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NHS
National Institute for
Health and Clinical Excellence

Surgical repair of vaginal wall prolapse using mesh

1 Guidance

1.1 The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh. Both efficacy and safety vary with different types of mesh, and the data on efficacy in the long term are limited in quantity. There is a risk of complications that can cause significant morbidity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake surgical repair of vaginal wall prolapse using mesh should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand that there is uncertainty about the long-term results and there is a risk of complications, including sexual dysfunction and erosion into the vagina, which would require additional procedures. They should provide them with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG267publicinfo).
- Audit and review clinical outcomes of all patients having surgical repair of vaginal wall prolapse using mesh (see section 3.1).

1.3 This is a technically challenging procedure that should only be carried out by gynaecologists with special expertise in the surgical management of pelvic organ prolapse. Specific training is required when trocar introducer systems are used for the insertion of mesh.

1.4 Further publication of safety and efficacy outcomes will be useful. Research should aim to address the performance of different methods of repair and different types of mesh. It should also include evidence about long-term outcomes and patient-reported outcomes, such as quality of life and sexual function. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Vaginal wall prolapse is a protrusion of one or more pelvic organs (such as the bladder or the rectum) through the vaginal fascia and the displacement ('prolapse') of the associated vaginal wall from its normal location into or outside the vagina. Vaginal wall prolapse can affect a woman's quality of life by its local physical effects (pressure, bulging, heaviness or discomfort) and its effect on 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 (such as urethrocele and cystocele) and posterior vaginal wall prolapse (such as rectocele and enterocele). A woman can present with prolapse of both of these sites.

2.1.2 Current treatment options for anterior and/or posterior 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.

2.1.3 The aims of using mesh in the repair of vaginal wall prolapse are to add additional support and to reduce the risk of recurrence, particularly for women with recurrent prolapse or with congenital connective tissue disorders (such as Ehlers–Danlos or Marfan's syndromes).

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

2.2 Outline of the procedure

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

2.2.2 A number of different synthetic and biological mesh materials are available, which vary in structure and in their physical properties such as absorbability.

2.2.3 The procedure is usually done 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, some excess tissue may be excised 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 undertaken using methods similar to colporrhaphy.

2.2.4 The technique for implanting meshes varies. Mesh placement is usually performed 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 and/or posterior vaginal wall prolapse.

A systematic review of the published evidence on the surgical repair of anterior and/or posterior vaginal wall prolapse using mesh was commissioned by the Institute. Sections 2.3 and 2.4 describe efficacy and safety outcomes which were reported on in the systematic review and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

2.3 Efficacy

Anterior repair

2.3.1 Thirty studies, including a total of 2472 women, provided data on the use of mesh for anterior repair (13 case series, 12 randomised controlled trials [RCTs], 4 non-randomised comparative studies and 1 registry report). Four of these studies reported on the use of absorbable synthetic mesh, 14 studies on absorbable biological mesh, 1 study on a combined biological and synthetic mesh and 14 studies on non-absorbable synthetic mesh. Of the 30 studies, 2 RCTs and 1 non-randomised comparative study compared different types of mesh. The median follow-up time was 14 months (ranging from 1 to 38 months). Of the 12 RCTs, 7 were available only as conference abstracts.

2.3.2 The majority of the evidence reported on objective failure rates, as assessed by the surgeon using measures such as the pelvic organ prolapse quantification system (POPQ) or the Baden–Walker system. In 10 RCTs, the objective failure rate of repair using mesh was significantly lower (14% [77/557]) than repair without mesh (30% [179/597]) (relative risk [RR] 0.48, 95% confidence interval [CI] 0.32 to 0.72). When evidence from all studies was considered, the objective failure rate for procedures was 29% without mesh (184/640, 95% CI 25.4 to 32.4), 23% with absorbable synthetic mesh (63/273, 95% CI 18.5 to 28.4), 18% for absorbable biological mesh (186/1041, 95% CI 15.7 to 20.3) and 9% for non-absorbable synthetic mesh (48/548, 95% CI 6.7 to 11.4).

