

# Post-Hysterectomy Vaginal Vault Prolapse

Green-top Guideline No. 46  
RCOG/BSUG Joint Guideline | July 2015

# Post-Hysterectomy Vaginal Vault Prolapse

This is the second edition of this guideline, previously published in 2007 as a joint guideline with the British Society of Urogynaecology as 'The Management of Post Hysterectomy Vaginal Vault Prolapse'.

## Executive summary of recommendations

### Diagnosis and investigation

What is the preferred classification for vault/pelvic organ prolapse?

**Standardised classification systems should be used for the assessment and documentation of pelvic organ prolapse (POP), including vault prolapse.**

D

When is urodynamic testing required?

**Routine urodynamic assessment is not recommended in women with post-hysterectomy vaginal vault prolapse (PHVP). [New 2015]**

B

In what setting should a patient with PHVP be assessed?

**Clinicians should work as part of a pelvic floor multidisciplinary team (MDT). [New 2015]**



Are quality of life (QoL) measures of value?

**Patient assessment should address QoL issues using standardised tools.**

C

### Prevention

What preventive techniques are of value at hysterectomy?

**McCall culdoplasty at the time of vaginal hysterectomy is effective in preventing subsequent PHVP.**

B

**Suturing the cardinal and uterosacral ligaments to the vaginal cuff at the time of hysterectomy is effective in preventing PHVP following both abdominal and vaginal hysterectomies.**

B

**Sacrospinous fixation (SSF) at the time of vaginal hysterectomy should be considered when the vault descends to the introitus during closure.**

C

Does subtotal hysterectomy have a place in the prevention of PHVP?

**Subtotal hysterectomy is not recommended for the prevention of PHVP. [New 2015]**

A

Are there preferred suture materials for vault support at the time of hysterectomy?

**There is inadequate and conflicting evidence over the use of permanent sutures in the short term and no evidence of benefit in the long term; they can be associated with high suture exposure rates. [New 2015]**

C

### Conservative management

Is pelvic floor therapy of value in the management of PHVP?

**Pelvic floor muscle training (PFMT) is an effective treatment option for women with stage I–II vaginal prolapse, including PHVP. [New 2015]**

B

What is the place of vaginal devices?

**Vaginal pessaries are an alternative treatment option for women with stage II–IV PHVP. [New 2015]**

**B**

### *Surgical management*

What are the indications for surgery?

**Surgical treatment should be offered to women with symptomatic PHVP after appropriate counselling. [New 2015]**

✓

Who should undertake surgery?

**PHVP surgery should be performed by an RCOG-accredited subspecialist urogynaecologist, or gynaecologists who can demonstrate an equivalent level of training or experience. [New 2015]**

✓

What is an acceptable successful result after surgical treatment?

**Patient-reported outcomes, including patient-reported success rates and relief of presenting symptoms, should be the primary assessment outcomes. [New 2015]**

**C**

**Objective cure is important as it correlates to symptoms of vaginal bulge; a Pelvic Organ Prolapse Quantification (POP-Q) stage of I or O in the apical compartment seems to be acceptable and widely used as the optimum postoperative result. [New 2015]**

**C**

What surgical procedures are available for the treatment of PHVP?

**The type of operation performed should be tailored to the individual patient's circumstances.**

✓

A comparison of surgical procedures

Open abdominal sacrocolpopexy (ASC) versus vaginal SSF

**Women should be aware that both ASC and SSF are effective treatments for primary PHVP.**

**A**

**ASC is associated with significantly lower rates of recurrent vault prolapse, dyspareunia and postoperative stress urinary incontinence (SUI) when compared with SSF. However, this is not reflected in significantly lower reoperation rates or higher patient satisfaction.**

**A**

**SSF is associated with earlier recovery compared with ASC.**

**A**

**SSF may not be appropriate in women with short vaginal length and should be carefully considered in women with pre-existing dyspareunia.**

✓

Laparoscopic and robotic sacrocolpopexy (LSC and RSC)

**LSC can be equally effective as ASC in selected women with primary PHVP. LSC can include mesh extension or be combined with other vaginal procedures to correct other compartment prolapse.**

**B**

**There is limited evidence on the effectiveness of RSC; therefore, it should only be performed in the context of research or prospective audit following local governance procedures. [New 2015]**

**C**

High uterosacral ligament suspension (HUSLS)

**HUSLS should only be offered as first-line management in women with PHVP within the context of research or prospective audit following local governance procedures.**

**B**

**Clinicians should be aware of the risk of ureteric injury, especially in the laparoscopic approach.**

**C**

Under what circumstances would transvaginal mesh (TVM) kits/grafts be considered?

**The limited evidence on TVM kits does not support their use as first-line treatment of PHVP.**

**B**

**If TVM is considered, women should be fully informed of the permanent nature of the mesh and potential mesh complications, some of which are serious and have long-term effects that can be difficult to treat. [New 2015]**

**C**

**If TVM is considered, women should be fully informed of alternative surgical and nonsurgical options and referral to other surgeons/units arranged as appropriate. [New 2015]**

✓

**TVM should only be performed by an appropriately trained urogynaecologist, after discussion of each individual case in an MDT meeting. [New 2015]**

✓

**The results of all surgical procedures involving mesh should be prospectively audited and submitted to a national surgical database (e.g. British Society of Urogynaecology [BSUG]) and any mesh complications reported to the Medicines and Healthcare Products Regulatory Agency (MHRA). [New 2015]**

✓

When should colpocleisis be used?

**Colpocleisis is a safe and effective procedure that can be considered for frail women and/or women who do not wish to retain sexual function.**

**C**

Is there an indication for concomitant surgery for occult SUI?

**Colposuspension performed at the time of sacrocolpopexy is an effective measure to reduce postoperative symptomatic SUI in previously continent women. [New 2015]**

**B**

Is there an indication for concomitant surgery for PHVP and overt SUI?

