Article type : Systematic review

Management of mesh complications following surgery for stress urinary incontinence or pelvic organ prolapse: a systematic review

P Carter[1*], L Fou[2], F Whiter[2], V Delgado Nunes[2], E Hasler[2], C Austin[3], F Macbeth[4], K Ward[5], R Kearney[5,6]

1 Research Department of Clinical, Educational & Health Psychology, University College London, 1-19 Torrington Place, London, WC1E 7HB.

2 National Guideline Alliance, Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, London, NW1 4RG.

3 National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BT.

4 Centre for Trials Research, Cardiff University, 6th Floor, Neuadd Meirionnydd, Health Park, Cardiff, CF14 4YS.

5 The Warrell Unit, St Mary's Hospital, Manchester, University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, M13 9WL.

6 University Institute of Human Development, Faculty of Medical Human Sciences, University of Manchester, Oxford Road, Manchester, M13 9PT.

*** Corresponding author:** Patrice Carter

Address: Research Department of Clinical, Educational & Health Psychology, University College London, 1-19 Torrington Place, London, WC1E 7HB.

Email: Patrice.carter@ucl.ac.uk

Tel: 0044 7841707994

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/1471-0528.15958

Running title: Management of mesh complications
Word count: Abstract –250. Main paper - 3,425

Abstract

Background: Mesh surgery for stress urinary incontinence or pelvic organ prolapse can result in complications such as mesh exposure, mesh extrusion, voiding dysfunction, dyspareunia and pain. There is limited knowledge or guidance on the effective management for mesh related complications.
Objective: To determine the best management of mesh complications; a systematic review was conducted as part of the national clinical guideline 'Urinary incontinence (update) and pelvic organ prolapse in women: management'.
Search strategy: Search strategies were developed for each indicator of referral.
Selection Criteria: Relevant Interventions included complete or partial mesh removal, mesh division and non-surgical treatments such as vaginal oestrogen.
Data collection and analysis: Characteristics and outcome data were extracted, due to the heterogeneous nature, a narrative synthesis was conducted.
Main Results: Twenty four studies were included, five provided comparative data and four studies stated the indication for referral. Reported outcomes (including pain, dyspareunia, satisfaction, quality of life, incontinence, mesh exposure, and recurrence) and the reported incidence of these varied widely.
Conclusions: The current evidence base is limited in quantity and quality, and does not permit firm recommendations to be made on the most effective management for mesh-related complications. Robust data is needed so effective management of mesh complications can be provided.
Funding: The guideline referred to in this article was produced for the National Institute for Health and Care Excellence (NICE) as part of the national clinical guideline 'Urinary incontinence (update) and pelvic organ prolapse in women: management'.
Key words: Stress urinary incontinence, pelvic organ prolapse, mesh revision

Tweetable abstract: Systematic review demonstrates outcomes following mesh revision surgery are highly variable.

Introduction

Mesh-augmented surgery for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) using minimally invasive surgical techniques and polypropylene mesh were widely adopted in the 1990's.[1] Randomised controlled trials (RCTs) showed the effectiveness of mesh surgery compared to conventional

surgery [2-4]; but the majority did not report long-term complications. Reports of mesh-related complications are increasing [5], which has led to warnings from the Scientific Commitee on Emerging and Newly Identified Health Risks (SCENIHR) and the Food and Drug Administration (FDA).[6-8]

Mesh surgery can result in mesh complications such as exposure, extrusion and infection, in addition to the complications following any procedure for incontinence and prolapse, such as voiding dysfunction, dyspareunia and pain.[9, 10] Estimates of complications due to mesh surgery vary from 0 to 33%.[11] A review of NHS patient data found 10% of women in England who had a midurethral mesh sling (MUS) implanted were admitted for a complication (which was not necessarily mesh related) within five years, with a mesh removal rate of 3.3% over a 9 year period.[12]

Despite concern about these potential complications, there is little evidence on how they should be managed.[13, 14] Different indications may determine different treatment choices: e.g. a midline division of an MUS may be effective in resolving voiding dysfunction but may not relieve pain.[15] To date, there is no guidance on managing mesh-related complications.[16]

Study objective

We conducted a systematic review to determine the best treatment options for mesh complications according to the indication for referral: vaginal complications, pain, urinary complications and bowel complications. The review was conducted as part of the new national clinical guideline 'Urinary incontinence (update) and pelvic organ prolapse in women: management' released by the National Institute for Health and Care Excellence (NICE).[17]

Methods

Following the NICE guidelines manual [18] we developed review protocols for each indication for referral which were approved by NICE in advance of the review being conducted. These were published as part of the guideline. [17]

Patient and public involvement

The review was developed by a committee which includes lay members, who provided input at all stages of the review - protocol development, discussion of the evidence and drafting of recommendations.

