

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

Apical prolapse happens when the womb (uterus), cervix or vaginal vault slips down from its usual position. A vaginal vault is formed at the top of the vagina after surgery to remove the womb and cervix (hysterectomy). This procedure involves inserting a mesh inside the abdomen using several small cuts (keyhole surgery). Each end of the mesh is attached to a ligament at either side of the pelvis. It acts like a sling to support the uterus or the top of the vagina.

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## 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 July 2017 and updated in January 2018.

***Procedure name***

- Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

***Specialist societies***

- Royal College of Obstetricians and Gynaecologists (RCOG)
- British Society of Urogynaecology (BSUG)
- British Society for Gynaecological Endoscopy.

**Description of the procedure*****Indications and current treatment***

Apical prolapse is the descent of the uterus, cervix, or vaginal vault. 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. Apical prolapse can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.

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. Several surgical procedures are available including hysterectomy, mesh sacrocolpopexy, uterine suspension sling (including sacrohysteropexy) and uterine or vault suspension (without sling). Some procedures involve using mesh to provide additional support.

***What the procedure involves***

Laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina is done with the patient under general anaesthesia. Using a laparoscopic approach, a polyvinylidene fluoride (PVDF) monofilament mesh is inserted into the abdominal cavity. The ends of the mesh are attached to the iliopectineal ligaments on each side of the pelvis using nonabsorbable suture material. The cervical stump or vaginal apex is elevated to the intended tension-free position and sutured to the central part of the mesh. The mesh is then completely covered with peritoneum, secured using absorbable suture material, so that no mesh is visible in the abdominal cavity.

This procedure may offer an alternative to laparoscopic sacrohysteropexy when access to the sacral promontory is limited, for example because of abnormal anatomy, obesity, adhesions, or previous surgery.

### ***Outcome measures and disease classification***

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 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).

The Pelvic Organ Prolapse Quantification system (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**

### **Prolapse recurrence**

In a randomised controlled trial (RCT) of 83 patients who had laparoscopic mesh pectopexy or sacral colpo/cervicopexy, there was no statistically significant difference in the proportion of patients with relapse of apical prolapse (2% [1/42] compared with 10% [4/41],  $p=0.361$ ) at follow-up (mean of 22 months for pectopexy and 20 months for colpo/cervicopexy)<sup>1</sup>. In a case series of 12 patients, there was no prolapse recurrence at 12-month follow-up<sup>3</sup>.

### **Patient satisfaction**

In the RCT of 83 patients who had laparoscopic mesh pectopexy or sacral colpo/cervicopexy, a similar proportion of patients in each group were satisfied with their surgery (98% [41/42] compared with 95% [39/41],  $p=0.164$ ) at follow-up (mean 22 months for pectopexy and 20 months for colpo/cervicopexy)<sup>1</sup>. In a case series of 7 patients, the satisfaction rates were described as high in all patients<sup>4</sup>.

### **Mean intraoperative blood loss**

In the RCT of 83 patients, the mean intraoperative blood loss was statistically significantly lower in the mesh pectopexy group compared with the sacral colpo/cervicopexy group (4.6 ml compared with 15.3 ml,  $p=0.0002$ )<sup>2</sup>.

### **Mean operating time**

In the RCT of 83 patients, the mean operating time was statistically significantly shorter in the mesh pectopexy group compared with the sacral colpo/cervicopexy group (43 minutes compared with 52 minutes,  $p=0.0002$ )<sup>2</sup>.

## **Safety summary**

### **Infection**

Postoperative urinary tract infection was reported in 2 patients who had laparoscopic mesh pectopexy and 1 patient who had laparoscopic sacral colpo/cervicopexy in the RCT of 83 patients<sup>2</sup>.

### **Urinary symptoms**

Postoperative voiding difficulties were reported in 3 patients who had laparoscopic mesh pectopexy and 1 patient who had laparoscopic sacral colpo/cervicopexy in the RCT of 83 patients<sup>2</sup>.

