Effective Health Care

Midurethral Slings for Urinary Incontinence

Results of Topic Selection Process & Next Steps

The nominator, the American Urogynecologic Society (AUGS) is interested in using a new systematic review that includes observational data to inform research efforts and priorities regarding the use of midurethral slings, as well as to update the AUGS clinical guidelines and quality outcome measures. Due to limited program resources, the program is unable to develop a review at this time. No further activity on this topic will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Name: Midurethral Slings for Urinary Incontinence

Topic #: 0686

Nomination Date: 06/27/2016

Topic Brief Date: March 2017

Authors:
Mark Helfand
Kara Winchell
Jennifer Gilbert
Rose Revelo

Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report. Dr. Helfand has a financial relationship with a law firm that is involved in litigation on vaginal slings, but is not involved in any work related to that litigation.

Summary of Key Findings:

- Appropriateness and importance: The nomination is both appropriate and important.
- Duplication: An evidence review on the topic would not be duplicative. There were no evidence reviews addressing key questions 1a (new RCTs on the benefits and harms of midurethral slings) and 3 (subgroups of women who are higher or lower risk for complications). Most importantly, the identified evidence reviews do not primarily focus on long-term observational data, which is what the nominator desires.
- Impact: Unclear. A new systematic review could potentially address the uncertainty raised by the nominator, but only if it includes observational study data, such as regulatory data, with long-term outcomes including harms.
- Feasibility: The feasibility of an AHRQ evidence review on this topic is uncertain due to lack of regulatory data (see below)
    - *Size/scope of review:* The size of the randomized trial literature through 2014 is well-characterized in a Cochrane review.[2] We estimate that approximately 15 relevant trials have been published since then. We identified

approximately 25 relevant observational studies would be included in the review.
    - *Regulatory data:* An additional feasibility concern is the ability to access to all pre- and post-marketing safety data for a comprehensive review, which may not be publicly available. Efforts to obtain and analyze this data will likely be highly resource-intensive.
- Value: The value of this topic is unclear. An AHRQ review could have limited value considering the FDA safety communications about vaginal mesh, as well as the litigation regarding mesh.

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Introduction

Stress incontinence of urine is a common condition. Exercise, lifestyle change, physical therapy, biofeedback, medications, devices, injections, and other measures are used to treat stress incontinence. A 2012 AHRQ review synthesized the evidence about non-surgical treatments for urinary incontinence.

Surgery is used for selected patients with stress incontinence. Most surgical approaches fall into two categories: bladder neck suspension procedures and slings. "Traditional surgery" for pelvic organ prolapse (POP) uses sutures to suspend the bladder neck (colposuspension). It may be done laparoscopically or in an open procedure. Slings support the urethra and keep it closed to prevent leakage of urine.

Different sling procedures are classified by location (eg, retropubic, transobturator), approach, type of incision, and the materials used. Surgical mesh has been used in stress incontinence surgery since at least the 1990's. For example, mesh tapes include "tension-free vaginal tape" (introduced in 1996) and "transobturator tape" (2001). Most commonly, it is made of non-absorbable synthetic compounds such as polypropylene or polyester, but slings can also be made from absorbable material and may be made from the patient's own tissues.

In 2008, the FDA issued a public health notification to inform clinicians of adverse effects related to urogynecologic use of surgical mesh.[3] The most common use was for stress urinary incontinence repairs. The 2008 statement said that serious adverse events were rare. In 2011 the FDA issued a report on the "safety and effectiveness of transvaginal placement for pelvic organ prolapse (POP)" that said serious adverse events "are NOT rare" and that "transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair."[4] In 2012 the FDA issued a requirement that manufacturers conduct new clinical trials to assess the risk of serious adverse events.[5] In 2014, the FDA proposed increasing regulatory requirements for surgical mesh for transvaginal pelvic organ prolapse repair (that is, reclassification from a class II to a class III device).[5] The accompanying document cited systematic reviews concluding that the incidence of mesh exposure is 10.3% within 12 months of surgery.[6] Mesh exposure, or erosion of the mesh so that it can be seen through the vaginal epithelium, causes other complications and frequently requires reoperation. The FDA also cited systematic reviews of the effectiveness of vaginal mesh kits, noting the lack of long-term studies indicating an advantage over traditional surgery.

