# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse

Pelvic organ prolapse is when 1 or more of the pelvic organs (uterus, bladder or rectum) bulge into the vagina. This may be caused by weakness or stretching of ligaments that support the uterus and hold the organs in place. This procedure is done during or after a hysterectomy. The ligaments are replaced by plastic mesh tapes, using open abdominal or keyhole surgery. The aim is to lift the bladder or rectum back to a normal position.

## Contents

# Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

## *Date prepared*

This overview was prepared in August 2019.

## *Procedure name*

- Bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse

## *Specialist societies*

- Royal College of Obstetricians and Gynaecologists
- British Society of Urogynaecology
- British Society for Gynaecological Endoscopy

# Description of the procedure

## *Indications and current treatment*

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.

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.

## *What the procedure involves*

Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) for pelvic organ prolapse are abdominal mesh procedures. They are done through an open or laparoscopic approach. 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.

## *Outcome measures*

The 2 main systems for staging the degree of pelvic organ prolapse are the Baden–Walker halfway scoring system and Pelvic Organ Prolapse Quantification (POP-Q). Both systems measure the most distal portion of the prolapse during straining or the Valsalva manoeuvre.

In the Baden–Walker halfway system, pelvic organ prolapse is classified as grade 0 (no prolapse), grade 1 (halfway to hymen), grade 2 (to hymen), grade 3 (halfway past hymen) or grade 4 (maximum descent).

POP-Q classifies pelvic organ prolapse from stage 0 to stage 4, as follows:

| | |
|---|---|
| Stage 0 | no prolapse |
| Stage 1 | the most distal portion of the prolapse is more than 1 cm above the hymen |
| Stage 2 | the most distal portion of the prolapse is between 1 cm above and 1 cm below the hymen |
| Stage 3 | the most distal portion of the prolapse protrudes more than 1 cm below the hymen but no further than 2 cm less than the total vaginal length (not all of the vagina has prolapsed) |
| Stage 4 | complete vaginal eversion |

# Efficacy summary

### Improvement in prolapse symptoms

In a case series of 50 patients who had an open bilateral CESA or VASA, 3 months after the procedure, no patients had a POP-Q stage 3 to 4 prolapse compared with 44% (22/50) at baseline. The proportion of patients with a stage 2 prolapse reduced from 46% (23/50) to 2% (1/50). The proportion of patients with bulge symptoms reduced from 100% (50/50) at baseline to 6% (3/50) at 3 month follow up. The mean score on the International Consultation on Incontinence Questionnaire (ICIQ) for vaginal symptoms (scale 0 to 53) improved from 25.3 (range 16 to 48) to 4.1 (range 2 to 10).[1]

In a case series of 120 patients who had a laparoscopic bilateral CESA or VASA, 4 months after the procedure, 97% (116/130) of patients had no prolapse and 3% (4/120) of patients had stage 1 prolapse.[2]

In a case series of 71 patients with pelvic organ prolapse and mixed or urge urinary incontinence who had an open procedure, all patients had a normal apical vaginal fixation (POP-Q stage 0) after the procedure.[3]

In a case series of 10 patients who had a laparoscopic procedure, anatomical success was reported in all patients; 2 patients had no prolapse and 8 patients had POP-Q stage 1 prolapse.[5]

### Improvement of urinary symptoms

In the case series of 50 patients, the proportion of patients with overactive bladder reduced from 50% (25/50) before the procedure to 8% (4/50) at 3 month follow up. The proportion of patients with stress urinary incontinence reduced from 22% (11/50) to 2% (1/50). The mean score on the ICIQ for urinary incontinence (scale 0 to 21) improved from 9.5 (range 7 to 15) to 2.5 (range 1 to 5).[1]

In the case series of 120 patients, the proportion of patients with mixed urinary incontinence reduced from 78% (94/120) at baseline to 28% (34/120) at 4 month follow up ($p<0.001$). The proportion of patients with urge urinary incontinence reduced from 22% (26/120) to 7% (8/120) ($p<0.001$).[2]

In the case series of 71 patients, 62% (16/26) of patients who had CESA and 33% (15/45) of patients who had VASA had no urinary incontinence (mixed and urge) after the procedure. When 40 patients who had a subsequent transobturator tape (TOT) procedure were taken into account, 77% (20/26) of

patients who had CESA and 71% (32/45) of patients who had VASA had no urinary incontinence.[3]

In a case series of 133 patients with mixed or urge incontinence who had an open procedure, 32% (42/133) had no incontinence (mixed or urge); 91 (68%) patients developed stress urinary incontinence within 3 months and had a TOT procedure. The overall cure rate was 77% (102/133) and a further 24 patients reported a subjective improvement in symptoms after surgery.[4]

In the case series of 10 patients, 80% (8/10) had resolution of overactive bladder symptoms after the procedure. There were no symptoms of stress urinary incontinence in 5 of the 6 patients who reported it before surgery.[5]

