



Topic Brief: Chronic Pelvic Pain Syndrome in Men

Date: 7/6/2021

Nomination Number: 0951

Purpose: This document summarizes the information addressing a nomination submitted on May 18, 2021 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: There are currently inconsistencies in the treatment of chronic pelvic pain syndrome (CPPS) in men. Further, there are no contemporary guidelines specifically tailored to men with CPPS. The American Urological Association requests the development of a new systematic review, which would be used to create a guidance document that would advise practitioners regarding the evaluation and treatment of CPPS in men.

Program Decision:

The scope of this topic met all EHC Program selection criteria and was considered for a systematic review. However, it was not selected.

Key Findings

- We found two Cochrane systematic reviews with older search dates for which the nominators requested an updated systematic review be conducted.
- We found 17 studies addressing nonpharmacological interventions published after the August 2017 search end date of the published systematic review on nonpharmacological interventions. We found six studies addressing pharmacological interventions published since the July 2019 search end date of the published systematic review on pharmacological treatments for CPPS.
- Our search methods provide a comprehensive picture of existing studies that would be included in an update of the nonpharmacologic and pharmacologic treatments of chronic pelvic pain syndrome in men, and we project an updated systematic review to be limited in size. If AHRQ chooses to commission a de novo systematic review the size would be large.
- Through communication with the authors of the existing systematic reviews on nonpharmacological and pharmacological interventions, we learned that they are conducting routine surveillance for new studies and do not feel the need for an update at this time.

Background

Chronic pelvic pain syndrome (CPPS) in men is a chronic pain disorder characterized by pain located primarily in the perineum, testes, suprapubic area, and penis.¹ CPPS has a worldwide prevalence between 2 and 16 percent.² The condition has a significant impact on quality of life to the degree that it can be compared to other diseases such as diabetes mellitus, Crohn's disease,

angina, and myocardial infarction.³ Additionally, the economic costs associated with this disease compare with or surpass the annual direct costs associated with other common chronic diseases such as peripheral neuropathy, fibromyalgia, lower back pain, and rheumatoid arthritis.⁴

Etiology and effective treatment for this condition have not been firmly established.⁵ Additionally, there is a lack of formal evidence-based guidance in this topic area, as guidelines are more often directed toward women.^{6,7} At present, there is a clinical practice guideline produced by the European Association of Urology (EAU) on CPPS that covers both female and male pelvic pain and is based on a scoping review conducted in 2017.⁸ An updated guideline specifically for men would help to inform appropriate treatment for CPPS.

Nomination Summary

We found two existing Cochrane systematic reviews that address nonpharmacological⁹ and pharmacological¹⁰ interventions, respectively. Because the search end dates for these reviews were August 2017 and July 2019, respectively, the nominators requested a new systematic review that would serve as an update to these existing reviews.

Scope

Key Questions:

- 1) For men suffering from chronic pelvic pain syndrome (CPPS):
 - a. What are the effectiveness and harms of treatments?
 - b. What are the comparative effectiveness and harms of treatments?
 - c. How does the effectiveness and harms of treatments vary by patient characteristics?

Contextual Questions:

1. Describe how patient preferences influence the choice of treatment for chronic pelvic pain in men.
2. Describe the different approaches for diagnostic assessment and monitoring of chronic pelvic pain in men.

Table 1. Questions and PICOs (population, intervention, comparator, outcome)

Questions	1. Effectiveness and harms of treatment
Population	Male adults (≥ 18) with CPPS (including prostatitis/chronic pelvic pain syndrome; chronic prostatodynia/prostate pain syndrome; chronic orchialgia, orchidynia, testalgia, scrotal contents pain, chronic scrotal pain, or chronic testicular pain) that includes physical pain and may also include voiding symptoms, and/or sexual dysfunction, and is not due to infection KQ1c: Consider patient characteristics (e.g., age, socioeconomic factors, comorbidities, etc.)
Interventions	Any treatment, such as: Lifestyle changes (e.g., diet, exercise); Physical therapy; Psychotherapy; Pharmacotherapy (e.g., alpha adrenergic antagonist, antibiotics, pain relievers (NSAIDs), antidepressants, 5-alpha reductase inhibitor, onabotulinumtoxin A);

