Conservative management of pelvic organ prolapse in women (Review)

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[Intervention Review]

Conservative management of pelvic organ prolapse in women

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ABSTRACT

Background

Pelvic organ prolapse is common, and some degree of prolapse is seen in 50% of parous women. Women with prolapse can experience a variety of pelvic floor symptoms. Treatments include surgery, mechanical devices and conservative management. Conservative management approaches, such as giving lifestyle advice and delivering pelvic floor muscle training, are often used in cases of mild to moderate prolapse.

Objectives

To determine the effects of conservative management (physical interventions and lifestyle interventions) for women with pelvic organ prolapse in comparison with no treatment or other treatment options (such as mechanical devices or surgery).

Search strategy

We searched the Cochrane Incontinence Group Specialised Trials Register (searched on 19 September 2005), MEDLINE (January 1966 to August 2005), MEDLINE In Process & Other Citations (15 September 2005), EMBASE (January 1996 to Week 43 2005), CINAHL (January 1982 to October 2005), PEDro (September 2005), the UK National Research Register (Issue 3, 2005), the US National Institute of Health clinical trial register (5 October 2005), Current Controlled Trials register (5 October 2005), Controlled Clinical Trials (September 2005) and ZETOC (September 2005). We searched the reference lists of relevant articles.

Selection criteria

Randomised and quasi-randomised trials in women with pelvic organ prolapse that included a physical or lifestyle intervention in at least one arm of the trial.

Data collection and analysis

Two reviewers assessed all trials for inclusion/exclusion and methodological quality. Data were extracted by the lead reviewer onto a standard form and cross checked by another. Disagreements were resolved by discussion. Data were processed as described in the Cochrane Handbook for Systematic Reviews of Interventions.

Main results

Three trials of relevance to this review were identified. The largest of these, of pelvic floor muscle training in preventing anterior prolapse from worsening, had significant limitations which affect the generalisability and rigor of the findings. A small feasibility study (which is to be followed up with a larger trial) randomised 47 women to pelvic floor muscle training or control and found suggestions of better outcomes (better self-reported improvement, decreased severity) in the intervention group. The third trial evaluated peri-operative physiotherapy for women undergoing surgery for prolapse and/or incontinence. The authors report that urinary symptoms, pelvic floor muscle function and quality of life were improved more in the treatment group than the control group, but data were not provided to allow this to be assessed. The trial was small and no prolapse-specific outcome measures were used. It was not possible to combine data from the three trials.

Authors' conclusions

Despite there now being reports of three eligible trials in this update, the evidence available is not significant to guide practice. There is some encouragement from a feasibility study that pelvic floor muscle training, delivered by a physiotherapist to symptomatic women in an outpatient setting, may reduce severity of prolapse. Further evidence from larger, better quality randomised control trials is however still necessary.

PLAIN LANGUAGE SUMMARY

Conservative management of pelvic organ prolapse in women

Pelvic organs, such as the uterus, cervix, bladder or bowel, may protrude into the vagina because of weakness in the tissues that normally support them. The symptoms that they cause vary, depending on the type of prolapse. Conservative treatments, such as physiotherapy or lifestyle change, are commonly recommended for prolapse with less severe symptoms. The review found three randomised trials of conservative management from which to gauge their effects. One relatively large trial was not sufficiently well conducted or reported to provide a reliable basis for assessing an exercise programme for elderly Thai women living in the community. A feasibility study involving 47 women provided some evidence of benefit, which is sufficient to justify the large trial that is planned to follow it. The third trial claimed benefits but was reported in a way that could not be used in the analysis. The evidence considered in this review is not sufficient for judging the value of conservative management of pelvic organ prolapse. Large better quality randomised controlled trials are still needed.

BACKGROUND

Pelvic organ prolapse is common and is seen in 50% of parous women (Beck 1991). One recent community survey found that 40% of the general female population aged 45 to 85 years had evidence of pelvic organ prolapse of at least stage two (within 1 cm above or below the hymen) (Slieker-tenHove 2004). Around 10% of women in the community undergo surgery at some time in their lives for the management of prolapse (Olsen 1997). Pelvic organ prolapse includes anterior vaginal wall prolapse (urethrocele, cystocele), posterior vaginal wall prolapse (enterocele, rectocele) and prolapse of the apical segment of the vagina (cervix/uterus, cuff or vault prolapse) (Bump 1996). A woman can present with prolapse of one or more of these compartments.

The aetiology of pelvic organ prolapse is complex and multi-factorial. Risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, ageing, menopause and factors associated with chronically raised intra-abdominal pressure (e.g. heavy lifting) (Bump 1998; Gill 1998; MacLennan 2000).

Women with prolapse commonly have a variety of pelvic floor symptoms. Symptoms directly related to the prolapse include pelvic heaviness; dragging sensation in the vagina; bulge, lump or protrusion coming down from the vagina; and backache. Symptoms of bladder, bowel or sexual dysfunction are frequently present. These symptoms may be related to the prolapsed organ (e.g. poor urinary stream when a cystocele is present or constipation when a rectocele is present) or may be independent of the prolapse (e.g. symptoms of overactive bladder when a cystocele is

present).

Choice of treatment for prolapse depends on the severity of prolapse and its symptoms, and the woman's general health and preference. Options available for treatment can be categorised as conservative, mechanical and surgical.