Criteria for inclusion in the review

Population

Only studies with women aged 18 years or older, who were experiencing complications - vaginal (e.g. exposure, extrusion and mesh infection), pain (e.g. sexual dysfunction/dyspareunia), urinary, or bowel symptoms - following mesh surgery for SUI, POP or both, were included.

Types of studies

RCT, cohort studies and case series were considered for inclusion with the latter two required to have a minimum of 50 participants. Case series were included only if no comparative data were available.

Types of interventions

Relevant interventions included: partial or complete removal of mesh (vaginal, abdominal or laparoscopic), mesh trimming, vaginal oestrogen, antibiotics (systemic or local), pus drainage, vaginal dilation, vaginal reconstruction, vaginoplasty, pain management (including psychosexual counselling, local anaesthetic, physiotherapy, analgesia, and botulinum toxin), transurethral excision, and mesh division.

Outcomes

Relevant outcomes were: bowel complications, continued or repeated exposure/extrusion/infection, continued or repeat sexual dysfunction, health-related quality of life (HRQOL) , intraoperative complications (severe bleeding, requiring blood transfusion, and internal organ injury), long term complications (pain, mesh exposure or extrusion, de novo overactive bladder and sexual dysfunction), satisfaction, recurrence, and repeat surgery. No relevant core outcome set currently exists for mesh revision surgery; therefore outcomes were selected according to known reported complications.

Exclusion criteria

Studies only reporting rates of complications following mesh surgery were excluded, as were those that only described management of complications. Studies not published in the English language were excluded.

Search strategy

Search strategies were developed for each indication (Appendix S1) and included medical subject headings and free text terms based on the eligibility criteria. The search was conducted on Embase Classic + Embase (1947 onwards), Ovid MedLINE (R) In-process & Other Non-Indexed Citations and Ovid MedLINE(R) (1946 onwards) and the Cochrane Library via Wiley Online. The dates of the searches for

each indication were: urinary complications 20th September 2017, vaginal complications 30th November 2017, sexual dysfunction and pain complications 22nd November 2017, and bowel complications 26th March 2018.

Study selection

Retrieved titles and abstracts were imported into the National Guideline Alliance (NGA) in-house database. Initial screening of titles and abstracts was conducted by one reviewer; a ten percent random sample was then screened by a second reviewer. Full texts of potentially relevant articles were obtained and independently screened by two reviewers. Any disagreements were resolved by discussion to reach a consensus between the two reviewers. When they were unable to reach consensus, a third reviewer arbitrated.

Study synthesis

Characteristics and outcome data of the included studies were extracted by one reviewer, with a second reviewer checking all data for accuracy and completeness. Due to the heterogeneous nature of the included studies, a narrative synthesis of the results was conducted.

Validity assessment

The Cochrane ROBINS-I checklist was used to assess the risk of bias of observational studies,[19] on seven domains: confounding bias, participant selection bias, intervention classification, bias due to deviations from intended interventions, missing data bias, outcome measurement bias, and reporting bias. The tool was applied to each study by two review authors working independently, justification for judgements were recorded, and any discrepancies were resolved by discussion.

Results

After removing duplicates, the search strategy returned 6,443 potentially eligible articles. Abstract and title screening identified 184 full-text articles, of which twenty-four studies met the inclusion criteria and were included. Details are presented in the PRISMA flow diagram including reasons for exclusion (Figure 1.).

Study characteristics

Included studies

Characteristics of included studies and a summary of outcomes comparing complete to partial mesh removal are presented in Table S1 and Table S2, respectively. One study reviewed a prospectively-collected database [20], while all other studies were retrospective; seventeen studies were conducted in the USA, three each in Germany [21-23] and France [24-26], and one in Taiwan [27]. Five studies [15, 16, 25, 28, 29] provided comparative data.

Three studies concerned women specifically referred for pain, [15, 20, 30] two referred for vaginal complications[15, 27] and one for those referred for urinary complications.[31] No studies in women who were referred specifically because of bowel complications were identified. Nineteen studies examined the general management of mesh complications, most reporting the range of indications women presented with.

Only four studies specified that women underwent initial mesh surgery for POP[14, 16, 23, 32] and eight specified that initial mesh surgery was for SUI[15, 21, 26, 28, 29, 31, 33, 34]. The remaining studies included women who had initial mesh surgery for POP and/or SUI; but did not report outcomes separately for these women. Also, they did not all report the same outcomes; therefore, the data could not be combined. None of the included studies provided data on the use of oestrogen or alternative therapies.