2.3.3 Indirect comparisons of different types of mesh using Bayesian analysis indicated that absorbable synthetic mesh (odds ratio [OR] 4.12, 95% credible interval [CrI] 2.27 to 7.70) and absorbable biological mesh (OR 2.97, 95% CrI 1.93 to 4.61) both had statistically significant higher objective failure rates than non-absorbable synthetic mesh (reference technique).

2.3.4 Across all studies, the re-operation rate was higher in women treated with absorbable synthetic mesh (9% [16/174]) compared with those treated with biological mesh (3% [9/280]) and non-absorbable synthetic mesh (1% [3/234]) at mean follow-up of 1.5 years.

2.3.5 There was less evidence available on subjective failure rates (patient reports of persistent prolapse symptoms) and other outcomes, such as urinary, bowel and sexual function. Two RCTs, one non-randomised comparative study and four case series, including a total of 832 women, reported data on subjective failure. Meta-analysis of the RCT evidence showed no statistically significant difference in subjective failures rates in repair with and without mesh (10% [15/153] using biological mesh compared with 12% [19/160] without; RR 0.83, 95% CI 0.44 to 1.57). Across all studies, the subjective failure rate ranged from 2% (1/55, 95% CI 0 to 5.5) to 7% (36/486, 95% CI 5.4 to 10.1) using mesh compared with 11% (19/179, 95% CI 6.9 to 16.0) for procedures without mesh.

2.3.6 The effect of the procedures on bowel symptoms and dyspareunia was not reported in any of the studies. A non-randomised comparative study including 28 women reported no statistically significant difference in the mean quality of life scores between the biological mesh group and the no-mesh group at 2-year follow-up (p = 0.137).

Posterior repair

2.3.7 Nine studies reported on the use of mesh in posterior repair in 417 women (three RCTs, three case series, two non-randomised comparative studies and one registry report). Two studies used absorbable synthetic mesh, three used absorbable biological mesh, one used combined synthetic and biological mesh, two used non-absorbable synthetic mesh and one used both absorbable synthetic mesh and combined mesh. The median follow-up was 12 months (ranging from 1 to 17 months).

2.3.8 Two RCTs reported on objective failure and one reported on subjective failure. No significant differences were found between repair with or without mesh for both objective failure (20% [18/91] vs 14% [17/22]; RR 1.61, 95% CI 0.57 to 4.54) and subjective failure (21% [6/28] vs 15% [9/60]; RR 1.43, 95% CI 0.56 to 3.62).

2.3.9 An RCT (using biological mesh) and two case series (using biological and combined mesh) reported on failure to relieve bowel symptoms. The event rates of persistent bowel symptoms were 33% (19/58, 95% CI 22.1 to 45.6) for procedures without mesh, 17% (14/82, 95% CI 10.5 to 26.4) for those with absorbable biological mesh and 12% (5/43, 95% CI 5.2 to 24.6) for those with non-absorbable synthetic mesh.

2.3.10 In an RCT of 45 women, there were no statistically significant differences in quality of life scores for women who had procedures using absorbable biological mesh and those whose procedures did not use mesh at 2-year follow-up (RR –11, 95% CI –24.15 to 2.15).

Anterior and/or posterior repair

2.3.11 Fourteen studies, including a total of 1680 women treated with mesh, reported data on the use of mesh in anterior and/or posterior repair (nine case series, three RCTs, one non-randomised comparative study and one registry report). One study used absorbable synthetic mesh, one study used a combined synthetic and biological mesh, 10 studies used non-absorbable synthetic mesh and two studies used more than one of the above types of mesh. The median follow-up was 13 months (ranging from 1 to 51 months).

