of epidemiologic data and data from noncomparative studies to which we refer end users of this report. These studies did not meet the specific scope or inclusion criteria for our review, but they provide important information on long term outcomes for individuals with cryptorchidism. Because we did not review these studies systematically as part of the scope of this review, we do not suggest that the references included here are comprehensive; rather they are representative and provide additional context for decision makers. Of particular note is a series of studies by Peter Lee and colleagues that describe long term outcomes, including paternity rates, among men treated surgically for cryptorchidism who have attempted paternity.[83-85] These studies suggest that while men who were treated for unilateral cryptorchidism as children do not have substantially lower paternity rates than control subjects, men treated for bilateral cryptorchidism experience substantially lower paternity than both those with previous unilateral cryptorchidism and controls.[85] These studies do not include untreated individuals with cryptorchidism; rather the cryptorchid groups are "previously cryptorchid" having undergone surgery.

Methodologic Issues

The literature available to assess treatment for cryptorchidism is characterized by a lack of standardization of outcomes. Studies routinely use the term "success rates" but fail to define a successful outcome. In some cases, the authors report "success rates" as proper placement of the testicle in the scrotum in the early post-operative period and then report 6-month or greater atrophy rates separately. Given that the goal of the procedure is usually to place the testicle in the scrotum and to maximize long-term endocrine function and fertility, the definition of success should always reflect both of these important endpoints (testicular location and size), and we encourage researchers to report both.

Because the majority of reviewed studies were observational, the potential for confounding and effect measure modification in this literature to obscure true effects is significant. Studies intended to address comparative effectiveness of treatment in this condition, including one-stage versus two-stage FS orchiopexy for nonpalpable abdominal testicles should either use a randomized design or carefully control for covariates such as testicular location, size and appearance, ectopia and unilateral or bilateral disease. This is particularly important for initial testicular location, which may be both a modifier of effectiveness and a factor used to choose the surgical procedure. Finally, these studies must include follow-up for at least 6 to 12 months to observe for delayed atrophy of the testicle.

Research Gaps

Although a number of studies are available on US and magnetic resonance approaches, very few studies are available on MRA and MRV, which could be useful for confirming findings after negative US and MRI. A study comparing multiple imaging modalities, such as US or MR, in the same patient followed by diagnostic laparoscopy and appropriate treatment would be of tremendous value in assessing the equivalence or superiority of any imaging approach.

Studies of hormonal treatment of cryptorchidism have focused primarily on LHRH and its agonists because it is easily administered intranasally. A wide range of success rates is seen across studies, possibly due to heterogeneity in the study populations or potentially due to variability in drug absorption through the intranasal route. Some literature suggests that differences may be due to initial location of the testicle, but this is an area warranting more attention, including conducting additional studies in which patients are carefully selected to assess efficacy by testicle location, or analyses carefully controlled for this effect. Long term data on effects of hormones are missing from the literature and more complete data on harms should be gathered.

Current literature lacks assessment of whether a one-stage or two-stage surgical method is superior, or if they are similar in terms of outcomes after controlling for testicular location. An RCT of one-stage versus two-stage FS in children with nonpalpable presumably intra-abdominal testicles who are determined by the surgeon not to be candidates for primary orchiopexy is needed. The primary outcome should be successful placement of a normal sized testicle in the dependent portion of the scrotum. The trial would also need to control for location within the abdomen at the time of presentation in order to avoid the shortfalls of the current observational literature. Ideally, outcomes would be measured both immediately and in the longer term (6 to 12 months later) to assess late complications, recurrences and atrophy. Such a trial would be ethical, as primary orchiopexy would not be the focus of the study and would not be denied to patients in whom it could be performed.

The appropriate age for treatment remains unknown, with very little data available on the modifying effect of age on outcomes. Across all approaches to treatment planning and therapy, this important question has yet to be answered.

Studies of long-term outcomes of treatment, both fertility and cancer, are notably missing from this literature. Certainly, these are difficult studies to complete, but development of a long-term cohort or a registry could provide broader and longer-term data, and warrants consideration. When studies are published on fertility outcomes, the specific measures are inadequate, focusing understandably on the easier measures of semen analysis (normal: > 15 sperm per millimeter, >50 percent having normal motility and >4 percent normal morphology).[86] More appropriate measures should be included such as the ability to achieve paternity when desired. Additional outcomes that warrant study are good measures of endocrine function, which is assessed by serum testosterone levels (normal values vary by patient age and laboratory but are generally 10–44 nmol/l).

Conclusions

No specific imaging technique is adequate to identify anorchia or complete descent of the testicles and thus eliminate the need for further surgical evaluation. The lack of good quality studies affects our degree of confidence in establishing a rate of prediction of anorchia, but results do not seem to be directly related to study quality. Accuracy varies by location of the testicles, with less invasive methods (nine studies of ultrasound including one good,[62] two of fair,[63, 64] and six poor quality;[68, 72, 73, 75, 77, 79] ten studies of MRI, including three of fair[63, 65, 78] and seven of poor quality[68-70, 72, 74, 76, 77]) demonstrating poor accuracy for abdominally located testicles and those that are atrophied. Hormonal stimulation testing may predict anorchia, but more research is needed with only two studies (one fair[37] and one poor[39] quality) of fewer than 50 participants. Hormonal treatment is marginally effective relative to placebo, with moderate strength of evidence, but is successful in some children and with minimal side effects, suggesting

that it may be an appropriate trial of care for some patients. If successful, these patients should continue to be monitored for late re-ascent, as most of the studies on this issue did not include long-term followup. Surgical options appear effective, with rates of normal post-operative scrotal position above 75 percent. Our ability to draw definitive conclusions regarding the comparative effectiveness of the surgical approaches is limited by confounding by indication in the individual studies, which also affects the quality of the literature. The strength of the evidence for the effects of either one-stage or two-stage FS procedures on testicular descent is moderate (low for atrophy) and high for primary orchiopexy (moderate for atrophy). Comparable outcomes have been seen with laparoscopic and open approaches to surgical repair (low strength of evidence for testicular descent and atrophy in studies comparing these approaches).

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Acronyms/Abbreviations/Symbols

ARHQ	Agency for Healthcare Research and Quality
CER	Comparative Effectiveness Review
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CT	Computed Tomography
DWI	Diffusion-weighted Imaging
FS	Fowler-Stephens
GnRH	Gonadotropin-releasing Hormone
hCG	Human Chorionic Gonadotropin
hMG	Human Menopausal Gonadotropin
IM	Intramuscular
IU	International Unit
kg	Kilogram
KQ	Key Question
LHRH	Luteinizing Hormone-releasing Hormone
MeSH	Medical Subject Heading
mmol	Millimolar
MRA	Magnetic Resonance Angiogram
MRAr/V	Magnetic Resonance Imaging in combination with arteriography/venography
MRI	Magnetic Resonance Imaging
MRV	Magnetic Resonance Venogram/Venography
N	Number
NPT	Non-Palpable Testicles
NPV	Negative Predictive Value
OAC	Overall Accuracy Rate
PICOTS	Population, Interventions, Comparators, Outcomes, Timing, Settings
PPV	Positive Predictive Value
QUADAS	Quality Assessment of Diagnostic Accuracy Studies Revised
RCT	Randomized Controlled Trials
Se	Sensitivity
Sp	Specificity
TEP	Technical Expert Panel
UDT	Undescended Testicle
µg	Microgram
US	Ultrasonography

Appendix A. Exact Search Strings and Results

Table A-1. PubMed search strategies

Search terms		Preliminary search results
#1	cryptorchidism[mh] OR cryptorchidism[tiab] OR cryptorchid[tiab] OR ((testis[mh] OR testis[tiab] OR testes[tiab] OR testicle[tiab] OR testicles[tiab] OR testicular[tiab]) AND (undescended[tiab] OR ascended[tiab] OR retractile[tiab] OR retracted[tiab] OR nonpalpable[tiab] OR non-palpable[tiab] OR palpable[tiab] OR unilateral[tiab] OR bilateral[tiab]))	12,879
#2	therapeutics[mh] OR diagnosis[mh] OR surgical procedures, operative[mh] OR laparoscopy[mh] OR diagnostic imaging[mh] OR therapy[sh] OR diagnosis[sh] OR therapeutic[tiab] OR therapeutics[tiab] OR therapy[tiab] OR therapies[tiab] OR treatment[tiab] OR treatments[tiab] OR manage[tiab] OR management[tiab] OR evaluate[tiab] OR evaluation[tiab] OR diagnose[tiab] OR diagnosis[tiab] OR diagnostic[tiab] OR surgery[tiab] OR surgeries[tiab] OR surgical[tiab] OR reoperation[tiab] OR reoperate[tiab] OR orchiopexy[tiab] OR orchiopexies[tiab]OR orchidopexy[tiab] OR orchidopexies[tiab] OR orchiectomy[tiab] OR orchiectomies[tiab] OR orchidectomy[tiab] OR orchidectomies[tiab] OR laparoscopy[tiab] OR laparoscopic[tiab] OR imaging[tiab] OR image study[tiab] OR image studies[tiab]	12,124,573
#3	#1 AND #2 AND english[la] AND humans[mh]	5,937
#4	#3 AND editorial[pt]	41
#5	#3 AND letter[pt]	186
#6	#3 AND comment[pt]	115
#7	#3 AND case reports[pt]	1,955
#8	#3 AND review[pt]	668
#9	#3 AND news[pt]	1
#10	#3 AND guideline[pt]	4
#11	#3 AND practice guideline[pt]	3
#12	#3 AND meta-analysis[pt]	13
#13	#3 AND historical article[pt]	10

#14	#3 AND jsubsetk	0
#15	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14	2,668*
#16	#3 NOT #15	3,269
#17	#16 AND 1980:2012[dp]	2,755

Key: [mh] medical subject heading; [sh] subheading; [tiab] keyword in title or abstract; [la] language; [pt] publication type; jsubsetk consumer health subset; [dp] publication date. * numbers may not add up as some records are indexed in multiple publication types.

Table A-2. EMBASE search strategies

Search terms		Search results
#1	cryptorchism/ OR (cryptorchidism OR cryptorchid).mp OR ((testis/ OR (testis OR testes OR testicle OR testicles OR testicular).mp) AND ((undescended OR ascended OR retractile OR retracted OR nonpalpable OR non-palpable OR palpable OR unilateral OR bilateral).mp))	14,529
#2	exp therapy/ OR exp diagnosis/ OR exp surgery/ OR orchidopexy/ OR orchiectomy/ OR diagnostic imaging/ OR laparoscopy/ OR (therapeutic OR therapeutics OR therapy OR therapies OR treatment OR treatments OR manage OR management OR evaluate OR evaluation OR diagnose OR diagnosis OR diagnostic OR surgery OR surgeries OR surgical OR reoperation OR reoperate OR orchiopexy OR orchiopexies OR orchidopexy OR orchidopexies OR orchiectomy OR orchiectomies OR orchidectomy OR orchidectomies OR laparoscopy OR laparoscopic OR imaging OR image study OR image studies).mp	11,565,532
#3	1 AND 2	10,630
#4	limit 3 to human AND English language	6,001
#5	Limit 4 to MEDLINE records	799
#6	4 AND review.pt	665
#7	4 AND conference paper.pt	233
#8	4 AND editorial.pt	56
#9	4 AND letter.pt	177
#10	4 AND note.pt	113
#11	4 AND short survey.pt	53
#12	4 AND case report/	2,065
#13	4 AND practice guideline/	54
#14	4 AND systematic review/	29
#15	4 AND meta analysis/	22
#16	5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15	3,634*
#17	4 NOT 16	2,367

	16 limited 1980-2012	2,367

Key: / all fields; exp explode term; .mp map term as keyword; .pt publication type.
* numbers may not add up as some records are indexed in multiple publication types.

Table A-3. CINAHL search strategies

Search terms		Search results
#1	(MH "Cryptorchidism") OR cryptorchidism OR cryptorchid OR (((MH "Testis") OR testis OR testes OR testicle OR testicles OR testicular) AND (undescended OR ascended OR retractile OR retracted OR nonpalpable OR non-palpable OR palpable OR unilateral OR bilateral))	203
#2	(MH "Therapeutics+") OR (MH "Diagnosis+") OR (MH "Surgery, Operative+") OR (MH "Orchiectomy") OR (MH "Laparoscopy") OR (MH "Diagnostic Imaging+") OR therapeutic OR therapeutics OR therapy OR therapies OR treatment OR treatments OR management OR evaluate OR evaluation OR diagnose OR diagnosis OR diagnostic OR surgery OR surgical OR reoperation OR reoperate OR orchiopexy OR orchiopexies OR orchidopexy OR orchidopexies OR orchiectomy OR orchiectomies OR orchidectomy OR orchidectomies OR laparoscopy OR laparoscopic OR imaging OR image study OR image studies	1,488,221
#3	#1 AND #2	163
#4	#3 AND limiters: English language; Human	51
#5	#3 AND limiters: English language; Human; Exclude MEDLINE records	4

Appendix B. Sample Abstract and Full-Text Review Forms

Abstract Review Form 1

Primary Inclusion/Exclusion Criteria			
1. Original research (Exclude reviews, editorials, commentaries, letters to editor, etc.)	Yes	No	Cannot Determine
2. Study includes relevant population: • Children and Adolescents with Cryptorchidism	Yes	No	Cannot Determine
3. Study includes an intervention (diagnostic or therapeutic): • Workup evaluation (imaging, laparoscopy, hormonal stimulation therapy), • medical therapies or hormones, • surgical therapy, • specific surgical techniques (i.e., one-stage vs. two-stage, laparoscopic vs. open approach, orchiectomy vs. orchiopexy)	Yes	No	Cannot Determine
4. Study published in English	Yes	No	Cannot Determine

Retain for: _____BACKGROUND/DISCUSSION _____REVIEW OF REFERENCES ____OTHER

Reason for Other:

_____

COMMENTS:

Abstract Review Form 2

Primary Inclusion/Exclusion Criteria			
1. Does the study include an appropriate diagnostic or therapeutic intervention? [Imaging (CT, MRI, ultrasound, etc), laparoscopy, hormonal stimulation therapy, medical therapies, surgical therapy, specific surgical techniques (one-stage vs two-stage, laparoscopic vs open approach, orchiectomy vs orchiopexy)]	Yes	No	Cannot Determine
2. Does the study utilize a relevant comparison group? (Comparison of different treatments, hormonal vs. surgical therapy, treatment vs. no treatment)	Yes	No	Cannot Determine
3. Is this a study of the effectiveness of imaging in determining the presence and location of a nonpalpable testicle?	Yes	No	Cannot Determine
4. Does the study include hormonal stimulation testing in prepubescent males with bilateral, nonpalpable testes?	Yes	No	Cannot Determine

Retain for: _____BACKGROUND/DISCUSSION _____REVIEW OF REFERENCES ____OTHER

Reason for Other:

_____

COMMENTS:

Full Text Review Form

Primary Inclusion/Exclusion Criteria
1. Original research (exclude reviews, editorials, commentaries, letters to editor, etc.) **YES** **NO**
2. Study published in English **YES** **NO**
3. Is this a study of the effectiveness of imaging in determining the presence and location of a nonpalpable testicle? **YES** **NO** **If yes**: does the study include ≥10 participants with cryptorchidism? **YES** **NO**
4. Is this a study of hormonal stimulation testing for treatment planning in prepubescent males with **bilateral, nonpalpable** testes? **YES** **NO** **If yes:** does the study include ≥10 participants with **bilateral, nonpalpable** testes? **YES** **NO**
5. Is the study an effectiveness evaluation of included therapeutic interventions for cryptorchidism? (ex: laparoscopy, medical therapies, surgical therapy, specific surgical techniques (one-stage vs two-stage, laparoscopic vs open approach, orchiectomy vs orchiopexy) **YES** **NO** **If yes:** does the study utilize a relevant comparison group? (i.e. comparison of different treatments, hormonal vs. surgical therapy, treatment vs. no treatment) **YES** **NO** **If relevant comparison group:** does the study include ≥10 participants ***per group***? **YES** **NO**

Retain for:

_____BACKGROUND/DISCUSSION

_____REVIEW OF REFERENCES

_____OTHER_____

COMMENTS:

Appendix C. Excluded Studies

Reasons for exclusion:
X-1: Not original research
X-2: Does not include relevant population
X-3: Does not include an intervention for cryptorchidism
X-4: Does not utilize a relevant comparison group (for intervention studies only)
X-5: Does not assess the effectiveness of imagining techniques
X-6: Is not a study of hormonal stimulation testing for treatment planning
X-7: Is not an evaluation of the effectiveness of a therapeutic intervention
X-8: Ineligible study size
X-9: Not published in English
X-10: Cannot extract usable data to answer a key question

Excluded During Abstract Review

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2. International Symposium on Pediatric and Surgical Andrology: Cryptorchidism. March 26-27, 1987, Basle, Switzerland. On the occasion of the 125th anniversary of the Children's Hospital Basle. Eur J Pediatr. 1987;146 Suppl 2:S1-68. X-1.
3. Clinical diagnosis of cryptorchidism. John Radcliffe Hospital Cryptorchidism Study Group. Arch Dis Child. 1988 Jun;63(6):587-91. X-3.
4. Cryptorchidism: a prospective study of 7500 consecutive male births, 1984-8. John Radcliffe Hospital Cryptorchidism Study Group. Arch Dis Child. 1992 Jul;67(7):892-9. X-3, X-4, X-5, X-6.
5. Cryptorchidism and male pseudo-hermaphroditism. Eur J Pediatr. 1993;152 Suppl 2:S1-92. X-1.
6. Aetiology of testicular cancer: association with congenital abnormalities, age at puberty, infertility, and exercise. United Kingdom Testicular Cancer Study Group. BMJ. 1994 May 28;308(6941):1393-9. X-2, X-3.
7. Social, behavioural and medical factors in the aetiology of testicular cancer: results from the UK study. UK Testicular Cancer Study Group. Br J Cancer. 1994 Sep;70(3):513-20. X-2, X-3.
8. Efficacy and safety of highly purified urinary follicle-stimulating hormone with human chorionic gonadotropin for treating men with isolated hypogonadotropic hypogonadism. Fertility and Sterility. 1998 Aug;70 (2):256-262. X-2, X-3.
9. Testicular self-examination. Postgraduate Medicine. 1999;105 (4):241. X-1, X-2, X-3.
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Appendix D. Evidence Tables

Acronyms/Abbreviations/Symbols

LHRH	Luteinizing Hormone-releasing Hormone
GnRH	Gonadotropin-releasing Hormone
hCG	Human Chorionic Gonadotropin
hMG	Human Menopausal Gonadotropin
KQ	Key Questions
PICOTS	Population, Interventions, Comparators, Outcomes, Timing, Settings
UDT	Undescended Testis
CER	Comparative Effectiveness Review
ARHQ	Agency for Healthcare Research and Quality
TEP	Technical Expert Panel
MeSH	Medical Subject Heading
CINAHL	Cumulative Index to Nursing and Allied Health Literature
PPV	Positive Predictive Value
NPV	Negative Predictive Value
OAC	Overall Accuracy Rate
RCT	Randomized Controlled Trials
QUADAS	Quality Assessment of Diagnostic Accuracy Studies Revised
US	Ultrasonography
MRI	Magnetic Resonance Imaging
CT	Computed Tomography
MRA	Magnetic Resonance Angiogram
MRV	Magnetic Resonance Venogram/Venography
MRA/V	Magnetic Resonance Imaging in combination with arteriography/venography
DWI	Diffusion-weighted Imaging
NPT	Non-Palpable Testes
Se	Sensitivity
Sp	Specificity
IU	International Unit
µg	Microgram
mmol	Millimolar
N	Number
IM	Intramuscular
kg	Kilogram
FS	Fowler-Stevens
SOE	Strength of Evidence

