

Conservative management for female urinary incontinence and pelvic organ prolapse review 2013: Summary of the 5th International Consultation on Incontinence

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Potential conflicts of interest: Dr. Bradley reports grants from NIH and Dept Veterans Administration, outside the submitted work. Dr. Hunter reports grants from Allergan, outside the submitted work.

Abstract

Aims

The objective of the 5th International Consultation on Incontinence (ICI) chapter on Adult Conservative Management was to review and summarize the new evidence on conservative management of urinary incontinence (UI) and pelvic organ prolapse (POP) in order to compile a current reference source for clinicians, health researchers, and service planners. In this paper, we present the review highlights and new evidence on female conservative management.

Methods

Revision and updates of the 4th ICI Report using systematic review covering years 2008–2012.

Results

Each section begins with a brief definition and description of the intervention followed by a summary, where possible, of both the state and level of evidence for prevention and treatment, and ends with a “grade of recommendation.” The paper concludes with areas identified as requiring further research.

Conclusions

For UI, there are no prevention trials on lifestyle interventions. There are, however, few new intervention trials of lifestyle interventions involving weight loss and fluid intake with improved

levels of evidence and grade of recommendation. Outside of pre- and post-natal pelvic floor muscle training (PFMT) trials for the prevention of female UI, there is a dearth of PFMT prevention trials for women with UI. PFMT remains the first-line treatment for female UI with high levels of evidence and grades of recommendation. Bladder training levels of evidence and grades of recommendation are maintained. For POP, new evidence supports the effectiveness of physiotherapy in the treatment of POP and there are now improved levels of evidence and grades of recommendation. *Neurourol. Urodynam.* 35:15–20, 2016. © 2014 Wiley Periodicals, Inc.

INTRODUCTION

Conservative treatment for urinary incontinence (UI) or pelvic organ prolapse (POP) is defined as any therapy that does not involve medication or surgical treatment, including lifestyle interventions, physical therapies, scheduled voiding regimens, complementary and alternative medicines, and/or anti-incontinence devices or pessaries.[1] Research on the effectiveness of conservative management continues to grow and was updated in the 2013 International Consultation on Incontinence (ICI), in Chapter 12 “Adult Conservative Management.”[2] The following paper presents the review highlights in conservative management and provides the levels of evidence and grades of recommendation.

MATERIALS AND METHODS

Using the previous review published in 2008 as a baseline,[1] an updated literature search of randomised controlled trials (RCTs) on female conservative management was conducted from January 2008 to August 2012. For each conservative intervention, a brief definition and description is provided, followed by the state of the science, level of evidence, and grade of recommendation. In addition, areas identified for further research are presented in the Appendix.

In line with the recommendations of the Cochrane Incontinence Review group and the International Consultation on Incontinence Research Society (ICI-RS), the primary outcome of interest was the individual's subjective report of UI and the secondary outcomes were UI-specific QoL questionnaires, symptom severity and objective measurements such as those provided by pad testing. Full descriptions of the quality of data, the quantitative results of individual trials or meta-analyses, and the outcomes such as economic analyses, pelvic floor muscle (PFM) function and adherence measures can be found in the 2013 ICI chapter.[2]

RESULTS

1. Urinary incontinence

(1a) Lifestyle interventions

Lifestyle interventions include weight loss, diet changes, fluid intake modifications, avoiding constipation and straining, smoking cessation, and increased physical activity.[3]

Weight loss. Obesity is an independent risk factor for the prevalence of UI. Three new RCTs were added; all report significant improvement in UI associated with weight loss.[4-6] Massive weight loss (15 to 20 BMI points) decreases UI in morbid obesity (Level of Evidence: 2). Moderate weight loss is effective in decreasing UI if combined with exercise. (Level of Evidence: 1).

Physical activity. A new prospective study[7] on the risk of incident UI was added. There is good prospective cohort information suggesting that moderate exercise decreases the incidence of UI in middle-aged and older women; this effect may be mediated by weight control (Level of Evidence: 3).

Physical forces (exercise and work). It was previously reported that strenuous exercise may potentially unmask SUI and heavy lifting may predispose women to genital prolapse and/or UI. No new research was found comparing the prevalence of UI with heavy or high impact activity.

Smoking. Smoking may increase the risk for more severe UI,[8] but no RCTs were found.

Dietary factors.

- Diet. Epidemiological data suggest diet may play a role in UI but no RCT was identified that examined the effect of dietary changes alone. One new population study[9] found that greater energy intake was associated with LUTS.
- Caffeine. Subjective data provides some support for caffeine reduction as part an overall healthy diet.[10, 11] No new trials were found.
- Fluid intake. One new crossover trial[12] was added that found a 25% reduction in fluid intake could decrease frequency, urgency, and nocturia but not UI.
- Constipation. No published RCTs were identified on reduction of UI and bowel function regulation.

Recommendations:

- Weight loss in obese and morbidly obese individuals should be considered a first-line treatment to reduce UI prevalence (Grade of Recommendation: A).
- Moderate exercise may help to decrease the incidence of UI; however, this effect may be mediated by weight control (Grade of Recommendation: C).
- A minor decrease in fluid intake (25%) may alleviate UI provided that the individual's baseline consumption is not below 30 ml/kg a day (Grade of Recommendation: B).
- Caffeine reduction may help alleviate incontinence (Grade of Recommendation: B).

(1b) Pelvic floor muscle training (PFMT)

Pelvic floor muscle training (PFMT) involves directly contracting the PFMs in an exercise program specifically designed to increase muscle strength, endurance, rapidity, and coordination.

