

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Interventional procedure consultation document

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

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. Uterine suspension using mesh involves attaching 1 end of the mesh to the lower part of the uterus or the cervix. The other end is attached to a bone at the base of the spine or to a ligament in the pelvis. The procedure can be done through open abdominal surgery or laparoscopy (keyhole surgery). The aim is to support the womb.

The National Institute for Health and Care Excellence (NICE) is examining uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse 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 uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.

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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 24 March 2017

Target date for publication of guidance: June 2017

1 Draft recommendations

- 1.1 Current evidence on the safety of uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse shows there are serious but 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](#) *[add URL]*.

- 4.1 In a systematic review of surgery for women with apical prolapse including 183 women with uterine prolapse (2 randomised

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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 (19%, [12/64] laparoscopic hysteropexy versus 16%, [9/61] vaginal mesh hysteropexy; p=0.16) or anterior failure (9% [6/65] laparoscopic hysteropexy versus 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.

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](#) [add URL].

- 5.1 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, 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). 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.
- 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. Over-active 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.

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.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 Patient commentary was sought but none was received.
- 7.3 This guidance is a review of NICE's interventional procedure guidance on [insertion of mesh uterine suspension sling \(including sacrohysteropexy\) for uterine prolapse repair](#).

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February 2017