**Colposuspension at the time of ASC does not appear to be effective treatment for SUI. [New 2015]**

**B**

**Concomitant mid-urethral sling surgery may be considered when vaginal surgical approaches are used for the treatment of PHVP. [New 2015]**

✓

What is the optimal treatment of recurrent vault prolapse?

**The management of recurrent vault prolapse should be through a specialist MDT with experience and training in this field. [New 2015]**

✓

#### *Clinical governance*

**National databases, such as the BSUG surgical database, should be used to document surgical outcomes and complications. [New 2015]**

✓

**The International Urogynecological Association (IUGA)/International Continence Society (ICS) terminology and classification of complications should be used for the documentation of graft-related complications. [New 2015]**

✓

**All complications related to the use of devices and mesh should be reported to the MHRA. [New 2015]**

✓

## 1. Purpose and scope

This guideline aims to assist generalist and subspecialist gynaecologists in the management of post-hysterectomy vaginal vault prolapse (PHVP). The management of urinary incontinence is not covered in this guideline; however, the role of concomitant continence procedures at the time of surgery for vault prolapse is addressed.

## 2. Introduction and background epidemiology

There is no precise definition of PHVP; however, the International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on female pelvic floor dysfunction defines it as 'descent of ... the apex of the vagina (vaginal vault or cuff scar after hysterectomy)'.<sup>1</sup> The vaginal cuff scar corresponds to point C on the Pelvic Organ Prolapse Quantification (POP-Q) grid (Appendix I).<sup>2</sup> Prolapse of the vaginal vault after hysterectomy may occur when the structures that support the top of the vagina and uterus are not reattached at the time of the initial procedure or due to weakening of these supports over time.

Case series dating back to 1960 have identified the incidence of PHVP as ranging from 0.2% to 43%.<sup>3-5</sup> More recently, PHVP has been reported to follow 11.6% of hysterectomies performed for prolapse and 1.8% for other benign diseases.<sup>6</sup> A large study from Austria estimated the frequency of PHVP requiring surgical repair to be between 6% and 8%.<sup>7</sup>

## 3. Identification and assessment of evidence

A search of MEDLINE, EMBASE and The Cochrane Library from 2006–2013 for relevant systematic reviews, meta-analyses, randomised controlled trials (RCTs) and other clinical trials was conducted. A top-up search was performed in January 2015 for more recent evidence. The main Medical Subject Headings (MeSH) and non-MeSH terms used included 'uterine prolapse', 'vault prolapse', 'pelvic organ prolapse' and 'hysterectomy' with text words: 'sacrocolpopexy', 'sacrospinous fixation/suspension', 'intravaginal slingplasty (IVS)', 'posterior IVS', 'infracoccygeal sacropexy', 'colpocleisis', 'uterosacral ligament suspension/plication', 'prolift', 'perigee', 'apogee', 'elevate', 'capio', 'i-stitch' and 'avaulta'.

## 4. Diagnosis and investigation

### 4.1 What is the preferred classification for vault/pelvic organ prolapse?

**Standardised classification systems should be used for the assessment and documentation of pelvic organ prolapse (POP), including vault prolapse.**

**D**

A number of classification systems for POP are used in both research and clinical settings.<sup>1,2,8,9</sup> The use of standardised terminology is recommended as it enables assessment of outcomes for individual women and facilitates the comparison of results for audit and research purposes.

Evidence level 4

The ICS POP-Q system is the most comprehensive and widely used.<sup>2</sup>

### 4.2 When is urodynamic testing required?

**Routine urodynamic assessment is not recommended in women with PHVP.**

**B**

Performing preoperative urodynamic testing with and without prolapse reduction in continent women undergoing POP surgery does not always predict postoperative stress incontinence. Prophylactic treatment for women thought to have occult stress urinary incontinence (SUI) will result in unnecessary treatment for some women. Clinical assessment remains the most important assessment tool.

In the Colpopexy and Urinary Reduction Efforts (CARE) trial,<sup>10-12</sup> patients undergoing sacrocolpopexy, who were asymptomatic for SUI, were randomised to undergo either a concomitant Burch colposuspension or no Burch colposuspension (control group). The group demonstrated that the preoperative incidence of urodynamic stress incontinence (USI) increased from 3.7% to 19% following manual prolapse reduction, while using pessaries or speculum reduction for prolapse was associated with detection rates of 6% and 30% respectively.<sup>13</sup> Women who demonstrated preoperative USI were at higher risk of postoperative SUI, even if they underwent a concomitant Burch colposuspension. Preoperative urodynamic testing did not, however, accurately predict USI in all cases, with 38% of women with negative testing in the control group and 21% in the Burch group still developing symptomatic postoperative SUI.

Evidence level 1+

The role of concomitant assessment and management of symptomatic SUI in women with POP, including PHVP, is outwith the scope of this guideline.

#### 4.3 *In what setting should a patient with PHVP be assessed?*

**Clinicians should work as part of a pelvic floor multidisciplinary team (MDT).**



Clinicians involved in the management of patients with PHVP should demonstrate an appropriate level of training and clinical practice. Involvement of other specialties (e.g. coloproctology or urology) or allied health professionals may be useful in the management of PHVP in patients with concomitant bladder/bowel symptoms.<sup>14</sup>

Evidence level 4

#### 4.4 *Are quality of life (QoL) measures of value?*

**Patient assessment should address QoL issues using standardised tools.**



Many standardised and validated QoL assessment tools exist for use in women with vaginal prolapse, but not specifically for use in women with PHVP. Some QoL tools are condition specific and address symptom complexes (e.g. Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire -12, International Consultation on Incontinence Modular Questionnaire [ICIQ]-Vaginal Symptoms, ICIQ-Urinary Incontinence)<sup>15,16</sup> while others look at the impact of the condition on patients' activities (e.g. Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, Colorectal-Anal Distress Inventory, Incontinence Impact Questionnaire, Urogenital Distress Inventory).<sup>17-19</sup> Using these will require time and resources, such as preprinted questionnaires and/or the availability of computers in clinics.