Tables

Table D-1. Evidence table for studies assessing imaging accuracy

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Al-Shareef et al., 1996 **Country:** Saudi Arabia **Setting:** Hospital **Enrollment period:** December 1992 to November 1994 **Design:** Prospective case series	**Groups:** Boys evaluated via USG, MRI, and subsequent laparoscopy **Inclusion criteria:** • Non-palpable undescended testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 19 (24) **N at follow-up (N testes):** 19 (24) **Bilateral testes: N (%):** 5 /19 (26.3) **Age, range yrs:** 1-11 **Comorbidities:** NR **Verification method:** Laparoscopy	**USG:** **Overall proportion of testes identified, n (%):** 4/24 (16.7) **By side:** NR **By position:** Intra-abdominal near deep ring: 3/4 (75.0) High intra-abdominal: 1/4 (25.0) **MRI:** **Overall proportion of testes identified, n (%):** 7/24 (29.2) **By side:** NR **By position:** Intra-abdominal near deep ring: 5/7 (71.4) High intra-abdominal: 1/7 (14.3) Atrophic: 1/7 (14.3) **Laparoscopy:** **Overall proportion of testes identified, n (%):** Present: 21/24 (87.5) Absent: 3/24 (12.5) **By side:** Left: NR Right: NR Both: 10/24 (41.7) **By position:** Intra-abdominal near deep ring: 15/24 (62.5) High intra-abdominal: 1/24 (4.2) Atrophic: 5/24 (20.8)	**Presence / absence of testes:** **USG:** **Sensitivity:** 0.19 **Specificity:** 1 **PPV:** 1 **NPV:** 0.15 OAC:29.2% **MRI :** **Sensitivity:** 0.33 **Specificity:** 1 **PPV:** 1 **NPV:** 0.18 OAC:41.7% **Testes Correct location:** **USG:** Intra-abdominal near deep ring: 3/ 15 (20.0) High intra-abdominal 1/1 (100.0) **MRI:** Intra-abdominal near deep ring: 5/ 15 (33.3) High intra-abdominal 1/1 (100.0) Atrophic: 1/5 (20.0) **Incorrect location:** **USG & MRI: None** **False negatives:** USG missed 12 testes at IA near deep ring and 5 atrophic testes MRI missed 10 testes at IA near deep ring & 4 atrophic testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Cain et al., 1996 **Country:** US **Setting:** Hospital **Enrollment period:** 1991-1995 **Design:** Prospective case series	**Groups:** Participants undergoing ultrasound (7.5 MHz) followed by **Inclusion criteria:** • Nonpalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 64 (74) **N at follow-up (N testes):** 64 (74) Bilateral testes: 10/64 (15.6%) **Age, range yrs (mean):** 0.5 –17 (4.5) **Comorbidities, n (%):** NR **Verification method, n (%):** Surgical exploration	**USG:** **Overall proportion of testes identified:** 48/74 (64.9) **By side:** NR **By position, n (%):** Inguinal: 40/48 (83.3) Intra-abdominal: 1/ 48 (2.1) Atrophic: 7/48 (14.6) **Surgery:** **Overall proportion of testes identified:** Present: 74 (100) Absent: none **By side:** NR **By position:** Inguinal: 42/74 (56.8) Intra-abdominal: 11/74 (14.9) Atrophic: 21/74 (28.4)	**Presence/absence of testes:** Sensitivity: 0.65 Specificity: NA PPV: 1 NPV: 0 OAC:64.9% **Testes Correct location, n (%):** Inguinal: 40/42 (95.2) Intra-abdominal: 1/21 (4.8) Atrophic: 7/11 (63.6) **Incorrect Location**: None **False negatives**: USG Missed 2 inguinal, 10 IA, & 14 atrophic testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Desireddi et al., 2008 **Country:** US **Setting:** Hospital **Enrollment period:** November 2003 to November 2005 **Design:** Prospective case series	**Groups:** **G1:** MRI (1.5T) **G2:** MRI with magnetic resonance arteriography/venography (MRA/V) **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Refusal of imaging or surgery **N at enrollment (N testes):** **G1**: 12 (15) **G2**: 14 (14) **N at follow-up (N testes):** **G1**: 12 (15) **G2**: 14 (14) Bilateral testes: 3/26 boys (11.5%) **Age, mean months (range):** 28 (3-144) **Comorbidities, n (%):** Hydrocele : 1 / 26 boys(3.8) **Verification method, n (%):** surgical exploration:26(100) (inguinal=23, laparoscopic =3)	**MRI + MRA/V:** **Overall proportion of testes identified:** 8/14 (57.1) **By side:** NR **By position:** Intra-abdominal: 4/8 (50.0) Intracanalicular: 2/8 (25.0) Scrotal: 0/8 (0) Testes nubbins: 2/8 (25.0) **Surgery:** **Overall proportion of testes identified:** Present: 14/14 (100) Absent: none **By side:** NR **By position:** Intra-abdominal: 5/14 (35.7) Intracanalicular: 3/14 (21.4) Scrotal: 1/14 (7.1) Testes nubbins: 5/14 (35.7)	**Presence/absence of testes:** **MRI + MRA/V: (with nubbins)** Sensitivity: 0.57 Specificity: NA PPV: 1 NPV: 0 OAC:57% **Correct location:** Intra-abdominal: 4/5 (80.0) Intracanalicular: 2/3 (66.7) Scrotal: 0/1 (0) Testes nubbins: 2/5 (40.0) **Incorrect location:** 0 **False negatives**: MRI+MRA/V missed 1 testes each in IA, IC and scrotal positions & also missed 3 nubbins

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Green, 1985 **Country:** US **Setting:** Hospitals **Enrollment period:** July 1978 to October 1983 **Design:** Prospective case series	**Groups:** Participants undergoing CT scan and subsequent spermatic venography if CT scan failed to localize testes **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 26 (30)* **N at follow-up (N testes):** 26 (30)* Bilateral: 4/26 boys (15.4%) **Age, range yrs:** 2-18 **Comorbidities:** NR **Verification method:** Unspecified surgery	**CT:** **Overall proportion of testes identified:** 16/30 (53.3) **By side:** Left : 10/16 (62.5) Right: 6/16 (37.5) **By position: n (%)** Internal ring: 10/16 (62.5) Inguinal canal: 1/16 (6.3) Intra-abdominal: 5/16 (31.3) **Surgery: n (%)** **Overall proportion of testes identified:** **Present:28/30 (93.3)** **Absent: 2/30 (6.7)** **By side: n (%)** Left : 13/28 (46.4) Right: 15/28 (53.6) **By position: n (%)** Internal ring: 17/28 (60.7) Inguinal canal: 1/28 (3.6) Intra-abdominal: 9/28 (32.1) Canalicular: 1/28 (3.6)	**Presence/absence of testes:** **CT:** Sensitivity:0.57 Specificity: 1 PPV:1 NPV: 0.14 OAC: 60% **Testes correct location:** Internal ring: 10/17 (58.8) Inguinal canal: 1/1 (100.0) Intra-abdominal: 5/9 (55.6) **Incorrect location: None** **False negatives:** CT missed 4 Intra-abdominal, 1 canalicular & 7 testes at internal ring

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Guvenc et al., 2005 **Country:** Turkey **Setting:** Hospital **Enrollment period:** NR **Design:** Retrospective case series	**Groups:** Participants undergoing US examination followed by surgery **Inclusion criteria:** • Nonpalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 15 (17) **N at follow-up (N testes):** 15 (17) Bilateral testes: 2/15 boys (13.3%) **Age, mean months:** 47 **Comorbidities:** NR **Verification method:** Laparoscopy & Open surgery	**US:** **Overall proportion of testes identified: n (%)** 8/17 (47.1) **By side:** Left: 4/8 (50.0) Right: 2/8 (25.0) Both: 2/8 (25.0) **By position:** Abdominal atrophic:1/8 (12.5) Inguinal atrophic: 1/8 (12.5) Abdominal normal: 6/8 (75) Laparoscopy: **Overall proportion of testes identified: n (%)** Present:15/17 (88.2) Absent: 2/17 (11.8) (abdominal vanishing, n=2) By side: Left: 8/15 (53.3) Right: 7/15 (46.7) By Position: Abdominal atrophic: 2/15 (13.3) Abdominal normal: 7/15 (46.7) Internal ring: 6/15 (40.0) **Surgery:** **Overall proportion of testes identified: n (%)** Present: 13/17 (76.5) Absent: 4/17 (23.5) (abdominal + inguinal vanishing, n=4) **By side:** Left: 8/17 (47.1) Right: 5/17 (29.4) Both: 4/17 (23.5) **By position:** Abdominal atrophic: 2/13 (15.4) Abdominal normal: 7/13 (53.9) Inguinal atrophic: 4/13 (30.8)	**Presence/absence of testes:** **USD vs. open surgery:** **Sensitivity: 0.62** **Specificity: 1** **PPV: 1** **NPV: 0.44** **OAC: 70.6%** **USD vs. Laparoscopy:** **Sensitivity:0.40** **Specificity:1** **PPV:1** **NPV:0.18** **OAC: 47.1** **Correct location: USD vs. open surgery:** Abdominal atrophic:1/2 (50.0) Inguinal atrophic: 1/4 (25.0) Abdominal normal: 6/7 (85.7) **Incorrect location: None** **False Negatives:** US missed 5 testes identified by surgery (2 abdominal (1 normal,1 atrophic) & 3 inguinal (atrophic) testes When compared with laparoscopy, US did not identify 7 testes (2 abdominal, 4 IR, 1 abdominal atrophy) and identified 2 normal size testes at IR as 1 inguinal small and another as abdominal normal in size

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Kanemoto et al., 2005 **Country:** Japan **Setting:** Hospital **Enrollment period:** 1993 to 2002 **Design:** Prospective case series	**Groups:** **G1:** USG (3.5MHz) examination followed by surgery **G2:** MRI (1.5T) examination followed by surgery **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** **G1**: 46 (55) **G2**: 40 (47) **N at follow-up (N testes):** **G1**: 46 (55) **G2**: 40 (47) **Age, range yrs:** 1-12 Bilateral testes: 9/46 (19.6%) **Comorbidities:** NR **Verification method:** Inguinal exploration and laparoscopy	**Imaging: USG, MRI:** **Overall proportion of testes identified:** **G1:** 29/55 (52.7) **G2:** 28/47 (59.6) **By side:** NR **By position:** **G1:** Inguinal canal / near internal ring: 28/29 (96.6) Scrotum : 1/29 (3.4) G2: Inguinal canal: 19/28 (67.9) Scrotum: 3/28 (10.7) Abdomen: 2/28 (7.1) Lymph node structure: 4/28 (14.3) **Surgery:** **Overall proportion of testes identified:** **G1:** Present: 51/55 (92.7) Absent: 4/55 (7.3) **G2:** Present: **3**8/47 (80.9) Absent 9/47 (19.1) **By side: NR** **By position:** G1:Inguinal canal/internal ring: 34/55 (61.8) Scrotum: 1/55 (1.8) Abdominal: 3/55 (5.5) Atrophy: 13/55 (23.6) G2: Inguinal canal: 23/47 (48.9) Scrotum: 3/47 (6.4) Abdomen: 2/47 (4.3) Atrophic: 10/47 (21.3)	**Presence/absence of testes:** **G1:** Sensitivity: 0.57 Specificity: 1 PPV: 1 NPV: 0.15 OAC: 60% **G2:** Sensitivity: 0.63 Specificity: 0.56 PPV: 0.86 NPV: 0.26 OAC: 61.7% **Testes Correct location:** **USG:** Inguinal canal / near internal ring: 28/34 (82.4) Scrotum : 1/1 (100.0) **MRI:** Inguinal canal: 19/23 (82.6) Scrotum: 3/3 (100.0) Abdomen: 2/2 (100.0) **Incorrect location:** MRI identified 4 Lymphnode structure as testes: **False Negatives:** US missed 3 abdominal & 6 testes in inguinal canal and 13 atrophied testes MRI missed 4 inguinal & 10 atrophic testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Kantarci et al., 2010 **Country:** Turkey **Setting:** Hospital **Enrollment period:** NR **Design:** Retrospective case series	**Groups:** Participants undergoing MRI (1.5T) examination followed by surgery **Inclusion criteria:** • Physical examination findings concordant with the absence of a palpable testis in the scrotum, perineum, or inguinal canal **Exclusion criteria:** • No surgery following MRI **N at enrollment (N testes):** 36 (38) **N at follow-up (N testes):** 36 (38) Bilateral: 2/36 (5.6%) **Age, mean yrs ± SD:** 7 ± 1.9 **Comorbidities:** NR **Verification method:** Laparoscopy within 2 weeks of pre-operative MRI	**Technique (MRI):** **Overall proportion of testes identified:** **DWI:*** Observer 1:31/38 (81.6) Observer 2: 29/38 (76.3) **Conventional MRI:** Observer 1: 29/38 (76.3) Observer 2: 30/38 (78.9) **MRI+DWI:** Observer 1: 31/38 (81.6) Observer 2: 31/38 (81.6) **By side:** Left: NR Right:NR Both: NR **By position: NR** **Verification technique laparoscopy:** **Overall proportion of testes identified:** Present: 34/38 (89.5) Absent: 4/38 (10.5) **By side, n (%):** Left: 13/34 (38.2) Right:21/34 (61.8) **By position, n (%)** **I**ntracanalicular**:** 19/38 (50) Low intraabdominal: 11/38 (29) High intraabdominal: 4 / 38 (10.5) (1/ 15 abdominal testes was atrophic: (6.7%))	**Presence/absence of testes:** **Observer 1 / Observer2:** **DWI:** Sensitivity: 0.88 / 0.82 Specificity: 0.75 / 0.75 PPV: 0.97/0.97 NPV:0.43 / 0.33 OAC: 0.86/0.81 **Conventional MRI:** Sensitivity: 0.85 / 0.85 Specificity: 1 / 0.75 PPV: 1 / 0.97 NPV: 0.44 / 0.44 OAC: 0.86 / 0.84 **MRI+DWI:** Sensitivity: 0.91 / 0.88 Specificity: 1 / 0.75 PPV: 1 / 0.97 NPV: 0.57 / 0.43 OAC: 0.92 / 0.86 **Testes Correct location: NR** **Incorrect location:** An infected lymph node was misidentified as a testis (1 FP) with all techniques **False Negatives:**1/38 (2.6%) intra-abdominal testes was atrophic and missed by both Observers on DWI & conventional MRI

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Kato et al., 2010 **Country:** Japan **Setting:** Hospital **Enrollment period:** February 2006 to September 2009 **Design:** Prospective case series	**Groups:** Participants undergoing MRI (1.5T) examination (T1 & T2 weighted imaging, fat-suppressed T2 weighted imaging, DWI) **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 56 (63) **N at follow-up (N testes):** 56 (63) Bilateral: 7/56 (12.5%) **Age, mean months (range):** 24.7 (8-132) **Comorbidities:** NR **Verification method:** Laparoscopy or open surgery	**Technique (MRI):** **Overall proportion of testes identified:** 45/63 (71.4) **By side:** NR **By position:** Intra-abdominal: 14/45 (31.1) Intra-canalicular: 13/15 (33.3) Testicular nubbins: 18/45 (40.0) **Surgery:** **Overall proportion of testes identified:** Present: 56/63 (88.9) Absent: 7/63 (11.1) **By side:** NR **By position:** Intra-abdominal: 13/ 63 (20.6) Intra-canalicular: 13/ 63 (20.6) Testicular nubbins: 30/ 63 (47.6)	**Presence/absence of testes:** Sensitivity: 0.80 Specificity: 1 PPV: 1 NPV: 0.39 OAC: 83% **Testes Correct location:** Intra-abdominal: 13/13 (100.0) Intra-canalicular: 13/13 (100.0) Testicular nubbins: 18/30 (60.0) **Incorrect location:** MRI misidentified 1 testicular nubbin as Intra-abdominal testes **False negatives:** MRI missed 11 testicular nubbins

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Kier et al., 1988 **Country:** US **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective case series	**Groups:** Participants undergoing MRI (1.5T) followed by surgery **Inclusion criteria:** • Proof of surgery **Exclusion criteria:** NR **N at enrollment (N testes):** 14 (15) **N at follow-up (N testes):** 14 (15) **Bilateral, n (%):** 1 (6.7) **Age, range months:** 11-60 **Comorbidities:** NR **Verification method:** Laparoscopy and/or exploration	**MRI:** **Overall proportion of testes identified:** **Prospectively: 6/15 (40%)** **By side:** Left: NR Right: NR Both: NR **By position:** **Prospectively, n (%):** **Inguinal: 5/6 (83)** **External iliac: 1/6 (17)** **Surgery:** **Overall proportion of testes identified:** Present:8/15 (53.3) Absent: 7/15 (46.7) **By side: NR** **By position: n (%)** Inguinal: 5/15 (33.3) External iliac: 2/15 (13.3) High abdomen: 1/15 (6.7)	**Presence/absence of testes:** **Prospectively:** Sensitivity: 0.63 Specificity:0.86 PPV:0.83 NPV:0.67 OAC: 73.3% **Testes Correct location:** **Inguinal: 4/5 (80.0)** **External iliac: 1/2 (50.0)** **Incorrect location:** identified an absent testis as located at inguinal region. **False negatives:** Prospectively: MRI did not locate 3 testes (1 inguinal, 1 external iliac, 1 high abdominal)

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Kullendorff et al., 1985 **Country:** Sweden **Setting:** Hospital **Enrollment period:** November 1981 to June 1983 **Design:** Prospective case series	**Groups:** Participants undergoing US (5.0 or 7.5MHz) examination followed by surgery **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 12 (12) **N at follow-up (N testes):** 12 (11)* **Bilateral, n (%):** 0 **Age mean yrs (range):** 4 (3-8) **Comorbidities:** NR **Verification method:** Unspecified surgery	**US:** **Overall proportion of testes identified:** 6/11 (55.0) **By side:** NR **By position:** Anulus internus: 1/6 (16.7) Inguinal canal: 2/6 (33.3) Anulus external: 1/6 (16.7) Non-testis like formation: 2/6 (33.3) **Surgery: Overall proportion of testes identified:** Present: 5/11 (45.5) Absent: 6/11 (54.5) **By side:** NR **By position:** Anulus internus: 1/11 (9.1) Inguinal canal: 2/11 (18.2) Anulus external: 1/11 (9.1) Intra-abdominal: 1/11 (9.1)	**Presence/absence of testes:** Sensitivity: 0.80 Specificity: 0.67 PPV: 0.67 NPV: 0.80 OAC: 0.73 **Testes Correct location:** Anulus internus: 1/1 (100.0) Inguinal canal: 2/2 (100.0) Anulus externa: 1/1 (100.0) **Incorrect location:** 2 with scar tissues after an earlier operation were identified as non-testis like formations by ultrasound **False negatives:** Ultrasound did not locate 1 intra-abdominal testis

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Lam et al., 2001 **Country:** China **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective case series	**Groups:** Participants undergoing MRI* (1.5T) and magnetic resonance venography (MRV) **Inclusion criteria:** • Those presenting with impalpable undescended testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 34 (44) **N at follow-up (N testes):** 34 (44) **Bilateral, n (%):** 10 (29.4) **Age, mean yrs (range):** 6.4 (1-16) **Comorbidities, n (%):** NR **Verification method, n (%):** Laparoscopy or surgical exploration	**MRV:** **Overall proportion of testes identified:** 37/44 (84.1) **By side:** NR **By position:** Hypoplastic testis inside (canalicular): 26/37 (70.3) Pelvic skinfold: 2/37 (5.5) Intra-abdominal: 5/37 (13.5) Atrophic testis: 4/37 (10.8) Vanishing testes at scrotum: 5/44 (11.4) Vanishing testes at inguinal canal: 2/44 (4.5) **Surgery:** **Overall proportion of testes identified:** Present: 37/44 (84.1) Absent: 7/44 (15.9) (Vanishing testes at scrotum: 5, at inguinal canal: 2) **By side:** NR **By position:** Hypoplastic testis inside (canalicular): 26/44 (59.1) Pelvic skinfold: 2/44 (4.5) Intra-abdominal: 5/44 (11.4) Atrophic testis: 4/44 (9.1)	**Presence/absence of testes:** **MRV:** Sensitivity: 1 Specificity: 1 PPV: 1 NPV: 1 OAC: 1.00 **Correct location:** MRV correctly located all testes including vanishing testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Lam et al., 1998 **Country:** China **Setting:** Hospital **Enrollment period:** August 1996 to January 1997 **Design:** Prospective case series	**Groups:** Participants undergoing MRI (1.5T) and MRA * examination, followed by surgery **Inclusion criteria:** • Impalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 14 (17) **N at follow-up (N testes):** 14 (17) **Bilateral, n (%):** 3 (21.4) **Age, range yrs:** 1-16 **Comorbidities:** NR **Verification method:** Unspecified surgery	**MRI:** **Overall proportion of testes identified:** 14/17 (82.4) **By side:** NR **By position:** Intra-abdominal: 3/14 (21.4) Canalicular: 11/14 (78.6) **MRA:** **Overall proportion of testes identified:** 17/17 (100) **By side:** NR **By position:** Intra-abdominal: 3/17 (17.6) Canalicular: 11/17 (64.7) Atrophic: 3/17 (17.6) **Surgery: Overall proportion of testes identified:** Present: 17 /17 (100.0) Absent: none **By side:** NR **By position:** Intra-abdominal: 3/17 (17.6) Canalicular: 11/17 (64.7) Atrophic: 3/17 (17.6)	**Presence/absence of testes:** **MRI:** Sensitivity: 0.82 Specificity: NA PPV: 1 NPV: 0 OAC: 82.0% **MRA:** Sensitivity: 1 Specificity: NA PPV: 1 NPV: NA OAC: 100 % **Correct location:** **MRI:** Intra-abdominal: 3/3 (100.0) Canalicular: 11/11 (100.0) **MRA: Correctly located all testes** **Incorrect location: None** **False negatives:** MRI missed 3 atrophic testes located in the scrotum

