Comparative Effectiveness Review
Number 41

Effective Health Care Program

Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness

Executive Summary

Background

Chronic pelvic pain in women is a commonly occurring and poorly understood condition. Little consensus on the definition of the condition exists—the duration of pelvic pain considered chronic in published studies varies from 3 months to more than 6 months, and the location and pathology of the pain are largely unspecified.[1] The American College of Obstetricians and Gynecologists defines chronic pelvic pain as "noncyclical pain of at least 6 months' duration that appears in locations such as the pelvis, anterior abdominal wall, lower back, or buttocks, and that is serious enough to cause disability or lead to medical care."[2] Noncyclic chronic pelvic pain (CPP) is the focus of this review. Noncyclic CPP excludes chronic pelvic pain that is limited to dysmenorrhea (pain with menstruation), dyspareunia (pain with intercourse), dyschezia (pain with bowel movement), or dysuria (pain with urination).[3,4] Noncyclic CPP is sometimes described simply as "chronic pelvic pain" in the literature because many subdivide chronic pelvic pain into dysmenorrhea, dyspareunia, and nonmenstrual CPP.[2]

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.

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For this review, we defined noncyclic CPP as pain that has persisted for more than 3 months, is localized to the anatomic pelvis (lower abdomen below the umbilicus), and is of sufficient severity that it causes the patient to become functionally disabled or to seek medical care. The chronic pelvic pain must always have a noncyclic component; however, there could also be cyclic pain in some individuals. CPP as described throughout this review refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

The causes of CPP are not well understood and may be associated with gynecologic (e.g., endometriosis) and nongynecologic (e.g., irritable bowel syndrome [IBS]) conditions. Diagnosis of an underlying cause is complicated because the pain is rarely associated with a single underlying disorder or contributing factor;[5] Howard outlined more than 60 diseases and conditions associated with CPP.[5] Frequently diagnosed etiologies include endometriosis, adhesions, IBS, and interstitial cystitis (IC)/painful bladder syndrome (PBS);[6] however, a definitive diagnosis is often not made.

Objectives

Population. We focused this review on women age 18 and older with noncyclic or mixed cyclic/noncyclic chronic pelvic pain. Throughout this review, CPP refers to noncyclic or mixed cyclic/noncyclic pelvic pain unless otherwise noted.

Interventions. Interventions included surgical approaches, such as hysterectomy and laparoscopy, and nonsurgical approaches, including medical management and integrative interventions.

Comparators. Comparators included no treatment, placebo, and comparative interventions or combinations of interventions.

Outcomes. Our outcomes of interest included:

- Pain status (reduction in pain, pain recurrence, subsequent intervention for unresolved or worsening pain)
- Functional status (activities of daily living, sexual functioning)
- Quality of life
- Patient satisfaction with pain management
- Harms or adverse effects of nonsurgical interventions

Key Questions

The Key Questions (KQs) were:

KQ1: Among women who have been diagnosed with noncyclic/mixed cyclic and noncyclic CPP, what is the prevalence of the following comorbidities: dysmenorrhea, major depressive disorder, anxiety disorder, temporomandibular joint pain disorder, fibromyalgia, IBS, interstitial cystitis (IC)/painful bladder syndrome (PBS), complex regional pain syndrome, vulvodynia, functional abdominal pain syndrome, low back pain, headache, and sexual dysfunction?

KQ2: Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of surgical interventions on pain status, functional status, satisfaction with care, and quality of life?

KQ3: What is the evidence that surgical outcomes differ if the etiology of noncyclic/mixed cyclic and noncyclic CPP is identified after surgery?

KQ4: Among women with noncyclic/mixed cyclic and noncyclic CPP, what is the effect of nonsurgical interventions on pain status, functional status, satisfaction with care, quality of life, and harms?