### Recurrence

In the case series of 133 patients, 19 (15%) patients who were initially cured of incontinence had a recurrence of their primary symptoms. In 5 of these patients, who agreed to further surgery, the tape was disrupted at the side of the vaginal vault. After refixation, the patients were continent again. In 8 patients who had stress urinary incontinence, TOT cured the symptoms. The reason for recurrence could not be evaluated in 6 patients.[4]

In the case series of 120 patients, 4 patients had a relapse of an apical prolapse within 2 months of surgery because of insufficient cervical fixation (absorbable sutures were used). These patients had another laparoscopy with refixation at the cervix using nonabsorbable sutures, which restored anatomy and urinary continence.[2]

In the case series of 10 patients, recurrence of a mild cystocele was reported in 1 patient; no treatment was needed.[5]

### Need for further prolapse repair surgery

In the case series of 50 patients, 1 patient with a cystocele had a subsequent anterior repair.[1]

## Safety summary

### Erosion of the peritoneum

One patient in the case series of 10 patients presented with lower abdominal pain about 3 months after the procedure. A diagnostic laparoscopy revealed a 1.5 cm long opening in the peritoneum overlying the right lateral mesh arm about 2 cm from the cervical attachment point. The peritoneum was mobilised

laparoscopically and closed above the underlying portion of the mesh. The authors reported this as erosion of the peritoneum.[5]

### Intraoperative bladder injury

Bladder injury was reported in 1 patient in the case series of 50 patients. During the procedure, the patient's bladder was found to have stuck to the vault. In an attempt to separate the bladder from the vault, the authors report there was partial-thickness bladder injury. [1]

### Bleeding and haematoma

Bleeding of the sacral venous plexus was reported in 2% (2/133) of patients in the case series of 133 patients (blood loss was 1.2 litres in 1 patient and 1.5 litres in the other).[4]

Postoperative intraperitoneal haematoma was reported in 1 patient in the case series of 10 patients; the patient had a repeat laparoscopy on day 2. The same patient had an intraperitoneal haematoma and adhesions more than 90 days after the procedure (treated by repeat laparoscopy).[5]

### Wound infection or dehiscence

Wound infection was reported in 4% (2/50) of patients in the case series of 50 patients. Readmission within 4 weeks of the procedure for wound dehiscence was reported in 1 patient in the same study.[1]

### New urinary problems

New stress urinary incontinence was reported in 8% (4/50) of patients in the case series of 50 patients; 3 of the 4 patients had a tension-free vaginal tape procedure to resolve the symptoms.[1]

New stress urinary incontinence (treated by tension-free vaginal tape procedure) was reported in 1 patient in the case series of 10 patients.[5]

### Urinary tract infection

Recurrent urinary tract infection (treated with antibiotics) was reported in 1 patient in the case series of 10 patients.[5]

### Bowel problems

Readmission within 4 weeks of the procedure for obstructed defecation was reported in 1 patient in the case series of 50 patients. Bowel dysfunction was

reported in 4% (2/50) of patients in the same study; 1 patient needed a referral to a colorectal surgeon for further management.[1]

**Other**

Paraesthesia in the right thigh was reported in 1 patient in the case series of 10 patients; this resolved spontaneously.[5] Mild sacral pain was reported in 2 patients in the same study.

### *Anecdotal and theoretical adverse events*

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 happened). For this procedure, specialist advisers listed the following anecdotal adverse events: detachment of mesh from the cervix and other mesh complications, including erosion, exposure and infection. They considered that the following were theoretical adverse events: osteomyelitis at the point of attachment to the sacrum, ureteric damage and risks associated with morcellation if concurrent laparoscopic hysterectomy is done.

## The evidence assessed

### *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to CESA or VASA using mesh for pelvic organ prolapse. The following databases were searched, covering the period from their start to 2 April 2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

| Characteristic | Criteria |
|---|---|
| Publication type | Clinical studies were included. Emphasis was placed on identifying good quality studies.<br>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| Patient | Patients with pelvic organ prolapse |
| Intervention/test | Bilateral cervicosacropexy or vaginosacropexy |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base |

## *List of studies included in the IP overview*

This IP overview is based on 384 patients from 5 case series.[1–5]

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the appendix.

# *Table 2 Summary of key efficacy and safety findings on bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse*

## Study 1 Rajshekhar S (2016)

**Details**

| | |
|---|---|
| Study type | **Case series** |
| Country | UK |
| Recruitment period | 2013 to 2014 |
| Study population and number | **n=50**<br>Patients with symptomatic posthysterectomy vault prolapse or with recurrent prolapse after previous vaginal repair |
| Age | Median 66 years (range 43 to 83) |
| Patient selection criteria | Patients with symptomatic posthysterectomy vault prolapse or with recurrent prolapse after previous vaginal repair were included. Patients for whom an abdominal procedure was unsuitable were excluded. All women had either not had a response to, or declined, alternative treatment options, including use of a vaginal pessary, pelvic floor physiotherapy and sacrospinous fixation. |
| Technique | Open abdominal approach.<br>Ligament-replacement structure device: PVDF tapes (DynaMesh-CESA or DynaMesh-VASA; FEG Textiltechnik mbH, Germany)<br>Patients with posthysterectomy vault prolapse were offered VASA, and those with uterovaginal prolapse were offered subtotal hysterectomy and CESA with or without bilateral salpingo-oophorectomy. The sacrocolpopexy was VASA in 38 patients and CESA in 12 patients. Each arm of the ligament-replacement structure was attached to the anterior longitudinal ligament over S2 using 2 interrupted sutures.<br>None of the patients had concomitant vaginal repair. Four patients had a concomitant tension-free vaginal tape procedure. |
| Follow up | **3 months** |
| Conflict of interest/source of funding | Two authors have received travel bursaries from Kebomed (Cullompton, UK) and Cook Medical (Bloomington, USA). |