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results**	Test Characteristics
Author: Maghnie et al., 1994 **Country:** Italy **Setting:** Hospital **Enrollment period:** 1989-1993 **Design:** Prospective case series	**Groups:** Participants undergoing USG (7.5MHz) and MRI (1.5T), followed by surgery **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 17 (22) **N at follow-up (N testes):** 17 (21) **Bilateral, n (%):** 5/17 (29.4) **Age, range months:** 10-174 **Comorbidities:** Kallmann's syndrome (n=1) **Verification method:** Unspecified surgery	**USG:** **Overall proportion of testes identified:** 13/21 (61.9) **By side:** Left: 7/13 (53.8) Right: 6/13 (46.2) **By position: n (%)** Abdominal/ near Internal inguinal ring: 2/13 (15.4) includes 1 atrophic Within inguinal canal: 10/13 (76.9) includes 4 atrophic 1/13--- false positive (7.7) **MRI:** **Overall proportion of testes identified:** 11/21 (52.3) **By side:** Left: 5/11 (45.5) Right: 6/11 (54.5) **By position:** Abdomen: 4/11 (36.4) Inguinal canal: 6/11 (54.5) Atrophy-inguinal 1/11(9.1) **Surgery: Overall proportion of testes identified:** Present: 16/21 (76.2) Absent: 5/21(23.8) **By side:** Right: 8/16 (50%) Left: 8/16 (50%) **By position: n (%)** Abdominal / near internal ring: 4/21 (19.1) Inguinal: 6/21 (28.6) Abdominal atrophic: 2/21(9.5) Inguinal atrophic: 4/21 (19.1)	**Presence/absence of testes:** **USG:** Sensitivity: 0.75 Specificity: 0.80 PPV: 0.92 NPV: 0.50 OAC: 76% **MRI:** Sensitivity: 0.69 Specificity: 1 PPV: 1 NPV: 0.50 OAC: 76% **Testes Correct location:** **USG:** Near Internal inguinal ring: 1/4 (25.0) Abdominal atrophic: 1 / 2 (50.0) Within inguinal canal: 6/6 (100.0) Inguinal atrophic: 4/4 (100.0) **MRI:** Abdominal: 4/4 (100.0) Inguinal canal: 6/6 (100.0) Atrophy-inguinal 1 / 4 (25.0) **Incorrect location: USG** identified 1 absent testis as present **False negatives:** US missed 3 abdominal normal & 1 abdominal atrophic testes MRI missed 5 atrophic testes (3 inguinal , 2 abdominal)

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Malone and Guiney, 1985 **Country:** Ireland **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective case series	**Groups:** Patients undergoing US examination followed y laparoscopy **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 11 (14) **N at follow-up (N testes):** 11 (14) **Bilateral, n (%):** 3 (27.3) **Age, mean yrs (range):** 6 (3-12) **Comorbidities, n (%):** NR **Verification method:** Laparoscopy & surgery*	**US:** **Overall proportion of testes identified:** 2/14 (14.3) **By side:** NR **By position:** Abdominal: 1/2 (50.0) Canalicular: 1/2 (50.0) **Laparoscopy & Surgery:** **Overall proportion of testes identified:** Present: 13/14 (92.9) Absent: 1/14 (7.1) **By side:** NR **By position:** Abdominal: 7/14 (50.0) Canalicular: 5/14 (35.7) Atrophic: 1/14 (7.1)	**Presence/absence of testes:** Sensitivity: 0.15 Specificity: 1 PPV: 1 NPV: 0.08 OAC: 21.4 % **Correct location:** Abdominal: 1/7 (14.3) Canalicular: 1/5 (20.0) **Incorrect location: None** **False negatives:** US missed 6 abdominal, 4 canalicular testes & 1 atrophic testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Miyano et al., 1991 **Country:** Japan **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective case series	**Groups:** Participants undergoing MRI (1.5T) examination followed by surgery **Inclusion criteria:** • Impalpable testes not demonstrated by US **Exclusion criteria:** NR **N at enrollment (N testes):** 17 (? 17) **N at follow-up (N testes):** 17 (? 17) **Bilateral, n (%): NR** **Age, mean yrs (range):** 2.7 (1-5.3) **Comorbidities, n (%):** NR **Verification method, n (%):** Surgery	**Technique (MRI):** **Overall proportion of testes identified:** 9 / 17 (52.9 %) **By side:** NR **By position:** Inguinal canal: 8/9 (89%) Abdominal: 1/9 (11%) **Verification technique** **Surgery: Overall proportion of testes identified:** Present: 11/17 (64.7) Absent: 6/17 (35.3) **By side: NR** **By position: n (%)** Inguinal canal : 10/17 (58.8) Abdominal : 1/17 (5.9)	**Presence/absence of testes:** **Pre-operatively:** Sensitivity: 0.82 Specificity: 1 PPV:1 NPV:0.75 OAC:88 % **Correct location: n(%)** Inguinal canal: 8/10(80.0) Abdominal : 1/1 (100.0) **Incorrect location: None** **False negatives:** Pre-operatively, MRI missed 2 testes at inguinal canal

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Nijs et al., 2007 **Country:** Netherlands **Setting:** Hospital **Enrollment period:** 7 years (unspecified) **Design:** Prospective case series	**Groups:** Participants undergoing USG (5-12 MHz) followed by surgery **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Mullerian inhibitory factor deficiency syndrome (implying abnormal testis position) **N at enrollment (N testes):** 137 (156) **N at follow-up (N testes):** 135 (152) **Bilateral, n (%):** 17 (12.6) **Age, range:** 4 wks – 16.2 yrs **Comorbidities, n (%):** NR **Verification method:** Laparoscopy or orchiopexy,	**USG:** **Overall proportion of testes identified: 103/152 (67.8%)** **By side: NR** **By position:** Abdominal: 16/103 (15.5) Inguinal: 87/103 (84.5) **Surgery:** **Overall proportion of testes identified:** Present: 143/152 (94.1) Absent: 9/152 (5.9) **By side:** Left: 70/152 Right:48/152 **By position:** Abdominal: 33/152 (21.7) Inguino-scrotal : 86/152 (56.6) Atrophic: 24/152 (15.8) (2=abdominal, 17 inguinal , 5 scrotal)	**Presence/absence of testes:** Sensitivity: 0.72 Specificity:1 PPV:1 NPV:0.18 OAC: 73.7% **Correct location:** Abdominal: 16/33 (48.5) Inguinal: 84/86 (97.7) **Incorrect location:** USG located 3 abdominal testes as inguinal **False negatives:** USG missed 14 normal abdominal, 2 normal inguinal, 17 inguinal atrophic, 2 abdominal atrophic and 5 scrotal atrophic testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Siemer et al., 2000 **Country:** Germany **Setting:** Hospital **Enrollment period:** 1987 to 1997 **Design:** Prospective case series	**Groups:** Participants undergoing MRI (1.0-1.5T) followed by surgery **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 29 (29) **N at follow-up (N testes):** 29 (29) **Bilateral, n:** 0 **Age, range yrs (mean):** 1-15 (4.5) **Comorbidities, n (%):** NR **Verification method:** Operative exploration	**MRI:** **Overall proportion of testes identified:** 17/29 (58.6) **By side:** NR **By position:** Inguinal: 10/17 (58.8) Abdominal: 7/17 (41.2) **Surgery:** **Overall proportion of testes identified:** Present: 25/29 (86.2) Absent: 4/29 (13.8) **By side: NR** **By position:** Inguinal: 17/29 (58.6) Abdominal: 8/29 (27.6)	**Presence/absence of testes:** Sensitivity:0.68 Specificity:1 PPV:1 NPV:0.33 OAC: 72.4% **Testes Correct location:** Inguinal: 10/17 (58.8) Abdominal: 7/8 (87.5) **Incorrect location:** None **False Negatives:** MRI did not locate 7 inguinal & 1 abdominal testes

Table D-1. Evidence table for studies assessing imaging accuracy (continued)

Study Description	Imaging Technique & Population	Results	Test Characteristics
Author: Yeung et al., 1983 **Country:** China **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective case series	**Groups:** Participants undergoing US (5-10 MHz), Plain MRI and MRA (1.5T) followed by surgery **Inclusion criteria:** NR **Exclusion criteria:** NR **N at enrollment (N testes):** 21 (23) **N at follow-up (N testes):** 21 (23) **Bilateral, n (%):** 2 (9.5) **Age, range yrs (mean):** 1-10 (3.8) **Comorbidities, n (%):** NR **Verification method:** Laparoscopy and surgical exploration	**USG & MRI:** **Overall proportion of testes identified:** 9/23 (39.1) **By side:** NR **By position:** **USG:** Inguinal: 9/9 (100.0) **MRI:** Intra-abdominal: 1/9 (11.1) Inguinal: 8/9 (88.9) **MRA:** **Overall proportion of testes identified:** 22/23 (95.7) **By side:** NR **By position:** Intra-abdominal: 4/22 (18.2) Inguinal: 10/22 (45.4) Atrophy: 8/22 (36.4) **Verification technique:** **Overall proportion of testes identified:** Present: 22/23 (95.7) Absent: 1/23 (4.3) **By side: NR** **By position:** Intra-abdominal: 4/23 (17.4) Inguinal: 10/23 (43.5) Atrophy: 8/23 (34.8)	**Presence/absence of testes:** **USG & MRI:** Sensitivity:0.41 Specificity:1 PPV:1 NPV:0.07 OAC: 43.5% **MRA:** Sensitivity:1 Specificity:1 PPV:1 NPV:1 OAC: 100.0% **Testes Correct location:** **USG:** Inguinal: 9/10 (90.0) **MRI:** Intra-abdominal: 1 / 4 (25%) Inguinal: 8/10 (80.0) **MRA: correctly located all the testes (100.0%)** Intra-abdominal: 4/4 Inguinal: 10/10 Atrophy: 8/8 **Incorrect location**: None **False negatives**: USG missed all th4 intra-abdominal, 1 inguinal and all the 8 atrophied testes MRI missed 3 intra-abdominal, 2 inguinal and all the 8 atrophied testes

Table D-2. Evidence table for studies assessing hormonal stimulation testing

Study Description	Population Description	Pre-testing Levels	Post-testing Levels
Author: Davenport et al., 1995 **Country:** UK **Setting:** Hospital **Enrollment period:** 1974 to 1990 **Design:** Prospective cohort	**Groups:** **G1**: Particpants diagnosed as anorchic following surgical exploration **G2**: Participants diagnosed with bilateral, intraabdominal testes of normal volume following surgical exploration **G3:** Participants diagnosed with either unilateral, intraabdominal testes only or with bilateral dysplastic testes following surgical exploration Participants received three doses of IM hCG on successive days. Dosage varied by age: <1 yr : 500 units/dose 1-10 yrs: 1000 units/dose >10 yrs: 1500 units/dose **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Children with ambiguous genitalia or intersex • History suggestive of neonatal torsion or trauma **N at enrollment (N testes):** **G1**: 8 (0) **G2**: 14 (28) **G3**: 9 (NR) **N at follow-up (N testes):** **G1**: 8 (0) **G2**: 14 (28) **G3**: 9 (NR) **Age, median yrs (range):** 9 (1-12) **Comorbidities, n (%):** NR	**Hormone levels:** Testosterone, basal median value (range): **G1:** 0.64 (0.5-2) **G2:** 0.5 (0.3-4.6) **G3**: 0.7 (0.4-4)	**Hormone levels:** Testosterone, peak median value (range): **G1:** 0.7 (0.3-2) **G2:** 5.1 (1.8-38.9) **G3**: 1.8 (0.7-21.7) **Overall proportion with surgery:** 31 (100) **Proportion with hormone response followed by surgery:** 31 (100) **Proportion with no hormone response followed by surgery:** NR **Proportion of testes palpable after testing:** NR **Confirmation of presence of testes:** NA

Table D-2. Evidence table for studies assessing hormonal stimulation testing (continued)

Study Description	Population Description	Pre-testing Levels	Post-testing Levels
Author: Merksz et al., 1992 **Country:** Hungary **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective cohort	**Groups:** **G1**: Particpants with bilateral undescended testes **G2**: Participants with undescended testes with hypospadia Participants received 4500 IU of hCG over three consecutive days **Inclusion criteria:** • Suspected impaired androgen secretion • Impalpable testes • Hypospadias associated with undescended testes **Exclusion criteria:** • Unilateral retention • Both testes palpable inguinally before surgery or found to be normally developed during surgery **N at enrollment (N testes):** **G1**: 20 (40) **G2**: 10 (17) **N at follow-up (N testes):** **G1**: 20 (40) **G2**: 10 (17) **Age, range yrs:** 1-12 **Comorbidities, n (%):** Hypospadias: 10 (33.3)	**Hormone levels:** Serum testosterone value, basal median value (range): **G1:** 0.67 (0.01-2) **G2:** 0.53 (0.01-1.4)	**Hormone levels:** Serum testosterone value, median value (range): **G1:** 4.16 (0.5-14.5) **G2:** 4.18 (0.42-13.5) **Overall proportion with surgery:** NR **Proportion with hormone response followed by surgery:** NR **Proportion with no hormone response followed by surgery:** NR **Proportion of testes palpable after testing:** NR **Confirmation of presence of testes:** NR

Table D-3. Evidence table for studies assessing hormonal treatment

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Aycan et al., 2006 **Country:** Turkey **Setting:** Hospital **Enrollment period:** NR **Design:** Prospective cohort **Length of followup:** 3 weeks	**Groups:** **G1:** hCG 500 IU/week for three weeks **G2:** hCG 1500 IU/m^2 (min 500 IU/dose- max 1500 IU/dose) three times a week for three weeks **Inclusion criteria:** • Diagnosis of cryptorchidism from pediatric endocrinology specialist **Exclusion criteria:** See inclusion criteria **N at enrollment:** **G1**: 21 **G2**: 14 **N at follow-up:** **G1**: 21 **G2**: 14 **Age at intervention, mean yrs ± SD (range):** **G1**: 5.2 ± 3.1 (0.5-10.8) **G2**: 5.9 ± 3.9 (0.6-13.9) **Sidedness, %:** Left: **G1**: 38.1 **G2**: 71.4 Right: **G1**: 81 **G2**: 57.1 **Comorbidites:** NR	**Unilateral, %:** **G1+G2**: 77 Left: 37 Right: 63 **Bilateral, %:** **G1+G2:** 23 **Palpability, n (%):** **Left** **G1**: 21 (100) **G2**: 11 (78.6) Right: **G1**: 20 (95.2) **G2**: 12 (85.7) **Testicle location, n (%):** **Scrotal, left** **G1**: 13 (61.9) **G2**: 4 (28.6) Scrotal, right **G1**: 4 (19) **G2**: 6 (42.9) Prescrotal, left **G1**: 2 (9.5) **G2**: 2 (14.3) Prescrotal, right **G1**: 2 (9.5) **G2**: 1 (7.1) Inguinal, left **G1**: 6 (28.6) **G2**: 5 (35.7) Inguinal, right **G1**: 14 (66.7) **G2**: 5 (35.7) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position, %:** Undescended, left: **G1**: 9.5 **G2**: 35.7 Right: **G1**: 23.8 **G2**: 4.3 P> 0.05 Total success rate, %: **G1**: 66.7 **G2**: 57.1 **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Bertelloni et al., 2001 **Country:** Italy **Setting:** Hospital **Enrollment period:** 1989-1998 **Design:** RCT **Length of followup:** 6 months post discontinuation of therapy	**Groups:** **G1:** hCG 500 IU/week if ≤ 2 years or 1,000 IU/week if > 2 years for 6 weeks **G2:** hCG 500 IU/week (≤ 2years) + hMG 75 IU/week or hCG 1000 IU/week (> 2 years) + hMG 75 IU/week for 6 weeks **G3**: GnRH 1,200 µg/daily for 28 days **G4**: GnRH 1,200 µg/daily for 28 days + hCG 1,500 IU/week for 3 weeks **Inclusion criteria:** • Unilateral inguinal palpable testis • No clinical evidence of hernia or other endocrine or syndromic conditions impairing descent **Exclusion criteria:** • Retractile testes **N at enrollment (N testes):** **G1**: 37 (37) **G2**: 39 (39) **G3**: 39 (39) **G4**: 40 (40) **N at follow-up (N testes):** **G1**: 37 (37) **G2**: 39 (39) **G3**: 39 (39) **G4**: 40 (40) **Age at intervention, range:** 10-48 months **Sidedness, n (%):** Left: 69 (44.5) Right: 86 (55.5) **Comorbidites:** NR	**Unilateral, n (%):** **G1**: 37 (100) **G2**: 39 (100) **G3**: 39 (100) **G4**: 40 (100) **Bilateral, n:** 0 **Palpability, n (%):** **G1**: 37 (100) **G2**: 39 (100) **G3**: 39 (100) **G4**: 40 (100) **Testicle location: Inguinal** **G1**: 37 (100) **G2**: 39 (100) **G3**: 39 (100) **G4**: 40 (100) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Temporary descent **G1**: 8 (21.6) **G2**: 7 (17.9) **G3**: 6 (15.4) **G4**: 9 (22.5) Permanent descent (6 months) n (%) **G1**: 7 (18.9) **G2**: 5 (12.8) **G3**: 5 (12.8) **G4**: 6 (15.0) **Pain:** Local pain in injection site in majority of hCG treated boys **Adverse effects:** **G1**: NR **G2:** NR **G3**: 0 **G4**: 0 **Andronization, n (%):** **G1**+**G2**+**G4**: 86 (74.1) **G3**: 2 (5.1) **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Bica and Hadziselimovic 1992, 1993 **Country:** Brazil **Setting:** Hospital **Enrollment period:** March 1989 to May 1990 **Design:** RCT **Length of followup:** 3 months	**Groups:** **G1:** Buserelinvia nasal spray 20 µg per day every 8 hours for 28 days + 1,500 IU HCG intramuscularly once a week for 3 weeks **G2:** Placebo (physiological saline solution) nasal spray for 28 days + 1,500 IU HCG intramuscularly once a week for 3 weeks G3:Orchiopexy **Inclusion criteria:** • True cryptorchidism **Exclusion criteria:** • Retractile testes • Ectopic testes • Concomitant hernia • Unsuccessful previous orchiopexy • Unsuccessful hormone treatment • Aarskog syndrome **N at enrollment (N testes):** **G1**: 23 (26) **G2**: 20 (20) G3: 20 (23) **N at follow-up:** **G1**: 22 **G2**: 19 G3: 18 **Age at intervention, (n) mean ± SD:** **G1**: (22) 3.7 ± 2.0 **G2**: (19) 4.3 ± 2.0 G3: (18) 4.8 ± 1.9 **Sidedness:** NR **Comorbidites,:** NR	**Unilateral, n (%):** **G1**: 19/22 (86) **G2**: 19/19 (100) G3: 15/18 (85) **Bilateral, n (%):** **G1**: 3/22 (14) **G2**: 0/19 (0) G3: 3/18 (17) **Palpability:** NR **Testicle location, n (%):** Abdominal G1: 2/25 (8) G2: 3/19 (16) G3: 3/21 (14) Inguinal G1: 12/25 (45) G2: 7/19 (37) G3: 10/21 (48) Prescrotal G1: 11/25 (44) G2: 9/19 (47) G3: 8/21 (38) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Descent, %: **G1**: 28 **G2**: 0 **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Christiansen et al., 1988 **Country:** Denmark **Setting:** 6 participating centers and private physicians' offices **Enrollment period:** NR **Design:** RCT (modified double blind) **Length of followup:** 4-8 weeks	**Groups:** **G1:** hCG 100 IU/kg im (maximum 1500 IU) twice weekly for 3 weeks **G2:** GnRH, 200 µg in each nostril three times a day for 28 days **G3**: placebo, 200 µg in each nostril three times a day for 28 days **Inclusion criteria:** • Unilateral or bilateral cryptorchidism • No previous hormonal treatment • No operation in inguino-scrotal region • Retractile testes(testes that were spontaneously in position 0-3 but could be manipulated into position 4) **Exclusion criteria:** • Inguinal hernia • Ectopic testes • Endocrine or chromosomal disorders • Testes in position 4 at beginning of exam but retracted to suprascrotal location by strong cremaster muscle **N at enrollment : 317 boys** **N at follow-up (N testes):** Total 243 boys (398) **G1:** 88 (145) **G2:** 74 (126) **G3**: 81 (127) **Age at intervention, years, n (range):** Bilateral : 155 (1.8 – 13.0) Unilateral: 88 (1.5-13.1) **Sidedness:** See testicle location **Comorbidites:** NR	**Unilateral, n (N testes):** **G1**: 31 (31) **G2**: 22 (22) **G3**: 35 (35) **Bilateral, n (N testes):** **G1**: 57 (114) **G2**: 52 (104) **G3**: 46 (92) **Palpability:** See below **Testicle location, (%):** Not palpable Bi L: 10 Bi R: 8 Uni L: 5 Uni R: 9 Inguinal Bi L: 64 Bi R: 73 Uni L: 34 Uni R: 41 Suprascrotal Bi L: 12 Bi R: 12 Uni L: 2 Uni R: 7 High Scrotal Bi L: 14 Bi R: 7 Uni L: 1 Uni R: 1 Normal Uni L: 58 Uni R: 42 **Other anomalies:** NR	Bilateral, rate of descent %* (retractile testes excluded, n=21): **G1**: 23 **G2**: 9 **G3**: 0 P=0.001 (Fisher's exact) Unilateral, rate of descent %*: (retractile testes excluded, n=2): **G1**: 15 **G2**: 0 **G3**: 0 P=0.017 (Fisher's exact) **Adverse effects, %:** Pain in genital region : **G1**: 0 **G2**: 7 **G3**: 1 Erections **G1**: 14 **G2**: 1 **G3**: 0 Growth of penis **G1**: 7 **G2**: 0 **G3**: 0 Pain at site of injection **G1**: 4 Nose Bleeding **G2**: 1 **G3**: 1 Psychological changes **G1**: 7 **G2**: 12 **G3**: 10 **<u>Long-term:</u>** NR

