NICE National Institute for Health and Care Excellence

NICE guidance

Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse

HealthTech guidance
Published: 22 March 2017

www.nice.org.uk/guidance/htg435

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG284 and IPG577.

1 Recommendations

1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse should:

- Inform the clinical governance leads in their trusts.
- During the consent process, ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection and treatment should only be done by specialists with experience in managing pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training in the procedure.

1.4 Clinicians should enter details about all patients having sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical device used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

1.5 NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Uterine prolapse is when the uterus descends from its usual position, into and sometimes through, the vagina. It can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.

2.2 Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Different surgical procedures can be used, including hysterectomy, infracoccygeal sacropexy, uterine suspension sling (including sacrohysteropexy) and uterine or vault suspension (without sling). Some of these procedures involve the use of mesh, to provide additional support.

3 The procedure

3.1 Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is done with the patient under general anaesthesia. An open or laparoscopic abdominal approach is used after the hysterectomy. Mesh is attached to the apex of the vagina and may also be attached to the anterior or posterior vaginal wall, to prevent future vaginal vault prolapse.

3.2 This procedure can be combined with surgery for stress urinary incontinence such as colposuspension or suburethral sling placement. Several different types of synthetic and biological mesh are available, which vary in structure and in their physical properties, such as absorbability.

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 procedures overview.

4.1 A non-randomised study, included in a systematic review of 311 women with uterine prolapse, compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy with concomitant sacrocolpopexy. There was no objective failure (defined as prolapse at less than 6 cm above the hymen) in either group. This was at a mean follow-up of 51 months.

4.2 In the same non-randomised study included in the systematic review of 311 women, none of the 75 women needed a further operation for recurrent or de novo prolapse at a mean follow-up of 51 months. In a prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy, recurrent stage 2 rectocele without any cystoceles or vault prolapse occurred in 8% (4/64) of women at a median follow-up of 27 months. A retrospective comparative study of 182 women with uterovaginal prolapse compared 123 women treated by total vaginal hysterectomy with concomitant laparoscopic sacrocolpopexy (TVH+LSC) with 59 women treated by laparoscopic supracervical hysterectomy with concomitant laparoscopic sacrocolpopexy (LSCH+LSC). There was no difference in anatomical success (defined as no prolapse at or beyond the hymen and no apical prolapse beyond the mid-vagina; TVH+LSC 94% versus LSCH+LSC 93%, p=0.8) or subjective success (defined as the absence of bulge symptoms and overall Patient Global Impression of Improvement-I response of 'very much better' or 'much better'; TVH+LSC 91% versus LSCH+LSC 81%, p=0.3) between the 2 groups.

4.3 In the prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy, 93% (60/64) of women reported satisfaction with the procedure at a median follow-up of 27 months. Mean pelvic floor distress inventory scores improved from 50 to 10 (p=0.001).

4.4 The specialist advisers considered key efficacy outcomes as patient satisfaction, correction of prolapse and reduction of a bulge.

4.5 Six commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

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 procedures overview.

Mesh erosion

Abdominal sacrocolpopexy with concomitant hysterectomy

5.1 The risk of mesh erosion varied across 4 studies on abdominal sacrocolpopexy with concomitant hysterectomy to repair uterine prolapse included in a systematic review.

- Mesh erosion was reported in 4% (1/23) of women treated by hysterectomy with concomitant sacrocolpopexy in a randomised controlled trial of 47 women available as a conference abstract (mean follow-up 33 months).
- In a non-randomised comparative study of 75 women, mesh erosion occurred in 8% (3/39) of women treated by hysterectomy with concomitant sacrocolpopexy and in no women (0/36) in the sacrohysteropexy group (mean follow-up 51 months); all women with mesh erosion needed further surgery.
- In another non-randomised comparative study of 88 women, erosion rates of 11% (8/76) were reported in women treated by total hysterectomy with concomitant sacrocolpopexy and in 4% (1/28) of women treated by supracervical hysterectomy with concomitant sacrocolpopexy (median follow-up 4 months); 4 of the 8 women with mesh erosion needed further surgery.
- In a case series of 324 women, 7% (7/101) of women reported mesh erosion after hysterectomy with concomitant sacrocolpopexy at a median follow-up of 8.4 months (range 1.4 to 13 months).