**Analysis**

**Follow-up issues**: All included patients were followed up to 3 months.

**Study design issues**: Retrospective, single-centre, observational cohort study. The primary outcome measure was cure of prolapse at 3 months' follow up. The secondary outcome measures were the complications of the procedure and the effects on bladder and bowel function. The POP-Q scale was used to quantify the degree and type of prolapse at all sites. All patients with urinary symptoms had preoperative urodynamic testing. Patients also completed the ICIQ-VS and ICIQ-UI. No statistical analysis was done.

**Study population issues**: The median body mass index (BMI) at baseline was 28 kg/m$^2$ (range 23 to 32). Thirty (60%) patients had a vault prolapse after abdominal hysterectomy. Twenty (40%) patients had had a previous prolapse procedure (vaginal hysterectomy with or without pelvic floor repair, and/or sacrospinous fixation).

**Other issues**: VASA was not possible in an additional 3 patients scheduled to have it. Two patients had adhesions between the bowel and the left pelvic sidewall, and it was difficult to mobilise the bowel safely. One patient had a conventional sacrocolpopexy using polypropylene mesh and the other had only the right arm of VASA mesh attached to

the vault. The third patient's bladder was adherent to the vault and a partial-thickness bladder injury happened during the procedure, which was subsequently abandoned. These 3 patients were excluded from the study.

**Key efficacy and safety findings**

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 50<br><br>
Median operating time=106 minutes (range 60 to 171)<br>
Mean hospitalisation=1.2 days (range 1 to 3)<br><br>
Symptoms before surgery and at 3-month follow up (n=50)
<table>
<tr><th>Outcome</th><th>Before surgery</th><th>After surgery</th></tr>
<tr><td>Prolapse (POP-Q scale)</td><td></td><td></td></tr>
<tr><td>Stage 1</td><td>5 (10%)</td><td>4 (8%)</td></tr>
<tr><td>Stage 2</td><td>23 (46%)</td><td>1 (2%)</td></tr>
<tr><td>Stage 3 to 4</td><td>22 (44%)</td><td>0 (0%)</td></tr>
<tr><td>Point C, mean (range)</td><td>+2 (-1 to 4)</td><td>-7.6 (-6 to -8)</td></tr>
<tr><td>Bulge symptoms</td><td>50 (100%)</td><td>3 (6%)</td></tr>
<tr><td>Overactive bladder</td><td>25 (50%)</td><td>4 (8%)</td></tr>
<tr><td>Stress urinary incontinence</td><td>11 (22%)</td><td>1 (2%)</td></tr>
<tr><td>Bowel dysfunction</td><td>16 (32%)</td><td>3 (6%)</td></tr>
<tr><td>Sexual dysfunction</td><td>11 (22%)</td><td>0 (0%)*</td></tr>
<tr><td>ICIQ-VS score (scale 0 to 53); mean (range)</td><td>25.3 (16 to 48)</td><td>4.1 (2 to 10)</td></tr>
<tr><td>ICIQ-UI score (scale 0 to 21); mean (range)</td><td>9.5 (7 to 15)</td><td>2.5 (1 to 5)</td></tr>
</table>
* only 4 patients had resumed sexual intercourse<br><br>
Retreatment<br>
1 patient with a cystocele had a subsequent anterior repair.<br>
1 patient with persistent overactive bladder needed referral to physiotherapy for bladder training.
</td><td>
Complications<br>
• bladder injury=2% (1/50)<br>
• wound infection=4% (2/50)<br><br>
Readmission within 4 weeks<br>
• wound dehiscence=2% (1/50)<br>
• obstructed defecation=2% (1/50)<br><br>
New symptoms after surgery<br>
• stress urinary incontinence=8% (4/50) (3 of the 4 patients needed a tension-free vaginal tape procedure to resolve their symptoms)<br>
bowel dysfunction=4% (2/50) (1 patient needed a referral to a colorectal surgeon for further management)
</td></tr>
<tr><td colspan="2">Abbreviations used: CESA, cervicosacropexy; ICIQ-UI, International Consultation on Incontinence Questionnaire for urinary incontinence; ICIQ-VS, International Consultation on Incontinence Questionnaire for vaginal symptoms; POP-Q, Pelvic Organ Prolapse Quantification; PVDF, Polyvinylidene fluoride; VASA, vaginosacropexy</td></tr>
</table>