*Percentage is rate of descent without retractile testes

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: DeMuinck Keizer -Schrama et al., 1986, 1987 and Hazebroek et al, 1987 **Country:** Netherlands **Setting:** Hospital **Enrollment period:** October 1982 to April 1985 **Design:** RCT followed by open cohort **Length of followup:** 6 months to 2 years	**Groups:** **G1:** Synthetic LHRH intranasal 1.2 mg/day, one 200µg puff in each nostril three times a day before meals for 4 weeks **G2:** Placebo Results evaluated at 8 weeks. All non-responders were offered additional treatment with LHRH. Failure of hormonal treatment followed by surgical intervention: 170 boys (196 testes)* **Ga**: 36 **Gb**: 72 **Gc**: 62 **Inclusion criteria:** • Cryptorchidism (one or both testes not located in or could not be manipulated fully into the scrotum) **Exclusion criteria:** • Previous hormonal or surgical treatment for cryptorchidism • Retractile testes • Truly ectopic testicular positions (perineal, penile, etc) • Concomitant inguinal hernia • Chromosomal or dysmorphic syndromes **N at enrollment (N testes):** **G1 + G2**: 252 (301) **Ga + Gb + Gc:** 170 (196) **N at follow-up:** **G1**: 151 **G2**: 130 **Age at intervention, mean**	**Unilateral, n (%):** **G1+ G2:** 203 (80.6) **Bilateral, n (%):** **G1**+**G2**: 49 (19.4) **Palpability, n (%):** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Descent after 8 weeks, n (%): **G1**: 14 testicles (9) **G2**: 10 testicles (8) After open study: **G1**: 13 **G2**: 21 Complete descent after 8 weeks, n (%): **G1**A: 1/30 (3) **G2**A: 0/25 (0) **G1**B: 1/55 (2) **G2**B: 6/52 (11) **G1**C: 12/66 (18) **G2**C: 4/53 (7) Complete descent after two courses of LHRH in **G1** and **G2** together n (%) **Ga**: 4 (7) **Gb**: 12 (12) **Gc**: 32 (28) Total: 48 (18) Late descent, n (%) **Ga**: 3 (5) **Gb**: 1 (1) **Gc**: 10 (9) Total: 14 (5) **Need for further surgical intervention:** **G1**+**G2**: 170 (196 testes) Bilateral 26 Unilateral 144 (69 right, 75 left) **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
	yrs ± SD: 5.6 ± 3.3 **Sidedness, n (%):** Left: **G1**+**G2**: 99 (48.8) Right: **G1**+**G2**: 104 (51.2) **Comorbidites:** NR		

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Esposito et al., 2003 **Country:** Italy **Setting:** Hospital **Enrollment period:** January 1997 to June1999 **Design:** RCT **Length of followup:** 4-10 weeks	**Groups:** **G1:** hCG 500 IU i.m. twice a week for 6 weeks **G2:** hMG 150 IU i.m. twice a week for 4 weeks **G3**: LH-RH nasal spray 1.2 mg/day for 4 weeks **G4**: hMG 150 IU i.m. twice a week for 4 weeks followed by hCG 500 IU i.m. twice a week for 6 weeks **G5**: LH-RH nasal spray 1.2 mg/day for 4 weeks followed by hCG 500 IU i.m. twice a week for 6 weeks **Inclusion criteria:** • Testes palpable in the inguinal canal **Exclusion criteria:** • Retractile (non-scrotal testes that could be manipulated into the bottom of the scrotum but immediately retracted to initial prescrotal upon release) • Non-palpable testes **N at enrollment:** **G1**: 113 **G2**: 35 **G3**: 85 **G4**: 27 **G5**: 64 **N at follow-up:** **G1**: 113 **G2**: 35 **G3**: 85 **G4**: 27 **G5**: 64 **Age at intervention, media yrs, (range):** 3.5 (1.2-6) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** 230 (71.0) Left: 111 (48.3) Right: 119 (51.7) **Bilateral, n (%):** 94 (29.0) **Palpability, n (%):** **G1**-**G5**: (100) **Testicle location, %:** Inguinal: 100 **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Descent, n %: **G1**: 39/113 (34.5) **G2**: 0/35 (0) **G3**: 25/85 (29.4) **G4**: 7/27 (25.9) **G5**: 19/64 (29.6) Total: 90 (27.7) Bilateral: 36 (38.2) Unilateral: 54 (23.4) P=0.007 Need for further surgical intervention: 14 (4.3) Adverse effects: **G1, G4, G5:** frequent erections, aggressive behavior, development of pubic hair, pain at injection site or inguinal area (n not reported) **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Forest et al, 1988 **Country:** France **Setting:** Clinic **Enrollment period:** 1983 to 1988 **Design:** RCT with prospective and retrospective aspects **Length of followup:** NR	**Groups:** **G1:** hCG (1,500 IU/injection) 7 intramuscular injections every other day **G1a:** Retrospective study (n=352) **G1b:** Prospective study (n=88) **G2:** 4 intramuscular injections of hCG in dose related to body weight (100 IU/kg) to a maximum dose of 3,000 IU) at 4 day (**G2**a) or 5 day (**G2**b) intervals **Inclusion criteria:** • Undescended testes **Exclusion criteria:** • Retractile testes • Inguinal hernia • Overt endocrine disturbances **N at enrollment:** **G1**: 440 **G1a**: 352 **G1b**: 88 **G2**: 95 **N at follow-up:** **G1**: 440 **G2**: 95 **Age at intervention:** **G1b**+**G2**: range 7 months-12 years **Sidedness, n (%):** Left: **G1**: 118/263 **G2**: 18/57 Right: **G1**: 145/263 **G2**: 39/60 **Comorbidites:** NR	**Unilateral, n (%):** **G1**: 263 (60) **G1a**: 204 (58) **G1b**: 59 (67) **G2**: 57 (60) **Bilateral, n (%):** **G1**: 177 (40) **G1a**: 148 (42) **G1b**: 29 (33) **G2**: 38 (40) **Palpability, n (%): NR** **G1**: 123 **G2**: 123 **Testicle location:** **Abdominal** **G1a**: 320 **G1b**: 50 **G2**: 56 Inguinal **G1a**: 180 **G1b**: 67 **G2**: 77 **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Successful descent unilateral **G1**: 107 (40.7) **G1a**: 77 (37.8) **G1b**: 30 (50.8) **G2**: 29 (50.9) Success in bilateral **G1**: One side 42 Both sides 88 Total 130 (36.7) **G1a**: One side 34 Both sides 68 Total 102 **G1b**: One side 8 Both sides 20 Total 28 **G2**: One side 52 Both sides 116 Total 168 (39.1) **Long-term:** **Endocrine function:** Testosterone levels, mean ± SD (median): **G1a**: 5.86 ± 2.89 (5.25) ng/ml 20.3 ± 10 (182) nmol/l **G1b**: 5.16 ± 2.73 (4.43) ng/ml 17.9 ± 9.5 (15.4) nmol/l **G2**: 4.08 ± 2.07 (3.84) ng/ml 14.2 ± 7.2 (13.3) nmol/l

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Hadziselimovic, 2008 **Country:** Switzerland **Setting:** Hospital, clinic **Enrollment period:** NR **Design:** Retrospective case series **Length of followup:** 15-19 years following initial treatment	**Groups:** **G1:** Schoemakers type of orchiopexy between ages 1-6 years subsequently treated within 3 months after surgery with LH-RH, 10 µg applied as intranasal spray in the evening on alternate dats for 6 months **G2:** Age matched controls who had undergone successful Schoemaker type orchiopexy with testicular biopsy results and no additional LH-RH treatment **Inclusion criteria:** • Unilateral cryptorchid boys located outside of scrotum since birth • **G1**: No additional surgeries or severe illnesses requiring hospitalization during the 15-19 years following treatment; no chronic medication use or drug abuse; • **G2**: no Ad spermatogonia and total # germ cells < 0.2 per tubule **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 15 (15) **G2**: 15 (15) **N at follow-up (N testes):** **G1**: 15 (15) **G2**: 15 (15) **Age at intervention, mean yrs (range):** **G1**: 3 (1-6) **G2**: 4 (NR) Age at spermiogram, mean yrs: **G1**: 19 **G2**: 21 P< 0.02 **Sidedness:** NR **Comorbidites:**NR	**Unilateral, n (%):** 30 (100) **Bilateral, n:** 0 **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR **Testicular volume** **G1**: Crytorchid testis 1.4 (95% CI 0.8-2.1) Descended testis 1.2 (95% CI 1-3.2) Penis length 4.5cm (CI 4-5) Ad spermatogonia at surgery **G1**: 0 **G2**: 0 S/T at surgery **G1**: 0 (95%CI 0-0.05) **G2**: 0.02 (95% CI 0-2) p=0.22 Unsuccessful HCG treatment prior to surgery **G2**: 13/15	**Immediate/short-term:** NR **Long-term:** **Testicular size and appearance:** **G1**: Cryptorchid testis 1.2(95% CI 1-3.2) P=0.65 Descended testis 1.4 (95% CI 1-2.5) P=0.52 Penis length 5.0 cm (CI 4.5-6) P<0.001 **Germ cells, average # per tubular cross section:** **G1**: 0 (95% CI 0- 0.05) **G2**: 0.02 (95% CI 0-0.05) P=0.22 **Infertility/subfertility:** Sperm count/ejaculate (mio): **G1**: 90 (95% CI 53-164) **G2**: 1.0 (95%CI 0-13) P≤ 0.0001 Ejaculate volume (mL) **G1**: 4.1 (95% CI 1.2-7) **G2**: 4.6 (95% CI 2.9- 8.2) P=0.074 Normal morphology **G1**: 11% (95%CI 0-21) **G2**: 0

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Hadziselimovic et al., 1997 **Country:** Switzerland **Setting:** NR **Enrollment period:** NR **Design:** Retrospective cohort **Length of followup:** NR	**Groups:** **G1:** Previously underwent orchiopexy after failure to respond to hCG treatment, then received long-term treatment of buserelin nasal spray 10µg every other day for 6 months after successful orchiopexy **G2:** No hormone treatment after orchiopexy **Inclusion criteria:** • Previously underwent orchiopexy **Exclusion criteria:** • None had secondary testicular ascent, previous inguinal surgery before orchiopexy, congenital malformation, or long-standing illness **N at enrollment (N testes):** **G1**: 10 (14) **G2**: 23 (33) **N at follow-up (N testes):** **G1**: 10 (14) **G2**: 23 (33) **Age at study, mean yrs ± SD:** **G1**: 22.1 ± 2.07 (underwent orchiopexy at 9.4 ± 2.8) **G2**: 20.9 ± 2.5 **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** **G1**: 6 **G2**: 13 **Bilateral, n:** **G1**: 4 **G2**: 10 **Palpability, n (%):** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term: NR** NR **Long-term:** **Infertility/subfertility:** Spermiogram results: Increase in number of spermatozoa, increased number of normal forms of spermatozoa per ejaculate, improved sperm motility in G1 Number of sperm: G1: 29.4 G2: 6.5 P<0.005 Percent of normal sperm: G1: 31.8 G2: 15.2 P < 0.03 Percent of motile sperm G1: 41.3 G2: 11.2 P<0.001

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Hagberg and Westphal, 1982 **Country:** Sweden **Setting:** Hospital **Enrollment period:** NR **Design:** RCT **Length of followup:** 4 weeks to 12 months	**Groups:** G1: Two nasal applications of 100 µg LH-RH with an interval of 30-60 minutes 3 times a day for 28 days (total daily dose 600 µg) **G2:** Placebo nasal spray for 28 days **G2**a: Subsequently treated with LH-RH after 28 days **Inclusion criteria:** • Undescended testes **Exclusion criteria:** • Testes that could be manipulated to bottom of scrotum even if spontaneous location was in the scrotal neck **N at enrollment (N testes):** **G1:** 25 **G2:** 25 **N at follow-up (N testes):** **G1**: 23 (29 testes) **G2**: 24 (32 testes) **Age at intervention, mean yrs (range):** 5 (1.5 – 10.5) **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Therapeutic effect: **G1**: 18/29 testes (3 non-palpable moved to inguinal; 7 inguinal moved to scrotal neck; 2 inquinal and 6 scrotal neck- complete descent) **G2**: 1/32 testes placebo **G2a**: 19 testes moved (1 nonpalpable moved to inguinal; 1 nonpalpable moved to scrotal neck; 9 inguinal moved to scrotal neck; 5 inguinal and 3 scrotal neck – complete descent) **G1**+**G2**a combined (n=46, 60 testes): 4 palpable moved to inguinal; 1 non palpable moved to scrotal neck; 16 inguinal moved to scrotal neck; 7 inguinal and 9 scrotal neck – complete descent. 5 non palpable, 10 inguinal and 8 scrotal neck unchanged. Follow-up study 6-12 months after LH-RH treatment in 23 cases with initial descent from inguinal to scrotal position 18 testes remained completely descended 2 inguinal relapsed to scrotal neck and 3 relapsed to inguinal **Adverse effects, n:** More active **G1**: 3 **G2**:1 **G2a**:6 More aggressive **G1**: 1 **G2**: 1 **G2a**: 6 Furunculosis **G1**: 0 **G2**: 0 **G2a**: 2

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
			Impetigo **G1**: 0 **G2**: 0 **G2a**: 1 Local symptoms of nasal application **G1**: 1 **G2**: 1 **G2a**: 0 **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Hesse and Fischer, 1988 **Country:** Germany **Setting:** Hospital **Enrollment period:** NR **Design:** RCT **Length of followup:** 8 wks to 6 months	**Groups:** **G1:** hCG 300-1000 IU, 2 IM injections/week **G2:** hCG 1000-500 IU, IM injection every 7-10 days **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Treatment continued outside catchment area **N at enrollment (N testes):** 395 (NR) **N at follow-up (N testes):** 332 (435) **G1**: 163 (NR) **G2**: 169 (NR) **Age at intervention range yrs:** 1-13 **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%)*:** 173 (52.1) **Bilateral, n (%)*:** 163 (49.1) **Palpability:** NR **Testicle location, n:** Abdominal: **G1**:54 **G2**:37 Inguinal: **G1:**134 **G2**:114 Retractile: **G1:** 15 **G2:** 41 Scrotal **G1:**39 **G2**l: 46 **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Scrotal descent, %: **G1**: 39.4 **G2**: 29.9 **Long-term: NR** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Karpe et al., 1983 **Country:** Sweden **Setting:** Hospital **Enrollment period:** NR **Design:** RCT **Length of followup:** 6 months	**Groups:** **G1:** LHRH (HOE 471) intranasal spray 100µg in each nostril 6 times a day, minimum time lapse of 1 hour between doses for 28 days **G2:** Placebo **Inclusion criteria:** • Unilateral undescended but palpable testes • No previous treatment for undecended testis **Exclusion criteria:** • Retractile testes • Any sign of hernia • Previous inguinal surgery **N at enrollment (N testes):** **G1**: 25 (25) **G2**: 25 (25) **N at follow-up (N testes):** **G1**: 25 (25) **G2**: 25 (25) **Age at intervention, mean yrs ± SD (range):** 6.3 ± 1.4 (3-8) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** **G1**: 25 (100) **G2**: 25 (100) **Bilateral, n:** 0 **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR Mean basal serum testosterone: **G1**: 36.9 ± 17.3 **G2**: 31.7 ± 11.5	**Immediate/short-term:** **Testicular position:** Descent after treatment, n (%): **G1**: 5 (20.0) (3 complete, 2 borderline) **G2**: 3 (12.0) 6 months later **G1**: 2 (8.0) **G2**: 1 (4.0) Mean basal serum testosterone: after treatment **G1**: 58.9 ± 31.7 pmol/L **G2**: 34.9 ± 20.9 pmol/L Post treatment FSH peak decreased in significant # of patients (p<0.001) **Need for further surgical intervention, n (%):** 39 (78.0) **Adverse effects, n (%):** Sparse moustache:1 Hydrocele of tunica vaginalis: **G1:** 3 (12.0) **G2:** 0 Bilateral increase of < 1ml testicular volume occurred in significant number of **G1** followed by decrease during months after treatment (p< 0.001) **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Olsen et al, 1992 **Country:** Denmark **Setting:** Hospitals **Enrollment period:** NR **Design:** RCT **Length of followup:** 2 weeks (not including 4 week intervention)	**Groups:** **G1:** LHRH nasal spray (0.4 mg three times daily) **G2:** Placebo nasal spray three times daily **Inclusion criteria:** • At least one non descended testis at clinical examination • No former treatment for non-descended testis • No clinical signs of endocrine disease • No clinical signs of beginning puberty • No former surgery in the inguinal area • No clinical sign of inguinal hernia or ectopia • Age ≥ 2 years • Retractile (testes located in high scrotal position but could be manipulated into bottom of scrotum) **Exclusion criteria:** • Testes remaining non-palpable after manipulation and caudal traction in the inguinal region or bilateral retention on both sides **N at enrollment:** **G1**: 70 **G2**: 71 **N at follow-up (N testes):** **G1**: 62 (97) **G2**: 61 (90) **Age at intervention, median yrs (range):** 6 (2-12) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n:** **G1**: 27 **G2**: 32 **Bilateral, n:** **G1**: 35 **G2**: 29 **Palpability:** NR **Testicle location:** **Non palpable, n testes:** **G1**: 7 **G2**: 9 Inguinal **G1**: 76 **G2**: 73 High scrotal **G1**: 14 **G2**: 8 **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Full response for non descended testes, n participants (%) **G1**: 6/62 (9.7) **G2**: 1/61 (1.6) Therapeutic gain of **G1**: 8.1% (95% CI 0.1-16.6%) p=0.12 Unilateral non-descended, n participants (%): **G1**: 1/27 (3.7) **G2**: 1/32 (3.1) Therapeutic gain of **G1** 0.6% (95% CI 0.0-16.1) p=1.0 Bilateral non descended-both descended, n participants (%): **G1**: 5/35 (14.2) **G2**: 0/29 (0) Therapeutic gain of **G1** 14.3% (95% CI 2.7-25.1) p=0.09 Total full response, n testes (%) **G1**: 19/97 (19.6) **G2**: 2/90 (2.2) Therapeutic gain of **G1**: 17.4% (95% CI 8.9-25.8, p=0.0002) Bilateral non descended (n=128) **G1**: 18/70 (25.7) **G2**: 1/58 (1.7) Therapeutic gain of **G1**: 24.0% (95% CI 13.2-34.8, p=0.0001) Need for further surgical intervention: **G1**+**G2**: 74 (95 testes) **Adverse effects:** Reversible changes in behavior **G1**: 0 **G2**: 2 **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Rajfer et al, 1986 **Country:** US **Setting:** Hospital **Enrollment period:** NR **Design:** RCT **Length of followup:** 3 months (after treatment)	**Groups:** **G1:** Intranasal GnRH spray 100 µg + placebo injection **G2:** hCG 3300 IU per 1.65 ml injection + placebo nasal spray **Inclusion criteria:** • Cryptorchidism-intraabdominal (non palpable) intracanalicular, emergent at external inguinal ring or ectopic in superficial pouch **Exclusion criteria:** • Retractile testes • Endocrine disorder **N at enrollment (N testes):** **G1**: 16 (17) **G2**: 17 (20) **N at follow-up (N testes):** **G1**: 16 (17) **G2**: 17 (20) **Age at intervention, range yrs:** 1-5 **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n:** **G1**: 15 **G2**: 14 **Bilateral, n:** **G1**: 1 **G2**: 3 **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR **LH level, mean ± SD:** 2.7 ± 0.2 (n=16) **Testosterone level, mean ± SD:** **G1:** 15.4 ± 2.4 **G2**: NR	**Immediate/short-term:** **Testicular position:** **Descent, n:** **G1**: 3 **G2**: 1 **Endocrine:** **Serum LH levels:** 30 minutes after 1st treatment: **G1**: 9.4 ± 1.3 (n=16) 60 minutes after 1st treatment **G1**: 8.6 ±1.3 (n=15) **Adverse effects, n:** Increase in penile size: 7 Increase in testicular size: 4 Scrotal redness: 2 Increase in erections: 2 Demonstrated aggressive behavior: 2 **Long-term:** NR

