Surgical management of pelvic organ prolapse in women: a short version Cochrane review
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Abstract

Background
Pelvic organ prolapse may occur in up to 50% of parous women. A variety of urinary, bowel and sexual symptoms may be associated with prolapse.

Objectives
To determine the effects of the many different surgeries in the management of pelvic organ prolapse.

Search strategy
We searched the Cochrane Incontinence Group Specialised Trials Register (searched 3 May 2006) and reference lists of relevant articles. We also contacted researchers in the field.

Selection criteria
Randomised or quasi-randomised controlled trials that included surgical operations for pelvic organ prolapse.

Data collection and analysis
Trials were assessed and data extracted independently by two reviewers. Six investigators were contacted for additional information with five responding.

Main results
Twenty two randomised controlled trials were identified evaluating 2368 women.
Abdominal sacral colpopexy was better than vaginal sacrospinous colpopexy in terms of a lower rate of recurrent vault prolapse (RR 0.23, 95% CI 0.07 to 0.77) and less dyspareunia (RR 0.39, 95% CI 0.18 to 0.86), but the trend towards a lower re-operation rate for prolapse following abdominal sacrocolpopexy was not statistically significant (RR 0.46, 95% CI 0.19 to 1.11). However, the vaginal sacrospinous colpopexy was quicker and cheaper to perform and women had an earlier return to activities of daily living. The data were too few to evaluate other clinical outcomes and adverse events. The three trials contributing to this comparison were clinically heterogeneous.

For the anterior vaginal wall prolapse, standard anterior repair was associated with more recurrent cystoceles than when supplemented by polyglactin mesh inlay (RR 1.39, 95% CI 1.02 to 1.90) or porcine dermis mesh inlay (RR 2.72, 95% CI 1.20 to 6.14), but data on morbidity, other clinical outcomes and for other mesh or graft materials were too few for reliable comparisons.

For posterior vaginal wall prolapse, the vaginal approach was associated with a lower rate of recurrent rectocele and/or enterocele than the transanal approach (RR 0.24, 95% CI 0.09 to 0.64), although there was a higher blood loss and postoperative narcotic use. However, data on the effect of surgery on bowel symptoms and the use of polyglactin mesh inlay or porcine small intestine graft inlay on the risk of recurrent rectocele were insufficient for meta-analysis.

Meta-analysis on the impact of pelvic organ prolapse surgery on continence issues was limited and inconclusive, although about 10% of women developed new urinary symptoms after surgery. Although the addition of tension-free vaginal tape to endopelvic fascia plication (RR 5.5, 95% CI 1.36 to 22.32) and Burch colposuspension to abdominal sacrocolpopexy (RR 2.13, 95% CI 1.39 to 3.24) were followed by a lower risk of women developing new postoperative stress incontinence, but other outcomes, particularly economic, remain to be evaluated.

Authors' conclusions
Abdominal sacrocolpopexy is associated with a lower rate of recurrent vault prolapse and dyspareunia than the vaginal sacrospinous colpopexy. These benefits must be balanced against a longer operating time, longer time to return to activities of daily living and increased cost of the abdominal approach. The use of mesh or graft inlays at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele. Posterior vaginal wall repair may be better than transanal repair in the management of rectoceles in terms of recurrence of prolapse. The addition of a continence procedure to a prolapse repair operation may reduce the incidence of postoperative urinary incontinence but this benefit needs to be balanced against possible differences in costs and adverse effects. Adequately powered randomised controlled clinical trials are urgently needed.

Background
Objectives

To determine the effects of surgery in the management of pelvic organ prolapse and associated bladder, bowel and sexual function.

The following specific comparisons were made, and trials that made other related comparisons were described:

A For the management of upper vaginal prolapse (uterine and vaginal vault)
1. Abdominal sacral colpopexy versus vaginal sacrospinous colpopexy.
2. Vaginal hysterectomy versus uterine preservation.
3. Vaginal hysterectomy with McCall culdoplasty versus vaginal hysterectomy and sacrospinous colpopexy.
4. Vaginal McCall culdoplasty and uterosacral ligament plication versus vaginal sacrospinous colpopexy and repair.

B For the management of anterior vaginal wall prolapse
5. Anterior vaginal wall repair versus the abdominal paravaginal repair in the management of anterior vaginal wall prolapse.
6. For midline cystocele defects, a traditional anterior vaginal wall repair versus anterior vaginal wall repair with graft reinforcement.