Conservative or mechanical treatment is generally considered for women with a mild degree of prolapse, those who wish to have more children, and the frail or those unwilling to undergo surgery. Separate Cochrane reviews of surgical (Maher 2004) and mechanical interventions (Adams 2004) have been undertaken.

Conservative treatment for the management of prolapse is defined here as physical or lifestyle interventions. Physical interventions include pelvic floor muscle assessment, pelvic floor exercises and pelvic floor muscle bracing against increased intra-abdominal pressure (e.g. lifting, coughing). The term "pelvic floor muscle training" is used in this review to encompass these components of treatment which are normally used together. For consistency, when describing studies, if authors have used the term "pelvic floor exercises" or "pelvic floor exercise programme" we have referred to pelvic floor muscle training instead. Electrical stimulation and biofeedback are also included under the heading of physical interventions. Lifestyle interventions include weight loss, reducing exacerbating activities (e.g. lifting, coughing) and treating constipation.

Pelvic floor muscle training appears to be effective in the treatment of urinary stress, urge and mixed incontinence (Hay-Smith 2006). However, its role in managing prolapse is not established (Poma 2000). The extent to which any of the lifestyle interventions are effective in managing prolapse is also unknown (Bump 1998). A recent article highlighted the importance of clarifying the place of conservative treatment in the prevention and management of prolapse, particularly in relation to the role of pelvic floor muscle training (Thakar 2002).

The aims of conservative treatment in the management of pelvic organ prolapse include:

- to increase strength, endurance and support of the pelvic floor muscles;
- to prevent the prolapse becoming worse;
- to help decrease the frequency or severity of symptoms caused by prolapse (vaginal, bladder, bowel and sexual symptoms, and backache);
- to avert or delay the need for surgery.

OBJECTIVES

To determine the effects of specified conservative interventions on severity and/or symptoms of pelvic organ prolapse.

The following comparisons were made.

1. Physical interventions versus control/waiting list/no active treatment.

2. Lifestyle interventions versus control/waiting list/no active treatment.

3. Physical interventions versus lifestyle interventions.

4. Physical interventions versus surgery.

5. Lifestyle interventions versus surgery.

6. Physical interventions versus mechanical devices.

7. Lifestyle interventions versus mechanical devices.

8. Combination of physical and lifestyle interventions versus lifestyle interventions alone.

9. Combination of physical and lifestyle interventions versus physical interventions alone.

10. Combination of physical and lifestyle interventions versus surgery.

11. Combination of physical and lifestyle interventions versus mechanical devices.

12. Combination of physical and lifestyle interventions versus control/waiting list/no active treatment.

13. Physical and/or lifestyle interventions supplementing surgery versus surgery alone.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials in which at least one arm was a conservative intervention for pelvic organ prolapse.

Types of participants

Adult women with all severities of pelvic organ prolapse. Prolapse included one or more of the following types:

- anterior vaginal wall prolapse (cystocele, urethrocele);
- posterior vaginal wall prolapse (enterocele, rectocele);
- prolapse of the apical segment of the vagina.

Types of interventions

One arm of the trial was allocation to a physical or lifestyle intervention or a combination of such interventions. Comparison interventions were to include no treatment, surgery or a mechanical device, or physical or lifestyle intervention if appropriate.
The conservative interventions being considered were as follows:

1. physical interventions:

- pelvic floor muscle training;
- pelvic floor muscle training with biofeedback;
- learning to brace pelvic floor muscles against increased intra-abdominal pressure (e.g. lifting, coughing);
- electrical stimulation.

2. lifestyle interventions:

- weight reduction;
- reduction of exacerbating activities (e.g. lifting, coughing);
- treatment of constipation.

Types of outcome measures

The aim of any intervention was to be a reduction in the prolapse or its symptoms while keeping side-effects of the intervention to a minimum. The range of outcome measures to be reviewed included:

A. Patients' observations (primary outcomes)

- perceived resolution of prolapse symptoms
- perceived improvement in prolapse symptoms
- satisfaction with outcome of treatment

B. Objective measures

- severity of prolapse judged on clinical examination e.g. ICS POP-Q system (Bump 1996)
- pelvic floor muscle contraction strength e.g. Modified Oxford Grading scale (Laycock 2001)
- pelvic floor muscle fatigue resistance (e.g. number of repetitions and duration of pelvic floor muscle contractions)
- flow and voiding cystometry
- pad test
- bowel function (e.g. evacuating proctography)

C. Questionnaire measures

- prolapse symptom questionnaire
- bladder, bowel, sexual function questionnaires
- prolapse-specific quality of life questionnaire
- generic quality of life or health status measures e.g. SF-36 (Ware 1992)
- psychological outcome measures e.g. Hospital Anxiety and Depression Score (Zigmond 1983)

D. Socio-economic evaluations

- cost comparisons

E. Adverse events

- associated with pelvic floor muscle training: discomfort, worsening of prolapse
- associated with use of biofeedback, electrical stimulation, surgery: vaginal irritation, vaginal infection, urinary tract infection, pain, intolerance, surgical complications

F. Non pre-specified outcomes judged important when performing the review

Search methods for identification of studies

This review has drawn on the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described under the Incontinence Group's details in *The Cochrane Library* (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library). The register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. Date of the most recent search of the trials register for this review: 15 September 2005. The trials in the Incontinence Group Specialised Register are also contained in CENTRAL. The terms used to search the Incontinence Group Trials Register are given below:
({design.cct*} OR (design.rct*})
AND
{topic.prolapse*}
(All searches were of the keywords field of Reference Manager 9.5 N, ISI ResearchSoft).
For this review extra specific searches were performed by the review authors. These are detailed below.
No language or other restrictions were imposed on any of the searches.

