



Effective Health Care Program

Surgical Options for Inguinal Hernia: Comparative Effectiveness Review

Executive Summary

Background

An inguinal hernia is a protrusion of abdominal contents into the inguinal canal through an abdominal wall defect. The lifetime rate of inguinal hernia is 25 percent in males and 2 percent in females.¹ The risk of inguinal hernia increases with age, and the annual incidence is about 50 percent in males by the age of 75 years.² Approximately 10 percent of cases are bilateral.³ In children, the incidence ranges from 0.8 to 4.4 percent.⁴ It is 10 times as common in boys as in girls and also more common in infants born before 32 weeks' gestation (13-percent prevalence) and in infants weighing less than 1,000 grams at birth (30-percent prevalence).⁴

Surgical repair of hernias is the most commonly performed general surgical procedure in the United States.⁵ In 2003, U.S. surgeons performed an estimated 770,000 surgical repairs⁵ of inguinal hernia. (Note, however, that a more recent study, presently in press, estimates the U.S. prevalence at 600,000 and asserts that approximately 42 percent of males will develop an inguinal hernia in their lifetime.⁶) These repairs are typically performed on an outpatient basis (87 percent in 1996).⁵

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Such a large volume of procedures suggests that even modest improvements in patient outcomes would have a substantial impact on population health.⁷



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The primary goals of surgery include preventing strangulation, repairing the hernia, minimizing the chance of recurrence, returning the patient to normal activities quickly, and minimizing postsurgical discomfort and the adverse effects of surgery. The various surgeries include a constellation of benefits and risks, which presents some clinical uncertainty in the choice between approaches. Recurrence occurs in approximately 1 to 5 percent of cases.⁸ Balancing all the factors (e.g., recurrence, adverse events, time to return to work [RTW]) is a difficult yet critical process in making the best possible medical decisions.

Surgical procedures for inguinal hernia repair generally fall into three categories: open repair without the use of a mesh implant (i.e., sutured), open repair with a mesh, and laparoscopic repair with a mesh. Within each of these categories, several specific procedures have been employed. Until the 1980s, open suture repair was the standard; however, the resulting tension along the suture line yielded relatively high rates of recurrence and patient discomfort. Nonsutured “tension-free” surgical mesh has gained in popularity, and many specific open procedures are used. One author estimates that in 2003, 93 percent of groin hernia repairs involved the use of a mesh, and of these, about three-fourths involved either a Lichtenstein repair or mesh plug.⁵ In the Lichtenstein procedure, surgeons suture the mesh in front of the hernia defect. Mesh plug repair involves a preshaped mesh plug that surgeons introduce into the hernia weakness during open surgery; they then position a piece of flat mesh on top of the hernia defect. The near-universal adoption of mesh means that the most important questions about hernia repair involve various mesh procedures.

In terms of setting, most hernia surgeries are performed not in specialized hernia centers but by general surgeons who also perform many other types of surgeries.⁹ The laparoscopic surgical repair of inguinal hernia is generally recognized as a highly specialized skill, and patients receiving care from more experienced surgeons may fare better than patients receiving care from less experienced surgeons. This review specifically examines evidence on the association between laparoscopic surgical experience and hernia recurrence (See Key Questions below). The most commonly performed laparoscopic repair procedures are transabdominal preperitoneal (TAPP) repair and totally extraperitoneal (TEP) repair. During TAPP repair, surgeons enter the peritoneal cavity to place a mesh through an incision over the hernia site. With TEP surgery, surgeons do not enter the peritoneal cavity but use a mesh to cover the hernia from outside the peritoneum.

Given the clinical uncertainty, a systematic review of the existing evidence on comparative effectiveness will help inform important medical decisions about surgical options for inguinal hernia. The findings of the review may affect clinical decisions by patients and surgeons, treatment recommendations by professional societies, purchasing decisions by hospitals, and coverage decisions by payers.

Objectives

We sought to thoroughly summarize the evidence pertaining to nine Key Questions (listed below and presented graphically in Figure A):

Among adults with pain-free primary inguinal hernias:

Key Question 1. Does hernia repair differ from watchful waiting in patient-oriented effectiveness outcomes and/or adverse events?

Among adults with painful inguinal hernias without incarceration/strangulation:

Key Question 2. Does open hernia repair with a mesh differ from laparoscopic hernia repair with a mesh in patient-oriented effectiveness outcomes and/or adverse events?

- a. For primary hernias?
- b. For bilateral hernias?
- c. For recurrent hernias?

Key Question 3. Do different open mesh-based repair procedures (e.g., Lichtenstein repair, mesh plug) differ in patient-oriented effectiveness outcomes and/or adverse events?

Key Question 4. Do different laparoscopic mesh-based repair procedures (e.g., transabdominal preperitoneal repair, totally extraperitoneal repair) differ in patient-oriented effectiveness outcomes and/or adverse events?

Key Question 5. Do different mesh products differ in patient-oriented effectiveness outcomes and/or adverse events?