Quality of the evidence

All included studies were assessed using the ROBINS-I tool [19] and all were considered as being at serious risk of bias overall (Appendix S2).

Outcome data

Indication for referral – Pain

Three studies [15, 20, 30] included women who had been referred for mesh revision surgery because of pain. One provided comparative data [15] and found no significant difference in postoperative SUI, pain, or urge between complete and partial removal after six weeks. At 29 weeks follow up, women who had complete rather than partial mesh removal were at increased risk of having SUI symptoms (65.4% versus 28.6%, respectively, p=0.01) and of having repeat SUI surgery (37.2% versus 14.3%, respectively, p=0.09).[15]

Overall, mesh removal appears to improve pain outcomes for women following partial or complete removal, with resolution of pain reported at 29 weeks by 72% and 76% of women respectively.[15] When assessed by initial mesh procedure, more women reported being pain-free following sub-urethral incontinence mesh removal (81%) compared to vaginally inserted mesh for POP removal (67%).[20]

Persistent pain following mesh revision was reported by 11.4% of women in this study. In another study, at 12 months follow up 72.5% of women reported some pain improvement following mesh revision surgery, 19.3% no change, and 8.2% a worsening of pain.[30]

Indication for referral – vaginal complications

Two studies [15, 27] included women who had been referred for vaginal complications. One compared complete to partial mesh removal in women who had mesh for incontinence. At 29 weeks follow up, more women who had complete mesh removal required SUI reoperation (43.8% versus 8.3%, respectively, p=0.02).[15] No differences in postoperative SUI, pain, or de novo urgency were reported. The second study [27] reported that 16.7% of women had recurrent mesh exposure after mesh revision surgery, all requiring a second surgical revision procedure.

Indication for referral – urinary complications

One study included women who had been referred for urinary complications (voiding symptoms), and had initially undergone synthetic midurethral mesh for SUI. [31] Following mesh revision surgery, 23.5% and 78.9% of women had complete resolution of urge urinary incontinence and of obstructive voiding symptoms respectively. However, de novo urge incontinence and de novo SUI developed in, respectively, 43.6% and 35.5% of women, with only 22.2% of women reporting that they were satisfied or very satisfied with their initial midurethral mesh procedure.[31]

Indication for referral – unclear/multiple indicators

Nineteen studies reported outcomes following mesh revision surgery, although they did report them according to the specific indication for referral. Three compared complete to partial mesh removal,[14, 16, 25] one compared complete removal to segment excision[29], and one compared mesh division to mesh excision. [28]

Comparative studies

One study, with a mixed cohort of women (initial mesh surgery for either incontinence or prolapse)[25] found that more women had recurrent SUI and recurrent cystocele following complete mesh removal compared to partial removal, but this was not statistically significant. Another study, including women all who had initial mesh surgery for incontinence, did not find a difference in incontinence outcomes following complete mesh removal and mesh excision; 36.7% of women in this study required a second incontinence procedure.[29] A third study in women who had originally undergone mesh for SUI reported

that, compared to mesh division, mesh excision resulted in significantly more women experiencing recurrent SUI symptoms (56.1% versus 13%, respectively, p =0.02) and having a reoperation for SUI (28.1% versus 4.4%, respectively, p=0.002).[28]

One study reported no significant difference in pain resolution between women who had complete compared to partial mesh removal (58.1% versus 70.1%, respectively, p=0.4).[14] Overall, complete resolution of presenting symptoms was reported in 51.1% of women who had mesh removal surgery. However, 30% of women who had dyspareunia before revision surgery reported that it persisted at follow up.[14]

Only one study reported HRQOL,[16] with a statistically significant improvement in the SF-12 mental composite score reported by women who had complete mesh removal compared to those who had partial removal. No other differences were reported in HRQOL as assessed by other scales (SF-12 physical composite score, Pelvic Floor Distress Inventory 20 (PFDI-20), Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), Colorectal-Anal Distress Inventory 8 (CRADI-8) or Urinary Distress Inventory 6 (UDI-6) questionnaires).[16]

Non-comparative studies

Improvement in overall symptoms

Five studies [14, 23, 24, 35, 36] reported an overall change in symptoms following mesh revision surgery, with the number of women experiencing symptom resolution varying from 24% [35] to 80% [24]. One reported that 80% of women who had mesh revision surgery experienced some symptom improvement as measured by the Global Sense questionnaire. [36]