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Wit et al., 1986 **Country:** Netherlands **Setting:** Hospital **Enrollment period:** NR **Design:** RCT followed by open label **Length of followup:** RCT: 8 weeks Open label: 12 months	**Groups:** **G1:** 400 µg LHRH in nasal spray 3 times a day for 4 weeks **G2:** Spray with no LHRH Code was broken after 8 weeks. LHRH offered for second course to both groups. After 1 or 2 unsuccessful LHRH treatments, surgery or hGH therapy proposed. **Inclusion criteria:** • Unilateral or bilateral cryptorchidism (one or both testes are not localized in or cannot be moved into the lower part of the scrotum) **Exclusion criteria:** • Patients with one of the indications for primary surgical intervention • Congenital syndromes • Previously treated for cryptorchidism **N at enrollment (N testes):** **G1:** 26 (35) **G2**: 23 (34) **N at followup (N testes), 8 weeks:** **G1:** 26 (35) **G2**: 23 (34) **N at followup, 12 months:** 48 **Age at intervention mean yrs (range):** 5.9 (1.2-11.9) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** **G1:** 17 (65.4) **G2**: 12 (52.2) **Bilateral, n (%):** **G1:** 9 (34.6) **G2**: 11 (47.8) **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR **LH (IU/l), median (range)** 0 **G1:** 1.3 (1.0-3.4) **G2**: 1.3 (<1.0-1.8) 30 **G1:** 5.3 (1.0-20.0) **G2**: 6.3 (1.8-18.2) 60 **G1:** 4.05 (2.0-16.0) **G2**: 4.2 (1.6-11.5) **FSH (IU/l) median (range)** 0 **G1:** <0.9 (<0.9-2.1) **G2**:1.0 (<0.9-2.2) 30 **G1:** 4.0 (0.9-5.6) **G2**: 3.3 (2.0-8.5) 60 **G1:** 4.0 (1.0-7.1) **G2**: 3.5 (1.4-9.7) **Testosterone (nmol/l) Mean, median (range)** **G1:** 0.20 0.17 (0.08-0.50) **G2**: 0.17 0.17 (<0.05-0.40) **SHBG (nmol/l) Mean ±SD Median (range)** **G1:** 79±20 80 (46-134) **G2**: 80±27 84 (23-123)	**Immediate/short-term:** **Testicular position:** **4 weeks** To the scrotum **G1:** 1 (3) **G2**: 2 (6) To scrotal neck **G1:** 3 (9) **G2**: 0 (0) To inguinal canal **G1:** 6 (17) **G2**: 7 (21) Unchanged **G1:** 21 (60) **G2**: 23 (68) Impalpable **G1:** 4 (11) **G2**: 2 (6) **8 weeks** **To the scrotum** **G1:** 3 (9) **G2**: 0 (0) To scrotal neck **G1:** 2 (6) **G2**: 2 (6) To inguinal canal **G1:** 8 (23) **G2**: 4 (12) Unchanged **G1:** 20 (57) **G2**: 26 (76) Impalpable **G1:** 2 (6) **G2**: 2 (6) **Change in position of undescended testes at 8 weeks[#] ,mean cm ± SD (number testes):** Supine before caudal traction **G1** (unilateral): 0.9±1.4 (17) **G2** (unilateral): 0.3±0.9 (12) **G1** (bilateral): 0.5±1.7 (18) **G2** (bilateral): 0.4±1.7 (22) Supine during caudal traction **G1** (unilateral): 1.1±1.2 (17) **G2** (unilateral): 0.7±1.3 (12) **G1** (bilateral): 1.5±1.7 (18) **G2** (bilateral): 0.3±1.1 (20) Squatting without traction **G1** (unilateral): 1.0±1.6 (17) **G2** (unilateral): 0.4±0.9 (11) **G1** (bilateral): 1.0±1.0 (17) **G2** (bilateral): 0±1.9 (19)

Table D-3. Evidence table for studies assessing hormonal treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
			Endocrine function: **LH (IU/l), median (range)** 0 **G1:** 4.7(1.0-11.7)* **G2**: 1.2 (<1.0-1.8) 30 **G1:** 7.5 (4.2-15.3)* **G2**: 5.1 (1.8-16.6) 60 **G1:** 4.8 (2.6-11.1) **G2**: 3.0 (1.8-11.4) **FSH (IU/l) median (range)** 0 **G1:** 1.2 (<0.9-3.4)* **G2**: 0.9 (<0.9-2.5) 30 **G1:** 2.4 (<0.9-4.9)* **G2**: 2.8 (<0.9-6.7) 60 **G1:** 2.0 (<0.9-4.9)* **G2**: 3.3 (<0.9-7.7) **Testosterone (nmol/l)** **Mean, median (range)** **G1:** 0.39 0.21 (0.07-2.10) **G2**: 0.16 0.13 (<0.05-0.65) **G2**:after LHRH treatment 0.36 0.30 (0.05-1.20) **SHBG (nmol/l)** **Mean ±SD Median (range)** **G1:** 76±24 76 (39-141) **G2**: 77±26 80 (31-115) **G2** after LHRH treatment 75±22 75 (49-109)* *P < 0.01 compared to baseline **Adverse effects:** Aggressive behavior **G1:** 23% **G2**: 0 **<u>Long-term:</u>** **Testicular size and appearance:** No changes observed in testicular volume **Testicular position:** **One year:** Bilateral n=19 (38 testes) 21 testes did not descend 17 showed some descent but 7 re-ascended 23 testes were operated on Unilateral n=29 (29 testes) 4 testes descended to retractile position 23 testes were operated on

Table D-4. Evidence table for studies assessing surgical treatment

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Abolyosr et al., 2006 **Country:** Egypt **Setting:** Hospital **Enrollment period:** December 2001 to May 2005 **Design:** RCT **Length of followup:** 9-31 months	**Groups:** **G1:** Participants with high abdominal testes **G1a:** Laparoscopic FSI followed by open FSII **G1b:** Laparoscopic FSI followed by laparoscopic FSII **G2:** Low abdominal and peeping testes **G2a:** Laparoscopic primary orchiopexy **G2b:** Open primary orchiopexy **Inclusion criteria:** • Patients with non-palpable testes confirmed by laparoscopy **Exclusion criteria:** • Vanished testes • Vessels and vas enter the internal ring **N testes at enrollment:** **G1a:** 20 **G1b:** 21 **G2a:** 18 **G2b:** 16 **N testes at follow-up:** **G1a:** 20 **G1b:** 21 **G2a:** 18 **G2b:** 16 **Age at intervention, mean yrs (range):** 5.3 (1-16) **Sidedness, n (%):** Left: 32 (37) Right: 45 (52) Bilateral: 10 (11) **Comorbidites:** NR	**Unilateral, n (%):** 65 (86.7) **Bilateral, n (%):** 10 (13.3) **Palpability:** See inclusion criteria **Testicle location, n (%):** High abdominal: 41 (54.7) Low abdominal: 34 (45.3) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** All patients had satisfactory scrotal position post-operatively **Adverse effects:** Atrophy, n(%): **G1a:** 2 (10.0) **G1b:** 0 **G2a:** 0 **G2b:** 3 (18.8) **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Al-Mandil et al., 2008 **Country:** Canada **Setting:** Academic medical **Enrollment period:** January 2004 to March 2007 **Design:** Retrospective cohort **Length of followup:** 6 to 42 months	**Groups:** **G1:** Participants operated on via a prescrotal approach by a single surgeon **G2:** Age-matched participants, operated on via an inguinal approach by another surgeon **Inclusion criteria:** • Palpable undescended testes • Position of the testis confirmed under general anesthesia **Exclusion criteria:** • Retractile testis • Ectopic testis • Lack of postoperative follow-up data and operative time documentation **N at enrollment (N testes):** **G1**: 56 (63) **G2**: 47 (53) **N at follow-up:** **G1**: 56 (63) **G2**: 47 (53) **Age at intervention, mean yrs:** **G1**: 4.6 **G2**: 4.7 **Sidedness, n (%):** Left: **G1**: 33 (52) **G2**: 24 (45) Right: **G1**: 30 (48) **G2**: 29 (55) **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location, n (%):** External ring: **G1**: 26 (41) **G2:** 21 (40) Canalicular: **G1**: 37 (59) **G2:** 32 (60) **Other anomalies:** NR	**Immediate/short-term:** Need for further surgical intervention, n (%): Testicular ascent requiring redo inguinal orchiopexy **G1**: 1 (1.6) **G2**: 1 (1.9) p = NS Adverse effects, n (%): Wound infection **G1**: 1 (1.6) **G2**: 1 (1.9) p = NS Hernia: **G1**: 2 (3.2) – one incarcerated hernia at one week postop requiring emergency operation and bowel resection; one asymptomatic swelling at 8 months **G2**: 0 p = NS Testicular atrophy: **G1**: 0 **G2**: 0 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Anoussakis et al., 1983 **Country:** Greece **Setting:** NR **Enrollment period:** NR **Design:** Retrospective cohort **Length of followup:** NR	**Groups:** **G1 and G2:** Prepubertal boys with true cryptorchidism **G1a:** Unilateral cryptorchidism without surgery **G1b:** Bilateral cryptorchidism without surgery **G2a:** Unilateral cryptorchidism with surgery **G2b:** Bilateral cryptorchidism with surgery **G3:** Comparison group with normal testes **Inclusion criteria:** • True undescended testes defined as one or both testicles outside the scrotum **Exclusion criteria:** • Testicles outside the scrotum that could be retracted into the scrotum through palpation • Obese children • patients given hCG previously • Patients with previous orchiopexy **N at enrollment (N testes):** **G1 and G2**: 52 (71) **G1a:** 13 (13) **G1b:** 17 (34) **G2a:** 10 (10) **G2b:** 12 (24) **G3**: 10 (normal testes) **N at follow-up:** **G1 and G2**: 52 (71) **G1a:** 13 (13) **G1b:** 17 (34) **G2a:** 10 (10) **G2b:** 12 (24) **G3**: 10 (normal testes) **Age at intervention, mean yrs (range):** **G1a:** 9.3 (6.1-12.5) **G1b:** 8.6 (6.1-11.3) **G2a:** 8.5 (7.8-9.8) **G2b:** 9.1 (6.1-11.3) **G3:** 8.2 (6.8-10.2), no	**Unilateral, n (%):** **G1a:** 13 (100) **G1b:** 0 **G2a:** 10 (100) **G2b:** 0 **G3:** N/A **Bilateral, n (%):** **G1a:** 0 **G1b:** 34 testicles, 17 patients (100) **G2a:** 0 **G2b:** 24 testicles, 12 patients (100) **G3:** N/A **Palpability:** NR **Testicle location:** Upper ingunial canal: **G1a:** 2 **G1b:** 5 **G2a:** 2 **G2b:** 6 Middle inguinal canal: **G1a:** 7 **G1b:** 14 **G2a:** 5 **G2b:** 10 Low inguinal canal: **G1a:** 4 **G1b:** 11 **G2a:** 2 **G2b:** 4 Internal inguinal ring: **G1a:** 0 **G1b:** 2 **G2a:** 1 **G2b:** 2 Intraabdominal: **G1a:** 0 **G1b:** 2 **G2a:** 0 **G2b:** 2 **Other anomalies:** NR	**Immediate/short-term:** NR **Long-term:** Endocrine function: Plasma testosterone concentrations before hCG stimulation, mean ± SD (range): **G1a:** 0.221±0.191 (0.05 to 0.80) **G1b:** 0.159±0.117 (0.05 to 0.60) **G2a:** 0.164±0.166 (0.05 to 0.36) **G2b:** 0.142±0.071 (0.08 to 0.31) **G3:** 0.183 ± 0.042 p = NS Plasma testosterone concentrations after hCG stimulation, mean ± SD (range): **G1a:** 1.589±-0.680 (0.70 to 3.40) **G1b:** 0.939±0.536 (0.35 to 2.50) **G2a:** 1.532±0.338 (1.12 to 2.10) **G2b:** 1.577 ± 0.720 (0.45 to 3.10) **G3:** 1.674± 0.399 G1a vs G2a: p = NS G1b vs G2b: p <0.05 G1b vs G1a: p<0.01 G1b vs G2b: p = NS G2a vs G2b vs G3: p = NS G1b vs G3: p < 0.001

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
	intervention **Sidedness:** NR **Comorbidites:** NR		

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Arda et al., 2001 **Country:** Turkey **Setting:** Hospital **Enrollment period:** 4-year period **Design:** RCT **Length of followup, mean months ± SD (range):** 28.0 ±11.4 (6-48)	**Groups:** **G1:** Testes fixed to the scrotum with 4-0 polyglactin suture (Vicryl) passed through the tunica vaginalis of the testis by everting the scrotal wall **G2:** Testes placed in the scrotal pouch without fixation but fascial opening of the pouch was narrowed around the ductus deferens and vessels to just permit passage **G3:** Testes fixed to the scrotal wall as in G1 and fascial opening narrowed as in G2 **Inclusion criteria:** • Unilateral cryptorchidism • All testes palpated before operation and deemed manually non-retractable **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 50 (50) **G2**: 50 (50) **G3:** 50 (50) **N at follow-up, testes:** **G1**: 50 (50) **G2**: 50 (50) **G3:** 50 (50) **Age at intervention, mean yrs ± SD (range):** 3.7 ± 1.4 (1-10) **Sidedness, n (%):** Left: 36 (24.0) Right: 114 (76.0) **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** **G1**: Inguinal canal No: 4 Moderate: 5 Severe: 2 Outside the inguinal canal No: 26 Moderate: 12 Severe: 1 **G2**: Inguinal canal No: 3 Moderate: 3 Severe: 2 Outside the inguinal canal No: 20 Moderate: 19 Severe: 3 **G3:** Inguinal canal No: 6 Moderate: 5 Severe: 2 Outside the inguinal canal No: 22 Moderate: 13 Severe: 2 **Other anomalies:** NR	**Immediate/short-term:** Testicular size and appearance: Testicular atrophy, n (%): **G1**: 1 (0.6) **G2**: 1 (0.6) **G3:** 0 Both developed in first or second postoperative months Testicular position: **Postoperative ascensus** **G1:** Inguinal canal, 3 (6.0) No: 0 Moderate: 1 Severe: 2 Outside the inguinal canal, 1 (2.0) No: none Moderate: none Severe: 1 **G2:** 0 **G3:** 0 p = NS for location of testes among groups **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Baker et al., 2001 **Country:** United States **Setting:** Hospital **Enrollment period:** 1990 to 1999 **Design:** Retrospective cohort **Length of followup (mean months):** **G1**: 7.7 **G2**: 8.6 **G3:** 20	**Groups:** **G1:** Primary laparoscopic orchidopexy **G2:** One-stage Fowler-Stephens orchidopexy **G3:** Two-stage Fowler-Stephens orchidopexy **Inclusion criteria:** • Testis was intraabdominal at laparoscopic examination • Patients of participating pediatric urology centers **Exclusion criteria:** • Managed through an open approach • Underwent orchidectomy **N at enrollment (N testes):** **G1**: 178 (208) **G2**: 25 (28) **G3**: 63 (74) **N at follow-up (N testes):** **G1**: 153 (178) **G2**: 24 (27) **G3**: 49 (58) **Age at intervention (mean months):** **G1**: 36.2 **G2**: 31.3 **G3:** 54.6 **Sidedness:** NR **Comorbidites, n (%):** Prune belly: 3 (1.3) Other*: 38 (16.8)	**Unilateral, n (%):** At baseline **G1**: 148 (83.1) **G2**: 22 (88.0) **G3:** 52 (82.5) At follow-up **G1**: 128 (83.7) **G2**: 21 (87.5) **G3:** 40 (81.6) **Bilateral, n (%):** At baseline **G1**: 30 (16.9) **G2**: 3 (12.0) **G3:** 11 (17.5) At follow-up **G1**: 25 (16.3) **G2**: 3 (12.5) **G3:** 9 (18.4) **Palpability:** NR **Testicle location:** **G1**: Ectopic: 9 <2 cm from ring: 71 >2 cm from ring: 54 Peeping: 47 **G2**: Ectopic: 1 <2 cm from ring: 1 >2 cm from ring: 26 Peeping: 1 G3: Ectopic: 10 <2 cm from ring: 14 >2 cm from ring: 46 Peeping: 1 **Other anomalies:** NR	**<u>Immediate/short-term:</u>** Testicular size and appearance: Atrophy, %: **G1**: 2.2 **G2**: 22.2 **G3:** 10.3 p < 0.001 Testicular position: Bad positioning, %: **G1**: 0.6 **G2**: 7.4 **G3:** 1.7 Overall success, %: **G1**: 97.2 **G2**: 74.1 **G3:** 87.9 19 surgical failures including 13 testes >2cm from internal ring, 3 ectopic, 2 <2cm from ring, and one peeping. Adverse effects (not provided by group): Major complications, n: Caecal volvulus: 1 Bladder perforation: 2 Ileus: 2 Spermatic vessels torn leading to one-stage Fowler-Stephens orchiopexy: 2 Small laceration of the vas: 1 Veress needle puncture into the sigmoid colon: 1 Minor complications, n: Preperitoneal insufflations: 2 Desaturation with an intraabomdinal pressure of >10mmHg: 1 Wound separation: 1 Hydrocele: 1 Wound infection: 1