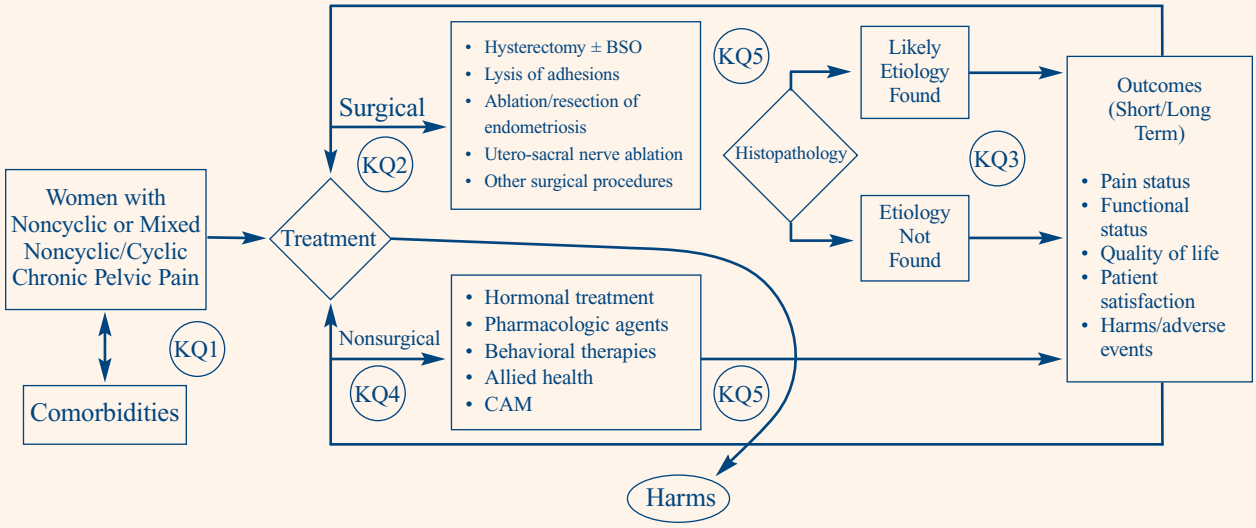
KQ5: What is the evidence for choosing one intervention over another to treat persistent or recurrent noncyclic/mixed cyclic and noncyclic CPP after an initial intervention fails to achieve target outcome(s)?

Analytic Framework

We developed the analytic framework (Figure A) based on clinical expertise and refined it with input from our Key Informants and Technical Expert Panel (TEP) members. The framework summarizes the process by which women with CPP make and modify treatment choices. Treatment choices include surgical or nonsurgical approaches and may lead to outcomes that include changes in pain status (e.g., resolution of pain, continuing pain, continued need for pain medication), patient satisfaction, quality of life, or harms/adverse effects.

Treatment choices may not provide pain relief or improvements in functional status or quality of life, and women with CPP may undergo additional interventions after a treatment approach has failed. In addition, outcomes may vary by diagnosis in those patients receiving a confirmed diagnosis for the etiology of their CPP.

Figure A. Analytic framework for therapies for women with CPP



Note: BSO = bilateral salpingo oopherectomy, CAM = comlementary and alternative medicine, CPP = noncyclic chronic pelvic pain, KQ = Key Question.

Methods

Input From Stakeholders

The topic was nominated in a public process. With Key Informant input, we drafted initial KQs, which the Agency for Healthcare Research and Quality (AHRQ) reviewed and posted to a public Web site for public comment. Using public input, we drafted final KQs, which AHRQ reviewed. We convened a TEP to provide input during the project on issues such as setting inclusion/exclusion criteria and assessing study quality. In addition, the draft report was peer reviewed and available for public comment.

Data Sources and Selection

Data sources. We searched four databases: MEDLINE® via the PubMed interface, PsycINFO (psychology and psychiatry literature), Embase Drugs and Pharmacology, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database. We hand searched reference lists of included articles and recent reviews for additional studies.