Pain

Ten studies reported on pain outcomes following mesh revision surgery. The number of women reporting complete or significant pain resolution ranged from 19%, [35] 36.2% [33] to 97.5% [21] and 100% [26]; one reported that 78% of women experienced some improvements in pain.[36]

Residual or persistent pain was reported as 12% in two studies, [24, 37] 7.6% in one study (which included dyspareunia), [22] and 24.1% in another.[23] One study reported that 23% of women reported no change in pain after revision surgery, with 51.5% of the total sample reporting pain (abdominal, buttock, leg, pelvic, rectal, vaginal) at 25 weeks follow-up, it was unclear if this was de novo or residual pain.[37]

Dyspareunia

Seven studies reported dyspareunia following mesh revision surgery. Improvement in dyspareunia was reported in 60% and 86% of women in two studies.[35, 38] Following mesh revision surgery, one study reported a significant improvement in dyspareunia (p=0.034),[38] and significantly reduced Pelvic Floor Impact Questionnaire (PFIQ) scores following mesh revision (p=0.02); one study reported dyspareunia was much or a little better in 44.9% of women[33]; one study reported 30% of women had persistent dyspareunia following mesh revision; [25] and one study reported 32.2% of women had dyspareunia, but it was unclear if this was de novo or persistent.[37] Only one study reported on de novo dyspareunia following mesh revision, and this was only reported by one woman.[21]

Satisfaction

Two studies reported on women's satisfaction of mesh revision surgery: 64% of women were 'satisfied' in one study,[33] while 46% of women were 'satisfied', 'pleased' or 'delighted' in another [36].

Quality of Life

Two studies reported on quality of life: one study found that women who rated their quality of life as 'terrible' reduced from 48% before revision surgery to 20% (p≤0.05) after;[35] one study found significant improvements six months after revision surgery on PFDI and PFIQ scores (p=0.004 and 0.002, respectively).[32]

Stress urinary incontinence

Rates of de novo SUI ranged from 5% to 26% after mesh revision surgery.[21, 34, 35] One study reported de novo SUI as 11%, 18% and 19% respectively, following midurethral mesh removal, transvaginal mesh removal, and mesh removal for both procedures respectively;[37] One study reported 52% of women had recurrent SUI following revision surgery;[26] one study reported that SUI increased from 59% prior to mesh revision surgery to 83% after mesh revision surgery;[21] one study reported 7.1% of women had persistent SUI,[34] whilst one study reported 58.1% of women experienced SUI resolution[35] and one study found no change in SUI scores (as measured by the UDI scale). [36]

Urge urinary incontinence

Urinary urge incontinence (UUI) was reported in various ways across studies: One study reported de novo UUI rates according to the type of initial mesh procedure; reported as midurethral mesh removal (18%),

transvaginal mesh removal (15%) and mesh removal for both procedures (25%) of women with de novo UUI.[37] Another study reported a de novo UUI rate of 63% (although this data was only from women who had returned for follow up). When the UUI rate was calculated from the whole cohort, this was 21.2% [22]; one study reported 1% of women had de novo UUI,[32] whilst 6.1% had persistent UUI.[34] Resolution of UUI was reported in 36.4% of women in one study. Two studies [33, 36] reported no change in UUI (as measured by the MESA score or UDI scores).

Mesh exposure

Two studies reported on mesh exposure or extrusion following mesh revision surgery: One reported 9% of women had persistent mesh exposure after surgery,[23] while the other study reported only one case of mesh exposure.[22]

Repeat mesh revision procedures

Studies did not consistently report the number of procedures received by women nor what additional mesh revision procedures were performed. One study reported that 11% of women had repeat revision surgery, with 50% of the whole sample needing some additional treatment; [39] one study reported that 20% of women required more than two repeat interventions for mesh complications.[40] A further study, reported that 16.6% of women had one or more additional treatments for pain after mesh removal.[36] These studies all included women having revision surgery following incontinence mesh procedures or mesh for POP.

One study reported that 30% of women had already undergone treatment for mesh complications, indicating that these women needed at least one or more mesh revisions.[23] Another reported that 29.3% of women required repeat mesh excision [35]. In these two studies women had all had initial mesh surgery to treat prolapse. One study, where all women initially had mesh for incontinence showed 20.5% of women had multiple procedures for mesh revision.[29]

Recurrent POP

Four studies reported the recurrent POP rate after mesh revision surgery, ranging from 3.7% to 16%.[23, 32, 35, 39]

Intraoperative complications

Studies did not consistently report adverse events due to mesh revision surgery. The available data suggests that the injury rate is low, with all studies reporting rates less than 4% for bladder, urethra or bowel injury during surgery [16, 21, 24, 25, 32, 35, 37, 39]; the injury rate in half of these studies was 1% or less.[21, 24, 31, 32, 35] One study reported that 3% of women required a blood transfusion during surgery.[39]

Discussion

Main finding

Overall, this review shows that there is little evidence on the effective management of mesh complications. The majority of studies did not specify the indicator for referral, studies pooled outcomes across all revision surgery procedures, and few compared different management strategies. The very low quality of the evidence therefore made it difficult to draw firm conclusions, or to provide strong recommendations for how mesh-related complications should be managed.