C For the management of posterior vaginal wall prolapse
7. Posterior vaginal wall repair versus a transanal repair.
8. Posterior vaginal wall repair versus an abdominal posterior repair.
9. Posterior vaginal wall repair versus posterior vaginal wall repair with graft reinforcement.

D For the management of any type of prolapse
10. Surgical treatment versus conservative treatment in the management of symptomatic pelvic organ prolapse.
11. Surgical treatment versus mechanical devices in the management of pelvic organ prolapse.
12. Open abdominal surgery versus the laparoscopic approach for the management of prolapse.
13. Potential stress urinary incontinence (e.g. detected on reduction of prolapse prior to surgery) treated with formal continence surgery at the time of prolapse surgery, versus being left untreated.
14. Use of native (no mesh) tissue versus mesh or grafts.
15. One type of mesh / graft versus another type of mesh / graft.
16. One type of suture versus another type of suture.
Methods

See full version of Cochrane review

Description of studies

Full reports of 33 potentially eligible studies were assessed, of which twenty two randomised controlled trials were identified on the surgical management of pelvic organ prolapse and met the inclusion criteria: fuller details are tabulated in the complete Cochrane review.

Methodological quality of included studies

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Results

A. Upper vaginal prolapse (uterine and vaginal vault) (Comparison 01)

Six trials provided data regarding the outcome of prolapse surgery for upper vaginal prolapse (Benson 1996; Culligan 2005; Lo 1998; Maher 2004; Meschia 2004a; Roovers 2004). All the trials which used mesh used non-absorbable, permanent mesh except one trial in which an absorbable was compared with a non-absorbable mesh (Culligan 2005).

Objective 1: abdominal sacral colpopexy versus vaginal sacrospinous colpopexy

Three trials were considered to be similar enough to allow combination of data for comparison of abdominal sacral colpopexy and vaginal sacrospinous colpopexy (Benson 1996; Lo 1998; Maher 2004). Abdominal sacral colpopexy was better than vaginal colpopexy in terms of:

- a lower rate of recurrent vault prolapse (3 out of 84 versus 13 out of 85; RR 0.23, 95% CI 0.07 to 0.77, Figure 1) (Benson 1996; Maher 2004);
- the number of women failing to improve to Stage 2 or better (3 out of 52 versus 13 out of 66; RR 0.29, 95% CI 0.09 to 0.97) (Lo 1998);
- less postoperative dyspareunia (7 out of 45 versus 22 out of 61; RR 0.39, 95% CI 0.18 to 0.86) (Benson 1996; Lo 1998; Maher 2004);
- less postoperative stress urinary incontinence (14 out of 47 versus 28 out of 81, RR 0.55, 95% CI 0.32 to 0.95) (Benson 1996; Maher 2004).

However, caution should be exercised when evaluating these data due to significant variation in the methodology of the two trials as described above. There was no statistically significant difference in reoperation rates for stress urinary incontinence (RR 0.6, 95% CI 0.21 to 1.73) (Benson 1996; Lo 1998; Maher 2004).
The lower reoperation rate for prolapse after abdominal surgery did not reach statistical significance (6 out of 84 versus 14 out of 85, RR 1.46, 95% CI 0.19 to 1.11) (Benson 1996; Maher 2004).

The results for intraoperative blood loss were inconsistent in two studies with a mean difference of 298 ml less blood loss in the abdominal group in Lo's study (Lo 1998) and 33 ml more blood loss in Maher's trial (Maher 2004) (Comparison 01.15.01). Benson did not report blood loss but the postoperative change in haemoglobin was not statistically different (Benson 1996).

Women treated abdominally took significantly longer to present with recurrent prolapse (WMD for months to recurrence -10.90, 95% CI -17.12 to -4.68) in one trial (Benson 1996). On the other hand, the sacral (abdominal) colpopexy was associated with a longer operating time (WMD 21 minutes, 95% CI 12 to 30) (Benson 1996; Lo 1998; Maher 2004), longer time to recover (WMD 8.3 days, 95% CI 3.9 to 12.7) (Maher 2004) and was more expensive (WMD US$1334, 95% CI 1027 to 1641) (Benson 1996; Maher 2004) than the vaginal approach.

Although the results for subjective prolapse symptoms favoured the abdominal group, the difference was statistically not significant (subjective failure after abdominal surgery: 9/84 versus 18 out of 85, RR 0.53, 95% CI 0.25 to 1.09) (Benson 1996, Maher 2004). On the limited evidence available, patient's satisfaction (RR 0.82, 95% CI 0.32 to 2.06) (Maher 2004) and objective failure at any site (any pelvic organ prolapse: RR 0.77, 95% CI 0.39 to 1.53,) (Maher 2004) were not clearly different in both groups. Although data were available for bowel outcomes (Comparisons 01.10 and 01.11) and adverse events (Comparison 01.25), they were too few to provide sufficiently precise estimates to identify or rule out clinically important differences.