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Chandrasekharam, 2005 **Country:** India **Setting:** NR **Enrollment period:** 3.5 years **Design:** Retrospective cohort **Length of followup:** 4-6 weeks	**Groups:** **G1:** Initial laparoscopic evaluation for unilateral nonpalpable undescended testicle **G2:** Age-matched children that had undergone initial inguinal exploration for nonpalpable undescended testicle **Inclusion criteria:** • Nonpalpable undescended testicle **Exclusion criteria:** • Testis became palpable under anesthesia **N at enrollment, testes:** **G1**: 20 **G2**: 20 **N at follow-up, testes:** **G1**: 13 underwent orchiopexy **G2**: 14 underwent orchiopexy **Age at intervention, mean years:** **G1**: 3.1 **G2**: 3.4 **Sidedness, n (%):** NR **Comorbidites, n (%):** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** **G1**: Canalicular: 11 Low abdominal 5: High abdominal: 4 **G2**: Canalicular: 8 Low abdominal: 9 High abdominal: 3 **Other anomalies:** NR	**Immediate/short-term:** Atrophy at 4-6 weeks, n testes (%): **G1**: 2 (15.4) **G2**: 2 (14.3) Success of orchiopexy, n testes (%): **G1**: 11 (84.6) **G2**: 12 (85.7) **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Chang et al., 2001 **Country:** United States **Setting:** Hospital **Enrollment period:** 1994 to 1999 **Design:** Retrospective cohort **Length of followup, mean months (range):** 8 (1- 60)	**Groups:** **G1:** Standard laparoscopic orchidopexy **G2:** Single-stage Fowler-Stephens orchidopexy **G3:** Two-stage Fowler-Stephens orchidopexy **Inclusion criteria:** • Underwent laparoscopic orchidopexy for impalpable testis identified in records **Exclusion criteria:** • First-stage Fowler-Stephens orchidopexy **N at enrollment, testes:** **G1**: 72 **G2**: 20 **G3:** 9 **N at follow-up, testes:** **G1**: 72 **G2**: 18 **G3:** 9 **N at 6-month followup, testes:** **G1:** 66 testicles **G2 and G3:** 26 testicles **Age at intervention median yrs (range):** 1.5 (0.5 – 12) **Sidedness, n (%):** Left: 39 (50) Right: 20 (25) Bilateral: 21 patients (25) **Comorbidites:** NR	**Unilateral, n (%):** 59 (75) **Bilateral, n (%):** 21 (25) **Palpability:** All impalpable **Testicle location, n testes:** Intraabdominal: 46 Iliac: 14 Internal ring: 22 Peeping: 12 Retrovesical: 3 Intracanalicular: 4 **Other anomalies:** NR	**Immediate/short-term:** Success rate defined as intrascrotal testis with no atrophy at least 6 months later, n (%) **G1**: 62 (92%) **G2 and G3**: 26 (100%) **G2**: 19 (100%) **G3**: 7 (100%) Subsequent atrophy: **G2 and G3**: 4 testes Testes near the pubic bone: 4 **Adverse effects, n participants:** Serosal tear or colon: 1 Ileus: 3 Scrotal wound separation: 1 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Chang et al., 2008 **Country:** US **Setting:** Hospital **Enrollment period:** August 1995 to February 2007 **Design:** Retrospective cohort **Length of followup, mean months:** **G1**: 17.5 **G2**: 11.8	**Groups:** **G1:** One-stage Fowler-Stephens orchiopexy **G2:** Two-stage Fowler-Stephens orchiopexy **Inclusion criteria:** • Nonpalpable testis **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 38 (38) **G2**: 10 (10) **N at follow-up (N testes):** **G1**: 35 (35) **G2**: 10 (10) **Age at intervention. Mean months:** **G1**: 34.9 **G2**: 45.3 **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** 48 (100) **Bilateral, n:** 0 **Palpability:** See inclusion criteria **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position, n (%):** Success rate: **G1**: 33 (94.3) **G2**: 8 (80.0) **Adverse effects:** Atrophy: **G1**: 2/38 **G2**: 2/10 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Cloutier et al., 2011 **Country:** Canada **Setting:** Hospital **Enrollment period:** January 2003 to September 2009 **Design:** Retrospective cohort **Length of followup:** Minimum of 3 months	**Groups:** **G1:** Orchiopexy via low scrotal mid-raphe incision **G2:** Orchiopexy via high scrotal (Bianchi) incision **G3:** Orchiopexy via conventional inguinal 2-incision technique **Inclusion criteria:** • Participants who underwent orchiopexy for palpable undescended testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 214 (286) **G1**: 81 (125) **G2**: 44 (60) **G3:** 89 (101) **N at follow-up, testes:** 214 (286) **G1**: 81 (125) **G2**: 44 (60) **G3:** 89 (101) **Age at intervention, mean months ± SD:** **G1**: 63 ± 24 **G2**: 53 ± 23 **G3:** 26 ± 11 **Sidedness, n (%):** Left: 60 (28.0) Right: 82 (38.4) **Comorbidites:** NR	**Unilateral, n (%):** **G1**: 37 (45.7) **G2**: 28 (63.6) **G3:** 77 (86.5) **Bilateral, n (%):** **G1**: 44 (54.3) **G2**: 16 (36.4) **G3:** 12 (13.5) **Palpability:** See inclusion criteria **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Successful repair (descent), n testes (%): **G1**:124 (99.2) **G2**: 59 (98.3) **G3:** 101 (100) p = NS **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Comploj et al., 2011 **Country:** Austria **Setting:** Hospital **Enrollment period:** January 1993 to June 2009 **Design:** Retrospective cohort **Length of followup:** 1, 3, and 12 months postoperatively; then annually Time of last follow-up, median months (range): **G1:** 20 (3 months-14.2 years) **G2:** 95 (6-164)	**Groups:** **G1:** Open one-stage Fowler-Stephens procedure **G2:** Open two-stage Fowler-Stephens procedure Choice of one- vs. two-stage FS left at discretion of surgeon **Inclusion criteria:** • Admitted to institution for treatment of undescended testes • Testicular vessels too short for standard orchidopexy **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 27 (33) **G2**: 14 (17) **N at follow-up (N testes):** **G1**: 27 (33) **G2**: 14 (17) **Age at intervention, months (range):** **G1**: 26 (9-135) **G2**: 24 (16-162) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** 32 (78) **Bilateral, n (%):** 9 (22) **Palpability:** NR **Testicle location:** NR **Other anomalies, n (%):** Epididymal separation from the testes 24 (88) **Time to diagnosis of testicular atrophy, median months (range):** **G1**: 20 (3-171) **G2**: 60 (1-160)	**Immediate/short-term:** **Testicular size and appearance:** Volume, mean cm^3 **G1**: 0.38 **G2**: 1.64 Volume, median cm^3 **G1**: 0.18 **G2**: 1.19 Volume, SD **G1**: 0.78 **G2**: 1.66 Volume, min-max cm^3 **G1**: 0.03-3.92 **G2**: 0.18-5.96 G1 vs G2 volume p<0.005 **Long-term:** **Testicular position:** Result at last follow-up, n testes (%): Successful **G1**: 21 (64) **G2**: 13 (76) Acceptable (testis not at deepest point) **G1**: 5 (15) **G2**: 1 (6) Unsuccessful (atrophy) **G1**: 7 (21) **G2**: 3 (18) Overall success rate, %: **G1**: 79 **G2**: 82

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Denes et al., 2008 **Country:** Brazil **Setting:** Hospital **Enrollment period:** September 1994 to September 2005 **Design:** Retrospective cohort **Length of followup:** 6 to 100 months	**Groups:** **G1:** Primary orchiopexy **G2:** 1-stage Fowler-Stephens **G3:** 2-stage Fowler-Stephens **Inclusion criteria:** • Impalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 90 (124) **N at follow-up (N testes):** **G1:** 24 (26) **G2:** 3 (3) **G3:** 19 (25) **Age at intervention, mean yrs (range):** 6.4 (0.9 – 22) **Sidedness, n (%):** Right: 20 (16.1) Left: 36 (29.0) **Comorbidites:** NR	**Unilateral, n (%):** 56 (45.2) **Bilateral, n (%):** 68 (54.8) **Palpability:** See inclusion criteria **Testicle location, n (%):** Absent: 26 (21.0) Canalicular: 32 (25.8) Intraabdominal: 66 (53.2) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Descent, n (%) **G1**: 25 (96.1) **G2**: 1 (33.3) **G3:** 22 (88.0) **Adverse effects:** Atrophy, n (%) **G1**: 1 (3.9) **G2**: 2 (66.7) **G3:** 3 (12.0) **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Dhanani et al 2004 **Country:** United States **Setting:** academic medical **Enrollment period:** 1994 to 2001 **Design:** retrospective **Length of followup:** mean 9 months, median 1 year	**Groups:** **G1:** Primary orchiopexy without division of the spermatic vessels performed If any portion of the testis or epididymis was able to reach the pubis **G2:** Staged Fowler-Stephens orchiopexy in patients with high testes and short vessels precluding the testis from reaching the pubis **Inclusion criteria:** • Nonpalpable testes **Exclusion criteria:** • Palpable inguinal testis after induction of general anesthesia **N at enrollment (N testes):** **G1**: 27 (28) **G2**: 47 (55) **N at follow-up (N testes):** 69 (NR) **Age at intervention:** NR **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** See inclusion criteria **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Success defined as dependent scrotal location and testis size equivalent to the contralateral mate, %: **G1:** 100 **G2:** 98 Atrophy at 1-year follow-up, n: **G1:** 0 **G2:** 1 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Escarcega-Fujigaki et al., 2011 **Country:** Mexico **Setting:** Hospital **Enrollment period:** August 2006 to March 2009 **Design:** Prospective cohort **Length of followup, median months:** 18	**Groups:** **G1:** Traditional surgical technique **G2:** Laparoscopy **Inclusion criteria:** • Diagnosed with palpable undescended testis needing surgical treatment **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 33 (37) **G2**: 30 (38) **N at follow-up (N testes):** **G1**: 33 (37) **G2**: 30 (38) **Age at intervention, median years (range):** 2.3 (1-10) **Sidedness, n (%):** Left: 31 (49.2) Right: 44 (69.8) **Comorbidites, n (%):** Hernia: **G1**: 23 (62.2) **G2**: 14 (36.8)	**Unilateral, n (%):** 51 (81) **Bilateral, n (%):** 12 (19) **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** No difference between testicular position between groups post-operatively **Pain:** Authors note that laparoscopy caused less pain when compared with the other technique in 80% of cases. **Adverse effects, n:** Hematoma **G1**: 1 **G2**: 0 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Ferro et al 1999 **Country:** Italy **Setting:** Hospital **Enrollment period:** April 1997 to February 1998 **Design:** RCT **Length of followup:** At least one month	**Groups:** **G1:** Open surgery only **G2:** Laparoscopy via Hasson technique and subsequent open surgery **Inclusion criteria:** • Impalpable testis based on clinical examination by surgeon • No other imaging studies done to locate the gonad • Testis remained impalpable under anesthesia **Exclusion criteria:** • Associated anomalies such as ambiguous genitalia, prune belly syndrome or genetic disorders **N at enrollment:** **G1**: 30 **G2**: 31 **N at follow-up (N testes):** **G1**: 24 **G2**: 19 **Age at intervention, mean months ± SD:** **G1**: 37.7 ± 35.2 **G2**: 32.7 ± 29.7 **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** See inclusion criteria **Testicle location, n:** **G1**: Truly abdominal: 17 Peeping: 4 Canalicular: 1 Interstitial or preperitoneal ectopic: 2 **G2**: Truly abdominal: 15 Peeping: 2 Canalicular: 0 Interstitial or preperitoneal ectopic: 2 **Other anomalies, n:** No normal appearing gonad **G1:** 6 **G2:** 12	**Immediate/short-term:** **Need for further surgical intervention, n:** Recurrences in **G1**: 2/24 **G2**: 1/19 P>0.05 Total operative time, mean mins ± SD: **G1:** 37.9 ± 9.6 **G2:** 50.5 ± 19.3 P=0.002 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Gheiler et al., 1997 **Country:** US **Setting:** Hospital **Enrollment period:** January 1994 to March 1996 **Design:** Retrospective cohort **Length of followup, mean months (range):** 12 (1 to 27)	**Groups:** **G1:** Jones approach **G2:** Standard inguinal orchiopexy **Inclusion criteria:** • Underwent orchiopexy for nonpalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G1**: 19 **G2**: 10 **N at follow-up (N testes):** **G1**: 19 **G2**: 10 **Age at intervention, mean yrs (range):** 6 (0.9 to 17) **Sidedness:** NR **Comorbidites:** NR	**Unilateral** NR **Bilateral:** NR **Palpability:** See inclusion criteria **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** Testicular position: Satisfactory scrotal position: **G1**: 19 **G2**: 8 (other two were in low inguinal location) Satisfactory result: **G1:** 18 **G2**: 7 Adverse effects: Testicular atrophy **G1**: 1 **G2:** 1 Both in patients whose testicular vessels were ligated **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Gilhooly et al., 1984 **Country:** US **Setting:** Hospital **Enrollment period:** 1936 to 1968 **Design:** Retrospective cohort **Length of followup:** NR	**Groups:** Treated for bilateral or unilateral cryptorchidism 36 bilateral and 70 unilateral had unsuccessful hCG therapy preoperatively 9 bilateral and 30 unilateral underwent orchiopexy without prior gonadotropin treatment **Inclusion criteria:** • Parents of children with cryptorchid testes who had orchiopexy completed surveys about children's outcomes **Exclusion criteria:** • Patients with genetic disorders, multiple genitourinary anomalies, simple testicular ectopia, and migratory or retractile testes **N at enrollment:** 800 **N at follow-up (N testes):** 145 (190) **Age at intervention, mean yrs (range):** **Fertile:** Unilateral: 9.3 (4 to 17) Bilateral: 7.5 (3 to 11) **Infertile:** Unilateral: 9.3 (7 to 13) Bilateral: 8.5 (1 to 13) **Sidedness, n (%):** NR **Comorbidites, n (%):** NR	**Unilateral, n (%):** 100 **Bilateral, n (%):** 45 **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** NR **Long-term:** **Paternity rate:** 80% in unilateral group 35% (16/45) in bilateral patients Additional 10/20 unilateral and 12/29 bilateral had made no attempt at paternity No difference in rates between gonadotropin-treated and orchiopexy-along groups hCG + orchiopexy: unilateral: 80% paternity reported, 10% no paternity, 10% paternity no attempted bilateral: 36% paternity; 39% no paternity, 25% paternity not attempted orchiopexy only: unilateral: 80% paternity, 10% no paternity, 10% paternity not attempted bilateral: 33% paternity, 33% no paternity, 33% paternity not attempted

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Humphrey et al., 1998 **Country:** UK **Setting:** Hospital **Enrollment period:** Over 30 months (unspecified) **Design:** Retrospective cohort **Length of followup, mean years (range):** **G1**: 2.5 (2-4) **G2:** 1.5 (0.5-3.5)	**Groups:** **G0:** Laparoscopy evaluation **G1:** Single-stage orchidopexy **G2:** Two-stage Fowler-Stephens procedure **Inclusion criteria:** • Undergoing evaluation for unilateral impalpable testis **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** **G0**: 48 (48)* **G1**: 10 (10) **G2**: 10 (10) **N at follow-up (N testes):** **G0**: 48 (48)* **G1**: 10 (10) **G2**: 10 (10) **Age at intervention, mean years (range):** 3.3 (1-9) **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** 48 (100) **Bilateral, n:** 0 **Palpability:** See inclusion criteria **Testicle location:** Absent 28* Intra-abdominal 20 **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Lower half of scrotum **G1**: 3 **G2**: 8 Upper half of scrotum **G1**: 6 **G2**: 2 Adverse effects: Atrophy **G1**: 1 **G2**: 0 Technical failures **G1**: 0 **G2**: 0 Laparoscopy-related complications **G1**: 0 **G2**: 0 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Kim et al., 2010 **Country:** South Korea **Setting:** Hospital **Enrollment period:** September 1996 to April 2008 **Design:** Retrospective cohort **Length of followup, mean months ± SD (range):** 21.8 ± 20 (0.3 to 138.4)	**Groups:** **G1:** Primary laparoscopic orchiopexy **G2:** One-stage Fowler-Stephens laparoscopic orchiopexy **G3: T**wo-stage Fowler-Stephens laparoscopic orchiopexy **Inclusion criteria:** • Underwent laparoscopic orchiopexy for nonpalpable intra-abdominal testis during enrollment period **Exclusion criteria:** See inclusion criteria **N at enrollment:** 67 participants (86 testes) **G1**: 69 testes **G2**: 14 testes **G3**: 3 testes **N at follow-up (N testes):** 1 month: 67 participants (86 testes) **G1**: 69 testes **G2**: 14 testes **G3**: 3 testes Beyond 3 months: 48 participants (63 testes) **G1**: 49 testes **G2**: 11 testes **G3:** 3 testes **Age at intervention, mean yrs ± SD (range):** 2.4 ± 2.2 (0.5 to 9) **Sidedness, n (%):** Left: 16 (18.6) Right: 32 (37.2) **Comorbidites:** NR	**Unilateral, n (%):** 48 (55.8) **Bilateral, n (%):** 38 (44.2) **Palpability:** NR **Testicle location, n (%):** Within 3cm of internal ring: 63 (73.2) Beyond 3cm from internal ring: 14 (16.3) Peeping: 9 (10.5) **Other anomalies:** NR	**Immediate/short-term:** **Testicular position:** Distance from internal ring, 1 month: **G1**: 57 (98.3) <3cm; 2 (100) ≥3cm; 9 (100) peeping **G2**: 5 (100) <3cm; 8 (88.9) ≥3cm; 0 peeping **G3:** 0 <3cm; 3 (100) ≥3cm; 0 peeping Distance from internal ring, beyond 3 months: **G1**: 42 (97.7) <3cm; 1 (100) ≥3cm; 5 (100) peeping **G2**: 3 (100) <3cm; 6 (75) ≥3cm; 0 peeping **G3:** 0 <3cm; .2 (66.7) ≥3cm; 0 peeping Location of the viable testis: **G1**: 39 (79.6) low; 9 (18.4) mid-high **G2**: 7 (63.6) low; 2 (18.2) mid-high **G3**: 2 low (66.7) Testicular survival rate beyond 3 months: **G1:** 48/49 (8) **G2:** 9/11 (81.8) **G3:** 2/3 (66.7) **G2**: 123 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Lintula et al., 2008 **Country:** Finland **Setting:** Hospital **Enrollment period:** January 1992 to December 2004 **Design:** Retrospective cohort **Length of followup, median months (range):** **G1:** 16 (12-72) **G2:** 30 (12-132)	**Groups:** **G1:** Laparoscopic orchidopexy **G2:** Open orchidopexy **Inclusion criteria:** • Patients with intra-abdominal testes who underwent either laparoscopic or open orchidopexy **Exclusion criteria:** • Testis that were palpable at any point • Atrophic, vanishing, or distal canalicular testicles **N at enrollment (N testes):** **G1**: 16 (19) **G2**: 18 (18) **N at follow-up (N testes):** **G1**: 16 (18) **G2**: 17 (17) **Age at intervention, yrs mean ± SD (range):** **G1**: 2.5 ± 3.5 (1-13) **G2**: 2.5 ± 2.3 (1-10) **Sidedness, n (%):** Left: **G1**: 9 (56.3) **G2**: 7 (38.9) Right: **G1**: 4 (25.0) **G2**: 11 (61.1) **Comorbidites, n:** Previous laparoscopic Fowler-Stephens I procedure: **G1**: 2 **G2**: 0 Conversion from laparoscopic to open: **G1**: 1 **G2**: 0	**Unilateral, n (%):** **G1**: 13 (81.3) **G2**: 18 (100) **Bilateral, n (%):** **G1**: 3 (18.7) **G2**: 0 **Palpability, n (%):** **G1**: 0 **G2**: 0 **Testicle location, n (%):** Intra-abdominal: **G1**: 16 **G2**: 18 <1 cm from IIR: **G1**: 9 (47) **G2**: 13 (72) 1-4 cm from IIR: **G1**: 6 (32) **G2**: 2 (11) At the iliac vessels: **G1**: 4 (20) **G2**: 3 (17) **Other anomalies, n (%):** Processus vaginalis open **G1**: 16 (84) **G2**: 15 (83) Processus vaginalis closed **G1**: 3 (16) **G2**: 3 (17)	**Immediate/short-term:** **Testicular size and appearance, n (%):** Normal **G1**: 10 (55) **G2**: 9 (53) Small **G1**: 7 (39) **G2**: 7 (41) Atrophied **G1**: 1 (6) **G2**: 7 (6) **Testicular position, n (%):** Low scrotal **G1**: 12 (66) **G2**: 10 (59) Mid-scrotal **G1**: 4 (22) **G2**: 4 (23) High scrotal **G1**: 1 (6) **G2**: 1 (6) Inguinal canal **G1**: 0 **G2**: 2 (12) Vanished **G1**: 1 (6) **G2**: 0 **Need for further surgical intervention:** Reoperation due to unacceptable position or atrophy, n (%): **G1**: 2 (11) **G2**: 3 (18) **Adverse effects, n (%):** Early readmission to the outpatient clinic: **G1**: 2 (11) **G2**: 1 (6) Minor postoperative complications: **G1**: 1 (6) scrotal wound infection **G2**: 1 (6) scrotal hematoma **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Moursy et al., 2011 **Country:** Egypt **Setting:** Hospital **Enrollment period:** January 2005 to June 2009 **Design:** Retrospective cohort **Length of followup:** Patients evaluated 3 months postoperatively and then every 6 months for 3 years Followup mean months (range): 34 (3-55)	**Groups:** **G1:** Low intra-abdominal testes managed by laparoscopic orchiopexy **G2:** High intra-abdominal testes managed by laparoscopic two-stage Fowler-Stephens or laparoscopic orchiectomy **Inclusion criteria:** • Nonpalpable testes **Exclusion criteria:** See inclusion criteria **N at enrollment (N testes):** 78 (88) **G1**: 33 testes **G2**: 45 testes **N at follow-up (N testes):** 66 (76) **G1**: 28 testes **G2**: 36 testes **Age at intervention, median months (range):** 16 (11-42)* **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** 68 (87.2) **Bilateral, n (%):** 10 (12.8) **Palpability:** NR **Testicle location:** Intra-abdominal, low 33 Intra-abdominal, high 45 **Other anomalies:** NR	**Immediate/short-term:** **Testicular size and appearance:** Normal sized and well positioned in scrotum, n testes (%) **G1**: 28 (100) **G2:** 32 (88.8) **Adverse effects, n:** Testicular displacement **G1**: 0 **G2**: 2 Testicular atrophy **G1**: 0 **G2**: 2 Port hernias requiring repair 3 **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Na et al., 2011 **Country:** Korea **Setting:** Hospital **Enrollment period:** January 2007 to December 2010 **Design:** RCT **Length of followup, mean months ± SD:** **G1**: 12.9 ± 3.4 **G2**: 12.7 ± 3.3	**Groups:** **G1:** Participants undergoing single scrotal incision orchiopexy **G2:** Participants undergoing traditional inguinal incision orchiopexy **Inclusion criteria:** • Palpable, undescended testicles **Exclusion criteria:** • Previous inguinal or pelvic surgery • Secondary ascending testis • Ectopic testis • Undescended testis related to ambiguous genitalia or intersex condition • Primary and secondary hypogonadism • A detected hormonal abnormality or a history of hormonal treatment **N at enrollment (N testes):** **G1**: 147 (201) **G2**: 145 (197) **N at follow-up (N testes):** **G1**: 107 (146) **G2**: 105 (141) **Age at intervention, mean months ± SD:** **G1**: 40.1 ± 10.3 **G2**: 41.8 ± 11.4 **Sidedness:** NR **Comorbidites:** NR	**Unilateral, n (%):** **G1**: 68 (63.6) **G2**: 69 (65.7) **Bilateral, n (%):** **G1**: 39 (36.4) **G2**: 36 (34.3) **Palpability, n (%):** 212 (100) **Testicle location, n testicles (%):** Inguinal canal: **G1**: 26 (17.8) **G2**: 31 (22.0) Distal to external inguinal ring: **G1**: 120 (82.2) **G2**: 110 (78.0) **Other anomalies:** NR	**Immediate/short-term:** Testicular position: Successful result*, n testes (%): **G1**: 135 (92.5) **G2**: 136 (96.5) p = 0.86 9 G1 participants converted to traditional surgery due to insufficient dissected cord length 4 G2 participants underwent laparoscopy or orchiectomy for hidden or atrophied testicles Adverse effects: Scrotal hematoma and swelling, n (%) **G1:** 1 (1.0) **G2**: 0 Wound dehiscence: **G1:** 1 (1.0) **G2**: 1 (1.0) **Long-term:** Testicular position: Ascension: 0 Parent satisfaction, n testes (%): Satisfied: **G1**: 141 (96.6) **G2**: 136 (96.5) Not fully satisfied: **G1**: 5 (3.4) **G2**: 5 (3.5) Unsatisfied: 0 Torsion: 0

