NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse

Uterine prolapse happens when the womb (uterus) slips down from its usual position into the vagina. Uterine suspension using mesh involves attaching 1 end of the mesh to the lower part of the uterus or cervix. The other end is attached to a bone at the base of the spine or to a ligament in the pelvis. The procedure can be done through open abdominal surgery or laparoscopy (keyhole surgery). The aim is to support the womb.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) 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 IP overview was prepared in January 2016.

Procedure name

- Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.

Specialist societies

- Royal College of Obstetricians and Gynaecologists (RCOG)
- British Society of Urogynaecology (BSUG)
- British Association of Urological Surgeons (BAUS).

Description

Indications and current treatment

Uterine prolapse is when the uterus descends from its usual position, into and sometimes through, the vagina. It can affect quality of life by causing symptoms of pressure and discomfort, and by its effects on urinary, bowel and sexual function.

Current treatment options include pelvic floor muscle training, use of pessaries and surgery. Some surgical procedures involve the use of mesh, with the aim of providing additional support.

What the procedure involves

Uterine suspension using mesh to repair uterine prolapse involves attaching the uterus (or cervix) either to the sacrum (sacrohysteropexy) or to the ileopectineal ligaments. This procedure can also be used for women with cervical prolapse after supracervical hysterectomy. The procedure is done with the patient under general anaesthesia by an open or laparoscopic abdominal approach. In sacrohysteropexy, the mesh can be attached to the uterus either in the midline of the posterior cervix or bilaterally, where the uterosacral ligaments join the uterus (in both cases the other end of the mesh is attached to the sacrum). Another mesh suspension technique involves attaching the mesh to the front of the uterine cervix and to the lateral ileopectineal ligaments. Each of the above procedures can be described as a 'uterine suspension using mesh’.

This procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or minimally invasive sling placement.

Several different types of synthetic and biological mesh are available that vary in structure and in their physical properties, such as absorbability.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse. The following databases were searched, covering the period from their start to 11.10.2016: 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

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. 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 uterine prolapse.
Intervention/test	Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.
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 1,962 patients from 2 systematic reviews[1-2], 2 randomised controlled trails (RCTs) included in the systematic reviews[3-4], 3 non-randomised comparative studies[5-7] and 6 case series[8-13].

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

Table 2 Summary of key efficacy and safety findings on uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.

Study 1 Maher C 2016

Details

Study type	Systematic review and meta-analysis
Country	Australia
Study period	Search date: inception to July 2015; Databases searched: Cochrane Incontinence Group's Specialised Register of controlled trials, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, WHO ICTRP and hand searching of journals and conference proceedings (2012-15) and ClinicalTials.gov (searched January 2016). Reference lists of relevant articles were also searched.
Study population and number	The review covered 3,414 women in 30 randomised controlled trials (RCTs), of these 6 trials reported only on uterine prolapse (n=663 women). **2 separate trials with a total of 183 women with uterine prolapse compared vaginal hysterectomy with abdominal sacrohysteropexy** (Rahmanou 2015; Roovers 2004). **(92 abdominal sacrohysteropexy** versus **91 vaginal hysterectomy with vault support/repair)**
Age	Mean age was between 55 and 60 years in the 2 relevant RCTs. Mean parity was 3.8
Patient selection criteria	Inclusion criteria: RCTs on different types of surgeries (transvaginal or abdominal routes, repair with or without mesh or native tissue repair, extent of surgery included hysterectomy or uterine sparing, with or without incontinence surgery) for women with apical vaginal prolapse, with at least 6 months' follow-up and at least 20 women in each arm were included. Types of apical prolapse included: uterine prolapse, vault prolapse (post-hysterectomy), unspecified vaginal prolapse (uterine and/or vault prolapse). Exclusion criteria: quasi-randomised studies, cross over studies were excluded.
Technique	**Techniques in 2 trials related to abdominal sacrohysteropexy** **Abdominal sacrohysteropexy with preservation of uterus (in 41); laparoscopic hysteropexy (in 50).** Type of meshes/graft used: non-absorbable synthetic mesh, polypropylene, Gore-Tex/Prolite, Amid classification type II (microporous). Concomitant procedures: Colposuspension for stress urinary incontinence (SUI): in 16 **Vaginal hysterectomy and vault fixation by uterosacral ligament plication combined with anterior and/or posterior colporrhaphy (n=91)**; No mesh/graft. Concomitant procedures: Colposuspension in 11
Follow-up	**Varied in systematic review; for sacrohysteropexy mean 94 months [range 84 to 120 months] in 1 trial (Roovers 2004); and median of less than 1 year in another trial (Rahmanou 2015).**
Conflict of interest/source of funding	The lead author is an author of 2 studies included in the review. No other authors have any conflicts of interest. Review was supported by the Cochrane Incontinence Review Group-supported by NIHR UK.

Analysis

Follow-up issues: varied follow-up. 37% attrition rate at 1 year in 1 trial (Rahmanou 2015) and 27% attrition rate at 8 years in another trial (Roovers 2004). Only 73% (60/82) completed questionnaires at 8 years follow-up.

Study design issues: Cochrane review methods were used. GRADEPRO software was used to assess the overall quality of evidence. Where data was sufficiently similar, meta-analysis was done using a fixed effect model. Evidence quality ranged from low to moderate (blinding was not possible in the 2 relevant trials). Limitations included imprecision, poor reporting of study methods and inconsistency. Primary outcomes in the 2 trials included awareness of prolapse (using pelvic floor distress inventory PFDI 20), recurrent prolapse at any site defined as any stage 2 or greater vaginal prolapse (assessed using Pelvic organ prolapse quantification POP-Q) and reoperation for prolapse.

Other issues: Evidence from 4 other trials on uterine prolapse (with 3 comparing vaginal hysterectomy with vaginal sacrospinous hysteropexy [Detollenaere 2015; Dietz 2010; Jeng 2005] and 1 comparing vaginal hysterectomy with abdominal hysterectomy [Braun 2007]) is not extracted from this paper as it is out of the scope of this review. Evidence from trials on vault prolapse (post-hysterectomy) and unspecified vaginal prolapse (uterine and/or vault prolapse) is also not extracted as it is outside the scope of this overview.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **findings from 2 separate relevant trials in the systematic review, n=183 (92 versus 91)** **Awareness of prolapse at 8 year follow-up** Women who have vaginal hysterectomy may have lower rates of awareness of prolapse than those who have sacrohysteropexy (RR 0.38, 95% CI 0.15 to 0.98; 1 RCT, n=84, low-quality evidence). These data suggest that if 31% of women were aware of prolapse after sacrohysteropexy, then 5% to 30% would be aware of prolapse after vaginal hysterectomy with vault support. **Repeat surgery for prolapse** There may be no difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for repeat surgery for prolapse (RR 0.68, 95% CI 0.36 to 1.31; 2 RCTs, n=182, I^2 = 0%, low-quality evidence). These data suggest that if 21% of women need repeat prolapse surgery after abdominal sacrohysteropexy, then 7% to 28% would need prolapse surgery after vaginal hysterectomy with vault support. **Any recurrent prolapse** No data were reported for any recurrent prolapse for the comparison of vaginal hysterectomy with vault support versus abdominal sacrohysteropexy. **Objective failure** The authors reported that they are 'uncertain' whether there is a difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for objective failure of anterior vaginal compartment (RR 1.04, 95% CI 0.60 to 1.82; 1 RCT, n=83); objective failure of apical compartment (RR 1.00, 95% CI 0.15 to 6.76; 1 RCT, n=82) and objective failure of posterior vaginal compartment (RR 3.07, 95% CI 0.66 to 14.35; 1 RCT, n = 83). **Pelvic organ prolapse quantification (POPQ) scores** There may be no difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for point Ba (MD -0.30; 95% CI -0.65 to 0.05, 1 RCT, n=208), point Bp (MD 0.10, 95% CI -0.14 to 0.34; 1 RCT, n=208) but there may be a difference between vaginal hysterectomy and sacrohysteropexy in favour of sacrohysteropexy for point C (MD 0.80; 95% CI 0.27 to 1.33; 1 RCT, n=208). **Operating time** Operating time may be longer for vaginal hysterectomy with vault support versus abdominal sacrohysteropexy (MD 10.00 minutes, 95% CI 8.20 to 11.80; 1 RCT, n = 83). **Length of hospital stay (days)** There may be no difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy (MD -0.10, 95% CI -0.21 to 0.01; 1 RCT, n = 83).	**Mesh exposure** The authors reported that they are 'uncertain' whether there is a difference in the rate of mesh exposure between vaginal hysterectomy with vault support and abdominal sacrohysteropexy. (RR 0.20, 95% CI 0.01 to 4.04, 1 RCT, n=82). **Repeat surgery for mesh exposure** The authors reported that they are 'uncertain' whether there is a difference in the need for repeat operation for mesh exposure between vaginal hysterectomy with vault support versus abdominal sacrohysteropexy (RR 0.20, 95% CI 0.01 to 4.04, 1 RCT, n=82). **Bowel injury** The authors reported that they are 'uncertain' whether there is a difference in the rate of bowel injury between vaginal hysterectomy with vault support and abdominal sacrohysteropexy (RR 3.00, 95% CI 0.13 to 71.56; 1 RCT, n=82). **Blood transfusion** The authors reported that they are 'uncertain' whether there is a difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for the need for a blood transfusion (RR 2.00, 95% CI 0.19 to 21.21; 1 RCT, n=82). **Death, bladder injury, bladder function, bowel function, dyspareunia** No data were reported for the comparison of vaginal hysterectomy with vault support versus abdominal sacrohysteropexy.
Abbreviations used: CI, confidence interval; MD, mean difference; RCT, randomised controlled trial; RR, risk ratio.	

Study 2 Jia X 2010

Details

Study type	**Systematic review**
Country	UK
Study period	Search date: 1980 to 2008; searched 17 electronic databases (including Medline, Embase), conference proceedings, relevant websites, contacted manufacturers and checked bibliographies of published papers.
Study population and number	The review covered 54 studies (with 7,054 women) having surgery for uterine or vaginal vault prolapse using mesh. Of these, **6 studies (n=239/7,054] women) reported on uterine suspension sling operations for uterine prolapse (of these 5 studies with 219 women reported sacrohysteropexy and 1 study with 20 women reported suspending the uterus to the pectineal ligaments).**
Age	Average age 37 years (for women treated with uterine suspension sling
Study selection criteria	Randomised controlled trials (RCTs), RCTs published as conference abstracts from 2005 onwards, non-randomised comparative studies and case series (with sample size of 100 and a mean follow-up of 1 year, no sample size restriction for uterine suspension sling studies); with women having uterine or vaginal vault prolapse surgery; all surgical techniques using mesh (RCTs comparing with any other techniques with or without mesh); with other concomitant procedures such as hysterectomy, anti-incontinence, anterior or posterior vaginal wall prolapse repair were included. Studies of women with cancer or with prolapse caused by congenital anomalies inherited conditions or creation of a neovagina were excluded.
Technique	**Uterine suspension sling operation (including sacrohysteropexy) for uterine prolapse** **(studies included in review)** 1. Roovers 2004 RCT 2. Costantini 2005 –non randomised comparative study 3. Banu 1997 (case series) 4. Barranger 2003 (case series) 5. Leron 2001 (case series) 6. Joshi 1993 (case series)Case series Mesh type used: varied across studies.
Follow-up	**Varied in systematic review; for uterine suspension sling -median 33 months (range 12 to 95 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: varied follow-up across studies.

Study design issues: this systematic review included all surgical techniques using mesh for uterine or vaginal vault prolapse (including sacrocolpopexy, infracoccygeal sacropexy, sacrocolpoperinopexy, and uterine suspension sling). Data extraction and quality assessment of studies were done by 2 independent reviewers. Quality assessment checklists developed by the Review Body of Interventional Procedures (ReBIP) (an independent body that carries out systematic reviews for NICE's Interventional procedures programme) were used according to study design. Data analyses were done separately for each technique and also presented according to type of prolapse repaired: uterine, vault, and uterine and/or vault prolapse (where data not reported separately). Sub-group analyses were done for different surgical techniques, types of mesh and primary versus secondary repairs. Meta-analysis was not possible as studies used different comparators.

Other issues: studies with other surgical techniques (that use mesh) other than uterine suspension sling (sacrocolpopexy alone, sacrocolpopexy with concomitant hysterectomy for uterine prolapse, infracoccygeal sacropexy and sacrocolpoperinopexy, for vault prolapse and uterine and/or vault prolapse where data were not reported separately) have been excluded in this overview as they are outside the scope of this review.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **239**

Summary of 6 studies with uterine suspension sling including sacrohysteropexy for uterine prolapse

Study	no of patients	Intervention (route) A	Comparator (route) B	Mean follow-up months (range)
Roovers 2004 (RCT)	82	Abdominal (open) sacrohysteropexy n=41 Mesh-polypropylene, Gore-Tex	Burch with vaginal hysterectomy, uterosacral ligament suspension, +anterior or posterior colporrhaphy and needle suspension n=41 Mesh-no mesh	33 (20-41)
Costantini 2005 (non-randomised comparative study)	75	sacrohysteropexy (abdominal) n=36 Mesh-polypropylene, Marlex	hysterectomy +sacrocolpopexy (abdominal) n=39 Mesh-polypropylene, Marlex	51 (12-115)
Banu 1997 (case series)	19			3-5 years
Barranger 2003 (case series)	30	Abdominal (open) sacrohysteropexy Mesh: polyester, Mersuture		Efficacy:44.5 (2-156) Safety: 94.6 (8-160)
Leron 2001 (case series)	13	Abdominal (open) sacrohysteropexy Mesh; non-absorbable synthetic mesh, Teflon		16 (4-49)

Safety

Adverse events across studies

Study	Intervention (route) A % (n)	Comparator (route) B % (n)
Blood loss needing transfusion		
Non-randomised comparative study (n=1)	5.6 (2/36)	0
RCT (n=1)	2.4 (1/41)	4.9 (2/41)
Mesh erosion and further operation		
Non-randomised comparative study (n=1)	0 (0/36)	7.7 (3/39)
Case series (n=1)	3.3 (1/30)	
Damage to surrounding organs (bowel injury)		
RCT (n=1)	0	2.4 (1/41)
Infection		
Non-randomised comparative study (n=1)	2.8 (1/36)	0
RCT (n=1)	17 (7/41)	4.9 (2/41)
Case series (n=1)	6.7 (2/30)	
Other serious adverse events not otherwise specified		
RCT (n=1)	2.4 (9/41)	0
Non-randomised study	5.5 (2/36)	
Case series (n=1)	6.7 (2/30)	

Joshi 1993 (case series)	20	Abdominal (open) Uterine suspension sling technique (uterus suspended to the pectineal ligaments) Mesh: Mersilene		6-30

Summary of efficacy outcomes

	Sacrohysteropexy % (n)	vaginal hysterectomy % (n)
Subjective failure : persistent prolapse symptoms		
RCT (n=1)	39 (16/41)	12 (5/41) RR 3.20, 95% CI 1.29 to 7.92
Case series (n=2)	2 (1/50)	
Objective failure: recurrent prolapse at original site		
RCT (n=1)	5.3 (2/38)	5 (2/40)
Non-ran study (n=1)	0 (0/36)	
Case series (n=3)	3.2 (2/62)	
Further operation needed for prolapse (recurrent or de novo)		
RCT (n=1)	22 (9/41)	2.4 (1/41)
Non-ran study (n=1)	0 (0/36)	
Case series (n=1)	3.3 (1/30)	
Persistent urinary symptoms		
Case series (n=1)	15.8 (3/19)	
Persistent bowel symptoms		
Case series (n=1)	20 (1/5)	
Persistent sexual symptoms		
Case series (n=1)	11.1 (3/27)	

Other adverse events not otherwise specified		
RCT (n=1)	22 (9/41)	22 (9/41)
Non-randomised study	16.7 (6/36)	
Case series (n=2)	10.2 (5/49)	

*Other serious adverse effects (not otherwise specified) that occurred included incisional hernia and intestinal occlusion;

** Other adverse effects (not otherwise specified) that occurred included urinary tract symptoms, dysmenorrhoea during the 1st menstrual cycle, haematoma, haemorrhage of presacral vein (no transfusion needed), dullness in upper leg, and sciatic pain.

Abbreviations used: CI, confidence interval; m, months, RCT, randomised controlled trial; RR, risk ratio.

Study 3 Roovers JP 2004 (included in Maher C 2016 and Jia X 2010)

Details

Study type	Randomised controlled trial
Country	The Netherlands (3 teaching hospitals)
Recruitment period	1998-2000
Study population and number	n=**82 (41 abdominal sacrohysteropexy versus 41 vaginal hysterectomy combined with anterior and/or posterior colporrhaphy)** patients with uterine prolapse primary or secondary repair: not reported
Age and sex	A: mean 57.9 years, B: 56.4 years.
Patient selection criteria	Inclusion criteria: patients with intact uterine and having surgical correction of uterine prolapse stages II-IV (ICS). Exclusion criteria: presence of an adnexal mass, a history of >2 abdominal pelvic surgical procedures, extreme obesity (BMI >35 kg/m2), prior inflammatory bowel or pelvic disease and faecal incontinence because of an internal or external anal sphincter defect.
Technique	INTERVENTION A (n=41): Abdominal sacrohysteropexy Type of mesh/graft: non-absorbable synthetic mesh, polypropylene, Gore-Tex, Amid classification type II (microporous). Surgical route: abdominal 'Mesh inlay' or 'total mesh': neither Concomitant procedures: colposuspension: 16/41; hysterectomy: 2/41 (patients preferred intervention B) INTERVENTION B (n=41): No mesh/graft: vaginal hysterectomy combined with anterior and/or posterior colporrhaphy Surgical route: vaginal Concomitant procedures: colposuspension: 11/41; hysterectomy: 41/41
Follow-up	**1 year**
Conflict of interest/source of funding	not reported

Analysis

Follow-up issues: patients were followed up for a year. 5% (4/82) patients were lost to follow-up.