Electronic searches

MEDLINE (January 1966 to Week 2 January 2003) was searched on 3 February 2003 and PREMEDLINE (15 January 2003) was searched on 16 January 2003. For the 2005 update MEDLINE (January 2003 to Week 5 August 2005) was searched on 14 September 2005 and MEDLINE In Process & Other Citations (15 September 2005) was searched on 19 September 2005. All databases were searched on OVID, using the following search terms:
1.prolapse/
2.uterine prolapse/
3.Rectocele/
4.(prolaps$ adj5 (pelvi$ or vagin$ or genit$ or uter$ or vault$ or apical or urethr$ or segment$ or wall$)).tw.
5.cystoc?ele$.tw.
6.rectoc?ele$.tw.

7.urethroc?ele$.tw.
8.enteroc?ele$.tw.
9.proctoc?ele$.tw.
10.sigmoidoc?ele$.tw.
11.(pelvi$ adj3 dysfunct$).tw.
12.(pelvi$ adj3 (disorder$ or relax$)).tw.
13.(vagin$ adj3 defect$).tw.
14.(urogenital adj5 prolaps$).tw.
15.(cervi$ adj5 prolaps$).tw.
16.or/1-15

This set of terms was combined with the first two parts of the Cochrane Highly Sensitive Search Strategy for randomised controlled trials (Appendix 5b.2, Cochrane Handbook, version 4.2, March 2003) using the Boolean operator 'AND'.

EMBASE (1996 to Week 2 2003) was searched on 20 January 2003. For the 2005 update EMBASE (2003 to Week 43 2005) was searched on 25 October 2005. The database was searched on OVID, using the following search terms:

1.pelvic adj5 prolaps$.tw.
2.uterus prolapse/
3.rectocele/
4.vagina prolapse/
5.cystocele/
6.or/1-5
7.randomised controlled trial/
8.controlled study/
9.clinical study/
10.major clinical study/
11.prospective study/
12.meta analysis/
13.exp clinical trial/
14.randomisation/
15.crossover procedure/ or double blind procedure/ or parallel design/ or single blind procedure/
16.placebo/
17.latin square design/
18.exp comparative study/
19.follow up/
20.pilot study/
21.family study/ or feasibility study/ or study/
22.placebo$.tw.
23.random$.tw.
24.(clin$ adj25 trial$).tw.
25.((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
26.factorial.tw.
27.crossover.tw.
28.latin square.tw.
29.(balance$ adj2 block$).tw.
30.or/7-29
31.(nonhuman not human).sh.
32.30 not 31
33.6 and 32

CINAHL (January 1982 to February Week 4 2003) was searched on 13 March 2003, and CINAHL (January 2003 to October Week 1 2005) was searched on 5 October 2005 for the updated review. Both searches were conducted on OVID, using the following search terms:

1.exp pelvic organ prolapse/
2.genital diseases, female/
3.prolapse/
4.uterine prolapse/
5.Rectocele/
6.(prolaps$ adj5 (pelvi$ or vagin$ or genit$ or uter$ or vault$ or apical or urethr$ or segment$ or wall$)).tw.
7.cystoc?ele$.tw.
8.rectoc?ele$.tw.
9.urethroc?ele$.tw.
10.enteroc?ele$.tw.
11.proctoc?ele$.tw.
12.sigmoidoc?ele$.tw.
13.(pelvi$ adj3 dysfunct$).tw.
14.(pelvi$ adj3 (disorder$ or relax$)).tw.
15.(vagin$ adj3 defect$).tw.
16.(urogenital adj5 prolaps$).tw.
17.(cervi$ adj5 prolaps$).tw.
18.((descen$ adj2 (uter$ or genit$ or pelv$)).tw.
19.procident$.tw.
20.(vagin$ adj2 (eversion$ or evert$)).tw.
21.(hernia$ adj2 (bladder$ or cystic or vesico$)).tw.
22.(bladder$ adj2 protru$).tw.
23.(viscer$ adj2 prolap$).tw.
24.hysteropex$.tw.
25.or/1-24
26.placebo$.tw.
27.random$.tw.
28.(clin$ adj25 trial$).tw.
29.((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
30.factorial.tw.
31.crossover.tw.
32.latin square.tw.
33.(balance$ adj2 block$).tw.
34.or/26-33
35.25 and 34

PEDro (the Physiotherapy Evidence Database) (url: www.pedro.fhs.usyd.edu.au) produced by the Centre for Evidence-Based Physiotherapy (CEBP), University of Sydney, Australia was searched on 13 October 2003, and on 30 September 2005 for the updated review, using the search term "prolapse".

The UK National Research Register (Issue 3, 2003, and Issue 3, 2005), the US National Institutes of Health clinical trials register (5 October 2005), the Current Controlled Trials register (5 Oc-

tober 2005), Controlled Clinical Trials (April 2003 and September 2005) and ZETOC database of conference abstracts (April 2003 and September 2005) were searched using the search terms: cystocele, urethrocele, rectocele, vault prolapse, uterine prolapse, vaginal prolapse, pelvic organ prolapse, pelvic floor.

