NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Infracoccygeal sacropexy using mesh to repair uterine prolapse

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. Infracoccygeal sacropexy involves inserting a mesh through a small cut in 1 buttock. The mesh is passed up the side of the vagina, across the top, and then out through a cut in the other buttock. Both ends of the mesh are cut so they end just below the surface of the skin. The mesh is attached to the top of the vagina. It acts like a sling, with the aim of holding the womb in place.

The National Institute for Health and Care Excellence (NICE) is examining infracoccygeal sacropexy using mesh 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 infracoccygeal sacropexy using mesh 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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 27 February 2017

Target date for publication of guidance: May 2017

1 Draft recommendations

1.1 Current evidence on the safety of infracoccygeal sacropexy using mesh to repair uterine prolapse shows there are serious but well recognised complications. The evidence on efficacy is inadequate in quality. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do infracoccygeal sacropexy using mesh to repair uterine prolapse should:

- Inform the clinical governance leads in their NHS trusts.
- 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, use of NICE's information for the public is recommended.

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

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

1.5 Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. NICE may update the guidance on publication of further evidence into infracoccygeal sacropexy using mesh to repair uterine prolapse.

2 Indications and current treatments

2.1 Uterine prolapse is when the uterus descends from its usual position, sometimes out through the vagina opening. 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 Treatments include pelvic floor muscle training, use of pessaries and surgery. Several surgical procedures can be used, including hysterectomy, mesh sacrocolpopexy, 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 Infracoccygeal sacropexy is usually done with the patient under general or regional anaesthesia. An incision is made in the posterior wall of the vagina and a small puncture incision is made in each buttock. A mesh tape is introduced through 1 buttock incision and using a tunnelling device, guided by a finger through the vaginal incision, the mesh is passed around the rectum. The mesh is then passed up the side of the vagina, across the top, and out through the incision in the other buttock. The free ends are excised below the level of the skin. The mesh is sutured to the top of the vagina and acts as a tension-free sling to suspend the uterus in its natural position. The procedure is sometimes described as posterior intravaginal slingplasty.

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

3.3 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 using mesh for uterine or vaginal vault prolapse in 7,054 patients (976 patients treated by infracoccygeal sacropexy) after a median follow-up of 13 months, the median results were as follows: prolapse recurrence rate 5% (range 0 to 25%, n=402), rate of patient-reported persistent symptoms 9% (range 2 to 21%, n=262), and reoperation rate 8% (range 0 to 30%, n=288). For uterine prolapse only, prolapse recurrence rates were 1% (1/79 of patients, 1 non-randomised comparative study) and 10% (1/10 of patients, 1 case series). In a systematic review of 3,093 patients with uterine prolapse (143 patients treated by infracoccygeal sacropexy), the reoperation rate for prolapse recurrence was 3% within 6 to 30 months after the procedure.

4.2 In a randomised controlled trial (RCT) of 49 patients with uterine or vaginal vault prolapse treated by infracoccygeal sacropexy or sacrospinous suspension, postoperative rates of stress urinary incontinence or urgency and quality-of-life scores were not statistically significantly different between the treatment groups after a mean follow-up of 17 months. The only statistically significant difference was for the Pelvic Organ Prolapse Distress Inventory score, which improved by 50% or more in 75% of patients treated by infracoccygeal sacropexy compared with 65% for sacrospinous suspension (p=0.02).

4.3 In the systematic review of 3,093 patients the anatomical cure rates for apical support ranged from 90% to 97%.

4.4 In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, 86% and 79% of patients respectively were satisfied or very satisfied after the procedure.

4.5 The specialist advisers listed the key efficacy outcomes as: patient satisfaction and comfort, quality of life, change in urinary, bowel and sexual function, objective prolapse assessment and long-term prolapse recurrence risk.

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 erosion was reported in 0 to 21% of patients (median 7%, n=889 patients) in a systematic review of 7,054 patients at a median follow-up of 13 months. In a case series of 118 patients, mesh erosion happened up to 30 months after the procedure.

5.2 Reoperation for mesh erosion was needed in up to 17% of patients (median 7%, n=678), in the systematic review of 7,054 patients. In an RCT of 49 patients, 10% (2/21) of patients who had infracoccygeal sacropexy had reoperation for anterior vaginal wall erosion up to a mean of 17 months after the procedure. In the case series of 118 patients, 2% (2/118) of patients had reoperation for erosion and 3% (3/118) for a fistula during a 59-month mean follow-up. In a case series of 577 patients reoperation was needed in 4%

(21/486) of patients to remove the mesh, in 1 patient to loosen the mesh, in 2% (12/496) of patients for stress urinary incontinence, in less than 1% (2/496) for evacuation of an abscess and in 1 patient for persistent dysfunctional uterine bleeding up to 4 years after the procedure.

5.3 Blood loss during the procedure needing transfusion was reported in 0 to 2% of patients (n=383) in the systematic review of 7,054 patients.

5.4 Haematoma was reported in 1% of patients (n=655) in a systematic review of 2,653 patients.

5.5 Organ damage during the procedure was reported in 0 to 3% of patients (n=684) in the systematic review of 7,054 patients.

5.6 Infection was reported in 0 to 9% of patients (n=698) in the systematic review of 7,054 patients at a median follow-up of 13 months. Pararectal abscess was reported in 1 patient in the systematic review of 2,653 patients (timing not reported).

5.7 Gluteovaginal sinus formation 3 months after the procedure and rectocutaneous fistula 2 months after the procedure were each described in a case report, included in the review of 2,653 patients.

5.8 Dyspareunia was reported in 2% of patients (n=655) in the systematic review of 2,653 patients up to a mean follow-up of 120 weeks.

5.9 Prolonged pain was reported in less than 1% of patients (4/655) in the systematic review of 2,653 patients up to a mean follow-up of 120 weeks. Buttock pain after the procedure was reported in 3%

(3/118) of patients in the case series of 118 patients. It resolved spontaneously within a few days.

5.10 Lower urinary tract symptoms were reported in 0 to 6% of patients (n=143) in a systematic review of 3,093 patients with uterine prolapse. De novo urge urinary incontinence or bladder overactivity symptoms were reported in 9% (10/118) of patients and de novo stress urinary incontinence was reported in 6% (7/118) of patients in the case series of 118 patients.

5.11 De novo constipation after the procedure was reported in 6% (7/118) of patients in the case series of 118 patients.

5.12 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 did not list any anecdotal adverse events or theoretical adverse events.

6 Committee comments

6.1 This procedure is rarely done and has been replaced by laparoscopic techniques using mesh.

6.2 A national standard consent form is being developed.

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 infracoccygeal sacropexy using mesh for uterine prolapse repair.

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