

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Surgical repair of vaginal wall prolapse using mesh

Vaginal wall prolapse happens when the normal support structures for the pelvic organs are weakened, for example by previous pregnancy and childbirth or hysterectomy. As a result, one or more of the organs can drop down (prolapse) into the vagina. Surgical repair with mesh involves removing some of the stretched tissue, and tightening the underlying tissue (colporrhaphy). The mesh aims to support the repair.

The National Institute for Health and Care Excellence (NICE) is examining surgical repair of vaginal wall prolapse using mesh and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about surgical repair of vaginal wall prolapse using mesh.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 17 July 2017

Target date for publication of guidance: September 2017

1 Draft recommendations

- 1.1 Current evidence on the safety of surgical repair of vaginal wall prolapse using mesh shows there are serious but well-recognised safety concerns. Evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.
- 1.2 Further research should include details of patient selection, long-term outcomes including complications, type of mesh used and method of fixation.

2 Indications and current treatments

- 2.1 Vaginal wall prolapse is a protrusion of one or more pelvic organs (such as the bladder or the rectum) through the vaginal fascia. The vaginal wall then moves from its normal position (prolapses), into or outside the vagina. Vaginal wall prolapse can affect a woman's quality of life because of its local physical effects (pressure, bulging, heaviness or discomfort). It can also affect urinary, bowel or sexual function. There are different types of vaginal wall prolapse depending on the organs and sites involved. These include anterior vaginal wall prolapse (including urethrocele and cystocele) and posterior vaginal wall prolapse (including rectocele and enterocele). A woman can present with prolapse of one or both of these sites.
- 2.2 Current treatment options for vaginal wall prolapse include pelvic floor muscle training, use of mechanical devices (ring or shelf pessaries) and surgery, including anterior or posterior colporrhaphy, and site-specific defect repair such as paravaginal repair.
- 2.3 The aims of using mesh in the repair of vaginal wall prolapse are to add extra support and to reduce the risk of recurrence, particularly for women with recurrent prolapse or with congenital connective tissue disorders (such as Ehlers–Danlos syndrome or Marfan's syndrome).

3 The procedure

- 3.1 Surgical repair with mesh involves removing some of the stretched tissue if needed, and tightening the underlying tissue (colporrhaphy). Mesh is used to support the repair.

- 3.2 The procedure is usually done with the patient under general anaesthesia. Anterior colporrhaphy involves dissection of the vaginal mucosa through a midline incision in the anterior vaginal wall to expose the bladder and pubocervical fascia. The fascia is then plicated (folded), some excess tissue may be removed and the incision is closed. Posterior colporrhaphy involves a vaginal incision and plication of the levator ani. Other site-specific procedures, such as paravaginal repair, may also be done using methods similar to colporrhaphy.
- 3.3 The technique for inserting mesh varies. Mesh placement is usually done using an open technique, although trocar introducers can also be used without direct visualisation. The mesh may be positioned and sutured over the fascial defect as an 'inlay', or the whole vagina may be surrounded by mesh ('total mesh' technique). Mesh repair is theoretically suitable for any degree of symptomatic anterior or posterior vaginal wall prolapse.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 In a randomised controlled trial (RCT) of 865 women with anterior or posterior vaginal wall prolapse treated by synthetic mesh augmented repair or standard repair alone, there were no statistically significant differences in prolapse symptom scores (5.3 versus 4.9, $p=0.37$). There were also no statistically significant differences in symptomatic prolapse (85% [291/341] compared with 82% [283/347], $p=0.30$) or the proportion of women reporting

'something coming down' (34% [116/342] compared with 31% [106/347], $p=0.59$) at 2 year follow-up. The quality-of-life scores were also similar. In an RCT of 735 women with anterior or posterior vaginal wall prolapse treated by biological graft augmented repair or standard repair alone, there were no statistically significant differences in prolapse symptom scores (5.5 compared with 4.9, $p=0.43$) or symptomatic prolapse (82% [245/299] compared with 81% [242/298], $p=0.85$). The proportion of women reporting 'something coming down' was statistically significantly higher in the graft augmented repair group (40% [120/299] compared with 31% [91/298], $p=0.04$) at 2 year follow-up. The quality-of-life scores were similar between the 2 groups.

