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[Intervention Review]

# Surgery for women with apical vaginal prolapse

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## ABSTRACT

### Background

Apical vaginal prolapse is a descent of the uterus or vaginal vault (post-hysterectomy). Various surgical treatments are available and there are no guidelines to recommend which is the best.

### Objectives

To evaluate the safety and efficacy of any surgical intervention compared to another intervention for the management of apical vaginal prolapse.

### Search methods

We searched the Cochrane Incontinence Group's Specialised Register of controlled trials, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, ClinicalTrials.gov, WHO ICTRP and handsearching of journals and conference proceedings (searched July 2015) and ClinicalTrials.gov (searched January 2016).

### Selection criteria

We included randomised controlled trials (RCTs).

### Data collection and analysis

We used Cochrane methods. Our primary outcomes were awareness of prolapse, repeat surgery and recurrent prolapse (any site).

### Main results

We included 30 RCTs (3414 women) comparing surgical procedures for apical vaginal prolapse. Evidence quality ranged from low to moderate. Limitations included imprecision, poor methodological reporting and inconsistency.

### Vaginal procedures versus sacral colpopexy (six RCTs, n = 583; one to four-year review).

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*Awareness of prolapse* was more common after vaginal procedures (risk ratio (RR) 2.11, 95% confidence interval (CI) 1.06 to 4.21, 3 RCTs, n = 277,  $I^2 = 0\%$ , moderate-quality evidence). If 7% of women are aware of prolapse after sacral colpopexy, 14% (7% to 27%) are likely to be aware after vaginal procedures.

*Repeat surgery for prolapse* was more common after vaginal procedures (RR 2.28, 95% CI 1.20 to 4.32; 4 RCTs, n = 383,  $I^2 = 0\%$ , moderate-quality evidence). The confidence interval suggests that if 4% of women require repeat prolapse surgery after sacral colpopexy, between 5% and 18% would require it after vaginal procedures.

We found no conclusive evidence that vaginal procedures increase *repeat surgery for stress urinary incontinence (SUI)* (RR 1.87, 95% CI 0.72 to 4.86; 4 RCTs, n = 395;  $I^2 = 0\%$ , moderate-quality evidence). If 3% of women require repeat surgery for SUI after sacral colpopexy, between 2% and 16% are likely to do so after vaginal procedures.

*Recurrent prolapse* is probably more common after vaginal procedures (RR 1.89, 95% CI 1.33 to 2.70; 4 RCTs, n = 390;  $I^2 = 41\%$ , moderate-quality evidence). If 23% of women have recurrent prolapse after sacral colpopexy, about 41% (31% to 63%) are likely to do so after vaginal procedures.

The effect of vaginal procedures on *bladder injury* was uncertain (RR 0.57, 95% CI 0.14 to 2.36; 5 RCTs, n = 511;  $I^2 = 0\%$ , moderate-quality evidence).

*SUI* was more common after vaginal procedures (RR 1.86, 95% CI 1.17 to 2.94; 3 RCTs, n = 263;  $I^2 = 0\%$ , moderate-quality evidence).

*Dyspareunia* was also more common after vaginal procedures (RR 2.53, 95% CI 1.17 to 5.50; 3 RCTs, n = 106,  $I^2 = 43\%$ , low-quality evidence).

#### **Vaginal surgery with mesh versus without mesh (6 RCTs, n = 598, 1-3 year review).**

*Awareness of prolapse* - There may be little or no difference between the groups for this outcome (RR 1.08 95% CI 0.35 to 3.30 1 RCT n = 54, low quality evidence). The confidence interval was wide suggesting that if 18% of women are aware of prolapse after surgery without mesh, between 6% and 59% will be aware of prolapse after surgery with mesh.

*Repeat surgery for prolapse* - There may be little or no difference between the groups for this outcome (RR 0.69, 95% CI 0.30 to 1.60; 5 RCTs, n = 497;  $I^2 = 9\%$ , low-quality evidence). If 4% of women require repeat surgery for prolapse after surgery without mesh, 1% to 7% are likely to do so after surgery with mesh.

We found no conclusive evidence that surgery with mesh increases *repeat surgery for SUI* (RR 4.91, 95% CI 0.86 to 27.94; 2 RCTs, n = 220;  $I^2 = 0\%$ , low-quality evidence). The confidence interval was wide suggesting that if 2% of women require repeat surgery for SUI after vaginal colpopexy without mesh, 2% to 53% are likely to do so after surgery with mesh.

