

# Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse

Interventional procedures guidance

Published: 28 June 2017

[www.nice.org.uk/guidance/ipg584](http://www.nice.org.uk/guidance/ipg584)

## 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.

This guidance replaces IPG282.

# 1 Recommendations

- 1.1 Current evidence on the safety of uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse shows there are serious and well-recognised complications. The evidence on efficacy is adequate in quantity and quality. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 During the consent process, clinicians should ensure that patients understand the risk of uterine prolapse happening again and of potentially serious complications, including mesh erosion (for example, into the bladder). Patients should be told about all treatment options and provided with clear written information about the procedure and its complications. In addition, the use of NICE's information for the public is recommended.
- 1.3 Patient selection should be done by a multidisciplinary team with experience in managing pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training and do the procedure regularly.
- 1.4 Clinicians should enter details about all patients having mesh uterine suspension (including sacrohysteropexy) to repair uterine prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical devices (including mesh) used in this

procedure should be reported to the [Medicines and Healthcare products Regulatory Agency](#).

## 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 symptoms of pressure and discomfort, and by its effects on urinary, bowel and sexual function.
- 2.2 Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Some surgical procedures involve the use of mesh, with the aim of providing additional support.

## 3 The procedure

- 3.1 Uterine suspension using mesh to repair uterine prolapse involves attaching the uterus (or cervix) either to the sacrum (sacrohysteropexy) or to the ileopectineal ligaments. This procedure can also be used for women with cervical prolapse after supracervical hysterectomy. The procedure is done with the patient under general anaesthesia by an open or laparoscopic abdominal approach. In sacrohysteropexy the mesh can be attached to the uterus either in the midline of the posterior cervix or bilaterally, where the uterosacral ligaments join the uterus (in both cases the other end of the mesh is attached to the sacrum). Another mesh suspension technique involves attaching the mesh to the front of the uterine cervix and to the lateral ileopectineal ligaments. Each of the above procedures can be described as a 'uterine suspension using mesh'.
- 3.2 This procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or minimally invasive sling placement. Several different types of synthetic and biological mesh are available that 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 procedure overview](#).

- 4.1 In a systematic review of surgery for women with apical prolapse including 183 women with uterine prolapse (2 randomised controlled trials [RCTs]) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, there was no difference in repeat prolapse surgery between the groups at 1 to 8-year follow-up (risk ratio [RR] 0.68, 95% confidence interval [CI] 0.36 to 1.31, n=182, low quality evidence). In a retrospective case series of 507 women with uterine prolapse treated by laparoscopic sacrohysteropexy, 3% (14/507) of women had further apical prolapse at a median follow-up of 12 months (range 6 to 84 months) because the mesh had stretched. Of these, 10 women had plication of mesh and 3 had cervical amputation for elongation. Ongoing uterine prolapse was reported in 2 women and treated by vaginal hysterectomy; 7% (36/507) of women had further vaginal wall repair. In a case series of 194 premenopausal women with uterine prolapse treated by pectineal ligament hysteropexy (PLH) by open or laparoscopic approach, the overall reoperation rate after PLH was 15% (29/194) at a mean follow-up of 6.5 years; 6% (10/176) of women had grade 3 uterine prolapse recurrence (7 occurred in pregnant women after vaginal delivery; 3 in non-pregnant women, of which 1 was a tape erosion into the bladder). Twelve women developed cystocele and 7 developed cervical elongation. Laparoscopic procedures had no recurrence of prolapse over 2 years.
- 4.2 In the systematic review including 183 women with uterine prolapse, evidence from 1 RCT (n=82) did not show a statistically significant difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for objective failure of anterior vaginal compartment (RR 1.04, 95% CI 0.60 to 1.82), apical compartment (RR 1.00, 95% CI 0.15 to 6.76) or posterior vaginal compartment (RR 3.07, 95% CI 0.66 to 14.35) at 1-year follow-up. In a non-randomised comparative study of 151 women comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), there was no difference between groups in the rate of apical failure (19% [12/64] laparoscopic hysteropexy compared with 16% [9/61] vaginal mesh hysteropexy, p=0.16) or

anterior failure (9% [6/65] laparoscopic hysteropexy compared with 6% [4/61] vaginal mesh hysteropexy,  $p=0.93$ ) at 1-year follow-up.