Objective 2: vaginal hysterectomy versus uterine preservation

In the fourth trial, Roovers compared abdominal sacral hysteropexy against vaginal hysterectomy and repair with vault fixation to the uterosacral-cardinal ligament complex (Roovers 2004). Although more women had subjective prolapse symptoms at one year after abdominal surgery (RR 3.2, 95% CI 1.29 to 7.92), there was no statistically significant difference in the prolapse domain of the urinary distress inventory (UDI) (mean difference 4.1, 95% CI -5.4 to 13.6); nor the score for urinary incontinence (mean difference 6, 95% CI -2 to 14). However, at one year after surgery the vaginal group scored significantly better (lower) scores on the discomfort/pain domain (7.1, 95% CI 1.1 to 13.2), overactive bladder domain (8.7, 95% CI 0.5 to 16.9) and the obstructive micturition domain (10.3, 95% CI 0.6 to 20.1) as compared to the abdominal group. More women in the abdominal group required repeat prolapse repair (RR 9.00, 95% CI 1.19 to 67.85); in the abdominal group, five women (13%) had a reoperation for recurrent cystocele and four women (10.5%) for recurrent uterine prolapse, whereas in the vaginal group only one patient required surgery in the first year for vaginal vault prolapse. The operating time was less for the
abdominal group (WMD -10 minutes, 95% CI -12 to -8), possibly reflecting the less invasive nature of the abdominal procedure in this trial (the uterus was preserved in the abdominal group as opposed to removed in the vaginal group).

In another trial, sacrospinous uterine suspension with uterine preservation was compared with vaginal hysterectomy (Jeng 2005). There were few reports of dyspareunia in either group (Comparison 01.13.03) but there were more adverse symptoms in the sacrospinous suspension arm, mostly due to buttock pain (RR 4.23, 97% CI 1.25 to 14.25) (Jeng 2005). This trial could not be combined with the Roovers 2004 trial as the non-hysterectomy groups were too different (clinical heterogeneity).

**Objective 3: vaginal hysterectomy with McCall culdoplasty versus vaginal hysterectomy and sacrospinous colpopexy:**
No trials identified.

**Objective 4: vaginal McCall culdoplasty and uterosacral ligament plication versus vaginal sacrospinous colpopexy and repair:**
No trials identified.

**Objective 13: Potential stress urinary incontinence (e.g. detected on reduction of prolapse prior to surgery) treated with formal continence surgery at the time of prolapse surgery, versus being left untreated.**
One trial evaluated the effects of adding Burch colposuspension to abdominal sacrocolpopexy (Brubaker 2006). The trial was terminated early (after the first 232 women had been randomised, but data were finally available for a total of 322 women) because of a significant difference in the incontinence rates at 3 months after surgery. Data were not provided for prolapse outcomes, but the addition of Burch colposuspension significantly decreased the incidence of stress urinary incontinence at 3 months after surgery (67 out of 152, 44% versus 35 out of 147, 24% with Burch, RR 1.85, 95% CI 1.32 to 2.6) (Brubaker 2006). However, the operating time was longer (MD -20 minutes, 95% CI -33 to -7) and the blood loss higher (MD -73 ml, 95% CI -73 to -30) (Brubaker 2006) in the Burch group.

**Objective 14: Use of native (no mesh) tissue versus mesh or grafts:**
In one trial (Meschia 2004a) the data were too few to address possible differences in the objective recurrence rate between a repair using the sacrospinous colpopexy and the posterior intravaginal (mesh) sling (0 out of 33 versus 1 out of 33; RR 0.33, 95% CI 0.01 to 7.90, Figure 1) (Meschia 2004a). The operating time was 11 minutes shorter (WMD 11 minutes, 95% CI 2.8 to 19.2) (Meschia 2004a) and blood loss less (WMD 70ml, 95% CI 56 to 84) (Meschia 2004a) with the intravaginal sling. Other clinical outcomes included dyspareunia, faecal incontinence, constipation, stress urinary incontinence, overactive bladder syndrome and voiding dysfunction, but the numbers were too few to draw conclusions. Mesh erosions occurred in 3 out of 33 (9%) women in the IVS group of events.
Objective 15: One type of mesh / graft versus another type of mesh / graft:

One trial (Culligan 2005) compared the abdominal sacral colpopexy using either absorbable cadaveric fascia lata graft (Tutuplast) or nonabsorbable (permanent) monofilament polypropylene mesh (Trelex). There were no recurrences of vaginal vault prolapse in either group, but the objective failure rate for recurrence at any other vaginal site was 14 out of 44 in the fascial graft group and 4 out of 45 in the mesh group (RR 3.58, 95% CI 1.28 to 10.03) (Culligan 2005). There were no vaginal erosions in the 46 women in the fascial graft group but 2 out of 54 women had mesh erosion in the non-absorbable mesh group. No data on bladder, bowel or sexual function were provided.

B. Anterior vaginal wall prolapse (cystocele, urethrocele, paravaginal defect) (Comparison 02)

Eleven trials included a variety of surgical procedures to treat anterior vaginal wall prolapse, with or without stress or occult stress urinary incontinence. (Bump 1996a; Colombo 1996a; Colombo 1997; Colombo 2000; Meschia 2004; Sand 2001; Weber 2001; Cervigni 2005; De Ridder 2004; Gandhi 2005; Meschia 2007). Combination of data was possible for two sets of trials: two were comparable in terms of type of population (women with prolapse only) and types of operation (anterior repair with and without mesh) (Sand 2001; Weber 2001); and the other two in terms of types of operation (endopelvic fascia plication versus needle suspension) (Bump 1996a; Colombo 1997).

Objective 5: anterior vaginal wall repair versus the abdominal paravaginal repair in the management of cystocele:

No trials identified.

Objective 6: for midline cystocele defects, a traditional anterior vaginal wall repair versus anterior vaginal wall repair with mesh reinforcement:

Data from two small trials suggested that traditional anterior repair may be followed by higher objective failure rates than after polyglactin mesh reinforcement of anterior repair (RR 1.48, 95% CI 1.07 to 2.04, Figure 2) (Sand 2001; Weber 2001), but data on reoperation rates were not given and complication rates were similar. Weber did not find significant differences in cure rates for cystocele between the standard cystocele repair (30%), ultralateral repair (46%) and standard plus polyglactin mesh inlay (42%) at mean follow up of 24 months, but the trial was only powered to detect a 30% difference between the groups (Weber 2001).

One trial (Meschia 2007) compared the anterior colporrhaphy without and with porcine dermis inlay (Pelvicol). The trial demonstrated at one-year follow up the objective failure rate of the anterior compartment was 20 out of 103 in the colporrhaphy group as compared to 7/98 in the porcine dermis group (RR 2.72 95% CI 1.20 to 6.14, Figure 2) (Meschia 2007). There were no differences between groups in blood loss, inpatient-days, change in haemoglobin, postoperative voiding dysfunction and dyspareunia but all with wide confidence
intervals. There was one porcine dermis graft rejection requiring surgical removal.

Another trial (Gandhi 2005) compared the anterior colporrhaphy without or with Tutoplast (solvent dehydrated cadaveric fascia lata). At 13 months the objective and subjective failure rates of the anterior compartment were similar (23 out of 78 and 16/76; RR 1.4, 95% CI 0.8 to 2.44, Figure 2 and 6 out of 57 and 6 out of 55; RR 0.96, 95% CI 0.33 to 2.81) (Gandhi 2005). Apart from urinary voiding function there were no other bladder, bowel or sexual function outcomes reported.

The nature of the different mesh types in the latter two trials (Gandhi 2005; Meschia 2007) were considered too dissimilar to combine them in a meta-analysis.

**Objective 15: One type of mesh / graft versus another type of mesh / graft:**

Two trials evaluated different mesh inlays (Cervigni 2005; De Ridder 2004).

Cervigni compared Prolene Soft (n = 36) with porcine dermis (Pelvicol, n = 36) with a mean follow up of 8 months. The objective failure rates (calculated for grade two at the Baden-Walker half-way system) were similar between groups (14 out of 36 and 12 out of 36; RR 1.17, 95% CI 0.63 to 2.16, Figure 2) (Cervigni 2005). Dyspareunia occurred in 11 out of 36 (30%) and 5 out of 36 (14%) (RR 2.2, 95% CI 0.85 to 5.69) (Cervigni 2005) and mesh erosions in 3 out of 36 and 1 out of 36 (RR 3.00, 95% CI 0.33 to 27.5) (Cervigni 2005). Postoperative voiding dysfunction rates were 9 out of 36 and 5 out of 36 (RR 2.07, 95% CI 0.62 to 6.92) (Cervigni 2005).