Evidence level 2+

QoL questionnaires are useful audit and research tools that help with patient-centred assessment and goals,<sup>20</sup> but their use can be time consuming and may require additional resources that may not alter patient outcomes.

Evidence level 4

## 5. Prevention

### 5.1 *What preventive techniques are of value at hysterectomy?*

**McCall culdoplasty at the time of vaginal hysterectomy is effective in preventing subsequent PHVP.**



**Suturing the cardinal and uterosacral ligaments to the vaginal cuff at the time of hysterectomy is effective in preventing PHVP following both abdominal and vaginal hysterectomies.**



**Sacrospinous fixation (SSF) at the time of vaginal hysterectomy should be considered when the vault descends to the introitus during closure.**



A small RCT compared vaginal Moschcowitz-type operation, McCall culdoplasty and peritoneal closure of the cul-de-sac as preventive measures against the development of enterocele. It

Evidence level 1+

showed that McCall culdoplasty was more effective than vaginal Moschcowitz or simple closure of the peritoneum in preventing enterocele at 3 years' follow-up.<sup>21</sup>

McCall culdoplasty involves approximating the uterosacral ligaments using continuous sutures, so as to obliterate the peritoneum of the posterior cul-de-sac as high as possible.<sup>22</sup> A similar approach has been described for abdominal hysterectomy.<sup>23,24</sup> No comparative studies are available to assess the value of such a step at the time of abdominal hysterectomy, which is often carried out for indications other than prolapse.

Evidence  
level 1+

A retrospective study evaluated the anatomical and functional results of the McCall culdoplasty in a total of 185 patients undergoing vaginal hysterectomy for mild or moderate uterine prolapse. At 24 months' follow-up, the vaginal vault was well supported in 99.2%, with 89.2% showing stage 0 vaginal vault prolapse and 10% showing stage I prolapse that did not require revision surgery. Functional analysis showed satisfactory sexual function at 24 months post surgery for 81.2% of patients.<sup>25</sup>

Attaching the uterosacral and cardinal ligaments to the vaginal cuff and high circumferential obliteration of the pouch of Douglas have been shown to prevent PHVP and subsequent enterocele formation.<sup>26</sup> No cases of vault prolapse or enterocele were recorded among 112 patients over a follow-up period extending from 7–42 months.

Evidence  
level 2+

One observational study showed that incorporation of the cardinal–uterosacral ligaments into the vaginal cuff margins at the time of total abdominal hysterectomy may help to minimise subsequent apical vault prolapse.<sup>27</sup>

A systematic review<sup>28</sup> of vaginal uterosacral ligament suspension provided a meta-analysis of anatomical outcomes and a summary of subjective outcomes. In the apical compartment, the pooled rates for a successful outcome were 98.3%.

Evidence  
level 1++

Prophylactic SSF has been suggested at the time of vaginal hysterectomy for marked uterovaginal prolapse,<sup>29</sup> when the vault (point C on the POP-Q system) could be pulled to the introitus at the end of anterior vaginal wall closure. A small retrospective study reported only one case of recurrent PHVP in 48 patients with a mean follow-up of 2 years.<sup>29</sup> In this series, twenty women complained of right buttock pain; all resolved spontaneously by 6 weeks' follow-up, while five women subsequently developed de novo anterior vaginal wall prolapse. No information was provided about sexual dysfunction in this study.

Evidence  
level 2+

### 5.2 Does subtotal hysterectomy have a place in the prevention of PHVP?

**Subtotal hysterectomy is not recommended for the prevention of PHVP.**

A

There is no evidence to support the role of subtotal hysterectomy in preventing PHVP. A meta-analysis showed that although subtotal hysterectomy is quicker to perform and there are fewer intra- and postoperative complications, more women suffered with urinary incontinence and prolapse compared with women who had a total hysterectomy.<sup>30</sup>

Evidence  
level 1+

### 5.3 Are there preferred suture materials for vault support at the time of hysterectomy?

**There is inadequate and conflicting evidence over the use of permanent sutures in the short term and no evidence of benefit in the long term; they can be associated with high suture exposure rates.**

C

In a retrospective analysis of 248 patients who underwent uterosacral ligament suspension, permanent (2-0 Ti-Cron®, Covidien, Dublin, Ireland) and delayed absorbable polydioxanone

Evidence  
level 2+



(O-Maxon®, Covidien, Dublin, Ireland) sutures were compared for failure of anatomical support. In the short term, the use of permanent sutures for uterosacral ligament suspension of the vaginal apex was associated with a lower failure rate than delayed absorbable sutures, but there were 16 cases of permanent suture exposure that required removal.<sup>31</sup> Another study found that permanent sutures do not offer significantly better apical support at short-term follow-up and are also associated with a high rate of suture erosion.<sup>32</sup>

Evidence  
level 2+

## 6. Conservative management

### 6.1 *Is pelvic floor therapy of value in the management of PHVP?*

**Pelvic floor muscle training (PFMT) is an effective treatment option for women with stage I–II vaginal prolapse, including PHVP.**

**B**

No trials looking specifically at the role of PFMT in women with PHVP were identified.

A large multicentre RCT (the Pelvic Organ Prolapse Physiotherapy [POPPY] trial)<sup>33</sup> showed that one-to-one PFMT for prolapse is effective for the improvement of prolapse symptoms. This study included, but did not exclusively address, women with PHVP.

Evidence  
level 1+

There is growing evidence, including a small number of RCTs, to indicate that PFMT has a positive effect on prolapse symptoms and severity<sup>34–36</sup> in women with POP-Q stage I–II vaginal prolapse compared with no treatment. These trials included, but were not specific to, PHVP.