- 4.2 In a systematic review of 4,023 patients, there was a statistically significantly lower risk of awareness of prolapse in women treated by transvaginal permanent mesh compared with native tissue repair (relative risk [RR] 0.66, 95% confidence interval [CI] 0.54 to 0.81; $n=1,614$, 12 RCTs) at 1 to 3 year follow-up.
- 4.3 In the RCT of 865 women with anterior or posterior vaginal wall prolapse treated by synthetic mesh augmented repair or standard repair alone, there were no statistically significant differences in the proportion of women with an overall Pelvic Organ Prolapse Quantification (POP-Q) score of 2b, 3 or 4 (16% [54/336] compared with 14% [47/338], $p=0.52$) at 1 year follow-up. In the RCT of 735 women with anterior or posterior vaginal wall prolapse treated by biological graft augmented repair or standard repair alone, the proportion of women with an overall POP-Q score of 2b, 3 or 4 was 18% (54/298) and 16% (47/303) respectively at 1 year follow-up ($p=0.47$). In the systematic review of 4,023 patients, women who had a transvaginal mesh repair were less likely to have a stage 2 or

more anterior compartment prolapse on examination than those having a native tissue repair (RR 0.45, 95% CI 0.36 to 0.55, 13 RCTs, n=1,406, I²=35%) at 1 to 3 year follow-up. The risk of recurrent prolapse was lower in the transvaginal permanent mesh group compared with native tissue repair (RR 0.40, 95% CI 0.30 to 0.53, 21 studies, n=2,494, I²=73%).

4.4 In the systematic review of 4,023 patients, those who had a transvaginal mesh repair were less likely to have repeat surgery for prolapse (RR 0.53, 95% CI 0.31 to 0.88, 12 RCTs, n=1,675) at 1 to 3 year follow-up. In a population-based cohort study of 27,809 patients who had mesh or native tissue repair, surgery for recurrent prolapse was reported in a similar proportion of patients: 5% of patients in both groups at 1 year follow-up and 10% (95% CI 9 to 12%) in the mesh group at 5 year follow-up compared with 9% (95% CI 9 to 10%) in the native tissue group. In the RCT of 865 patients who had synthetic mesh or standard repair, further prolapse surgery was needed in a similar proportion of patients (4% [15/343] compared with 5% [16/348]) at 2 year follow-up. In the RCT of 735 patients who had biological graft or standard repair, further prolapse surgery was needed in 5% of patients in both groups (15/300 and 15/299) at 2 year follow-up.

4.5 The specialist advisers listed anatomical success, restoration of bladder, bowel and sexual function, and long-term success as the key efficacy outcomes.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more

detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Immediate postoperative complications were reported in 4% (20/278) of patients who had anterior prolapse repair with mesh and 4% (343/7643) of patients who had repair without mesh in a cohort study of 18,986 patients. Late postoperative complications were more common in patients who had mesh repair compared with a non-mesh repair (adjusted incidence rate ratio 3.15, 95% 2.46 to 4.04) in the same study.
- 5.2 Mesh complications were reported in 12% (51/434) of patients who were exposed to synthetic mesh at 2 year follow-up in an RCT of 865 patients. Surgical removal of the mesh was needed in 9% (37/434) of patients in the same study. Mesh complications were reported in less than 1% (2/368) of patients who had a biological graft repair and less than 1% (2/367) of patients who had a standard repair in an RCT of 735 patients. Surgical removal was needed in 3 of the 4 patients. Surgery for mesh complications was reported in 6% of patients who had a mesh repair in a cohort study of 27,809 patients.
- 5.3 Mesh exposure was reported in 12% (134/2,097) of patients who had a transvaginal permanent mesh repair in a systematic review of 4,023 patients at 1 to 3 year review. Surgery for mesh exposure was reported in 8% (100/1,227) of patients. The overall rate of graft erosion (by meta-analysis of 110 studies) was 10% (95% CI 10 to 11%) of procedures in a systematic review of 126 studies. Mesh erosion was reported in 5% (32/677) of patients and vesicovaginal fistula with mesh extrusion was reported in less than 1% of patients (2/677) in a case series of 677 patients.