## Study 2 Rexhepi S (2018)

### Details

| | |
|---|---|
| Study type | **Case series** |
| Country | Germany |
| Recruitment period | 2013 to 2016 |
| Study population and number | **n=120**<br>Patients with apical prolapse and urinary incontinence |
| Age | Median 66 years (range 30 to 88) |
| Patient selection criteria | Consecutive patients with an apical prolapse of the uterus or vaginal vault (POP-Q stage 1 or above, point C or D of at least -4 cm) and concurrent urge urinary incontinence or mixed urinary incontinence.<br>Patients for whom a laparoscopic procedure was unsuitable, those with a BMI greater than 35, and those with pure stress urinary incontinence were excluded. |
| Technique | Laparoscopic approach.<br>Ligament-replacement structure device: PVDF tapes (DynaMesh-CESA or DynaMesh-VASA, FEG Textiltechnik mbH, Germany)<br>Nonabsorbable polyester sutures were used to secure the device to the cervix or vaginal vault, apart from the first 4 patients who had fast absorbable sutures. Each arm of the ligament-replacement structure was attached with 3 titanium helices to the prevertebral fascia of S1 using a fixation device.<br>31% (37/120) of patients had a VASA procedure and 69% (83/120) had a CESA procedure with hysterectomy.<br>No concurrent vaginal repair or anti-incontinence surgery was done. |
| Follow up | **4 months** |
| Conflict of interest/source of funding | Two authors have received travel bursaries from FEG Textiltechnik mbH |

### Analysis

**Follow-up issues**: The paper states that patients were assessed at 2, 4, 8 and 16 weeks after surgery in the outpatient clinic and, 1 year after surgery, they were contacted once a year. Results are only presented for the 16-week follow up. No losses to follow up were described.

**Study design issues**: Retrospective, single-centre, observational cohort study. The primary outcome measure was the restoration of apical fixation, defined as apical POP-Q stage 0 at 4 months after surgery. The secondary outcome measure was the restoration of urinary continence.

**Study population issues**: The mean BMI at baseline was 28 kg/m$^2$ (range 18 to 39). Of the 120 patients, 63 (53%) had POP-Q stage 1 apical prolapse and 57 (47%) had POP-Q stages 2 to 4. Patients with POP-Q stage 1 prolapse had had conservative treatment, including anticholinergic drugs, or anti-incontinence surgical procedures. A total of 37 (31%) patients had had prolapse or anti-incontinence surgical procedures.

**Key efficacy and safety findings**

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed: 120<br><br>Median operating time=88 minutes (range 34 to 194)<br>Mean hospitalisation=3 days (range 2 to 5)<br><br>Pelvic organ prolapse stage before and 4 months after surgery, n (%)
<table>
<tr><th>Clinical outcome</th><th>Before surgery</th><th>After surgery</th></tr>
<tr><td>Apical POP-Q stage 0</td><td>0 (0)</td><td>116 (97)*</td></tr>
<tr><td>Apical POP-Q stage 1</td><td>63 (53)</td><td>4 (3)*</td></tr>
<tr><td>Apical POP-Q stage 2 to 4</td><td>57 (47)</td><td>0 (0)</td></tr>
</table>
* Relapse of apical prolapse within the first 2 months after surgery in 4 patients because of insufficient cervical fixation (fast absorbable sutures at the cervix). These patients had another laparoscopy with refixation at the cervix by using nonabsorbable sutures, which restored anatomy and urinary continence.<br><br>Patient reported symptoms before and 4 months after surgery
<table>
<tr><th></th><th>Before</th><th>After</th><th>p</th></tr>
<tr><td>Clinical diagnosis, n (%)</td><td></td><td></td><td></td></tr>
<tr><td>Mixed urinary incontinence</td><td>94 (78)</td><td>34 (28)</td><td><0.001</td></tr>
<tr><td>Urge urinary incontinence</td><td>26 (22)</td><td>8 (7)</td><td><0.001</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Questionnaire, median (range)</td><td></td><td></td><td></td></tr>
<tr><td>ICIQ-SF score ‘cured’</td><td>15 (6 to 21)</td><td>0 (0 to 3)</td><td><0.001</td></tr>
<tr><td>ICIQ-SF score ‘not cured’</td><td>14 (5 to 20)</td><td>12 (9 to 20)</td><td><0.001</td></tr>
</table>
</td><td>The report states that ‘no major complications were observed intraoperatively’</td></tr>
<tr><td colspan="2">Abbreviations used: BMI, body mass index; CESA, cervicosacropexy; ICIQ-SF, International Consultation on Incontinence Questionnaire short form; POP-Q, Pelvic Organ Prolapse Quantification; PVDF, Polyvinylidene fluoride; VASA, vaginosacropexy</td></tr>
</table>

