Evidence review summaries

Transvaginal Mesh Implants Oversight (TVMO) Group

December 2019
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Background

This report summarises key points from five evidence reviews produced between January 2018 and November 2019. The evidence reviews were produced as part of the Transvaginal Mesh Implants Oversight (TVMO) group’s role to review published secondary evidence and publications on the use of transvaginal mesh implants.

Four of the reviews focused on identifying relevant evidence to answer the following question:

What is the evidence on the use, efficacy and safety of transvaginal mesh (TVM) implants for women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP) compared with appropriate comparators?

One review focused on identifying relevant evidence to answer following questions:

What are the experiences and perceptions of women with SUI and POP of TVM implants?
What is the usefulness of the information women receive before and after the procedures?

Appendix 1 is a glossary of terms from within this report.
Key findings – Research Question 1

<table>
<thead>
<tr>
<th>Research Question (1)</th>
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<tbody>
<tr>
<td>What is the evidence on the use, efficacy and safety of transvaginal mesh (TVM) implants for women with stress urinary incontinence (SUI) and pelvic organ prolapse (POP) compared with appropriate comparators?</td>
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Safety and decision making

- There are inadequate systems for ensuring patient safety with regards to data collection and reporting of adverse events on the use of mesh. A number of recommendations have been made to help improve decision making, data collection, post-operative follow up and adverse event reporting. One of these highlights the need to review Office of Population Censuses and Surveys Classification of Interventions and Procedures (OPCS-4) codes to facilitate the assessment of repeat mid-urethral tape procedures and surgical operations undertaken in response to tape complications.

- Surgical treatment should be considered only after conservative management (such as local estrogenic and rehabilitative treatments) have been unsuccessful.

- Shared decision making between clinicians and patients is important to help balance the risks and benefits for individual patients.

- Other individual factors, including: clinician’s expertise, comorbidities as well as patient preferences and cultural distinctions, should also be adequately considered during decision making.

Limitations

- It should be noted that the overall quality of the evidence base reviewed in the evidence reports was considered to range from very low to moderate due to a number of limitations.

- It should be noted that there is considerable overlap between the primary studies included in the majority of the evidence. Some of the studies were non-randomised, non-controlled or non-blinded studies. There was also some overlap between the studies included in evidence reports conducted in 2018.

- The surgical treatments and comparators investigated in the reviewed evidence varied and, therefore, no overall conclusion can be drawn for the use, efficacy and safety of TVM implants for women.
Further research defining new management strategies, investigating preventive measures and examining the comparative safety profile for mesh products are required.

**NICE guidance**

National institute for Health and Care Excellence (NICE) published an update to their guideline on the management of SUI and POP in women\(^1\) in April 2019. This includes updates on the surgical management of both these conditions.

NICE recommends the use of a retropubic mid-urethral mesh sling (MUS) as options for managing SUI if non-surgical management has failed, provided that the NICE patient decision aid on SUI is used to promote informed preference and shared decision making.

NICE recommends sacro-hysteropexy with mesh as an option for managing anterior prolapse and sacrocolpopexy with mesh as an option for managing vaginal vault prolapse for women who have not improved with or women who have declined non-surgical treatment.

Recommendations which related to the use of synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse, have been withdrawn in June 2019.

The recommendations highlight that for all of the mesh procedures, there is some evidence of benefit, but limited evidence on long-term effectiveness and adverse effects. They state, in particular, that the true prevalence of long-term complications is unknown.

**Pelvic organ prolapse**

**Evidence review report - April 2018**

The evidence review report highlighted relevant evidence published since the 2017 ‘Scottish Independent Review (IR) of the use, safety and efficacy of transvaginal mesh implants in the treatment of SUI and POP in women’\(^2\).

The report identified four systematic reviews\(^3\)\(^-\)\(^6\) assessing procedures for the treatment of vaginal or uterine prolapse and concluded:

- Overall, there was insufficient evidence to draw conclusions about the relative effectiveness or safety of different procedures for vaginal prolapse.
- The evidence identified did not support the use of any mesh or graft materials at the time of posterior vaginal repair.
- For uterine prolapse, one of the reviews reported no difference in the rate of recurrence of uterine prolapse when all surgical techniques were analysed, and the other review found the Manchester procedure more efficient and safer than vaginal hysterectomy for the treatment of uterine prolapse.
Three reports published by NHS England, the International Federation of Gynecology and Obstetrics and the Canadian Urological Association were also identified. The reports concluded:

- Among vaginal operative procedures, the sacrospinous ligament fixation and the uterosacral ligament suspension show comparable outcomes and efficacy with a different low complication patterns.
- Sacrocolpopexy had a good durability and quality of life performance.
- Minimally invasive techniques are as effective as open abdominal techniques and show no difference in mesh exposure.
- The current evidence base does not support the use of transvaginal mesh for prolapse repair.