2.3.12 Three RCTs and five case series (923 women in total), reported on objective failure. Across all studies, the objective failure rate was 25% (27/109, 95% CI 17.6 to 33.6) for procedures without mesh and ranged from 6% (41/645, 95% CI 4.7 to 8.5) to 8% (2/26, 95% CI 2.1 to 24.1) for procedures using absorbable synthetic mesh.

2.3.13 An RCT of 66 women and two case series of 148 women in total reported on subjective failure. There was no significant difference in rates of subjective failure between the use of absorbable synthetic mesh and procedures without mesh (44% [14/32] vs 41% [14/34]; RR 1.1, 95% CI 0.42 to 2.95). In the two case series using non-absorbable synthetic mesh there were no reported cases of subjective failure (0/148).

2.3.14 One case series reported on persistent bowel symptoms and another on dyspareunia. After a mean follow-up of 39 months, bowel symptoms persisted in 5% (1/21) of women following mesh repair. Pre-procedural dyspareunia was resolved in 90% (9/10) of women after a mean follow-up of 13 months.

2.3.15 An RCT of 60 women reported no difference in quality of life scores after 6-month follow-up between the absorbable synthetic mesh and the no-mesh group (RR –0.10, 95% CI –1.44 to 1.24).

2.3.16 For all types of mesh repair (both anterior and/or posterior), the Specialist Advisers commented on the lack of long-term data and the uncertainty about recurrence rates following mesh repair. They also considered patient satisfaction and quality of life to be key efficacy outcomes.

2.4 Safety

Anterior repair

2.4.1 In five studies, which included a total of 251 women, there were six reported cases (2%) of damage to organs following non-absorbable synthetic mesh repair. This included four instances of bladder injury or perforation and two cases of urethral perforation.

2.4.2 Seven RCTs, four non-randomised comparative studies and nine case series, including a total of 1394 women, reported rates of mesh erosion. Types of mesh erosion included vaginal erosion, vaginal mesh extrusion and minor mesh exposure. Erosion rates varied depending on the type of mesh used. Erosion occurred in 1% (1/147, 95% CI 0.1 to 3.8) of procedures using absorbable synthetic mesh, 6% (35/581, 95% CI 4.4 to 8.3) using absorbable biological mesh and 10% (68/666, 95% CI 8.1 to 12.7) using non-absorbable synthetic mesh. Women who had non-absorbable synthetic mesh repair were most likely to require an operation to partially or completely remove the mesh because of erosion (7% [22/335], 95% CI 4.5 to 9.7, compared with 3% [1/35], 95% CI 0.0 to 3.3 for absorbable synthetic mesh and 3% [4/154], 95% CI 1.0 to 6.5 for absorbable biological mesh).

2.4.3 Four case series reported de novo urinary incontinence rates of 0% (0/63, 95% CI 0.0 to 5.7) in women treated with absorbable synthetic mesh, 7% (3/42, 95% CI 2.4 to 19.0) with absorbable biological mesh and 7% (3/44, 95% CI 2.3 to 18.2) with non-absorbable synthetic mesh.

2.4.4 A case series using non-absorbable synthetic mesh reported de novo dyspareunia in 36% (4/11) of women at a mean follow-up of 17 months.

Posterior repair

2.4.5 Four studies of 276 women in total reported that damage to surrounding organs during surgery occurred in 3% (2/79, 95% CI 0.7 to 8.8) of women treated with procedures without mesh and ranged from 0% (0/5, 95% CI 0.0 to 43.4; 0/90, 95% CI 0.0 to 4.1) to 4% (3/71, 95% CI 1.4 to 11.7) using mesh. Two cases of bladder injury and three cases of rectal perforation were reported.

2.4.6 Two RCTs of 53 women in total and two case series of 121 women in total reported mesh erosion rates of 0% (0/28, 95% CI 0.0 to 12.1) for absorbable biological mesh, 14% (16/115, 95% CI 8.7 to 21.4) for combined synthetic mesh and 7% (2/31, 95% CI 1.8 to 20.7) for non-absorbable synthetic mesh at a mean follow-up ranging from 6 to 18 months.