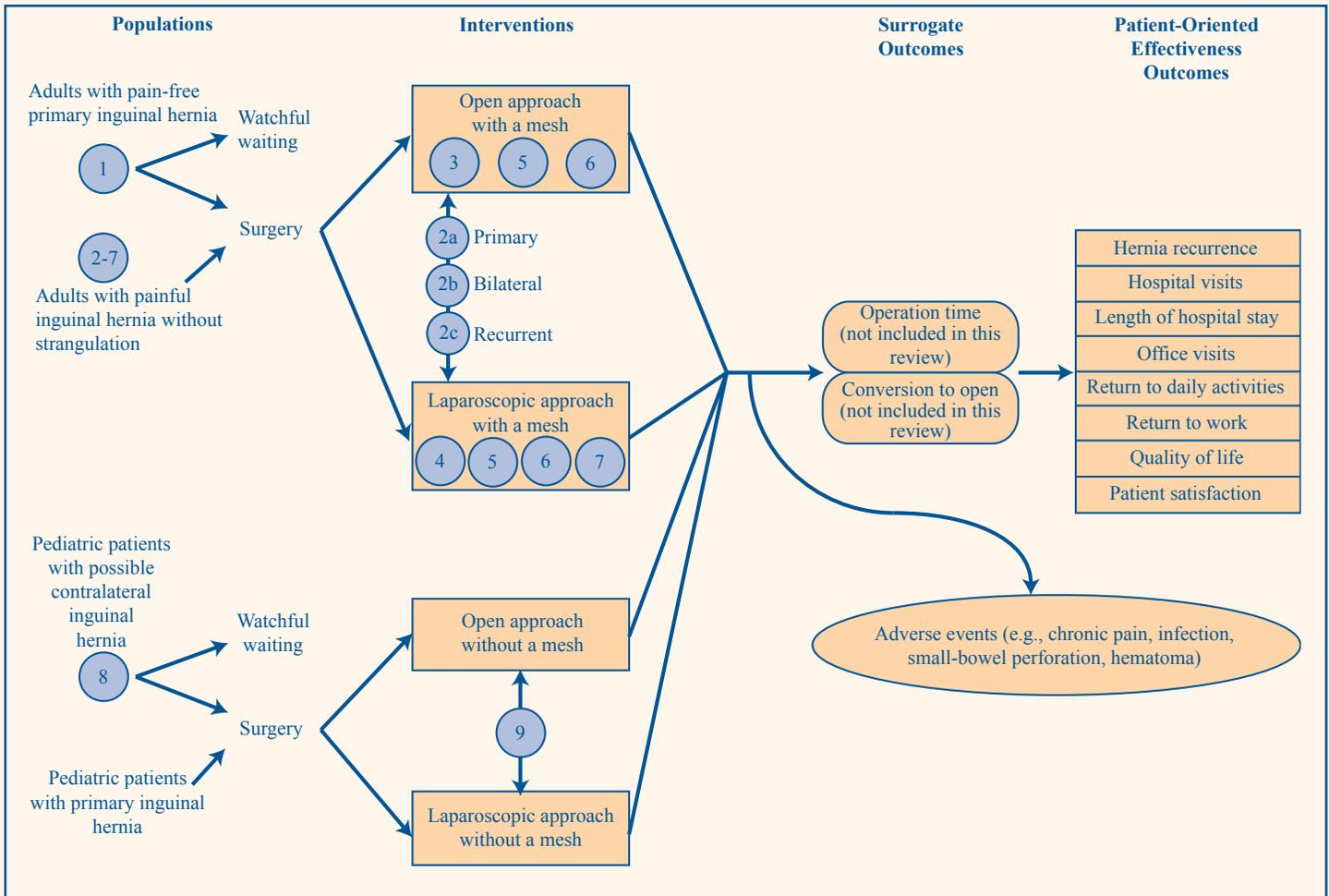
Key Question 6. Do different mesh-fixation methods (e.g., no fixation, sutures, glue) differ in patient-oriented effectiveness outcomes and/or adverse events?

Key Question 7. For each type of laparoscopic mesh repair, what is the association between surgical experience and hernia recurrence?

Among pediatric patients (age 21 years or younger):

Key Question 8. For a possible contralateral hernia, does same-operation repair/exploration differ from watchful

Figure A. Analytic framework



Note: Circled numbers are Key Questions.

waiting in patient-oriented effectiveness outcomes and/or adverse events?

Key Question 9. Does open hernia repair without a mesh differ from laparoscopic hernia repair without a mesh in patient-oriented effectiveness outcomes and/or adverse events?

Methods

We developed and refined the topic in late 2010 in collaboration with five Key Informants: two hernia surgeons, two individuals from payer organizations, and one individual from a mesh manufacturer. The Key Questions were posted on the Agency for Healthcare Research and Quality Web site for public comments for 1 month. We finalized the review protocol in spring 2011 based on input from the public comment period and four Technical Experts (three hernia surgeons and a product specialist from a mesh manufacturer).

Information professionals in the Evidence-based Practice Center Information Center performed literature searches and followed established guidelines and procedures as identified by the Director of Health Technology Assessment/Evidence-based Practice Center Information Center. We searched MEDLINE® and PreMEDLINE; Embase; the Cochrane Library, including the Central Register of Controlled Trials, the Cochrane Database of Methodology Reviews, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the Health Technology Assessment Database; and the United Kingdom National Health Service Economic Evaluation Database. The searchers applied no limits on language, and search dates were January 1, 1990, to November 17, 2011.