Searching other resources

The reference lists of relevant articles were searched for other possibly relevant trials.

Data collection and analysis

Reports of all possibly eligible studies were assessed for their methodological quality and relevance to the review objectives. Methodological quality was assessed on the basis of: provision of clear inclusion/exclusion criteria, quality of random allocation, use of blinding, similarity of randomised groups, potential for selection bias in analysis (based on assessment of withdrawals and drop-outs, use of an intention to treat analysis). Two reviewers assessed each study independently in terms of whether it related to pelvic organ prolapse, included a conservative intervention and was a randomised controlled trial, and came to an agreement on whether it should be included or excluded. Data extraction was undertaken independently by at least two reviewers and comparisons made to ensure accuracy. Where trial data were not reported adequately, attempts were made to acquire the necessary information from the authors. Studies were excluded if they were not randomised or quasi-randomised trials for women with pelvic organ prolapse. Excluded studies were listed with the reasons for their exclusion. Data were processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2005).

Physical interventions and lifestyle interventions were to be analysed as separate subgroups within the same analyses, if sufficient trials existed.

Meta-analysis was not performed since the two trials which reported prolapse-related outcomes did not have comparable data. If appropriate, in future updates of this review, meta-analysis would be undertaken. For categorical outcomes the numbers reporting an outcome would be related to the numbers at risk in each group to derive a relative risk. For continuous variables means and standard deviations would be used to derive a weighted mean difference. A fixed effect model would be used for calculation of pooled estimates and associated 95% confidence intervals. Differences between trials would be further investigated if significant heterogeneity existed or appeared obvious from visual inspection of results.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Three randomised controlled trials relevant to the review objectives were identified (Hagen 2005; Jarvis 2005; Piya-Anant 2003). The latter two were ongoing trials identified in the original review. There is one trial still awaiting completion (Frawley 2003). Three studies were excluded because they were not comparative trials (Adamkiewicz 2001; Aguirre 2005; Mimura 2000).

Piya-Anant (Piya-Anant 2003) described a trial of pelvic floor muscle training, and advice on reducing constipation, in an elderly Thai population. All women over 60 years of age and living within 10 km of the hospital where the study was conducted were originally assessed for the presence of anterior wall pelvic organ prolapse (the authors refer to this as "genital prolapse"). Clusters of women defined by post-code area were then randomised to an intervention (pelvic floor muscle training and advice to reduce constipation) or control group. The success of the intervention in preventing the worsening of anterior wall prolapse was assessed. There were 654 women included in this cluster randomised controlled trial. Follow-up was conducted at 6, 12 and 24 months. It is not clear from the report that clustering had been taken into account in the analyses.

Hagen (Hagen 2005) described a feasibility study designed to inform the development of a larger multi-centre trial to assess the use of pelvic floor muscle training in the management of pelvic organ prolapse. The feasibility study took the form of a small randomised controlled (n=47), single blind, study and thus the outcome measures from the study are of relevance to this review. The intervention group had 5 physiotherapy appointments and the control group were sent a lifestyle advice leaflet only. Prolapse was assessed by vaginal examination at baseline and at 20 weeks by the woman's physician. A postal questionnaire (including assessment of symptoms and quality or life) was completed by women at baseline, 20 and 26 week follow-up.

Jarvis (Jarvis 2005) described a study to assess the effectiveness of pelvic floor muscle training as an adjunct to surgery. Women who were booked to have surgery to correct pelvic organ prolapse or incontinence were randomised to an intervention (pre-operative and 1 post-operative physiotherapy appointment) or a control group (no physiotherapy). Sixty women were randomised; however, two of those women were not having surgery to correct prolapse. Outcome measures included urinary diaries and pad volume test, pelvic floor muscle strength, bladder symptoms and continence-related quality of life. There were no prolapse-specific outcomes measured.

Risk of bias in included studies

Women were randomised in the Piya-Anant study (Piya-Anant 2003) to either the intervention (n = 330) or the control arm (n

= 324) It was not stated whether women without prolapse were excluded, however numbers presented in the article would suggest they were not. The authors did not report who provided the intervention only that women attended a clinic. The method of randomisation was not described. It was stated that the assessor was blinded both to the previous assessment results of the participant and to their group status. The method of blinding was not reported. There was insufficient detail of women lost to follow-up, and it was unclear whether an intention to treat analysis had been undertaken. The lead author was contacted by letter and then telephone and some clarification regarding methods was obtained, although language was a barrier to communications. It was agreed with the author that a further request for greater detail regarding the results was to be faxed. A response to this request was not received.

In the Hagen study (Hagen 2005) women were randomised using a telephone service set up for the study using the minimisation method of randomisation. Outcome assessment was predominantly by self-reported questionnaire, in which the women taking part knew the group they had been allocated to. Prolapse severity was assessed at a follow-up clinic by the woman's physician who was blind to the group allocation of the woman. Blinding was not always successful as some women disclosed their group allocation during their assessment. Sufficient information on drop-outs was given and an intention to treat analysis was undertaken.

In the Jarvis study (Jarvis 2005) randomisation was generated by a computer in balanced blocks of 20, and randomisation outcomes were stored in opaque envelopes separate from the clinic. It was stated that the physiotherapist assessing the women at follow-up was blind to their status. Sufficient information on drop-outs was given and an intention to treat analysis was undertaken.

Effects of interventions

Trial results are reported under the appropriate comparison heading.