A number of updates to reviews considered in the IR were also identified. Overall, there was no new clinical evidence that could impact on the conclusions of the 2017 IR. Similar to the conclusions of the IR, the majority of the evidence identified provided the following recommendations:

- Use of transvaginal mesh should be restricted to specific clinical situations and performed only by specialised, trained and experienced clinicians.
- Patients must be adequately informed about the potential risks of the procedure data collection (including long-term data) and reporting on use and adverse events should be adequately captured.
- Further studies evaluating long-term outcomes (cure rates and possible mesh complications) are required.

The evidence review report highlighted that there was considerable overlap between the primary studies included in the majority of the evidence identified. Some of the studies were non-randomised, non-controlled or non-blinded studies or studies that were reported as abstracts. These should be taken into account when interpreting the findings.

**Evidence review update - December 2018**

An evidence review of five systematic reviews and one evidence-based surgical pathway suggested that:

- The therapeutic effect of laparoscopic sacrocolpopexy (LSC) is comparable to abdominal sacrocolpopexy (ASC) for the treatment of apical prolapse but LSC is associated with more mesh-related complications, repeat surgery of the posterior compartment and cystocele recurrence.
- Uterine preservation should be considered as a treatment option for appropriate women without contraindications for apical prolapse repair as they offer more benefits without significantly affecting short-term prolapse outcomes compared with prolapse repairs with hysterectomy.
- Transvaginal repairs are associated with better subjective and objective outcomes compared with transanal repairs.
• There is insufficient evidence to support the use of mesh or biological graft materials for posterior vaginal repair.
• Although combination surgery is associated with more serious adverse events, concurrent MUS during vaginal POP surgery might reduce the risk of postoperative development of SUI in women with POP and SUI (symptomatic or occult).

Evidence review update - June 2019

The evidence review update from June 2019 identified two systematic reviews\textsuperscript{16, 17} and one meta-analysis\textsuperscript{18} which investigated various surgical interventions for the management of prolapse.

The first review\textsuperscript{16} which looked at outcomes and adverse events associated with uterine preserving procedures for POP (hysteropexies) found that:

• Laparoscopic approach had lower recurrent prolapse symptoms, urinary retention and blood loss than open sacrohysteropexy.
• LSC had longer operative times than vaginal mesh hysteropexy.
• Most commonly reported adverse events included mesh exposure, urinary retention and sexual dysfunction.

Limitations included limited comparative data to inform the choice of one type of hysteropexy over another and most data on hysteropexy was low quality, as many trials are case series or have poorly reported or defined outcomes.

Erosion, pain, bleeding and dyspareunia were the most frequently reported outcomes in the second review\textsuperscript{17} which investigated surgical interventions using synthetic mesh for POP. Most randomised control trials included in the review failed to report on clinically important outcomes and to evaluate efficacy and safety over the medium- and long-term.

The meta-analysis\textsuperscript{18} evaluated changes in female sexual function after TVM repair versus native tissue repair for POP and found that:

• There was no significant difference in postoperative dyspareunia after TVM repair versus native tissue repair.
• There was no significant difference in de novo dyspareunia after TVM repair versus native tissue repair.
• There was also no significant difference in the short form Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire score after TVM mesh repair versus native tissue repair.
Stress urinary incontinence

Evidence review update - April 2018

The evidence review did not identify any assessing procedures for treatment of SUI.

Evidence review update - December 2018

The evidence review update from December 2018 identified evidence from six systematic reviews\(^\text{19-24}\) and one evidence-based care pathway\(^\text{25}\) that examined the effectiveness and safety of surgical treatment for female SUI suggested that:

- Adjustable single-incision mini-slings (SIMS) have equivalent efficacy with MiniArcs and transobturator slings, while MiniArcs have comparable efficacy with transobturator slings.
- There is no difference in erosion rates between tension-free vaginal tape (TVT) and TVT-obturator (TVT-O) surgery.
- There is no significant difference in sexual function between patients who received SIMS and standard mid-urethral slings (SMUS) surgery, even though SIMS were generally associated with a shorter operation time and a lower degree of postoperative pain (that was significant ≤7 days after surgery but not 30 days after surgery).
- SMUS are superior to SIMS (except TVT-Secur) with regards to objective cure rate in the long term (up to 60 months).
- TOT may be the optimal regimen for SUI as it was found to demonstrate higher efficacy and moderate safety when compared with Ajust, TVT-S, TVT-O and TVT.