For inclusion in the review, we selected only full articles published in English. For questions comparing interventions (i.e., all Key Questions except Key Question 7, on surgical experience), the study must

have either randomly assigned patients to treatments or used an analytic method to address selection bias, such as intentional baseline matching on multiple characteristics, propensity scoring, or other analytic approach. Studies could be prospective or retrospective, but retrospective studies must have used consecutive enrollment (or enrollment of a random sample of eligible participants). The treatments being compared must have been administered during the same time period, so any observed difference between treatment outcomes were not attributable to differences in other aspects of care during different timeframes. For a study to be included for a given Key Question, at least 85 percent of its patients must have had the condition specified in the Key Question. The study must have reported data on at least one of the included outcomes for at least one of the Key Questions; outcome data must not have relied on retrospective recall; data must have included at least 6 months' followup for hernia recurrence, quality of life (QOL), and patient satisfaction (SFN); and data must have been reported on at least 10 patients with the condition of interest, who represented at least 50 percent of enrolled patients.

From each included study, we extracted all important information. This included author, publication year, country, study design, number of centers, dates of patient enrollment, type of setting, length of followup, funding source, which Key Question(s) the study addressed, all authors' reported patient enrollment criteria, specific procedure, specific mesh (if applicable), fixation method (if applicable), number of surgeons, surgeons' length of experience with the repair procedures performed, surgical setting (i.e., specialized hernia center, general surgery), type of anesthesia, methods of followup for data collection, and all reported baseline characteristics. We also extracted the numerical data needed to compute an effect size (such as an odds ratio [OR] or standardized mean difference) and its standard error for all included outcomes for each study.

We assessed the risk of bias (i.e., internal validity) separately for each outcome and each time point of each study using 15 risk-of-bias items, such as randomization, concealment of allocation, blinding of outcome assessors, and whether the surgeons had similar experience performing the study procedures. Some studies involved one surgeon performing different procedures, whereas other studies assigned surgeons to procedures. Based on these items, each data point from each study was assigned a risk-of-bias category of low, moderate, or high. This assessment was performed in duplicate, with disagreements resolved by consensus.

Within each treatment comparison, we examined all included outcomes from all relevant studies. The outcomes were divided into the following eight categories: hernia recurrence; hospital-related information, including the length of hospital stay and subsequent hospital/office visits; the time to return to daily activities (RTDA); the time to RTW; QOL; patient SFN; pain, including visual analog scale scores and the rates of chronic pain; and other adverse events not involving pain.

We performed meta-analysis if appropriate and possible. This decision depended on the judged clinical homogeneity of the different study populations, cointerventions, and outcomes, as well as whether studies reported the outcome in the same way. In the choice of effect size metrics, for hernia recurrence we used the relative risk (RR) because of its ease of interpretation and because some studies reported only an adjusted RR. Thus, only a relative-risk meta-analysis for hernia recurrence would include all the studies. For all continuous outcomes, we used the weighted mean difference, which is on the same scale as the measured outcome. For adverse events and pain reported dichotomously, we analyzed ORs.

To aid interpretation, for each outcome in the review, we estimated the smallest difference between groups that could still be considered clinically significant (minimum clinically significant difference). For example, for the outcome of hernia recurrence, we defined the minimum clinically significant difference as 3 percentage points (e.g., 1 percent vs. 4 percent for two separate treatments). This definition aids interpretation in two main ways: (1) determining whether a statistically significant difference is important and (2) determining whether a statistically nonsignificant difference is small enough to exclude the possibility of an important difference. Our estimates were based on published literature, guidance from the U.S. Food and Drug Administration, input from the Technical Expert Panel, and the consensus of the research team.

If meta-analysis was deemed appropriate and possible for a given comparison and a given outcome, we performed DerSimonian and Laird random-effects meta-analysis using comprehensive meta-analysis software (Biostat, Inc., Englewood, NJ). To measure heterogeneity, we used both I^2 and tau. If there was substantial heterogeneity and 10 or more studies of the same patient outcome of the same treatment comparison were available, we conducted meta-regressions using a variety of predictors (e.g., whether the study used concealment of allocation).

For major comparisons and outcomes, we rated the strength of evidence using the Evidence-based Practice Center system described by Owens and colleagues.¹⁰ This system includes four core domains (risk of bias, consistency, precision, and directness) as well as four optional domains (large magnitude of effect, all plausible confounders would reduce the effect, publication bias, and dose-response association). The directness domain does not encompass applicability, which is considered outside the evidence rating system. The various domains were considered together using transparent rules to rate the evidence for the outcome as high, moderate, low, or insufficient. We performed strength-of-evidence rating for all Key Questions except Key Question 7, which did not involve comparing treatments but rather an assessment of the relationship between surgical experience and hernia recurrence.

To assess applicability, we first abstracted data from each included study on factors that may affect the study's applicability. Using the PICOTS (populations, interventions, comparators, outcomes, timing, and setting) approach as a guide, we primarily focused on the three categories most relevant to inguinal hernia repair:

- Population—demographic characteristics, comorbidity or general physical fitness, and types of hernia
- Intervention and comparators—inguinal repair procedure being compared, timeframes of the procedure being performed, cointerventions, and experience of the surgical team
- Setting—geographic and clinical factors

Based on a review of the data abstracted, we narratively summarized any patterns reflected from these factors that might affect the applicability of the evidence. We made no attempt to generate any rating or score for the applicability of the evidence. Our narrative summaries are intended to draw stakeholders' attention to potential applicability issues embedded in the evidence.