Over 300,000 lawsuits involving vaginal mesh have been filed, involving products from 8 device manufacturers.[7] The nominator asserts that since these concerns about adverse events from the use of mesh for POP, the number of surgical mesh manufacturers in the US is now limited. The nominator is concerned that only RCT data is included in most evidence reviews, and does not include important observational data. RCT data on midurethral slings does not typically record long-term outcomes data, and therefore sheds a negative light on the operation. The nominator asserts that long-term observational data, especially regarding harms, could provide useful information to balance the data from RCTs. The nominator believes that a new systematic review that includes observational data could inform decision-making by alleviating unfounded concerns about vaginal mesh by clinicians, patients, and those that manufacture surgical mesh for urogynecologic procedures.

Topic nomination #0686 was received on June 27, 2016. It was nominated by the American Urogynecologic Society (AUGS). The questions for this nomination are:

Key Question 1. What are the long-term outcomes of midurethral slings in women with stress incontinence? Outcomes of interest include symptoms, functional status, and quality of life.

Key Question 1a. In controlled trials, what are the relative benefits and harms of midurethral sling operations versus other treatments?

Key Question 2. How frequent and severe are complications of midurethral sling operations?

Key Question 3. Are there subgroups of women who are at higher or lower risk of complications?

The nominator is particularly interested in observational data about the long-term outcomes of surgery (KQ1) to inform the assessment of long-term benefits and harms. We separated this question from the comparative effectiveness question of which procedures (or no procedure) has the best outcomes (KQ 1a). This separation allows us to estimate the observational and randomized literatures for shorter and long-term outcomes.

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, outcomes (PICOs) of interest. See Table 1. For KQ1, the outcomes overlap those of the AHRQ report on nonsurgical treatment for urinary incontinence, but patients would be those who have failed nonsurgical treatments and comparators include nonsurgical controls as well as patients who undergo traditional surgery.

Table 1. Key Questions and PICOs

Key Question	1. What are the long-term outcomes of midurethral slings in women with stress incontinence?	1a. In controlled trials, what are the relative benefits and harms of midurethral sling operations versus other treatments?	2. How frequent and severe are complications of midurethral sling operations?	3. Are there subgroups of women who are at higher or lower risk of complications?
Population	Women with stress incontinence who have failed nonsurgical treatments	Women with stress incontinence who have failed nonsurgical treatments	Women who had a midurethral sling operation	Women who had a midurethral sling operation; subgroups include age, weight, previous surgery and obstetric history, and urodynamic parameters.
Intervention	Midurethral sling operation	Midurethral sling operation	Midurethral sling operations	Midurethral sling operation
Comparators	Nonsurgical controls, traditional surgery	Nonsurgical controls, traditional surgery	Traditional surgery	Traditional surgery
Outcomes	Continence, functional status, and quality of life	Continence, functional status, and quality of life, mesh exposure, pelvic pain, dyspareunia	Mesh exposure, pelvic pain, dyspareunia, reoperation rate, bladder/vaginal perforation, hematoma, bladder erosions, vaginal erosion, urinary tract infection	Mesh exposure, pelvic pain, dyspareunia, reoperation rate, bladder/vaginal perforation, hematoma, bladder erosions, vaginal erosion, urinary tract infection

Methods

To assess topic nomination *0686 Midurethral Slings for Urinary Incontinence* for priority for a systematic review or other AHRQ EHC report, we used a modified process based on established criteria. Our assessment is hierarchical in nature, with the findings of our assessment determining the need for further evaluation. Details related to our assessment are provided in Appendix A.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance (see Appendix A).

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews pertaining to the key questions of the nomination. Table 1 includes the citations for the reviews that were determined to address the key questions. Appendix B includes the list of the sources searched and potentially relevant titles identified by our research librarian.

Impact of a New Evidence Review

The impact of a new evidence review was assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was hypothetically 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 July 2011 to July 2016. We reviewed all identified titles and abstracts for inclusion and classified identified studies by study design, to assess the size and scope of a potential evidence review. We also conducted additional searches for cohort studies, then selecting potentially relevant articles. The results of these searches are included in Appendix C and in the detailed feasibility results. See Table 1, *Feasibility Column, Size/Scope of Review* section for the citations of included studies.