De Ridder (De Ridder) performed four-defect Raz anterior vaginal wall repairs and added a porcine dermis (Pelvicol) or polyglactin (Vicryl) inlay. Both mesh types are absorbable. Objective failure rates of the anterior compartment at 25 months follow up were 6 out of 63 (9.5%) and 19 out of 62 (31%) respectively (RR 0.31, 95% CI 0.13 to 0.73, Figure 2) (De Ridder 2004). Further prolapse surgery had to be performed in 3 out of 63 and 9 out of 62 women (RR 0.33, 95% CI 0.09 to 1.16) (De Ridder 2004).

The nature of the different types of mesh in the two trials (Cervigni 2005; De Ridder 2004) were considered too dissimilar to combine them in a meta-analysis.

**Other comparisons for anterior vaginal wall prolapse:**

Five other trials were identified which compared different operations for anterior vaginal wall prolapse or different continence procedures for women with urinary incontinence or occult urinary incontinence as well as anterior vaginal wall prolapse (Bump 1996a; Colombo 1996a; Colombo 1997; Colombo 2000; Meschia 2004).

One single trial comparing anterior repair with Burch colposuspension showed statistically significant lower rates of cystocele recurrence (RR 0.09, 95% CI 0.01 to 0.64, Figure 2) (Colombo 2000), but higher rates of persisting urinary
incontinence (RR 3.39, 95% CI 1.40 to 8.22) (Colombo 2000). However, this was not reflected in differences in reoperation rates for either prolapse or incontinence (Comparisons 02.18.03 and 02.19.03) (Colombo 2000). Another small trial reported that more women were incontinent after endopelvic fascia plication than after TVT supplementing prolapse surgery (RR 9, 95% CI 1.23 to 65.85) (Meschia 2004) but the data were too few to comment on the effect on prolapse or other clinical outcomes. However, there was a shorter operating time for the former operation (WMD -19 minutes, 95% CI -29 to -9) (Meschia 2004).

C. Posterior vaginal wall prolapse (rectocele) (Comparison 03)
Two small trials compared vaginal and transanal approaches to the management of rectoceles (Kahn 1999; Nieminen 2004), and two others examined posterior repair with and without mesh reinforcement (Paraiso 2006; Sand 2001). The most recent of these trials compared three techniques to correct posterior vaginal compartment prolapse (Paraiso 2006).

**Objective 7: posterior vaginal wall repair versus a transanal repair:**
Many of the important outcome parameters were not reported thus limiting the data available and the ability to perform meta-analyses. The results for posterior vaginal wall repair were better than for transanal repair in terms of subjective (RR 0.36, 95% CI 0.13 to 1) (Kahn 1999; Nieminen 2004) and objective (RR 0.24, 95% CI 0.09 to 0.64, Figure 3) (Kahn 1999; Nieminen 2004) failure rates (presence of rectocele and/or enterocele). Analysing women with rectocele alone showed that recurrent rectocele occurred in 2 out of 39 in the vaginal group and 7 out of 48 following the transanal repair, a difference that did not reach statistical significance (RR 0.32, 95% CI 0.07 to 1.34, Figure 3) (Kahn 1999; Nieminen 2004). Postoperative enterocele was, however, significantly less common following the vaginal surgery as compared to the transanal group (RR 0.23, 95% CI 0.07 to 0.83, Figure 3) (Kahn 1999; Nieminen 2004).

Postoperative hospital stay was longer after vaginal surgery than after transanal surgery in one trial (mean difference (MD) 1 day, 95% CI 0.47 to 1.53) (Kahn 1999) despite a shorter operating time (MD -7 minutes, 95% CI -12 to -2) (Kahn 1999). The operating times in the other trial (Nieminen 2004) were the same for both groups (35 minutes). When data for operating time were combined (WMD -3.6 minutes), there was significant heterogeneity (P = 0.07, I-squared = 69%) and the difference was not significant if a random effects model was used (95% CI -10.4 to 3.3 minutes). The vaginal approach was associated with a significantly higher blood loss (79 ml, 95% CI 40 to 119) (Kahn 1999; Nieminen 2004) and postoperative narcotic use (Comparison 03.12.01, Kahn 1999) as compared to the transanal approach.