*****Successful result defined as no complications, postoperative intrascrotal location of the testicle, and no conversion to the other method.

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Nazem et al., 2011 **Country:** Iran **Setting:** Hospital **Enrollment period:** June 2008 to April 2010 **Design:** RCT **Length of followup:** 6 months	**Groups:** **G1:** Closed technique orchidopexy **G2:** Conventional/open orchidopexy **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Age more than 2 yrs • Parents disagree to participate • Undescended testicle located in peritoneal cavity or inguinal canal • Retractile testis **N at enrollment:** **G1**: 52 **G2**: 52 **N at follow-up:** **G1**: 52 **G2**: 52 **Age at intervention, mean months ± SD:** **G1**: 13.2 ± 4.4 **G2**: 13.6 ± 3.8 **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** Adverse effects, n (%): Surgical site hematoma: **G1**: 1 (1.9) **G2**: 2 (3.8) Infection: **G1**: 2 (3.8) **G2**: 3 (5.8) Scrotal hematoma: **G1**: 1 (1.9) **G2**: 0 Medial thigh sensory loss: **G1**: 1 (1.9) **G2**: 6 (11.5) P=0.05 Testicular atrophy: **G1**: 1 (1.9) **G2**: 2 (3.8) **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Okuyama et al., 1989 **Country:** Japan **Setting:** Hospital **Enrollment period:** NR **Design:** Retrospective cohort **Length of followup:** Examination occurred when patients were 19-39 years old	**Groups:** **G1a:** Prepubertal (ages 2-5 years) bilateral orchiopexy **G1b:** Early pubertal (ages 9-12 years) bilateral orchiopexy **G2a:** Prepubertal unilateral orchiectomy for unilateral undescended testis **G2b:** Early pubertal unilateral orchiectomy for unilateral undescended testis **G3a:** Prepubertal unilateral orchiectomy for unilateral undescended testis that was grossly abnormal **G3b:** Early pubertal unilateral orchiectomy for unilateral undescended testis that was grossly abnormal **G4:** Had not undergone any surgical treatment for a unilateral undescended testis **Inclusion criteria:** See exclusion criteria **Exclusion criteria:** • Underwent orchiopexy when 5-9 years of age • Retractile testis as determined in clinic by palpation and during Valsalva's maneuver • Those with a small testicle or dislocated testis at follow-up when 19-39 years old despite previous orchiopexy **N at enrollment:** 274 **N at follow-up for sperm density:** **G1a:** 46 **G1b:** 15 **G2a:** 121 **G2b:** 28 **G3a:** 16 **G3b:** 10 **G4:** 38 N at follow-up for sperm motility: **G1a:** 9 **G1b:** 5 **G2a:** 116 **G2b:** 23 **G3a:** 15 **G3b:** 9	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** NR **Long-term:** Sperm Density Normal (%) **G1a:** 0 **G1b:** 0 **G2a:** 75 **G2b:** 61 **G3a:** 81 **G3b:** 70 **G4:** 42 Decreased (%) **G1a:** 24 **G1b:** 20 **G2a:** 20 **G2b:** 25 **G3a:** 13 **G3b:** 20 **G4:** 45 No sperm (%) **G1a:** 76 **G1b:** 80 **G2a:** 5 **G2b:** 14 **G3a:** 6 **G3b:** 10 **G4:** 13 P<0.001 between group 1 or 2 and group 3. P<0.05 between group 2 or 3 and group 4. Sperm motility Normal (%) **G1a:** 11 **G1b:** 0 **G2a:** 73 **G2b:** 65 **G3a:** 80 **G3b:** 78 **G4:** 58 Decreased (%) **G1a:** 56 **G1b:** 60 **G2a:** 21 **G2b:** 22 **G3a:** 20 **G3b:** 22 **G4:** 33 Nonmotile (%) **G1a:** 33 **G1b:** 40 **G2a:** 6

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
	G4: 33 **Age at follow-up, mean yrs (range):** **G1a & G1b:** 25.7 (18-39) **G2a & G2b:** 26.9 (18-37) **G3a & G3b:** 25.0 (19-33) **G4:** 27.7 (21-36) **Sidedness:** NR **Comorbidites:** NR		**G2b:** 13 **G3a:** 0 **G3b:** 0 **G4:** 9 P<0.001 between group 1 or 2 and group 3. P<0.05 between group 2 or 3 and group 4.

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Radmayr et al., 2003 **Country:** Austria **Setting:** Hospital **Enrollment period:** 1992 to September 2000 **Design:** Retrospective cohort **Length of followup, mean yrs (range)** 6.2 (2-10)	**Groups:** **G1:** Direct laparoscopic orchiopexy (intraabdominal testes) **G2:** 2-stage Fowler Stephens orchiopexy (intraabdominal testes) **G3:** Classic orchiopexy (inguinal testes) **Inclusion criteria:** • Underwent laparoscopic evaluation for nonpalpable testes **Exclusion criteria:** • Primarily impalpable testes but inguinal position located under general anesthesia **N testes at enrollment:** **G1**: 28 **G2**: 29 **G3**: 36 **N testes at follow-up:** **G1**: 28 **G2**: 29 **G3**: 36 **Age at intervention, mean yrs (range):** 1.9 (0.8 – 12) **Sidedness:** NR **Comorbidites:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** NR **Long-term:** Testicular size and appearance: **G1**: mean volume 1.5 ml (range 1.1 -1.9); 0% atrophic **G2**: mean volume 1.8 ml (range 0.9-2.4) ; 2% atrophic **G3**: NR Testicular position: **G1**: 28 (100%) normal testes, 0% atrophic; described as in a dependent scrotal position with normal consistency, comparable in size to contralateral gonad **G2**: 27 (93.1%) normal testes, 2 (6.9%) atrophic **G3:** described as in a dependent scrotal position with normal consistency, comparable in size to contralateral gonad

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Stec et al,. 2009 **Country:** US **Setting:** Hospital **Enrollment period:** 1998 to 2007 **Design:** Retrospective cohort **Length of followup, mean months (range):** 16 (6 – 93)	**Groups:** **G1:** One-stage laparoscopic orchiopexy **G2:** One-stage open orchiopexy **G3:** one-stage laparoscopic Fowler-Stephens orchiopexy **G4:** One-stage open Fowler-Stephens Orchiopexy **G5:** Two-stage Fowler-Stephens orchiopexy with laparoscopic stages 1 and 2 **G6:** Two-stage Fowler-Stephens orchiopexy with laparoscopic stage 1 and open stage 2 **G7:** Two-stage Fowler-Stephens orchiopexy with open stages 1 and 2 Choice of open vs. laparoscopic technique was up to surgeon depending on comfort level with techniques. Decision to do FSO vs. 1-stage orchiopexy was based on patient anatomy (high testes or noticeable short vessels had FSO). **Inclusion criteria:** • Orchiopexy • Testes thought to be of sufficient size and texture that they could grow • Intraabdominal testis **Exclusion criteria:** • Atrophic testis • Orchiectomy at surgery • Incomplete medical records • Less than 6 months of followup **N at enrollment (N testes):** **G1:** 32 **G2:** 60 **G3:** 8 **G4:** 19 **G5:** 11 **G6:** 21 G7: 5 **N at follow-up:**	**Unilateral, n (%):** 116 across all groups **Bilateral, n (%):** 20 of 136 across all groups **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** **Testicle location, n (%):** Successful, defined as testis brought down into the scrotum, which was in a dependent location, normal in consistency, and of a size comparable to the contralateral testis at follow-up, number: **G1:** 31 (96.9) **G2:** 51 (85.0) **G3:** 5 (62.5) **G4:** 12 (63.2) **G5:** 8 (72.7) **G6:** 13 (61.9) **G7:** 4 (80.0) Failure, defined as a testis that was brought down into the scrotum but had failed to grow, become atrophic compared to contralateral testis, or not dependent in the scrotum at followup, number: **G1:** 1 (3.1) **G2:** 9 (15.1) **G3:** 3 (37.5) **G4:** 7 (36.8) **G5:** 3 (27.3) **G6:** 8 (38.1) **G7:** 1 (20.0) Patent processus vaginalis was insignificant to success on multiple variable logistic regression analysis. One and 2-stage FSO had an OR that significantly correlated with worse outcome compared to 1-stage abdominal orchiopexy (OR 0.24, p=0.007 and 0.29, p=0.019, respectively, table 2). **Long-term:** NR

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
	G1: 32 **G2:** 60 **G3:** 8 **G4:** 19 **G5:** 11 **G6:** 21 **G7**: 5 **Age at intervention, median months (range):** 12 (3 to 167) **Sidedness:** NR **Comorbidites:** NR		

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
Author: Yavetz et al, 1992 **Country:** Israel **Setting:** Outpatient infertility clinic **Enrollment period:** 1979 to 1990 **Design:** Retrospective cohort **Length of followup:** NR	**Groups:** **G1:** Bilateral orchidopexy **G2:** Unilateral orchidopexy **G3:** Successful hormonal therapy **G4:** Late spontaneous descent **G5:** Untreated cryptorchid patients **G6:** Fertile men **Inclusion criteria:** • Cryptorchidism in medical history for groups G1-G5 • Fertile men participating in in-vitro fertilization-embryo transfer for G6 **Exclusion criteria:** • Additional pathology that may have interfered with fertility, such as varicocele, inguinal hernia repair, and previous mumps orchiditis **N at enrollment:** **G1:** 40 **G2:** 51 **G3:** 24 **G4:** 6 **G5:** 13 **G6:** 105 **N at follow-up:** **G1:** 40 **G2:** 51 **G3:** 24 **G4:** 6 **G5:** 13 **G6:** 105 N at follow-up for hormone levels: **G1:** 33 **G2:** 51 **G3:** 24 **G4:** 6 **G5:** 13 **G6:** 105 **Age at intervention, mean yrs ± SD (range):** **G1**: 11.6±4.0 (1-21) **G2**: 10.8±4.1 (2-23) **G3:** NR **G4:** NR **G5:** NR **G6:** NR	**Unilateral:** NR **Bilateral:** NR **Palpability:** NR **Testicle location:** NR **Other anomalies:** NR	**Immediate/short-term:** NR **Long-term:** **Testicular position, n (%):** **G1:** 11 (30) with abnormal position of the testes **G2:** 13 (25.5) with abnormal position of the testes **G3:** NR **G4:** NR **G5:** one testis absent in 7 (53.8) patents, one testis in the inguinal canal in 6 (46.2) patients **Endocrine function:** FSH (mIU/ml±SD) **G1:** 24.6±1.4, p<0.001 **G2:** 9.4±1.3, p<0.001 **G3:** 14.3±1.6, p<0.001 **G4:** 25.7±1.4, p<0.001 **G5:** 12.6±1.1, p<0.001 G6: 4.2±0.5 LH (mIU/ml±SD) **G1:** 6.2±0.8 **G2:** 3.4±0.7 **G3:** 2.6±0.6 **G4:** 5.9±0.9 **G5:** 2.3±0.5 G6: 4.2±0.6 Testosterone (ng/ml±SD) **G1:** 6.0±2.3 **G2:** 5.5±2.3 **G3:** 6.4±1.9 **G4:** 4.8±1.0 **G5:** 6.0±2.0 **G6:** 5.6±0.9 **Semen volume, ml±SD** **G1:** 3.0±1.7 **G2:** 3.4±1.7 **G3:** 3.1+1.8 **G4:** 3.1±1.5 **G5:** 2.8±0.9 G6: 2.8±1.2 **Sperm concentration (millions/ml ±SD)** **G1:** 0.3±1.9 **G2:** 17.0±2.9 **G3:** 15.1±5.8 **G4:** 25.5±6.1 **G5:** 16.6±4.6 **G6:** 90.1±3.3

Table D-4. Evidence table for studies assessing surgical treatment (continued)

Study Description	Intervention & Population	Baseline Characteristics	Intervention Outcomes
	Sidedness: NR **Comorbidites** NR		All groups G1-G5 p<0.001 compared to G6 **Total sperm count (millions±SD)** **G1:** 1 ±1.8, p<0.001 **G2:** 50±5.0, p<0.001 **G3:** 43±9.1, p<0.01 **G4:** 96±9.9, p<0.05 **G5:** 40±7.2 , p<0.05 **G6:** 230±5.2 **Sperm motility (%±SD)** **G1:** 8.4%±17.2, p<0.001 **G2:** 57.2%±21.4, p<0.001 **G3:** 27.2%±20.8, p<0.001 **G4:** 23.7%±18.1 **G5:** 35.0%±22.1, p<0.05 **G6:** 52.3%±9.2 **Degree of sperm motility (range 1-4±SD)** **G1:** 0.93+1.37, p<0.001 **G2:** 2.49±0.94, p<0.001 **G3:** 1.55±1.25, p<0.001 **G4:** 2.57±0.70, p<0.05 **G5:** 2.55±1.25, p<0.05 **G6:** 3.53±0.53 **Sperm morphology, (% normal forms±SD)** **G1:** 9.0%±16.9, p<0.001 **G2:** 38.1%±23.2, p<0.01 **G3:** 29.6%±25.4, p<0.05 **G4:** 27.8%±24.5, p<0.05 **G5:** 45.6%±29.3 **G6:** 51.8%±11.5

Appendix E. Quality of the Literature

The Quality Assessment of Diagnostic Accuracy Studies-Revised[1] (QUADAS-2) tool was used to assess the quality of studies included in Key Question 1a. We constructed an evaluation form using the criteria outlined in the QUADAS-2 and completed one form for each technique assessed by studies included in our review. Each individual item could receive an assessment of yes, no, or unclear. Some included studies analyzed more than one imaging technique; in these instances, a separate evaluation form was completed for each technique.

Two authors independently completed evaluation forms for each study. Discrepancies were discussed and adjudicated by the two authors and the methods lead. The results of the evaluations of each study are presented below (Tables E-1–E-3), separated by imaging technique.

QUADAS-2 Evaluation Form

Domain/question	Yes/No/Unclear	Comments
Patient Selection		
1. Was a consecutive or random sample of patients enrolled?		
2. Was a case–control design avoided?		
3. Did the study avoid inappropriate exclusions?		
Index Test		
4. Were the index test results interpreted without knowledge of the results of the reference standard?		
5. If a threshold was used, was it pre-specified?		
Reference Standard		
6. Is the reference standard likely to correctly classify the target condition?		
7. Were the reference standard results interpreted without knowledge of the results of the index test?		
Flow and Timing		
8. Was there an appropriate interval between index tests and reference standard?		
9. Did all patients receive a reference standard?		
10. Did all patients receive the same reference standard?		
11. Were all patients included in the analysis?		

Comments:

QUADAS-2 Assessments

Table E-1. QUADAS-2 assessments of ultrasound accuracy studies

	Patient Selection			Index Test		Reference Standard		Flow and Timing			
Study	**Consecutive or random sample**	**Non-case-control**	**Avoid exclusions**	**Knowledge of standard**	**Pre-specified threshold**	**Likely to correctly classify the target condition**	**Knowledge of index test**	**Appropriate interval between tests**	**All receive standard**	**Same reference standard**	**All patients analyzed**
Al-Shareef et al., 1996[2]	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Cain et al., 1996[3]	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Guvenc et al., 2005[4]	N	Y	Y	Y	Y	Y	N	N	Y	N	Y
Kanemoto et al., 2005[5]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Kullendorf et al., 1985[6]	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y
Maghnie et al., 1994[7]	N	Y	Y	Y	Y	Y	Y	U	Y	Y	N
Malone et al., 1985[8]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Nijs et al., 2007[9]	N	Y	Y	Y	Y	Y	N	U	Y	Y	N
Yeung et al., 1999[10]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y

Y= yes; N = no; U = unclear

Table E-2. QUADAS-2 assessments of MRI accuracy studies

	Patient Selection			Index Test		Reference Standard		Flow and Timing			
Study	**Consecutive or random sample**	**Non-case-control**	**Avoid exclusions**	**Knowledge of standard**	**Pre-specified threshold**	**Likely to correctly classify the target condition**	**Knowledge of index test**	**Appropriate interval between tests**	**All receive standard**	**Same reference standard**	**All patients analyzed**
Al-Shareef et al., 1996[2]	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Kanemoto et al., 2005[5]	N	Y	Y	Y	Y	Y	N	U	Y	Y	N
Kantarci et al., 2010[11]	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Kato et al., 2011[12]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Kier et al., 1988[13]	N	Y	Y	N	Y	Y	N	U	Y	Y	Y
Lam et al., 1998[14]	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Maghnie et al., 1994[7]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Miyano et al., 1991[15]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Siemer et al., 2000[16]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Yeung et al., 1999[10]	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y

Y= yes; N = no; U = unclear

Table E-3. QUADAS-2 assessments of other accuracy technique studies

	Patient Selection			Index Test		Reference Standard		Flow and Timing			
Study Technique	**Consecutive or random sample**	**Non-case-control**	**Avoid exclusions**	**Knowledge of standard**	**Pre-specified threshold**	**Likely to correctly classify the target condition**	**Knowledge of index test**	**Appropriate interval between tests**	**All receive standard**	**Same reference standard**	**All patients analyzed**
Desireddi et al., 2008[17] MRI + MRA/V	N	Y	Y	Y	Y	Y	Y	U	Y	N	N
Green, 1985[18] CT Scan	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Lam et al., 2001[19] MRV	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Lam et al., 1998[14] MRA	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y
Yeung et al., 1999[10] MRA	N	Y	Y	Y	Y	Y	N	U	Y	Y	Y

Y= yes; N = no; U = unclear ; CT=computed tomography; MRA=magnetic resonance angiography; MRA/V= Magnetic Resonance Imaging in combination with arteriography/venography ; MRI=magnetic resonance imaging

Risk of Bias and Quality

Per the methods of the QUADAS-2, a risk of bias (ROB) score was calculated for each of the four domains assessed in the evaluation of each study: patient selection, index test (imaging technique), reference standard (surgical verification technique), and flow and timing. Each domain could receive a rating of high, low, or unclear ROB.