Strengths and Limitations

This review describes a body of evidence not previously synthesised. We used robust methodology, including an inclusive search strategy encompassing multiple databases; however, as this review was conducted as part of the recently published NICE guideline, more research may have since been published.

We have fully described the included studies and extracted data on a range of complications. The main limitation is the inclusion of low quality evidence: the majority of studies were not comparative in design, did not examine treatments according to complication type, and did not compare outcomes according to different management strategies. Interpretation of the evidence is therefore difficult. Also we found no studies that included women specifically referred for bowel complications or that provided data on conservative treatments. Finally, the majority of studies did not report outcomes according to the indication for referral, essential information for determining the effective management of complications.

Interpretation of results

Due to the paucity of data, reliable estimates of the effect sizes of the different revision procedures are not possible and so a narrative synthesis was presented. Although the included studies provided data on women who had received treatment for mesh complications, various mesh products were used in the initial surgery (SUI, POP or both) and the complications associated with them varied considerably.

Few of the included studies directly compared complete mesh removal with partial removal. However, the evidence suggests that complete rather than partial mesh removal results in an increased risk of experiencing recurrent urinary complications, and this was shown in studies where women had originally had mesh surgery for SUI or POP.[15, 25, 31]

This review found that mesh removal surgery can resolve complications associated with mesh surgery for SUI and/or POP. However, the reported success rate varies widely; for example mesh removal resulted in between 19% and 100% of women experiencing pain resolution across studies. After removal, some women may have persistent problems, develop de novo complications, or need additional surgery for complications arising from the revision surgery itself.

Conclusion

The current evidence is not sufficient to support strong recommendations on how mesh complications should be managed in women who have had mesh surgery for SUI, POP or both.

The review shows that women can present with more than one mesh-related complication and may have persistent symptoms after mesh removal surgery. Given the variety of these persisting symptoms, input from a range of professionals is likely to be required. Therefore, as recommended in the updated NICE guideline, women who are considering mesh revision surgery should be given the opportunity to discuss their case with the relevant specialist multidisciplinary teams.[17]

Practical recommendations

Clinicians should discuss the different treatment options with a woman who is experiencing complications associated with mesh. She should be informed that:

- surgery to remove mesh may not relieve symptoms and may lead to further complications
- urinary incontinence or prolapse can recur
- removing part of the mesh may be as effective as complete removal.

Health care professionals should refer to the published NICE guideline for full recommendations on management of mesh complications. Furthermore, because of safety concerns associated with mesh products, robust data on the effective management of mesh-related complications is required and a national registry to collect data is needed to provide both accurate estimates of complication rates and effective management strategies.

Research recommendations

The review highlights the lack of high quality evidence on the effective management of mesh complications following mesh surgery for SUI, POP, or both. Evidence on how to best manage mesh related complications is urgently required; robustly conducted cohort studies, and ethically sound RCTs should be developed to determine effective management strategies for the different complications which women present with.

Acknowledgments

We thank the Guideline Committee for the NICE guideline on 'Urinary incontinence and pelvic organ prolapse in women: management' (Fergus Macbeth, Karen Ward, Rohna Kearney, Carmel Ramage, Catherine Heffernan, Doreen McClurg, Jacqueline Emkes, , Kate Welford, Lucy Ryan, Polly Harris, Suzanne Biers, Vikky Morris). We also thank co-opted Guideline Committee members including Carol Paton, James Stephenson, Sarah Love Jones, and Steven Brown; and also Charlotte Mahoney (Clinical Fellow), Melanie Davies (NGA Clinical Advisor), and Steve Pilling (NGA Clinical Advisor).

Disclosure of interest

PC, LF, FW, VDN, EH, CA and FM have nothing to declare

KW Chair of British Society of Gynaecologists Training committee. Grant holder of FUTURE study (Female Urgency, Trial of Urodynamics as Routine Evaluation) 15/150/05 funded by NIHR. Independent member of study steering committee: HS&DR project 14/70/162. Vice chair of UK Continence Society. Topic lead for Urinary Incontinence on the NICE guideline.