Nieminen reported that the mean depth of rectocele on postoperative defecography was 4.13 cm in the transanal group and this was significantly larger than the 2.73 cm in the vaginal group (WMD -1.43, 95% CI -2.86 to 0, P = 0.05, data not shown). Postoperative difficulties in bowel evacuation were seen in 9 out of 31 in the vaginal group as compared to 14 out of 34 in the transanal...
group, a difference that was not significantly different (RR 0.73, 95% CI 0.37 to 1.42) (Kahn 1999; Nieminen 2004). No significant differences were seen in the rate of incontinence to flatus or faeces postoperatively between the groups, nor in rates of postoperative dyspareunia but the trials were too small for these data to be reliable. There were differences between the trials for the outcome postoperative complications: in one trial, four women had a haematoma and one needed a blood transfusion in the vaginal arm (Kahn 1999) whereas in the other, one woman had a wound infection after transanal operation (Nieminen 2004) (Comparison 03.13.01).

**Objective 8: posterior vaginal wall repair versus an abdominal posterior repair:**
No trials identified.

**Objective 14: posterior vaginal wall repair versus posterior vaginal wall repair with mesh reinforcement:**
One trial compared posterior repair with and without mesh reinforcement (Sand 2001). Rectocele recurrence appeared equally common with and without polyglactin (Vicryl) mesh augmentation (7 out of 67 versus 6 out of 65), but the confidence intervals were wide (RR 1.13, 95% CI 0.40 to 3.19, Figure 3) (Sand 2001). No trial reported mesh erosion.

Another trial compared posterior colporrhaphy, site specific repair and site specific repair augmented with porcine small intestine submucosa graft inlay for repairing rectoceles (Paraiso 2006). There was no statistical difference in objective failure between posterior colporrhaphy and site specific repair (RR 0.64, 95% CI 0.20 to 2.03, Figure 3) (Paraiso 2006). There was a lower objective failure rate at 1 year following the posterior colporrhaphy as compared to porcine graft inlay (RR 0.31, 95% CI 0.11 to 0.84, Figure 3) (Paraiso 2006). However, there were no differences in subjective report of prolapse symptoms (Comparison 03.01.02 and 03). Rates of postoperative dyspareunia were similar between posterior colporrhaphy and site specific repair (RR 1.65, 95% CI 0.71 to 3.81) (Paraiso 2006) and between posterior colporrhaphy and porcine graft groups (RR 2.85, 95% CI 0.91 to 8.96) (Paraiso 2006). There were no significant differences between the groups in operating time (Comparison 03.11), change in haematocrit, postoperative complications (Comparison 03.13), duration of hospital stay, postoperative bowel and sexual function or reoperation rate for prolapse recurrence (Comparison 03.16). The nature of the different grafts utilised in the Sand and Paraiso study did not allow for meta-analysis.

**D. Any type of prolapse (Comparisons 04, 05, 06, 07, 08)**
For the remaining Comparisons, please see full version of Cochrane review

**Discussion**
This is one of three reviews of interventions for pelvic organ prolapse and it should be viewed in that context. In the other two reviews, no randomised trials evaluating either conservative, physical or lifestyle interventions (Hagen 2006) or mechanical devices or pessaries (Adams 2004) were identified.

Amongst the 21 trials that addressed surgical management of pelvic organ prolapse, the quality of the trials was variable. All trials reported an objective evaluation of the specific pelvic floor defect that was repaired, but full vaginal site specific outcomes were only available for seven trials (Colombo 1996a; Colombo 1997; Colombo 2000; Maher 2004; Weber 2001, Cervigni 2005; Meschia 2004a). All but three trials (Brubaker 2006; Cervigni 2005; Jeng 2005) reported median follow up of greater than one year but only three trials reported outcomes at greater than five years (Colombo 1997; Colombo 2000; Lo 1998).

Generally, the impact of surgery on associated pelvic floor symptoms including bladder, bowel and sexual function, quality of life, cost and patient satisfaction were poorly reported. Validated pelvic floor questionnaires were reported in two trials (Maher 2004; Roovers 2004), cost issues also by two trialists (Benson 1996; Maher 2004) and impact of surgery on quality of life and patient satisfaction in one trial (Maher 2004). These deficiencies generally reflect the difficulties associated with prolapse surgery. One of the principal aims of prolapse surgery is to correct the vaginal protrusion and any associated pelvic floor dysfunction, but the anatomical correction itself is likely to impact upon bladder, bowel and sexual function in unpredictable ways. Until recently, neither standardised history, validated pelvic organ prolapse or specific quality of life questionnaires or other outcome assessment tools were available.