Evidence review update - June 2019

The evidence review update from June 2019 identified two systematic reviews\(^\text{26,27}\) one described in two publications, examined the clinical effectiveness, safety and cost-effectiveness of surgical treatment for SUI in women. The first review\(^\text{26}\) found that:

- Interventions with highest cure rates were traditional sling, retropubic MUS, open colposuspension, and transobturator MUS.
- Women were more likely to experience an improvement in their incontinence symptoms after receiving retropubic MUS or transobturator MUS compared with other surgical procedures.
- The quality of evidence was moderate for retropubic MUS versus transobturator MUS and low or very low for retropubic MUS versus the other two interventions.
- Data on adverse events were available mainly for mesh procedures, which shown a higher rate of repeat surgery and groin pain but a lower rate of suprapubic pain, vascular complications, bladder or urethral perforation, and voiding difficulties after transobturator MUS compared with retropubic MUS.
- Data on adverse events for non-MUS procedures were sparse.
- The cost-effectiveness results suggest that over a lifetime, retropubic MUS is on average the least costly and most effective surgery.
- Women tended to prefer surgical treatments associated with no pain or mild chronic pain and shorter length of hospital stay as well as those treatments that have a smaller risk for urinary symptoms to reoccur after surgery.
The main limitation of the review was the lack of information on the severity of SUI in the included studies.

The second review\textsuperscript{27} compared the efficacy and safety of retropubic vs transobturator TVT in select groups including patients with obesity, intrinsic sphincter deficiency, POP and recurrent SUI. The main findings were

- The objective cure rate showed the significant superiority of retropubic compared to transobturator TVT in patients overall and in each subpopulation.
- The subjective cure rate of retropubic TVT was also significantly superior to that of transobturator TVT in patients overall and in those with intrinsic sphincter deficiency and recurrent SUI after MUS insertion.
- There was no significant difference in overall complications between retropubic and transobturator TVT.
Key findings – Research Question 2 and 3

Research Question (2)
What are the experiences and perceptions of women with SUI and POP of TVM implants?

Research Question (3)
What is the usefulness of the information women receive before and after the procedures?

Due to the heterogeneity of the included studies and the variety of research questions they intended to answer, the summary of the evidence proved to be difficult. The key points from individual studies are summarised below and where studies looked at similar outcomes these were summarised respectively.

Limitations
There was variation across studies in the methodology, outcomes and surgical procedures being studied which makes it difficult to draw overall conclusions. Furthermore, the sample characteristics (such as age of the women, prolapse stage, parity, body mass index, and previous surgery) varied across studies. The implications of these limitations, however, are unknown, because the individual studies did not control for how individual characteristics may impact the outcomes. It must also be noted that some of the quantitative studies gathered information retrospectively and some prospectively which has implications for recall bias.

Key findings
Women’s experiences and perceptions of TVM implants for POP
Evidence from a scoping review exploring the psychosocial factors in women treated for POP in the intervention and follow-up period suggested that:

- POP-specific quality of life (QOL) improves following reconstructive and obliterative surgery.
- General health-related QOL improves following reconstructive and obliterative surgery.
- Women report being satisfied after obliterative and reconstructive surgery.
- Outcomes for sexual function following reconstructive surgery vary across studies.
- Various factors can have an impact and predict improvement in sexual function, such as length of follow-up, reduced coital incontinence post-surgery, better overall health, and type of surgery undertaken.
• Reconstructive and obliteratorative surgery are associated with improvement in self-perceived body image.
• Women with recurrent POP experience similar barriers to seeking treatment as treatment-naive women—such as beliefs about aging and about the lack of available treatment options, trivialising the importance of symptoms, and the high workload of doctors.
• It must be noted that the studies included in the scoping review were not critically appraised, so the findings should be interpreted with some caution.

Evidence from five studies29-33 exploring patient reported QOL and improvement after TVM surgery for POP, which were not included in the scoping review, reported overall improvement in women’s QOL after TVM surgery for POP. It must be noted that the design of the studies (e.g. retrospective and prospective) varied which has implications for recall bias. Furthermore, each study looked at a different TVM surgery (laparoscopic sacrocolpopexy; trocar-guided TVM surgery; anterior or combined (anterior and posterior) TVM repair; uterine-sparing TVM procedure; transvaginal SIMs. Follow-up period in the studies ranged between several months and six years which has further implications for the interpretation of the results.

In a prospective cohort study34 evaluating patient satisfaction and sexual function outcomes after native-tissue repair compared to polypropylene mesh at one year follow-up, patients reported high subjective cure in both groups. There was no significant difference between the groups in regards to patients’ satisfaction. Sexual functioning was not significantly affected by the type of surgery. Patient-reported complications from eight weeks to one year showed a significant difference, with more complications needing medical attention in the native-tissue group. These results must be interpreted with some caution due to the significant difference between the sample sizes of the two groups: native-tissue group (n=3908) and mesh group (n=80). There was also missing data for each patient reported outcome. Furthermore, women in the mesh group had a larger degree of prolapse and were older than the women in the native-tissue group which implies a risk of confounding.