RK Topic lead for prolapse on the NICE guideline.

Completed disclosure of interest forms are available to view online as supporting information.

Contribution of authorship

PC wrote the initial draft of the manuscript, conducted abstract and full text screening, conducted risk of bias assessment, and synthesised data.

LF, FW and CA conducted screening of abstracts and full texts. FW conducted risk of bias assessment, and FW contributed to synthesis of the data.

EH developed and carried out the search strategies.

FM, KW, RK provided clinical input, interpretation and clinical implications of the data

VDN provided oversight of the guideline and review development

All authors contributed to the write up of the manuscript and approved the final version for submission.

Funding

The guideline referred to in this article was produced by the National Guideline Alliance (NGA) at the Royal College of Obstetricians and Gynaecologists (RCOG) for the National Institute for Health and Care Excellence (NICE). The views expressed in this article are those of the authors and not necessarily those of RCOG, NGA or NICE." "National Institute for Health and Care Excellence (2019) 'Urinary incontinence (update) and pelvic organ prolapse in women: management' released by the National Institute for Health and Care Excellence. https://www.nice.org.uk/guidance/NG123.Available from: https://www.nice.org.uk/guidance/NG123.

References

1. Gornall J. How mesh became a four letter word. 2018; 363:k4137.

2. Ward K, Hilton P. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. 2002; 325:67.

3. Nieminen K, Hiltunen R, Takala T, Heiskanen E, Merikari M, Niemi K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. American Journal of Obstetrics and Gynecology. 2010; 203:235.e1-.e8.

4. Withagen MIMD, Milani ALMD, den Boon JMD, Vervest HAMDP, Vierhout MEMDP. Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse: A Randomized Controlled Trial. Obstetrics & Gynecology. 2011; 117:242-50.

5. Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. 2011; 22:789-98.

6. Scientific Commitee on Emergin and Newly Indetified Health Risks (SCENIHR). Opinion on The safety of surgical meshes used in urogynecological surgery. 2015 [cited 2019 18th March]; Available from: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf.

7. U.S. Food and Drug Adminstration. FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address saftey risks. 2016 [cited 2019 18th March]; Available from: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm479732.htm.

8. Administration FUSFaD. FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling devices. 2019 [updated 16th April 2019; cited 2019 20th June]; Available from: https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal.

9. Mock S, Reynolds WS, Dmochowshi RR. Trans-Vaginal Mesh Revision: A Comprehensive Review on Etiologies and Management Strategies with Emphasis on Postoperative Pain Outcomes. 2014; 6:69-75.

10. Toozs-Hobson P, Cardozo L, Hillard T. Managing pain after synthetic mesh implants in pelvic surgery. Eur J Obstet Gynecol Reprod Biol. 2019; 234:49-52.

11. Shah HN, Badlani GH. Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review. Indian journal of urology : IJU : journal of the Urological Society of India. 2012; 28:129-53.

12. Gurol-Urganci I, Geary RS, Mamza JB, Duckett J, El-Hamamsy D, Dolan L, et al. Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary IncontinenceMesh Sling Removal After Midurethral Mesh Sling Insertion for Stress Urinary IncontinenceMesh Sling Removal After Midurethral Mesh Sling Insertion for Stress Urinary Incontinence. JAMA. 2018; 320:1659-69.

13. Cornu J-N, Peyrat L, Haab FJCUR. Update in Management of Vaginal Mesh Erosion. 2013; 14:471-5.

14. Crosby EC, Abernethy M, Berger MB, DeLancey JO, Fenner DE, Morgan DM. Symptom resolution after operative management of complications from transvaginal mesh. Obstetrics and gynecology. 2014; 123:134-9.

15. Jambusaria LH, Heft J, Reynolds WS, Dmochowski R, Biller DH. Incontinence rates after midurethral sling revision for vaginal exposure or pain. American Journal of Obstetrics and Gynecology. 2016; 215:764.e1-.e5.

16. Hokenstad EDMD, El-Nashar SAM, Blandon REMD, Occhino JAMD, Trabuco ECMD, Gebhart JBMD, et al. Health-Related Quality of Life and Outcomes After Surgical Treatment of Complications From Vaginally Placed Mesh. Female Pelvic Medicine & Reconstructive Surgery May/June. 2015; 21:176-80.

17. National Institute for Health and Care Excellence. Urinary incontinence and pelvic organ prolapse in women: managment. NICE guideline [NG123]. 2019 [5th April 2019]; Available from: https://www.nice.org.uk/guidance/NG123.