It was disappointing that few trials were found which evaluated conservative, physical, lifestyle or mechanical means of prolapse treatment (Adams 2004; Hagen 2004), and none which compared these interventions with surgery. One ongoing trial is comparing different types of sutures (Allahdin 2007).

**Upper vaginal prolapse**

The abdominal sacral colpopexy was associated with a lower rate of recurrent vault prolapse (Benson 1996; Maher 2004), reduced grade of residual prolapse (Lo 1998), greater length of time taken to recurrence of prolapse (Benson 1996) and less dyspareunia (Benson 1996; Lo 1998; Maher 2004) as compared to the vaginal sacrospinous colpopexy. The data were too few to assess possible differences in satisfaction, bowel outcomes or adverse effects reliably. However, the abdominal sacral colpopexy was associated with a longer operating time (Benson 1996; Lo 1998; Maher 2004), a longer time for recovery (Maher 2004), and it was more expensive (Benson 1996; Maher 2004) than the vaginal approach. The finding of less postoperative stress urinary incontinence after the abdominal approach must be viewed with caution due to the different continence procedures performed in the two trials (as described in the Methodology section). The trend towards a lower reoperation rate in the abdominal group did not reach
statistical significance (Benson 1996, Maher 2004). Culligan 2005 reported that there were no recurrent vault prolapses using either abdominal sacral colpopexy with monofilament polypropylene mesh or sacral colpopexy using cadaveric fascia lata graft inlay (Tutoplast), but there was less recurrence of prolapse at any other vaginal site at one year of follow up when mesh was used.

In a fifth trial, more women needed repeat prolapse surgery after abdominal sacral hysteropexy (without hysterectomy), and fewer women had pain, overactive bladder symptoms or obstructive micturition symptoms after vaginal surgery which included hysterectomy (Roovers 2004). A further trial in which women in one arm had uterine preservation reported few relevant outcomes (Jeng 2005). However, the clinical relevance of these trials, which compared different approaches and uterine preservation in one arm and hysterectomy in the other, is debatable.

One trial was too small to demonstrate a difference in anatomical outcome between the vaginal sacrospinous colpopexy and posterior intravaginal slingplasty (Meschia 2004a). Although the posterior intravaginal sling was quicker to perform and showed a significantly reduced blood loss, it was associated with a 9% rate of mesh complications (Meschia 2004a).

Anterior vaginal wall prolapse

There was some evidence from two small trials that absorbable polyglactin mesh (Vicryl) might reduce objective prolapse recurrence compared with anterior repair alone (Sand 2001; Weber 2001). A single randomised controlled trial demonstrated that the porcine dermis augmentation of the anterior vaginal wall might be beneficial in reducing recurrent anterior vaginal wall prolapse (Meschia 2007). Cadaveric fascia lata (Tutoplast) augmentation of anterior vaginal wall was not beneficial in reducing recurrent anterior vaginal wall prolapse (Gandhi 2005). Two further RCTs compared various mesh augmentations. In a single RCT (De Ridder 2004) it was demonstrated that porcine dermis reduces recurrent anterior vaginal wall prolapse compared to polyglactin augmentation whereas Prolene Soft and porcine dermis inlays resulted in similar failure rates (Cervigni 2005). It is pertinent, however, that of these four types of mesh or grafts, only one (Prolene Soft) was non-absorbable, and only used in 36 women in one trial (Cervigni 2005). Data for other symptoms were not reported. Importantly, long-term outcome data were not available, in particular regarding adverse effects such as mesh erosion.

These four studies evaluated five interventions, anterior colporrhaphy and four different grafts, making a meta-analysis inappropriate. The heterogeneity of the meshes used made the comparison of mesh complications impossible. There was a lack of information on functional (subjective) outcomes.
Julian et al found in a non-randomised prospective study that in women who had undergone at least two previous vaginal repairs, the overlaying of a Marlex (Bard) mesh to the anterior vaginal wall repair was associated with lower recurrence rates of cystocele from 33% to 0% (Julian 1996). The Marlex mesh was associated with a mesh erosion rate of 25% (Julian 1996). Flood et al, in a retrospective review of 142 women with Marlex mesh augmentation of anterior vaginal wall repair, reported a 100% success rate for cystoceles at 3.2 years and a mesh erosion rate of only 2% (Flood 1998).

In one other trial concerning women all of whom had stress urinary incontinence as well as prolapse, Burch colposuspension was subjectively better at curing the incontinence and anterior repair was better for the prolapse (Colombo 2000) but the trial was too small to judge whether this affected subsequent reoperation rates or the effect on other aspects of bladder, bowel or sexual function.

