NICE National Institute for Health and Care Excellence

2021 exceptional surveillance of urinary incontinence and pelvic organ prolapse in women: management (NICE guideline NG123)

Surveillance report

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Surveillance decision

We will not update the NICE guideline on urinary incontinence and pelvic organ prolapse in women.

Reason for the exceptional review

This exceptional surveillance review was triggered by publication of First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review (IMMDS review) and subsequent NICE discussions (see NICE's board paper from September 2020). This surveillance review examined the report's 'actions for improvement' around use of pelvic mesh implants and any potential impact on the NICE guideline, particularly guidance on transvaginal tension free vaginal tape-obturator use and full and partial mesh removals for managing mesh-related complications.

Methods

The exceptional surveillance process consisted of:

- Considering the new information that triggered the exceptional review (the IMMDS report).
- Literature searches to identify relevant evidence on full and partial mesh removals for the management of mesh-related complications in women with stress urinary incontinence (SUI) or pelvic organ prolapse (POP).
- Considering the evidence used when the section on managing complications associated with mesh surgery was developed in 2019.
- Assessing the new evidence against current recommendations to determine whether the guideline needs updating.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Search and selection strategy

We conducted literature searches to identify new evidence on partial or complete mesh removals for managing mesh-related complications published between 1 November 2017 and 9 November 2020 and found 605 studies.

We followed the inclusion and exclusion criteria described in the protocols of the review questions related to the management of mesh complications (see evidence review L of the NICE guideline) but focused on those studies that compared partial with complete mesh removals for the management of mesh-related complications. Given the concerns that were raised in the IMMDS report around the experiences of women and the impact of mesh-related complications on their lives, we included studies that assessed those aspects alongside those assessing the surgical management of the complications.

As with the original guideline, most of the references identified in the searches were observational (retrospective) studies. These studies varied in terms of the populations, interventions, outcomes and follow-up times evaluated. Fourteen references were initially identified, but after further assessment, only 6 studies were considered directly relevant. Two of these 6 studies were quantitative studies examining POP mesh (Bergersen et al. 2020, Sassani et al. 2020) and 4 examined life experiences and quality of life of women with mesh-related complications (Brown 2020, Kowalik et al. 2019, Huang et al. 2018, Javadian et al. 2018). For completeness, details of the additional 8 references identified are provided in appendix A. Although these references assessed mesh removals, they did not provide data comparing full removals with partial removals and were excluded from the review.

Information considered in this exceptional surveillance review

First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review (IMMDS review)

The IMMDS review assessed 'how the health care system in England responds to reports about harmful side effects from medicines and medical devices and to consider how to respond to them more quickly and effectively in the future'. The review focused on 3 main areas: hormone pregnancy test, sodium valproate, and pelvic mesh implants. It concluded that 'the system is not safe enough for those taking medications in pregnancy or being

treated using new devices and techniques. Patients are being exposed to a risk of harm when they do not need to be'.

The IMMDS review includes 9 recommendations and several 'actions for improvement'. These recommendations include specific actions to address the main concerns raised in the IMMDS review and put in place mechanisms to improve patients care, safety and avoid further harm.

Although the IMMDS report doesn't make any specific recommendations for NICE, the 'actions for improvement' were relevant. Actions that might impact on the NICE guideline, are as follows:

- 'NICE's most recent guidance states that the transvaginal tension free vaginal tape-obturator (TVT-O) should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all.'
- 'A consensus needs to be reached on whether it is better to carry out full or partial removals. This is a clinical matter, and it must be done collaboratively, including consulting international experts. This consensus should be validated by carrying out follow up on those who have removals at the specialist centres. We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached.'

Transvaginal tension free vaginal tape-obturator

The IMMDS review highlights that 'NICE's most recent guidance states that the TVT-O should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all'.

Recommendation 1.5.10 states: 'Do not offer a transobturator approach unless there are specific clinical circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided.' The recommendation is a 'do not offer recommendation' and an example of an 'exceptional circumstance' is provided. It is considered that the recommendation is in line with what was suggested in the IMMDS report and no amendment is needed.

Mesh: full or partial mesh removal

Information considered when developing the guideline

The NICE guideline includes a section on managing complications associated with mesh surgery and covers aspects related to general considerations before removing mesh, managing vaginal complications, urinary complications, and bowel symptoms.

