NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Sacrocolpopexy using mesh to repair vaginal vault prolapse

The vaginal vault is a structure formed at the top of the vaginal canal after surgery to remove the womb and cervix. Vaginal vault prolapse happens when the upper part of the vagina slips down from its usual position. Sacrocolpopexy is an operation that aims to support the pelvic organs in their natural position. This is achieved by attaching a piece of mesh, usually from the top and back of the vagina, to a ligament of the lower back bone.

The National Institute for Health and Care Excellence (NICE) is examining sacrocolpopexy using mesh for vaginal vault 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 using mesh to repair vaginal vault 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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 22 December 2016

Target date for publication of guidance: March 2017

1 Draft recommendations

1.1 Current evidence on the safety of sacrocolpopexy using mesh to repair vaginal vault prolapse shows there are serious but well-recognised safety concerns. 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 patients understand that there is a risk of vaginal vault prolapse happening

again, and of potentially serious complications, including mesh erosion (for example, into the vagina). Patients should be provided with clear written information about the procedure and its complications. In addition, the use of NICE's information for the public *[[URL to be added at publication]]* is recommended.

1.3 Patient selection and treatment should only be done by clinicians specialising in the management of 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 sacrocolpopexy using mesh to repair vaginal vault prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical devices used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

2 Indications and current treatments

2.1 Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. It is a common condition after hysterectomy and can affect quality of life by causing symptoms of pressure and discomfort, and by its effect on urinary, bowel and sexual function.

2.2 Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated with conservative measures such as pelvic-floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used. Surgery may be needed when the

prolapse is severe. A number of different surgical procedures are available for repairing vaginal vault prolapse using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve the use of mesh, with the aim of providing additional support.

3 The procedure

3.1 Sacrocolpopexy using mesh to repair vaginal vault prolapse is done with the patient under general anaesthesia, using an open or laparoscopic abdominal approach. Mesh is attached to the longitudinal ligament of the sacrum, most often at the level of the sacral promontory. The mesh is then attached to the apex of the vagina and sometimes to the anterior or posterior vaginal wall.

3.2 The procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or sub-urethral sling placement. Several different types of meshes or grafts have been used for this procedure, including synthetic meshes, allografts and xenografts. Different types of mesh may have different safety profiles.

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 and meta-analysis of 5,954 women from 56 randomised control trials (RCTs) comparing surgery for pelvic organ prolapse, 10 studies compared surgery for apical vaginal

prolapse repair. In 3 RCTs comparing abdominal sacrocolpopexy (SCP) with vaginal sacrospinous colpopexy (VSC), there was no statistically significant difference in the rate of subjective failure (11% [9/84] versus 21% [18/85], relative risk (RR) 0.53; 95% confidence interval [CI] 0.25 to 1.09).

4.2 In the systematic review and meta-analysis of 5,954 women from 56 RCTs, there were statistically significantly fewer women who did not improve to stage 2 (that is, the leading edge of the vagina descending within 1 cm of the hymen) or better in the SCP group than in the VSC group in 1 single centre RCT (6% [3/52] versus 20% [13/66], RR 0.29; 95% CI 0.09 to 0.97, median follow-up of 2 years). In another RCT with 2-year follow-up, included in the same systematic review, laparoscopic sacrocolpopexy (LSC) was statistically significantly better than total vaginal propylene mesh repair in reducing prolapse to less than stage 2 (23% [12/53] versus 58% [32/55], RR 0.39; 95% CI 0.23 to 0.67). In a systematic review of 1,176 women (from 13 comparative studies), mesh SCP was compared with native tissue repair. Prolapse reduction success was defined as a less than stage 2 prolapse or an above the hymen measurement. For a follow-up period between 1 and 2.5 years the meta-analysis of 4 RCTs from this systematic review reported that mesh SCP had statistically significantly better objective cure rates than native tissue vaginal repair (75% [132/177] versus 62% [119/192], odds ratio (OR) 2.04; 95% CI 1.12 to 3.72, I^2=31%). One comparative study included in this paper reports a statistically significantly higher recurrence of posterior wall prolapse after LSC (17% [10/60]) than after sacrospinous ligament fixation (0/51, $p<0.01$). The systematic review of 5,954 women reported that SCP had a statistically significantly lower rate of