	<p>Surgical interventions (e.g., transurethral microwave thermotherapy, transurethral resection of the prostate, prostatectomy, transrectal high-intensity focused ultrasound, transurethral needle ablation of the prostate);</p> <p>Other therapies (e.g., extracorporeal shock wave therapy, neurologic treatments/neuromodulation, acupuncture, nerve blocks);</p> <p>Combination treatments</p>
Comparators	<p>KQ1a: Placebo; combination treatments; no comparator</p> <p>KQ1b: Other treatment; other treatment combinations</p>
Outcomes	<p>Symptom relief (e.g., UPOINT score, National Institutes of Health-Chronic Prostatitis Symptom Index, physical exam)</p> <p>QOL and psychological measures</p>

Abbreviations: CPPS= chronic pelvic pain syndrome; NSAID=non-steroidal anti-inflammatory drug; UPOINT=urinary, psychosocial, organ-specific, infection, neurologic/systemic, tenderness of pelvic floor skeletal muscles; QOL= quality of life.

See Appendix A.

Summary of Literature Findings

We found two existing high-quality systematic reviews that address nonpharmacological⁹ (38 studies) and pharmacological¹⁰ (99 studies) interventions, respectively. Since the search end dates for these reviews were August 2017 and July 2019, respectively, the nominators requested a systematic review that would serve as an update to these existing reviews.

We then searched for primary studies of nonpharmacological interventions published between 2017 and date of the search, and studies of pharmacological interventions between 2019 and the date of the search. In total, we found 17 studies of nonpharmacological interventions and six studies of pharmacological interventions. Below, the studies are grouped by pharmacological category, and then by comparable treatment group type.

Nonpharmacological studies (n=17):

- 6 nutraceutical
 - 2 flower pollen extract^{11, 12}
 - 1 curcumin and calendula extracts¹³
 - 1 Boswellia resin extract and propolis derived polyphenols¹⁴
 - 1 essential oils¹⁵
 - 1 Proxelan-blend of herbs for topical soothing of anorectal canal¹⁶
- 3 extracorporeal shock wave therapy¹⁷⁻¹⁹
- 4 acupuncture²⁰⁻²³
- 1 psychological²⁴
- 1 sono-electro-magnetic therapy²⁵
- 1 thermotherapy²⁶
- 1 laser²⁷

Pharmacological studies (n=6):

- 2 including alpha-blockers^{28, 29}
- 1 dapoxetine³⁰
- 1 onaBoNT-A (200 U)³¹
- 1 Tadalafil³²
- 1 injections of lidocaine plus dexamethasone and traumeel³³

Since the entire search yield for primary studies, rather than a sample, was reviewed, and because the search included the time period since the end of the searches for the reviews being updated, these studies are a reasonable representation of relevant studies. Given this relatively small yield, we are recommending that a limited systematic review update be conducted.

Table 2. Literature identified for each Key Question

Question	Systematic reviews (7/2018-7/2021)	Primary studies (7/2017-7/2021)
Effectiveness and harms of treatment	Total: 0	Total: 23 includes out of 85 studies found <ul style="list-style-type: none"> • RCT: 8 • Pre-post: 6 • Non-randomized controlled: 8 Clinicaltrials.gov <ul style="list-style-type: none"> • Recruiting: 1

Abbreviations: RCT=randomized controlled trial.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