Full or partial mesh removals are considered as options of treatment for women who do not wish to have treatment with topical oestrogen or if the area of vaginal mesh sling exposure is 1 cm^2 or larger or if there is vaginal mesh extrusion or if there has been no response to non-surgical treatment after 3 months (recommendation 1.11.5). Adverse events and complications after mesh removal are also included (recommendations 1.11.7, 1.11.8, 1.11.9, 1.11.12 and 1.11.8). However, specific guidance about when to offer a partial or full mesh removal is not included.

When the section on managing complications associated with mesh surgery was developed in 2019, limited comparative evidence was identified. The evidence was observational (retrospective studies of very low quality) and limited to a short follow-up time. Case series were also identified, involving data from women with a variety of synthetic mesh products and different associated mesh complications. The committee agreed that some of the studies that did not meet the inclusion criteria for the individual reviews but reported on the general management of mesh complications would inform their decision-making on the general management of mesh complications and the treatment of specific complications.

The committee developed most of the recommendations by consensus based on their experience. They agreed that mesh removal can sometimes resolve mesh complications but that its success varies widely depending on the specific mesh complication (for example location, pain, urinary incontinence) and its complexity. The also noted that some women who have complete removal of mesh will experience complications and recurrence of the SUI or POP (or both) and need further surgery to resolve these problems.

New evidence identified

A retrospective observational study assessed the impact of mesh removal on women experiencing POP mesh-related complications (Bergersen et al. 2020). The study was conducted in a single institution in the US. A total of 78 patients were included, 45 (45/78,

57.6%) underwent complete mesh removal and 33 (33/45, 42.4%) partial mesh removal. The most common signs and symptoms at presentation were pain, dyspareunia, mesh exposure, and recurrent urinary tract infections. Forty-six percent of the patients (36) had undergone a prior attempt at mesh removal. No differences were identified in the resolution or improvement of symptoms between partial and complete mesh removals. Complete removals were associated with a higher rate of recurrent symptomatic POP, but the differences were not statistically significant (31.1% complete removal, 15.2% partial removal, p=0.12). Twenty-three patients (23/78, 30.3%) needed additional surgery. Overall, in 67 patients (67/78, 85.9%), painful symptoms were resolved or improved and in 9 (9/78, 23.23%) were unresolved (2 lost to follow up). The authors concluded that any degree of removal has a positive impact on complications associated with POP mesh.

One matched cohort study assessed the risk of prolapse recurrence in women after sacrocolpopexy mesh removal (Sassani et al. 2020). Surgical records of sacrocolpopexy procedures done between 2010 and 2019 in a single centre in the US were identified. A total of 26 mesh removals (full or partial) were included, most of them due to mesh exposure or pain. The cases were matched with 76 controls (women who underwent sacrocolpopexy but without subsequent mesh removal). The mean time from mesh insertion to mesh removal was 52 months. The most common symptoms before the removal were exposure, pain, and vaginal bleeding. In 50% of the cases, the mesh was completely removed. In the partial removal group (13 cases), 2 patients had persistent symptoms, and one full mesh removal was required. Three patients had a bladder injury and 2 patients had a bowel injury during the mesh removal, all resolved during the surgery. This study did not report if these 3 patients received a full or partial removal. Women who had mesh removal were more likely to have a prolapse recurrence than those without it (adjusted hazard ratio 15.4; 95% confidence interval 1.3 to 54.8). Authors reported that given the lower number of cases further subanalysis (such as recurrence compartment by location of mesh removed) were not conducted.

The other studies identified did not report comparative data between partial and full mesh removals for the management of mesh-related complications. They reported different degrees of symptom improvement after surgery and the need in some cases for more than 1 surgical procedure for managing symptoms and complications. They also cautioned about the risk of recurrence or development of new symptoms after the surgery (see appendix A).