recurrent vaginal vault prolapse (4% [3/84]) than VSC (15% [13/85]) in a meta-analysis of 2 RCTs (RR 0.23; 95%CI 0.07 to 0.77, I^2=0%, p=0.018). The systematic review of 5,954 women included 1 RCT that reported a statistically significantly lower objective recurrence rate for LSC compared with total vaginal propylene mesh (23% [12/53] versus 100% [32/55], RR 0.39; 95%CI 0.23 to 0.67) at 2-year follow-up. In a systematic review and meta-analysis of 1,488 women from 27 studies (17 single arm and 10 comparative studies) the objective failure rate (apical prolapse) was less than 1% (2/246). For all-compartment prolapse, the failure rate was 6% (66/1,029), for a minimum 2-year follow-up. In the RCT of 100 patients comparing SCP using polypropylene mesh against SCP using cadaveric fascia lata, overall objective anatomic success was statistically significantly higher in the polypropylene group (93% [27/29]) than in the fascia lata group (62% [18/29] at 5-year follow-up, p=0.02). A case series of 165 women treated by LSC reported recurrence of vault prolapse in 5% (7/138) of patients, recurrent rectocele in 1% (1/138) and cystocele in 4% (5/138) of women at 8-year follow-up.

4.3 In the systematic review and meta-analysis of 5,954 women from 56 RCTs, 1 RCT (Maher 2011) reported that 2% (1/53) of patients in the SCP group were unsatisfied compared with 7% (4/55) of patients treated by VSC. The difference was not statistically significant, RR 0.82; 95%CI 0.32 to 2.06 (n=89). In a prospective case series of 70 women treated by robot-assisted sacrocolpopexy (RASC), 55% (22/40) would recommend the procedure to a relative or friend, 25% (10/40) would probably recommend the procedure and overall satisfaction was 10 (0=not at all successful, 10=very successful) at the median follow-up of 90 months. The average

symptomatic improvement was 9 (0=much worse, 10=much better). In the prospective case series of 165 women treated by LSC, 83% (115/138) of women were 'quite satisfied', 12% (16/138) were 'satisfied enough' and 5% (7/138) were 'not satisfied'.

4.4 In the systematic review and meta-analysis of 5,954 women from 56 RCTs, 2 RCTs (n=128) showed there was a statistically significant lower rate of stress urinary incontinence in women treated by SCP (30% [14/47]) than in women treated by VSC (35% [28/81], RR 0.55; 95%CI 0.32 to 0.95).

4.5 The prospective case series of 165 women reported that constipation rates increased from 7% (10/138) before surgery to 13% (18/138) at the end of follow-up, and obstructed defaecation increased from 1% (2/138) to 6% (8/138). Urgency was not reported by any women before surgery and it was reported in 2% (3/138) of patients at the end of 43 months. The incidence of pelvic pressure symptoms reduced from 67% (92/138) to 9% (12/138) at the end of follow-up. Similarly, the incidence of false urge to defecate reduced from 51% (70/138) of women at baseline to 5% (7/138) at 43 months.

4.6 In the systematic review and meta-analysis of 5,954 women from 56 RCTs, 3 RCTs reported that reduction in postoperative dyspareunia was greater in the SCP group than in the VSC group (16% [7/45] compared with 36% [22/61], RR 0.39; 95%CI 0.18 to 0.86).

4.7 In the prospective case series of 101 women treated by LSC, the quality-of-life score improved from 5.6 at baseline to 9.1 at 12 months and 8.3 at 60 months (measured on a visual analogue scale between 1 and 10).

4.8 The specialist advisers listed the key efficacy outcomes as patient satisfaction, elimination of the bulge in the vagina, and bladder, bowel and sexual function changes.

4.9 Fourteen 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 ***[add URL]***.

5.1 Incidence of death was not statistically significantly different in women treated by abdominal sacrocolpopexy (SCP) using mesh (0/503) compared with women treated using native tissue (less than 1% [1/582], odds ratio [OR] 0.14; 95% CI 0.003 to 6.97) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Postoperative admission to intensive care was not statistically significantly different in the SCP using mesh group (1% [3/561]) compared with the native tissue repair group (0/506, OR 4.64; 95% CI 0.42 to 50.6) in the analysis of comparative studies in the same systematic review.