Inclusion and exclusion criteria. We excluded studies that:

- Did not include women age 18 and older with noncyclic CPP
- Did not report information pertinent to the KQs
- Were primarily focused on coexisting conditions, cancer pain, or pregnancy-related pain
- Were not published in English

- Were published prior to 1990
- Were not original research
- Were retrospective studies or case series (unless they included 100 or more participants and reported nonsurgical harms or comorbidity data)

We also excluded studies with fewer than 50 total participants if the studies assessed the effects of surgical or nonsurgical interventions, addressed differences in surgical outcomes by etiology, or presented evidence for selecting one intervention over another.

We accepted controlled trials and prospective cohort studies with at least 50 participants with CPP and case series and cross-sectional studies that had at least 100 participants with CPP and addressed nonsurgical harms or the prevalence of comorbidities identified in KQ1.

We did not address harms of surgical interventions in this review, as we felt that the studies meeting our inclusion criteria would necessarily provide only chance evidence of harms of surgical interventions. Most of the surgical interventions used for CPP are deployed in a broader context for other indications; a systematic review of the harms of the procedures would require a different and much larger search than the current review assignment, protocol, and KQs dictated. Reporting only the harms represented in the selected studies meeting our criteria for addressing surgical intervention for CPP would present only a partial picture of potential harms of surgery.

Screening of studies. Two reviewers separately evaluated each abstract. If one reviewer concluded that the article could be eligible, we retained it. Two reviewers independently read the full text of each included article to determine eligibility, with disagreements resolved via third-party adjudication.

Data Extraction and Quality Assessment

Data extraction. All team members entered information into the evidence tables. After initial data extraction, a second team member edited entries for accuracy, completeness, and consistency. In addition to outcomes for treatment effectiveness, we extracted data on harms/adverse effects.

Quality assessment. Two reviewers independently assessed quality, with differences resolved though discussion, review of the publications, and consensus with the team. We rated studies as good, fair, or poor quality and retained poor studies as part of the evidence base discussed in this review. More information about our quality assessment methods is in the full report.

Data Synthesis and Analysis

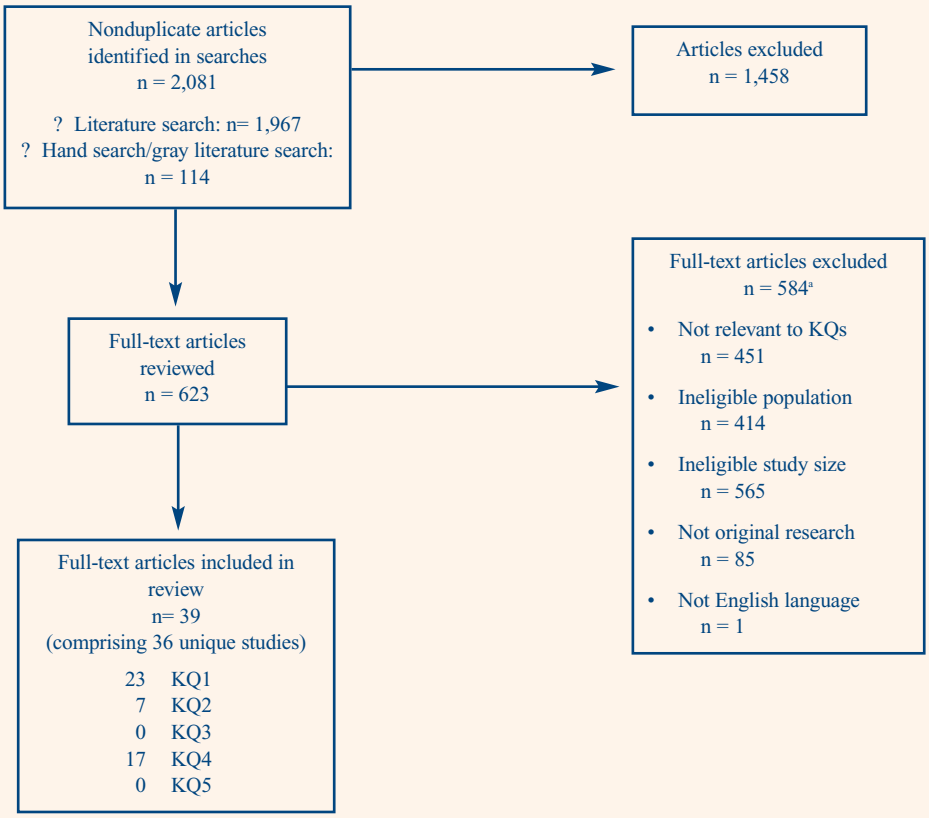
Evidence synthesis. We used summary tables to synthesize studies that included comparison groups and summarized the results qualitatively.