## Study 3 Ludwig S (2016)

### Details

| | |
|---|---|
| Study type | **Case series** |
| Country | Germany |
| Recruitment period | Not reported (ethical approval was granted in November 2012) |
| Study population and number | **n=71**<br>Patients with apical vaginal prolapse (POP-Q stage I or II) and mixed or urge urinary incontinence |
| Age | • CESA (n=26); mean 61 years (range 28 to 81)<br>• VASA (n=45); mean 66 years (range 44 to 83), p=0.293 |
| Patient selection criteria | Patients with pelvic organ prolapse of the uterus or vaginal vault that did not reach to the hymen (POP-Q stage I or II) and mixed or urge urinary incontinence. All patients had been offered conservative treatments that failed.<br>Exclusion criteria were stress urinary incontinence only, previous sacrospinous fixation, sacrocolpopexy, colposuspension and vaginal or abdominal pelvic mesh implantation. |
| Technique | Open abdominal approach.<br>Ligament-replacement structure device: PVDF tapes (DynaMesh-CESA or DynaMesh-VASA, FEG Textiltechnik mbH, Germany).<br>Patients with a uterus had a CESA with a supracervical hysterectomy. The tapes were attached distally on the cervical stump and proximally to the presacral fascia in front of the S1/S2 sacral vertebra by nonabsorbable sutures. In patients with total hysterectomy, VASA was done using 2 PVDF tapes placed at the vaginal stump on top of the vaginal cuff scar.<br>Patients who remained incontinent after the procedure were offered a transobturator tape procedure in a second operation. |
| Follow up | **Median 16 months (range 6 to 24)** |
| Conflict of interest/source of funding | Not reported |

### Analysis

**Follow-up issues**: Assessment of the clinical outcome was done 4 months after surgery. Patients were then contacted by a study nurse 12 months after surgery and thereafter. All patients were advised to contact the unit if urinary incontinence symptoms reappeared.

**Study design issues**: Retrospective, single-centre, observational study. Cure of urge urinary incontinence was defined as 7 or fewer voids per day and no involuntary urinary leakage during the day. Cure of stress urinary incontinence (only as part of mixed urinary incontinence) was defined as no urinary leakage during exercise, coughing or sneezing.

**Study population issues**: The mean BMI at baseline was 27 kg/m$^2$ (range 17 to 45). The VASA group had a statistically significantly higher proportion of patients who lost urine 5 or more times per day than the CESA group (78% compared with 46%, p=0.02).

**Key efficacy and safety findings**

| Efficacy | Safety |
|---|---|
| Number of patients analysed: **71**<br><br>**After the procedure, all patients had a normal apical vaginal fixation (POP-Q stage 0).**<br><br>**Cure of urinary incontinence (mixed and urge)**<br>• CESA=62% (16/26)<br>• VASA=33% (15/45)<br><br>**Cure of mixed urinary incontinence**<br>• CESA=58% (11/19)<br>• VASA=31% (12/39)<br><br>**Cure of urge urinary incontinence**<br>• CESA=71% (5/7)<br>• VASA=50% (3/6)<br><br>40 patients had a subsequent transobturator tape (TOT) procedure (10 CESA, 30 VASA).<br><br>Cure rate after CESA and TOT=77% (20/26)<br>Cure rate after VASA and TOT=71% (32/45) | The paper states that 'no severe complications of surgery occurred, and no side effects were noted'.<br><br>No mesh erosion was observed during follow up (median 16 months). |
| Abbreviations used: BMI, body mass index; CESA, cervicosacropexy; POP-Q, Pelvic Organ Prolapse Quantification; PVDF, polyvinylidene fluoride; TOT, transobturator tape; VASA, vaginosacropexy | |

## Study 4 Jäger W (2012)

### Details

| | |
|---|---|
| Study type | **Case series** |
| Country | Germany |
| Recruitment period | 2007 to 2009 |
| Study population and number | **n=133**<br>Patients with mixed or urge urinary incontinence |
| Age | • CESA (n=67); mean 65 years<br>• VASA (n=66); mean 62 years |
| Patient selection criteria | Patients with mixed or urge urinary incontinence were included. Patients with stress urinary incontinence only were excluded. Patients who had a high frequency of voiding even during the night (more than 1 time per 2 hours of sleep) but who were otherwise continent, were excluded.<br>Patients who had already had surgery with the intention of improving incontinence or any other kind of prolapse surgery were excluded. |
| Technique | Open abdominal approach.<br>Ligament-replacement structure device: PVDF tapes (DynaMesh, FEG Textiltechnik mbH, Germany).<br>The 2 procedures were described as 'cervical-rectal-sacral fixation' (CERESA) and 'vaginal-rectal-sacral fixation' (VARESA).<br>Patients with mixed urinary incontinence and those who developed a 'de novo' stress urinary incontinence were offered a transobturator (TOT) procedure as a second operation. |
| Follow up | **Median 22 months (range 12 to 41)** |
| Conflict of interest/source of funding | Not reported |

### Analysis

**Follow-up issues**: An additional 2 patients had treatment but were excluded from the study because their outcome could not be evaluated: 1 patient had a stroke 4 weeks after the procedure and another developed Alzheimer's disease during follow up.