18. National Institute for Health and Care Excellence. Developing NICE guidelines: the manual. 2014 [cited 2019 3rd January]; Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/developing-NICE-guidelines-the-manual.pdf.

19. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. 2016; 355:i4919.

20. Hou JC, Alhalabi F, Lemack GE, Zimmern PE. Outcome of Transvaginal Mesh and Tape Removed for Pain Only. The Journal of Urology. 2014; 192:856-60.

21. Fabian G, Kociszewski J, Kuszka A, Fabian M, Grothey S, Zwierzchowska A, et al. Vaginal excision of the sub-urethral sling: analysis of indications, safety and outcome. Archives of medical science : AMS. 2015; 11:982-8.

22. Renezeder K, Skala CE, Albrich S, Koelbl H, Naumann G. Complications following the use of alloplastic materials in urogynecological surgery. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2011; 158:354-7.

23. Skala CE, Renezeder K, Albrich S, Puhl A, Laterza RM, Naumann G, et al. Mesh complications following prolapse surgery: management and outcome. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2011; 159:453-6.

24. Warembourg S, Labaki M, de Tayrac R, Costa P, Fatton BJIUJ. Reoperations for mesh-related complications after pelvic organ prolapse repair: 8-year experience at a tertiary referral center. 2017; 28:1139-51.

25. Marcus-Braun N, von Theobald PJIUJ. Mesh removal following transvaginal mesh placement: a case series of 104 operations. 2010; 21:423-30.

26. Misrai V, Rouprêt M, Xylinas E, Cour F, Vaessen C, Haertig A, et al. Surgical Resection for Suburethral Sling Complications After Treatment for Stress Urinary Incontinence. The Journal of Urology. 2009; 181:2198-203.

27. Cheng Y-W, Su T-H, Wang H, Huang W-C, Lau H-H. Risk factors and management of vaginal mesh erosion after pelvic organ prolapse surgery. Taiwanese Journal of Obstetrics and Gynecology. 2017; 56:184-7.

28. Shaw JMBBB, Wohlrab KMD, Rardin CMD. Recurrence of Stress Urinary Incontinence After Midurethral Sling Revision: A Retrospective Cohort Study. Female Pelvic Medicine & Reconstructive Surgery May/June. 2017; 23:184-7.

29. Ramart P, Ackerman AL, Cohen SA, Kim J-H, Raz S. The Risk of Recurrent Urinary Incontinence Requiring Surgery After Suburethral Sling Removal for Mesh Complications. Urology. 2017; 106:203-9.

30. Danford JM, Osborn DJ, Reynolds WS, Biller DH, Dmochowski RRJIUJ. Postoperative pain outcomes after transvaginal mesh revision. 2015; 26:65-9.

31. Crescenze IM, Abraham N, Li J, Goldman HB, Vasavada S. Urgency Incontinence before and after Revision of a Synthetic Mid Urethral Sling. The Journal of Urology. 2016; 196:478-83.

32. George AMD, Mattingly MMD, Woodman PDO, Hale DMD. Recurrence of Prolapse After Transvaginal Mesh Excision. Female Pelvic Medicine & Reconstructive Surgery July/August. 2013; 19:202-5.

33. Parden AM, Tang Y, Szychowski J, Richter HE. Characterization of Lower Urinary Tract Symptoms Before and After Midurethral Sling Revision. Journal of Minimally Invasive Gynecology. 2016; 23:979-85.

34. Singla N, Aggarwal H, Foster J, Alhalabi F, Lemack Gary E, Zimmern Philippe E. Management of Urinary Incontinence Following Suburethral Sling Removal. Journal of Urology. 2017; 198:644-9.

35. Lee D, Dillon B, Lemack G, Gomelsky A, Zimmern P. Transvaginal Mesh Kits—How "Serious" Are the Complications and Are They Reversible? Urology. 2013; 81:43-9.

36. Rogo-Gupta LMD, Grisales TMD, Huynh LMD, Rodriguez LVMD, Raz SMD. Symptom Improvement After Prolapse and Incontinence Graft Removal in a Case Series of 306 Patients. Female Pelvic Medicine & Reconstructive Surgery November/December. 2015; 21:319-24.