Strength of evidence. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence. Strength of evidence can be regarded as insufficient, low, moderate, or high. It describes the adequacy of the current research, in quantity and quality, and the degree to which the entire body of current research provides a consistent and precise estimate of effect. We established methods for assessing the strength of evidence based on AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews,[7] which is used by Evidence-based Practice Centers.

Results

Our searches retrieved 2,081 nonduplicate citations (Figure B). We reviewed the full text of 623 articles and included 39 articles, comprising 36 unique studies, in the full review. The full report details reasons for exclusion.

Figure B. Disposition of articles located for the review



[a]The total number of articles in the exclusion categories exceeds the number of articles excluded because most of the articles fit into multiple exclusion categories.

Note: KQ = Key Question; n = number.

KQ1: Prevalence of Comorbidities

We identified 23 unique studies addressing the prevalence of comorbidities of interest for this review.[8-31] Dyspareunia (11 studies), dysmenorrhea (12 studies), and IBS (10 studies) were the most frequently reported comorbidities in women with CPP, with rates ranging from 15 to 88 percent for dyspareunia, 4 to 100 percent for dysmenorrhea, and 24 to 39 percent for IBS. Rates for other comorbidities also varied widely, and studies were largely of poor quality. Studies frequently failed to use validated diagnostic criteria and may not have provided an operational definition for a given comorbidity. We did not assess the strength of evidence for studies addressing this KQ about the prevalence of comorbidities; the strength of evidence evaluation was designed for assessing effectiveness of interventions and is thus not applicable.

KQ2: Outcomes of Surgical Interventions for CPP

We located seven unique studies addressing surgical interventions for CPP: five randomized controlled trials (RCTs)[9,13,32-34] and two prospective cohort studies.[16,35] All RCTs were conducted in Europe or New Zealand, and all prospective cohort studies were conducted in the United States. Three studies compared surgical with nonsurgical or medical approaches for CPP treatment.[13,16,35] Three studies compared an active surgical technique, either laparoscopic utero-sacral nerve ablation (LUNA) or adhesiolysis, with surgical control (diagnostic laparoscopy).[9,32,33] One study directly compared two surgical techniques (LUNA vs. utero-sacral ligament resection).[34]

One good-quality RCT evaluated laparoscopic lysis of intraabdominal adhesions[32] and reported no improvement in pain scores over diagnostic

laparoscopy. Similarly, no studies reported benefit of LUNA compared with simple diagnostic laparoscopy. One poor-quality study evaluated hysterectomy for CPP pain relief compared with nonsurgical management and reported greater patient satisfaction in the hysterectomy group, although data for women with noncyclic CPP alone are difficult to isolate and participants self-selected surgical or nonsurgical intervention. We assessed the strength of evidence for all surgical interventions except LUNA and lysis of adhesions as insufficient. With two RCTs, one of fair and one of poor quality, we assessed the strength of evidence as low for the lack of efficacy of LUNA to improve pain status over diagnostic laparoscopy alone and low for the effects of adhesiolysis on pain and quality of life (one good-quality RCT).