Study design issues: patients were randomly assigned to treatment groups, treatment allocation was concealed. The 2 groups were treated in the same way apart from the intervention received. It is unclear if assessors were blinded to treatment allocation. Intention to treat analysis was undertaken.

Study population issues: the groups were similar at baseline in terms of prognostic factors.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 82 (41 versus 41)
Operating time, mean (SD): A, N=41, 97 min (3.6); B, N=41, 107 min (4.7); mean difference, 10 min (-2 to 22)
Length of hospital stay, mean (SD): A, N=41, 7.7d (0.2); B, N=41, 7.6d (0.3); mean difference, 0.1d (-0.6 to 0.7).
Others: Visited a doctor because of:
symptoms related to surgery: A, 25/41; B 13/41;
defecation symptoms (NR persistent or new): A, 12/41; B 5/41;
micturition symptoms (NR persistent or new): A, 8/41; B, 3/41;
other symptoms: A, 11/41; B, 10/41.

<table>
<tr><td>Subjective failure*</td><td>n, mean (SD)</td><td>n, mean (SD)</td></tr>
<tr><td>Baseline</td><td>n=41, 68.3 (4.3)</td><td>n=41, 58.0 (4.7)</td></tr>
<tr><td>1 year</td><td>n=38, 9.2 (3.8)</td><td>n=40, 5.1 (3.0)</td></tr>
<tr><td>Visited a doctor because of prolapse symptoms</td><td>n=16/41</td><td>n=5/41</td></tr>
<tr><td>Objective failure ICS</td><td></td><td></td></tr>
<tr><td>Uterine or vault prolapse>stage II, at 1 year</td><td>2/38</td><td>2/40</td></tr>
<tr><td>Cystocele>stage II</td><td></td><td></td></tr>
<tr><td>Baseline</td><td>35/41</td><td>36/41</td></tr>
<tr><td>1 year</td><td>14/38</td><td>16/40</td></tr>
<tr><td>Rectocele>stage II</td><td></td><td></td></tr>
<tr><td>Baseline</td><td>13/41</td><td>15/41</td></tr>
<tr><td>1 year</td><td>2/38</td><td>6/40</td></tr>
<tr><td>Further operation needed for prolapse (recurrent or new at other sites)</td><td>9/41
(5 cystocele, not clear if new at other sites or not, 4 recurrent uterine prolapse)</td><td>1/41 (recurrent vault prolapse)</td></tr>
</table>
* measured by Urogenital Distress Inventory (UDI), range 0-100, higher score more bothersome symptoms
</td><td>
Blood loss, mean (SD): A, N=41, 244 ml (51.5); B, N=41, 248 ml (34.1)
Blood loss needing transfusion, n/N: A, 1/41; B, 2/41
Damage to surrounding tissue, e.g. urethra, bladder, bowel: bowel lesion, A, 0/41; B, 1/41
Infection:
Would infection: A, 0/41; B, 1/41;
Fever of unknown origin during admission: A, 3/41; B, 1/41;
Vault abscess during admission: A, 2/41; B, 0/41
Infected implant needing surgery, NR timing, NR: A, 2/41, B, NA.
Other serious adverse events:
Incisional peritoneal hernia needing surgery: A, 1/41; B, 0/41.
Other less serious adverse events:
Lower urinary tract symptoms during admission: A, 8/41; B, 8/41;
Dullness upper leg during admission: A, 1/41; B, 0/41;
Vaginal stricture needing readmission for excision: A, 0/41; B, 1/41;
</td></tr>
<tr><td colspan="2">Abbreviations used: NR, not reported; SD, standard deviation.</td></tr>
</table>

Study 4 Rahmanou P 2015 (included in Maher C 2016)

Details

Study type	Randomised controlled trial (single centre)
Country	UK
Recruitment period	2009-12
Study population and number	n=**101** women with symptomatic uterine prolapse [grade 2 -4] requesting surgery **(51 abdominal sacrohysteropexy using laparoscopic approach** versus **50 vaginal hysterectomy with vault support).**
Age	Mean age was between 63 and 65 years Median parity: 2 (range 1-6)
Patient selection criteria	Inclusion criteria: over 18 years of age with no desire to preserve fertility Exclusion criteria: abnormal cervical cytology or uterine bleeding: enlarged uterus and those not suitable for steep Trendelberg position or concomitant medical problems.
Technique	**Laparoscopic hysteropexy (LH)-** uterus suspended from sacral promontory with permanent polypropylene mesh (Prolite, Atrium) wrapped around the cervix and fixed to the cervix anteriorly (with Ethibond sutures) and reperitonealised to reduce risk of bowel adhesions. **Vaginal hysterectomy (VH) with vault support -** uterosacral ligaments reattached with Vicryl 1 sutures to the vaginal vault after hysterectomy at the time of vault closure and additional vault support with sacrospinous fixation (PDS 2.0 sutures) in those with complete procidentia. Concomitant vaginal floor repair done in 80-90% of women.
Follow-up	**Median of less than 1 year**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 1 patient in the laparoscopic hysterectomy group did not receive treatment due to low bifurcation of aorta. Attrition rate at 1 year was 37% (laparoscopic hysteropexy: 40/50; vaginal hysterectomy 39/50).

Study design issues: small pilot study not adequately powered, randomisation methods not stated; allocation by blind envelopes to either group. Blinding of patients and outcome assessment was not possible. Surgeons and trainees had extensive prior experience and done more than 50 procedures of each intervention before taking part in the study. Primary outcome was treatment failure defined as recurrent apical prolapse surgery within 1 year. The secondary outcome measures were change in anatomy assessed by pelvic organ prolapse quantification (POP-Q) scale and symptoms assessed using the validated International Consultation on Incontinence Questionnaire for Vaginal Symptoms (ICIQ-VS) questionnaire scores for prolapse, sexual wellbeing, quality of life, and subjective surgical outcome measured using the validated Patient Global Impression of Improvement (PGI-I) 7-point scale (1 being very much better and 7 being very much worse).

Study population issues: patient characteristics were similar between the groups. Additional sacrospinous fixation was done in patients with stage 4 prolapse.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **50 laparoscopic hysteropexy versus 50 vaginal hysterectomy**

Repeat surgery for prolapse

	Laparoscopic hysteropexy (n=50)	Vaginal hysterectomy (n=50)	P value within 1 year	P value at 1 year
Apical repair	3 (1 cervical amputation,2 laparoscopic mesh plication)	4+3 (laparoscopic sacrocolpopexies)	0.697	0.185
Vaginal wall repair	Anterior repair (+2), anterior and posterior repair (2+1)	0	0.151	0.022

+ numbers are those awaiting surgery at 1 year

Prolapse symptoms (assessed using objective and subjective scoring systems)

	Laparoscopic hysteropexy		Vaginal hysterectomy (n=37)		p value
	Preoperative (n=50)	Post-operative (n=37)	Preoperative (n=50)	Post-operative (n=35)	
ICIQ-VS					
Vaginal symptoms score	34.7	8.9	33.26	7.26	0.448
Sexual matters score	27.8	13.2	28.8	11.2	0.329
Quality of life score	7.2	2.2	7.8	1.34	0.154
POP-Q					
Point Ba	1.7	-0.8	0.9	-0.6	0.063
Point C	2.9	-5.4	1.9	-4.3	<0.001
Point D	0.6	-6.8	0	NA	NA
Point Bp	0.5	-2.7	0.6	-2.4	0.666
Total vaginal length	8.4	8.35	8.23	6.5	<0.001

PGI-I score was very similar in both groups, with 82 % of subjects in the LH group very much/much better with their prolapse symptoms, compared with 87 % in the VH group at 1 year., 89 % of them in the VH group recommended their primary prolapse operation to other women with prolapse, whereas 78 % in the LH group recommended the operation.

Operating time was significantly longer in the hysteropexy group compared with vaginal hysterectomy group (group A 39.5, group B 28.1 p<0.001).

Other outcomes

Time before return to normal activity was significantly shorter (p=0.012), estimated blood loss was significantly less (p<0.001), pain score 24 h post-operatively was significantly lower (p=0.002), and hospital stay was significantly shorter (p=0.005) in the hysteropexy group compared with the vaginal hysterectomy group.

Safety

Complications

No major intraoperative complications reported in either of the groups. No vaginal mesh exposure or any other mesh complications were observed in any of the women having LH. In the VH group 1 woman without postmenopausal bleeding had a coincidental stage 1A mucinous endometrial carcinoma.

Abbreviations used: ICIQ-VS International Consultation on Incontinence questionnaire for vaginal symptoms; POP-Q pelvic organ prolapse quantification; PGI-I, Patient Global Impression of Improvement.

Study 5 Gracia M 2015

Details

Study type	Non-randomised comparative study (single centre)
Country	Spain
Recruitment period	2010
Study population and number	n=**45** women with symptomatic pelvic organ prolapse grade 2 or more **Group A: 15 laparoscopic sacral hysteropexy** versus **Group B: laparoscopic subtotal hysterectomy plus cervicopexy**
Age	Mean age: group A 48.7 years, Group B 43.5 years. Median parity 2 (range 0-4).
Patient selection criteria	Inclusion criteria: over 18 years of age with symptomatic uterine prolapse, with initial urogynaecological evaluation, decided to have surgical treatment with no contraindication for laparoscopic surgery. Exclusion criteria: women with cervical elongation were excluded.
Technique	**Group A - Laparoscopic sacral hysteropexy -** 2 partly absorbable multifilament meshes (Vypro II) are used. The caudad end of posterior mesh is anchored by using Prolene sutures to the levator ani muscle bilaterally, posterior vaginal wall and cervix. The caudad end of the second mesh is sutured to the anterior vaginal wall and to the cervix. The 2 cephalad ends of the meshes are sutured (using Prolene) to the anterior sacral ligaments to suspend the uterus. The peritoneal defect is repaired. **Group B - laparoscopic subtotal hysterectomy plus cervicopexy -** uterus was removed by subtotal hysterectomy and the cervix was attached to the promontory by cervicopexy as described above in group A.
Follow-up	**1 year**
Conflict of interest/source of funding	None

Analysis

Study design issues: pilot prospective cohort study with small sample size, choice of treatment method was based on women's preferences. Primary outcome was to assess subjective success (defined by 2 measures: first by a negative answer to the question number 35 of the EPIQ questionnaire and second by rating the overall improvement in symptoms by using the validated Patient Global Impression of Improvement (PGI-I) 7 point scale (1 being 'very much better' and 7 being 'very much worse'). Objective success was assessed by pelvic organ prolapse quantification (POP-Q) scale and complications were also noted. All operations were done by 1 surgeon but assessments were done by independent examiners.

Study population issues: baseline demographic characteristics were similar between groups.

Key efficacy and safety findings

Efficacy

Number of patients analysed: 45 (**15 versus 30)**

Subjective success rates (assessed using EPIQ and PGI-I scales)

Follow-up	**Group A Laparoscopic sacral hysteropexy- (n=15)**	**Group B laparoscopic subtotal hysterectomy plus cervicopexy (n=30)**	**P value**
6 months EPIQ-Q 35* % (n)	100 (15/15)	100 (30/30)	
6 month PGI-I scale % (n)			0.001
Cure (score1- very much better)	26.7 (4/15)	76.7 (23/30)	
Improvement score (2,3-much better and little better)	73.3 (11/15)	23.3 (7/30)	
12 month EPIQ-Q35* % (n)	100 (15/15)	100 (30/30)	
12 month PGI-I scale % (n)			0.001
Cure (score1- very much better)	13.3 (2/15)	70 (21/30)	
Improvement score (2,3-much better and little better))	86.7 (13/15)	30(9/30)	

*negative answer to the question number 35 from EPIQ: 'do you have a sensation that there is bulge in vagina or that something is falling out from your vagina'.

Objective success rates (assessed using POP-Q scale)

Follow-up	**Group A Laparoscopic sacral hysteropexy - (n=15)**	**Group B laparoscopic subtotal hysterectomy plus cervicopexy (n=30)**	**P value**
6 month POP-Q (<2nd degree) %(n)			
Apex	53.3 (8/15)	90 (27/30)	0.009
Anterior vaginal wall	40 (6/15)	70 (21/30)	0.1
12 month POP-Q (<2nd degree) %(n)			
Apex	46.7 (6/15)	90 (27/30)	0.002
Anterior vaginal wall	27.6 (4/15)	66.7 (20/30)	0.02

None had further prolapse at the posterior wall or needed additional surgery for prolapse repair.

Safety

Adverse events

	Group A Laparoscopic sacral hysteropexy- (n=15)	**Group B laparoscopic subtotal hysterectomy plus cervicopexy (n=30)**
Fever	2	2
Urinary retention	1	1
Bladder injuries	0	2
Dyspareunia	0	0
Vaginal mesh erosions	0	0

Operating time was significantly longer in the laparoscopic subtotal hysterectomy plus cervicopexy group compared with laparoscopic sacral hysteropexy group (group A 98 minutes, group B 123 minutes p<0.001). The median length of hospital stay was 3 days in both groups.	
Abbreviations used: EPIQ-Q 35, epidemiology of prolapse and incontinence questionnaire- question number 35; POP-Q pelvic organ prolapse quantification; PGI-I, Patient Global Impression of Improvement.	

Study 6 Gutman RE 2016

Details

Study type	Non-randomised comparative study (multicentre)
Country	USA
Recruitment period	2011-14
Study population and number	n= **151** women with symptomatic pelvic organ prolapse grade 2 or more **Group A: 74 laparoscopic sacrohysteropexy (LSHP)** versus **Group B: 77 Vaginal mesh hysteropexy (VMHP)**
Age	Mean age: group A 58.3 years, Group B 65.7 years (p<0.001). Median parity: group A 2 (range 0-7); group B 3 (range 0-12) (p=0.006)
Patient selection criteria	Inclusion criteria: women aged 35-80 years who desired uterine conservation and were having 1 of the above procedures for stage 2-4 symptomatic anterior/apical uterovaginal prolapse (anterior descent at or beyond the hymen [Aa or Ba>0] and apical descent at or below the midvagina [C>-TVL2]), those completed childbearing or were practicing reliable contraception and had a normal sized uterus (<10cm) were included. Exclusion criteria: women with cervical elongation, prior mesh prolapse repair, foreign body complications, cervical dysplasia, chronic pelvic pain, uterine abnormalities and abnormal bleeding in the past 12 months were excluded.
Technique	**Group A – LSHP -** done using an anterior and posterior type 1 polypropylene mesh. Each mesh strap had 4cm attachment to the proximal vagina and cervix with permanent sutures. The posterior mesh was sutured to the anterior longitudinal ligament with 2 sutures and a longer extension was permitted toward but not to the perineal body. The central portion of the anterior mesh was attached to the vagina with extension to the uretherovesical junction and lateral arms through the windows in the broad ligament and were secured to the anterior longitudinal ligament or the posterior mesh with 2 sutures. **Group B – VMHP -** done using the Uphold/Uphold Lite system. An inverted U shaped anterior vaginal incision was done proximal to the uretherovesical junction and the dissection continued to the anterior cervix, residual fibromuscular layer adherent to bladder was plicated using sutures. The arms of the mesh are inserted into the sacrospinous ligament via the anterior approach. The graft was secured to the cervix with 1 suture and could be attached to the fibromuscular layer on the bladder using sutures. All patients had general anaesthesia (9% VMHP used regional), received antibiotic prophylaxis. Additional procedures such as mid-urethral slings, anterior colporrhaphy or posterior repair were done at the discretion of the surgeon.
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 20% loss to follow-up at 1 year. 1 patient in VMHP withdrew after procedure due to cystotomy.

Study design issues: parallel cohort study in 8 centres comparing 2 different hysteropexy procedures, Patients were not randomised, surgical approach was determined through shared decision making. Procedures were done by trained surgeons. Primary outcome was surgical success (anatomic and symptomatic cure at 12 months). Cure was defined as no prolapse beyond the hymen and cervix above midvagina (anatomic), no vaginal bulge sensation (symptomatic) and no reoperations. Pelvic organ prolapse quantification (POP-Q) and quality of life using validated questionnaires were collected at baseline, 3 and 12 months including the Pelvic Floor Distress Inventory Short Form (PDFI-20), Female Sexual Function Index (FSFI) , and Patient Global Impression of Improvement (PGI-I). POP examinations were done by an independent examiner. Pain was assessed using the modified Surgical Pain Scale. Functional activity was assessed using the Activity Assessment Scale (scores 0-100, higher scores indicating better functioning). Complications were categorised using the modified Clavien-Dindo surgical complication grading scale. In all, 72 women were needed to detect 94% versus 75% cure (80% power, 15% dropout). Intention to treat analysis was used with logistic regression adjusting for baseline differences.

