

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Interventional procedure consultation document**

**Infracoccygeal sacropexy using mesh to  
repair vaginal vault prolapse**

The vaginal vault is 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. 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, down the other side of the vagina 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 to support the vaginal vault.

The National Institute for Health and Care Excellence (NICE) is examining infracoccygeal sacropexy using mesh to repair vaginal vault 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 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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 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 vaginal vault 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 vaginal vault 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, 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 specialists experienced in managing pelvic organ prolapse and urinary incontinence in women. 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 vaginal vault 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.

## **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 common after hysterectomy and can affect quality of life by causing 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. Different surgical procedures are available 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 Infracoccygeal sacropexy is done with the patient under regional or general 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 and, using a tunnelling device, guided by a finger through the vaginal incision, the tape is passed around the rectum. The mesh is then passed up the side of the vagina, across the top, and down the other side, and out through the incision in the other buttock. Both ends are cut so that they end just below the surface of the skin. The mesh is sutured to the top of the vagina to act as a tension-free sling that aims to support the vaginal vault. The procedure is sometimes described as posterior intravaginal slingplasty.
- 3.2 This procedure can be combined with surgery for stress urinary incontinence, such as a sub-urethral sling placement.

- 3.3 Several different types of synthetic and biological mesh are available that vary in structure and in 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 vaginal vault or uterine prolapse in 7,054 patients (976 patients treated by infracoccygeal sacropexy) after a median follow-up of 13 months, the 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 vaginal vault prolapse only, recurrent prolapse at the original site was 7% (4/60 patients). In a case series of 118 patients with vaginal vault or uterine prolapse, the reoperation rate for recurrent prolapse was 2% (2/118) of patients after a mean follow-up of 59 months. In a case series of 577 patients, 4% (20/496) of patients had another operation for recurrent prolapse within 10 to 96 weeks.
- 4.2 In a systematic review of 2,653 patients with vaginal vault or uterine prolapse (655 patients treated by infracoccygeal sacropexy), the mean objective success rate was 88% (range 37 to 99%; 95% confidence interval [CI] 87.2 to 89.1). In a randomised controlled trial (RCT) of 49 patients with vaginal vault or uterine prolapse treated by infracoccygeal sacropexy or sacrospinous suspension, anatomical success rates were 95% (20/21) and 100% (24/24)

respectively ( $p=0.94$ ) after a mean follow-up of 17 months. In a case series of 44 patients with vaginal vault or uterine prolapse, the success rate was 93% (41/44 patients) at 9 year follow-up. In the case series of 577 patients, anatomical results at median 7 week follow-up were assessed as good or excellent in 88% of patients (436/496); functional results were assessed as good or excellent in 83% (412/496) of patients.

4.3 In the RCT of 49 patients treated by infracoccygeal sacropexy or sacrospinous suspension, postoperative rates of urinary stress incontinence were 0% (0/21) and 8% (2/24) respectively, compared with preoperative rates of 52% (11/21) and 29% (7/24) respectively. Postoperative rates of urgency were 14% (3/21) and 25% (6/24) respectively, compared with preoperative rates of 52% (11/21) and 50% (12/24) respectively. The differences between the treatment groups were not statistically significant. In the case series of 118 patients, persistent urinary stress incontinence, urge incontinence and bladder overactivity symptoms were reported in 3% (3/118), 3% (4/118) and 4% (5/118) of patients respectively, after a mean follow-up of 59 months. In the case series of 44 patients, none of the 18 patients who had nocturia at baseline and none of the 12 patients who had urgency at baseline reported these at 9 year follow-up ( $p=0.003$  and  $0.04$  respectively).

4.4 In the RCT of 49 patients, quality-of-life scores improved similarly in both treatment groups; 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 ( $p=0.02$ ). In the case series of 118 patients, the Urinary Impact questionnaire scores improved from 134.6 at baseline to

115.7 after surgery ( $p < 0.05$ ) and the Pelvic Organ Prolapse Impact questionnaire scores improved from 164.3 at baseline to 108.4 after surgery ( $p < 0.05$ ), with a mean follow-up of 59 months.