Results

Searches identified 2,722 potentially relevant articles, and we excluded 1,878 of these at the abstract level (Figure B). We excluded another 621 articles at the full-article level, typically because of irrelevance to our Key Questions (252 publications), background/review/commentary/protocol articles (80 publications), case-series design (81 publications), or nonrandomized designs with no control for selection bias (79 publications). The remaining 223 publications described 151 unique studies

that we included in our review. The largest number of studies addressed Key Question 2a (38 studies), which compared open mesh repair with laparoscopic mesh repair in patients with primary inguinal hernia. We found other large evidence bases for Key Question 3 (comparing different procedures for open mesh repair, 21 studies), Key Question 5 (comparing meshes, 32 studies), Key Question 6 (comparing fixation methods, 23 studies), and Key Question 7 (the association between laparoscopic hernia repair experience and hernia recurrence, 32 studies). We included no studies for Key Question 8 (comparing surgical exploration vs. watchful waiting [WW] for pediatric contralateral inguinal hernia). We included 17 studies for multiple Key Questions (e.g., two studies were each included for four Key Questions) because they included three or more groups or reported subgroup analyses.

Our synthesis of results included quantitative meta-analysis for seven of the Key Questions (2a, 2b, 2c, 3, 4, 5, and 6). We conducted these analyses only where reasonable and appropriate (i.e., similar patients, comparisons, outcomes). Meta-analyses allowed us to extract greater statistical power from the evidence.

Key Question 1 (Repair Vs. Watchful Waiting for Pain-Free Hernia)

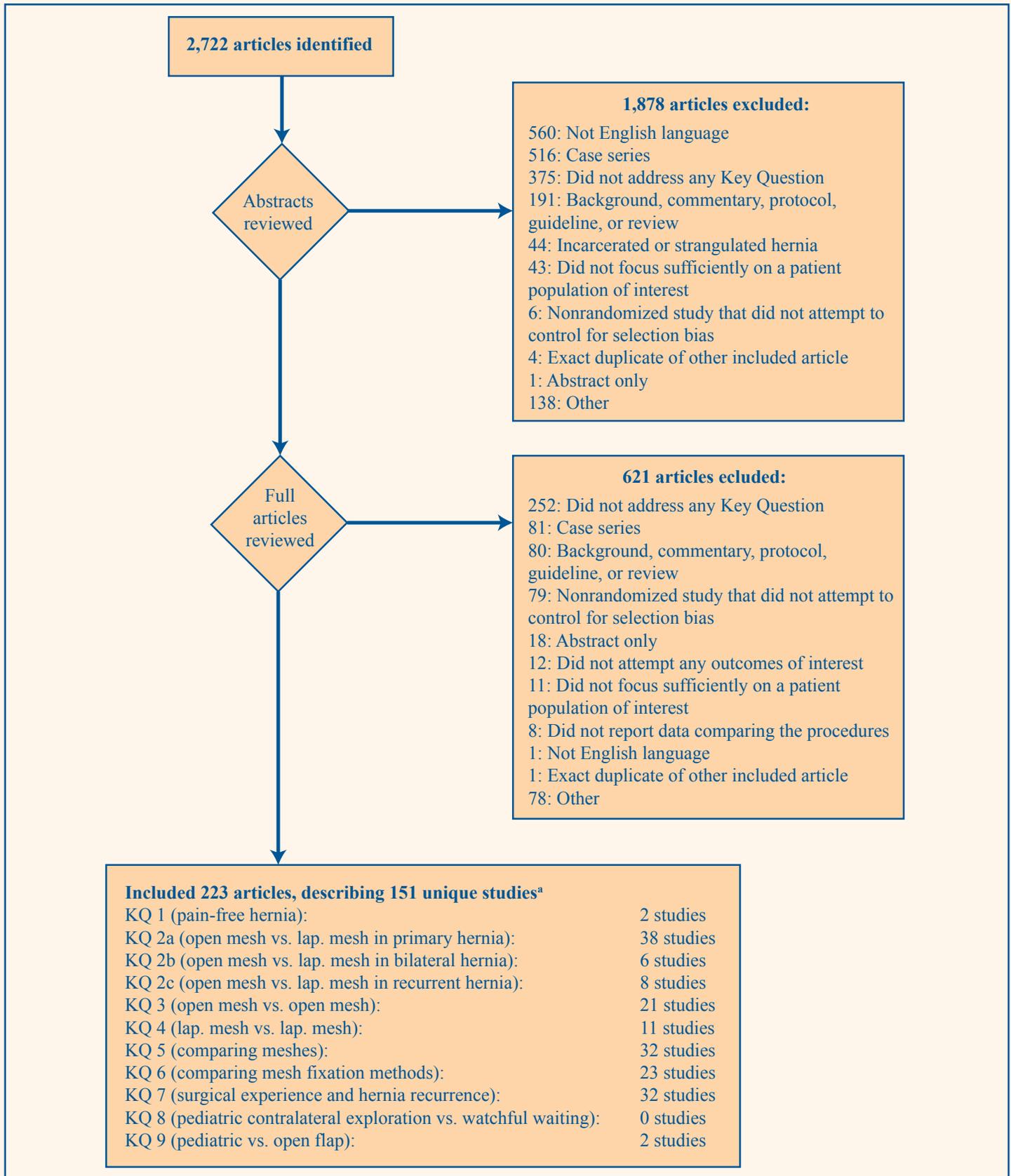
Two studies met inclusion criteria. One compared WW with Lichtenstein repair, and the other compared WW with “tension-free mesh repair” (which might have been Lichtenstein repair). Both studies were considered to have moderate risk of bias for all outcomes reported.

