Topic Brief: Pelvic Organ Prolapse

Date: 12/12/2019
Nomination Number: 891

Purpose: This document summarizes the information addressing a nomination submitted on 11/1/2019 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: Pelvic organ prolapse is a common benign problem among women, which is often underreported. The nominator requests an evidence review to determine the effectiveness and harms of screening for pelvic organ prolapse (POP) during routine pelvic exams. The report would be used to advocate for clinical practice changes, clinician education, and health care policies.

Program Decision: The EPC Program will not develop a new systematic review because we found two systematic reviews addressing the scope of this nomination.

Key Findings: We found two recent, high quality systematic reviews that cover the scope of this nomination. Neither review found primary research on screening for POP in asymptomatic women. Three recent guidelines are based on expert opinion.

Background

Pelvic organ prolapse (POP) is a common, benign anatomical finding in women. POP occurs when one or more aspects of the vagina and uterus descend, which allows nearby organs to herniate into the vaginal space. This may be termed cystocele, rectocele, or enterocele. Mild POP on physical exam is common and not considered pathologic. Treatment is indicated only if prolapse is causing bothersome bulge and pressure symptoms, sexual dysfunction, or difficulty with urination or defecation. [1]

Some estimate that 30-45 % of adult women have physical signs of pelvic organ prolapse; however, only 3 to 25% of these report any symptoms. Since treatment (conservative or surgical) is driven by women's symptoms and preferences, there is concern that stigma and lack of awareness by patients and providers may lead many women to suffer in silence. Also, there has been a decrease in POP surgeries following the 2011 FDA warnings about the safety of mesh used in some POP procedures.[2]

In current clinical practice, three recent guidelines recommend that the initial evaluation for a woman with suspected POP include a thorough history, assessment of symptom severity, physical examination, and goals for treatment. [3-5]

The nominator intends to use the report to help them advocate for standardized POP screening, improved clinician education, and policy changes.

Scope

1. What is the comparative effectiveness of screening for pelvic organ prolapse (POP) during routine pelvic exams?
2. What are the comparative harms of screening for pelvic organ prolapse (POP) during routine pelvic exams?
3. What are the test performance characteristics of the pelvic examination or other tools (i.e., sensitivity, specificity, positive and negative predictive values) in screening for pelvic organ prolapse?

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing and setting)

Key Questions	**1. Comparative effectiveness**	**2. Comparative harms**	**3. Accuracy of screening tests**
Population	Nonpregnant women age 18 years and older undergoing routine pelvic examination without symptoms related to pelvic organ prolapse	Nonpregnant women age 18 years and older undergoing routine pelvic examination without symptoms related to pelvic organ prolapse	Nonpregnant women age 18 years and older undergoing routine pelvic examination without symptoms related to pelvic organ prolapse
Interventions	Screening for POP	Screening for POP	Screening for POP
Comparators	Usual care	Usual care	Usual care
Outcomes	Quality of life Satisfaction Relief of symptoms	Unnecessary diagnostic workup Unnecessary treatment Physical pain/discomfort Psychological harms (e.g. Anxiety)	Sensitivity Specificity Positive predictive value Negative predictive value

Key Questions	1. Comparative effectiveness	2. Comparative harms	3. Accuracy of screening tests
Timing	Any	Any	Any
Setting	Primary care outpatient settings (or similar settings that are applicable to primary care)	Primary care outpatient settings (or similar settings that are applicable to primary care)	Primary care outpatient settings (or similar settings that are applicable to primary care)

Assessment Methods

See Appendix A.

Summary of Literature Findings

- We found two recent, high quality systematic reviews that cover the scope of this nomination. [6, 7] Additionally, neither of these reviews found primary research on screening for POP in asymptomatic women.
- Three recent guidelines by NICE, AUGS/ACOG and AAFP are based on expert opinion.[3-5] These three concur that screening is not indicated; that a standard history and physical be performed if POP is detected in asymptomatic women or suspected in a woman with symptoms; and that treatment is only indicated for those with bothersome symptoms.