Patient experience and quality of life

We have identified 4 relevant studies in the area (Brown 2020, Kowalik et al. 2019, Huang et al. 2018, and Javadian et al. 2018). The first study assessed the experiences lived by 7 women with pelvic surgical mesh complications (Brown 2020). Semi-structured interviews were conducted, and the quality of life was assessed using a modified version of the ICIQ-LUTSqol questionnaire. Most of the women had surgical mesh for POP and urinary incontinence, 2 for urinary incontinence and 1 for POP only. The quality of life was significantly affected in all of them (mean ICIQ-LUTSqol 62.2, standard deviation 10.01). The analysis showed the following emerging themes: feeling powerless in the medical space, living in a shrinking world, living with unrelenting pain, inhabiting a body that can no longer be relied on, living the gap between what was and what could be, suffering in silence, have other(s) as a source of strength. The second study compared the quality of life after mesh surgery in women with or without mesh complications after surgery (Kowalik et al. 2019). A total of 126 women (29, 23% with mesh-related complications) who had a vaginal mesh between 2007 and 2012 in a Dutch hospital were included. Quality of life was assessed using different questionnaires including the Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire (IIQ), Defecation Distress Inventory, and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12). No differences were identified in the domain scores of the quality of life questionnaires used between the groups assessed. Huang et al. (2018) evaluated the impact of surgical failure and complications on the quality of life of 78 women who underwent transobturator sling surgery for urodynamic stress incontinence (median follow up 13.5 months after surgery). Quality of life was assessed using the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7), preoperatively and 12 months after surgery. The analysis found that the quality of life improved even in the presence of surgical failure or complications. The last study assessed the disability impact and associated cost per disability in women who had undergone vaginal prolapse mesh revision or removal due to complications (Javadian et al. 2018). A total of 62 women who attended a single hospital between 2009 and 2014 in the US were included. They used the Sheehan Disability Scale and Years of life Lived with Disability questionnaires. Almost a third of cases were extremely disabled patients (18, 29%), and nearly 60% did not improve after mesh removal (37, 59.6%). Participants reported a median loss of 12 months of school or work due to mesh complications. Authors concluded that complications of transvaginal prolapse mesh kits have a sustained impact on disability, even after mesh removal.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

New evidence identified in this exceptional surveillance review comes from observational studies of very low quality. The studies assessed different populations, interventions and outcomes and provided limited comparative data.

The studies of patient experiences showed how mesh-related complications impact on women's lives, confirming the findings of the IMMDS review. Only 1 study provided data comparing full removals with partial removals in women experiencing POP mesh-related complications. No differences were identified in the resolution or improvement of the symptoms or the recurrence of symptomatic POP between full removal compared with partial removal of mesh. Most of the studies identified described some degree of symptom improvement after surgical management of mesh-related complications but also cautioned about the unpredictability of the efficacy of the interventions and the risk of developing new symptoms or recurrence of previous ones. The studies also advocated a shared decision-making approach before undertaking any mesh removal, including a full discussion of the patient's symptom burden and possible surgical outcomes and complications.

NICE's guideline does not recommend offering the transobturator approach except in exceptional circumstances. This reflects the IMMDS report and the guideline does not need amending.

Given the limited evidence identified on partial and full removals for managing mesh-related complications, it was considered that it is not possible to update the guideline at this time. We will monitor the situation and update it if required.

Appendix A: Summary of studies identified

Eight studies identified in searches and considered pertinent but not directly relevant to the surveillance review are summarised here (Shakir et al. 2020, Goodall et al. 2019, Dray et al. 2019, Kershaw et al. 2019, Salima et al. 2019, Mazloomdoost et al. 2018, Leonard et al. 2018). Note that these studies did not report data comparting full removals with partial removals.

- Four studies assessed stress urinary incontinence (SUI) populations (Shakir et al. 2020, Kershaw et al. 2019, Dray et al. 2019, Goodall et al. 2019).
- Four studies assessed mixed populations (SUI, pelvic organ prolapse; POP or hernia) (Mazloomdoost et al. 2018, Salima et al. 2019, Younan et al. 2019, Leonard et al. 2018).
- Two studies were conducted in the UK (Kershaw et al. 2019, Goodall et al. 2019), 1 of these studies was multicentre (Kershaw et al. 2019).
- Other studies were single centre studies and were conducted in the US (5) or France (2).
- One study was a narrative systematic review of observational studies on the management of synthetic mesh erosion of the rectum (Younan et al. 2019).