Study population issues: laparoscopic sacrohysteropexy patients were younger (p<0.001), had lower parity (p=0.006), were more likely to be premenopausal (p=0.008), and had more severe prolapse (p=0.02).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **151 (74 versus 77)**

Operative outcomes between groups

Laparoscopic sacrohysteropexy procedure (174 versus 64 minutes, p<0.0001) and total operating time including additional procedures (239 versus 112 minutes, p<0.0001) were longer than vaginal mesh sacrohysteropexy. There were no differences in blood loss and hospital stay.

Surgical success at 1 year

Outcome	LSHP % (n)	VMHP % (n)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	P value
Apical-cervix beyond mid vagina (C≥-TVL/2)	19 (12/64)	15 (9/61)	1.3 (0.51-3.4)	2.5 (0.70-9.7)	0.16
Anterior-prolapse beyond hymen (Aa, Ba, Ap, Bp any>0)	9 (6/64)	6 (4/61)	1.4 (0.39-5.4)	1.1 (0.2-5.9)	0.93
Reoperation for POP	0 (0/73)	3 (2/73)^	-	-	NA
Anatomical cure (C<-TVL/2; Aa, Ba, Ap, Bp all ≤ 0; and no reoperation or pessary use)	77 (49/64)	80 (49/61)	0.8 (0.34-1.9)	0.48 (0.2-1.5)	0.20
Symptomatic cure (negative response to seeing or feeling bulge, PFDI-20, question 3)	90 (62/69)	95 (58/61)	0.5 (0.11-1.9)	0.4 (0.7-1.8)	0.22
Composite outcome anatomic and symptomatic cure	72 (46/64)	74 (46/62)	0.9 (0.40-2.0)	0.58 (0.2-1.5)	0.27

*Adjusted for age, parity, POP-Q point Bp and C, menopausal status and clinical site; ** p value for adjusted OR

^1 had vaginal hysterectomy and sacralcolpopexy at 8.5 months, and 1 had vaginal trachelectomy for cervical elongation at 3 months.

POP-Q outcomes at 1 year (median, range)

POP-Q points	LSHP	VMHP	P value
Aa	-2 (-3 to+2)	-2 (-3 to +2)	0.71
Ba	-2 (-3 to+2)	-2(-3 to+2)	0.63
Ap	-2.5 (-3 to0)	-2.5 (-3 to+2)	0.96
Bp	-2.5 (-3 to +1)	-3 (-3 to+2)	0.87
C	-6.5 (-11 to-2)	-6 (-9 to+2)	0.15
D	-9 (-12 to-6)	-7.5 (-10 to -2)	<0.001
TVL	9 (9 to 12)	9 (5 to 10)	<0.001
GH	3 (1.5 to 5)	3 (2 to 4.5)	0.36

Safety

Adverse events

	LSHP % (n=74)	VMHP % (n=77)	P value
Perioperative			
Bladder injury	0	4 (3/77)	0.24
Small bowel injury	3 (2/74)	0	0.23
Deep vein thrombosis	1 (1/74)	0	0.31
Blood transfusion	1 (1/74)	0	0.30
Cardiac/myocardial infarction	1 (1/74)	0	0.30
Neurologic	1 (1/74)	0	0.30
Postoperative			
Urinary tract infections	11 (8/74)	25 (19/77)	0.03
Haematoma	0	1 (1/77)	0.99
Small bowel obstruction	1 (1/74)	0	0.99
Nerve injury	3 (2/74)	1 (1/77)	0.62
Uterine injury/cystotomy	0	3 (2/77)	0.50
Blood transfusion	0	1 (1/77)	0.99
Mesh exposure total (sling+POP)	6.8 (5/74)	6.6 (5/77)	0.99
POP	2.7 (2/74)*	6.6 (5/77)^	0.44
Sling	4.1 (3/74)+	0	0.06
Suture erosion	3 (2/74)	6.6 (5/77)	0.72
Urinary retention/voiding dysfunction	4.1 (3/74)	6.6 (5/77)	0.23

*1 excision, 1 spontaneous resolution. ^ 3 excision, 2 observation. + all excised.

Complications (according to modified Clavien-Dindo scores)

Clavien-Dindo grade	LSHP % (n=74)	VMHP % (n=77)
0	68 (50/74)	53 (41/77)

PB	4 (2 to 5.5)	3.25 (2 to 5)	0.02
Cervical length (C-D)	2 (0-5)	1.5 (0 to 7)	0.05

Pelvic floor distress inventory short form outcomes (mean ±SD)

Domain (score range)	LSHP		VMHP		P value (Change within group)	P value (between group adjusted*)
	Baseline	12 months	Baseline	12 months		
POPDI (0-100)	42±25	6±11	41±22	9±13	<0.0001	0.88
CRADI (0-100)	16±17	9±13	22±18	12±14	<0.0001	0.88
UDI (0-100)	35±28	8±13	40±26	17±19	<0.0001	0.29
Total PFDI-20 (0-300)	93±58	24±30	103±53	38±39	<0.0001	0.34

*linear regression used to adjust for age, parity, baseline POP-Q C and Bp, menopause status and baseline score. Higher scores indicate greater distress/bother.

Overall satisfaction was high (95%) and 79% of each group rated prolapse symptoms 'very much better' and 16% 'much better on PGI-I.

Female sexual function index outcomes

Domain (score range)	LSHP		VMHP		P value (between group adjusted*)
	Baseline sexually active n=32	12 months n=46	Baseline sexually active n=29	12 months n=25	
Total FSFI (2-36)	19.8 (2.4-34.8)	29.2 (2.4-36)	11.8 (2.6-35.2)	21.5 (2-34.9)	0.13

*linear regression used to adjust for age, parity, baseline POP-Q C and Bp, menopause status and baseline score. Higher scores indicate greater distress/bother.

Sexual satisfaction improved in women who chose to have LSHP than who chose VMHP (p=0.02). Less than half of the patients were sexually active at baseline but at 12 months more LSHP patient reported sexual activity (p=0.03).

Pain score and functional activity levels

No differences were observed in baseline and postoperative pain scores and functional activity levels between the groups. Activity Assessment Scale mean scores were high for most patients indicating a high level of function at baseline and 6 months.

I	11 (8/74)	18 (14/77)
II	15 (11/74)	19 (15/77)
III	7 (5/74)	9 (7/77)
IV and V	0	0

Abbreviations used: CI, confidence interval; CRADI, colorectal-anal distress inventory; FSFI, Female Sexual Function Index; LSHP, laparoscopic sacrohysteropexy; NA, not applicable; OR, odds ratio; PFDI-20, Pelvic Floor Distress Inventory Short Form; POP-Q pelvic organ prolapse quantification; POPDI, pelvic organ prolapse distress inventory; PGI-I, Patient Global Impression of Improvement; SD, standard deviation; TVL, total vaginal length; UDI, urinary distress inventory; VMHP, vaginal mesh sacrohysteropexy.

Study 7 Paek J 2016

Details

Study type	Non-randomised comparative study
Country	South Korea
Recruitment period	2006-14
Study population and number	n=**111 women with symptomatic (stage 2 or more) pelvic organ prolapse** **54 robotic or laparoscopic sacrohysteropexy** versus **57 open sacrohysteropexy** Median preoperative POP-Q stage: 3 (range 2-4)
Age	Mean age 62.2 years (laparoscopic/robotic approach); 64.8 years (open approach) Median parity: 3 (range 0-6) (laparoscopic/robotic approach); 3 (range 1-6) (open approach)
Patient selection criteria	Women with symptomatic pelvic organ prolapse (stage >2) (evaluated using an international classification of POP) were included.
Technique	**In robotic sacrohysteropexy (n=14),** the da Vinci Surgical system was used and the abdominal cavity was entered using an open technique. In **laparoscopic sacrohysteropexy (n=40)** 3 laparoscopic ports were placed after a pneumoperitoneum was created. The procedure is similar to **open sacrohysteropexy (n=57)** The peritoneum is incised from the sacral promontory and dissected until the anterior longitudinal ligament is identified. Peritoneal tunnel from sacral promontory to the uterosacral ligament is created. The anterior broad ligament is opened and tunnels from anterior broad ligament to the uterosacral ligament created. The mesh (Gynemesh) is passed through the bilateral tunnels created around the uterus, attached to the cervix and passed through the peritoneal tunnel to the sacral promontory. Both ends of the mesh are fixed to the anterior vagina and sacral promontory with Ethicon sutures. The peritoneum is approximated with sutures to cover the mesh.
Follow-up	**Median 30 months (range 12-108 months)**
Conflict of interest/source of funding	None

Analysis

Study design issues: Small number of patients. Data were collected by review of patient records retrospectively. Robotic surgeries were done by 1 experienced surgeon and laparoscopic/open surgeries were done by 2 experienced surgeons. Patients who wanted minimally invasive surgery had robotic or laparoscopic approaches. Subjective assessment of prolapse symptoms was done using a questionnaire before and 12 months after surgery. Objective failure was defined as POP-Q stage 2 or more at 12 months after surgery. Patients who needed reoperation within 12 months were regarded as both subjective and objective failures.

Study population issues: robotic/laparoscopic group had fewer previous pelvic surgeries compared to open group (25.9 versus 73.7%; p<0.001). There was no difference in presence of peritoneal adhesions between groups at baseline (p=0.690).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **111 (54 RLSH versus 57 OSH)**

Postoperative outcomes

	RLSH % (n=54)	OSH % (n=57)	P value
Subjective success rates (overall satisfaction)	94.4 (51/54)	91.2 (52/57)	0.717
Objective success rates	96.3 (52/54)	98.2 (56/57)	0.611
Median postoperative POP-Q stage (range)	0 (0-1)	0 (0-1)	0.682
Postoperative prolapse symptoms	13 (7/54)	45.6 (26/57)	<0.0001
Reoperation for postoperative complications	3.7 (2/54)*	1.8 (1/57)**	0.611

*2 had laparoscopic hysterectomy followed by sacrocolpopexy 6 months after surgery due to voiding dysfunction.

**1 patient need mesh removal at 5 months after surgery due to persistent abdominal pain.

Operating time

Compared with OSH group, the RLSH group had shorter operating time (120.2 versus 187.5 minutes, p<0.0001), less blood loss (50 versus 150 ml, p<0.0001).

Safety

Adverse events

	RLSH % (n=54)	OSH % (n=57)	P value
Intraoperative complications	0	3.5 (2/57)	0.496
Mesh erosion	0	5.3 (3/57)	0.244
Voiding dysfunction	0	15.8 (9/57)	0.003
Overactive bladder	5.6 (3/54)	17.5 (10/57)	0.075
Urinary incontinence	3.7 (2/54)	12.3 (7/57)	0.163
Constipation	9.3 (5/54)	3.5 (2/57)	0.263
Dyspareunia	5.6 (3/54)	0	0.112

Abbreviations used: POP-Q, pelvic organ prolapse quantification; OSH, open sacrohysteropexy; RLSH, robotic or laparoscopic sacrohysteropexy

Study 8 Jefferis H 2016

Details

Study type	Retrospective case series (single centre)
Country	UK
Recruitment period	2006-16
Study population and number	n=**507** women with symptomatic uterine prolapse [grade 2-4] requesting surgery Degree of prolapse (point C): stage 1 (n=2), stage 2 (n=90), stage 3-4 (n=48)
Age	Mean age 57.8 years; mean BMI: 26.1 kg/m2
Patient selection criteria	Inclusion criteria: women over 18 years of age with symptomatic uterine prolapse who wished to retain uterus but with no desire to conceive. Exclusion criteria: abnormal cervical cytology or uterine bleeding: enlarged uterus and those not suitable for steep Trendelberg position or concomitant medical problems.
Technique	**Laparoscopic hysteropexy (LH) –** the peritoneum over the sacral promontory is incised to access periosteum for fixation. A peritoneal relaxing incision is then made medial to the right ureter and the utero-vesical fold opened to reflect the bladder. uterus is suspended from the sacral promontory with permanent bifurcated type 1 polypropylene mesh (Prolite, Atrium; Prolene, Ethicon) wrapped around the cervix and fixed to the cervix anteriorly (with Ethibond sutures) and reperitonealised to reduce risk of bowel adhesions. The technique has been modified over the 10 year period. 55% (276/507) women had concomitant vaginal prolapse surgery and 4% (20/507) had concomitant continence surgery.
Follow-up	**3 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 86% (437/507) patients attended a routine follow-up conducted 3 months after surgery and 13% did not attend follow-up.

Study design issues: medical records over a 10-year period were reviewed. 72% (364/507) procedures were done by consultants and the remaining were done by urogynaecology subspecialty trainees and a visiting fellow. Primary outcome was safety. Subjective surgical outcome was measured using the validated Patient Global Impression of Improvement (PGI-I) 7 point scale (1 being 'very much better' and 7 being 'very much worse'). Change in anatomy was assessed by pelvic organ prolapse quantification (POP-Q) scale. POP-Q assessments were done by clinicians who have not done the surgery.

Study population issues: 38 women had previous prolapse or incontinence surgery. None had apical prolapse procedures.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 507
Mean duration of surgery (including additional procedures): 62.5 minutes (range 27 to 125 minutes).
Median length of stay: 2 days (range 1-7 days)
Hysteropexy was abandoned due to anatomical difficulties in 3.4% (17/507).

PGI-I score (n=404): 93.8% (379/404) women described their prolapse as ‘very much’ or ‘much’ better. 1.5% (6/404) felt there was no change in prolapse symptoms. No women described their prolapse as ‘worse’.

Repeat surgery for prolapse
2.8% (14/507) women had further apical prolapse and needed repeat apical surgery at a median of 12 months (range 6-84 months) because the mesh had stretched and was loose. Of these, 10 had plication of the mesh using sutures, 3 with cervical elongation had cervical amputation with or without plication, and all had successful outcome.
Ongoing uterine prolapse was reported in 2 patients and were treated by vaginal hysterectomy. 7.1% (36/507) had further vaginal wall repair.

Prolapse symptoms (assessed using objective scoring system at median 3 months follow-up)
<table><tr><td></td><td colspan="2">Laparoscopic hysteropexy</td><td>P value</td></tr><tr><td></td><td>Preoperative (mean)</td><td>Post-operative (mean)</td><td></td></tr><tr><td colspan="4">POP-Q (cm)</td></tr><tr><td>Point C (n=380)</td><td>1.1 (range 10 to 4)</td><td>-6.9 (range 0 to -10)
Change 7.9cm</td><td>P<0.001</td></tr></table>
Subsequent pregnancies reported in 6 women (all delivered normal birthweight babies by caesarean section with no significant complications)</td><td>Complications

<table><tr><td>Major complication rate</td><td>1.8 (9/507)</td></tr><tr><td>Adhesions (between bowel and non-peritonised mesh) noted in those wit
h abdominal pain between 4-8 months after surgery (carefully divided)*</td><td>0.6 (3/507)</td></tr><tr><td>Pulmonary embolism</td><td>0.4 (2/507)</td></tr><tr><td>Bladder injury (caused by insertion of the suprapubic port, repaired laparoscopically, no sequelae)</td><td>0.2 (1/507)</td></tr><tr><td>Haemorrhage (1 due to broad ligament vascular injury [needed laparotomy, uneventful recovery], 1 retropubic hematoma [drained and a bleeding vessel cauterised; 1 haemoperitoneum [no bleeding point found at laparotomy)</td><td>0.6 (3/507)</td></tr><tr><td>Perineal infection (concomitant posterior repair)</td><td>3.2 (16/507)</td></tr><tr><td>Urinary retention</td><td>3 (4/140)</td></tr><tr><td>Urinary tract infections</td><td>1.2 (6/507)</td></tr><tr><td>Voiding difficulties</td><td>2.2 (11/507)</td></tr></table>*all these cases occurred in 2007 and the technique was changed and standardised to complete peritonisation of the mesh
No vaginal mesh exposure noted.
2 women asymptomatic at time of surgery subsequently presented with endometrial cancer and 1 was diagnosed with cervical cancer after 2 years.</td></tr>
<tr><td colspan="2">Abbreviations used: ICIQ-VS International Consultation on Incontinence questionnaire for vaginal symptoms; POP-Q pelvic organ prolapse quantification; PGI-I, Patient Global Impression of Improvement.</td></tr>
</table>

Study 9 Grimminck K 2016

Details

Study type	Prospective case series (single centre)
Country	The Netherlands
Recruitment period	2009-14
Study population and number	n=**100 women with uterovaginal prolapse**
Age	Mean age 56.8 years (range 36-77) Mean parity: 2.2 (range 0-7)
Patient selection criteria	Women not responsive to non-surgical options (such as pessary/pelvic exercises) were included. Women with an American Society of Anaesthesiologists score of 3 or more, with a predisposition to pelvic adhesions due to former abdominal surgery, those suffering from diverticulitis and with a BMI above 35 were excluded.
Technique	**Robotic sacrohysteropexy -** uterus is suspended from the sacral promontory with permanent bifurcated polypropylene mesh.
Follow-up	**5 years (in first cohort, n=50), 1 year (second cohort, n=50)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 79% women in the short-term follow-up completed the 3 questionnaires and only 30 women completed all 3 questionnaires in the long-term follow-up.

Study design issues: uterine prolapse (pre and postoperative) was scored by the Baden-Walker system (in first cohort of 50 patients) and the POP-Q classification was used for the second cohort and for the 5-year follow-up. Recurrence of prolapse was defined as uterine prolapse POP-Q stage 2 or higher. Procedures were done by a consistent team and follow-up physical examinations were done by a trained independent clinician.