Value

We assessed the nomination for value (see Appendix A). We considered whether or not the topic would inform clinical policy in community and/or clinical settings, and if there was a partner organization that would use this evidence review to do disseminate this policy.

Compilation of Findings

We constructed a table outlining the selection criteria as they pertain to this nomination (see Appendix A).

Results

Appropriateness and Importance

This is an appropriate and important topic. A review comprised of long-term, primarily-observational data would aid in a more balanced look at these controversial devices, especially during this time of constant medical litigation.

Desirability of New Review/Duplication

A new evidence review examining midurethral slings would not be duplicative of an existing product. No evidence reviews were identified for key questions 1a (new RCTs on the benefits and harms of midurethal slings) and 3 (subgroups of women who are at a higher or lower risk of complications). A search for key question 1, pertaining to long-term outcomes of midurethral slings, resulted in four Cochrane reviews[2,8-10] and one evidence summary from the United Kingdom's Department of Health's Chief Medical Officer.[1] We identified two reviews[1,4] examining frequency and severity of complications of midurethral sling operations, including an FDA report.[4] Most importantly, these evidence reviews do not focus primarily on long-term observational data, which is what the nominator wishes to see. See *Table 1, Duplication* column for the systematic review citations that were determined to address the key questions.

Impact of a New Evidence Review

The impact of a new evidence review on midurethral slings for urinary incontinence is currently unclear. A new systematic review which includes observational study data with long-term outcomes including harms could potentially address this uncertainty. Furthermore it is not clear if a new AHRQ systematic review could inform the concern raised in the nomination about decision-making by mesh manufacturers as they may have other concerns such as regulation, litigation, and other market considerations.

Feasibility of a New Evidence Review

A feasibility of a new evidence review is uncertain due to the need to access and include regulatory data (see below).

Size/scope of review:

Our search of PubMed resulted in 16 observational studies and 21 RCTs relevant to the key questions. The observational studies covered physical activity, continence, sexual functioning, urethral mobility, levels of satisfaction, pain, body mass index, and lifestyle factors, among other long-term outcomes, after midurethral device surgery.[11-26] The RCTs primarily studied various operations and devices, including midurethral slings, pubovaginal slings, vaginal tape, transobturator slings, mini-slings, laparoscopic mesh, and adjustable single-incision slings.[27-47] See *Table 1, Feasibility* column for the citations that were determined to address the key questions. Our search for ongoing or recently completed clinical trials yielded zero relevant results.

Table 1. Key questions with the identified corresponding evidence reviews and original research

Key Question	Duplication (Completed and in-process evidence reviews)	Feasibility (Published and Ongoing)
KQ 1: Long-term outcomes	Total number of completed or in-progress evidence reviews – 5 • Cochrane – 4[2,8-10] • MHRA – 1[1]	Size/scope of review Relevant Studies Identified: 14 • RCT – 2[27,28] • Observational – 12[11-22] ClinicalTrials.gov Relevant Trials: None identified.
KQ 1a: New RCTs	None identified.	Size/scope of review Relevant Studies Identified: 13 • RCT – 13[29-41] ClinicalTrials.gov

		Relevant Trials: None identified.
KQ 2: Complications	Total number of completed or in-progress evidence reviews – 2 • FDA – 1[4] • MHRA – 1[1]	Size/scope of review Relevant Studies Identified: 13 • RCT – 4[39-42] • Observational – 9[16-24] ClinicalTrials.gov Relevant Trials: None identified.
KQ 3: Subgroups	None identified.	Size/scope of review Relevant Studies Identified: 7 • RCT – 5[43-47] • Observational – 2[25,26] ClinicalTrials.gov Relevant Trials: None identified.

Abbreviations: FDA=Food and Drug Administration; KQ=Key Question; MHRA=Medicines and Healthcare Products Regulatory Agency; RCT=Randomized Controlled Trial,

Regulatory data: An additional feasibility concern is access to all pre- and post-marketing safety data. Some of these data are available to regulatory authorities and the courts, but not to the public. A comprehensive systematic review would require access to this long-term outcome data from observational studies. Additional resources will be required to obtain this data and analyze in a systematic review.