*De novo* urgency was reported in 7% (3/42) of patients who had laparoscopic mesh pectopexy and 17% (7/41) of patients who had laparoscopic colpo/cervicopexy ( $p=0.194$ ) at follow-up (mean 22 months for pectopexy and 20 months for colpo/cervicopexy) in the RCT of 83 patients<sup>2</sup>. *De novo* stress urinary incontinence was reported in 5% (2/42) of patients who had laparoscopic mesh pectopexy and 5% (2/41) of patients who had laparoscopic colpo/cervicopexy ( $p=1.00$ ) in the same study<sup>2</sup>.

### **Bowel symptoms**

*De novo* constipation was not reported in any patients who had laparoscopic mesh pectopexy and in 20% (8/41) of patients who had laparoscopic colpo/cervicopexy ( $p=0.002$ ) at follow-up (mean 22 months for pectopexy and 20 months for colpo/cervicopexy) in the RCT of 83 patients<sup>2</sup>.

### ***De novo* prolapse or exacerbation of existing prolapse**

IP overview: laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

*De novo* central-defect cystocele or exacerbation of already existent central-defect cystocele was reported in 7% (3/42) of patients who had laparoscopic mesh pectopexy and 5% (2/41) of patients who had laparoscopic colpo/cervicopexy ( $p=1.00$ ) at follow-up (mean 22 months for pectopexy and 20 months for colpo/cervicopexy) in the RCT of 83 patients<sup>2</sup>. *De novo* lateral-defect cystocele was not reported in any patients who had laparoscopic mesh pectopexy and in 12% (5/41) of patients who had laparoscopic colpo/cervicopexy ( $p=0.026$ ) in the same study. *De novo* rectocele or exacerbation of already existent rectocele was reported in 10% (4/42) of patients who had laparoscopic mesh pectopexy and 10% (4/41) of patients who had laparoscopic colpo/cervicopexy ( $p=1.00$ ).

### ***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 did not describe any anecdotal adverse events. They considered that the following were theoretical adverse events: damage to the abdominal organs as a result of laparoscopy (damage to bowel, blood vessels), damage to the large iliac vessels during dissection of the pectineal ligament, damage to the bladder, and mesh erosion into the vagina, which could be a late complication.

## **The evidence assessed**

### ***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina. The following databases were searched, covering the period from their start to 27 November 2017: 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 appendix C for details of 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**

| <b>Characteristic</b> | <b>Criteria</b>  |
|-----------------------|--|
| 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 apical prolapse of the uterus or vagina.   |
| Intervention/test     | Laparoscopic mesh pectopexy  |
| 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 103 patients from 1 randomised controlled trial (2 reports), 2 case series and 1 case report <sup>1-5</sup>.

## Table 2 Summary of key efficacy and safety findings on laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina

### Study 1 Noé KG (2015)

#### Details

|  |  |
|--|--|
| Study type                             | <b>Randomised controlled trial</b>   |
| Country                                | Germany  |
| Recruitment period                     | Not reported   |
| Study population and number            | <b>n=83 (42 laparoscopic pectopexy versus 41 laparoscopic sacral colpo/cervicopexy)</b><br>Patients with an apical defect and symptomatic vaginal prolapse   |
| Age                                    | <ul style="list-style-type: none"> <li>• Pectopexy: mean 62 years</li> <li>• Sacral colpo/cervicopexy: mean 61 years</li> </ul>  |
| Patient selection criteria             | Patients with symptomatic primary vaginal prolapse POP-Q stage 2 or higher. Exclusion criteria: previous operations for vaginal prolapse correction, pelvic inflammatory disease, and contraindications to 1 of the surgical methods used in the study, thereby making randomisation impossible.   |
| Technique                              | All operations were done using a laparoscopic approach. In the 59 patients who had not had a hysterectomy, a supracervical hysterectomy was done in combination with the prolapse surgery. Other additional interventions were anterior colporrhaphy (n=40), laparoscopic Burch colposuspension (n=8), laparoscopic lateral repair (n=18), posterior colporrhaphy (n=38).<br>A polyvinylidene fluoride (PVDF) monofilament mesh (such as DynaMesh) was used for both procedures. |
| Follow-up                              | <ul style="list-style-type: none"> <li>• Pectopexy: mean 21.8 months (range 12 to 35)</li> <li>• Sacral colpo/cervicopexy: mean 19.5 months (range 12 to 37)</li> </ul>  |
| Conflict of interest/source of funding | None   |