1. Physical interventions versus control/waiting list/no active treatment.

Piya-Anant (Piya-Anant 2003)

At six month follow-up there were no significant differences in the number of women with worse prolapse between the intervention and control groups, either for women classified initially with mild or severe prolapse. For women with mild prolapse at the outset, those in the intervention group were less likely to have worse prolapse at 12 month follow-up than those in the control group ($p < 0.05$) (no data reported). By the 24 month follow-up this difference between groups was no longer evident. For women initially classified with severe prolapse it was reported that, there was no difference between the intervention and control groups at the 12 month follow-up (no figures reported). However, women in the intervention group were reported to be less likely to have worse prolapse at 24 month follow-up (28%) than those in the control group (72%). Actual denominators and numerators were not clearly reported, nor whether analyses accounted for clustering effects (Piya-Anant 2003).

Hagen (Hagen 2005)

Women self-reported at 26 weeks the change they had experienced in their prolapse since the start of the study. The percentage of women reporting their prolapse was the same or worse was significantly less in the intervention group (7/19) than in the control group (16/21) (RR 0.48, 95% CI 0.26 to 0.91, Comparison 01.01.01) (Hagen 2005). Change in prolapse severity was assessed in terms of the change in POP-Q stage and the change in specific POP-Q measurements (anterior measures Aa and Ba were of most interest since most women had anterior prolapse). The percentage of women who had no change or had a deterioration in their POP-Q stage from baseline to 20 weeks was significantly less in the intervention group (6/11) than in the control group (9/9) (RR 0.55, 95% CI 0.32 to 0.94, Comparison 01.01.02) (Hagen 2005). Mean change in Aa for the intervention group (-0.36 (SD 1.86)) did not differ significantly from mean change in the control group (0.67 (SD 0.71)) (mean difference -1.03, 95% CI -.22 to 0.16, Comparison 01.03.02) (Hagen 2005). Mean change in Ba for the intervention group (-1.09 (SD 1.22)) indicated significantly more improvement than for the control group (0.56 (SD 1.01) (mean difference -1.65, 95% CI -2.63 to -0.67, Comparison 01.03.01) (Hagen 2005). There were no significant differences between groups at 26 weeks in either the prolapse symptom score (mean 12.8 (SD 3.4) for intervention, mean 14.5 (SD 4.8) or control (mean difference -1.70, 95% CI -4.35 to 0.95, Comparison 01.08.01) (Hagen 2005) or prolapse QoL score (mean 2.0 (SD 1.5) intervention, mean 2.1 (SD 2.3) control (mean difference -0.10, 95% CI -1.29 to 1.09, Comparison 01.12.01) (Hagen 2005).

2. Lifestyle interventions versus control/waiting list/no active treatment.

No trials identified.

3. Physical interventions versus lifestyle interventions.

No trials identified.

4. Physical interventions versus surgery.

No trials identified.

5. Lifestyle interventions versus surgery.

No trials identified.

6. Physical interventions versus mechanical devices.

No trials identified.

7. Lifestyle interventions versus mechanical devices.

No trials identified.

8. Combination of physical and lifestyle interventions versus lifestyle interventions alone.

No trials identified.

9. Combination of physical and lifestyle interventions versus physical interventions alone.

No trials identified.

10. Combination of physical and lifestyle interventions versus surgery.
No trials identified.
11. Combination of physical and lifestyle interventions versus mechanical devices.
No trials identified.
12. Combination of physical and lifestyle interventions versus control/waiting list/no active treatment.
No trials identified.
13. Physical and/or lifestyle interventions supplementing surgery versus surgery alone.
One trial looked at this comparison (Jarvis 2005). No prolapse-specific outcomes were measured. Results included data for two women who had incontinence surgery only, i.e. who may not have had prolapse. The report describes a significant improvement in urine leakage (measured via a pad volume test) for both the intervention and control groups, but no significant difference in improvement between the groups. Both groups had an improvement in urinary symptoms but the improvement for the intervention group was reported to be significantly greater than for the control group (between group difference in mean reduction 3.8; p = 0.017; 95% CI 0.7, 6.9). Reduction in diurnal frequency was significantly greater in the intervention group (mean reduction 1.5) than in the control group (mean reduction 0.4) (p = 0.024). Improvement in mean maximum pelvic floor muscle squeeze was significantly greater in the intervention group (mean change 2.7 cm H_2O) than the control group (mean change -1.8 cm H_2O) (p = 0.022; 95% CI -9.92, -0.81).

DISCUSSION

Three trials of relevance to this review were identified. The largest of these which considered the effect of pelvic floor muscle training in preventing anterior prolapse from worsening had limitations which affect the generalisability and rigor of the findings (Piya-Anant 2003). The trial focused on anterior prolapse only in a group which included both symptomatic and non-symptomatic women. The outcome for those randomised women who had no prolapse at the outset was not reported. Prolapse severity was measured in a crude and non-standardised fashion, and measurement of other important outcomes (e.g. prolapse symptoms) was not attempted. Denominators and numerators were not clearly reported and analyses did not take into account clustering effects. For these reasons, the authors' conclusion that the pelvic floor muscle programme was effective for severe prolapse should be treated sceptically. Women from the same post-code area (i.e. within a cluster) will have been more similar to each other than to those from a different area. That is, women within a cluster cannot be treated as independent, and analysis of the data should reflect this.