- 4.3 In the systematic review including 183 women with uterine prolapse, 1 RCT reported that awareness of prolapse (defined as any positive response to questions related to awareness of prolapse or vaginal bulge) was less likely after vaginal hysterectomy than after abdominal sacrohysteropexy at 8-year follow-up, but this result was not statistically significant (RR 0.38, 95% CI 0.15 to 0.98,  $n=84$ , moderate quality evidence). In the case series of 507 women there was significant improvement for pelvic organ prolapse quantification point C assessment ( $p<0.001$ ), with a mean change of 7.9 cm between preoperative and postoperative scores at 3-month follow-up; 94% (379/404) of women felt that their prolapse (assessed using 7-point Patient Global Impression of Improvement [PGI-I] subjective measure) was 'very much' or 'much' better and 2% (6/404) felt there was no change in symptoms. No women described their symptoms as worse. In the non-randomised comparative study of 151 women comparing laparoscopic sacral hysteropexy with vaginal mesh hysteropexy, prolapse stage was similar but laparoscopic hysteropexy was associated with increased vaginal length ( $p<0.001$ ), increased perineal body length ( $p=0.02$ ) and better apical support ( $p=0.05$ ) at 1-year follow-up. Overall satisfaction (measured on PGI-I scale) was high and 79% of women in each group rated prolapse symptoms as 'very much better' and 16% 'much better' at 1-year follow-up.
- 4.4 In a case series of 100 women with uterovaginal prolapse treated by robotic sacrohysteropexy, overall quality of life (measured using the validated urogenital distress inventory and incontinence impact questionnaires [UDI/IIQ], with scores ranging from 0 to 6) improved from a mean score of 4.5 to 5.12 ( $p<0.05$ ), and overall health status (based on a visual analogue scale of 0 to 100) improved from 73% to 82% ( $p<0.05$ ), 6 weeks after surgery. Postoperatively women also experienced less feelings of nervousness ( $p=0.01$ ), shame ( $p<0.05$ ) and frustration ( $p<0.05$ ). After 5 years the positive effects of these feelings remained and quality of life and overall health status remained stable.
- 4.5 In the case series of 194 premenopausal women with uterine prolapse, there were 46 births (32 vaginal and 14 caesarean deliveries) in 40 women after PLH. Prolapse recurred (tape avulsed from the uterus) in 7 women after vaginal delivery and was treated by vaginal hysterectomy. There were no recurrences

after caesarean deliveries.

- 4.6 The specialist advisers listed key efficacy outcomes as resolution of prolapse symptoms and recurrent apical prolapse.
- 4.7 Twenty one 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 procedure overview](#).

- 5.1 Mesh complications were reported in 3% (2/74) of women in the laparoscopic hysteropexy group (1 excision and 1 spontaneous resolution) and in 7% (5/77) of women in the vaginal mesh hysteropexy group (treated by excision in 3 and observation in 2) in a non-randomised comparative study of 151 patients. Tape erosion into the bladder occurred in 1 non-pregnant woman who had grade 3 uterine prolapse recurrence after open sacrohysteropexy, in a case series of 194 premenopausal women with uterine prolapse treated by pectineal ligament hysteropexy (PLH). Further treatment details were not reported. In a systematic review of surgery for women with apical prolapse including 183 women with uterine prolapse (2 randomised controlled trials [RCTs]) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, evidence from 1 RCT (n=82) did not show a statistically significant difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy in the rate of mesh exposure (risk ratio [RR] 0.20, 95% confidence interval [CI] 0.01 to 4.04), or the need for repeat operation for mesh exposure (RR 0.20, 95% CI 0.01 to 4.04).
- 5.2 In the systematic review including 183 women with uterine prolapse, evidence from 1 RCT (n=82) did not show a statistically significant difference in the rate of bowel injury between vaginal hysterectomy with vault support and abdominal sacrohysteropexy (RR 3.00, 95% CI 0.13 to 71.56). Small bowel injuries were reported in 3% (2/74) of women in the laparoscopic hysteropexy group and