#### Analysis

**Follow-up issues:** An additional 8 patients were randomised but 6 patients did not have the allocated intervention because the treatment was postponed (n=4) or temporarily cancelled (n=2; 1 because of pelvic inflammatory disease and 1 because of blood clotting anomalies). Of the 85 patients who had the allocated intervention, 2 (2.4%) were lost to follow-up (both in the pectopexy group). These patients were not included in the analysis.

**Study design issues:** Randomisation was done using numbered, sealed, non-transparent envelopes. Neither the medical team nor the patients were blinded to the intervention.

**Study population issues:** The baseline characteristics of the 2 patient groups were not reported. A similar proportion of patients in each treatment group had an additional intervention such as hysterectomy or colporrhaphy. Follow-up periods were similar in the 2 groups.

**Other issues:** short-term outcomes from this trial were reported in Noé KG et al., 2013 (study 2).

**Key efficacy and safety findings**

| Efficacy   | Safety   |                          |         |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
|--|--|--------------------------|---------|--|--|-----------|--------------------------|---------|--|-------------|-------------|------|---|---|--------------|-------|--|-------------|-------------|------|-----------------------------|---|--------------|-------|------------------------|-------------|--------------|-------|--|-------------|-------------|------|
| <p>Number of patients analysed: <b>83 (42 versus 41)</b></p> <p><b>Follow-up results</b></p> <p><b>Proportion of patients who were satisfied with the surgery:</b></p> <ul style="list-style-type: none"> <li>• Pectopexy=97.6% (41/42)</li> <li>• Sacral colpo/cervicopexy=95.1% (39/41), p=0.164</li> </ul> <p><b>Relapse of apical prolapse:</b></p> <ul style="list-style-type: none"> <li>• Pectopexy=2.3% (1/42)</li> <li>• Sacral colpo/cervicopexy=9.8% (4/41), p=0.361</li> </ul> | <p><b>Follow-up results</b></p> <table border="1" data-bbox="821 275 1507 1052"> <thead> <tr> <th></th> <th>Pectopexy</th> <th>Sacral colpo/cervicopexy</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td><i>De novo</i> central-defect cystocele or exacerbation of already existent central-defect cystocele</td> <td>7.1% (3/42)</td> <td>4.9% (2/41)</td> <td>1.00</td> </tr> <tr> <td><i>De novo</i> lateral-defect cystocele</td> <td>0</td> <td>12.2% (5/41)</td> <td>0.026</td> </tr> <tr> <td><i>De novo</i> rectocele or exacerbation of already existent rectocele</td> <td>9.5% (4/42)</td> <td>9.8% (4/41)</td> <td>1.00</td> </tr> <tr> <td><i>De novo</i> constipation</td> <td>0</td> <td>19.5% (8/41)</td> <td>0.002</td> </tr> <tr> <td><i>De novo</i> urgency</td> <td>7.1% (3/42)</td> <td>17.0% (7/41)</td> <td>0.194</td> </tr> <tr> <td><i>De novo</i> stress urinary incontinence</td> <td>4.8% (2/42)</td> <td>4.9% (2/41)</td> <td>1.00</td> </tr> </tbody> </table> |                          |         |  |  | Pectopexy | Sacral colpo/cervicopexy | p value | <i>De novo</i> central-defect cystocele or exacerbation of already existent central-defect cystocele | 7.1% (3/42) | 4.9% (2/41) | 1.00 | <i>De novo</i> lateral-defect cystocele | 0 | 12.2% (5/41) | 0.026 | <i>De novo</i> rectocele or exacerbation of already existent rectocele | 9.5% (4/42) | 9.8% (4/41) | 1.00 | <i>De novo</i> constipation | 0 | 19.5% (8/41) | 0.002 | <i>De novo</i> urgency | 7.1% (3/42) | 17.0% (7/41) | 0.194 | <i>De novo</i> stress urinary incontinence | 4.8% (2/42) | 4.9% (2/41) | 1.00 |
|  | Pectopexy  | Sacral colpo/cervicopexy | p value |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> central-defect cystocele or exacerbation of already existent central-defect cystocele   | 7.1% (3/42)  | 4.9% (2/41)              | 1.00    |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> lateral-defect cystocele  | 0  | 12.2% (5/41)             | 0.026   |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> rectocele or exacerbation of already existent rectocele   | 9.5% (4/42)  | 9.8% (4/41)              | 1.00    |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> constipation  | 0  | 19.5% (8/41)             | 0.002   |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> urgency   | 7.1% (3/42)  | 17.0% (7/41)             | 0.194   |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |
| <i>De novo</i> stress urinary incontinence   | 4.8% (2/42)  | 4.9% (2/41)              | 1.00    |  |  |           |                          |         |  |             |             |      |   |   |              |       |  |             |             |      |                             |   |              |       |                        |             |              |       |  |             |             |      |