5.2 Deep vein thrombosis or pulmonary embolism was not statistically significantly different between the SCP using mesh group (less than 1% [2/569]) and the native tissue repair group (less than 1% [1/599], OR 1.36; 95% confidence interval [CI] 0.14 to 13.7) in women included in comparative studies from the same analysis.

5.3 Mesh or suture complications were statistically significantly more frequent in patients treated by SCP using mesh (4% [28/650]) compared with patients who had native tissue repairs (1% [6/537], OR 3.26; 95%CI 1.62 to 6.56) in an analysis of comparative studies in the systematic review of 1,176 women. Mesh or suture complications were statistically significantly more frequent in patients treated by SCP using mesh (4% [348/7,831]) than in patients treated by native tissue repair (less than 1% [13/1,169], $p<0.001$) in the analysis of 40 SCP versus 11 native tissue repair non-comparative studies. Mesh erosion was not statistically significantly different when comparing patients treated by robot-assisted sacrocolpopexy (RASC) with patients treated by laparoscopic sacrocolpopexy (LSC; OR 1.82; 95%CI 0.51 to 6.45 [n=438], $I^2=0\%$, $p=0.86$) in the systematic review of 1,488 patients. The risk of mesh erosion was statistically significantly different in patients treated by RASC with supracervical hysterectomy (0%) compared with patients treated by RASC after total hysterectomy (14%, $p=0.008$, in 1 comparative study included in the same systematic review. Mesh erosion was reported in 1% (1/99) of patients at 12 months and 3% (2/85) at 60 months in women treated by LSC in the prospective case series of 101 patients.

5.4 Reoperation rates were similar for women treated by SCP or sacrospinous ligament fixation (13% [6/46] versus 16% [7/43], $p=0.67$) in an RCT (reported in the systematic review of 1,176 women) with follow-up of 6 to 66 months. Pooled reoperation rates were 7% (46/615) for SCP and 10% (51/511) for native tissue repair (OR 0.76, 95% CI 0.28 to 1.09) in 7 comparative studies from the same systematic review and meta-analysis. Pooled reoperation rates in non-comparative studies were 5% (367/7,218)

for SCP and 3% (114/3,872) for native tissue repair (p=0.28) in the systematic review of 1,176 patients. The reoperation rate was 3% (23/687) in patients treated by RASC reported in the systematic review and meta-analysis of 1,488 patients from 27 studies. A feeling of traction needing reoperation was reported in less than 1% (2/1118) of the patients treated by RASC reported in the same systematic review. Reoperation for stress urinary incontinence in women treated by LSC was reported in 15% (15/99) and 19% (16/85) of patients at 12 and 60 months respectively in the prospective case series of 101 women. Reoperation rates in women treated by RASC were 2%, 5% and 10% at years 1, 3 and 6 respectively in the prospective case series of 70 patients.

5.5 The vaginotomy rate in patients treated by RASC was 1% (14/1,488) in the systematic review and meta-analysis of 1,488 patients from 27 studies.

5.6 Urinary tract injury was not statistically significantly different in patients treated by SCP using mesh (2% [20/1,068]) compared with women treated by native tissue repair (1% [9/1,108], OR 1.68; 95% CI 0.79 to 3.55) in 8 comparative studies from the systematic review of 1,176 women. Urinary tract injury was statistically significantly higher in women treated by SCP using mesh (2% [113/6,894]) compared with native tissue repair (1% [46/5,111], $p<0.05$) in the analysis of non-comparative studies from the same review. Bladder injury in patients treated by RASC was 2% (26/1,488) in the systematic review of 1,488 patients. Ureteral injury was less than 1% (1/1,488) in patients from the same systematic review.

5.7 Bowel injury in women treated by RASC was less than 1% (4/1,488) in the systematic review of 1,488 patients.

5.8 Stress incontinence in women who had not had this before and who were treated by LSC was 24% (24/99) and 38% (32/85) at 12 and 60 months respectively in the case series of 101 women. Postoperative voiding disorders occurred in 8% (8/99) and 13% (11/85) of women at 12 and 60 months respectively in the same patient group. Urge incontinence in women who had not had it before occurred in 2% (2/99) women at 12 months and in 8% (7/85) at 60 months. Detrusor overactivity rate was 9% (15/165) in the case series of 165 women.