Quality of life was assessed pre-operative, post-operative and 5 years after robotic sacrohysteropexy using the validated urogenital distress inventory and incontinence impact questionnaire (UDI-IIQ) designed for Dutch speaking patients. Pain was scored with a visual analogue scale (0, no pain and 10, unbearable pain). Clinical and operative data were collected prospectively up to 5 years.

Study population issues: 21 women had additional surgeries and 3 cases were converted to laparotomy due to anatomical issues.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **100**

Quality of life (assessed using UDI-IIQ questionnaire)

	Before surgery	6 weeks after surgery	P value
1 year follow-up group (n=79)			
Overall quality of life (0-6 scale), mean	4.5	5.12	<0.05
Overall health status (0-100 VAS scale), mean	72.6	82.2	<0.05
'Ball like' sensation % (n)	86.7 (65/79)	8.0 (/79)*	
Sexual function (0-4 scale) , mean	2.6	3.2	<0.05
5 year follow-up group (n=30)			
Quality of life (0-6 scale), mean	4.43	5.15	0.0004
Overall health status (0-100 VAS scale), mean	69.02	83.32	0.00008
	Before surgery	**After 5 years**	
Quality of life (0-6 scale), mean	4.43	5.17	0.0004
Overall health status (0-100 VAS scale), mean	69.02	83.50	0.0003

No difference in quality of life (mean 5.17 versus 5.17, p=0.918) or overall health status (mean 83.32 versus 83.50, p=0.962) was observed between 1 and 5 year follow-up.

After surgery patients experienced less feelings of nervousness, (p=0.01), shame (p<0.05), and frustration (p<0.05). The positive effects of these feelings remained after 5 years.

Satisfaction: 87.3% patients were satisfied with the surgery,10% felt much better and 2.6% (2/79) women were less satisfied (1 developed ileus and 1 had de novo incontinence).

*1 woman had a grade 1 uterine prolapse.1 year after surgery.

Anatomical outcomes

1 year	**% (n)**
Anatomical success (assessed using Baden-Walker score) (n=50)	98 (49/50)
Recurrent prolapse (grade 2 or higher)	2 (1/50)*
Anatomical success (assessed using POP-Q score) (n=50)	94 (47/50)
Recurrent prolapse (stage 2 or higher	2 (1/50)
Anterior compartment prolapse	18 (13/50) grade 1 (8); 2 (5)
Posterior compartment prolapse	18 (13/50) grade 1 (9), 2 (3), 3 (1)
5 years	
Anatomical success (assessed using POP-Q score) (n=37)	81
Recurrent prolapse	10.8 (4/37) stage 2 8.1 (3/37) stage 1
Anterior compartment prolapse	18.9 (7/37) stage 2 2.7 (1/37) stage 3
Posterior compartment prolapse	13.5 (5/37) stage 2 8.1 (1/37) stage1
Overall success rate	89.2

*grade 3 prolapse treated by sacrospinous colpopexy and cervical amputation.

Safety

Postoperative complications

	n
Ileus	1
Oedema in right arm leading to temporary sensitive malfunction	1
Feeling of 'traction' in abdomen (reduced after mesh was removed)	1
De novo stress urinary incontinence (treated with vaginal tape)	13
Mesh erosion (12 months after surgery)	4
Median pain score	2.6 (range 0-8)

Abbreviations used: POP-Q, pelvic organ prolapse quantification; UDI IIQ, urogenital distress inventory and incontinence impact questionnaire; VAS, visual analogue scale.

Study 10 Joshi VM 2015

Details

Study type	Retrospective case series (including open and laparoscopic approaches)
Country	India
Recruitment period	1998-2011
Study population and number	n=**194 women with uterine prolapse (176 open pectineal ligament hysteropexy [PLH] and 18 laparoscopic PLH)** Degree of uterine prolapse (grade II n=10, grade III n=184)
Age	Mean age 26.5 years (open approach), 28 years (laparoscopic approach) Mean parity: 2 (range 0-4)
Patient selection criteria	Premenopausal women presenting with grade 2 or 3 uterine prolapse with cervix at or outside the introitus, with or without vaginal prolapse were included. Women with cervical elongation without concomitant uterine prolapse and those needing hysterectomy were excluded.
Technique	**Pectineal ligament hysteropexy (PLH)** - prolapsed uterus was suspended with polyester (Mersilene) tape to pectineal ligament on either side through a Cherney incision (laparotomy n=176) or laparoscopically (n=18). Preoperative antibiotic prophylaxis was given to all women. Ancillary procedures were done at the time of PLH. Concurrent or prior tubectomies were done.
Follow-up	**Mean 6.5 years (range 0.5-14 years) for open method and 1 year (range 0.5-2 years) for laparoscopic method**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: patients were followed at 1 and 6 months and annually thereafter. Long duration of follow-up. Overall 12% (24) women in the open approach group were lost to follow-up.

Study design issues: large study conducted in 3 urban and 3 rural hospitals. Surgeons had varying levels of surgical experience (5 had 10-20 years' experience and 3 had 3 years' experience). Laparoscopic procedure was done in only 1 centre. Data were collected by chart review of patient records. Primary outcome measure was recurrence of uterine prolapse beyond first degree (the descent of the cervix into the lower half of the vagina). Secondary outcomes were presence of prolapse in other compartments, cervical elongation, dyspareunia, erosion of tape and lower urinary tract infections. The Baden-Walker halfway system was used for prolapse assessment.

Study population issues: in addition to uterine prolapse, 20 women had stress urinary incontinence, 18 had cervical elongation, 29 women had cystocele, 70 had rectocele, and 48 had dyspareunia.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **194**

	Open hysteropexy % (n=176)	**Laparoscopic hysteropexy % (n=18)**
Recurrent uterine prolapse	5.7 (10/176)*	0
Cystocele grade 2 or more (needed colporrhaphy)	6.8 (12/176)	0
Enterocele	0	0
Rectocele	0	0
Cervical elongation (at 2-3 years needed cervical amputation and reconstruction)	3.4 (6/176)	5.5 (1/18)

*7 recurred after vaginal delivery (tape avulsed from the uterus) and treated by vaginal hysterectomy. There were no recurrences after caesarean deliveries. 3 were in non-pregnant women (2 recurred within 2 months, had vaginal hysterectomy with vault suspension.1 recurred after 1 year (had haematuria and urinary urgency [tape eroded into the bladder because of pelvic tuberculosis] treated by excision of tape and hysterectomy).

Overall failure rate after PLH: grade III uterine prolapse 5.7% (10/176)

Overall reoperation rate after PLH: 14.9% (29/194)

Pregnancy outcome: there were 46 births (32 vaginal and 14 caesarean deliveries) in 40 women after PLH.

Safety

Adverse events

No intraoperative complications.

No haemorrhage or need for blood transfusion.

	Open hysteropexy % (n=176)	**Laparoscopic hysteropexy % (n=18)**
Tape erosion into bladder	0.5 (1/176)	0
Wound morbidity	8.5 (15/176)	0

Abbreviations used: PLH, Pectineal ligament hysteropexy

Study 11 Pandeva I 2016

Details

Study type	Retrospective case series (single centre)
Country	UK
Recruitment period	2010-14
Study population and number	n= **159 women with symptomatic vaginal prolapse** POP-Q point C >stage 2: 85% (136/159)
Age	Mean age 56 years (range 23-83) Mean parity: 2.5 (range 1-6), median BMI 25 kg/m^2.
Patient selection criteria	Women with symptomatic vaginal prolapse described as 'moderately' or 'a lot' on the P-QOL questionnaire, anatomical uterine prolapse stage>1 descending below the upper third of the vagina, those with stage 1 uterine prolapse and symptomatic anatomical prolapse of stage >2 in other compartments, those who have completed family and no further fertility wishes, those who have failed conservative therapies and with desire for future childbearing were included. Those not suitable for general anaesthesia, with previous abdominal surgeries or history of menstrual dysfunction opting for hysterectomy were excluded.
Technique	**Modified laparoscopic single sheet mesh sacrohysteropexy (avoids broad ligament opening and need for bladder/bowel dissection), -**a single rectangular sheet (synthetic type 1 polypropylene mesh [Restorelle]) was used. The caudal part of the mesh was attached with polypropylene sutures to the posterior aspect of the cervix at the level of the uterosacral ligaments and extended to the level of the uterine isthmus bilaterally. The uterus was pushed up and the mesh adjusted with maximum uterine elevation. After folding the mesh over, the cephalad portion of the mesh was attached using helical fasteners. Excess mesh was excised and the peritoneum over the mesh was closed using sutures. Concomitant surgeries were done for anterior/posterior vaginal wall prolapse (n=142) and stress urinary incontinence (n=8).
Follow-up	**ranged 3-48 months (101 completed 2 years follow-up)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 91% (144/159) patients completed follow-up assessment.

Study design issues: retrospective cohort study, primary outcome was defined as pelvic organ prolapse quantification (POP-Q) point C at stage 0. Uterine prolapse was scored using the prolapse quality of life (P-QOL) questionnaire which includes 20 items in 9 domains and objectively by the POP-Q classification system. Subjective outcomes were assessed using the patient global impression of improvement (PGI-I) scale. Complications, reoperation for prolapse and pregnancy outcomes were evaluated.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **144**

Median operative time : 45 minutes

Median blood loss: 100 ml (50-400ml)

Anatomical success (defined as point C at stage 0) was achieved in 95.1% (137/144) of patients.

The time interval between surgery and recurrence of uterine prolapse: median 12 months (range 12-23 months).

Objective outcomes at last follow-up (3-48 months (assessed using POP-Q classification)

	Preoperative (mean)	Postoperative (mean)	P value
Point Aa	2.1	-1.6	
Point Ba	3.8	-1.3	<0.01
Point C	1.2	-6.3	<0.01
Point Ap	0.3	-2.1	
Point Bp	1.2	-2.0	<0.01
Point D	-1.5	-7.2	<0.01
Total Vaginal Length	7.8	7.9	

Postoperatively, 32.4% of patients had anatomical stage 2 or more anterior vaginal wall prolapse.

Recurrence (assessed using P=QOL questionnaire)

11% (16/144) patients had recurrence of prolapse symptoms (defined as a response of 'moderately' or 'a lot' to the question of feeling a bulge from or in the vagina on the questionnaire).

3 had recurrence of the uterine prolapse, 8 had anterior compartment recurrence, and 5 had posterior vaginal prolapse. 12 of these patients had further surgery for prolapse (7 had anterior vaginal mesh repair, and other surgeries included vaginal hysterectomy with sacrospinous fixation, posterior colporrhaphy, posterior vaginal mesh repair and colpocleisis).

PGI-1 response at last follow-up (3-48 months)

81% of patients (117/144) reported feeling either 'much better' or 'very much better'.

Pregnancy outcomes and prolapse recurrence

5% (8/144) women became pregnant (between 6 months and 3 years) after the procedure. 7 had full term and delivered by an elective caesarean section. 1 woman had a miscarriage in the first trimester.

1 woman developed symptomatic recurrence of prolapse and had deficient perineum 3 years after the procedure which was treated.

Safety

Adverse events at 1 year

	n
Bowel obstruction (1 due to umbilical port hernia, 1 with bowel volvulus around the barbed suture used for peritoneal closure), both needed surgical re-intervention to release bowel adhesions.	2

No mesh related complications were reported.

Abbreviations used: POP-Q, pelvic organ prolapse quantification system; PGI-I, Patient Global Impression of Improvement; QOL, quality of life.

Study 12 Viet-Rubin N 2016

Details

Study type	Prospective case series (single centre)
Country	Switzerland
Recruitment period	2004-11
Study population and number	n= **245 women with symptomatic apical prolapse**
Age	Median age 57 years (range 33-81) Median parity: 2 (range 0-8)
Patient selection criteria	Patients with prolapse related symptoms such as feeling of heaviness in the lower abdomen or a sensation of a bulge or lump in the vagina and those with significant prolapse stage 2 pelvic organ prolapse or greater in at least 2 or the 3 compartments were included.
Technique	**Uterus preserving laparoscopic lateral suspension with mesh- avoiding dissection at the promontory.** A T-shaped synthetic mesh graft (polyester or polypropylene) is placed in the vesicovaginal septum and suspended bilaterally to the abdominal wall, posterior to the anterior superior iliac spine. 59% women had concomitant surgery for stress urinary incontinence either by suburethral tape insertion or by Burch colposuspension. 50% women had concomitant surgery for posterior prolapse. Some patients were additionally treated with polypropylene mesh placed in the retrovaginal septum or with standard vaginal posterior colporrhaphy. Surgical time varied between 90-300 minutes depending on the number of surgical steps.
Follow-up	**Median 7.5 years (range 4-10 years)**
Conflict of interest/source of funding	One author is a medical advisor for PMF medical and all others have no conflicts of interest.

Analysis

Follow-up issues: 6 patients were lost to clinical follow after 3 months and 13 additional patients after 1 year. At a median of 7.5 years follow-up, only 152 patients participated in telephone interview. 25% patients were lost to follow-up, 12 refused to participate and 56 were not reachable after few attempts.

Study design issues: primary outcomes were subjective and objective cure, and secondary outcomes were rates of reoperation for symptomatic recurrence and mesh related complication rates. Uterine prolapse (pre and postoperative) was scored by the POP-Q classification system. Patient satisfaction was assessed in a telephone interview using a visual analogue scale (VAS) and the patient global impression of improvement (PGI-I) scale. Complications were reported using Clavien Dindo scale and mesh related complications were rated using the joint International Urogynecology Association/International Continence Society (IUGA/ICS) complication classification calculator.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **245**

Anatomical success for all compartments (assessed using POP-Q classification)

	Preoperative % (n=245)	3 months follow-up % (n=239)	12 months follow-up % (n=226)	P value
POP-Q point Ba>-1	96.7 (237/245)	6.5 (10/239)	11.8 (10/226)	P<0.0001
POP-Q point V>-1	92.2 (226/245)	8.6 (15/239)	13.9 (15/226)	P<0.0001
POP-Q point Bp>-1	81.4 (243/245)	8.8 (21/239)	19.2 (28/226)	P<0.0001

Anatomical success rates at 1 year were 82.2% for the anterior, 86.1% for the apical and 80.8% for the posterior compartment.

Reoperation for prolapse recurrence: 7.4%

Reoperation for SUI recurrence: 2.8%

Satisfaction at 1 year

Overall satisfaction rate at 1 year was 92.3% and 82.7% patients were asymptomatic after prolapse.

Patient satisfaction (assessed using PGI-I and VAS) (n=152), median follow-up7.5 years (range 4-10 years).

	% (n)
Overall satisfaction (on VAS), median (range)	9 (2-10)
PGI-I	
Much better	61.8 (94/152)
Better	21.1 (32/152)
Unchanged	6.6 (10/152)
A little worse	3.9 (6/152)
Worse	3.9 (6/152)
Much worse	2.6 (4/152)
Recommendation to a relative or friend	81.8 (124/152)

Safety

Adverse events at 1 year

	%
Minor complications (grade 1-2)	9.1
De novo SUI	2
Urinary retention	2.2
Recurrent urinary tract infection	2.2
Urgency	4.8
De novo dyspareunia	4.7
Constipation	5.3
Grade 3 complications (needing re-intervention) - 2 hernia, 1 vaginal hematoma	1.3
Mesh exposure*	1.2 (3/245)

*2 had vaginal exposure of the anterior polyester mesh and 1 had exposure of the posterior polypropylene mesh. All were subsequently removed.

Abbreviations used: POP-Q, pelvic organ prolapse quantification system; PGI-I, Patient Global Impression of Improvement; SUI, stress urinary incontinence; VAS, visual analogue scale.

Study 13 Chen G 2010

Details

Study type	Prospective case series (single centre)
Country	China
Recruitment period	2007-09
Study population and number	n=**28 women with uterovaginal prolapse stage 2 or greater who desired uterine preservation**
Age	Mean age: 62 years (range 57-66 years) Mean parity: 4 (range 3-5)
Patient selection criteria	All women with uterine prolapse grade 2 or greater were included. Women with uterine prolapse less than grade 2, previous abnormal cervical cytological findings, abnormal uterine bleeding, and concomitant medical problems that precluded the use of anaesthesia were excluded.
Technique	**Laparoscopic extraperitoneal uterine suspension to the anterior abdominal wall bilaterally using monofilament polypropylene surgical mesh (herniamesh, SRL)** Additional transvaginal repairs of cystocele and rectocele done without synthetic mesh in 12 women**.**
Follow-up	**Range 6 to 27 months**
Conflict of interest/source of funding	None, study funded by the clinical project of the provincial department of public health.

Analysis

Study design issues: degree of prolapse evaluated by using pelvic organ prolapse quantification (POP-Q) system. Primary objective outcome was absence of grade 2 or greater uterine prolapse evaluated using point C on POP-Q. Subjective outcomes were absence of prolapse symptoms, and reduction in scores for prolapse symptoms, sexual function and quality of life. Quality of life was evaluated using validated Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) and sexual symptoms evaluated using pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12). Questionnaires were administered at 1, 6 and 12 months. Pain was measured on a visual analogue scale (VAS) 0-10, with highest scores representing ‘most severe pain’. A 4-point scale was used to grade VAS score.