## Study 2 Noé KG (2013)

### Details

|  |   |
|--|---|
| Study type                             | <b>Randomised controlled trial</b>  |
| Country                                | Germany   |
| Recruitment period                     | Not reported  |
| Study population and number            | <b>n=83 (43 laparoscopic pectopexy versus 40 laparoscopic sacral colpo/cervicopexy)</b><br>Patients with an apical defect and symptomatic vaginal prolapse  |
| Age                                    | <ul style="list-style-type: none"> <li>• Pectopexy: mean 62 years (range 35 to 80)</li> <li>• Sacral colpo/cervicopexy: mean 61 years (range 41 to 83)</li> </ul>   |
| Patient selection criteria             | Patients with symptomatic primary vaginal prolapse POP-Q stage 2 or higher. Exclusion criteria: previous operations for vaginal prolapse correction, pelvic inflammatory disease, and contraindications to 1 of the surgical methods used in the study, thereby making randomisation impossible.  |
| Technique                              | All operations were done using a laparoscopic approach. In the 58 patients who had not had a hysterectomy, a supracervical hysterectomy was done in combination with the prolapse surgery. Other additional interventions were anterior colporrhaphy (n=41), laparoscopic Burch colposuspension (n=8), laparoscopic lateral repair (n=18), posterior colporrhaphy (n=42), tension free transobturator tape (n=1). A polyvinylidene fluoride (PVDF) monofilament mesh (such as DynaMesh) was used for both procedures. |
| Follow-up                              | <b>To hospital discharge</b>  |
| Conflict of interest/source of funding | None  |

### Analysis

**Follow-up issues:** An additional 8 patients were randomised but did not have the allocated intervention because the treatment was postponed (n=6) or temporarily cancelled (n=2; 1 because of pelvic inflammatory disease and 1 because of blood clotting anomalies).

**Study design issues:** Randomisation was done using numbered, sealed, non-transparent envelopes. Neither the medical team nor the patients were blinded to the intervention.

**Study population issues:** The baseline characteristics of the 2 patient groups were similar with regard to mean age and body mass index (25.8 kg/m<sup>2</sup> [range 17.2 to 37.4] versus 25.6 kg/m<sup>2</sup> [range 21.2 to 36.2]). A similar proportion of patients in each treatment group had an additional intervention such as hysterectomy or colporrhaphy.