5.2 In a retrospective non-randomised comparative study of 179 women, mesh

erosion was reported in 6.5% (5/74) of women in the hysterectomy with concomitant sacrocolpopexy group, in 5.9% (3/51) of women in the sacrohysteropexy group and in 7.4% (4/54) of women in the sacrocolpopexy group with previous hysterectomy at a mean follow-up 57 months. The time to mesh erosion ranged from 2 to 66 months. Four erosions were asymptomatic and 5 presented with vaginal bleeding, associated with dyspareunia in 2 women and infection in 3 women. In all women, surgery was needed to remove the mesh because conservative management did not work.

5.3 In a case-control study of 336 women treated by abdominal sacrocolpopexy (ASC n=43, control n=147) or vaginal mesh procedure (VMP n=41, control n=105) with concomitant hysterectomy, concomitant hysterectomy was associated with mesh extrusion among women who had ASC (odds ratio [OR], 3.18; 95% confidence interval [CI] 1.27 to 7.93, p=0.01) and VMP (OR 3.72, 95% CI 1.20 to 11.54, p=0.02).

5.4 In a retrospective non-randomised comparative study of 292 women treated by ASC (74 with concomitant hysterectomy, 218 with previous hysterectomy), the rates of mesh exposure were lower in women with previous hysterectomy (mesh erosion 53% [10/19] versus no erosion 76% [208/273], p=0.03) at a median follow-up of 42 months. Also, the study found that concomitant hysterectomy (mesh erosion 47% [9/19] versus no erosion 24% [65/273], p=0.03) or 3 or more additional procedures (mesh erosion 32% [6/19] versus no erosion 11% [31/273], p=0.02) increased the risk of mesh exposure.

Robotic assisted sacrocolpopexy with concomitant hysterectomy

5.5 Mesh erosion rate after robotic assisted sacrocolpopexy (RASC) with a concomitant hysterectomy or RASC alone was not significantly different (2.7% [3/112] versus 5.1% [6/118]; p=0.50) in a retrospective non-randomised comparative study of 230 women at 6-week follow-up. The 2.7% (3/79) of mesh exposures in the hysterectomy group were associated with total hysterectomy and none with supracervical hysterectomy (n=33), this difference was not significant (p=0.50). In another retrospective non-randomised comparative study, there was a mesh exposure rate of 14% (8/57) in the combined RASC with total hysterectomy group compared with 0% (0/45) in the RASC with supracervical hysterectomy group

(p<0.01) at 3-month follow-up. All erosions occurred at the vaginal apex.

Laparoscopic sacrocolpopexy with concomitant hysterectomy

5.6 Mesh erosion rates were higher in women having conventional laparoscopic sacrocolpopexy (LSC) with concomitant total vaginal hysterectomy (TVH) compared with both robotic or conventional sacrocolpopexy after hysterectomy (23% [13/57] versus 5% [5/110]; p=0.003) and robotic LSC with supracervical hysterectomy (23% [13/57] versus 5% [1/21]; p=0.984) in a retrospective cohort study of 188 women (mean follow-up of 20 weeks). In multivariate regression analysis, the odds ratio of erosion for TVH done at the same time as sacrocolpopexy was 5.67 (95% CI 1.88 to 17.10; p=0.002) compared with sacrocolpopexy with concomitant hysterectomy.