Population issues: none of the women had a history of previous pelvic surgery to treat prolapse.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **28**

Mean operating time (including transvaginal repair): 88.57 minutes

Mean hospital stay: 5 days

Objective cure rate (recurrence of grade 2 prolapse evaluated using point C on POP-Q)

6 months (n=28)	1 year (n=17)*
96.4 (27/28)	94.1 (16/17)

Recurrence of prolapse: 1 patient had grade 2 uterine prolapse at 2 months after surgery (due to disruption of the suture in the cervix).

*1 woman had grade 2 cystocele without uterine prolapse 1 year after surgery

Preoperative and postoperative POP-Q measurements, values are mean (SD)

Measurement	Baseline (n=27)	6 months (n=27)	1 year (n=16)
Aa	1.2 (1.4)	-2.5 (0.3) P<0.001	-2.5 (0.3) P<0.001
Ba	2.0 (1.7)	-2.6 (0.2) P<0.001	-2.6 (0.2) P<0.001
C	2.6 (2.4)	-7.8 (0.9) P<0.001	-8.0 (0.9) P<0.001
Ap	-1.8 (2.0)	-2.9 (0.2) P=0.002	-2.9 (0.2) P=0.009
Bp	-1.7 (2.2)	-2.9 (0.2) P=0.001	-2.9 (0.2) P=0.006
Total vaginal length	3 (0.7)	0	0

Subjective cure rate

6 months (n=28)	1 year (n=17)
96.4 (27/28)	94.1 (16/17)

Health related quality life scores, values are mean (SD)

Variable	Baseline (n=27)	6 months (n=27)	1 year (n=16)
PFDI-20	105.4 (26.9)	15.1 (9.1) P<0.001	19.5 (9.2) P<0.001
POPDI-6	49.4 (13.4)	5.9 (4.5) P<0.001	7.0 (3.6) P<0.001
CRADI-8	4.2 (8.3)	1.4 (2.3) P=0.066	1.8 (2.0) P=0.167
UDI-6	51.9 (17.6)	8.2 (7.1) P<0.001	10.7 (7.0) P<0.001
PFIQ-7	79.7 (25.4)	8.7 (8.9) P<0.001	11.6 (9.0) P<0.001
POPIQ-7	36.7 (12.0)	1.1 (2.7) P<0.001	1.5 (2.9) P<0.001
CRAIQ-7	1.8 (4.2)	0.7 (1.7)	1.5 (2.3)

Safety

No major intraoperative or postoperative complications.

Adverse events

	% (n)
Mesh erosions	0
Wound infections	0
Dragging pain at all points of puncture ports where the mesh was fixed to the abdominal wall and cervix*	100 (28/28)

*VAS score decreased from mean 2.61 at 3 days to 0 at 1 month follow-up (20 women had mild pain and 8 had moderate pain, none needed medication).

		P=0.206	P=0.781
UIQ-7	41.3 (18.6)	6.9 (7.5) P<0.001	8.7 (8.4) P<0.001

The PFDI-20 and PFQI-7 each have a range of 0-300, with higher scores indicating greater distress. Each of the respective subscales have arrange 0-100, with higher scores indicating greater distress.

Sexual symptoms (n=9)

Mean baseline PISQ-12 scores changed significantly compared with the value at 6 months after surgery (28.4 [2.7] versus 29.3 [2.9]; p=<0.001).

Satisfaction: all women reported satisfaction with the outcome of surgery and did not report any cosmetic defect associated with the tension on the abdominal wall.

Abbreviations used: POP-Q, pelvic organ prolapse quantification system; PFDI-20, Pelvic Floor Distress Inventory= POPDI-6, pelvic organ distress inventory 6; CRADI-8, colorectal-anal distress inventory -8; UDI-6, urinary distress inventory -6; PFIQ-7, Pelvic Floor Impact Questionnaire; POPIQ-7, pelvic organ prolapse impact questionnaire-7; CRAIQ-7, colorectal and anal impact questionnaire -7; UIQ-7, urinary impact questionnaire -7. PISQ-12, pelvic organ prolapse/urinary incontinence sexual questionnaire.

Efficacy

Repeat surgery for prolapse

In a systematic review of surgery for women with apical prolapse including 183 patients with uterine prolapse (2 RCTs) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, there was no difference in repeat prolapse surgery between the groups at 1- to 8-year follow-up (RR 0.68, 95% CI 0.36 to 1.31, n=182, low-quality evidence)[1].

In a systematic review of 239 patients, 1 RCT, 1 non-randomised comparative study, and 1 case series reported the need for further surgery for prolapse. In the RCT, there was evidence of a statistically significant difference at 1-year follow-up in the need for further (de novo or recurrent) prolapse surgery between sacrohysteropexy and vaginal hysterectomy (22% [9/41] versus 2% [1/41]; RR 9.00, 95% CI 1.19 to 67.85). In the non-randomised comparative study that compared sacrohysteropexy with hysterectomy followed by sacrocolpopexy, none of the 75 women needed a further operation for recurrent or de novo prolapse at a mean follow up of 51 months. In the case series, 1 woman (1/30, 3%) needed further surgery 3 years after sacrohysteropexy[2].

In a non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), at 1-year follow-up none of the women in the laparoscopic hysteropexy group needed a further operation for recurrent or de novo prolapse but 3% (2/73) of women in the vaginal mesh hysteropexy group reported the need for further surgery for prolapse[6].

In a retrospective case series of 507 women with uterine prolapse treated by laparoscopic sacrohysteropexy, 3% (14/507) of women had further apical prolapse at a median follow-up of 12 months (range 6 to 84 months) because the mesh had stretched. Of these, 10 had plication of mesh and 3 had cervical amputation for elongation. Ongoing uterine prolapse was reported in 2 women and treated by vaginal hysterectomy. 7% (36/507) of women had further vaginal wall repair[8].

In a case series of 194 premenopausal women with uterine prolapse treated by pectineal ligament hysteropexy (PLH) by open or laparoscopic approach the overall reoperation rate after PLH was 15% (29/194) at a mean follow-up of 6.5 years. 6% (10/176) of women had grade 3 uterine prolapse recurrence (7 occurred in pregnant women after vaginal delivery; 3 in non-pregnant women, of which 1 was a tape erosion into the bladder). 12 women developed cystocele and 7 developed cervical elongation. Laparoscopic procedures had minimal mortality with no recurrence of prolapse over 2 years[10].

Objective failure: recurrent prolapse at original site

In the systematic review of surgery for women with apical prolapse including 183 patients with uterine prolapse (2 RCTs) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, evidence from 1 RCT (n=82) did not show a was a difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy for objective failure of anterior vaginal compartment (risk ratio [RR] 1.04, 95% confidence interval [CI] 0.60 to 1.82); apical compartment (RR 1.00, 95% CI 0.15 to 6.76) or posterior vaginal compartment (RR 3.07, 95% CI 0.66 to 14.35) at 1 year follow-up[1].

In the systematic review of 239 patients, 1 RCT, 1 non-randomised comparative study and 3 case series reported objective failure. The mean follow-up time ranged from 12 to 51 months. In the RCT, there was no evidence of a statistically significant difference at 1 year follow-up in objective failure between sacrohysteropexy and vaginal hysterectomy (5% [2/38] versus 5% [2/40]; RR 1.05, 95% CI 0.16 to 7.10). The non-randomised comparative study comparing sacrohysteropexy with hysterectomy followed by sacrocolpopexy reported that no women had objective failure (defined as prolapse less than 6 cm above the hymen) in either group, at a mean follow up of 51 months. All 3 case series of 30, 19 and 13 women reported objective failure in 3% (2/62) of women following sacrohysteropexy (4-month to 5-year follow-up). No studies reported time to failure[2].

In the non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77) there was no difference between groups in the rate of apical (19%, [12/64] laparoscopic hysteropexy versus 16%, [9/61] vaginal mesh hysteropexy; p=0.16) or anterior failure at 1 year follow-up (9% [6/65] laparoscopic hysteropexy versus 6% [4/61] vaginal mesh hysteropexy, p=0.93)[6].

Subjective failure: persistent prolapse symptoms

In a systematic review of surgery for women with apical prolapse including 183 patients with uterine prolapse (from 2 randomised controlled trials [RCT]) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, 1 RCT reported that awareness of prolapse was less likely after vaginal hysterectomy than after abdominal sacrohysteropexy at 8-year follow-up (RR 0.38, 95% CI 0.15 to 0.98, n=84, moderate quality evidence). Awareness of prolapse was defined as any positive response to questions relating to awareness of prolapse or vaginal bulge or to question 3 of Pelvic floor distress inventory-20[1].

In the systematic review of 239 patients, 1 RCT and 2 case series reported subjective failure. The randomised controlled trial (RCT) of 82 women reported statistically significantly higher subjective failure (consulted clinician within 1 year

because of prolapse symptoms) following sacrohysteropexy compared with hysterectomy (39% (16/41) versus 12% (5/41); RR 3.20, 95% CI 1.29 to 7.92)[2].

A case series of 30 and 20 women reported prolapse symptoms in 3% (1/30, 3-year follow-up) and 0% (0/20, 6- to 30-month follow-up) respectively[2].

In a non-randomised comparative study of 45 patients comparing laparoscopic sacral hysteropexy (n=15) with subtotal hysterectomy plus cervicopexy (n=30) in pelvic organ prolapse, subjective success rate (assessed using 7-point Patient Global Impression of Improvement [PGI-I] scale) was significantly higher in the subtotal hysterectomy plus cervicopexy group both after 6- and 12-month follow-up (p=0.001). Similarly, there was significant improvement for apical outcome in pelvic organ prolapse quantification [POP-Q] scale in the subtotal hysterectomy plus cervicopexy group both after 6 and 12 months follow-up (p=0.009 and p=0.002, respectively) and for anterior vaginal wall compartment (p=0.1 and p=0.02, respectively)[5].

In the non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), prolapse stage was similar, but laparoscopic hysteropexy was associated with increased vaginal length (p<0.001), increased perineal body length (p=0.02) and better apical support (p=0.05) at 1 year follow-up[6].

In a non-randomised comparative study of 111 patients comparing robotic or laparoscopic sacrohysteropexy (n=54) with open sacrohysteropexy (n=57), postoperative prolapse symptoms were significantly less in the robotic or laparoscopic group at a median follow-up of 30 months (13% [7/54] versus 46% [26/57], p<0.0001)[7].

In a case series of 507 women, there was significant improvement for POP-Q point C assessment (p<0.001), with a mean change of 7.9cm between preoperative and postoperative scores at 3-month follow-up. 94% (379/404) of women felt that their prolapse (assessed using 7-point PGI-I subjective measure) was ‘very much’ or ‘much’ better and 2% (6/404) felt there was no change in symptoms. no women described their symptoms as worse[8].

In a case series of 28 patients with uterovaginal prolapse treated with laparoscopic extraperitoneal uterine suspension to the anterior abdominal wall bilaterally using synthetic mesh, there was significant improvement in all pelvic organ prolapse quantification (POP-Q) measurements after surgery. The POP-Q score for point C was significantly farther from the hymen at 6-months and 1-year follow-up compared with the preoperative value (-7.8 and -8.0 vs 2.6, respectively; p <0.001). The objective and subjective cure rates at 6 months and 1 year were 96% and 94%, respectively[13].

Surgical success (a dichotomous outcome of anatomic and symptomatic cure)

In a non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), 1-year outcomes for the available laparoscopic (n=64) and vaginal hysteropexy (n=61) patients revealed no differences in anatomic (77% [49/64] versus 80% [49/61]; adjusted odds ratio, 0.48; p=0.20), symptomatic (90% [62/69] versus 95% [58/61]; adjusted odds ratio, 0.40; p=0.22), or composite (72% [46/64] versus 74% [46/62]; adjusted odds ratio, 0.58; p=0.27) cure. Anatomic cure was defined as no anterior or posterior prolapse beyond the hymen (Aa, Ba, Ap, Bp all ≤0), cervix above mid vagina (C<-TVL/2) and no prolapse reoperation or pessary use. Symptomatic cure was defined as no bulge sensation (indicated by a negative response to question 3 of the pelvic floor distress inventory: 20)[6].

Operating time and length of stay

In the systematic review of surgery for women with apical prolapse including 183 patients with uterine prolapse (from 2 RCTs) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, evidence from 1 RCT (n=82) showed that operating time may be longer for vaginal hysterectomy with vault support compared with abdominal sacrohysteropexy (mean difference 10.00 minutes, 95% CI 8.20 to 11.80) but there was no difference in length of hospital stay (mean difference −0.10, 95% CI −0.21 to 0.01)[1].

Satisfaction

In the non-randomised comparative study of 111 patients, comparing robotic or laparoscopic sacrohysteropexy (n=54) with open sacrohysteropexy (n=57), overall satisfaction did not differ between groups at a median follow-up of 30 months (94% versus 91%; p=0.717)[7].

In the non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), overall satisfaction (measured on PGI-I scale) was high (95%) as 79% of women in each group rated prolapse symptoms as ‘very much better’ and 16% ‘much better’ at 1-year follow-up[6].

Quality of life

In the non-randomised comparative study of 151 patients comparing laparoscopic sacral hysteropexy (n=74) with vaginal mesh hysteropexy (n=77), at 1-year follow-up, pelvic floor symptom (measured using PFDI-20) and sexual function (measured using female sexual function index) scores improved for both groups with no difference between groups after adjusting for baseline differences. Sexual satisfaction improved in a higher proportion of women who chose to have laparoscopic hysteropexy than who chose vaginal mesh hysteropexy (p=0.02)[6].

In a case series of 100 women with uterovaginal prolapse treated by robotic sacrohysteropexy, overall quality of life (measured using the validated urogenital

distress inventory and incontinence impact questionnaires [UDI/IIQ], with scores ranging from 0 to 6) improved from a mean score of 4.5 to 5.12 ($p<0.05$), and overall health status (based on a visual analogue scale of 0 to100); improved from 73% to 82% ($p<0.05$), 6 weeks after surgery. Postoperatively patients also experienced less feelings of nervousness ($p=0.01$), shame ($p<0.05$) and frustration ($p<0.05$). After 5 years the positive effects of these feelings remained and quality of life and overall health status remained stable[9].

In the case series of 28 patients with uterovaginal prolapse treated with laparoscopic extraperitoneal uterine suspension to the anterior abdominal wall bilaterally using synthetic mesh, baseline sexual symptoms (measured using PISQ-12 score) changed significantly compared with the value at 6 months after operation (28.4 [2.7] vs 29.3 [2.9]; $p <0.001$). The health related quality of life (measured using PFDI-20 and PFIQ-7 scores) at 6 and 12 months after surgery improved significantly compared with the baseline scores ($p <0.001$)[13].

Subsequent pregnancy and prolapse recurrence

In the case series of 194 premenopausal women with uterine prolapse treated by pectineal ligament hysteropexy (PLH) by open or laparoscopic approach, there were 46 births (32 vaginal and 14 caesarean deliveries) in 40 women after PLH. Prolapse recurred (tape avulsed from the uterus) in 7 women after vaginal delivery and was treated by vaginal hysterectomy. There were no recurrences after caesarean deliveries[10].

Safety

Mesh exposure and repeat surgery for mesh exposure

In a systematic review of surgery for women with apical prolapse including 183 patients with uterine prolapse (2 randomised controlled trials [RCTs]) comparing abdominal sacrohysteropexy (open or laparoscopic approach) with vaginal hysterectomy and vault repair/support, evidence from 1 RCT (n=82) did not show a statistically significant difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy in the rate of mesh exposure (Risk Ratio [RR] 0.20, 95% confidence interval [CI] 0.01 to 4.04) or the need for repeat operation for mesh exposure (RR 0.20, 95% CI 0.01 to 4.04)[1].

Mesh erosion was reported in 1 non-randomised comparative study and 1 case series included in a systematic review of 239 patients. No mesh erosions occurred in the sacrohysteropexy group and 3 erosions (8%, 3/39) occurred in sacrocolpopexy following hysterectomy group in the non-randomised study (mean follow-up of 51 months). The case series of 30 women reported mesh erosion in 3% (1/30) at 2-year follow-up. All erosions (after sacrohysteropexy and after hysterectomy followed by sacrocolpopexy) needed further surgery (partial or complete mesh removal)[2].

Mesh complications were reported in 3% (2/74) of women in the laparoscopic hysteropexy group (1 excision and 1 spontaneous resolution) and in 7% (5/77) of women in the vaginal mesh hysteropexy group (treated by excision in 3 and observation in 2) in the non-randomised comparative study of 151 patients[6].

No mesh erosions occurred in robotic or laparoscopic sacrohysteropexy group 0% (0/54) and 3 erosions (5%, 3/57) occurred in open sacrohysteropexy group (p=0.244) in a non-randomised study of 111 women at a median follow-up of 30 months[7]. Mesh erosion was reported in 4% (4/100) of patients 12 months after surgery in a case series of 100 patients treated by robotic sacrohysteropexy[9].

Tape erosion into the bladder occurred in 1 non-pregnant woman who had grade 3 uterine prolapse recurrence after open sacrohysteropexy, in a case series of 194 premenopausal women with uterine prolapse treated by pectineal ligament hysteropexy (PLH). Further treatment details were not reported[10].

Bowel or bladder injury

In the systematic review of surgery for women with apical prolapse including 183 patients, evidence from 1 RCT (n=82) did not show a statistically significant difference in the rate of bowel injury between vaginal hysterectomy with vault support and abdominal sacrohysteropexy (RR 3.00, 95% CI 0.13 to 71.56)[1].