For the patient selection, index test, and flow and timing domains, a "Yes" response to all individual items was necessary to receive a low ROB assessment. One answer of "No" or "Unclear" for any individual item within these three domains resulted in an assessment of high ROB.

The QUADAS-2 ROB assessments were then converted into the AHRQ quality standards of good, fair, and poor using the following criteria:

- **Good quality = an assessment of low ROB for all four domains**
- **Fair quality = an assessment of high ROB for one domain**
- **Poor quality = an assessment of high ROB for two or more domains**

The quality and ROB assessments for each study are presented below (Tables E-4–E-6), separated by imaging technique.

Table E-4. ROB and quality scores of ultrasound accuracy studies

Study	Quality Score	Patient Selection	Imaging	Surgery	Flow and Timing
Al-Shareef et al., 1996[2]	Fair	L	L	L	H
Cain et al., 1996[3]	Fair	L	L	L	H
Guvenc et al., 2005[4]	Poor	H	L	L	H
Kanemoto et al., 2005[5]	Poor	H	L	L	H
Kullendorf et al., 1985[6]	Good	L	L	L	L
Maghnie et al., 1994[7]	Poor	H	L	L	H
Malone et al., 1985[8]	Poor	H	L	L	H
Nijs et al., 2007[9]	Poor	H	L	L	H
Yeung et al., 1999[10]	Poor	H	L	L	H

H = high; L = low; ROB=risk of bias

Table E-5. ROB and quality scores of MRI accuracy studies

Study	Quality Score	Patient Selection	Imaging	Surgery	Flow and Timing
Al-Shareef et al., 1996[2]	Fair	L	L	L	H
Kanemoto et al., 2005[5]	Poor	H	L	L	H
Kantarci et al., 2010[11]	Fair	H	L	L	L
Kato et al., 2011[12]	Poor	H	L	L	H
Kier et al., 1988[13]	Poor	H	H	L	H
Lam et al., 1998[14]	Fair	L	L	L	H
Maghnie et al., 1994[7]	Poor	H	L	L	H
Miyano et al., 1991[15]	Poor	H	L	L	H
Siemer et al., 2000[16]	Poor	H	L	L	H
Yeung et al., 1999[10]	Poor	H	L	L	H

H = high; L = low; MRI=magnetic resonance imaging; ROB=risk of bias

Table E-6. ROB and quality scores of other accuracy technique studies

Study Technique	Quality Score	Patient Selection	Imaging	Surgery	Flow and Timing
Desireddi et al., 2008[17] MRI + MRA/V	Poor	H	L	L	H
Green, 1985[18] CT Scan	Poor	H	L	L	H
Lam et al., 2001[19] MRV	Poor	H	L	L	H
Lam et al., 1998[14] MRA	Fair	L	L	L	H
Yeung et al., 1999[10] MRA	Poor	H	L	L	H

H = high; L = low; CT=computed tomography;MRA=magnetic resonance angiography; MRA/V= Magnetic Resonance Imaging in combination with arteriography/venography; MRI=magnetic resonance imaging; ROB=risk of bias

Cochrane Risk of Bias Tool for Randomized Controlled Trials

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**	
Criteria for a judgment of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgment of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.

ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.**	
Criteria for a judgment of 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgment of 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting.**	
Criteria for a judgment of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified

	(unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.

OTHER BIAS **Bias due to problems not covered elsewhere in the table.**	
Criteria for a judgment of 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for the judgment of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgment of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.
BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgment of 'Low risk' or 'High risk'; • The study did not address this outcome.

BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgment of 'Low risk' or 'High risk'; • The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Attrition bias due to amount, nature or handling of incomplete outcome data.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;

	• For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.

Thresholds for Converting the Cochrane Risk of Bias Tool to AHRQ Standards (Good, Fair, and Poor)

Good quality: All criteria met (i.e. low for each domain)

Using the Cochrane ROB tool, it is possible for a criterion to be met even when the element was technically not part of the method. For instance, a judgment that knowledge of the allocated interventions was adequately prevented can be made even if the study was not blinded, if EPC team members judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.

Fair quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **unlikely** to have biased the outcome, and there is no known important limitation that could invalidate the results

Poor quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **likely** to have biased the outcome, and there are important limitations that could invalidate the results

Poor quality: Two or more criteria listed as high or unclear risk of bias

Table E-7. Quality ratings for randomized control trials included in Key Question 2

Study	Quality rating	Random sequence generation	Allocation concealment	Selective reporting	Other sources of bias	Blinding (participants and personnel)	Blinding (outcome assessment)	Incomplete outcome data
Key Question 2: Effectiveness of hormone therapy for the treatment of cryptorchidism								
Bertelloni et al., 2001[20]	Poor	H	U	L	U	H	H	L
Bica and Hadziselimovic, 1992 & 1993[21, 22]	Poor	U	U	L	U	L	H	L
Christiansen et al., 1988[23]	Fair	L	L	L	H	L	L	L
De Muinck Keizer-Schrama and Hazebroek et al., 1986-1987[24-26]	Poor	U	U	L	U	L	L	L
Forest et al., 1988[27]	Poor	H	H	L	H	H	H	L
Hagberg and Westphal, 1982[28]	Poor	U	U	L	U	L	L	L
Hesse and Fischer, 1988[29]	Poor	H	H	L	U	L	L	L
Karpe et al., 1983[30]	Poor	U	U	L	L	L	L	L
Olsen et al., 1992[31]	Fair	L	L	L	L	L	L	H
Rajfer et al., 1986[32]	Good	L	L	L	L	L	L	L
Wit et al., 1986[33]	Poor	U	U	L	L	L	L	L

H=high; L=low; U=unclear

Table E-8. Quality ratings for randomized control trials included in Key Question 3

Key Question 3: Effectiveness of surgical therapies for the treatment of cryptorchidism								
Study	**Quality rating**	**Random sequence generation**	**Allocation concealment**	**Selective reporting**	**Other sources of bias**	**Blinding (participants and personnel)**	**Blinding (outcome assessment)**	**Incomplete outcome data**
Abolyosr, 2006[34]	Poor	H	H	H	L	H	H	U
Arda and Ersoy, 2001[35]	Poor	H	H	U	L	L	H	L
Ferro et al., 1999[36]	Good	L	L	L	L	L	L	L
Na et al., 2011[37]	Poor	U	U	L	L	L	L	H
Nazem et al., 2011[38]	Poor	H	U	H	L	L	L	L

H = high; L = low; U = unclear

Newcastle-Ottawa Quality Assessment Form for Cohort Studies

Note: A study can be given a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Selection

1) Representativeness of the exposed cohort

   a) Truly representative ***(one star)***
   b) Somewhat representative ***(one star)***
   c) Selected group
   d) No description of the derivation of the cohort

2) Selection of the non-exposed cohort

   a) Drawn from the same community as the exposed cohort ***(one star)***
   b) Drawn from a different source
   c) No description of the derivation of the non exposed cohort

3) Ascertainment of exposure

   a) Secure record (e.g., surgical record) ***(one star)***
   b) Structured interview ***(one star)***
   c) Written self report
   d) No description
   e) Other

4) Demonstration that outcome of interest was not present at start of study

   a) Yes ***(one star)***
   b) No

Comparability

1) Comparability of cohorts on the basis of the design or analysis controlled for confounders

   a) The study controls for age, sex and marital status ***(one star)***
   b) Study controls for other factors (list) _____ ***(one star)***
   c) Cohorts are not comparable on the basis of the design or analysis controlled for confounders

Outcome

1) Assessment of outcome

   a) Independent blind assessment ***(one star)***
   b) Record linkage ***(one star)***
   c) Self report
   d) No description
   e) Other

2) Was follow-up long enough for outcomes to occur

   a) Yes ***(one star)***
   b) No

Indicate the median duration of follow-up and a brief rationale for the assessment above:_____

3) Adequacy of follow-up of cohorts

   a) Complete follow up- all subject accounted for ***(one star)***
   b) Subjects lost to follow up unlikely to introduce bias- number lost less than or equal to 20% or description of those lost suggested no different from those followed. ***(one star)***
   c) Follow up rate less than 80% and no description of those lost
   d) No statement

Thresholds for converting the Newcastle-Ottawa scales to AHRQ standards (good, fair, and poor):

Good quality: 3 or 4 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Fair quality: 2 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Poor quality: 0 or 1 star in selection domain OR 0 stars in comparability domain OR 0 or 1 stars in outcome/exposure domain

Table E-9. Quality ratings for cohort studies included in Key Question 1b

		Selection (0-4 stars)				Comparability (n/a, 0-2 stars)	Outcome (0-3 stars)		
Citation	**Quality rating**	**Represen-tativeness of exposed cohort**	**Selection of non exposed**	**Ascertain-ment of exposure**	**Outcome not present at start of study**	**Comparability of cohorts**	**Assess-ment**	**Long enough followup**	**Adequacy of follow up**
Davenport et al., 1995[39]	Poor	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	c) no	b)record linkage	a) yes	a)complete followup
Merksz et al., 1992[40]	Fair	b)somewhat representative	a)drawn from same community	a)secure record	b) no	b) other	b)record linkage	a) yes	a)complete followup

Table E-10. Quality ratings for cohort studies included in Key Question 2

		Selection (0-4 stars)				Comparability (n/a, 0-2 stars)	Outcome (0-3 stars)		
Citation	**Quality rating**	**Represen-tativeness of exposed cohort**	**Selection of non exposed**	**Ascertain-ment of exposure**	**Outcome not present at start of study**	**Comparability of cohorts**	**Assessment**	**Long enough followup**	**Adequacy of follow up**
Aycan et al., 2006[41]	Good	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	a) yes	a)independent blind assessment	a) yes	a)complete followup
Esposito et al., 2003[42]	Poor	d) no description	a)drawn from same community	d)no description	a) yes	c) no	a)independent blind assessment	a) yes	a)complete followup
Hadziselimovic and Herzog, 1997 & 2008[43, 44]	Good	c)selected group	a)drawn from same community	a)secure record	a) yes	a) yes	a)independent blind assessment	a) yes	a)complete followup

Table E-11. Quality ratings for cohort studies included in Key Question 3

		Selection (0-4 stars)				Comparability (n/a, 0-2 stars)	Outcome (0-3 stars)		
Citation	**Quality rating**	**Represen-tativeness of exposed cohort**	**Selection of non exposed**	**Ascertain-ment of exposure**	**Outcome not present at start of study**	**Comparability of cohorts**	**Assessment**	**Long enough followup**	**Adequacy of follow up**
Al-Mandil et al., 2008[45]	Good	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	a) yes	a)independent blind assessment	a) yes	d)no statement
Anousskasis et al., 1983[46]	Good	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	a) yes	a)independent blind assessment	a) yes	d)no statement
Baker et al.,2001[47]	Poor	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	a) yes	c)>80%
Chandrasekharam, 2005[48]	Poor	b)somewhat representative	a)drawn from same community	d)no description	a) yes	a) yes	d) no description	b) no	d)no statement
Chang et al., 2001[49]	Poor	c)selected group	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	b) no	c)>80%
Chang et al., 2008[50]	Poor	c)selected group	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	a) yes	c)>80%
Cloutier et al., 2011[51]	Poor	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	b) other	a)independent blind assessment	b) no	d)no statement
Comploj et al., 2011[52]	Poor	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	a) yes	c)>80%
Denes et al., 2008[53]	Poor	d) no description	a)drawn from same community	d)no description	a) yes	c) no	d)no description	b) no	c)>80%
Dhanani et al., 2004[54]	Poor	d)no description	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	a) yes	c)>80%

Table E-13. Quality ratings for cohort studies included in Key Question 3 (continued)

		Selection (0-4 stars)				Comparability (n/a, 0-2 stars)	Outcome (0-3 stars)		
Citation	**Quality rating**	**Represen-tativeness of exposed cohort**	**Selection of non exposed**	**Ascertain-ment of exposure**	**Outcome not present at start of study**	**Comparability of cohorts**	**Assess-ment**	**Long enough followup**	**Adequacy of follow up**
Escarcega-Fujigaki et al., 2011[55]	Fair	b)somewhat representative	a)drawn from same community	d)no description	b) no	b) other	c) self report	a) yes	c)>80%
Gheiler et al., 1997[56]	Poor	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	b) no	d)no statement
Gilhooly et al., 1984[57]	Poor	d)no description	b)drawn from different source	d)no description	b) no	c) no	c)self report	b) no	d)no statement
Humphrey et al., 1998[58]	Poor	d)no description	a)drawn from same community	d)no description	a) yes	c) no	d) no description	a) yes	d)no statement
Kim et al., 2010[59]	Poor	d)no description	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	b) no	c)>80%
Lintula et al., 2008[60]	Poor	a)truly representative	a)drawn from same community	a)secure record	a) yes	c) no	a)independent blind assessment	a) yes	b) <20%
Moursy et al., 2011[61]	Poor	d)no description	a)drawn from same community	d)no description	a) yes	c) no	d) no description	a) yes	c)>80%
Okuyama et al., 1989[62]	Poor	d)no description	b)drawn from different source	d)no description	b) no	c) no	a)independent blind assessment	a) yes	d)no statement
Radmayr et al., 2003[63]	Poor	d)no description	a)drawn from same community	d)no description	a) yes	c) no	d) no description	a) yes	d)no statement

Table E-13. Quality ratings for cohort studies included in Key Question 3 (continued)

		Selection (0-4 stars)				Comparability (n/a, 0-2 stars)	Outcome (0-3 stars)		
Citation	**Quality rating**	**Represen-tativeness of exposed cohort**	**Selection of non exposed**	**Ascertain-ment of exposure**	**Outcome not present at start of study**	**Comparability of cohorts**	**Assess-ment**	**Long enough followup**	**Adequacy of follow up**
Stec et al., 2009[64]	Good	b)somewhat representative	a)drawn from same community	a)secure record	a) yes	a & b	a)independent blind assessment	a) yes	c)>80%
Yavetz et al., 1992[65]	Poor	d)no description	b)drawn from different source	d)no description	b) no	c) no	a)independent blind assessment	a) yes	d)no statement

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Appendix F. Applicability

Table F-1. Applicability for Key Question 1a

Domain	Description of applicability of evidence compared to question
Population	The study populations were pre-pubescent boys with non-palpable undescended testes. The enrollment selection criteria and participant characteristics were not always explicitly detailed. Participants were excluded if they refused imaging or surgery and inappropriate exclusions were avoided.
Intervention	Studies used ultrasound with varying frequency ranging between 3.5-12 MHz for imaging. CT scan and various magnetic resonance imaging techniques including conventional MRI, diffusion weighted MRI, MRA, MRV either alone or in combination were also employed. Imaging results were most always interpreted without the knowledge of the surgical results
Comparators	The comparators include open or laparoscopic surgical results
Outcomes	The outcomes were pre-operative identification and location of presence or absence of non-palpable undescended testes by imaging along with their concordance with surgical results. The assessments of outcomes were by radiologists or specialists and surgeons.
Setting	Only four of 18 studies were conducted in the U.S while half of the studies were conducted in Asia. Use of different types of scanners with different levels of operator experience along with lack of information on participants' physical examination make comparisons of standard care difficult.

Table F-2. Applicability for Key Question 1b

Domain	**Description of applicability of evidence compared to question**
Population	The study population primarily consisted of children with bilateral non-palpable cryptorchidism. One of the studies also included children with unilateral non-palpable cryptorchidism but the results were reported separately which allowed easy identification of the applicable results.
Intervention	Both studies used three daily injections of hCG to stimulate testosterone production although varying doses were used. Serum testosterone levels were measured by standard radioimmunoassays which are commonly available
Comparators	Not applicable.
Outcomes	All studies confirmed the presence or absence by surgical exploration, which would be considered the gold standard for diagnosing anorchia in cryptorchidism.
Setting	Both studies were performed in Europe. However, there are minimal differences in the standard of care in this setting between Europe and the U.S. It is assumed that the initial hCG stimulation test was performed in the outpatient setting although this is not specifically mentioned.

Table F-3. Applicability for Key Question 2

Domain	**Description of applicability of evidence compared to question**
Population	The study populations include children with both bilateral and unilateral cryptorchidism of varying ages. The study populations included the entire gamut of possible locations of the cryptorchid testicle, ranging from very low-lying testis in the high scrotum to nonpalpable abdominal testes and all locations in between. Most but not all of the studies made an effort to explicitly exclude children with retractile testes.
Intervention	Varying hormonal agents were used alone and in combination, including hCG, LHRH (and its analogues) and hMG. Differing doses were used across the study in addition to differing dosing schedules. Most of the agents studied are available in the United States and represent the most commonly used hormones in this setting although some of the doses studied may not reflect standard practice in the U.S.
Comparators	The comparators include placebo (in matched dosing schedules) and various hormonal agents alone and in combination. These comparators are commonly used in practice, although some of the doses studied may not be consistent with standard of care in the U.S.
Outcomes	The most common outcome assessed was successful testicular descent into the scrotum. This was commonly assessed by the study or clinic staff as opposed to seeking the opinion of the affected child's parent, whose opinion might differ with the clinician. Most but not all of the studies had adequate follow-up to assess for late recurrence/re-ascent of the testicle. Side-effects of hormonal therapy were infrequently described. Semen analysis in adulthood was asses in some studies as a proxy for fertility which is fairly widely accepted.
Setting	The majority of studies were performed in Europe where use of hormonal therapy in the treatment of cryptorchidism is presumably more common. The results of these studies, however, are still applicable to the U.S.

Table F-4. Applicability for Key Question 3

Domain	**Description of applicability of evidence compared to question**
Population	The study populations include children of varying ages with both unilateral and bilateral cryptorchidism. Like Key Question 2, The study populations included the entire gamut of possible locations of the cryptorchid testicle, ranging from very low-lying testis in the high scrotum to nonpalpable abdominal testes and all locations in between.
Intervention	The surgical interventions studied included open and laparoscopic approaches to the diagnosis and treatment of cryptorchidism. The surgical techniques studied include open and laparoscopic abdominal exploration for the localization of the cryptorchid testicle; laparoscopic and open primary orchiopexy, one-stage and two-stage Fowler-Stevens orchiopexy and; various minor modifications of open orchiopexy. While a number of the minor modifications studied are not commonly employed in the U.S. today, the most common surgical techniques (primary orchiopexy and one- and two-stage Fowler-Stevens orchiopexy) are included using both open and laparoscopic approaches.
Comparators	Comparators included the same approaches mentioned in the intervention section above.
Outcomes	The most common outcomes assessed were appropriate testicular position into the scrotum and testicular atrophy. These were commonly assessed by the study or clinic staff as opposed to seeking the opinion of the affected child's parent, whose opinion might differ with the clinician. Most but not all of the studies had adequate follow-up to assess for late recurrence of atrophy. Long-term fertility outcomes were also assessed in some studies using either semen analysis or actual paternity rates.
Setting	Seven of the studies were performed in the U.S. while six were performed in Europe and eight in other countries. While the standard of care is similar between the U.S. and Europe, it is difficult to determine if the studies from the other countries truly reflect the U.S. standard of care.