**Other issues:** this study reported short-term outcomes from the same trial reported by Noé KG et al., 2015 (study 1).

**Key efficacy and safety findings**

| Efficacy  |                       |                          |         | Safety  |                           |                           |         |
|---|-----------------------|--------------------------|---------|---|---------------------------|---------------------------|---------|
| Number of patients analysed: <b>83 (43 versus 40)</b> |                       |                          |         | <b>Intraoperative and postoperative results</b>                               |                           |                           |         |
| <b>Intraoperative and postoperative results</b>       |                       |                          |         |   | Pectopexy                 | Sacral colpo/cervicopexy  | p value |
|   | Pectopexy             | Sacral colpo/cervicopexy | p value | Mean onset of bowel movements (postoperative days)                            | 2.1 (range 1 to 3)        | 2.1 (range 1 to 4)        | 0.4711  |
| Mean operating time (minutes)                         | 43.1 (range 27 to 63) | 52.1 (range 40 to 95)    | 0.0002  | Average C-reactive protein (mg/dl, internal laboratory norm value <0.5 mg/dl) | 1.77 (range 0.11 to 7.74) | 1.03 (range 0.27 to 3.35) | 0.0028  |
| Mean blood loss (ml)                                  | 4.6 (range 0 to 40)   | 15.3 (range 0 to 80)     | 0.0002  | Urinary tract infection   | 2                         | 1                         | -       |
| Mean hospital stay (days)                             | 5.1 (range 3 to 11)   | 4.9 (range 4 to 7)       | 0.2267  | Intraoperative complications (injuries)                                       | 0                         | 0                         | -       |
|   |                       |                          |         | Voiding difficulties (number of patients)                                     | 3                         | 1                         | -       |

## Study 3 Banerjee C (2011)

### Details

|  |   |
|--|---|
| Study type                             | <b>Case series</b>  |
| Country                                | Germany   |
| Recruitment period                     | Not reported  |
| Study population and number            | <b>n=12</b> (and historical comparative data on 242 patients who had laparoscopic sacropexy)<br>Pelvic organ prolapse of POPQ level grade 2 or above, combined with an expected difficult surgical field.     |
| Age                                    | Not reported  |
| Patient selection criteria             | In all 12 patients, laparoscopic sacropexy was thought to be a higher risk to the patients than laparoscopic pectopexy; 10 patients had a body mass index >30 and 2 patients had a history of diverticulitis. |
| Technique                              | In patients with an extant uterus, the procedure was combined with laparoscopic supracervical hysterectomy.   |
| Follow-up                              | <b>12 months</b>  |
| Conflict of interest/source of funding | None  |

### Analysis

**Follow-up issues:** No losses to follow-up were described.

**Study design issues:** Small, prospective case series. Limited data on the outcomes of patients who had laparoscopic sacropexy were also presented from a previous publication, for comparison.

**Study population issues:** No information was presented on the baseline characteristics.

### Key efficacy and safety findings

| Efficacy   | Safety  |
|--|---|
| <p>Number of patients analysed: <b>12</b></p> <p><b>No patients had recurrence of prolapse at 12-month follow-up</b></p> <p>In a cohort of 242 patients who had laparoscopic sacropexy, 7.8% had prolapse recurrence (follow-up of 28 months).</p> | <p><b>Complications</b></p> <p><i>Laparoscopic pectopexy (n=12)</i></p> <p>There were no cases of severe bleeding, nerve or vessel injury, bladder or bowel injury.</p> <p>There were no data on the incidence of postoperative infection.</p> <p>At 12-month follow-up, there were no cases of ileus or mesh erosion.</p> <p><i>For the cohort of patients who had laparoscopic sacropexy, the following complications were reported:</i></p> <ul style="list-style-type: none"> <li>• Bladder injury 0.7%</li> <li>• Bowel injury 1.2%</li> <li>• Lower urinary tract infection 11.4%</li> <li>• Wound infection 2.1%</li> <li>• Ileus (at follow-up) 1.7%</li> </ul> |