Evidence  
level 1-

Both the National Institute for Health and Care Excellence and the American College of Obstetricians and Gynecologists list PFMT as a treatment option in women with all types of vaginal prolapse.<sup>37–40</sup>

Evidence  
level 4

### 6.2 *What is the place of vaginal devices?*

**Vaginal pessaries are an alternative treatment option for women with stage II–IV PHVP.**

**B**

A randomised crossover trial (the PESSRI study) compared two different vaginal pessaries (Gellhorn versus ring) in women with stage II–IV prolapse and showed clinically significant improvements in prolapse symptoms with both types of pessaries, but no significant differences between pessary groups.<sup>41</sup>

Evidence  
level 1+

Pessaries should be considered in all women with POP, including PHVP.<sup>37–40</sup> Consideration needs to be given to sexual function, regular pessary changes and possible complications such as ulceration, vaginal bleeding and a small risk of fistula formation.

Evidence  
level 4

## 7. Surgical management

### 7.1 *What are the indications for surgery?*

**Surgical treatment should be offered to women with symptomatic PHVP after appropriate counselling.**

**✓**

The decision to offer surgical treatment for PHVP should primarily be determined by the woman's symptoms, her response to conservative treatment, the impact of PHVP on her QoL and daily activities and also on her fitness for surgery. The planned procedure should be fully discussed, including success rates, recurrence, potential complications, and the impact of treatment and potential complications on women's QoL and sexual function.



## 7.2 Who should undertake surgery?

**PHVP surgery should be performed by an RCOG-accredited subspecialist urogynaecologist, or gynaecologists who can demonstrate an equivalent level of training or experience.**



No studies were identified that evaluated the level of training and/or experience that a surgeon is required to achieve prior to undertaking PHVP surgery, nor the workload per year that is required to maintain skills. In the UK at the present time, PHVP surgery is not part of the urogynaecology Advanced Training Skills Module, but is part of subspecialty training in urogynaecology. There will of course be established consultants who completed their training prior to the creation of such programmes who will be able to demonstrate equivalent training and experience if they undertake such surgery.

For all surgeons, an adequate workload of each procedure per year is required to maintain skills; however, there is no robust evidence to advise on the volume of such workload. A clear referral pathway should be in place to refer the patient to the appropriate surgeon to undertake the required procedure.

## 7.3 What is an acceptable successful result after surgical treatment?

**Patient-reported outcomes, including patient-reported success rates and relief of presenting symptoms, should be the primary assessment outcomes.**



**Objective cure is important as it correlates to symptoms of vaginal bulge; a POP-Q stage of I or 0 in the apical compartment seems to be acceptable and widely used as the optimum postoperative result.**



The primary aims of surgical treatment are the restoration of normal vaginal anatomy, improvement in vaginal bulge symptoms and the restoration/maintenance of normal bladder, bowel and sexual function. Most of the studies in the literature, however, have used the anatomical outcome as the primary outcome, with POP-Q stages I or 0 defined as the anatomical cure.<sup>42</sup> A recent qualitative study based on patient interviews showed that women are most affected by the actual physical symptoms of prolapse (bulge, pain and bowel problems) as well as by the impact that prolapse has on their sexual function.<sup>43</sup> The prevalence of pelvic floor dysfunction symptoms was found to be quite high 6 years after primary POP surgery: urinary leakage (once or more/week, 41%), vaginal bulge (18%), faecal incontinence (15%) and refraining from sexual intercourse (15%).<sup>44</sup>

Evidence level 2+

A number of studies have showed that vaginal descent distal to the hymen (point C greater than 0 cm) accurately predicts the symptoms of prolapse bulging/protrusion; however, these studies failed to identify a threshold of prolapse severity that predicted other pelvic floor symptoms.<sup>45-47</sup> An updated definition of objective failure was therefore proposed in the long-term outcome of a large RCT,<sup>48</sup> which defined failure as point C greater than (–two-thirds x total vaginal length), i.e. the vaginal apex descending below the upper third of the vagina, or one of points Ba or Bp being greater than 0 cm, i.e. the anterior (Ba) or posterior (Bp) vaginal wall prolapsing beyond the hymen.

The outcome reporting scheme proposed by IUGA/ICS is recommended.<sup>49</sup>

Evidence level 4

## 7.4 What surgical procedures are available for the treatment of PHVP?

**The type of operation performed should be tailored to the individual patient's circumstances.**



A variety of procedures exist for surgical treatment of PHVP in women who are deemed fit for surgery. There is no robust evidence to guide the clinician as to the best surgical technique for a particular patient. The type of operation performed should be tailored to the individual patient's circumstances, such as concomitant prolapse in other compartment(s), sexual

Evidence level 4

activity, previous abdominal surgery, previous prolapse surgery, the total vaginal length, and associated comorbidities. Women with multiple compartment prolapse and/or a history of extensive abdominal surgery can be quite challenging with the abdominal/laparoscopic approach and a vaginal approach may be appropriate. An abdominal approach would be more appropriate in women with short vaginal length<sup>50</sup> and those undergoing concomitant abdominal surgery. An elderly, sexually inactive woman or a woman unfit for a long surgical operation would be a candidate for colpocleisis.

