



# Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse

Interventional procedures guidance Published: 4 March 2020

www.nice.org.uk/guidance/ipg669

## 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 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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

#### 1 Recommendations

- 1.1 Evidence on the safety and efficacy of bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research should include randomised controlled trials, and report details of patient selection, technique, improvement in the prolapse, procedure-related adverse events and patient-reported outcome measures.

# 2 The condition, current treatments and procedure

#### The condition

2.1 Pelvic organ prolapse is defined as symptomatic descent of 1 or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff). Symptoms include a vaginal bulge or sensation of something coming down, urinary, bowel and sexual symptoms, and pelvic and back pain. These symptoms affect women's quality of life.

#### **Current treatments**

2.2 NICE's guideline on urinary incontinence and pelvic organ prolapse describes its management. Non-surgical management options include lifestyle modification, such as losing weight and minimising heavy lifting, topical oestrogen, pelvic floor muscle training and vaginal pessaries. 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 using mesh, the aim being to provide additional support.

#### The procedure

2.3 Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) for pelvic organ prolapse are mesh procedures, done through open or laparoscopic approaches using general anaesthesia. If the uterus is still in place, the first step of the procedure is a hysterectomy. A polyvinylidene fluoride (PVDF) mesh ligament-replacement structure is then placed within the peritoneal fold of both the left and right uterosacral ligaments. Anterior fixation of each PVDF structure is done by centrally suturing it to the cervix or vaginal vault with 3 or 4 interrupted, nonabsorbable polyester sutures. For posterior fixation, the PVDF structures are fixed to the left and right prevertebral fascia of the sacral vertebra at the level of S1 and S2, using a fixation device or sutures. The peritoneum above the cervix or vaginal vault is then closed to cover the PVDF structure. The aim is to support the pelvic organs in their correct position, and to improve symptoms associated with the prolapse.

#### 3 Committee considerations

#### The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 7 case series. It is

presented in <u>table 2 of the interventional procedures overview</u>. Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: prolapse resolution, urinary symptoms, sexual function and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: intraoperative complications, mesh erosion, new urinary symptoms, chronic pain, need for mesh removal and reintervention rate.
- 3.4 Patient commentary was sought but none was received.

#### Committee comments

- 3.5 The committee noted that there was a potential risk of damage to the sacral plexus veins, and care had to be taken not to damage the sigmoid colon during the procedure.
- 3.6 The committee noted that this procedure may be done either by open surgery or laparoscopically.
- The committee noted that this procedure has been used to treat different types of prolapse and urinary incontinence.

ISBN: 978-1-4731-3690-8

### **Endorsing organisation**

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.