5.7 Mesh exposure was more common when the vaginal cuff was opened, either in the course of hysterectomy or during vaginal attachment of mesh in women with a previous hysterectomy (4.9% [10/205] versus 0.5% [1/185]; relative risk [RR] 9.0; p=0.012) in a retrospective non-randomised comparative study of 390 women at a median follow-up 26 weeks. In women who had a concomitant hysterectomy, a higher mesh exposure rate was seen in open-cuff hysterectomy (TVH or laparoscopically assisted vaginal hysterectomy [LAVH]) compared with supracervical hysterectomy (4.9% [9/185] versus 0% [0/92], p=0.032). Mesh exposure was more common when the mesh was sutured laparoscopically compared with transvaginally in women treated by open-cuff hysterectomy (14.3% [5/35] versus 2.7% [4/150]; relative risk, 5.4; p=0.013). There was no difference in exposure rates between TVH and LAVH groups (6.8% [4/59] versus 4% [5/126]; p=0.469).The rate of mesh complications was not significantly different among women who had TVH with LSC compared with women who had laparoscopic supracervical hysterectomy (LSCH) with LSC (1.6% [2/123] versus 1.7% [1/59]; p=1.0) in a retrospective non-randomised comparative study of 182 women with a median prospective follow-up of 9 months.

5.8 Extrusion of permanent suture was more common in women treated by LSCH with LSC compared with women treated by TVH with LSC (5.6% [13/233] versus 0.6% [1/157]; relative risk, 8.8; p=0.010) in a retrospective cohort study of 390 women. Most of these extrusions were asymptomatic and were managed

non-surgically. The rate of suture erosion was not significantly different among women who had TVH with LSC compared with women who had LSCH with LSC (1% versus 2%; p=1.0) in the retrospective non-randomised comparative study of 182 women with a median prospective follow-up of 9 months.

Other complications

5.9 Wound infection was reported in 8% (3/39) of women treated by hysterectomy with concomitant sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review.

5.10 The presence of granulation tissue was not significantly different among women who had TVH with LSC compared with women who had LSCH with LSC (10% versus 7%; p=0.6) in the retrospective non-randomised comparative study of 182 women with a median prospective follow-up of 9 months. This was treated in the operating room.

5.11 Peri-vesical haematoma was reported in 5% (2/36) of women treated by sacrohysteropexy and 10% (4/39) of women who had hysterectomy with concomitant sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review. The time of occurrence and further details were not reported.

5.12 Incisional hernia was reported in 5% (2/36) of women treated by sacrohysteropexy and 2% (1/39) of women who had hysterectomy with concomitant sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review.

5.13 Severe abdominal pain because of bowel obstruction was reported in 1 patient in the LSCH+LSC group (n=59) in the non-randomised comparative study of 182 women. This was managed by small bowel resection and re-anastomosis of the bowel. The patient recovered completely and there was no evidence of mesh exposure.

5.14 Voiding dysfunction was reported in 11% (4/36) of women treated by sacrohysteropexy and 2% (1/39) of women who had hysterectomy with

concomitant sacrocolpopexy in the non-randomised comparative study of 75 women included in the systematic review.

5.15 In addition to 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 listed the following anecdotal adverse event: osteomyelitis because of vagina being opened and inserting mesh.

5.16 Six commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

6 Committee comments

6.1 Concomitant total hysterectomy with sacrocolpopexy is associated with a higher risk of mesh erosion when compared with concomitant subtotal hysterectomy with sacrocolpopexy. This may be because of the closeness of the mesh to a fresh suture line.

6.2 Because of an increased risk of mesh erosion, sacrocolpopexy with concomitant hysterectomy is now used less commonly and a 2-stage procedure (hysterectomy followed by sacrocolpopexy at a future date) is preferred.

6.3 There appears to be under-reporting of complications of the procedure to the Medicines and Healthcare products Regulatory Agency.

6.4 Registry data collection has been disappointing.

6.5 There is a subspecialty training programme in urogynaecology with a General Medical Council approved curriculum for clinicians who wish to do this procedure, which incorporates laparoscopic urogynaecology training.

6.6 Different mesh materials are used in this procedure.

6.7 Patient commentaries supported use of the procedure.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 577 has been migrated to HealthTech guidance 435. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8589-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.