NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. Sacrocolpopexy involves inserting a piece of mesh typically between the top and back of the vagina, to a ligament of the lower backbone, with the aim of holding the pelvic organs in place, after surgical removal of the womb (hysterectomy).

The National Institute for Health and Care Excellence (NICE) is examining sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair 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 sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair.

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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 22 December 2016

Target date for publication of guidance: March 2017

1 Draft 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.

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.

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 effect on urinary, bowel and sexual function.

2.2 Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Several 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, with the aim of providing additional support.

3 The procedure

3.1 Sacrocolpopexy with hysterectomy using mesh for uterine prolapse is done with the patient under general anaesthesia. An open or laparoscopic abdominal approach is used, following on from a concomitant hysterectomy procedure. Mesh is attached to the apex of the vagina and may also be attached to the anterior or posterior vaginal wall, with the aim of preventing future vaginal vault prolapse.

3.2 This procedure can be combined with surgery for stress urinary incontinence such as colposuspension or suburethral sling placement.

3.3 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 procedure overview ***[add URL]***.

4.1 In a systematic review of 311 women with uterine prolapse, a non-randomised study that compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy with concomitant sacrocolpopexy reported no objective failure (defined

as prolapse at less than 6 cm above the hymen) in either group (0/36 and 0/39) at a mean follow-up of 51 months.

4.2 In the systematic review of 311 women, the non-randomised study that compared 36 women treated by mesh sacrohysteropexy with 39 women treated by hysterectomy with concomitant sacrocolpopexy reported that none of the 75 women needed a further operation for recurrent or de novo prolapse at a mean follow-up of 51 months. A prospective case series of 67 women treated by sacrocolpopexy with concomitant total abdominal hysterectomy reported recurrent stage 2 rectocele without any cystoceles or vault prolapse in 8% (4/64) of women at a median follow-up of 27 months. A retrospective comparative study of 182 women with uterovaginal prolapse that compared 123 women treated by total vaginal hysterectomy with concomittant laparoscopic sacrocolpopexy (TVH+LSC) with 59 women treated by laparoscopic supracervical hysterectomy with concomittant laparoscopic sacrocolpopexy (LSCH+LSC) reported 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.

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]***.

Mesh erosion

Abdominal sacrocolpopexy with concomitant hysterectomy

5.1 The risk of mesh erosion varied across 4 studies on abdominal sacrocolpopexy with concomitant hysterectomy for 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).
- A non-randomised comparative study of 75 women reported mesh erosion in 8% (3/39) of women treated by hysterectomy with concomitant sacrocolpopexy group and no mesh erosions (0/36) in the sacrohysteropexy group (mean follow-up 51 months); all women with mesh erosion needed further surgery.
- Another non-randomised comparative study of 88 women reported erosion rates of 11% (8/76) in women treated by total hysterectomy with concomitant sacrocolpopexy and 4% (1/28) in women treated by supracervical hysterectomy with concomitant sacrocolpopexy (median follow-up 4 months); 4 of the 8 women with mesh erosion needed further surgery.

- A case series of 324 women reported that 7% (7/101) of women had mesh erosion after hysterectomy with concomitant sacrocolpopexy at a median follow-up of 8.4 months (range 1.4 to 13 months).

5.2 A retrospective non-randomised comparative study of 179 women reported mesh erosions in 6.5% (5/74) of women in the hysterectomy with concomitant sacrocolpopexy group, 5.9% (3/51) of women in the sacrohysteropexy group and 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 (2), and infection (3). In all cases surgery was needed to remove the mesh as women did not respond to conservative management.

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

5.4 A retrospective non-randomised comparative study of 292 women treated by ASC (74 with concomitant hysterectomy, 218 with previous hysterectomy) reported that 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, it 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 weeks 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). Another retrospective non-randomised comparative study reported a mesh exposure rate of 14% (8/57) in the combined RASC with total hysterectomy group compared to 0% (0/45) in the RASC with supracervical hysterectomy group (p<0.01) at 3 months 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, the odds 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 sacrocolpoexy 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 cases where concomitant hysterectomy was done, a higher mesh exposure rate was seen in open-cuff hysterectomy (TVH or laparoscopically assisted vaginal hysterectomy [LAVH]) compared to 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 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 LSH 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 rate of 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. All women were managed 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 due to 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 reanastomosis 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 due to vagina being opened and inserting mesh.

6 Committee comments

6.1 The committee was informed that because of an increased risk of mesh erosion, sacrocolpopexy with concomitant hysterectomy is now used less commonly and that a 2-stage procedure (hysterectomy followed by sacrocolpopexy at a defined future date) is preferred.

6.2 The committee was informed that a concomitant total hysterectomy with sacrocolpopexy is associated with a higher risk of mesh erosion when compared to a concomitant subtotal hysterectomy with sacrocolpopexy.

6.3 The committee was informed that there appears to be underreporting of complications of the procedure to the Medicines and Healthcare products Regulatory Agency.

6.4 The committee noted that to date registry data collection has been disappointing.

6.5 The committee was informed that there is subspecialty training program in urogynaecology with a General Medical Council approved curriculum for clinicians who wish to do this procedure which incorporates laparoscopic urogynaecology training.

6.6 The committee noted that there are different mesh materials used in this procedure.

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 sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair : http://www.nice.org.uk/IPG284

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