- bladder injuries were reported in 4% (3/77) of women in the vaginal mesh hysteropexy group, in the non-randomised comparative study of 151 women.
- 5.3 Bowel obstructions were reported in 2 women in a case series of 159 women treated by modified single-sheet mesh sacrohysteropexy. Both needed surgical re-intervention to release bowel adhesions. Adhesions were noted between bowel and non-peritonised mesh in less than 1% (3/507) of women who reported lower abdominal pain 4 to 8 months after surgery, in a case series of 507 women treated by laparoscopic hysteropexy. These were carefully divided. Damage to surrounding organs causing haemorrhage was reported in less than 1% (3/507) of women in the same study.
- 5.4 Infections were reported in 1 RCT, 1 non-randomised comparative study, and 1 case series included in a systematic review of 239 women. In the RCT, infections were reported as vault abscess during admission (2/41), infected implant needing surgery (2/41) and fever of unknown origin (3/41). In total, 17% (7/41) of women had an infection after sacrohysteropexy compared with 5% (2/41) in the vaginal hysterectomy group. The outcome was reported as wound infection and fever in the non-randomised comparative study. Three cases of infection (3/39) occurred in the hysterectomy followed by sacrocolpopexy group, and 1 (1/36) occurred in the sacrohysteropexy group. In the case series, 1 urinary tract infection (1/30) and 1 wound infection (1/30) were reported after sacrohysteropexy.
- 5.5 In the systematic review including 183 women with uterine prolapse, evidence from 1 RCT (n=82) did not show a statistically significant difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy in the need for a blood transfusion (RR 2.00, 95% CI 0.19 to 21.21).
- 5.6 Other serious adverse effects reported in the systematic review of 239 women included incisional hernia in 4 women and 1 intestinal occlusion by the mesh after sacrohysteropexy. Pulmonary embolism was reported in 2 women in the case series of 507 women treated by laparoscopic sacrohysteropexy.
- 5.7 Other complications including perineal infection in 3% (16/507) of women, urinary tract infections in 1% (6/507) and voiding difficulties in 2% (11/507) were reported in the case series of 507 women treated by laparoscopic sacrohysteropexy. In a



case series of 245 patients, after 1 year, 2% of women had urinary retention needing treatment, 2% had de novo stress urinary incontinence, 5% had urgency, 5% developed de novo constipation and 5% reported de novo dyspareunia. Overactive bladder occurred in 6% (3/54) of women treated by robotic or laparoscopic sacrohysteropexy and in 18% (10/57) treated by open sacrohysteropexy in the non-randomised study of 111 women (median follow-up of 30 months). One patient reported a feeling of traction in the abdomen that reduced after the mesh was partially removed several weeks after robotic sacrohysteropexy, in a case series of 100 women. The study also reported ileus (n=1), oedema of the right arm leading to temporary sensitive malfunction (n=1) and de novo stress urinary incontinence (n=13). All patients reported postoperative dragging pain, at the points where the mesh was fixed to the abdominal wall, in a case series of 28 women.

- 5.8 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: sacral discitis. They considered that the following were theoretical adverse events: risk related to sacral promontory mesh fixation (vascular damage and discitis) and risk of performing a hysterectomy after a hysteropexy.
- 5.9 Twenty one commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

## 6 Committee comments

- 6.1 The committee was advised that a national standard consent form is being developed.
- 6.2 The committee was informed that although the procedure preserves the uterus, future pregnancy is not recommended.
- 6.3 Patient commentaries supported use of the procedure.



## 7 Further information

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-2572-8

## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).