Women’s sexual function of TVM implants for SUI
Evidence from three studies35-37 exploring women’s satisfaction and sexual function after TVT and TOT procedures for SUI, suggested that outcomes for sexual function vary across studies. More detailed sexual questioning is needed to define problems related to sexual experience.

Quality of information provided for patients who have had MUS surgery for SUI
Evidence from a regional audit report38 of the use of MUS for SUI in Northern Ireland suggested that the quality of information given to women during the consent process is variable. The report concluded that the most common advice given to patients is on the risk
of infection, bladder trauma and voiding disorder whereas information on the risk of failure of the technique and de novo urge and urge incontinence is provided less frequently.

**Women’s experiences of long-term impact of vaginal mesh complications**

Evidence from one qualitative study\(^{39}\) looking at women’s experience of vaginal mesh complications after optimised tertiary care level treatment suggested that women’s experiences of vaginal mesh complications are different. Some women feel that their health is out of control and some feel that their degraded health status is permanent. Some women, however, have positive experiences of ‘returning to health’ and a resolution of symptoms and issues despite minor complications.

**Decision factors about treatment choice**

Evidence from one study on patients’ perspectives on peri-urethral bulk injection (PBI) therapy and MUS surgery for SUI suggested that:

- There are five different decision factors which can influence patients’ treatment choice: procedural, personal, professional, social and external treatment.
- Procedural factors include the efficacy and invasiveness of the procedure, the risk of the procedure, and efficacy of treatment.
- Personal factors refer to the severity of symptoms, age, and familiarity of the treatment.
- Professional factors refer to advice and expertise of physicians when choosing their treatment option.
- Social factors such as experience from other patients and also advice from social contacts and family contribute to patients’ preference.
- External factors such as reimbursement and possible costs of the treatment might contribute to patients’ preferences.

**Personal experiences and reported outcomes amongst Scottish women who have received mesh implants**

Evidence from chapter three of the “The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of SUI and POP”\(^{40}\) suggested that:

- Some women experience adverse outcomes which related to decline in overall QOL, pain and emotional distress. However, there are some women who have positive experiences of improvement of physical health, overall QOL and reduction of incontinence symptoms.
- Some women report that their consent to mesh surgery is not informed.
- Some women feel that their surgeon is not open to the idea that complications are a result of mesh and for some their case is not followed up.
• A small number of women mention issues related to concerns over the processes of medical device manufacture and regulation; and the lack of financial support available from the public sector.

• It must be noted that the data in the review was collected from three different sources: patient stories written to the Cabinet Secretary, collected experiences of those women who are associated with the Scottish Mesh Survivors Group, and the experiences of women within a PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) trial of POP surgery. Only the data in the PROSPECT trial was collected as part of a formal research. It is difficult to draw firm scientific conclusions from this review because of the bias of “double-counting” of responses and because of the lack of depth of interpretation of the result provided in the review.
References

1. www.nice.org.uk/guidance/ng123/chapter/Recommendations


38. Authority TRaQI. Regional Audit of the Use of Mid-Urethral Tapes for Stress Urinary Incontinence in Northern Ireland 2018.


## Appendix 1 – Glossary of terms

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<th>Term</th>
<th>Description</th>
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<tr>
<td>ASC</td>
<td>Abdominal Sacrocolpopexy</td>
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<td>IR</td>
<td>Independent Review</td>
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<tr>
<td>LSC</td>
<td>Laparoscopic Sacrocolpopexy</td>
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<tr>
<td>MUS</td>
<td>Mid-urethral Mesh Sling</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<tr>
<td>OPCS</td>
<td>Office of Population Censuses and Surveys Classification of Interventions and Procedures</td>
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<tr>
<td>PBI</td>
<td>Peri-urethral Bulk Injection</td>
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<tr>
<td>POP</td>
<td>Pelvic Organ Prolapse</td>
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<tr>
<td>QOL</td>
<td>Quality of Life</td>
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<tr>
<td>SIMS</td>
<td>Single-incision Mini-slings</td>
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<td>SMUS</td>
<td>Standard Mid-urethral Slings</td>
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<tr>
<td>SUI</td>
<td>Stress Urinary Incontinence</td>
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<tr>
<td>TVM</td>
<td>Transvaginal Mesh</td>
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<tr>
<td>TVMO</td>
<td>Transvaginal Mesh Implants Oversight Group</td>
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<tr>
<td>TVT</td>
<td>Tension-free Vaginal Tape</td>
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<tr>
<td>TVT-O</td>
<td>Tension-free Vaginal Tape - obturator</td>
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