SUI population studies

One retrospective study reported outcomes of women undergoing full suburethral sling removal placed for the management of SUI in a single institution in the US (Shakir et al. 2020). Authors reviewed a prospectively maintained database of women undergoing suburethral sling removal and assessed outcomes before and after the procedure. A total of 230 women were included and the mean follow up was 30 months. The most common symptoms at presentation were storage/irritative voiding, pain, and urinary incontinence. Forty-two percent of the patients with recurrent urinary tract infections, had no evidence of recurrent urinary tract infection at their last follow up. Twenty-three percent of the patients with dyspareunia reported a complete resolution of the symptoms, and 11 of those with SUI prior to the mesh removal. Patients also reported new symptoms after the mesh removal including recurrent urinary tract infections, SUI, urgency urinary incontinence, and mixed urinary incontinence. Sixty-four patients with SUI have a

subsequent procedure post mesh removal. There was statistically significant improvement in the UDI-6 score before and after the procedure (50 pre-surgery, 38 last follow up, p<0.001). Fifty-three percent of the patients achieved success by UDI-6 (success defined by UDI-6 score of 25). Authors reported a multi-composite ideal outcome of resolution of incontinence, pain, resumption of sexual activity, and no need for further anti-incontinence procedures. Ten percent of the patients achieved this outcome at 6 months to 12 months and most recent follow up. This percentage improved up to 49% if 1 minimal intervention was allowed and the sexual activity was excluded. Authors concluded that after a full suburethral sling removal, there was a sustained improvement of the symptoms in the around a half of the patients studied.

One observational study assessed the surgical management of mesh-related complications in women who underwent midurethral sling in 2 NHS Trusts in the UK (Kershaw et al. 2019). A total of 127 patients returned to the theatre at least once during the period assessed: 71 for the management of mesh complications (mesh exposure, pain, voiding dysfunction) or treatment failures (repeat SUI surgery) and 56 for diagnostic procedures (cystoscopy). Mean follow-up time was 60 months, and the time from the primary mesh surgery and the second surgery was 22 months. Common symptoms at presentation were chronic postoperative pain (with or without mesh exposure), voiding dysfunction, overactive bladder, or recurrent/persistent SUI. Different types of surgical procedures for the management of mesh complications or treatment failures were performed. These included shortening, reburying, incision or midurethral sling surgery excision, steroid injections along the midurethral sling surgery tract, surgical management of detrusor overactivity or further stress incontinence surgery, among others. In 2 patients the chronic pain was not resolved after surgery (1 or more interventions). Authors concluded that there was a low incidence of mesh removal following midurethral sling surgery, and outcomes improved after the surgical management of the mesh-related complications.

A retrospective analysis of medical records in a single hospital in the US assessed the efficacy of sling revision or removal for the management of mesh-related complications in women with synthetic mid urethral slings (Dray et al. 2019). A total of 430 women who received transobturator tape, retropubic mid urethral sling or mini-sling between 2004 and 2016 were included in the study. The main complaints reported were mesh incontinence, pain or dyspareunia, exposure or erosion, and bladder outlet obstruction. One hundred and nine were partial vaginal mesh excisions and 247 complete vaginal mesh excisions. Eighty-one patients had a prior sling revision. The American Urological Association Symptom Index significantly decreased after removal or revision of the mesh as well as the Michigan

Incontinence Symptom Index and bother scores. Symptoms were not resolved in 40% of patients with pain and 20% of those with obstruction, and 5% of those with mesh exposure or erosion developed recurrent mesh complains. Authors concluded that symptoms improve after mesh revision or removal, but it is unlikely to achieve a complete resolution of all the symptoms after revision.

An observational study identified all women with chronic pain who underwent laparoscopic removal of midurethral sling for SUI between 2011 and 2016 in a single hospital in the UK (Goodall et al. 2019). The study assessed operative safety, pain, symptom severity and satisfaction. A total of 56 women were identified most of them with vaginal, abdominal and groin pain. They also reported other symptoms, including urinary tract infection (persistent and recurrent), lower-limb swelling and chronic fatigue. All patients received conservative measures before going to surgery. Nine women had previous mesh surgery for mesh complications. The combined laparoscopic and vaginal approach was used for complete removals, and laparoscopic approach only for partial removals with preservation of at least the suburethral component. Most of the patients reported a complete improvement of their symptoms (48%) at 12 weeks, 30% reported partial improvement and 11% no improvement. De novo or worse SUI was associated with excision of the suburethal portion of the mesh (odds ratio 10.75; 95% confidence interval [95% CI] 1.10 to 104.00). All patients were contacted via questionnaire (median follow up 22 months, range 1 month to 60 months), 26 (46%) returned the questionnaire. Most of these patients reported that they would recommend the procedure (46%). Authors concluded that laparoscopic removal is feasible, but the risk of early and late complications as well as the unpredictable efficacy should be considered in the decision-making process with the patients.