For this Key Question, we considered the following outcomes to be major: long-term QOL, which was reported as “overall change in health status in previous 12 months”; long-term pain; and acute hernia/strangulation. The evidence was sufficient to permit a conclusion for one outcome: long-term QOL, for which the results favored repair over WW.

Key Question 2a (Open Vs. Laparoscopic Repair, Primary Hernia)

Thirty-eight studies met inclusion criteria. The most commonly compared specific surgical procedures were TAPP repair versus Lichtenstein (14 studies), TEP repair versus Lichtenstein (14 studies), TAPP repair versus mesh plug (3 studies), TEP repair versus mesh plug (3 studies), and TAPP repair/TEP repair versus Lichtenstein (4 studies). All but two studies (which were registry studies) were considered to have moderate risk of bias.

Figure B. Literature flow diagram



^aThe counts for Key Questions add to more than the number of included studies because some studies were included for multiple Key Questions.

For this Key Question, we considered the following outcomes to be major: hernia recurrence, length of hospital stay, RTDA, RTW, QOL, patient SFN, long-term pain, epigastric vessel injury, small-bowel injury, small-bowel obstruction, urinary retention, hematoma, and wound infection. The evidence was sufficient to permit the following conclusions:

- Results favored laparoscopy for five outcomes (RTDA, RTW, long-term pain, hematoma, and wound infection).
- Results favored open surgery for two outcomes (hernia recurrence and epigastric vessel injury).
- Results indicated approximate equivalence for one outcome (length of stay).

Key Question 2b (Open Vs. Laparoscopic Repair, Bilateral Hernia)

Six studies met inclusion criteria. Three studies compared TEP repair with the Stoppa procedure, two compared TAPP repair with Lichtenstein repair, and a Danish registry compared either TAPP repair or TEP repair with Lichtenstein procedure (authors combined data on TAPP repair and TEP repair procedures). We considered all but one study (which was the registry study) to have moderate risk of bias.

For this Key Question, we considered as major the same outcomes as for Key Question 2a. The only outcome for which evidence was sufficient to permit a conclusion was RTW: patients with bilateral hernias returned to work sooner if they received laparoscopic repair.

Key Question 2c (Open Vs. Laparoscopic Repair, Recurrent Hernia)

Eight studies met our inclusion criteria. The open mesh procedure was the Lichtenstein repair in six studies and the Stoppa procedure in the other two studies. For the laparoscopic mesh procedure, two studies reported results of TAPP repair; two reported on TEP repair; in one other study, investigators performed both and reported data separately; and in the final three, the investigators performed both TAPP repair and TEP repair and combined the data. All but two studies (which were registry studies) were considered to have moderate risk of bias.

For this Key Question, we considered as major the same outcomes as for Key Question 2a. The evidence favored laparoscopic repair over open repair for hernia recurrence

(lower rates after laparoscopy), return to daily activities (faster after laparoscopy), and long-term pain (lower rates after laparoscopy).

Key Question 3 (Comparing Different Types of Open Mesh Repair)

Twenty-one studies met inclusion criteria. For this Key Question, we considered the following comparisons to be major: Lichtenstein repair versus mesh plug (seven studies), Lichtenstein versus Prolene™ Hernia System (PHS) (five studies), Lichtenstein versus open preperitoneal mesh (three studies), mesh plug versus PHS (two studies), and Lichtenstein versus Kugel® patch (two studies). Most studies were considered to have moderate risk of bias; a registry study was considered to have high risk of bias.

For each comparison, we considered the following outcomes to be major: hernia recurrence, length of hospital stay, RTDA, return to work, short-term pain, intermediate-term pain, seroma, urinary retention, hematoma, and wound infection. Evidence was sufficient to permit the following conclusions:

- For Lichtenstein repair compared with mesh plug technique, recurrence rates were similar, but Lichtenstein yielded better results for RTW and rates of seroma.
- For Lichtenstein compared with PHS, outcomes for short-term pain were similar.
- For Lichtenstein compared with open preperitoneal mesh, outcomes for short-term pain were similar.
- For mesh plug compared with PHS, outcomes for short-term pain were similar.
- For Lichtenstein versus Kugel mesh, outcomes were similar for both short-term pain and intermediate-term pain.

Key Question 4 (Comparing Different Types of Laparoscopic Mesh Repair)

Eleven studies met inclusion criteria. For this Key Question, we considered only the comparison of TAPP repair versus TEP repair to be major (nine studies). The remaining two studies compared different variant types of TEP repair (one study) or TAPP repair versus intraperitoneal onlay mesh (one study). Most studies were considered to have moderate risk of bias.