**Study design issues**: Prospective observational study. The outcome was classified as cure, improvement or failure and recurrences. Cure was determined by the patients' subjective measurements. The articles states that the 'PETROS questionnaire' was used to assess the outcome, but it was reduced to 19 questions with 3 main categories; urge urinary incontinence was subdivided between 'frequency' and 'holding' and the third category was stress incontinence.

**Study population issues**: 48% (64/133) of patients had mixed urinary incontinence and 52% (69/133) had urge urinary incontinence. 114 patients had severe holding problems and 91 patients went to the toilet more than 8 times per day. No patients had a grade 4 uterine of vaginal prolapse, 2 patients had a descensus grade 3 and 2 had a grade 2.

## Key efficacy and safety findings

**Efficacy**

Number of patients analysed: 133

Mean operating time=85 minutes (range 58 to 145; excluding 2 patients with bleeding)
Mean blood loss was less than 50 ml (excluding 2 patients with bleeding)

**Incontinence symptoms before and after surgery, n**

| | VASA | | | CESA | | |
|---|---|---|---|---|---|---|
| | before | after | p | before | after | p |
| **Stress** | | | | | | |
| *No* | 32 | 58 | <0.05 | 37 | 60 | <0.05 |
| *Yes* | 34 | 8 | <0.01 | 30 | 7 | <0.01 |
| **Holding** | | | | | | |
| *No problem* | 9 | 44 | <0.01 | 10 | 50 | <0.01 |
| *Longer than 3 minutes but less than 10 minutes* | 37 | 18 | <0.05 | 35 | 16 | <0.05 |
| *Less than 3 minutes* | 20 | 4 | <0.01 | 22 | 1 | <0.01 |
| **Frequency** | | | | | | |
| *No problem* | 22 | 44 | <0.01 | 20 | 60 | <0.01 |
| *Between 8 and 15 times per day* | 19 | 10 | <0.05 | 25 | 6 | <0.01 |
| *More than 15 times per day* | 25 | 2 | <0.01 | 22 | 1 | <0.01 |

**Outcome at end of study by type of incontinence and surgery, n**

| | VASA | CESA | Total | p |
|---|---|---|---|---|
| **Mixed** | **34** | **30** | **64** | |
| Cured | 26 | 23 | 49 | Not significant |
| Improved | 6 | 5 | 11 | Not significant |
| Failed | 2 | 2 | 4 | Not significant |
| **Urgency** | **32** | **37** | **69** | |
| Cured | 26 | 27 | 53 | Not significant |
| Improved | 4 | 9 | 13 | Not significant |
| Failed | 2 | 1 | 3 | Not significant |

91 (68%) patients developed stress urinary incontinence within 3 months of the primary surgery and had a TOT procedure. All patients were continent thereafter.

**Cure without a TOT=32% (42/133)**

**Overall cure rate=77% (102/133). A further 24 patients reported a subjective improvement after surgery.**

**No cure or improvement=5% (7/133)**

**Recurrence**
19 (15%) of the patients whose symptoms were cured or improved developed a recurrence of their primary symptoms during follow up. In 5 of these patients, who agreed to further surgery, the tape was disrupted at the side of the vaginal vault. After refixation, the patients were continent again. In 8 patients who had stress urinary incontinence, TOT cured the symptoms. The reason for recurrence could not be evaluated in 6 patients.

**Safety**

Bleeding of the sacral venous plexus was reported in 2 patients (blood loss was 1.2 and 1.5 litres respectively)

Abbreviations used: CESA, cervicosacropexy; TOT, transobturator tape; VASA, vaginosacropexy

## Study 5 Joukhadar R (2015)

### Details

| | |
|---|---|
| Study type | **Case series** |
| Country | Germany |
| Recruitment period | 2013 to 2014 |
| Study population and number | **n=10**<br>Patients with pelvic organ prolapse (POP-Q stage II to III) and overactive bladder |
| Age | Mean 62 years |
| Patient selection criteria | Women with symptomatic uterine or vault prolapse (POP-Q stages II or III) with overactive bladder symptoms. The overactive bladder was diagnosed either by urodynamics, micturition diary, or both.<br>Patients with previous vault prolapse surgery of any kind and those with contraindications for sacropexy were excluded. |
| Technique | Laparoscopic approach.<br>Device: PVDF tapes (DynaMesh-CESA and DynaMesh-VASA, FEG Textiltechnik mbH, Germany).<br>Patients with previous hysterectomy had a sacrocolpopexy and those without previous hysterectomy had a laparoscopic supracervical hysterectomy with a sacrocervicopexy.<br>The articles describes the procedure as a 'modified laparoscopic bilateral sacropexy'.<br>At the end of the procedure, MRI was used to visualise the mesh.<br>1 patient had a concomitant anterior and posterior colporrhaphy. |
| Follow up | **Mean 7.4 months** |
| Conflict of interest/source of funding | Speaker fee in conferences in issues partially concerning the product used |

### Analysis

**Follow-up issues**: Patients were invited to the follow up at 1, 3, 6 and 12 months. The follow up included a gynaecological examination, a POP-Q determination and evaluation of micturition diaries.