- 5.4 Serious adverse effects of any kind (but excluding mesh complications) were reported in 8% (34/435) of patients who had a synthetic mesh repair and 7% (31/430) of patients who had a standard repair ($p=0.73$) at 1 year follow-up in the RCT of 865 patients. Serious adverse effects of any kind (but excluding mesh complications) were reported in 10% (36/368) of patients who had a biological graft repair and 6% (23/367) of patients who had a standard repair ($p=0.08$) at 1 year follow-up in the RCT of 735 patients.
- 5.5 Bladder injury was more common in women who had a transvaginal permanent mesh repair than those who had a native tissue repair (RR 3.92, 95% confidence interval [CI] 1.62 to 9.50, 11 RCTs, $n=1,514$, $I^2=0\%$, moderate-quality evidence) in the systematic review of 4,023 patients. Bowel injury was reported in 1 study in the same systematic review, and there was no evidence of a difference between the 2 groups (relative risk [RR] 3.26, 95% CI 0.13 to 78.81, $n=169$). Bladder injury and rectal damage were reported in 2% (11/677) and 1% (5/677) of patients respectively in a case series of 677 patients. In 2 patients, urinary tract injury was not recognised at the time of surgery and led to stone formation. One patient needed a laparotomy and removal of the mesh with resection of the bladder wall. Ureteric trauma was reported in 1 patient in the same study; this was treated by ureterneocystotomy.
- 5.6 Bleeding more than 500 ml was reported in 2% (15/677) of patients in the case series of 677 patients. Vaginal or pelvic haematoma was reported in 6% (37/677) of patients in a case series of 677 patients. In 10 patients, major vaginal haematomas led to urinary retention or transformed into an abscess. Several of them

needed to be drained transcutaneously. Perineal haematoma was reported in 3% (17/677) of patients in the same study.

- 5.7 Pelvic abscess was reported in 1% (4/677) of patients in the case series of 677 patients. One patient, with a history of intrauterine device inserted 30 years ago, had necrotising fasciitis. The patient developed signs of systemic toxicity 6 days after the prolapse repair. She was treated by fasciotomy and debridement but died after 18 days.
- 5.8 De novo stress urinary incontinence was more common in patients who had a transvaginal permanent mesh repair than those who had a native tissue repair (RR 1.39, 95% CI 1.06 to 1.82, 12 RCTs, n=1,512, I²=0%, low-quality evidence) in the systematic review of 4,023 patients. Incontinence surgery admissions were more common after anterior repair with mesh than after anterior repair without mesh (adjusted incidence rate ratio 3.20, 95% CI 2.06 to 4.96) in a cohort study of 18,986 patients.
- 5.9 Urinary retention within 90 days was more common in patients who had a mesh repair than those who had a repair without mesh (8% compared with 6%, risk ratio 1.33, 95% CI 1.18 to 1.51) in a cohort study of 27,991 patients.
- 5.10 The overall rate of dyspareunia (by meta-analysis of 70 studies) was 9% (95% CI 8 to 10%) of procedures in the systematic review of 126 studies. Pain and dyspareunia was reported in 2% (16/677) of patients in the case series of 677 patients.
- 5.11 As well as safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events

(events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not describe any additional anecdotal or theoretical adverse events.

6 Committee comments

- 6.1 There are many different types of mesh in use, which have variable physical properties. There have been new materials, including newer lightweight mesh, developed.
- 6.2 The surgical technique and method of fixation are important.
- 6.3 Removal of mesh can be technically difficult, should it be needed.
- 6.4 Randomised controlled trial data showed no added benefit of using mesh compared with native tissue repair.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance is a review of NICE's interventional procedure guidance on [surgical repair of vaginal wall prolapse using mesh](#).

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

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