Small bowel injuries were reported in 3% (2/74) of patients in the laparoscopic hysteropexy group and bladder injuries were reported in 4% (3/77) of women in the vaginal mesh hysteropexy group in the non-randomised comparative study of 151 patients[6].

Damage to surrounding organs during operation

Damage to surrounding organs was reported in 1 RCT of 82 patients included in the systematic review of 239 women. No organ damage occurred in the sacrohysteropexy group (0/40), and 1 bowel lesion occurred in the hysterectomy group (no mesh, 1/41)[2].

Bowel obstructions (1 due to umbilical port hernia, 1 with bowel volvulus around the barbed suture used for peritoneal closure) were reported in 2 women in a case series of 159 women treated by modified single sheet mesh sacrohysteropexy. Both needed surgical re-intervention to release bowel adhesions[11].

Adhesions were noted between bowel and non-peritonised mesh in less than 1% (3/507) of women who reported lower abdominal pain 4 to 8 months after surgery, in a case series of 507 women treated by laparoscopic hysteropexy. These were carefully divided[8].

Damage to surrounding organs causing haemorrhage (1 due to broad ligament vascular injury during procedure [needed laparotomy and had uneventful

recovery], 1 retropubic hematoma [drained and a bleeding vessel cauterised; 1haemoperitoneum [with no bleeding point found at laparotomy) was reported in less than 1% (3/507) of women in the case series of 507 patients[8].

Infection

Infections were reported in 1 RCT, 1 non-randomised comparative study, and 1 case series included in the systematic review of 239 women. In the RCT, infections were reported as vault abscess during admission (2/41), infected implant needing surgery (2/41), and fever of unknown origin (3/41). In total, 17% (7/41) of women had an infection after sacrohysteropexy compared with 5% (2/41) in the vaginal hysterectomy group (no mesh). The outcome was reported as wound infection and fever in the non-randomised comparative study. Three cases of infection (3/39occurred in the hysterectomy followed by sacrocolpopexy group, and 1 (1/36occurred in the sacrohysteropexy group. In the case series, 1 urinary tract infection (1/30, 3%) and 1 wound infection (1/30) were reported after sacrohysteropexy[2].

Blood loss needing transfusion

In the systematic review including 183 patients with uterine prolapse (evidence from 1 RCT (n=82) did not show a statistically significant difference between vaginal hysterectomy with vault support and abdominal sacrohysteropexy in the need for a blood transfusion (RR 2.00, 95% CI 0.19 to 21.21)[1].

Blood loss needing transfusion was reported in 1 RCT, 1 non-randomised comparative study, and 1 case series included in the systematic review of 239 patients. In the RCT, there was no evidence of a statistically significant difference between sacrohysteropexy and vaginal hysterectomy (no mesh) in the number of women whose blood loss needed transfusion (1/41, 2% vs. 2/41, 5%), nor in the non-randomised comparative study, in which sacrohysteropexy was compared with hysterectomy followed by sacrocolpopexy (2/36, 6% vs. 2/39, 5%). No women needed blood transfusion in the 2 case series (0/50)[2].

Other serious adverse effects

Other serious adverse effects not otherwise specified were reported in 1 RCT, 1 non-randomised comparative study, and 1 case series included in the systematic review of 239 women. In the RCT, 1 incisional hernia occurred in the sacrohysteropexy group (1/41, 2%). In the non-randomised comparative study, 6% (2/36) of women had an incisional hernia after sacrohysteropexy, compared with 3% (1/39) in women who had a hysterectomy followed by sacrocolpopexy. One (1/30, 3%) case of incisional hernia and 1(1/30, 3%) case of intestinal occlusion by the mesh occurred after sacrohysteropexy in the case series[2]. Pulmonary embolism was reported in 2 women in the case series of 507 women treated by laparoscopic sacrohysteropexy[8].

Minor adverse events

Other minor adverse effects not otherwise specified were reported in 1 RCT, 1 non-randomised comparative study, and 2 case series included in the systematic review of 239 women. In the RCT, outcomes were reported as lower urinary tract symptoms during admission, upper leg dullness during admission, and vaginal stricture needing excision. In the sacrohysteropexy group, 22% (9/41) of women had 1 of these problems compared with 22% (9/41) in the vaginal hysterectomy group (no mesh). In the non-randomised comparative study, 17% (6/36) of women had perivesical haematoma or voiding dysfunction after sacrohysteropexy, compared with 13% (5/39) in women who had hysterectomy followed by sacrocolpopexy. In the 2 case series, 2 women (2/19, 11%) had dysmenorrhoea during the first menstrual cycle after sacrohysteropexy; 1 women each (1/30, 3%) had retroperitoneal haematoma, haemorrhage of presacral vein without need for transfusion, and sciatic pain after sacrohysteropexy[2].

Other complications including perineal infection in 3% (16/507) of women, urinary tract infections in 1% (6/507) and voiding difficulties in 2% (11/507)) were reported in the case series of 507 women treated by laparoscopic sacrohysteropexy[8]. In the case series of 245 patients, after 1 year, 2% of women had urinary retention needing treatment, 2% had de novo stress urinary incontinence, 5% had urgency, 5% developed de novo constipation and 5% reported de novo dyspareunia[12]. Overactive bladder occurred in 6% (3/54) of women treated by robotic or laparoscopic sacrohysteropexy and in 18% (10/57) treated by open sacrohysteropexy in the non-randomised study (median follow-up of 30 months)[7]. One patient reported a feeling of traction in the abdomen that reduced after the mesh was partially removed several weeks after robotic sacrohysteropexy, in a case series of 100 women. The study also reported ileus (n=1), oedema of the right arm leading to temporary sensitive malfunction (n=1) and de novo stress urinary incontinence (n=13)[5]. All patients reported postoperative dragging pain at the points of puncture ports where the mesh was fixed to the abdominal wall in a case series of 28 women. The mean visual analogue score decreased from a mean score of 2.61 after surgery to 0 at 1-month follow-up[13].

Validity and generalisability of the studies

- Uterus preserving procedures are done through the vaginal and abdominal (open, laparoscopic and robotic) approaches. The procedures that involve the use of synthetic mesh for uterine preservation through abdominal approaches are only considered here.
- Of the 2 randomised controlled trials included in the systematic review[1], 1 RCT used an open approach and the other RCT used a laparoscopic sacrohysteropexy approach with a bifurcated polypropylene mesh. Both

studies compared abdominal sacrohysteropexy with vaginal hysterectomy and vault fixation to the uterosacral ligaments.

- Only 1 non-randomised study compared laparoscopic mesh hysteropexy with vaginal hysteropexy[4].
- Many types of laparoscopic/open procedures have been described including suspension to the sacral promontory[1-7], pectineal ligaments[8], uterosacral ligaments[9] and to the anterior abdominal wall[10-11].
- The majority of the studies were small, retrospective studies.
- There are many variations in the operative techniques employed, including the site, type, size and shape of mesh attached.
- Follow up varied in studies and ranged from mean 1 year to 7.5 years.

Existing assessments of this procedure

A review on safety and efficacy of uterine preservation surgery published on behalf of Committee 15 on "surgical management of pelvic organ prolapse", part of the 5th International Consultation on Incontinence (2012), under the auspices of the international Consultation on Urological Diseases (supported by the European Association of Urology), concluded that level 1 evidence from a single randomised controlled trial suggests that vaginal hysterectomy and uterosacral suspension were superior to sacral hysteropexy based on reoperation rates, despite similar anatomical and symptomatic improvement. Consistent level 2 and 3 evidence (prospective cohort studies, case series or retrospective studies) suggests that sacral hysteropexy (open or laparoscopic) was as effective as sacralcolpopexy and hysterectomy in anatomical outcomes; however, the sacralcolpopexy and hysterectomy were associated with a 5 times higher rate of mesh exposure than with sacral hysteropexy[14].

In December 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on 'The safety of surgical meshes used in urogynecological Surgery'[15]. It stated: "The SCENIHR considers three factors as being important when assessing the risks associated with mesh application: the overall surface area of material used, the product design and the properties of the material used. In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP) than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.

The body of evidence suggests that, when assessing the health risks of synthetic meshes, there is a need to clearly separate the smaller risks associated with stress urinary incontinence sling surgery from those of pelvic organ prolapse mesh surgery.

Based on the currently marketed products, assessment of the risks reported indicates that polypropylene type 1 meshes are the most appropriate synthetic meshes for vaginal use and polypropylene type 1 and polyester type 3 for insertion via the abdominal route. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for female pelvic organ prolapse surgery."

SCENIHR's recommendations include:

- Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (for example, hysterectomy) and surgeon's experience are aspects influencing the clinical outcome following mesh implantation. Such aspects are to be considered when choosing appropriate therapy.
- For all procedures, the amount of mesh should be limited where possible.
- The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery.
- A certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.

A mesh working group interim report was published in December 2015 by NHS England. Its recommendations included: reviewing the current NICE guidance and creating new guidance, raising awareness amongst GPs of complications and how to address them, improving rates of reporting of adverse events to MHRA, and submissions to the BSUG and BAUS databases, improving HES coding, raising awareness amongst patients of their option to use MHRA reporting procedures for adverse incidents, and developing information leaflets on mesh implant procedures for both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) which provide consistent and understandable information to be used in the consenting process[16].

A Scottish Independent Review of the 'Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women' interim report was published in October 2015 by The Scottish Government[17].

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA. It stated: MHRA's current position is that, for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the individua/ patient. This conclusion is entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. While some women have experienced distressing and severe effects, the current evidence shows that when these products are

used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks18.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009). Available from https://www.nice.org.uk/guidance/IPG284
- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (2009). Available from https://www.nice.org.uk/guidance/IPG283
- Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE Interventional procedure guidance IPG282 (2009). Available from https://www.nice.org.uk/guidance/IPG282
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009). Available from https://www.nice.org.uk/guidance/IPG281
- Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009). Available from https://www.nice.org.uk/guidance/IPG280
- Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (2008). Available from https://www.nice.org.uk/guidance/IPG267
- Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE Interventional procedure guidance IPG566 (2016). Available from https://www.nice.org.uk/guidance/IPG566 (replaces IPG262)

NICE guidelines

- Urinary incontinence in women (2013) NICE guideline CG171 (2013). Available from https://www.nice.org.uk/guidance/cg171

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 Advisor Questionnaires for uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse were submitted and can be found on the NICE website.

Patient commentators' opinions

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

Company engagement

A structured information request was sent to 6 companies who manufacture a potentially relevant device for use in this procedure. NICE received 2 completed submissions. These was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

Ongoing trials

- **ISRCTN86784244:** Two parallel randomised controlled trials of surgical options for upper compartment (vault or uterine) pelvic organ prolapse Vault or Uterine prolapse surgery Evaluation: The VUE Study; study type: multicentre randomised controlled trial; condition: vault or uterine prolapse; n=800; primary outcome: prolapse symptoms measured using the Pelvic Organ Prolapse Symptom Scale (POP-SS), at 1 year after surgery; location: Scotland, UK; status: recruitment completed.
- Uterine Trial

  The 2 options for uterine prolapse concern removal or retention of the uterus.

Patients will be randomised to either

1. Vaginal hysterectomy (Vaginal hysterectomy, with a vault suspension technique using sutures or mesh if necessary) OR

2. Uterine preservation (vaginal sacrospinous fixation of uterus with sutures or mesh, OR open abdominal or laparoscopic sacrohysteropexy with a mesh bridge) http://isrctn.com/ISRCTN86784244

Location: UK (funded by NIHR); Trial end date 31/10/2016

- **NTR4029:** Hysteropexy in treatment of uterine prolapse stage = 2: laparoscopic sacrohysteropexy versus vaginal sacrospinous hysteropexy - LAVA trial; study type: randomised controlled trial; n=124; condition: uterine prolapse; primary outcome: anatomical outcome and recurrence rate assessed by the POP-Q test at 1- and 5-year follow-up; location: Netherlands; completion date December 2019; status: unknown. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4029
- **NCT01320215:** Complications Associated With Promontofixation for Pelvic Organ Prolapse: a Randomized Trial Comparing Robot Assisted Laparoscopic and Non-robot Assisted Laparoscopic Surgical Procedures (sacrohysteropexy with robotic assistance versus laparoscopic sacrohysteropexy); Randomised controlled trial; n=364, location: France; study completion date September 2012.
- **NCT02345954:** Laparoscopic Supracervical Hysterectomy and Sacropexy Compared to Uterus Conserving laparoscopic Hysteropexy: a Randomized Clinical Trial n=100, primary outcome: comparison of operation time in 2 arms; completion date: September 2019; Switzerland.

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10. Joshi VM, Otiv SR, Dagade VB et al (2015). Pectineal ligament hysteropexy for uterine prolapse in premenopausal women by open and laparoscopic approach in Indian Urban and Rural Centers. Female Pelvic Medicine and Reconstructive Surgery (21) 4 215-219.
11. Pandeva I, Mistry M and Fayyad A (2016). Efficacy and pregnancy outcomes of laparoscopic single sheet mesh sacrohysteropexy. Neurourology and Urodynamics no pagination.

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Appendix A: Additional papers on uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.

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
Api M, Kayatas S et al (2014). Laparoscopic sacral uteropexy with cravat technique--experience and results. International braz j urol: official journal of the Brazilian Society of Urology (40) 4 526-532.	Prospective case series N=33 patients with severe (stage II-IV) uterine prolapse Laparoscopic sacral uteropexy with "Cravat technique"- involving suspension of the uterus from the sacral promontory by using polypropylene mesh (wrapping the mesh around the uterus). Follow-up: median 23.9 months	Sacral uteropexy was successfully done by laparoscopy in 32/33 patients (1needed to be converted to laparotomy). 9 patients had a concurrent colporrhaphy anterior, colporrhaphy posterior or transobturator tape. Postoperative recovery uneventful, subjective and objective cure rates were 96.9% and 93.9%, respectively at 6 months. 1 recurrence of prolapse needed to be reoperated and 2 patients with sacrouteropexy remained at stage 2 prolapse. There have been no cases of graft exposure, rejection or infection.	Slightly modified technique (similar to that described in Rahmanou paper). Larger studies with longer follow-up included in table 2.
Banu LF (1997). Synthetic sling for genital prolapse in young women. Int J Gynecol Obstet; 57:57-64.	case series n=19 patients with uterine prolapse Abdominal sacrohysteropexy (with polyester Mersiline) Follow-up: 3-5 years.	Objective failure: not defined, 0/19 adverse events: dysmenorrhea during the 1st menstrual cycle, 2/19; No significant intra-operative or post-operative complications.	Larger studies with longer follow-up included in table 2.

Barranger E, Fritel X, Pigne A (2003). Abdominal sacrohysteropexy in young women with uterovaginal prolapse: long-term follow-up. Am J Obstet Gynecol 18:1245-50.	case series n=30 patients with uterine prolapse Abdominal sacrohysteropexy (with polyester Mersuture) Concomitant procedures: anti-incontinence in all. Follow-up: efficacy mean 44.5 months; safety mean 94.6 months.	Subjective failure: symptomatic prolapse, 1/30 (3.3%), occurred after 3years. Objective failure: modified Bade and Walker classification, recurrent uterovaginal prolapse (no details on grade), 1/30 (3.3%), occurred after 3 years. Further operation needed for prolapse (recurrent or de novo): 1/30 (3.3%) Persistent bladder symptoms, n/N: incontinence, 3/19 Persistent bowel symptoms, n/N: 1/5 Persistent sexual problems, n/N: 3/27 not continue to sexual activities. **SAFETY** Blood loss needing transfusion, n/N: 0/30 Mesh/graft erosion, n/N: vaginal mesh erosion, 1/30 (3.3%), occurred 2y after procedure Further operation needed for mesh erosion, n/N: 1/30 (3.3%), treated successfully with a single transvaginal excision. New sexual problems, n/N: 1/2 dyspareunia Urinary tract infection, 1/30 (3.3%); wound infection, 1/30 (3.3%) Post incision abdominal hernia, 1/30 (3.3%); Intestinal occlusion by the mesh 4y after treatment: 1/30 (3.3%) Retroperitoneal hematoma, 1/30 (3.3%); Haemorrhage of presacral veins, but not needed transfusion, 1/30 (3.3%); Sciatic pain, 1/30 (3.3%).	Larger studies with longer follow-up included in table 2 Included in Jia 2010 review.
Bai SW, Kim EH et al (2005). A comparison of different pelvic reconstruction surgeries using mesh for pelvic organ prolapse patients. Yonsei Med j 46 (1): 112-118.	Retrospective cohort study Abdominal sacrohysteropexy with sacralcolpopexy with or without hysterectomy. Follow-up: 12 months.	Abdominal sacrohysteropexy: 100% (10/10) success rate; mesh exposure 0. Total hysterectomy plus sacralcolpopexy 95% (18/19). Mesh exposure- 16% (3/19) in the hysterectomy group that did not need reoperation. Other complications, transfusion 3, ileus 1 in hysteropexy, wound dehiscence in 2.	Larger studies with longer follow-up included in table 2.