2.4.7 De novo urinary incontinence was not reported in any study. In one case series, de novo defecation difficulties were reported in one (1/35) woman and constipation in two (2/45) women at 6- to 12-week follow-up. In a second case series, de novo faecal incontinence after surgery was reported in 3% (1/29) of women at a mean follow-up of 17 months.

2.4.8 Two case series reported de novo dyspareunia in 16% (4/25) of women treated with absorbable biological graft at a mean follow-up of 14 months and in 6% (2/36) of women treated with combined synthetic mesh at a follow-up of 6 months.

Anterior and/or posterior repair

2.4.9 In five studies, which included a total of 684 women, there were 16 reported cases of damage to organs, including bladder, rectal and urethral injury, following mesh repair. Damage occurred in 3% (4/143, 95% CI 1.1 to 7.0) of women treated with combined mesh and in 2% (12/451, 95% CI 1.3 to 3.8) of women treated with non-absorbable mesh.

2.4.10 Mesh erosion occurred in 6% (9/143, 95% CI 3.3 to 11.5) of women treated with combined mesh and 6% (62/1119, 95% CI 4.3 to 7.0) of women treated with non-absorbable synthetic mesh. Further surgical procedures were required in 4% (6/143, 95% CI 1.9 to 8.9) of women treated with combined mesh and 4% (45/1098, 95% CI 3.1 to 5.4) of women treated with non-absorbable synthetic mesh due to erosion.

2.4.11 Five case series of 355 women in total reported de novo urinary incontinence in 10% (34/355, 95% CI 6.9 to 13.1) of women after 6 to 51 months of follow-up.

2.4.12 De novo bowel symptoms were reported in one woman in a single case series of 47 women at a mean follow-up of 29 months. Two case series of 120 women in total reported de novo dyspareunia in 13% (10/78, 95% CI 7.1 to 22.0) of women treated with combined mesh at a mean follow-up of 13 months, compared with 7% (3/42, 95% CI 2.5 to 19.0) of women treated with non-absorbable synthetic mesh at a mean follow-up of 29 months.

2.4.13 The registry study and two case series, including 278 women in total who underwent repair with non-absorbable mesh, reported one recto-vaginal fistula (1/97) and two haematomas (2/110). In total, other serious complications occurred in 1% (3/278) of women.

2.4.14 For all types of mesh repair (both anterior and/or posterior), the Specialist Advisers listed potential complications as infection, erosion, de novo dyspareunia and vaginal narrowing secondary to mesh retraction. One Adviser also noted that use of a trocar introducer system increased the risk of damage to surrounding structures, particularly the blood vessels, bowel, bladder and nerves.

2.5 Other comments

2.5.1 The Committee noted that interpretation of the evidence was made particularly difficult because of the different meshes used and the variation in surgical approaches.

2.5.2 The Committee noted that there is a rapidly accumulating evidence base for this procedure. A number of further studies on mesh repair have been published since the systematic review was carried out, or are in progress with initial results to be made available in the near future. The updated evidence base will inform the review of this guidance in due course.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion) available from www.nice.org.uk/IPG267.

3.2 The Institute's Review Body for interventional procedures is preparing a systematic review of the use of mesh for vaginal vault and uterine prolapse repair (www.nice.org.uk/guidance/index.jsp?action=byID&o=11913). The Institute has published guidance on mesh sacrocolpopexy (www.nice.org.uk/IPG215) and posterior infracoccygeal sacropexy with mesh (www.nice.org.uk/IPG125) for vaginal vault prolapse, both of which will be updated if required following the systematic review. The Institute is developing guidance on laparoscopic uterine suspension slings (www.nice.org.uk/guidance/index.jsp?action=byID&o=11311).

Information for patients

NICE has produced information on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. See www.nice.org.uk/IPG267publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the systematic review, available at www.nice.org.uk/IP660overview

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1604 for this guidance or N1605 for the 'Understanding NICE guidance'.

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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