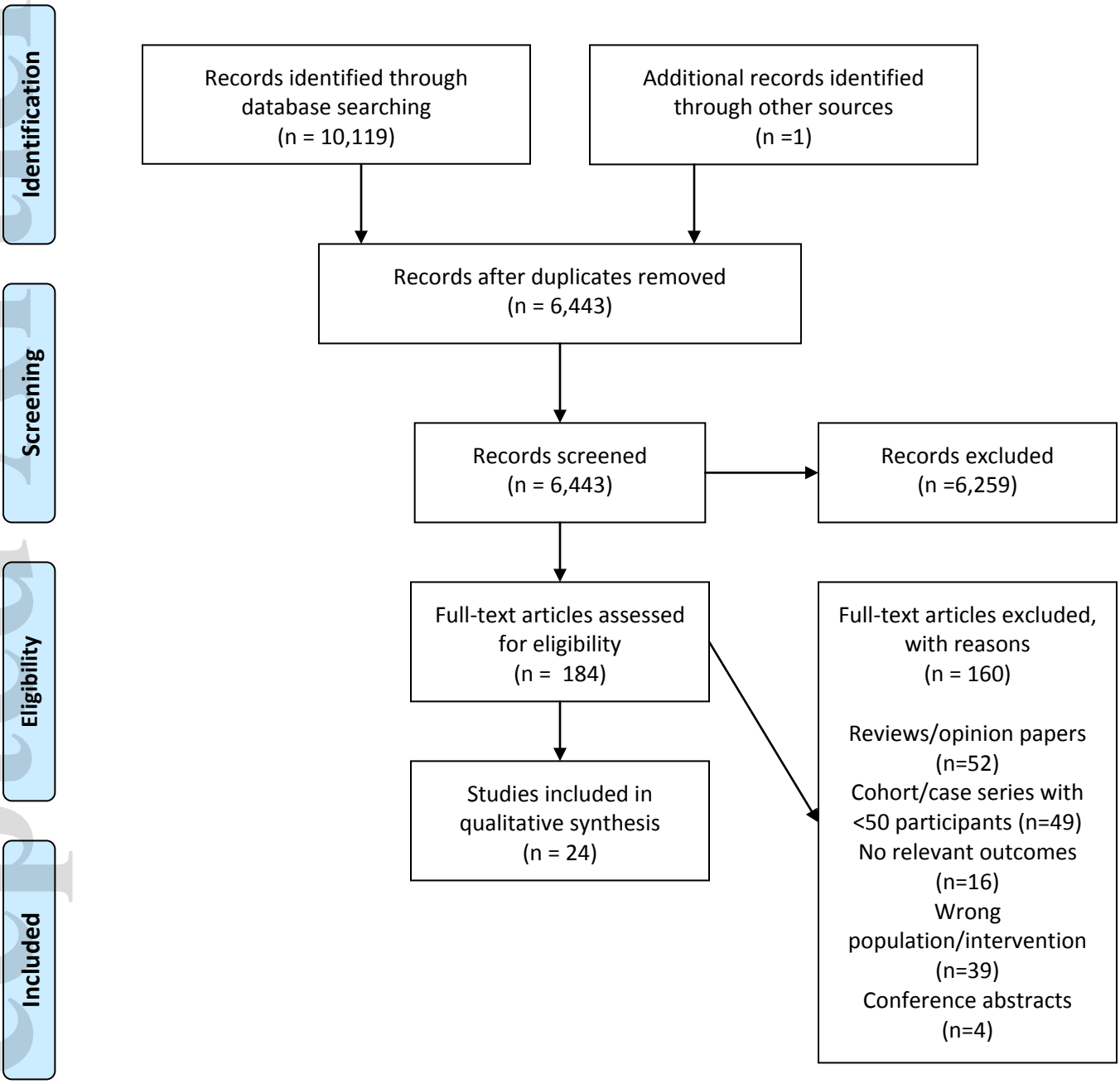
37. Cardenas-Trowers OOMD, Malekzadeh PBS, Nix DEP, Hatch KDMD. Vaginal Mesh Removal Outcomes: Eight Years of Experience at an Academic Hospital. Female Pelvic Medicine & Reconstructive Surgery November/December. 2017; 23:382-6.

38. Rac G, Greiman A, Rabley A, Tipton TJ, Chiles Leah R, Freilich Drew A, et al. Analysis of Complications of Pelvic Mesh Excision Surgery Using the Clavien-Dindo Classification System. Journal of Urology. 2017; 198:638-43.

39. Pickett SDMD, Barenberg BMD, Quiroz LHMD, Shobeiri SAMD, O'Leary DEMD. The Significant Morbidity of Removing Pelvic Mesh From Multiple Vaginal Compartments. Obstetrics & Gynecology. 2015; 125:1418-22.

40. Abbott S, Unger CA, Evans JM, Jallad K, Mishra K, Karram MM, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. American Journal of Obstetrics and Gynecology. 2014; 210:163.e1-.e8.

Figure 1: PRISMA flow chart



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.