For the studies that compared TAPP repair versus TEP repair, we considered the following outcomes to be major: hernia recurrence, length of hospital stay, RTDA, RTW, short-term pain, intermediate-term pain, long-term pain, urinary retention, hematoma, and wound infection. Evidence was sufficient to permit the following conclusions:

- For TAPP repair compared with TEP repair, TAPP resulted in quicker RTW, and data on short-term, intermediate-term, and long-term pain suggested equivalence.

Key Question 5 (Comparing Meshes)

Thirty-two studies met inclusion criteria. For this Key Question, we considered the following seven comparisons to be major: standard polypropylene (PP) versus low-weight PP (6 studies), standard PP versus combination materials (17 studies), standard PP versus coated PP (6 studies), standard PP versus three-dimensional PHS (2 studies), standard PP versus porcine (2 studies), combination materials versus porcine (1 study), and low-weight PP versus combination materials (3 studies). Most evidence was considered to have moderate risk of bias.

For this Key Question, we considered the following seven outcomes to be major: hernia recurrence, QOL, patient SFN, long-term pain, feeling of a foreign body, infection, and bleeding. Standard PP mesh and combination materials had similar rates of recurrence. Three types of meshes (standard PP, low-weight PP, and porcine) had approximately equivalent rates of long-term pain.

Key Question 6 (Comparing Fixation Approaches)

Twenty-three studies met inclusion criteria. For this Key Question, we considered five comparisons to be major: tacks or staples versus no fixation (seven studies), fibrin glue versus staples (three studies), sutures versus tacks (three studies), sutures versus glue (seven studies), and absorbable sutures (short or long term) versus nonabsorbable sutures (one study). Most studies were considered to have moderate risk of bias.

For this Key Question, we considered as major the same outcomes as for Key Question 5. We found approximate equivalence in recurrence rates for tacks or staples versus no fixation and sutures versus glue. Also, for long-term pain, we found approximate equivalence between sutures and glue, but less pain with fibrin glue than staple fixation.

Key Question 7 (Surgical Experience and Hernia Recurrence)

Thirty-two studies met inclusion criteria. Sixteen involved only TEP repair, 12 involved only TAPP repair, 1 reported separate data on TEP repair and TAPP repair, and 3 provided combined data on TAPP repair and TEP repair. Most studies failed to report data that factored out the length of followup; patients treated earlier in the series might have had higher recurrence rates simply because they were followed longer. Some studies reported changing important procedural aspects over time, such as the size of the mesh (which typically involved using larger meshes in later time periods), making it difficult to pinpoint the true impact of expertise.

Among studies comparing an early set with later set(s) of repairs, the size of the early set varied from a low of 10 repairs to a high of 825 repairs. It was unclear how authors chose their cutoff points. The reporting differences mean that one cannot use the data to estimate the length of the learning curve for TEP repair or TAPP repair. Most studies reported results in the expected direction: lower recurrence rates with increased experience. This was also true when examined more specifically for TEP repair (11 of 17 studies) and TAPP repair (11 of 13 studies).

Key Question 8 (Exploration Vs. WW for Pediatric Hernia)

No studies met inclusion criteria.

Key Question 9 (Open Vs. Laparoscopic for Pediatric Hernia)

Two studies met our inclusion criteria. One study enrolled patients aged 4 months to 16 years; the other study enrolled patients aged 3 months to 9 years. Both studies were considered to have moderate risk of bias.

For this Key Question, we considered the following outcomes to be major: hernia recurrence, length of hospital stay, RTDA, and patient/parent SFN. The evidence was sufficient to permit the conclusions that length of stay, long-term patient SFN, and long-term cosmesis favored laparoscopy, and RTDA data suggested equivalence.

Conclusions and Strength of Evidence

Table A lists the conclusions we drew from the evidence. The relevant populations, comparisons, outcomes, conclusions, and summary effect sizes are listed. Any conclusions of a clinically significant difference between

treatments are shown in bold in the Conclusion column. The rightmost column contains our strength-of-evidence ratings for each conclusion.

Discussion

The typical adult in the included studies was a man in his mid-50s, of average weight, experiencing a primary unilateral hernia. About a quarter of the men worked in physically strenuous jobs; for these men, a durable repair is relatively important to prevent recurrence. Our review can inform numerous treatment decisions faced by these men and their providers, including:

- Whether to undergo surgery or wait
- Whether to choose open surgery or laparoscopic surgery
- Which type of open surgery to choose

- Which type of laparoscopic surgery to choose
- Which type of mesh and fixation approach to choose
- Consideration of expertise with laparoscopic hernia repair

The evidence-based conclusions listed in the previous section are applicable only to the types of patients enrolled in the studies underlying those conclusions. For example, for Key Questions 2 to 7, a large majority of enrolled patients were middle-aged men; therefore, how well the conclusions apply to women or to men of other ages is uncertain. Similarly, for Key Question 9 on pediatric hernia, open versus laparoscopic high ligation, both studies excluded cases less than 3 months old, so it is uncertain whether the conclusions apply to patients younger than 3 months old.