KQ3: Evidence for Differences in Surgical Outcomes by Etiology

We did not locate any studies addressing this question.

KQ4: Outcomes of Nonsurgical Interventions for CPP

We located 17 unique studies addressing nonsurgical interventions.[8,10-16,35-44] Fourteen of these studies were RCTs, and three were prospective cohort studies. Most RCTs investigated hormone-based treatments for CPP. One evaluated antineuropathic agents, and another evaluated the neuromuscular blocking agent botulinum toxin A. Four RCTs examined nonpharmacologic therapies—pelvic floor physical therapy, photographic-enhanced counseling after surgery, pelvic ultrasonography plus counseling, and a standard versus integrated treatment approach. Cohort studies evaluated outcomes of hormone-based therapy and assessed nonsurgical compared with surgical approaches.[16,35]

Twelve of the 17 studies were performed in Europe, with the remainder conducted in the United States and Australia. Most were conducted at academic institutions. Only one study was rated as good quality,[14,15] three were fair quality,[10,36,37] and the balance were poor.[8,11-13,16,35,38-42,44]

Of the nine studies addressing hormonal treatments for endometriosis-associated CPP, all reported equal effectiveness among active agents investigated, with the exception of a placebo-controlled trial of raloxifene. This RCT reported more rapid return of pain in the raloxifene group, and the trial was stopped early.14 The few (n = 3) placebo-controlled studies were of fair or good quality and reported larger size of effect (60 to 70 percent range) than studies comparing two active agents. An RCT of botulinum toxin[36] reported some improvements in pain scores. An RCT of gabapentin plus amitriptyline or either agent alone8 reported some improvements in pain scores.

Few studies addressed nonhormonal or nonpharmacologic management. One fair-quality RCT of a pelvic physiotherapy technique reported improvement in pain scores in the treatment group; one poor-quality study reported no benefit from postoperative counseling augmented with displaying operative photographs while discussing findings with participants; and two poor-quality trials reported some benefits from an integrated treatment approach and ultrasonography plus counseling. Reporting of harms data was very limited among trials; among placebo-controlled trials, harms were more frequent in the placebo arms.

We assessed the strength of evidence for all nonsurgical interventions as insufficient, with the exception of low strength of evidence for the effects of raloxifene and depot leuprolide on pain status, both assessed in good- or fair-quality placebo-controlled trials.

KQ5: Evidence for Selecting One Intervention Over Another

We did not locate any studies addressing this question.

Discussion

Key Findings

The prevalence rates for the comorbidities we examined showed significant variation. Frequently no operational definition or diagnostic criteria for comorbidities were provided. When definitions or criteria were available, they were rarely consistent across studies. Diagnostic methods varied and included patient report of symptoms, patient report that she was given the diagnosis by a health care provider, evaluation by a health care provider, and objective diagnostic criteria.

Given that many women with CPP are treated with invasive surgical procedures, remarkably little evidence exists that supports a surgical approach to the treatment of CPP. We identified and reviewed two articles comparing nonspecific surgical approaches with nonsurgical approaches,[13,16] one study addressing hysterectomy specifically,[35] one study evaluating laparoscopic adhesiolysis at the time of diagnostic laparoscopy,[32] two articles evaluating LUNA compared with diagnostic laparoscopy,[9,33] and one paper directly comparing LUNA and utero-sacral ligament resection.[34]

In none of the studies with comparison data was surgery in general or any specific surgical technique better than either nonsurgical intervention or the comparator technique in improving pain status in patients. Given the limited number of studies addressing heterogeneous surgical interventions and with so few being of good or fair quality, it is difficult to summarize the evidence for the effect of surgical interventions on any of the outcomes proposed. Although no surgical technique emerged as a superior method for surgical intervention, the evidence is insufficient to conclude that surgical intervention is either effective or ineffective for the treatment of CPP.