We found no clear evidence that surgery with mesh decreases *recurrent prolapse* (RR 0.36, 95% CI 0.09 to 1.40; 3 RCTs n = 269;  $I^2 = 91\%$ , low-quality evidence). The confidence interval was very wide and there was serious inconsistency between the studies.

#### *Other outcomes*

There is probably little or no difference between the groups in rates of SUI (*de novo*) (RR 1.37, 95% CI 0.94 to 1.99; 4 RCTs, n = 295;  $I^2 = 0\%$ , moderate-quality evidence) or dyspareunia (RR 1.21, 95% CI 0.55 to 2.66; 5 RCTs, n = 501;  $I^2 = 0\%$  moderate-quality evidence). We are uncertain whether there is any difference for *bladder injury* (RR 3.00, 95% CI 0.91 to 9.89; 4 RCTs, n = 445;  $I^2 = 0\%$ ; very low-quality evidence).

#### **Vaginal hysterectomy versus alternatives for uterine prolapse (six studies, n = 667)**

No clear conclusions could be reached from the available evidence, though one RCT found that awareness of prolapse was less likely after hysterectomy than after abdominal sacrohysteropexy (RR 0.38, 95% CI 0.15 to 0.98, n = 84, moderate-quality evidence).

#### Other comparisons

There was no evidence of a difference for any of our primary review outcomes between different types of vaginal native tissue repair (two RCTs), comparisons of graft materials for vaginal support (two RCTs), different routes for sacral colpopexy (four RCTs), or between sacral colpopexy with and without continence surgery (four RCTs).

#### **Authors' conclusions**

Sacral colpopexy is associated with lower risk of awareness of prolapse, recurrent prolapse on examination, repeat surgery for prolapse, postoperative SUI and dyspareunia than a variety of vaginal interventions.

The limited evidence does not support use of transvaginal mesh compared to native tissue repair for apical vaginal prolapse. Most of the evaluated transvaginal meshes are no longer available and new lighter meshes currently lack evidence of safety

The evidence was inconclusive when comparing access routes for sacral colpopexy.

No clear conclusion can be reached from the available data comparing uterine preserving surgery versus vaginal hysterectomy for uterine prolapse.

## **PLAIN LANGUAGE SUMMARY**

### **Surgical management of pelvic organ prolapse in women**

#### **Review question**

Which surgical interventions for apical vaginal prolapse have the best outcomes?

#### **Background**

Apical vaginal prolapse is a descent of the uterus or (after hysterectomy) the upper vagina (vault). Various surgical treatments are available and there are no guidelines to recommend which is the best.

#### **Study characteristics**

Thirty randomised controlled trials evaluated 3414 women who underwent surgery for apical vaginal prolapse. The most common comparisons were between vaginal surgery and sacral colpopexy (an abdominal procedure suspending the upper vagina to the sacrum with a graft) (six RCTs), vaginal surgery with mesh versus without (six RCTs), vaginal hysterectomy versus alternatives (six RCTs), and different types or routes of sacral colpopexy (eight RCTs). The evidence is current to July 2015.

#### **Key results**

Compared to various vaginal repairs, sacral colpopexy was associated with lower rates of awareness of prolapse, repeat surgery for prolapse, prolapse on examination, urinary stress incontinence (SUI) and painful intercourse. If 7% of women are aware of prolapse after sacral colpopexy, 14% (7% to 27%) are likely to be aware after vaginal procedures. If 4% of women require repeat prolapse surgery after sacral colpopexy, between 5% and 18% would require it after vaginal procedures.

We found no conclusive evidence that vaginal procedures increase the need for repeat surgery for SUI. If 3% of women require repeat surgery for SUI after sacral colpopexy, between 2% and 16% are likely to do so after vaginal procedures.

The limited evidence does not support the use of transvaginal mesh compared to native tissue repairs. The evidence was imprecise, but suggests that if 18% of women are aware of prolapse after surgery without mesh, between 6% and 59% will be aware after surgery with mesh. If 4% of women require repeat surgery for prolapse after surgery without mesh, 1% to 7% are likely to do so after surgery with mesh. We found no clear evidence that surgery with mesh decreases recurrent prolapse. Most of the evaluated transvaginal meshes are no longer available and new lighter meshes lack evidence of safety.

The evidence was inconclusive in comparisons of uterine preserving surgery versus vaginal hysterectomy, and different access routes for sacral colpopexy.

#### **Quality of the evidence**

Evidence quality ranged from very low to moderate. Limitations included imprecision, poor reporting of study methods and inconsistency.