One limitation of this review is that we included only studies published in English. In an attempt to address this

Table A. Conclusions of this review

Population	Comparison	Outcome	Conclusion	Strength of Evidence
Adults with pain-free inguinal hernia	Repair vs. WW	Quality of life at 1 year	Favors repair Estimated difference on a 0-11 scale, 7 points (CI, 0.4 to 14.3)	Low
Adults with painful inguinal hernia, primary	Lap. vs. open	Recurrence	Favors open Relative risk, 1.43 (CI, 1.2 to 1.8)	Low
		Hospital stay	Approximate equivalence	Low
		Time to return to daily activities	Favors lap. 3.9 days earlier (CI, 2.2 to 5.6)	High
		Time to return to work	Favors lap. 4.6 days earlier (CI, 3.1 to 6.1)	High
		Long-term pain	Favors lap. Odds ratio, 0.61 (CI, 0.48 to 0.78)	Moderate
		Epigastric vessel injury	Favors open Odds ratio, 2.1 (CI, 1.1 to 3.9)	Low
		Hematoma	Favors lap. Odds ratio, 0.70 (CI, 0.55 to 0.88)	Low
		Wound infection	Favors lap. Odds ratio, 0.49 (CI, 0.33 to 0.71)	Moderate
Adults with painful inguinal hernia, bilateral	Lap. vs. open	Time to return to work	Favors lap. 14 days earlier (CI not calculable)	Low
Adults with painful inguinal hernia, recurrent	Lap. vs. open	Recurrence	Favors lap. Relative risk, 0.82 (CI, 0.70 to 0.96)	Low
		Time to return to daily activities	Favors lap. 7.4 days earlier (CI, 3.4 to 11.4)	High
		Long-term pain	Favors lap. Odds ratio, 0.24 (CI, 0.08 to 0.74)	Moderate

Table A. Conclusions of this review (continued)

Population	Comparison	Outcome	Conclusion	Strength of Evidence		
Adults with painful inguinal hernia	Lichtenstein vs. mesh plug	Recurrence	Approximate equivalence	Moderate		
	Lichtenstein vs. mesh plug	Return to work	Favors Lich. 4 days earlier (CI, 1 to 7)	Moderate		
	Lichtenstein vs. mesh plug	Seroma	Favors Lich. Odds ratio, 0.39 (CI, 0.16 to 0.94)	Moderate		
	Lichtenstein vs. PHS	Short-term pain	Approximate equivalence	Moderate		
	Lichtenstein vs. OPM	Short-term pain		Low		
	Mesh plug vs. PHS	Short-term pain		Moderate		
	Lichtenstein vs. Kugel	Short-term pain		Low		
	Lichtenstein vs. Kugel	Intermediate-term pain		Low		
	TAPP vs. TEP	Return to work		Short-term pain	Favors TAPP 1.4 days earlier (CI, 0.2 to 2.7)	Moderate
				Intermediate-term pain		Low
			Long-term pain	Low		
			Long-term pain (≥6 months)	Low		
	PP vs. low-weight PP	Recurrence			Moderate	
	PP vs. porcine	Long-term pain (≥6 months), VAS at rest			Low	
	PP vs. porcine	Long-term pain (≥6 months), VAS on movement			Low	
		Recurrence			Moderate	
	Tacks or staples vs. no fixation	Recurrence			Moderate	
	Fibrin glue vs. staples	Long-term pain (≥6 months)		Favors fibrin glue Difference in means, 0.47 (CI, -0.68 to -0.27)	Low	
	Sutures vs. glue	Recurrence		Approximate equivalence	Moderate	
		Long-term pain (≥6 months)			Low	

Table A. Conclusions of this review (continued)

Population	Comparison	Outcome	Conclusion	Strength of Evidence
Pediatric patients with inguinal hernia	Lap. vs. open	Return to daily activities	Approximate equivalence	Low
		Length of stay	Favors lap. 1.1 hours earlier (CI, 0.5 to 1.8)	Moderate
		Long-term patient/ parent satisfaction	Favors lap. Difference in satisfaction points, 1.0 (CI, 0.5 to 1.5)	Low
		Long-term cosmesis	Favors lap. Difference in satisfaction points, 0.25 (CI, 0.12 to 0.38)	Low

CI = confidence interval; lap. = laparoscopy; OPM = open preperitoneal mesh; PHS = Prolene™ Hernia System; PP = polypropylene; TAPP = transabdominal preperitoneal repair; TEP = totally extraperitoneal repair; VAS = visual analog scale; WW = watchful waiting
 Note: Conclusions in boldface are those involving a clinically significant difference between treatment options.

issue, we summarized the abstracts from non-English-language literature that might have been included for each Key Question. Another limitation of this review is that for many outcomes, the evidence was inconclusive because of low precision. Generally, the included studies were well conducted but small. We maximized the power of the data by conducting meta-analyses wherever appropriate and possible. Nevertheless, the data often precluded conclusions because they suggested contradictory conclusions (i.e., the evidence could favor option A or B by a clinically significant amount). A third limitation is that no studies met our inclusion criteria for Key Question 8 on pediatric contralateral hernia: no studies have compared surgical exploration with WW in this population. Therefore, we informally described some of the existing research in this area, such as the percentage of pediatric patients with a unilateral inguinal hernia who have a contralateral patent processus vaginalis (which is a risk factor for inguinal hernia).

Future Research Needs

We identified several gaps in the evidence in the course of conducting this review. We discuss potential areas for future research in greater detail in the full report but highlight some here that we consider particularly important.