Studies of nonsurgical interventions were similarly subject to significant variation in study design and interventions addressed, which detracts from the ability to apply these study results to a broader population or provide concrete estimates for clinical effect. We saw this variation in (1) definition of pelvic pain, (2) patient populations, (3) outcome measures, (4) interventions, (5) timing of outcome measures and participant followup, and (6) comparators.

Only 4 of the 17 studies included in this section had a placebo arm for comparison. All of the other studies employed active treatments as comparators. This lack of placebo comparison detracts from the active head-to-head trials because no initial validation of effect has been made. It could easily be assumed that each active intervention works simply by placebo effect, and this could explain why each hormone-based treatment seems equally effective. Many studies also included a population of patients with endometriosis; few studies include participants with CPP due to another etiology. We found the evidence insufficient to assess the effectiveness of any nonsurgical therapies for CPP.

In sum, we found that:

- Noncyclic CPP was variably defined, and diagnostic approaches were rarely reported.
- Disproportionately few studies addressed noncyclic CPP, given the prevalence of the condition.
- Comorbidities were similarly variably defined and frequently not diagnosed using standardized criteria.
- Dysmenorrhea, dyspareunia, and IBS were the most frequently reported comorbidities in the literature meeting our criteria.
- Intervention studies overall included a limited number of participants and typically included only short-term followup.
- Few studies of surgical approaches examined the same approach; none used a placebo control.
- No surgical approach was superior to a nonsurgical approach or comparative surgical approach.
- The strength of the evidence for surgical approaches overall was insufficient to low.
- Most studies of nonsurgical approaches meeting our criteria addressed hormonal approaches and included women with endometriosis-associated CPP.
- Few studies of nonsurgical interventions were placebo controlled, and few addressed nonpharmacologic approaches; strength of evidence was insufficient to low.
- Hormonal studies reported equal effectiveness among the active agents investigated, with the exception of a placebo-controlled trial of raloxifene reporting more rapid return of pain in the raloxifene group.
- Studies of nonhormonal and nonpharmacologic agents reported some positive effects on pain status.
- Few nonsurgical studies reported harms.
- No studies addressed evidence for differences in outcomes by etiology or evidence for selecting one intervention over another if an intervention failed.

- Studies overall addressed a heterogeneous group of interventions and likely had significant variability across populations.

Applicability of Evidence

We set inclusion criteria intended to identify studies with applicability to women with noncyclic or mixed chronic pelvic pain. Studies differed considerably in terms of study populations, interventions, and outcome measures. Many of the studies were noncomparative.

Lack of direct comparisons of treatment options further hinders our ability to know what findings will best extend to a specific patient or to decide about care protocols within clinics or health systems. Overall the data that are available have fair to good applicability to women with noncyclic/mixed CPP in settings within the United States, although many studies were conducted in specialty treatment centers. In the nonsurgical literature, many studies included women with endometriosis-associated CPP.

Gaps in the Evidence and Methodologic Concerns

Despite a prevalence of noncyclic CPP rivaling that of widely studied conditions such as asthma,[45] little research assessing therapies exists. While there are many publications regarding pelvic pain in general, there are relatively few addressing noncyclic CPP, and of those, few were evaluated as providing high-quality evidence. Eighteen of 36 studies meeting our criteria were RCTs; however, only 4 were placebo controlled.[10,14,36,44] Some surgical studies compared a surgical approach with diagnostic laparoscopy or compared surgical with nonsurgical management. In the nonsurgical literature, most studies compared active agents with active agents, and a number addressed hormonal therapies for endometriosis-associated CPP.

The quality of studies providing data about the prevalence of comorbidities varied by comorbidity, with the bulk of studies assessed as poor quality. Among studies reporting data on the prevalence of comorbidities, the range of prevalence estimates tended to be more narrow in studies that employed validated diagnostic criteria (e.g., Rome criteria for IBS), and studies using validated criteria were of higher quality.