Chen G, Wu D et al (2012). Modified laparoscopic extraperitoneal uterine suspension to anterior abdominal wall: The easier way to treat uterine prolapse. International Urogynecology Journal and Pelvic Floor Dysfunction (23) 7 887-891 2012.	Case series N=22 women with uterovaginal prolapse stage 2 Modified laparoscopic extraperitoneal uterine suspension to anterior abdominal wall for uterine prolapse using mesh. The mesh is anchored to the anterior cervix vaginally.	After surgery, there was significant improvement in POP-Q measurements of Ba, Bp, and C (P<0.001). The objective cure rate at 1 year was 100%. A significant improvement in quality-of-life scores was observed (P<0.001). There were no major complications. However, all patients reported postoperative dragging pain at the points of puncture ports where the mesh was fixed to the abdominal wall. The visual analogue scale decreased from a mean 3-day score of 2.9-0 at 1-month follow-up.	Modified procedure includes both laparoscopic and vaginal routes.
Costantini E, Mearini L, et al (2005). Uterus preservation in surgical correction of urogenital prolapse. Eur Urol 48:642-9.	non-randomised comparative study n=75 patients with uterine prolapse 36 sacrohysteropexy 39 hystrectomy+sacropexy (surgical route: vaginally) Mesh used: polypropylene, Marlex. (Concomitant procedures- anti-incontinence 58/75; hysterectomy 39/75. Follow-up : 51 months	Objective failure: recurrent cervical/vault prolapse (<6cm above the hymen): A, 0/36; B, 0/39 Further need for pelvic floor repair: A, 0; B, 0 Persistent bladder symptoms, n/N: incontinence, A, 4/22; B, 7/20; but all had surgeries for incontinence. **SAFETY** Blood loss, ml, median: A, 200; B, 325 Blood loss needing transfusion, n/N: A, 2; B, 2 Mesh/graft erosion, n/N: A, 0; B, 3 Further operation needed for mesh erosion, n/N: A, 0; B, 3 vaginal revision Wound infection: A, 0; B, 2 Other serious adverse events: incisional hernia, A, 2; B, 1 Other adverse events: fever, A, 1; B, 1; Perivesical haematoma, A, 2; B,	Larger studies with longer follow-up included in table 2. Included in Jia 2010.

Costantini E, Zucchi A et al (2011). Managing mesh erosion after abdominal pelvic organ prolapse repair: Ten years' experience in a single center. Urologia Internationalis (86) 4 419-423.	Case series N=179 patients who had integral pelvic floor reconstruction for advanced POP. 54 had CSP for vault prolapse 74 had CSP+ hysterectomy 51 had CSP+uterus preservation-hysterosacropexy Follow-up: 10 years	12 patients were diagnosed and treated for mesh erosion: in 10 of 179, surgery was done in our department and the mesh used was polypropylene (PP): 3 after colposacropexy (CSP) (5.5%), 5 after CSP + hysterectomy (Hys) (6.5%), and 2 after hysterosacropexy (HSP) (3.9%); in 1 case, Gore-tex mesh was used, and another case had had CSP in another hospital using PP mesh. Time to mesh erosion ranged from 2 to 66 months (mean 22.9), with 4 erosions (33%) within 6 months of POP repair. In 4 asymptomatic patients (33%) erosion was incidentally discovered during clinical check-ups at 4, 31, 36 and 66 months. Five cases (41%) presented with occasional vaginal bleeding, associated with dyspareunia in 2. Treatments were individualized but in all cases conservative treatment was unable to resolve the complications and surgery was needed. At a mean follow-up of 57 months (range 18-120) after surgical treatment all patients were asymptomatic and free from erosions.	Only 2 erosions after treated with sacrohysteropexy . Mesh erosion already reported in other studies included in table 2.
Costantini E, Lazzeri M, et al (2011). Five-year outcome of uterus sparing surgery for pelvic organ prolapse repair: A single-center experience International Urogynecology Journal and Pelvic Floor Dysfunction. 22 (3): 287-292	Case series n=55 patients with POP had sacrohysteropexy Follow-up: mean 5 years.	Anterior compartment prolapse (cystocele) stage > 2 was present in 4 out of 52 patients (7.7%), while posterior compartment prolapse (rectocele) stage > 2 was present in 3 (5.7%). Voiding symptoms were resolved in 42 out of 45 patients (93.4%) and storage symptoms in 30 out of 36 (83.3%); 1 patient reported de novo urgency. Sexual activity was maintained in 28 out of 29 patients (95.5%). Four patients showed de novo stress urinary incontinence.	Larger studies with longer follow-up included in table 2.
Cutner A, Kearney R and Vashisht A (2007). Laparoscopic uterine sling suspension: A new technique of uterine suspension in women desiring surgical management of uterine prolapse with uterine conservation. BJOG: An International Journal of Obstetrics and Gynaecology (114) 9 1159-1162.	Case series N=8 women with uterine prolapse who desired uterine conservation Laparoscopic uterine sling suspension with Mersiline tape to suspend the uterus to the sacral promontory bilaterally and to recreate new uterosacral ligaments. Follow-up: range 6 weeks to 12 months	Median operation time was 125 minutes, median hospital stay was 2.5 days. 1 woman developed surgical emphysema during the paravaginal procedure, this was resolved after the procedure was stopped.	Describes a new surgical technique.

Cvach K, Geoffrion R et al (2012). Abdominal sacaral hysteropexy: A pilot study comparing sacral hysteropexy to sacral colpopexy with hysterectomy. Female Pelvic Med Reconstr Surg.18: 286-90.	Cohort study 20 women having abdominal sacrohysteropexy versus 9 women having sacrocolpopexy with hysterectomy	Subjective outcomes were similar, anterior failure was higher in the hysteropexy group. Quality of life improved. Reoperation rate was higher in the hysterectomy group (25% versus 11%) compared with hysterectomy group. complications were rare, with only 3 mesh erosions.	Larger studies with longer follow-up included in table 2.
Cvach K. and Dwyer P (2012). Surgical management of pelvic organ prolapse: Abdominal and vaginal approaches. World Journal of Urology (30) 4 471-477.	Review of common surgical techniques to correct POP.	Current evidence suggests that attention to the apical compartment is paramount to decrease the risk of recurrent POP. Apical procedures include abdominal sacrocolpopexy (hysteropexy), vaginal uterosacral ligament suspension and sacrospinous ligament suspension. The use of vaginal polypropylene mesh is controversial but may have a place in repair of recurrent prolapse, particularly of the anterior compartment. The vaginal approach has a lower morbidity and is appropriate especially in the elderly or medically compromised. The abdominal sacrocolpopexy or sacrohysteropexy is our preferred procedure when vaginal capacity is reduced and ongoing sexual function is important, or when fertility and future pregnancies are desired.	General review.
Demicri F, Ozdemir I et al (2006). Abdominal sacrohysteropexy in young women with uterovaginal prolapse: results of 20 cases. J Reprod Med 51:539-43.	Case series n=20 young women with uterovaginal prolapse Abdominal sacrohysteropexy with propylene mesh with concomitant reconstruction surgery. Follow-up: mean 25 months	Vaginal wall prolapse and stress incontinence recurred in 5% (1/20) patients. 19 patients stated their sex life improved, 3 had dyspareunia. 1 patient was dissatisfied. Symptom and quality of life scores were significantly lower than preoperative scores.	Larger studies with longer follow-up included in table 2.
Demirci F, Demirci O et al (2014). Perioperative complications in abdominal sacrocolpopexy, sacrospinous ligament fixation and prolift procedures. Balkan Medical Journal (31) 2 158-163.	Case series N=105 45 patients had abdominal sacrocolpopexy/hysteropexy, 60 patients had sacrospinous fixation, and 43 patients had the total Prolift procedure. Follow-up: 6 weeks	In the abdominal group, 1 bladder injury, 4 haemorrhages, and 3 wound dehiscence's occurred. In the sacrospinous group, 1 rectal injury and 1 postoperative vault infection occurred. In the Prolift group, 1 bladder injury and 1 haemorrhage occurred. Minor complications were more frequent in the abdominal group than the others.	Results not reported separately for abdominal procedures.

Demirci F, Ozdemir I et al (2007). Perioperative complications in abdominal sacrocolpopexy and vaginal sacrospinous ligament fixation procedures. International Urogynecology Journal and Pelvic Floor Dysfunction (18) 3 257-261.	Case series N=105 45 patients had abdominal sacrocolpopexy n=25/hysteropexy n=20, 60 patients had sacrospinous fixation Follow-up: 6 weeks	Of the 105 patients, 13 had vaginal vault prolapse. In the abdominal group, 1 bladder injury, 4 haemorrhages, and 3 wound dehiscence's occurred. In the vaginal group, 1 rectal injury and 1 postoperative vaginal vault infection occurred. Major and minor complications were more frequent in the abdominal group than in the vaginal group. Blood loss was not significantly different. The operating time and hospital stay in the abdominal group were significantly longer than in the vaginal group.	Results not reported separately for abdominal procedures.
Van Geelen JM and Dwyer PL (2013). Where to for pelvic organ prolapse treatment after the FDA pronouncements?: A systematic review of the recent literature. International Urogynecology Journal and Pelvic Floor Dysfunction (24) 5 707-718.	Systematic review on the conservative and surgical management of POP Studies published between 2002-12 were included.	Over the last decade treatment of POP has been dominated by the use of mesh. Conservative treatment is the first option in women with POP. Surgical repair with or without mesh generally results in good short-term objective and functional outcomes. However, basic research into mesh properties with host response and comparative studies with long-term follow-up are urgently needed	A wide range of surgical treatments reviewed.
Gutman RE (2016). Does the uterus need to be removed to correct uterovaginal prolapse? Current Opinion in Obstetrics and Gynecology 28: 435-40	Evidence based review compares hysteropexy with hysterectomy during surgery for uterovaginal prolapse.	High satisfaction and low reoperation rates can be accomplished using a variety of hysteropexy techniques. The type of hysteropexy and possible graft configuration may impact reoperation rates for recurrent prolapse. Vaginal mesh risks must be considered and balanced.	Review.
Hefni M, and El-Toucky T (2011). Uterine prolapse in young women. Best Practice and Research: Clinical Obstetrics and Gynaecology 25 (2):157-165.	Management of uterine prolapse in women.	Fixing of the cervix to the strong ligament such as the sacrospinous ligament could give a more successful result and conservation of the uterus in young women. Other techniques such as abdominal mesh hysteropexy, or posterior intravaginal slingplasty with conservation of the uterus are alternative surgical options.	General review of management options for uterine prolapse mainly focusing on cervical and uterine suspension.

Joshi VM (1993). A new technique of uterine suspension to pectineal ligaments in the management of uterovaginal prolapse. Obstet Gynecol 81:790-3.	case series n=20 patients with uterine prolapse Abdominal uterine suspension sling (suspended to pectineal ligaments) (with non-absorbable synthetic mesh, Mersiline) anti-incontinence procedures in 5 patients Follow-up:6-30 months	Subjective failure: prolapse symptoms, 0/20 Blood loss needing transfusion, n/N: 0/20 No early or late morbidity.	Larger studies with longer follow-up included in table 2.
Jeon MJ, Jung HJ et al (2008). Is hysterectomy or the use of graft necessary for the reconstructive surgery for uterine prolapse? International Urogynecology Journal and Pelvic Floor Dysfunction (19) 3 351-355.	Retrospective cohort study n=168 patients with POP 3 arms Group I, abdominosacral colpopexy with mesh and hysterectomy (n = 63); group II, abdominosacral uteropexy with mesh (n = 35); group III, abdominal uterosacrocardinal colpopexy and hysterectomy (n = 70). Follow-up: median 36 months in all 3 groups.	In the complication rates and functional outcomes, no difference was noted, except for operation time (longer in group I, p = 0.001) and haemoglobin loss (greater in group II, p = 0.002). There was a significant difference in the cumulative anatomical cure rates (p < 0.0001). There were no recurrences in the hysteropexy group. The risk of recurrence in group III was 6.2 times higher than in group I.	Larger studies with longer follow-up included in table 2.
Khursheed F, Das C. M et al (2013). Abdominal sacrohysteropexy--a conservative surgical treatment of uterine prolapse. Journal of Ayub Medical College, Abbottabad: JAMC (25) 3-4 41-43.	Case series n=33 sacrohysteropexy Follow-up: 6 months	Blood loss during surgery was < 100 ml, in 1 case it was between 100-300 ml, blood was transfused. Only 1 case had wound sepsis. No complaints were found during follow up period of 6 months.	Larger studies with longer follow-up included in table 2.
Kupelian AS, Vashisht A et al (2016). Laparoscopic wrap round mesh sacrohysteropexy for the management of apical prolapse. International Urogynecology Journal and Pelvic Floor Dysfunction 1-9	Case series (retrospective) N=110 women with apical prolapse Laparoscopic sacrohysteropexy with bifurcated mesh implant, employing 'wrap round' uterine attachment. Follow-up: mean 2.6 years	Of 80 patients providing PGI-I data at 3 months, 75 (94 %) described their prolapse symptoms as 'much better' or 'very much better'. Anatomical success in the apical compartment was 98 %. ICIQ-UI and ICIQ-VS responses demonstrated significant improvement. Satisfaction at a mean follow-up of 2.6 years was 96 %. Repeat surgery for vaginal wall prolapse was needed in only 5 % of patients. No safety concerns or graft complications were recorded.	Prospective study with similar technique included in table 2 (Identical to Rahmanou 2014 paper).

Leron E, Stanton SL (2001). Sacrohysteropexy with synthetic mesh for the management of uterovaginal prolapse. BJOG 108:629-33.	case series n=13 patients with uterine prolapse Abdominal sacrohysteropexy (with non-absorbable synthetic mesh, Teflon) Anti-incontinence procedure in 4 patients Follow-up: 16 months	Objective failure: 1st degree uterine prolapse, i.e. prolapse reached about 1cm above the introitus, 1/13 (7.7%) Blood loss, ml: mean (range), 271ml (50-800), n=13 There were no intra- and post-operative complications. HOSPITAL STAY Mean (range), 4.6d (4-6)	Larger studies with longer follow-up included in table 2
van, IJsselmuiden MN, Coolen ALWM (2014). Hysteropexy in the treatment of uterine prolapse stage 2 or higher: A multicenter randomized controlled non-inferiority trial comparing laparoscopic sacrohysteropexy with vaginal sacrospinous hysteropexy (LAVA-trial, study protocol). BMC Women's Health (14) 1 no pagination.	LAVA trial NTR4029 is a randomized controlled multicentre trial, it compares laparoscopic sacrohysteropexy with vaginal sacrospinous hysteropexy in women with uterine prolapse stage 2 or higher.		Only study protocol, no results reported.
van Ijsselmuiden MN, Kerkhof MH et al (2014). Variation in the practice of laparoscopic sacrohysteropexy and laparoscopic sacrocolpopexy for the treatment of pelvic organ prolapse: a Dutch survey. International Urogynecology Journal and Pelvic Floor Dysfunction no pagination.	Web based survey to assess the variation between Dutch gynaecologists in executing LSH and LSC. N=375	There is a high practice variation in LSH and LSC done by a selected group of Dutch gynaecologists. Different methods have been described in the literature and there is no consensus on how to do these procedures. A well-designed prospective study or randomized controlled trial with regard to the specific parts of these procedures is needed to provide evidence for the best surgical technique. The outcomes of these studies will help to establish evidence-based guidelines.	Survey
Lee T, Rosenblum N et al (2013). Uterine sparing robotic-assisted laparoscopic sacrohysteropexy for pelvic organ prolapse: Safety and feasibility. Journal of Endourology (27) 9 1131-1136.	Case series n=15 Robotic-assisted laparoscopic sacrohysteropexy (Procedures utilized a type I polypropylene mesh securing the posterior uterocervical junction to the sacral promontory. This was later modified to utilize	No intraoperative complications were noted. The mean operating time was 159.4 minutes (130-201 minutes) and mean estimated blood loss was 35 mL (0-100 mL). Uterine prolapse improved in all 15 patients. Objective success was 93% (14/15) and subjective success was 80% (12/15).	Larger studies with longer follow-up included in table 2.