5.9 Dyspareunia was statistically significantly lower in women treated by SCP using mesh (5% [23/445]) than in women treated by native tissue repair (12% [46/384], OR 0.42; 95% CI 0.25 to 0.72) from the analysis of 5 comparative studies reported in the systematic review and meta-analysis of 1,176 women. The rate of dyspareunia was similar for SCP using mesh (12% [371/2,986]) and native tissue repair (9% [200/2,180]; p=0.48) in the analysis of non-comparative studies in the same systematic review. Dyspareunia in women who had not had this before who were treated by LSC was 2% (1/47) and 24% (10/41) at 12 and 60 months respectively in the prospective case series of 101 women.

5.10 Rectocele and cystocele incidence in patients who had not had these before and who treated by LSC were 12% (16/138) and 8% (11/183) respectively at 8-year follow-up in the case series of 165 women.

5.11 Infection rates were not statistically significantly different in women treated by SCP using mesh (3% [17/676]) compared with patients

treated by native tissue repair (1% [9/617] OR 2.01; 95% CI 0.91 to 4.45) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Infection rates were not statistically significantly different between women treated by mesh SCP (2% [114/5,519]) compared with native tissue repair (12% [558/4,743], p=0.6) in the analysis of non-comparative studies for the same systematic review. Abscess formation in patients treated by RASC was less than 1% (3/1,118) in the systematic review of 1,488 patients. Peritonitis caused by bowel injury was reported in less than 1% (2/1,118) patients in the same review.

5.12 Bleeding rates were not statistically significantly different in women treated by SCP using mesh (3% [43/1,317]) than in patients treated by native tissue repair (2% [37/1,863] OR 1.00; 95% CI 0.63 to 1.59) in the comparative studies reported in the systematic review of 1,176 women. Bleeding rates were statistically significantly lower in women treated by mesh SCP (2% [128/6,555]) compared with native tissue repair (5% [367/7,044], p=0.05) in the analysis of non-comparative studies for the same systematic review.

5.13 Ileus or small bowel obstruction was statistically significantly higher in patients treated by SCP using mesh (2% [16/814]) than in patients treated by native tissue repair (less than 1% [2/780], OR 9.45; 95% CI 3.39 to 26.4) in the analysis of comparative studies reported in the systematic review of 1,176 women. Ileus or small bowel obstruction was also statistically significantly higher in women treated by mesh SCP (3% [137/4,168]) than with native tissue repair (less than 1% [3/1,449], p<0.01) in the analysis of non-comparative studies for the same systematic review. Bowel obstruction in women treated by RASC was less than 1% (5/1,118)

in the systematic review of 1,488 patients. Postoperative constipation in women treated by LSC was 1% (1/99) and 5% (4/85) at 12 and 60 months respectively, in the case series of 101 women.

5.14 Lumbosciatica pain was reported in 3% (5/165) of women treated by LSC in the case series of 165 women.

5.15 Intraoperative complication rates were not statistically significantly different between women treated by RASC and women treated by LSC (OR 1.05; 95%CI 0.52 to 2.12 [n=443], I^2=0%, p=0.94) in the systematic review of 1,488 patients. Surgical conversion to open surgery was also not statistically significantly different between the RASC and LSC treatment groups (OR 0.89; 95%CI 0.25 to 3.19 [n=443], I^2=0%, p=0.72). The incidence of all postoperative complications was not statistically significant between RASC and LSC (OR 1.85; 95%CI 0.96 to 3.75 [n=350], I^2=37%, p=0.18) and this was also true for severe postoperative complications (of grade 3 or higher; OR 0.56; 95%CI 0.36 to 2.83 [n=430], I^2=24%, p=0.73).

5.16 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).The anecdotal adverse events reported for the procedure were osteomyelitis of the sacrum and haemorrhage from left iliac vein.

5.17 Ten 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 informed that there appears to be under-reporting of complications of the procedure to the Medicines and Healthcare products Regulatory Agency.

6.2 The committee noted that registry data collection has been disappointing.

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

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

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance is a review of NICE's interventional procedure guidance on sacrocolpopexy using mesh for vaginal vault prolapse repair.

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