NICE guidance

Infracoccygeal sacropexy using mesh to repair uterine prolapse

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg582

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

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those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG280.

1 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 the risk of 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 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

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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. 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 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

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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 (which included 976 patients who had infracoccygeal sacropexy), the results after a median follow-up of 13 months 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 (which included 143 patients who had 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 who had 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 who had 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 who had infracoccygeal sacropexy or sacrospinous suspension, 86% and 79% of patients respectively were satisfied or very satisfied

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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 at a median follow-up of 13 months was reported in 0 to 21% of patients (median 7%, n=889 patients who had infracoccygeal sacropexy) in a systematic review of 7,054 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse. In a case series of 118 patients who had infracoccygeal sacropexy, 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 patients who had infracoccygeal sacropexy), in the systematic review of 7,054 patients with uterine or vaginal vault prolapse. 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 patients who had infracoccygeal sacropexy) in the systematic review of 7,054 patients with uterine or vaginal vault prolapse.

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5.4 Haematoma was reported in 1% of patients (n=655 patients who had infracoccygeal sacropexy) in a systematic review of 2,653 patients who had had various types of surgery using mesh for uterine or vaginal vault prolapse.

5.5 Organ damage during the procedure was reported in 0 to 3% of patients (n=684 patients who had infracoccygeal sacropexy) in the systematic review of 7,054 patients with uterine or vaginal vault prolapse.

5.6 Infection was reported in 0 to 9% of patients (n=698 patients who had infracoccygeal sacropexy) in the systematic review of 7,054 patients with uterine or vaginal vault prolapse, at a median follow-up of 13 months. Pararectal abscess was reported in 1 patient who had infracoccygeal sacropexy in the systematic review of 2,653 patients with uterine or vaginal vault prolapse (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 with uterine or vaginal vault prolapse.

5.8 Dyspareunia was reported in 2% of patients (n=655 patients who had infracoccygeal sacropexy) in the systematic review of 2,653 patients with uterine or vaginal vault prolapse, up to a mean follow-up of 120 weeks.

5.9 Prolonged pain was reported in less than 1% of patients (4/655 patients who had infracoccygeal sacropexy) in the systematic review of 2,653 patients with uterine or vaginal vault prolapse up to a mean follow-up of 120 weeks.

5.10 Lower urinary tract symptoms were reported in 0 to 6% of patients (n=143 patients who had infracoccygeal sacropexy) in a systematic review of 3,093 patients who had had various types of surgery using mesh for 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.

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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.

6.3 One device that was used for this procedure has been withdrawn from the market.

7 Further information

7.1 NICE was unable to gather patient commentary for this procedure.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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