## Study 4 Kale A (2017)

### Details

|  |  |
|--|--|
| Study type                             | <b>Case series</b>   |
| Country                                | Turkey   |
| Recruitment period                     | 2014 to 2015   |
| Study population and number            | <b>n=7</b><br>Patients with apical prolapse  |
| Age                                    | Mean 53 years (range 39 to 67)   |
| Patient selection criteria             | Symptomatic primary vaginal or uterine prolapse with pelvic organ prolapse quantification (POP-Q) system II and above. Exclusion criteria were previous operations for vaginal prolapse correction, pelvic inflammatory disease, and previously identified, or strongly suspected, massive adhesions in the pelvic cavity. |
| Technique                              | A polyvinylidene fluoride (PVDF) monofilament mesh (DynaMesh) was used.  |
| Follow-up                              | <b>6 months</b>  |
| Conflict of interest/source of funding | None   |

### Analysis

**Follow-up issues:** No losses to follow-up were described.

**Study design issues:** Small, retrospective case series.

**Study population issues:** Body mass index ranged from 19.5 kg/m<sup>2</sup> to 24.4 kg/m<sup>2</sup> (mean 22.5 kg/m<sup>2</sup>).

### Key efficacy and safety findings

| Efficacy   | Safety   |
|--|--|
| <p>Number of patients analysed: 7</p> <p>All patients were discharged from hospital within 24 hours.</p> <p>'Satisfaction rates were high in all patients', who were followed up at 1 week and 6 months.</p> | <p>There were no intraoperative or postoperative complications.</p> <p>There were no conversions to laparotomy and no blood transfusions were needed.</p> <p>There were no occurrences of de novo apical prolapse, stress urinary incontinence, anterior or lateral defect cystoceles, or rectoceles during the 6 month follow-up.</p> |

## Study 5 Pirtea L (2016)

### Details

|  |   |
|--|---|
| Study type                             | <b>Case report</b>  |
| Country                                | Romania   |
| Recruitment period                     | Not reported  |
| Study population and number            | <b>n=1</b><br>Stage 3 POPQ genital prolapse.  |
| Age                                    | 59 years  |
| Patient selection criteria             | The patient had a body mass index of 41 kg/m <sup>2</sup> .                           |
| Technique                              | A laparoscopic supracervical hysterectomy was done in combination with the pectopexy. |
| Follow-up                              | <b>Not reported</b>   |
| Conflict of interest/source of funding | None  |

### Analysis

**Study design issues:** Case report with limited follow-up information. The 'successful outcome' is demonstrated through a photograph taken immediately after the surgery.

### Key efficacy and safety findings

| Efficacy  | Safety  |
|---|---|
| Number of patients analysed: <b>1</b>                                 | No adverse events were reported in the paper. |
| 'Successful outcome' (clinical assessment immediately after surgery). |   |

## Validity and generalisability of the studies

- There were no reports from the UK. Most of the published data were from Germany.
- All of the published studies had small sample sizes.
- None of the studies had a mean follow-up longer than 2 years.
- There was no blinding in the randomised controlled trial.
- Most of the patients in the case series of 12 patients had a body mass index above 30 kg/m<sup>2</sup>.<sup>3</sup>
- The procedure was combined with a laparoscopic hysterectomy in those patients who had not already had a hysterectomy.
- In addition to the peer-reviewed published articles, several conference abstracts were identified. None of these have been included in the overview because they did not describe any additional adverse events.

## 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

- Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse. NICE interventional procedure guidance 584 (2017). Available from <http://www.nice.org.uk/guidance/IPG584>
- Sacrocolpopexy using mesh to repair vaginal vault prolapse. NICE interventional procedure guidance 583 (2017). Available from <http://www.nice.org.uk/guidance/IPG583>
- Infracoccygeal sacropexy using mesh to repair uterine prolapse. NICE interventional procedure guidance 582 (2017). Available from <http://www.nice.org.uk/guidance/IPG582>

- Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse. NICE interventional procedure guidance 581 (2017). Available from <http://www.nice.org.uk/guidance/IPG581>
- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse. NICE interventional procedure guidance 577 (2017). Available from <http://www.nice.org.uk/guidance/IPG577>
- Surgical repair of vaginal wall prolapse using mesh. NICE interventional procedure guidance 267 (2008). Available from <http://www.nice.org.uk/guidance/IPG267>

### **NICE guidelines**

- Urinary incontinence in women: management. NICE clinical guideline 171 (2013). Available from <http://www.nice.org.uk/guidance/CG171>  
This guidance is currently under review and the scope is being extended to include pelvic organ prolapse; it is expected to be updated in 2019. For more information, see <https://www.nice.org.uk/guidance/indevelopment/gid-ng10035>.