- 4.5 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 ( $p = 0.85$ ). In the case series of 44 patients, all patients noted that their quality of life had improved and they would recommend the surgery to their friends.
- 4.6 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 11 studies ( $n = 889$ ) on infracoccygeal sacropexy, with rates of 0 to 21% of patients (median 7%), in a systematic review of 7,054 patients. Reoperation for mesh erosion was needed in up to 17% of patients (median 7%,  $n = 678$ ). Mesh erosion was reported in 8% of patients treated by infracoccygeal sacropexy ( $n = 655$ ) in a systematic review of 2,653 patients. Vaginal tape exposure was reported in 10% (50/496) of patients in a case series of 577 patients and surgery to remove the tape was reported in 4% (21/496) of patients. Reoperation for anterior

vaginal wall erosion was reported in 10% (2/21) of patients treated by infracoccygeal sacropexy and 8% (2/24) of patients treated by sacrospinous suspension, in an RCT of 49 patients.

- 5.2 Blood loss needing transfusion was reported in 7 studies (n=383) on infracoccygeal sacropexy, with rates ranging from 0 to 2%, in the systematic review of 7,054 patients.
- 5.3 Haematoma was reported in 1% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients. Haematoma was reported in 3% (4/118) of all patients in the case series of 118 patients with vaginal cuff or utero-vaginal prolapse; 1 patient needed surgical evacuation and blood transfusion.
- 5.4 Organ damage during the procedure was reported in 0 to 3% of patients (n=684) in the systematic review of 7,054 patients. Bladder injury was reported in 2 patients treated by infracoccygeal sacropexy and 1 patient treated by sacrospinous suspension in the RCT of 49 patients.
- 5.5 Infection was reported in 8 studies (n=698) on infracoccygeal sacropexy, with rates of 0 to 9%, in the systematic review of 7,054 patients. Pararectal abscess was reported in 1 patient treated by infracoccygeal sacropexy in the systematic review of 2,653 patients. Abscess or fistula was reported in 3% (3/118) of patients in the case series of 118 patients; all 3 patients needed surgery. Gluteovaginal sinus formation 3 months after infracoccygeal sacropexy and rectocutaneous fistula 2 months postoperatively were each described in a case report, included in the review of 2,653 patients.



- 5.6 Dyspareunia was reported in 2% of patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients. De novo dyspareunia was reported in 7% (25/348) of sexually active patients in the case series of 577 patients.
- 5.7 Prolonged pain was reported in 4 patients treated by infracoccygeal sacropexy (n=655) in the systematic review of 2,653 patients.
- 5.8 De novo urinary urge incontinence or bladder overactivity symptoms were reported in 9% (10/118) of patients and de novo urinary stress incontinence was reported in 6% (7/118) of patients in the case series of 118 patients. De novo urinary symptoms were reported in 6% (29/496) of patients in the case series of 577 patients.
- 5.9 De novo constipation after the procedure was reported in 6% (7/118) of patients in the case series of 118 patients. Constipation was reported in 2% (2/92) of patients treated by infracoccygeal sacropexy and 9% (9/98) of patients treated by abdominal sacrocolpopexy (p=0.039) in the non-randomised comparative study of 190 patients.
- 5.10 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 additional anecdotal or theoretical adverse events.

## **6 Committee comments**

- 6.1 Use of this procedure is declining.

6.2 A national standard consent form is being developed.

## **7 Further information**

7.1 Patient commentary was sought but none was received.

7.2 For related NICE guidance, see the [NICE website](#).

7.3 This guidance is a review of NICE's interventional procedure guidance on [infracoccygeal sacropexy using mesh for vaginal vault prolapse repair](#).

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

January 2017