Evidence level 4

#### 7.4.1 A comparison of surgical procedures

##### 7.4.1.1 Open abdominal sacrocolpopexy (ASC) versus vaginal sacrospinous fixation (SSF)

**Women should be aware that both ASC and SSF are effective treatments for primary PHVP.**

A

**ASC is associated with significantly lower rates of recurrent vault prolapse, dyspareunia and postoperative SUI when compared with SSF. However, this is not reflected in significantly lower reoperation rates or higher patient satisfaction.**

A

**SSF is associated with earlier recovery compared with ASC.**

A

**SSF may not be appropriate in women with short vaginal length and should be carefully considered in women with pre-existing dyspareunia.**

✓

The Cochrane review<sup>42</sup> included three RCTs that compared ASC versus SSF (also known as vaginal sacrospinous colpopexy [VSC]). Its meta-analysis showed that ASC was associated with significantly (i) lower rates of recurrent vault prolapse (risk ratio [RR] 0.23, 95% CI 0.07–0.77), (ii) less postoperative SUI (RR 0.55, 95% CI 0.32–0.95) and (iii) less postoperative dyspareunia (RR 0.39, 95% CI 0.18–0.86). There were no statistically significant differences in patient satisfaction, the number of women reporting prolapse symptoms, objective failure at any site, reoperation rates for SUI and reoperation rates for prolapse. SSF resulted in a reduction in operative time, it was less expensive to perform and women had an earlier return to their daily activities.

Evidence level 1+

ASC involves apical suspension of the vault with a permanent mesh fixed to the longitudinal ligament of the sacrum; typically, the mesh is attached to the anterior and posterior aspects of the vault with possible ‘mesh extension’ to correct prolapse in other compartments.<sup>51</sup> A systematic review of observational studies reported long-term success rates of 78–100%. Mesh erosion was observed in 2–11%.<sup>52,53</sup> Serious complications such as bowel injury, sacral myelitis and severe bleeding have an estimated incidence of 2% (range 0–8%).

Evidence level 2++

A recent high quality RCT with 7 years’ follow-up after ASC<sup>48</sup> showed that POP and SUI failure rates gradually increased over the follow-up period; however, of the 10% anatomical POP failures, one-half of the women were asymptomatic and were not retreated. Conversely, 9% were symptomatic failures, of which one-half did not meet the anatomical failure criteria. The estimated probability of mesh erosion was 10.5% and the reoperation rate was 16.7% divided almost equally into one-third for POP, one-third for SUI and one-third for mesh-related complications. Surgery for SUI was doubled in women who did not undergo concomitant colposuspension. The authors of the trial concluded that ‘as a gold standard for the surgical treatment of POP, abdominal sacrocolpopexy is less effective than desired’, with nearly one-third of women meeting their composite failure definition by 5 years. They also highlighted that although 95% had no retreatment for POP, one explanation may be related to other health issues taking priority over the vaginal bulge as patients grow older.

Evidence level 1+

SSF involves unilateral anchoring of the vaginal vault to the sacrospinous ligament (usually the right side) using either absorbable or non-absorbable sutures and can be done bilaterally.<sup>54,55</sup>

Several systematic reviews have shown that SSF is a highly effective therapy for vault prolapse, with low recurrence and complication rates and good patient satisfaction. One concern is the high incidence (8–30%) of postoperative anterior compartment prolapse and SUI, presumably due to posterior fixation of the upper vagina which predisposes the anterior compartment to excess intra-abdominal pressure.<sup>56–60</sup> Postoperative buttock pain has an estimated incidence of 18%,<sup>61,62</sup> although this usually resolves within 2–3 months and rarely requires any additional treatment apart from analgesics and anti-inflammatory agents. There are case reports of pudendal nerve injury with SSF,<sup>63</sup> primarily owing to the anatomical variations in the course of the pudendal nerve on crossing the ischial spine. However, placing the SSF sutures 1.5–2 cm medial to the ischial spines is recommended.<sup>63,64</sup> One large study showed temporary irritation of the sciatic nerve in 7.5% and temporary partial ureteral obstruction in 5.5% of 200 women who underwent SSF.<sup>65</sup> There is no evidence that bilateral SSF or using permanent suture material is associated with better success rates. Long-term follow-up studies showed patient-reported prolapse symptoms in 16% of women at 2–15 years' follow-up.<sup>66</sup>

Evidence level 1+

#### 7.4.1.2 Laparoscopic and robotic sacrocolpopexy (LSC and RSC)

**LSC can be equally effective as ASC in selected women with primary PHVP. LSC can include mesh extension or be combined with other vaginal procedures to correct other compartment prolapse.**

B

**There is limited evidence on the effectiveness of RSC; therefore, it should only be performed in the context of research or prospective audit following local governance procedures.**

C

A number of observational studies have shown good anatomical cure rates (more than 90%) in women undergoing LSC at 1–2 years' follow-up.<sup>67–71</sup> However, one study showed an 8% recurrence of vault prolapse and a 42% recurrence/persistence of other compartment prolapse at 5 years' follow-up. In this study, 70% reported their symptoms to be cured or improved; however, 38% still had symptoms of prolapse. The authors concluded that, for every two women who were cured of their urinary or bowel symptoms, one woman developed worse symptoms.<sup>72</sup>

Evidence level 2+

One relatively small multicentre RCT<sup>73</sup> compared ASC versus LSC in women with PHVP with or without other compartment prolapse. The results showed significant improvement in the objective outcome in both groups with no significant difference between groups. At 12 months, 67% of the ASC group and 54% of the LSC group reported themselves to be 'very much better'. The potential advantages of LSC were ascertained with significantly less intraoperative blood loss ( $P < 0.01$ ) and shorter hospital stays ( $P = 0.02$ ).

Evidence level 1-

The robotic approach is available in only a limited number of centres in the UK, being expensive to set up. A recent prospective cohort study of 90 women with POP-Q stage III undergoing RSC, with an additional procedure in 71 cases (either subtotal hysterectomy, adnexectomy, adhesiolysis or rectopexy), showed a mean operative time of 246 minutes (180–415 minutes) and a mean hospital stay of 3.48 days (2–11 days). Surgical complications were rare: one case of sigmoidal perforation and two cases of bowel hernia through port sites. At a mean follow-up of 15 months, six patients (6%) had persistent stage II prolapse.<sup>74</sup>

Evidence level 2+

One prospective single-blinded RCT<sup>75</sup> compared the outcomes of LSC ( $n = 33$ ) versus RSC ( $n = 35$ ) in patients with stages II–IV PHVP. The primary outcome measure was operative time from incision to closure. Results showed that LSC had a shorter operating time ( $199 \pm 46$  minutes versus  $265 \pm 50$  minutes) and less use of postoperative analgesia and that it was significantly less expensive compared with RSC. At 1 year, both groups reported significant and similar improvements in objective assessment and functional outcomes; however, the study was not powered to show significant differences in cure rates.