Value

The value of this topic is unclear. An AHRQ review could have limited value considering the FDA safety communications about vaginal mesh, as well as the litigation regarding mesh. The nominator indicates they would use a systematic review to update clinical guidelines and for quality outcomes measures.

Summary of Findings

- Appropriateness and importance: The nomination is both appropriate and important.
- Duplication: An evidence review on the topic would not be duplicative. There were no evidence reviews addressing key questions 1a (new RCTs on the benefits and harms of midurethral slings) and 3 (subgroups of women who are higher or lower risk for complications). Most importantly, the identified evidence reviews do not primarily focus on long-term observational data, which is what the nominator desires.
- Impact: Unclear. A new systematic review which includes observational study data and regulatory data with long-term outcomes including harms could potentially address this uncertainty.
- Feasibility: The feasibility of an AHRQ evidence review on this topic is uncertain due to lack of regulatory data (see below).
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    - *Regulatory data*: An additional feasibility concern is access to all pre- and post-marketing safety data for a comprehensive review, which AHRQ may not have. Efforts to obtain and analyze this data will likely be highly resource-intensive.
- Value: The value of this topic is unclear. An AHRQ review could have limited value considering the FDA safety communications about vaginal mesh, as well as the litigation regarding mesh.

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Appendices

Appendix A: Selection Criteria Summary

Appendix B: Search Strategy & Results (Feasibility)

Appendix A. Selection Criteria Summary

Selection Criteria	Supporting Data
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, this topic represents a health care drug and intervention available in the U.S.
1b. Is the nomination a request for a systematic review?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on both effectiveness and comparative effectiveness.
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, it is biologically plausible. Yes, it is consistent with what is known about the topic.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes, this topic represents a significant burden. Among women, the lifetime risk of stress incontinence is 3% to 4%, and symptoms can reduce quality of life and functional status.
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, this topic affects heath care decisions for a large population and addresses an area of controversy.
2c. Represents important uncertainty for decision makers	Yes, this topic represents important uncertainty for patients as well as for urogynecologists and clinicians who refer patients to them.
2d. Incorporates issues around both clinical benefits and potential clinical harms.	Yes, this nomination addresses both benefits and potential harms.
2e. 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.
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	A review that included a broader range of literature than the Cochrane review would not be redundant, however, several other systematic reviews have been cited by the FDA.
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, the standard of care is unclear due to conflicting data and a litigious environment.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Unclear.
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)	There is new evidence from recent trials as well as a large body of observational data and another body of regulatory adverse event reporting that has not been included in most reviews. The FDA as well as corresponding European regulators are examining the data continuously and may have new reports on this topic while an AHRQ review is underway.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Unclear. It is difficult to predict what might happen in the current litigious environment.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes, the American Urogyncologic Society nominated the topic. Their aim is not so much to use it to develop guidelines as it is to put a controversial issue in the hands of an agency that can produce an unbiased, respected, independent systematic review of all the relevant science.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; FDA=Food and Drug Administration; KQ=Key Question

Appendix B. Search Strategy & Results (Feasibility)

Topic: Midurethral sling Date: August 25, 2016 Database Searched: MEDLINE (PubMed)	
Concept	Search String
Midurethral Sling	("Dysthymic Disorder"[Mesh]) OR ((Dysthymia[Title/Abstract] OR Dysthymic[Title/Abstract]))
NOT	
Not Editorials, etc.	((((("Letter"[Publication Type]) OR "News"[Publication Type]) OR "Patient Education Handout"[Publication Type]) OR "Comment"[Publication Type]) OR "Editorial"[Publication Type])) OR "Newspaper Article"[Publication Type]
Limit to last 5 years ; human ; English ; birth – 18 years	Filters activated: published in the last 5 years, Humans, English, Child: birth-18 years.
N=151	
Systematic Review	PubMed subsection “Systematic [sb]”
Randomized Controlled Trials	Cochrane Sensitive Search Strategy for RCT’s “(((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])”
other	((((("JAMA"[Journal]) OR "The New England journal of medicine"[Journal]) OR "Lancet (London, England)"[Journal]) OR "BMJ (Clinical research ed.)"[Journal]) OR "Annals of internal medicine"[Journal]