Mixed population (SUI, POP, hernia)

An observational study assessed the characteristics and outcomes after surgery of 93 women who underwent surgical management for mesh-related complications (Mazloomdoost et al. 2018). They conducted a retrospective chart review of women treated for mesh-related complaints between 2010 and 2014 in a single centre in the US. They contacted the patients and followed them up using a validated questionnaire. The questionnaire included questions about health, sexual functioning, postoperative improvement, and satisfaction. Most of the women had a midurethral sling mesh only, followed by a prolapse-related mesh only, or both. The most common causes of surgical revision of a midurethral sling were pain or dyspareunia, mesh exposure and voiding dysfunction. The most common causes of surgical revision of POP mesh were pain or dyspareunia. Women with mesh exposure were younger, more likely to present with POP

grade 2, and less likely to present with pain compared with those without mesh exposure. Eighty percent of the women were contacted via questionnaire, 75% agreed to participate. No differences were identified in SF-12 scores and PISQ-12 scores before and after the procedure. Participants reported symptom improvement after surgery with low symptom severity and high satisfaction with the surgery. There were no changes in health or sexual function after treatment.

An observational study retrospectively assessed functional outcomes in women who underwent a tape/mesh surgical revision in a single institution in France between 2008 and 2016 (Salima et al. 2019). A total of 140 women undergoing tape removal (partial or complete), tape division, mesh removal (partial or complete) or tape and mesh removal were included (patients with previous revisions or with neurogenic disease were also included). The main indication for tape removal was voiding symptoms, for mesh removals it was vaginal erosion/extrusion. Mean time between tape/mesh insertion and revision was 52.1 months (range 5 days to 16 years). Most of the tape complications were related to the urinary tract and were asymptomatic. Most of the mesh complications were associated with a vaginal exposure (more than 1 cm) and were symptomatic or asymptomatic. Voiding symptoms were resolved in 63% of the patients and storage in 38% of the patients. Fifty-two percent of the patients with recurrent or persistent SUI underwent an additional surgical procedure. Only 1 patient presented a POP recurrence. Authors concluded that there is an improvement of the symptoms, but patients need to be informed that symptoms may persist after revision or removal.

An observational study assessed the efficacy of surgical removal of prosthetic material for the management of chronic postoperative pain caused by the placement of the prosthetic material (Leonard et al. 2018). The study included a total of 107 patients managed between 2004 and 2016 in a single centre in France for SUI, POP or hernia. The mean follow up was 8.4 months (standard deviation 10.3) and the mean time between insertion to removal of prosthetic material was 41.2 months (SD 35.4). Sixty-one percent of the patients (65) experienced pain at presentation. 18 percent erosion (19), 9% (10) infection, and 12% urinary symptoms (13). Sixty-seven percent of the patients reported a reduction of at least 50% of the pain at last follow up. However, 45% relapsed from the condition for which the mesh was placed. Sixty-two percent of the patients experienced a recurrence of the urinary incontinence after the removal of transobturador suburethral tape. Authors concluded that the removal of the prosthetic material has a positive impact on the pain in most of the patients, but there is a risk of recurrence of the initial disorder.

A systematic review assessed the management of synthetic mesh erosion of the rectum

after urogynaecological surgery (Younan et al. 2019). A total of 14 observational studies were identified, all of them reporting a total of 14 rectal mesh erosions. Given the low number of cases identified, the management of those cases were reported narratively. The rectal erosion of the mesh caused all the rectal complications in the cases assessed, rectal bleeding being the most common symptom reported. The rectal mesh erosions were managed by major surgery, transanal approach or no surgery. Authors concluded that rectal mesh erosion could be managed by the transabdominal or transanal approach and with partial or complete excision of the mesh. A non-surgical management of the mesh erosion can be considered before deciding a surgical one.

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