Evidence level 1-

### 7.4.1.3 High uterosacral ligament suspension (HUSLS)

**HUSLS should only be offered as first-line management in women with PHVP within the context of research or prospective audit following local governance procedures.**

**B**

**Clinicians should be aware of the risk of ureteric injury, especially in the laparoscopic approach.**

**C**

HUSLS can be done vaginally, abdominally or laparoscopically and involves bilateral suspension of the vaginal vault, using sutures, to the uterosacral ligaments near the level of the ischial spine.

The evidence regarding the value of HUSLS as first-line management in women with vault prolapse is limited and contradictory. One small prospective RCT<sup>76</sup> compared ASC (n = 54) versus HUSLS (n = 56) in women with point C greater than 1 cm beyond the introitus. With a loose definition of objective success at 1 year (point C less than -1 cm), they reported 100% versus 82.5% success in ASC and HUSLS respectively. Recurrence in the anterior or posterior compartments (5.3% versus 33.3% and 0% versus 6.2% respectively) and the reoperation rate for prolapse were significantly lower in the ASC versus HUSLS groups. Both intraoperative complications and postoperative complications were higher in the HUSLS versus ASC groups (3.7% versus 0%,  $P = 0.15$  and 20.4% versus 7.3%,  $P = 0.047$  respectively).

Evidence level 1+

An RCT (the Operations and Pelvic Muscle Training in the Management of Apical Support Loss [OPTIMAL] trial)<sup>77</sup> has compared HUSLS versus SSF (both with mid-urethral slings) in women with PHVP and USI. The 2-year results showed no difference in success rates (HUSLS 59.2% versus SSF 60.5%), serious adverse event rates (HUSLS 16.5% versus SSF 16.7%) or prolapse scores at 24 months. This well-designed RCT concluded that neither HUSLS nor SSF was significantly superior to the other for anatomical, functional or adverse event outcomes.

In a systematic review and meta-analysis<sup>28</sup> of transvaginal uterosacral ligament suspension, the pooled rates for a successful outcome in the anterior, apical and posterior compartments were 81.2%, 98.3% and 87.4% respectively. Outcomes, with respect to subjective symptoms, were reassuring; however, it was not possible to pool data because of methodological differences between studies.

Evidence level 1++

Complications of HUSLS include ureteric injury, the incidence of which can be as high as 10.9%, bladder injury, urinary tract infection, blood transfusion and small bowel injury.<sup>78-80</sup> Placing the sutures into the deep dorsal aspect of the ligament is reported to reduce the incidence of ureteric injury,<sup>81</sup> especially in the laparoscopic approach. Suture erosion was noted with permanent sutures; a similar risk has been reported with laparoscopic HUSLS.<sup>82</sup>

Evidence level 2+

### 7.5 Under what circumstances would transvaginal mesh (TVM) kits/grfts be considered?

**The limited evidence on TVM kits does not support their use as first-line treatment of PHVP.**

**B**

**If TVM is considered, women should be fully informed of the permanent nature of the mesh and potential mesh complications, some of which are serious and have long-term effects that can be difficult to treat.**

**C**

**If TVM is considered, women should be fully informed of alternative surgical and nonsurgical options and referral to other surgeons/units arranged as appropriate.**

✓

**TVM should only be performed by an appropriately trained urogynaecologist, after discussion of each individual case in an MDT meeting.**

✓

**The results of all surgical procedures involving mesh should be prospectively audited and submitted to a national surgical database (e.g. British Society of Urogynaecology [BSUG]) and any mesh complications reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).**



TVM has mesh arms that bilaterally anchor the vaginal vault to both sacrospinous ligaments, achieving level I support. These were originally delivered with trocars through anatomical landmarks via the obturator membrane/ischiorectal fossa; however, more recently they have been anchored through single vaginal incisions.

A systematic review and meta-analysis<sup>83</sup> evaluated the efficacy and safety of TVM in the treatment of apical vaginal prolapse in 30 observational studies with a total of 2653 women; they showed objective success rates of 87–95% with short-term follow-up (6–18 months). Mesh erosion occurred in 4.6–10.7% and reoperation rates were 0.4–6.0%.

Evidence level 2++

One RCT<sup>84</sup> compared LSC versus TVM in women with PHVP with 2 years' follow-up. The results showed that the women in the LSC group had a longer operating time, a shorter hospital stay and a quicker return to daily activities compared with the TVM group. At 2 years' follow-up, the objective success rate and mean patient satisfaction were significantly higher in the LSC group. Women in the TVM group had a shorter postoperative total vaginal length, a trend towards higher vaginal mesh erosions (13% versus 2%,  $P = 0.07$ ) and higher reoperation rates (22% versus 5%,  $P = 0.006$ ).

Evidence level 1+

One RCT<sup>85</sup> compared TVM versus SSF with 12 months' follow-up and showed POP recurrence rates of 16.9% versus 39.4% respectively ( $P = 0.002$ ). The mesh exposure rate was 20.8%. There was no significant difference in QoL improvement, de novo SUI and overactive bladder between the two groups.