A feasibility study randomised 47 women with grade one or two prolapse (any type) to pelvic floor muscle training or control and found suggestions of better outcomes (improvement in prolapse reported by women and decreased prolapse severity) in the intervention group (Hagen 2005). The sample size was small, however, and the findings need to be confirmed in a larger trial.

The third trial evaluated peri-operative physiotherapy for women undergoing surgery for prolapse and/or incontinence (Jarvis 2005). The authors report that urinary symptoms, pelvic floor muscle function and quality of life were improved more in the treatment group than the control group. The data were reported in such a way that they could not be used in the analysis. The trial was small and no prolapse-specific outcome measures were used.

In conclusion, there is still very little data from randomised controlled trials to inform the comparisons specified in this review. A large, rigorous trial of pelvic floor muscle training is needed in women with confirmed prolapse, using standardised measures of prolapse severity and symptoms. The next step might be to explore the effects of electrical stimulation and biofeedback as these have not been included in trials to date. No trials of lifestyle advice (either on its own or in combination with other treatments) were found. However (Piya-Anant 2003) and (Hagen 2005) reported an element of lifestyle advice within their interventions, although the main focus was pelvic floor muscle training. In order to encourage control women not to drop out Hagen (Hagen 2005) posted them lifestyle advice leaflets containing limited lifestyle information relevant to prolapse which could easily have been accessed from other sources. A trial similar to that of Jarvis (Jarvis 2005) is needed in a prolapse population, with prolapse-specific outcomes, to assess any added benefit of pelvic floor muscle training alongside prolapse surgery. An ongoing trial (Frawley 2003) may lead to evidence regarding the effectiveness of pelvic floor muscle training used in conjunction with surgery, although this is a trial in a mixed group of women, with no prolapse-specific outcomes being measured.

This review is one of three linked reviews addressing the evidence surrounding different types of treatment for pelvic organ prolapse. Together with the reviews of surgical treatment of prolapse (Maher 2004) and mechanical devices for prolapse (Adams 2004) these findings map out what controlled trials are needed in this area.

AUTHORS' CONCLUSIONS

Implications for practice

The limited evidence available from RCTs is not sufficient to provide a secure basis for assessing the value of the conservative management of women with pelvic organ prolapse.

Implications for research

There remains a pressing need for trials of pelvic floor muscle

training. A feasibility study recently completed by Hagen et al (Hagen 2005) is to be followed up with a multi-centre trial of 500 women. Trials are also needed to assess the value of other forms of conservative management.

The Cochrane reviews of surgery (Maher 2004) and mechanical devices (Adams 2004) for pelvic organ prolapse describe the evidence available regarding these other treatment options, and may provide information on suitable comparators for future trials of pelvic floor muscle training.

ACKNOWLEDGEMENTS

Sheila Wallace (Cochrane Incontinence Group) and Philippa Dall (Nursing, Midwifery and Allied Health Professions Research Unit) for assisting with the searching for this review.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Hagen 2005

Methods	Randomised controlled trial, single blind. Stratified by number of deliveries and centre. Automated telephone system for group allocation.
Participants	47 women with grade 1 or 2 prolapse of any type identified at their first appointment at gynaecology outpatient clinics at two centres in Scotland; 23 intervention, 24 control. Dropouts: intervention 4, control 3. Age: intervention mean 55 (SD 7.9) range 37-69, control mean 56 (SD 10.6) range 31-72
Interventions	Women in the intervention group attended 5 physiotherapy sessions over 16 weeks where pelvic floor exercise techniques were taught and advice on modifying lifestyle was given. An individually tailored exercise programme was provided by the physiotherapist which was performed by the women at home. 6 sets of exercises per day was recommended. The control group were sent a lifestyle advice leaflet. Both groups of women had a review appointment with their consultant at 18-20 weeks post-randomisation
Outcomes	POP-Q (baseline and 18-20 weeks), symptom and quality of life questionnaires relating to prolapse, urinary incontinence, faecal incontinence and sexual function (baseline, 20 and 26 weeks). Follow-up until 26 weeks post-randomisation Self-reported change in prolapse at 26 weeks: number same or worse 7/19 intervention , 16/21 control (RR 0.48 CI [0.26, 0.91]) Change in POP-Q severity by 20 weeks: no change or worse stage 6/11 intervention, 9/9 control (RR 0. 55 CI [0.32, 0.94]) Change in POP-Q measurement by 20 weeks: mean change in Aa -0.36 (SD 1.86) intervention, 0.67 (SD 0.71) control (mean difference -1.03 CI [-2.22, 0.16]); mean change in Ba -1.09 (SD 1.22) intervention, 0.56 (SD 1.01) control (mean difference -1.65 CI [-2.63, -0.67]) Prolapse symptom score: mean score 12.8 (SD 3.4) intervention, mean score 14.5 (SD 4.8) control (mean difference -1.70 [-4.35, 0.95]) Prolapse QoL score: mean score 2.0 (SD 1.5) intervention, mean score 2.1 (SD 2.3) control (mean difference -0.10 [-1.29, 1.09])
Notes	This study was a feasibility study intended to test the methods for a larger multi-centre trial