For adult inguinal hernia, it would be helpful to know recurrence rates over the very long term. The typical patient was middle-aged, presumably with a few decades of life ahead in which a hernia might recur. Studies have generally not reported recurrence rates past 5 to 10 years, but conceivably patients and clinicians would be interested

in much longer timeframes (e.g., 30 years). Projection factors have been proposed (e.g., to estimate the 25-year recurrence rates, multiply the 1-year rate by 5); however, they have not been tested empirically. We also encourage greater focus on outcomes that matter most to patients, such as chronic pain, long-term QOL, SFN, and the feeling of a foreign body. These outcomes may be associated with the type of mesh or mesh fixation methods, or size and severity of the hernia, but our evidence review neither revealed nor ruled out potential influencing factors because of low precision.

To characterize the gaps in the overall review, we examined the 87 comparisons and outcomes for which the evidence was insufficient to permit a conclusion and determined the primary reasons for the rating of insufficient. In 31/87 cases (36 percent), the only component preventing a conclusion was imprecision. Thus, quite often, there were simply not enough studies and/or the studies had insufficient patient enrollment. In a further 51/87 cases (60 percent), there was a problem with consistency as well as precision. Problems with consistency involved either the existence of only a single study (and therefore the inability to assess consistency) or conflicting results among multiple studies. In the remaining four cases, precision was sufficient, yet there were problems with both consistency and selective outcome reporting.

Much of the existing literature on inguinal hernia has been conducted outside the United States. The differences in health care systems and practice patterns between the United States and other countries might have an impact on the applicability of the evidence from the perspectives

of U.S. stakeholders. Future U.S. studies could elucidate issues unique to the United States and describe any important differences from other health care settings.

While a surgical registry could be useful for this purpose, existing registries are limited in part because of their voluntary nature. A large registry could address the widespread problem of imprecision, mentioned above. Many randomized trials have investigated important questions, but their modest size limits their ability to detect rare events, such as hernia recurrence, which require much larger sample sizes to permit clear inferences. Registry data require sophisticated analytic techniques, such as propensity scores or instrumental variables, to reduce the impact of confounding resulting from selection bias. The registries that we assessed (e.g., Swedish Hernia Registry) were large (e.g., 143,000 hernias), but authors did not use these techniques, so it was difficult to determine the potential impact of selection bias.

Specific recommendations for future research addressing the Key Questions appear in the full report, but we highlight some of them here. For Key Question 1, there were no studies of laparoscopic repair versus watchful waiting for pain-free hernia. Furthermore, the available comparative studies in the adult population did not report long-term outcomes that could be useful for decisionmaking, such as the risk of an eventual acute presentation (e.g., strangulation, incarceration) in an unrepaired pain-free hernia, the likelihood of recurrence for a repaired pain-free hernia, or the likelihood of developing pain or impairment in function in the long term with either repair or watchful waiting. In addition, there were no studies comparing surgical repair with watchful waiting in the pediatric population (Key Question 8). In the studies comparing mesh products and fixation methods, several important outcomes were infrequently reported, such as recurrence rates, perception of a foreign body, and long-term pain and infection rates.

References

1. Nicks BA, Askew K. Hernias. In: eMedicine [online database]. Omaha, NE: eMedicine.com; 2010 Jan 25. <http://emedicine.medscape.com/article/775630-overview>. Accessed July 14, 2010.
2. Inguinal hernia: epidemiology [online database]. San Mateo, CA: Epocrates, Inc.; 2010. <https://online.epocrates.com/noFrame/showPage.do?method=diseases&MonographId=723&ActiveSectionId=23>. Accessed July 14, 2010.
3. Schneider E. Inguinal hernia. Excerpt from The 5-Minute Pediatric Consult. Health Grades Inc.; 2008. www.wrongdiagnosis.com/i/inguinal_hernia/book-diseases-20a.htm. Accessed January 26, 2011.
4. Brandt ML. Pediatric hernias. *Surg Clin North Am*. 2008 Feb;88(1):27-43, vii-viii. PMID: 18267160.
5. Rutkow IM. Demographic and socioeconomic aspects of hernia repair in the United States in 2003. *Surg Clin North Am*. 2003 Oct;83(5):1045-51, v-vi. PMID: 14533902.
6. Farley D. Professor of Surgery, Mayo Clinic, Rochester, MN. Personal communication. December 1, 2011.
7. Zhao G, Gao P, Ma B, et al. Open mesh techniques for inguinal hernia repair: a meta-analysis of randomized controlled trials. *Ann Surg*. 2009 Jul;250(1):35-42. PMID: 19561484.
8. Sherwinter DA, Lavotshkin S. Hernia inguinal repair, open: treatment & medication. eMedicine. Updated 2009 Jul 24. <http://emedicine.medscape.com/article/1534281-treatment>. Accessed January 26, 2011.
9. Jacobs DO. Mesh repair of inguinal hernias--redux. *N Engl J Med*. 2004 Apr 29;350(18):1895-7. PMID: 15107484.
10. Owens DK, Lohr KN, Atkins D, et al. Grading the strength of a body of evidence when comparing medical interventions-Agency for Healthcare Research and Quality and the Effective Health Care Program. *J Clin Epidemiol*. 2010 May;63(5):513-23. PMID: 19595577.

Full Report

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