**Study design issues**: Prospective observational study. The objective of the study was to investigate the safety and outcome of the procedure. Anatomical success was defined as POP-Q stage 0 or I.

**Study population issues**: Mean BMI was 25.7 kg/$m^2$. Three patients had a history of anterior compartment prolapse surgery and 1 had a history of posterior compartment prolapse surgery. Of the 10 patients, 4 had POP-Q stage II prolapse and 6 had stage III prolapse at baseline. All patients had urgency and frequency and 6 patients also had stress urinary incontinence.

**Key efficacy and safety findings**

| Efficacy | Safety |
|---|---|
| Number of patients analysed: 10<br><br>Mean hospital stay=5.9 days (range 3 to 11)<br><br>**Anatomical success**<br>• POP-Q stage 0=20% (2/10)<br>• POP-Q stage 1=80% (8/10)<br><br>**Resolution of overactive bladder symptoms=80% (8/10)**<br>(1 patient had persistent overactive bladder-dry and 1 patient had a reduction of urgency and frequency but reported bothersome mild urgency.)<br><br>**Frequency of micturition (number per day)**<br>• Before surgery=13.3<br>• After surgery=8.6<br><br>**Nocturia (number per day)**<br>• Before surgery=2.3<br>• After surgery=1.2<br><br>**Pads used (number per day)**<br>• Before surgery=2<br>• After surgery=0.4<br><br>Symptoms of stress urinary incontinence were cured in 5 of the 6 patients who reported it before surgery. One patient had persistent stress urinary incontinence, which was treated by TVT (C-D grade IIIa).<br><br>**Recurrence**<br>1 patient had recurrence of a mild cystocele (no treatment needed; C-D grade I) | **Postoperative complications**<br>• Intraperitoneal haematoma, n=1* (relaparoscopy on day 2; Clavien-Dindo [C-D] grade IIIb)<br>• Recurrent urinary tract infection, n=1* (treated with antibiotics; C-D grade I)<br>• Paraesthesia in right thigh, n=1** (spontaneously resolving; C-D grade I)<br><br>**Early complications (days 1 to 30)**<br>• New stress urinary incontinence, n=1** (TVT; C-D grade IIIa)<br>• Mild sacral pain, n=2 (treated with reassurance and medication; C-D grade I)<br><br>There were no midterm complications (days 31 to 90)<br><br>**Late complications (>90 days)**<br>• Lower abdominal pain (erosion of the peritoneum), n=1 (relaparoscopy on day 119; C-D grade IIIb. The laparoscopy revealed a 1.5 cm long opening in the peritoneum overlying the right lateral mesh arm about 2 cm from the cervical attachment point. The peritoneum was mobilised laparoscopically and closed above the underlying portion of the mesh)<br>• Intraperitoneal haematoma and adhesions, n=1* (relaparoscopy; C-D grade IIIb)<br><br>* same patient<br>** same patient |
| Abbreviations used: BMI, body mass index; C-D, Clavien-Dindo; CESA, cervicosacropexy; POP-Q, Pelvic Organ Prolapse Quantification; PVDF, polyvinylidene fluoride; TVT, tension-free vaginal tape; VASA, vaginosacropexy | |

## Validity and generalisability of the studies

- No randomised controlled trials were identified.
- There are data from the UK and Germany.
- Patient populations were heterogenous. One study defined POP-Q stage 1 as a cure, whereas others included stage 1 in their inclusion criteria.
- All studies used the same mesh device.
- Some patients had concomitant procedures at the same time as the CESA or VASA, and some patients had an additional procedure afterwards.
- Some studies used an open abdominal approach, and some used a laparoscopic approach.

## Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

## Related NICE guidance

Below is a list of NICE guidance related to this procedure.

**Interventional procedures**

- Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina. NICE interventional procedures guidance 608 (2018). Available from http://www.nice.org.uk/guidance/IPG608
- Transvaginal mesh repair of anterior or posterior vaginal wall prolapse. NICE interventional procedures guidance 599 (2017). Available from http://www.nice.org.uk/guidance/IPG599
- Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse. NICE interventional procedures guidance 584 (2017). Available from http://www.nice.org.uk/guidance/IPG584

- Sacrocolpopexy using mesh to repair vaginal vault prolapse. NICE interventional procedures guidance 583 (2017). Available from http://www.nice.org.uk/guidance/IPG583
- Infracoccygeal sacropexy using mesh to repair uterine prolapse. NICE interventional procedures guidance 582 (2017). Available from http://www.nice.org.uk/guidance/IPG582
- Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse. NICE interventional procedures guidance 581 (2017). Available from http://www.nice.org.uk/guidance/IPG581
- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. NICE interventional procedures guidance 577 (2017). Available from http://www.nice.org.uk/guidance/IPG577

**NICE guidelines**

- Urinary incontinence and pelvic organ prolapse in women: management. NICE guideline 123 (2019) Available from http://www.nice.org.uk/guidance/NG123

# Additional information considered by IPAC

## *Specialist advisers' opinions*

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by specialist advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two Specialist Adviser Questionnaires for CESA or VASA using mesh for pelvic organ prolapse were submitted and can be found on the NICE website.