	a Y-shaped strip that was inserted through the broad ligaments to include the anterior uterocervical junction) Follow-up: mean 10.8 months		
Maher CM, Feiner B et al (2011). Surgical management of pelvic organ prolapse in women: The updated summary version Cochrane review. International Urogynecology Journal and Pelvic Floor Dysfunction (22) 11 1445-1457	Cochrane review on many different surgeries used in the management of pelvic organ prolapse. Randomised or quasi-randomised controlled trials were included.	Uterine suspension preservation versus vaginal hysterectomy. 3 trails addressed this comparison but could not be combined as they were too different. 1study reported abdominal uterine preservation versus vaginal hysterectomy (Roovers 2004). The other 2 trials (Jeng 2005, Dietz 2010) compared vaginal sacrospinous uterine suspension versus vaginal hysterectomy.	Evidence from only 1 trail (Roovers 2004) was relevant to our review. This study has already been included in another study in table 2.
Moiety FMS, Hegab HM et al (2010). Abdominal Sacrohysteropexy for uterovaginal prolapse: A prospective study on 33 cases. Gynecology and Obstetrics (281) 4 631-636.	Case series n=33 Pelvic organ prolapse (POP-Q) stage 2 was found in 27 cases (81.8%) and stage 3 in 6 women (12.2%). Sacrohysteropexy	One case suffered rectal injury, 1 case had median sacral vein injury, both were repaired immediately. Two cases had delayed voiding recovery. The mean follow up time was 6 months. At follow up, only 2 cases showed recurrence, and the objective and subjective success rates at 6 months were 93.93 and 81.8%, respectively.	Larger studies with longer follow-up included in table 2.
Mourik SL, Martens JE and Aktas M (2012). Uterine preservation in pelvic organ prolapse using robot assisted laparoscopic sacrohysteropexy: Quality of life and technique. European Journal of Obstetrics Gynecology and Reproductive Biology (165) 1 122-127.	Cohort study n=50 robot assisted laparoscopic sacrohysteropexy (RALS) Polypropylene mesh (Gynemesh) used. Follow-up: 29 months	Before operation, overall wellbeing was scored at 67.7% and after surgery this improved to 82.1% (p = 0.03). Feelings of nervousness, frustration and embarrassment reduced significantly. Sexual functioning improved, but not significantly. The mean operative time was 223 (103-340) min. Operative time decreased significantly with gained experience and became comparable to the operative time for abdominal sacrocolpopexy and classic laparoscopy. Average blood loss was > 50 ml and patients had a mean hospital stay of 2 days. Of all women, 95.2% were very satisfied with the result after RALS.	Larger studies with longer follow-up included in table 2.
Onwude JL (2009). Genital prolapse in women. BMJ clinical evidence (2009) no pagination.	Systematic review: What are the effects of non-surgical treatments in women with genital prolapse? What are the effects of surgical treatments in women with anterior vaginal wall prolapse? What are the effects of surgical treatments in	effectiveness and safety of the following interventions was presented: abdominal Burch colposuspension; abdominal sacral colpopexy; abdominal sacrohysteropexy; anterior colporrhaphy with mesh reinforcement; laparoscopic surgery; mesh or synthetic grafts; native (autologous) tissue; open abdominal surgery; pelvic floor muscle exercises; posterior colporrhaphy (with or	Data on abdominal sacrohysteropexy already reported in studies included in table 2.

	women with posterior vaginal wall prolapse? What are the effects of surgical treatments in women with upper vaginal wall prolapse? What are the effects of using different surgical materials in women with genital prolapse? 14 systematic reviews, RCTs, or observational studies that met our inclusion criteria.	without mesh reinforcement); posterior intravaginal slingplasty (infracoccygeal sacropexy); sacrospinous colpopexy (vaginal sacral colpopexy); sutures; traditional anterior colporrhaphy; transanal repair; ultralateral anterior colporrhaphy alone or with cadaveric fascia patch; vaginal hysterectomy; vaginal oestrogen; vaginal pessaries; and vaginal sacrospinous colpopexy.	
Nathan K, Goldman HB et al (2013). Management options for women with uterine prolapse interested in uterine preservation. Curr Urol Rep 14:395-402.	Surgical and nonsurgical treatments to correct apical prolapse while preserving uterus.		Review of nonsurgical and surgical treatment options.
Park AJ and Paraiso, MFR (2008). Surgical management of uterine prolapse. Minerva ginecologica (60) 6 493-507.	Review	Surgical treatment of uterine prolapse include open, laparoscopic, or vaginal approaches. Vaginal apical suspension procedures include the uterosacral vaginal vault suspension, sacrospinous ligament fixation, iliococcygeus fascia suspension, and the McCall or Mayo culdoplasty. The abdominal sacral colpopexy done via laparotomy or laparoscopy. Uterine preservation techniques include the Manchester procedure, sacrospinous hysteropexy, laparoscopic sacral hysteropexy and laparoscopic uterosacral vault suspension. Most of the data for subjective and objective outcomes for these prolapse procedures are from uncontrolled retrospective case series. Currently there is no definitive gold standard procedure to favour a particular route in the treatment of uterine prolapse.	Review of a wide range of options for surgical management.

Price N, Slack A et al (2010). Laparoscopic hysteropexy: The initial results of a uterine suspension procedure for uterovaginal prolapse. BJOG: An International Journal of Obstetrics and Gynaecology (117) 1 62-68.	Case series (clinical audit) N=51 women with uterovaginal prolapse had laparoscopic hysteropexy (bifurcated polypropylene mesh was used to suspend the uterus from the sacral promontory). The 2 arms of the mesh were introduced through bilateral windows created in the broad ligaments, and were sutured to the anterior cervix; the mesh was then fixed to the anterior longitudinal ligament over the sacral promontory, to elevate the uterus. Follow-up: 10 weeks	In 50 out of 51 women the procedure was successful, with no objective evidence of uterine prolapse on examination at follow-up; there was 1 failure. Significant subjective improvements in prolapse symptoms, sexual wellbeing and related quality of life were observed, as detected by substantial reductions in the respective questionnaire scores.	Larger studies with longer follow-up included in table 2.
Rahmanou N et al (2014). Laparoscopic hysteropexy: a novel technique for uterine preservation surgery. Int Urogynecol J 25: 139-140	Laparoscopic hysteropexy Describes technique in detail in a video.	Video article demonstrates uterine preservation surgery for women with uterine prolapse using laparoscopic abdominal Prolene mesh.	No clinical outcomes reported.
Ramm O and Kenton K (2012). Robotic/laparoscopic prolapse repair. role of hysteropexy: A urogynecology perspective. Urologic Clinics of North America (39) 3 343-348.	Review	Several case series outline the feasibility and effectiveness of suture and mesh-augmented hysteropexy. Even fewer data are available regarding pregnancy risks and outcomes following hysteropexy. Leaving the uterus in situ at the time of pelvic floor repair also raises unique issues, such as the risk and management of future cervical or uterine abnormalities.	Review
Ridgeway BM (2015). Does prolapse equal hysterectomy? the role of uterine conservation in women with uterovaginal prolapse. American Journal of Obstetrics and Gynecology (213) 6 802-809.	Review	The most studied approaches to hysteropexy are the vaginal sacrospinous ligament hysteropexy and the abdominal sacrohysteropexy, which have similar objective and subjective prolapse outcomes compared with hysterectomy and apical suspension. Pregnancy and delivery have been documented after vaginal and abdominal hysteropexy approaches, although very little is known about outcomes following parturition. Uterine-sparing procedures need more research but	Review

		remain an acceptable option for most patients with uterovaginal prolapse.	
Ridgeway B, Frick A. C et al (2008). Hysteropexy: A review. Minerva Ginecologica (60) 6 509-528.	Review on hysteropexy.	Vaginal sacrospinous hysteropexy is well-supported by literature. Favourable outcomes range from 62-100% and show improved quality of life and sexual function. Anatomic outcomes appear to be comparable to vaginal hysterectomy with sacrospinous ligament vault suspension. The sacrohysteropexy, done through a laparotomy or laparoscopically, also has favourable data, with cure rates ranging from 91-100% and improvements in quality of life and sexual function. Complications related to these procedures are similar to those described after vaginal vault suspension. Hysteropexy, either transvaginal or abdominal, seems to be a safe procedure with acceptable results in women who desire uterine preservation.	Review of different surgical methods for uterus preservation
Rosenblatt PL, Chelmow D et al (2008). Laparoscopic Sacrocervicopexy for the Treatment of Uterine Prolapse: A Retrospective Case Series Report. Journal of Minimally Invasive Gynecology (15) 3 268-272.	Retrospective case series n=40 women who had laparoscopic sacrocervicopexy. Synthetic mesh was used to attach the distal uterosacral ligaments and posterior endopelvic fascia to the anterior longitudinal ligament of the sacral promontory. Follow-up: 1 year	Pelvic organ prolapse quantification system measurements were used and apical support was evaluated using point C. Mean C was -1.13 (+9 to -4) preoperatively, -5.28 (-3 to -13) at 6 weeks postoperatively, -5.26 (-3 to -8) at 6 months postoperatively, and -4.84 (-3 to -7) at 1 year postoperatively. Laparoscopic sacrocervicopexy is an effective option for women with pelvic organ prolapse who desire uterine preservation.	Larger studies with longer follow-up included in table 2
Tola EN. and Erdemoglu E (2015). Uterine sparing surgical methods in pelvic organ prolapse. Turk Jinekoloji ve Obstetrik Dernegi Dergisi (12) 3 168-172.	Review	Vaginal, abdominal, laparoscopic, and robotic methods are defined in uterine preserving surgery. In our practice we prefer laparoscopic mesh sacrohysteropexy in patients who prefer to preserve their uterus because of the lower costs and high success rates compared with abdominal and robotic techniques.	Review

Zucchi A., Lazzeri M., et al (2010). Uterus preservation in pelvic organ prolapse surgery. Nature Reviews Urology (7) 11 626-633.	Review	Sacrospinous hysteropexy is the most studied vaginal technique for uterus preservation and favourable results have been demonstrated, although the majority of studies are flawed by selection and information bias, short follow-up and lack of adequate control groups. Abdominal and laparoscopic procedures are promising, providing similar functional and anatomical results to hysterectomy and sacrocolpopexy.	Different treatments options with and without mesh were reviewed.

Appendix B: Related NICE guidance for uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse

Guidance	Recommendations

Interventional procedures	**Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE Interventional procedure guidance IPG282 (2009).** **Current guidance** 1.1 Current evidence on the safety and efficacy of insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair and may review the procedure on publication of further evidence on different types of mesh. Future research should include short- and long-term efficacy, safety outcomes (such as mesh erosion in the long term), patient-reported quality-of-life outcomes using validated scales and subsequent successful pregnancy. **Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (2009).** **Current guidance** It replaces the previous guidance on mesh sacrocolpopexy for vaginal vault prolapse (Interventional Procedures Guidance no. 215, March 2007). 1.1 Current evidence on the safety and efficacy of sacrocolpopexy using mesh for vaginal vault prolapse repair appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit. 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of recurrence of vaginal vault prolapse after any prolapse repair procedure, and that there is also a risk of complications, including mesh erosion (for example, into the vagina), and provide them with clear written information. In addition, use of

	NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 Evidence on safety and efficacy outcomes is limited to 5 years. Evidence on outcomes beyond 5 years and on different types of mesh would be useful. Further research should include patient reported quality-of-life outcome measures using validated scales. **Draft recommendations** 1.1 Current evidence on the safety of sacrocolpopexy using mesh to repair vaginal vault prolapse shows there are serious but well-recognised safety concerns. The evidence on efficacy is adequate in quantity and quality. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit. 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of vaginal vault prolapse happening again, and of potentially serious complications, including mesh erosion (for example, into the vagina). Patients should be provided with clear written information about the procedure and its complications. In addition, the use of NICE's information for the public [[URL to be added at publication]] is recommended. 1.3 Patient selection and treatment should only be done by clinicians specialising in the management of pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training and do the procedure regularly. 1.4 Clinicians should enter details about all patients having sacrocolpopexy using mesh to repair vaginal vault prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical devices used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency. **Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009). Current guidance** 1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into

the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.

1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database.

1.5 NICE encourages further research into sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Future research should address short- and long-term efficacy, erosion rates and patient-reported quality-of-life outcome measures using validated scales.

Draft recommendations

1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse should :

• Inform the clinical governance leads in their trusts

• During the consent process, ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection and treatment should only be done by specialists with experience in managing pelvic organ prolapse and urinary incontinence in women. All clinicians doing this procedure should have specific up-to-date training in the procedure.

1.4 Clinicians should enter details about all patients having sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse onto an appropriate registry (for example, the British Society of Urogynaecology database). All adverse events involving the medical device used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.

Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009). Current guidance

This guidance replaces the previous guidance on posterior infracoccygeal sacropexy for vaginal vault prolapse (Interventional Procedures Guidance no. 125, May 2005).

	1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for vaginal vault prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for vaginal vault prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for vaginal vault prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. **Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009).** **Current guidance** 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for uterine prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.

	1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. **Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (2008).** **Current guidance** 1.1 The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh. Both efficacy and safety vary with different types of mesh, and the data on efficacy in the long term are limited in quantity. There is a risk of complications that can cause significant morbidity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake surgical repair of vaginal wall prolapse using mesh should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand that there is uncertainty about the long-term results and there is a risk of complications, including sexual dysfunction and erosion into the vagina, which would require additional procedures. They should provide them with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having surgical repair of vaginal wall prolapse using mesh (see section 3.1). 1.3 This is a technically challenging procedure that should only be carried out by gynaecologists with special expertise in the surgical management of pelvic organ prolapse. Specific training is required when trocar introducer systems are used for the insertion of mesh. 1.4 Further publication of safety and efficacy outcomes will be useful. Research should aim to address the performance of different methods of repair and different types of mesh. It should also include evidence about long-term outcomes and patient-reported outcomes, such as quality of life and sexual function. The Institute may review the procedure upon publication of further evidence. **Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE Interventional procedure guidance**

	IPG566 (2016). Available from https://www.nice.org.uk/guidance/ipg566 (replaces IPG 262) 1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. 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 single-incision short sling mesh insertion for stress urinary incontinence in women should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients with clear written information. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.1). 1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence. 1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery. 1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.

NICE guidelines	**Urinary incontinence in women (2013) NICE guideline CG171 (2013).** 1.10 Surgical approaches for SUI 1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. **[new 2013]** 1.10.2 If conservative management for SUI has failed, offer: • synthetic mid-urethral tape (see recommendations 1.10.3–8), **or** • open colposuspension (see also recommendation 1.10.9), **or** • autologous rectus fascial sling (see also recommendation 1.10.10). **[new 2013]** **Synthetic tapes** 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should: • use procedures and devices for which there is current high quality evidence of efficacy and safety[10] • only use a device that they have been trained to use (see recommendations in section 1.11) • use a device manufactured from type 1 macroporous polypropylene tape • consider using a tape coloured for high visibility, for ease of insertion and revision. **[new 2013]** 1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. **[new 2013]** 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. **[new 2013]** 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. **[new 2013]** 1.10.7 Refer to single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. **[new 2013]** 1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. **[new 2013]** **Colposuspension** 1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. **[2006]** **Biological slings** 1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. **[2006]**

	Intramural bulking agents 1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that: • repeat injections may be needed to achieve efficacy • efficacy diminishes with time • efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. **[2006, amended 2013]** 1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. **[2006]** **Artificial urinary sphincter** 1.10.13 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. **[2006]** **Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms** 1.10.14 Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be: • referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, **or** offered advice as described in recommendation 1.6.9 if the woman does not want continued invasive SUI procedures. **[new 2013]**

Appendix C: Literature search for uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse.

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	11/10/2016	Issue 10 of 12, October 2016
HTA database (Cochrane)	11/10/2016	Issue 3 of 4, July 2016
Cochrane Central Register of Controlled Trials (Cochrane)	11/10/2016	Issue 9 of 12, September 2016
MEDLINE (Ovid)	10/10/2016	1946 to September Week 4 2016
MEDLINE In-Process (Ovid)	10/10/2016	October 07, 2016
EMBASE (Ovid)	10/10/2016	1974 to 2016 Week 41
PubMed	11/10/2016	n/a
CINAHL (EBSCOhost)	11/10/2016	n/a
BLIC (British Library)	11/10/2016	n/a

Trial sources searched on 28/07/2016 (scoping search)

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

Websites searched on 28/07/2016 (scoping search)

- 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.

The MEDLINE search strategy was adapted for use in the other sources.

1 Uterine Prolapse/

2 pelvic organ prolapse/
3 ((vagina* or transvaginal* or genital* or genitourin* or uter* or womb* or apical or (pelvic adj2 organ*) or utero-vagin*) adj4 (prolaps* or collaps* or drop* or slip* or sag* or hernia* or fall* or sink* or relax*)).tw.
4 POP.tw.
5 (pelvic adj4 floor adj4 repair).ti,ab.
6 (stress* adj4 urin* adj4 incontinen*).ti,ab.
7 urinary incontinence, stress/
8 or/1-7
9 surgical mesh/
10 mesh*.ti,ab.
11 ((biologic* or synthetic*) adj4 (graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab.
12 *Polypropylenes/ or *Polyglactin 910/
13 ((Polypropylene* or Polyglactin*) adj2 (mesh* or graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab.
14 or/9-13
15 8 and 14
16 *gynecologic surgical procedures/ or reconstructive surgical procedures/ or organ sparing treatments/
17 suburethral slings/
18 urogential surgical procedures/ or urologic surgical procedures/ (8812)
19 (Colporrhaph* or colpoperineorraph* or cystopex* or sacrocolpopex* or sacropex* or hysteropex*).ti,ab.
20 ((pectineal* or uterosacral* or sacrum* or uterine or cervix*) adj2 ligament*).ti,ab.
21 ((uter* or womb* or ligament* or apical or (pelvic adj2 organ*) or utero-vagin*) adj4 (resuspen* or suspen* or preserv* or lift* or support* or conserve* or tape* or fix*)).ti,ab.
22 or/16-21
23 15 and 22
24 (marlex* or monofilament* or multifilament* or mersilene*).ti,ab.
25 8 and 24
26 25 or 23
27 robot-assisted/ or Robotic surgical procedures/
28 (robot* adj4 assist*).ti,ab.
29 exp Laparoscopy/
30 Laparoscopes/
31 laparoscop*.ti,ab.
32 (laparoscop* or telescop* or peritoneoscop* or celioscop*).ti,ab.
33 (pelvi* adj4 endoscop*).ti,ab.
34 abdomen/
35 abdomen,acute/
36 (abdom* or bell* or stomac* or tumm*).ti,ab.
37 or/27-36
38 26 and 37

39 sacrohysteropex*.ti,ab.
40 38 or 39
41 animals/ not humans/
42 40 not 41
43 limit 42 to ed=20070701-20161031