## **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 laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina were submitted and can be found on the [NICE website](#).

### ***Patient commentators' opinions***

NICE's Public Involvement Programme sent 40 questionnaires to 1 NHS trust for distribution to patients who had the procedure (or their carers). NICE did not receive any completed questionnaires.

### ***Company engagement***

A structured information request was sent to 2 companies who manufacture 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***

None other than those described above.

## References

1. Noé KG, Schiermeier S, Alkatout I et al. (2015) Laparoscopic pectopexy: a prospective, randomized, comparative clinical trial of standard laparoscopic sacral colpopocervicopexy with the new laparoscopic pectopexy—postoperative results and intermediate-term follow-up in a pilot study. *Journal of Endourology* 29: 210–5
2. Noé KG, Spüntrup C, Anapolski M (2013). Laparoscopic pectopexy: a randomised comparative clinical trial of standard laparoscopic sacral colpopocervicopexy to the new laparoscopic pectopexy. Short-term postoperative results. *Archives of gynecology and obstetrics* 287: 275–80
3. Banerjee C, Noe KG (2011) Laparoscopic pectopexy: a new technique of prolapse surgery for obese patients. *Archives of gynecology and obstetrics* 284: 631–5
4. Kale A, Biler A, Terzi H et al. (2017) Laparoscopic pectopexy: initial experience of single center with a new technique for apical prolapse surgery. *International Brazilian Journal of Urology* 43: 903–9
5. Pirtea L, Secosan C, Grigoras D et al. (2016) Laparoscopic pectopexy in the treatment of genital prolapse - Case report and review of literature. *Obstetrica si Ginecologie* 64: 53–8

## Literature search strategy

| Databases   | Date searched | Version/files                 |
|---|---------------|-------------------------------|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)           | 27/11/2017    | Issue 11 of 12, November 2017 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 27/11/2017    | Issue 10 of 12, October 2017  |
| HTA database (Cochrane Library)   | 27/11/2017    | Issue 4 of 4, October 2016    |
| MEDLINE (Ovid)  | 27/11/2017    | 1946 to November Week 3 2017  |
| MEDLINE In-Process (Ovid)   | 27/11/2017    | November 22, 2017             |
| EMBASE (Ovid)   | 27/11/2017    | 1974 to 2017 Week 47          |
| PubMed  | 27/11/2017    | n/a                           |

### 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 | POP.tw.   |
| 3 | Uterine Prolapse/   |
| 4 | Vagina/su   |
| 5 | Fascia/   |
| 6 | Cervix Uteri/su   |
| 7 | ((uter* or womb* or apical* or post-hysterect* or cuff* or fascia* or pelvic* or cervi* or transvagin* or vagin* or genital* or urogenit* or genito* or intravaginal* or utero-vagin* or colpocele* or colpoptos*) adj2 (prolaps* or collaps* or drop* or slip* or sag* or hernia* or fall* or sink* or relax*).tw. |

|    |  |
|----|--|
| 8  | or/1-7   |
| 9  | Laparoscopy/   |
| 10 | Surgical Mesh/   |
| 11 | Suture Techniques/   |
| 12 | Polypropylenes/  |
| 13 | or/10-12   |
| 14 | 9 and 13   |
| 15 | ((Laparoscop* or keyhole* or key-hole*) adj4 (surg* or techni* or procedur* or approach* or repair*) adj4 (mesh* or fascia* or suture* or gauze*)).tw. |
| 16 | 14 or 15   |
| 17 | Pectopexy*.tw.   |
| 18 | Dynamesh*.tw.  |
| 19 | 17 or 18   |
| 20 | 16 or 19   |
| 21 | 8 and 20   |
| 22 | animals/ not humans/   |
| 23 | 21 not 22  |