A large study has reported concerns on the safety and potentially serious complications (1%) associated with TVM, including serious infection and major haemorrhage.<sup>86</sup>

Evidence level 2+

Similar concerns were voiced by the US Food and Drug Administration<sup>87</sup> who proposed to reclassify these devices to class III (high-risk devices).<sup>88</sup> The MHRA has produced a report on TVM in prolapse and urinary incontinence.<sup>89,90</sup>

Evidence level 4

### 7.6 *When should colpocleisis be used?*

**Colpocleisis is a safe and effective procedure that can be considered for frail women and/or women who do not wish to retain sexual function.**



Colpocleisis entails closure of the vagina. The outcomes and complications of colpocleisis have been reviewed elsewhere.<sup>91</sup> Different techniques have been described, including vaginectomy,<sup>92</sup> purse-string closure,<sup>93</sup> colpocleisis after performing standard anterior and posterior vaginal wall repair,<sup>94</sup> purse-string closure of enterocele followed by approximation of perivesical and rectovaginal fascia and high levator plication<sup>95</sup> and LeFort colpocleisis,<sup>96</sup> where a bridge of tissue is created between the anterior and posterior vaginal wall to stop the vault prolapse from protruding.

Evidence level 2+

Colpocleisis has a short operating time and a low incidence of complications.<sup>93–95</sup> One published study included 33 women and a second included 92 women. Success rates of 97% and above have been reported.<sup>93–97</sup> The procedure can also be performed under local anaesthesia, which suits frail women who may be difficult to anaesthetise, as demonstrated in a study that included 30 women having tension-free vaginal tape sling insertion carried out under local anaesthetic.<sup>98</sup>



### 7.7 *Is there an indication for concomitant surgery for occult SUI?*

**Colposuspension performed at the time of sacrocolpopexy is an effective measure to reduce postoperative symptomatic SUI in previously continent women.**

**B**

A large RCT of 322 women<sup>11</sup> comparing ASC versus ASC and colposuspension in women with occult SUI stopped recruitment at the first interim analysis due to the significantly low incidence of postoperative SUI in the group of women who underwent concomitant colposuspension (44.1% versus 23.8%,  $P < 0.01$ ). The results were maintained at 7 years' follow-up, with the incidence of continence surgery almost halved in the group of women who underwent concomitant colposuspension. A meta-analysis that included two RCTs<sup>11,99</sup> confirmed the benefit of concomitant colposuspension.<sup>42</sup>

Evidence level 1+

There have been no clinical trials to assess delayed minimally invasive mid-urethral sling surgery, when required, after ASC and whether that would have led to higher overall continence rates.

There are no trials that evaluated performing prophylactic mid-urethral sling surgery at the time of SSF or ASC/LSC for occult SUI.

### 7.8 *Is there an indication for concomitant surgery for PHVP and overt SUI?*

**Colposuspension at the time of ASC does not appear to be effective treatment for SUI.**

**B**

**Concomitant mid-urethral sling surgery may be considered when vaginal surgical approaches are used for the treatment of PHVP. [New 2015]**

✓

In a small RCT of women with PHVP and concomitant SUI, 54.2% were still incontinent after combined ASC and Burch colposuspension, compared with 39.1% following ASC alone. Burch colposuspension does not provide any additional benefit in PHVP repair in patients with pre-existing SUI.<sup>100</sup>

Evidence level 1+

A 2013 Cochrane review assessed 16 RCTs, not specific to PHVP, which included data on bladder symptoms and concluded that 'Women undergoing prolapse surgery may have benefited from having continence surgery performed concomitantly, especially if they had [overt] stress urinary incontinence (RR 7.4, 95% CI 4.0 to 14)'.<sup>42</sup>

Evidence level 1++

A single RCT evaluated concomitant mid-urethral sling at the time of vaginal prolapse surgery (not specifically PHVP); combination surgery significantly reduced the risk of postoperative SUI at 1 year of follow-up (21% versus 59%).<sup>101</sup>

Evidence level 1+

### 7.9 *What is the optimal treatment of recurrent vault prolapse?*

**The management of recurrent vault prolapse should be through a specialist MDT with experience and training in this field.**

✓

A number of case series have reported good outcomes after vaginal HUSLS<sup>102</sup> and LSC<sup>103</sup> for recurrent vault prolapse. Evidence in relation to other management options, including PFMT and the use of pessaries, is very limited.<sup>104</sup> Patients should be counselled about the likely benefits and potential risks of each management option.

Evidence level 3

These patients should be assessed by those with expertise in the management of recurrent vaginal vault prolapse, ideally a subspecialist urogynaecologist (or those with equivalent experience) working within MDTs.

## 8. Clinical governance

National databases, such as the BSUG surgical database, should be used to document surgical outcomes and complications.



The IUGA/ICS terminology and classification of complications should be used for the documentation of graft-related complications.



All complications related to the use of devices and mesh should be reported to the MHRA.



Reporting of the complications of surgery for PHVP should describe the nature of the complication in terms of category, time and site. It should also describe any involvement of adjacent structures, such as the urinary tract or bowel, as well as any systemic effect.

The use of a standard method to report the outcome of surgery, including complications, for POP enables comparison for audit and research. Utilising the schemes proposed by IUGA/ICS facilitates the standardisation of terminology and the comparison of results for audit and research purposes.<sup>105,106</sup>

Evidence level 4

The BSUG registry (<https://nww.bsug.nhs.uk>) allows the use of these schemes and enables personal audit. Reporting can be made through medical device liaison officers or directly to the MHRA online (<https://yellowcard.mhra.gov.uk/>).

## 9. Recommendations for future research

- The role of concomitant continence surgery in patients with PHVP.
- The correlation of surgical workload and outcome.
- Robotic versus other abdominal and vaginal procedures for the treatment of PHVP.
- The use of mesh in the treatment of PHVP.

## 10. Auditable topics

- Documentation of management options offered including provision of patient information (100%).
- Documentation of the discussion of conservative measures (PFMT/pessaries) prior to surgery (100%).
- Compliance with relevant database, e.g. BSUG (100%).
- Documentation of the MDT discussion prior to surgery for recurrent prolapse (100%).
- Outcome following various surgical procedures for PHVP.
- Development of SUI following surgery for PHVP.