Posterior vaginal wall prolapse

Posterior vaginal wall repair performed better than the transanal repair of rectocele in terms of a significantly lower recurrence rate of posterior vaginal wall prolapse in two trials, despite a higher blood loss and greater use of pain relief (Kahn 1999; Nieminen 2004). However, the data were too few to comment on clinical outcomes such as flatus or faecal incontinence, or dyspareunia. More women had difficulties in bowel evacuation after transanal operation but this did not reach statistical significance. In total, five serious adverse effects were reported amongst the 87 women in the two trials.

The trials evaluating mesh augmentation of posterior repair were too small to address this question reliably (Paraiso 2006; Sand 2001), although no woman reported mesh erosion (Sand 2001). In one single well conducted study the posterior colporrhaphy was demonstrated to have a lower failure rate as compared to the site specific repair with Porcine small intestine submucosa graft for rectoceles. There were no significant other differences between the posterior colporrhaphy, site specific repair or site specific repair augmented with Porcine small intestine submucosa in terms of perioperative and postoperative morbidity, functional outcomes, quality of life and bowel and sexual function (Paraiso 2006).

Authors' conclusions

Implications for practice
The data from randomised trials are currently insufficient to guide practice.

The following conclusions from the review relate to the three areas of surgical management of pelvic organ prolapse where at least two randomised controlled
trials have been completed:

- Abdominal sacral colpopexy was associated with a lower rate of recurrent vault prolapse and less dyspareunia than the vaginal sacrospinous colpopexy. The abdominal colpopexy had a longer operating time, longer recovery and higher cost than the vaginal surgery. Data on the subjective success rate, patient satisfaction and impact of the surgery on quality of life were too few for reliable conclusions.
- The limited evidence suggested that the use of an absorbable polyglactin mesh inlay or absorbable porcine dermis at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele, but information on the effects on bladder, bowel or sexual function are limited and inconclusive.
- The limited evidence suggested that posterior vaginal wall repair may have a better anatomical success rate than transanal repair in the management of posterior vaginal wall prolapse but the clinical effects are uncertain.

There were insufficient data to allow evaluation of the impact of prolapse surgery on continence issues but limited information suggested that concomitant TVT or Burch colposuspension might reduce postoperative incontinence rates: this benefit needs to be balanced against possible differences in costs and adverse effects. There was generally a lack of information on the impact of the surgery on quality of life and cost issues.

**Implications for research**
None of the objectives prestated in the protocol for this review have been satisfactorily addressed, and all would benefit from testing in further good quality randomised trials.

More broadly, further evidence on the surgical management of pelvic organ prolapse should include but not be limited to the following:

- Upper vaginal prolapse: vaginal surgery (e.g. vaginal hysterectomy, cervical amputation, uterosacral ligament plication, posterior intravaginal slingplasty or sacrospinous colpopexy); abdominal surgery (e.g. open or laparoscopic sacral colpopexy, abdominal hysterectomy); laparoscopic pelvic floor repair; and the use of mesh or grafts.
- Anterior vaginal wall prolapse: vaginal surgery (e.g. anterior vaginal wall repair, vaginal paravaginal repair); and open or laparoscopic abdominal surgery (e.g. paravaginal repair); and the use of mesh or grafts.
- Posterior vaginal wall prolapse: vaginal surgery (e.g. midline posterior vaginal wall repair, fascial repairs); the abdominal or laparoscopic approach to rectoceles; and the use of mesh or grafts.
• Evaluation of different types of sutures, mesh and grafts.

Other trials relating to pelvic organ prolapse should include comparisons with conservative treatment, including but not limited to, pelvic floor exercises, lifestyle changes and mechanical devices (pessaries). The challenge in prolapse surgery is that while the prolapse itself may cause difficulties with bladder, bowel and sexual function, surgical correction may also affect these functions in unpredictable ways. Therefore, all trials need to include subjective, objective and patient determined outcomes, and the direct interaction with bladder, bowel and sexual function must be measured. The impact of interventions should also be assessed by utilising validated pelvic floor and quality of life questionnaires, morbidity and cost analysis. Ideally, long term outcomes should be reported at least at two and five years after surgery.

The results of a Cochrane Review can be interpreted differently, depending on people’s perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of review authors, and are not necessarily shared by The Cochrane Collaboration.

Potential conflict of interest

The lead review author, Christopher Maher, is an author of one of the included trials (Maher 2004). Another review author, CG, is an author of an ongoing trial (Allahdin 2007).

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