There is a lack of current guidelines for treatment of chronic pelvic pain syndrome in men. The nominators have requested a systematic review in order to inform the development of contemporary guidelines for treatment of the condition. We found a small body of studies that could serve to inform a limited systematic review that would update two existing Cochrane systematic reviews on pharmacological and nonpharmacological interventions, respectively; or a de novo large systematic review.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years July 15, 2018 – July 15, 2021 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
 - AHRQ Evidence Reports <https://www.ahrq.gov/research/findings/evidence-based-reports/index.html>
 - EHC Program <https://effectivehealthcare.ahrq.gov/>
 - US Preventive Services Task Force <https://www.uspreventiveservicestaskforce.org/>
 - AHRQ Technology Assessment Program <https://www.ahrq.gov/research/findings/ta/index.html>
- US Department of Veterans Affairs Products publications
 - Evidence Synthesis Program <https://www.hsrd.research.va.gov/publications/esp/>
 - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program <https://www.healthquality.va.gov/>
- Cochrane Systematic Reviews <https://www.cochranelibrary.com/>
- University of York Centre for Reviews and Dissemination database <https://www.crd.york.ac.uk/CRDWeb/>
- PROSPERO Database (international prospective register of systematic reviews and protocols) <http://www.crd.york.ac.uk/prospero/>
- PubMed <https://www.ncbi.nlm.nih.gov/pubmed/>
- PCORI <https://www.pcori.org>
- Epistemonikos <https://www.epistemonikos.org>

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a literature search in PubMed from the end date of the searches conducted by the authors of the two systematic reviews that we sought to update, 2017-July 15, 2021. We reviewed all identified titles and abstracts for inclusion and classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

Search strategy

("chronic prostatitis"[Title/Abstract] OR "chronic pelvic pain syndrome"[Title/Abstract] OR "chronic prostatitis/chronic pelvic pain syndrome"[Title/Abstract]) AND

("therapy"[Title/Abstract] OR "treatment"[Title/Abstract] OR "treating"[Title/Abstract])) OR
"prostatitis/therapy"[MeSH Terms]
AND
"adult"[MeSH Terms:noexp] AND "male"[MeSH Terms] AND "humans"[MeSH Terms] AND
"english"[Language]
AND
("groups"[Title/Abstract] OR "trial"[Title/Abstract] OR "randomly"[Title/Abstract] OR "drug
therapy"[MeSH Subheading] OR "placebo"[Title/Abstract] OR "randomized"[Title/Abstract] OR
"controlled clinical trial"[Publication Type] OR "randomized controlled trial"[Publication Type])
AND (y_5[Filter])

((("chronic prostatitis"[Title/Abstract] OR "chronic pelvic pain syndrome"[Title/Abstract] OR
"chronic prostatitis/chronic pelvic pain syndrome"[Title/Abstract]) AND
("therapy"[Title/Abstract] OR "treatment"[Title/Abstract] OR "treating"[Title/Abstract])) OR
"prostatitis/therapy"[MeSH Terms]
AND
"adult"[MeSH Terms:noexp] AND "male"[MeSH Terms] AND "humans"[MeSH Terms] AND
"english"[Language]
AND
((((("Cohort Studies"[Mesh]) OR "Controlled Clinical Trial"[Publication Type]) OR "Case-
Control Studies"[Mesh])) OR (("Evaluation Studies"[Publication Type]) OR "Comparative
Study"[Publication Type])) OR (("Comparative Study"[Publication Type]) OR "Follow-Up
Studies"[Mesh])

[Clinical Trials link](#)

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the US?	Yes.
1b. Is the nomination a request for an evidence report?	Yes.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. CPPS has a worldwide prevalence between 2% and 16%. ²
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. The condition has a significant impact on QoL that can compare to other diseases such as diabetes mellitus, Crohn's disease, angina, and myocardial infarction. ³
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. The economic costs associated with this disease compare with or surpass the annual direct costs associated with other common chronic diseases such as peripheral neuropathy, fibromyalgia, lower back pain, and rheumatoid arthritis. ⁴
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes. Existing systematic reviews on pharmacological and nonpharmacological interventions, respectively, are older and the nominator has requested an updated systematic review.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes. There are no contemporary guidelines specifically tailored to men with CPPS.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes. There are currently inconsistencies in the treatment of CPPS in men.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	Total: 23 includes out of 85 studies found <ul style="list-style-type: none"> • RCT: 8 • Pre-post: 6 • Non-randomized controlled: 8 Clinicaltrials.gov Recruiting: 1

	The estimated size of a new SR update would be limited. The estimated size of a de novo SR would be large.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes. The American Urological Association plans to develop an evidence-based guideline informed by a new SR.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; CPPS=chronic pelvic pain syndrome; SR=systematic review; QoL=quality of life; RCT=randomized controlled trial; US=United States.