Table 2. Literature identified for each Question

Question	Systematic reviews (10/2016 to 10/2019)
Question 1.: Comparative effectiveness	Total: 2 • AHRQ-1 [6] • Other- 1 [7]
Question 2: Comparative harms	Total: 2 • AHRQ-1 [6] • Other- 1 [7]
Question 3: Accuracy of screening tests	Total: 2 • AHRQ-1 [6] • Other- 1 [7]

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

Summary of Selection Criteria Assessment

Although POP affects many women, and thus is an appropriate and important topic, a new systematic review is not desirable at this time. Three recent systematic reviews are available, and these found very little primary evidence for screening asymptomatic women for POP.

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

Related Resources

We identified additional information in the course of our assessment that might be useful.

- A recent systematic review found no benefit for screening women for urinary incontinence, which is one of the symptoms related to POP.[12]
- Pelvic Floor Disorders: https://www.nichd.nih.gov/health/topics/pelvicfloor/conditioninfo/default
- We found one protocol in PROSPERO: ***How is the process of making diagnostic decisions about the female pelvic organ prolapse?*** This is based in Spain, and slated to start in September 2019. Detailed Key questions and comparators are well not described, and the review may focus on diagnostic criteria rather than screening.

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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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 October 2016 to October 2019 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/
- Cochrane Systematic Reviews https://www.cochranelibrary.com/
- 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/
- Joanna Briggs Institute http://joannabriggs.org/

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 U.S.?	Yes. Pelvic exams are readily available in the US.
1b. Is the nomination a request for an evidence report?	Yes, comparative effectiveness of screening for POP.
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	The prevalence of POP based on reported symptoms of vaginal bulging is much lower (3–6%) than the prevalence identified by examination (41–50%) [8] This discrepancy likely occurs because many women with POP are asymptomatic. Supporting this, among Medicaid beneficiaries with POP (defined by claims data), only 25% had surgical or pessary treatment.[9] In one study that monitored women with symptomatic, untreated POP, 78% had no change in the physical signs of prolapse over 16 months [10] Despite these reassuring data, there are approximately 300,000 POP surgeries each year in the United States, which equates to about a 13% lifetime risk of undergoing surgery for POP [11] Many are concerned that these numbers will increase as the population ages.
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	Since treatment is driven by women's symptoms and preferences, there is concern that stigma and lack of awareness by patients and providers may lead many women to suffer in silence.
2c. Incorporates issues around both clinical benefits and potential clinical harms	Also, there has been a decrease in POP surgeries following the 2011 FDA warnings about the safety of mesh used in some POP procedures.[2]
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	No.
3. Desirability of a New Evidence Review/Absence of Duplication	

Selection Criteria	Assessment
3. A recent high-quality systematic review or other evidence review is not available on this topic	No, we found two recent systematic reviews. • The USPSTF reviewed the benefits/harms and test performance of routine pelvic exam to detect any gynecologic condition (including POP, ovarian masses, and sexually transmitted infections) in asymptomatic non-pregnant women. This covered all 3 KQ, in the same population as our KQ.[6] Search dates were inception till January 2016.They found no primary literature on POP. The USPSTF concluded that there was insufficient evidence on the benefits of screening for any gynecologic condition with a pelvic exam. • NICE reviewed the benefits, harms, and test performance of a specialized exam for POP compared to usual care. They included asymptomatic as well as symptomatic and pregnant women. [7] They found only 5 studies of POP in the 4-decade search window. Four of these included only symptomatic women, one included asymptomatic pregnant women. Reviewers concluded that there was insufficient evidence on the benefits of screening for POP. NICE search dates were inception till October 2017, and studies were not limited to the UK. NICE concluded that there was insufficient evidence to recommend screening for POP in either symptomatic or asymptomatic women.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; POP-pelvic organ prolapse; FDA= Food and Drug Administration; NICE=National Institute for Health and Care Excellence; USPSTF=United States Preventive Services Task Force; UK=United Kingdom