The literature overall is muddled by a lack of standardized definitions for CPP and unclear diagnostic evaluation, which make it difficult to determine whether studies truly include women with CPP. Systematic reviews of the effectiveness of interventions for a symptom or syndrome are fraught with difficulty; the lack of specific diagnostic criteria results in heterogeneity within and across studies. In order to effectively treat any chronic pain, one would assume that a thorough diagnostic investigation would first take place. For many conditions, this typically follows some predetermined algorithm. However, for CPP, no such algorithm exists. Thus, in each study (and likely for each individual practitioner), the patient is approached in a variable manner, and some possible diagnoses may or may not be ruled out before treatment begins. There is no assurance that the treated condition is the causative condition. Treating a symptom means that a study group will likely have a variety of etiologies; some may be amenable to the intervention under study, others may not. Compared with an intervention trial that follows established diagnostic criteria and targets an identified condition, dilution of potential benefits and harms may occur.

Future Research

Research addressing therapies for CPP is largely composed of trials of active agents or approaches, with little placebo-controlled research and little evidence of thorough identification of patient characteristics and potential etiologies of CPP. Notably, we did not locate any studies providing evidence that surgical outcomes differ if the etiology of CPP is identified after surgery (KQ3). We did not locate any studies providing evidence for choosing one intervention over another to treat persistent or recurrent CPP after an initial intervention failed to achieve the target outcome(s) (KQ5). Future research needs include:

- Developing our understanding of the etiology of CPP, including analysis of the distribution of underlying causes (including iatrogenic causes); identification of subgroups at risk of developing CPP; understanding of myofascial dysfunction and visceral hyperplasia in CPP; and assessing the effects of sex steroid hormone levels on pain perception

- Understanding the impact of CPP on health care costs and resource utilization
- Standardizing terminology and definitions in CPP research and research investigating related comorbidities
- Formalizing and standardizing diagnostic approaches to promote clear delineation of patient populations in CPP research
- Standardizing outcome measures
- Investigating nonsurgical and nonpharmacologic approaches to CPP treatment, including acupuncture, psychotherapy, cognitive behavioral therapy, and patient education
- Assessing nonhormonal pharmacologic therapies
- Comparing surgical and nonsurgical approaches in prospective studies
- Investigating the benefit of surgical approaches, including understanding patient populations likely to benefit, timing of intervention, and potential therapeutic benefits of diagnostic laparoscopy
- Employing placebo controls and improving methodologic rigor in studies

Conclusions

Improved characterization of the targeted condition, intervention, and population in CPP research is necessary to inform treatment choices for this commonly reported entity. A uniform definition of CPP and standardized evaluation of participants are lacking across the literature; study populations are likely to vary widely, and studies may be reporting effects from treating symptoms rather than a diagnosed condition. Thus, our understanding of potential treatment effects is diluted. Similarly, understanding comorbidity prevalence with CPP is difficult, as a condition may be considered part of the differential diagnosis or a concomitant condition. Among studies addressing treatment effects, little evidence demonstrates the effectiveness of surgical approaches. Despite numerous surgical techniques used extensively in treating CPP, few studies included more than 50 participants, and few were considered high quality. All of the studies with comparison data failed to demonstrate that surgery in general or any specific surgical technique was more efficacious than either nonsurgical intervention or the comparator technique in improving pain status in patients. No surgical technique was superior, and the evidence to conclude that surgical intervention is either effective or ineffective for the treatment of CPP is insufficient.

Studies of nonsurgical approaches typically addressed hormonal management of endometriosis-related CPP and were not placebo controlled, thus limiting our ability to understand whether hormonal therapies would be beneficial for women with CPP without endometriosis and whether pain relief reported is due simply to the placebo effect. Some studies reported benefits of other nonsurgical approaches, but nonhormonal and nonpharmacologic management remains understudied.

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