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Jarvis 2005

Methods	randomised controlled, single blind trial. Recruitment April 2000 to December 2003
Participants	60 women who were scheduled to undergo surgery to correct prolapse and or incontinence. 30 intervention, 30 control. Age: intervention mean 62.6 (SD 10.5) range [40-76], control mean 62.8 (SD 11.1) range [47-78]. Dropouts: intervention 4, control 2. Surgery was cancelled for 3 intervention women and 1 control woman. It is not known how many women are therefore included in the data analysis
Interventions	Instructions were given by a physiotherapist on the performance of pelvic floor muscle exercises, and an individually tailored programme of pelvic floor muscle exercises was provided. Information and advice on pelvic bracing, voiding postures and techniques. Women in both the intervention and control group underwent surgical procedures for prolapse and/or incontinence and received standard care. Intervention women saw the physiotherapist on the second post-operative day also to reinforce the exercise program
Outcomes	Urinary frequency, pad volume test, pelvic muscle manometry, bladder function score from a questionnaire, urinary incontinence specific quality of life score from a questionnaire. Women were followed up for 3 months There was a significant improvement in urine leakage for the intervention and control group, but there was no significant difference in improvement between the groups (95% CI -11.4, 72.3 cm3; p=0.150). Both groups had an improvement in urinary symptoms but the improvement for the intervention group was significantly greater than for the control group (between group difference in mean reduction 3.8; p= 0.017; 95% CI 0.7, 6.9). Reduction in diurnal frequency was significantly greater in the intervention group (mean reduction 1.5) than in the control group (mean reduction 0.4) (p=0.024). Improvement in mean maximum squeeze was significantly greater in the intervention group (mean change 2.7 cm H2O) than the control group (mean change -1.8 cm H2O) (p=0.022; 95% CI -9.92, -0.81)
Notes	2 women in the study were to have incontinence surgery without concurrent prolapse surgery, both were in the intervention group The authors did not report the number of women in each analysis or the standard deviations, thus the data were not entered in this review

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Piya-Anant 2003

Methods	Cluster randomised controlled, single blind trial. No detail of randomisation method. Clustering by post code area. Follow-up was conducted at 6, 12 and 24 months.
Participants	654 community-dwelling Thai women, over 60 years of age and living within 10 km of the hospital where the study was conducted , with or without anterior wall pelvic organ prolapse. intervention: n=330, mean (SD) age 67.0 (5.6), dropouts 88 control: n=324, mean (SD) age 66.7 (5.7), dropouts 91

Piya-Anant 2003 (*Continued*)

Interventions	Intervention: instruction in the performance of pelvic floor muscle exercises once a month until performed correctly, 30 exercises "after one meal every day" (note: personal communication with the lead author suggested it was exercise after EACH meal). In addition, advice on diet regarding alleviating constipation (to eat more fruit, vegetables and boiled rice, and to drink at least 2 litres of water a day). No indication of who delivered the intervention. Control: not treatment.
Outcomes	The success of the intervention in preventing the worsening of anterior wall prolapse was assessed. The main outcome recorded was the severity of prolapse, assessed using a study-defined (ie. non-standardised) system: mild (protrusion of anterior wall seen and measured as an area) or severe (protrusion measured as a volume). There were no outcome measures relating to symptoms of prolapse or to constipation, other bowel or urinary symptoms All the women were eventually able to perform the exercises satisfactorily It was reported that at a 6 month follow-up, there were no significant differences in the number of women with worse prolapse between the treatment and control groups, either for women classified initially with mild or severe prolapse. For women with mild prolapse at the outset, those in the intervention group were reported to be less likely to have worse prolapse at 12 month follow-up than those in the control group. ($p<0.05$). By the 24 month follow-up, however this difference between the groups was no longer evident. For women initially classified with severe prolapse, there was no difference between the treatment and control groups at the 12 month follow-up. However, women in the intervention group were less likely to have worse prolapse at 24 month follow-up (28%) than those in the control group (72%) ($p<0.05$). These two percentages were the only outcome data reported. It is not clear whether or not clustering was allowed for in the analysis
Notes	Initially 682 women were examined for prolapse: 477 were found to have either "mild" or "severe" prolapse and 205 had no prolapse. 654 of the 682 women were eligible for the trial thus implying that some women with no prolapse were included. However trial results were only presented for women who originally had mild and severe prolapse The actual numbers of women who became worse, and the numbers of women assessed at each follow up were not always presented. Requests for additional data with more detailed breakdown have so far been unsuccessful It is not clear who delivered the intervention, only that women attended a clinic The duration of hold of the pelvic floor muscle contractions was not reported

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Adamkiewicz 2001	Not an RCT. Women with pelvic organ prolapse stage I to III (ICS classification) were included in the study. Intervention includes pelvic floor exercises combines with an intravaginal device (Kolpexin). No control group. Outcomes assessed at initial visit and at 6 weeks. The distance between the introitus and the cervix increased (from 6.7±0.9 to 9.0±1.4 cm) as did the distance between the introitus and levator ani (from 0.69±0.88 to 2.07±1.41 cm). The width of the genital hiatus decreased (from 4.12±0.27 to 3.78±0.30 cm). The separate effects of pelvic floor exercises and Kolpexin could not be elucidated
Aguirre 2005	Not an RCT. Thirty-nine women with stage three or higher vaginal prolapse were included in the study. Intervention includes pelvic floor exercises combines with an intravaginal device (Colpexin®). No control group. At sixteen weeks follow up, 63% showed increased muscle function, Incontinence Impact Questionnaire scores showed no change, however Urogenitary Distress Inventory ratings demonstrated a significant improvement
Mimura 2000	Not an RCT. Intervention includes defacetory behavioural therapy, counselling, health education, biofeedback (EMG), and coordination exercises (details in Storrie JB, British Journal of Nursing, 1997, Vol. 6, No. 3). No control group. Patients were 32 women with rectocele of 2 cm or more. At 10 months follow-up, 12% were cured of bowel symptoms, 88% still experiencing some bowel symptoms. Outcome for prolapse not measured. Three women went on to have a prolapse repair, one a colostomy

