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CONSERVATIVE PREVENTION AND MANAGEMENT OF PELVIC ORGAN PROLAPSE IN WOMEN: A MAJOR COCHRANE REVIEW UPDATE

Hypothesis / aims of study
Pelvic organ prolapse (POP) 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 (PFMT), are often used in cases of mild to moderate prolapse.

We sought to determine the effects of conservative management (physical and lifestyle interventions) for the prevention or treatment of pelvic organ prolapse in comparison with no treatment or other treatment options (such as mechanical devices or surgery). This is a major update of a Cochrane review previously updated in 2011 [1].

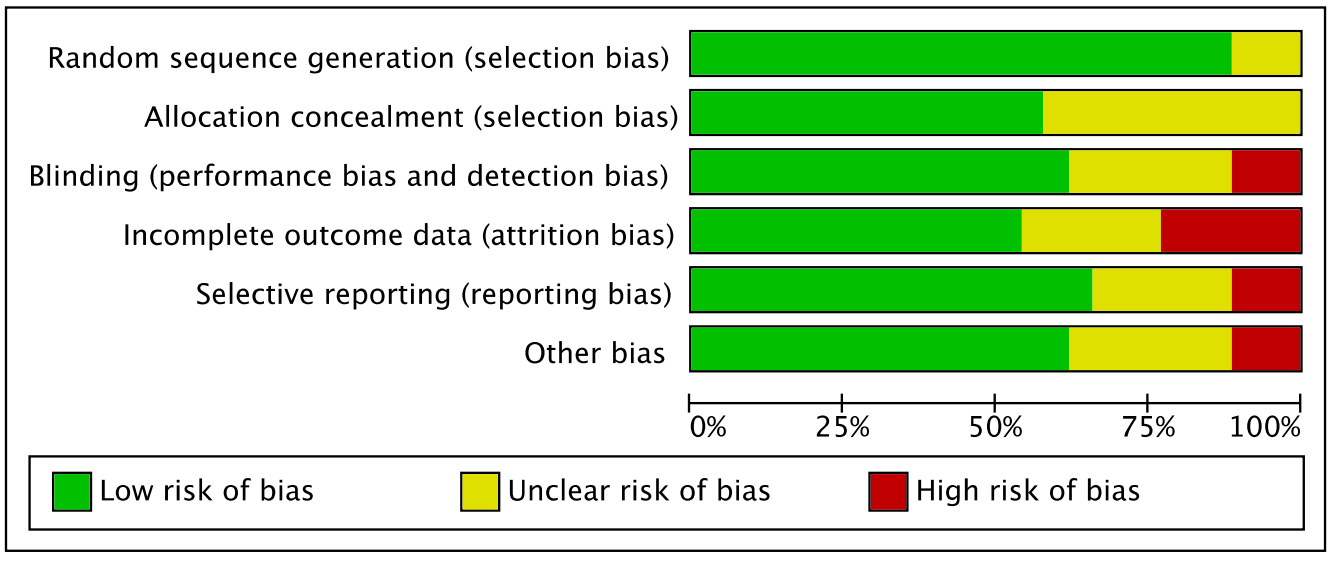
Study design, materials and methods
We systematically searched 10 electronic databases (from 01 May 2010 to 15 September 2015) including the Cochrane Incontinence Group Trials Register; CENTRAL; CINAHL; PEDro; EMBASE; WHO ICTRP; ClinicalTrials.gov; Current Controlled Trials register; ZETOC database of conference abstracts to identify published, unpublished and ongoing randomised controlled trials (RCTs). We included all RCTs in women with POP that included a physical or lifestyle intervention in at least one arm of the trial.

Two reviewers independently assessed quality of included RCTs and extracted data including study quality, study setting, participants (age and sex; how diagnosis was confirmed; POP severity; inclusion and exclusion criteria), intervention (description of materials, procedures, delivery mode, duration, regimen and adherence to treatment), outcome measures, attrition, duration of follow-up and the type and number of any reported adverse events. Details of intervention were reported in accordance with the template for intervention description and replication (TIDieR) checklist [2]. We also documented the outcome measures used and time points, whether there was evidence of an a priori sample size calculation and if intention-to-treat (ITT) analysis was employed. We contacted investigators for any missing data (or data in a suitable format) for inclusion in the review.

Results
We identified 7374 records. From 133 abstracts and 74 full papers we extracted data from 24 RCTs (n= 3320); 18 of these trials are new to this update. The majority of the RCTs (n=13) relate to PFMT as a treatment for prolapse versus a control or alternative type of physical intervention. Six trials examined the role of PFMT as an adjunct to surgery; 5 trials compared surgery plus PFMT with surgery alone, and one trial compared surgery with PFMT. We identified 3 trials involving PFMT and pessaries; one comparing pessary plus PFMT versus pessary alone and 2 RCTs comparing pessary plus PFMT versus PFMT alone. Two trials aimed at evaluating the role of PFMT in the prevention of POP were also identified. No trials were found of lifestyle interventions.

The quality of trials varied widely (see Figure 1). Although the risk of bias of the included studies was generally judged as low for randomisation; allocation concealment was not clearly reported in 45% of trials and assessor blinding was unreported (or assessors were not blinded) in 40% of trials; 20% of trials had incomplete data (Figure 1).

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Interpretation of results

Prevention

There is limited evidence from two robust trials that PFMT can prevent symptoms of prolapse in the longer term after childbirth, but not immediately after giving birth. However, the trials were conducted in different populations of women. Further high quality trials are needed in this area.

Treatment:

(i) PFMT alone

Based on previous studies and new evidence from two rigorously conducted trials, we conclude that PFMT compared to a minimal, no treatment control can improve the symptoms of prolapse. Evidence about PFMT in comparison to other types of control such as other forms of PFMT delivery is emerging but no strong conclusions can be made as yet.

(ii) PFMT and surgery

Although there were five new randomised studies in this update, only one trial was both at low risk of bias and of adequate size. It found no evidence of an effect of PFMT at 2 years in women having vault prolapse repair.

(iii) PFMT and pessary

We identified one pilot trial with a very small sample size, which did not contribute to the evidence. The other two trials were larger and concluded no difference between pessary plus PFMT and PFMT alone in terms of muscle strength at 4 months or symptoms at 12 months.

Concluding message

There are now some rigorous trial findings to support the use of PFMT as a treatment for women with prolapse. There is some new evidence that combined pessary and PFMT and PFMT alone can be equally effective. Other comparisons which have not been addressed in trials to date and warrant consideration include those involving lifestyle change interventions. Further evidence relating to effectiveness and cost-effectiveness of PFMT of different intensities, for symptomatic prolapse in the medium and long term is needed. Trials might also explore the effects of electrical stimulation and biofeedback as these have not been formally included in trials to date.

References

1. Hagen, S. and Stark, D. Conservative prevention and management of pelvic organ prolapse in women. Cochrane database of systematic reviews, 2011, 12, CD003882
2. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, Lamb SE, Dixon-Woods M, McCulloch P, Wyatt JC, Chan AW, Michie S. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687

Disclosures

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