## *Patient commentators' opinions*

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

## *Company engagement*

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

## *Issues for consideration by IPAC*

- Following advice from its Clinical Advisory Group, NHS England and NHS Improvement have announced that a process of high vigilance scrutiny should apply to the use of a group of procedures, including this procedure, that are used to treat stress urinary incontinence and pelvic organ prolapse in England. For details, see the letter from NHS England and NHS Improvement to trust medical directors.
- Trial: Surgical vs. Medical Treatment of Urge Urinary Incontinence in Women (URGE-I) (NCT01737411); RCT; Germany; estimated enrolment=120; study start date: January 2013; estimated study completion date: June 2018 (data last verified in April 2015).

## References

1. Rajshekhar S, Mukhopadhyay S, Morris E (2016) Early safety and efficacy outcomes of a novel technique of sacrocolpopexy for the treatment of apical prolapse. International Journal of Gynecology and Obstetrics 135: 182–6
2. Rexhepi S, Rexhepi E, Stumm M et al. (2018) Laparoscopic bilateral cervicosacropexy and vaginosacropexy: new surgical treatment option in women with pelvic organ prolapse and urinary incontinence. Journal of Endourology 32: 1058–64
3. Ludwig S, Stumm M, Mallmann P et al. (2016) Surgical replacement of the uterosacral and pubourethral ligaments as treatment for urgency urinary incontinence. Austin Journal of Women's Health 3 (1): 1019
4. Jäger W, Mirenska O, Brügge S (2012) Surgical treatment of mixed and urge urinary incontinence in women. Gynecologic and Obstetric Investigation 74: 157–64
5. Joukhadar R, Meyberg-Solomayer G, Hamza A et al. (2015) A novel operative procedure for pelvic organ prolapse utilizing a MRI-visible mesh implant: safety and outcome of modified laparoscopic bilateral sacropexy. BioMed Research International Article ID 860784

# Literature search strategy

| Databases | Date searched | Version/files |
|---|---|---|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 02/04/2019 | Issue 4 of 12, April 2019 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 02/04/2019 | Issue 4 of 12, April 2019 |
| HTA database (CRD website) | 02/04/2019 | n/a |
| MEDLINE (Ovid) | 02/04/2019 | 1946 to April 01, 2019 |
| MEDLINE In-Process (Ovid) | 02/04/2019 | 1946 to April 01, 2019 |
| MEDLINE Epubs ahead of print (Ovid) | 02/04/2019 | April 01, 2019 |
| EMBASE (Ovid) | 02/04/2019 | 1974 to 2019 Week 13 |

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

| | |
|---|---|
| 1 | pelvic organ prolapse/ |
| 2 | Uterine Prolapse/ |
| 3 | ((fascia* or pelvic* or cervic* or transvagin* or vagin* or genital* or uter* or urogenit* or womb* or genito* or intravaginal*) adj2 (prolaps* or collaps* or drop*)).ti,ab. |

| | |
|---|---|
| 4 | rectocele/ |
| 5 | cystocele/ |
| 6 | (rectocele* or cystocele* or enterocele*).ti,ab. |
| 7 | urinary incontinence/ or urinary incontinence, urge/ |
| 8 | (urge* adj4 incont*).tw. |
| 9 | UUI.tw. |
| 10 | or/1-9 |
| 11 | surgical mesh/ |
| 12 | suburethral slings/ |
| 13 | ((cervic* or transvagin* or vagin* or genital* or pelvic* or uter* or urogenit* or womb* or genito* or intravaginal* or fascia* or small intestine submucosa or SIS) adj2 (mesh* or graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab. |
| 14 | or/11-13 |
| 15 | ((anterior* or posterior* or apical* or prolaps* or drop* or collaps*) adj2 (repair* or reconstruct* or surg*)).ti,ab. |
| 16 | (AWP or PWP).ti,ab. |
| 17 | (cervicosacropex* or cervico?sacropex* or vaginosacropex* or vagino?sacropex* or CESA or VASA or CESA-VASA).tw. |
| 18 | or/15-17 |
| 19 | 10 and 14 and 18 |
| 20 | dynamesh*.tw. |
| 21 | 19 or 20 |
| 22 | animals/ not humans/ |
| 23 | 21 not 22 |
| 24 | limit 23 to english language |

# Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Ludwig S, Morgenstern B, Mallmann P et al. (2019) Laparoscopic bilateral cervicosacropexy: introduction to a new tunneling technique. International Urogynecology Journal 30:1215–7 | Case report<br>n=1 | Restoration of apical prolapse and urinary continence was achieved by bilateral uterosacral ligament replacement using a semicircular tunnelling device that was inserted through the lateral abdominal trocar incision | Larger studies are included |