## 11. Useful links and support groups

- Association for Pelvic Organ Prolapse Support (APOPS) [<http://www.pelvicorganprolapsesupport.org/>].
- British Society of Urogynaecology. *Patient Information* [<http://www.bsug.org.uk/patient-information.php>].
- International Continence Society [<http://www.ics.org/>].
- International Urogynecological Association [<http://www.iuga.org/>].



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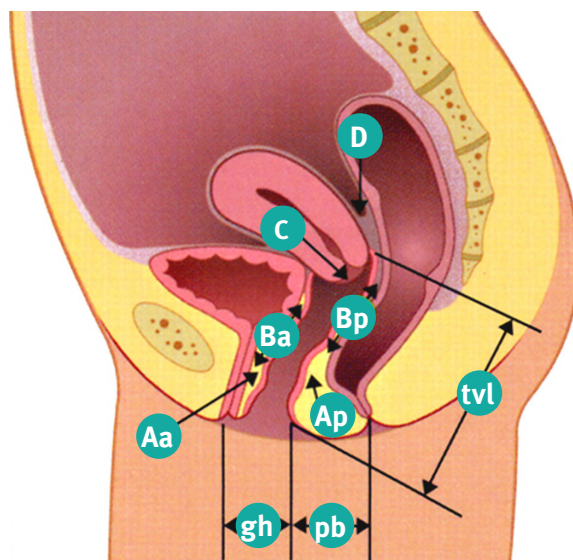
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## Appendix I: POP-Q exam – reference guide

The pelvic organ prolapse quantification (POP-Q) exam is used to quantify, describe and stage pelvic support.

- There are 6 points measured at the vagina with respect to the hymen.
- Points above the hymen are negative numbers; points below the hymen are positive numbers.
- All measurements except tvl are measured at maximum valsalva.



Point	Description	Range of values
Aa	Anterior vaginal wall 3 cm proximal to the hymen	-3 cm to +3 cm
Ba	Most distal position of the remaining upper anterior vaginal wall	-3 cm to +tvl
C	Most distal edge of cervix or vaginal cuff scar	
D	Posterior fornix (N/A if post hysterectomy)	
Ap	Posterior vaginal wall 3 cm proximal to the hymen	-3 cm to +3 cm
Bp	Most distal position of the remaining upper posterior vaginal wall	-3 cm to +tvl

**Genital hiatus (gh)** – measured from middle of external urethral meatus to posterior midline hymen

**Perineal body (pb)** – measured from posterior margin of gh to middle of anal opening

**Total vaginal length (tvl)** – depth of vagina when point D or C is reduced to normal position


POP-Q staging criteria	
<b>Stage 0</b>	Aa, Ap, Ba, Bp = -3 cm and C or D $\leq$ - (tvl - 2) cm
<b>Stage I</b>	Stage 0 criteria not met and leading edge < -1 cm
<b>Stage II</b>	Leading edge $\geq$ -1 but $\leq$ +1 cm
<b>Stage III</b>	Leading edge > +1 cm but < + (tvl - 2) cm
<b>Stage IV</b>	Leading edge $\geq$ + (tvl - 2) cm

**Reference:** Bump RC, Mattiasson A, Bø K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10-7.

## Appendix II: Explanation of guidelines and evidence levels

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1 *Development of RCOG Green-top Guidelines* (available on the RCOG website at <http://www.rcog.org.uk/green-top-development>). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels	Grades of recommendations
1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias	<b>A</b> At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; or A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias	<b>B</b> A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias	<b>C</b> A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal	<b>D</b> Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal	<b>Good practice point</b>
2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal	 Recommended best practice based on the clinical experience of the guideline development group
3 Non-analytical studies, e.g. case reports, case series	
4 Expert opinion	

This guideline was produced on behalf of the Royal College of Obstetricians and Gynaecologists and the British Society of Urogynaecology by:

**Mr AM El Naqa FRCOG, Wolverhampton; Miss KL Guerrero FRCOG, Glasgow; and Mr MS Abdel Fattah FRCOG, Aberdeen**

and peer reviewed by:

British Society for Gynaecological Endoscopy; Mr DCY Chou MRCOG, Australia; Mrs AHD Diyaf MRCOG, Barnstaple; Dr LM Dolan FRCOG, Belfast; Dr AA Elkady FRCOG, Greater Cairo, Egypt; Professor CMA Glazener FRCOG, Aberdeen; Mr P Hilton FRCOG, Newcastle upon Tyne; Dr A Khunda FRCOG, Middlesbrough; Mr CJ Mayne FRCOG, Leicester; Professor A Ostrzenski, USA; Mrs CMA Ramage FRCOG, Bradford; RCOG Women's Network; Dr JR Scott FRCOG, Salt Lake City, Utah, USA; Dr JA Short MRCOG, Christchurch, New Zealand; Mrs P Sinha FRCOG, St Leonards-on-Sea; Dr B Thomas MRCOG, Thrissur, India; and Mr PM Tooze-Hobson FRCOG, Birmingham.

RCOG Guidelines Committee lead reviewers were: Dr CJ Crowe MRCOG, London and Dr M Gupta MRCOG, London.

The chairs of the RCOG Guidelines Committee were: Dr M Gupta<sup>1</sup> MRCOG, London; Dr P Owen<sup>2</sup> FRCOG, Glasgow; and Dr AJ Thomson<sup>1</sup> MRCOG, Paisley.

<sup>1</sup> co-chairs from June 2014 <sup>2</sup> until May 2014.

*All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this guideline is available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg46/>.*

The final version is the responsibility of the Guidelines Committee of the RCOG.

The review process will commence in 2018, unless otherwise indicated.

#### DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available.

This means that RCOG Guidelines are unlike protocols or guidelines issued by employers, as they are not intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.