Characteristics of ongoing studies *[ordered by study ID]*

Frawley 2003

Trial name or title	The effect of a physiotherapy treatment program for gynaecological surgery: a prospective, single blind RCT
Methods	
Participants	58 women having vaginal gynaecological surgery (vaginal hysterectomy/ laparoscopic assisted vaginal hysterectomy/ prolapse repair) were initially recruited into the study. To date 11 women have dropped out of the study
Interventions	Intervention group: 1 pre-op and 7 post-op outpatient treatments consisting of PFMT, bladder/bowel advice and treatment of any other presenting symptoms Control group: routine medical and surgical care
Outcomes	Symptom severity (Urogenital Distress Inventory, Incontinence Impact Questionnaire, bowel, sexual function) general health and exercise, economic analysis - evaluated pre-op, 3, 6 and 12 months post-op
Starting date	June 2002
Contact information	Helena Frawley Pelvic Floor Physiotherapist, Melbourne Australia Tel: +61 3 98890809 e-mail h.frawley@pgrad.unimelb.edu.au

Notes	Recruitment has closed, and the last subject should complete the study in April 2006. Severity of prolapse is not measured objectively

DATA AND ANALYSES

Comparison 1. PFMT versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 number not improved or cured	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 self-report of prolapse same or worse at 26 weeks	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 no change or worse POP-Q stage at 20 weeks	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 number not satisfied	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
3 mean prolapse severity score	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 mean post - pre POP-Q Ba measurement	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 mean post - pre POP-Q Aa measurement	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 mean pelvic floor muscle strength	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 number with micturition abnormality	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
6 mean pad test volume	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7 number with defaecatory abnormality	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8 mean prolapse symptom score	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
8.1 mean prolapse symptom score at 26 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
9 mean bladder symptom score	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
10 mean bowel symptom score	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
11 mean sexual function symptom score	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
12 mean prolapse QoL score	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
12.1 mean score for prolapse interference with everyday life at 26 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
13 mean generic QoL score	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
14 mean psychological test score	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
15 mean cost	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
16 no. reporting adverse event	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

Analysis 1.1. Comparison 1 PFMT versus no treatment, Outcome 1 number not improved or cured.

Review: Conservative management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 1 number not improved or cured

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 self-report of prolapse same or worse at 26 weeks				
Hagen 2005	7/19	16/21		0.48 [0.26, 0.91]
2 no change or worse POP-Q stage at 20 weeks				
Hagen 2005	6/11	9/9		0.57 [0.33, 0.98]

Analysis 1.3. Comparison 1 PFMT versus no treatment, Outcome 3 mean prolapse severity score.

Review: Conservative management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 3 mean prolapse severity score

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 mean post - pre POP-Q Ba measurement						
Hagen 2005	11	-1.09 (1.22)	9	0.56 (1.01)		-1.65 [-2.63, -0.67]
2 mean post - pre POP-Q Aa measurement						
Hagen 2005	11	-0.36 (1.86)	9	0.67 (0.71)		-1.03 [-2.22, 0.16]

Analysis 1.8. Comparison 1 PFMT versus no treatment, Outcome 8 mean prolapse symptom score.

Review: Conservative management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 8 mean prolapse symptom score

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 mean prolapse symptom score at 26 weeks						
Hagen 2005	17	12.8 (3.4)	20	14.5 (4.8)		-1.70 [-4.35, 0.95]

Analysis 1.12. Comparison 1 PFMT versus no treatment, Outcome 12 mean prolapse QoL score.

Review: Conservative management of pelvic organ prolapse in women

Comparison: 1 PFMT versus no treatment

Outcome: 12 mean prolapse QoL score

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 mean score for prolapse interference with everyday life at 26 weeks						
Hagen 2005	19	2 (1.5)	21	2.1 (2.3)		-0.10 [-1.29, 1.09]

WHAT'S NEW

Last assessed as up-to-date: 22 August 2006.

Date	Event	Description
23 April 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2002

Review first published: Issue 2, 2004

Date	Event	Description
23 August 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

SH carried out searching, reviewed documents and produced the final review.

DS reviewed documents and contributed to the writing of the final review.

EA contributed to the writing of the final review.

CM contributed to the writing of the final review.

DECLARATIONS OF INTEREST

Suzanne Hagen was the Principal Investigator of one of the included studies (Hagen 2005), and was one of the reviewers who carried out the study quality assessment and data extraction.

SOURCES OF SUPPORT

Internal sources

- Chief Scientist Office, Scottish Executive Health Department, UK.

External sources

- National Health Service Research and Development Programme, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

Exercise Therapy; Pelvic Floor; Prolapse; Randomized Controlled Trials as Topic; Rectal Prolapse [*therapy]; Urethral Diseases [*therapy]; Urinary Bladder Diseases [*therapy]; Uterine Prolapse [*therapy]; Vaginal Diseases [*therapy]

MeSH check words

Adult; Female; Humans