Is PFMT effective in the prevention of UI in pregnant women? One new prevention trial was included in the update.[13] Continent women who were expecting their first baby and who participated in a more “intensive and supervised” PFMT program than in usual antepartum care were less likely to experience UI from late pregnancy up to 6 months postpartum (Level of Evidence: 1).

Recommendation: Continent primiparas should be offered a supervised, high-intensity strengthening antepartum PFMT program to prevent postpartum UI (Grade of Recommendation: A). The usual approach to PFMT during pregnancy (i.e., verbal or written instructions without confirmation of correct contraction or supervised training) should be reviewed.

Is PFMT effective in the treatment of UI in childbearing women? No new trials were added to those previously reviewed. Postpartum women with UI who are taught PFMT and supervised by a health professional are less likely to have UI than those in standard care or relaxation massage up to 6–12 months following delivery (Level of Evidence: 1).

Recommendation: PFMT should be offered as a first-line conservative therapy for persistent UI symptoms 3 months postpartum (Grade of Recommendation: A). Intensive PFMT (in terms of supervision and exercise content) is likely to increase treatment effect (Grade of Recommendation: B).

Is PFMT effective in the prevention AND treatment of UI in childbearing women? Two new trials[14, 15] were added to those previously published.

For antepartum PFMT: Intensive supervised PFMT reduces UI prevalence in late pregnancy and 3–6 months postpartum;[15, 16] but this effect was no longer evident 6 years after the indexed delivery in pregnant women having their first baby (Level of Evidence: 2).[16]

For postpartum PFMT: In primiparous and multiparous women at potentially greater risk of postpartum UI after a large baby or forceps delivery, intensive supervised PFMT reduces UI prevalence at 3 months postpartum but not at 1 year (Level of Evidence: 2).

Recommendation: Health providers should carefully consider the cost/benefit of population-based approaches to health professional taught antepartum or postpartum PFMT including health professional instruction to all pregnant or postpartum women regardless of their current or prior continence status (Grade of Recommendation: B).

Is PFMT effective for the treatment of UI in women in general? Three new trials[17-19] were added for a total of 16 RCTs comparing PFMT to an alternate. PFMT is better than no treatment, a placebo drug or an inactive control for women with stress (SUI), urge (UUI), or mixed (MUI) urinary incontinence (Level of Evidence: 1).[2] The benefit of PFMT in women with SUI does not seem to decrease with increased age.[20]

Recommendation: Supervised PFMT should be offered as a first-line conservative therapy to those with stress, urge, or mixed UI (Grade of Recommendation: A). Clinicians should provide the most intensive PFMT program possible. Programs taught and supervised by a trained health professional are better than self-directed programs and more instructor contact is better than less (Grade of Recommendation: A).

(1c) Biofeedback assisted PFMT

Biofeedback is a technique used to learn to control one's body function (in this case PFM function).

Is biofeedback assisted PFMT better than PFMT alone?

For clinic based biofeedback: Studies were inconsistent. The larger trials indicated no statistically significant differences between biofeedback assisted and non-biofeedback PFMT for self-reported cure, cure/improvement, or leakage episodes per day or quality of life (Level of Evidence: 1).[2]

For home biofeedback: There were fewer data. In a single robust trial, there were no statistically significant differences between home biofeedback and non-biofeedback PFMT for self-reported cure, cure/improvement, or quality of life for women with urodynamic SUI (Level of Evidence: 2).[2]

Although studies are inconsistent, there does not appear to be a clear benefit of adding clinic (Grade of Recommendation: A) or home based biofeedback (Grade of Recommendation: B) to a PFMT program.

(1d) Weighted vaginal cones (VCs)

Weighted vaginal cones (VCs) were developed to provide progressive muscular overload during PFMT.

Are VCs better than no treatment, placebo, or control? No new trials were added to the four previously published. VCs appear better than control for subjective reporting of cure, cure/improvement, and QoL impact in those with SUI (Level of Evidence: 1).[2]

Recommendation: For women with SUI, VCs with training sessions supervised by a trained health professional can be a first-line therapy for women who are able and prepared to use them (Grade of Recommendation: B). Assessment by a trained health professional is recommended (Grade of Recommendation: D).[2]

(1e) Electrical Stimulation (EStim)

Electrical stimulation (EStim) is delivered through an electrical device that emits a current through unbroken skin via small electrodes positioned to stimulate specific muscle groups. It is used to improve the functioning of severely weakened and/or atrophied PFMs in women with SUI and to inhibit detrusor over-activity (DO) in women with UUI.[2]

Is EStim better than no active treatment (placebo, sham, control, or no treatment) for the treatment of UI? No new trials were added to the list of 17 previously published trials that compared EStim with no active treatment.[2] But a recent systematic review of peripheral tibial nerve stimulation[21] supports the results of other methods of E-stimulation for treatment of UI symptoms. The evidence suggests that EStim might be more effective than no treatment in improving symptoms in women with SUI, UUI, or DO (Level of Evidence: 2). Adverse effects appear uncommon, but some experience discomfort with the treatment.[2]

Recommendation: EStim may be better than no treatment in improving symptoms. Some cannot use it due to contraindications or because they dislike it or experience difficulties in using it (Grade of Recommendation: B).[2]

(1f) Scheduled voiding regimens: Bladder Training

Bladder training (BT) is a term used to describe any type of scheduled toileting intervention, creating difficulty in interpreting research reports with few details. Regimens share a common feature of a toileting schedule but differ in adjustments of the schedule, active/passive involvement of the patient, patient education (urgency control, stress leakage prevention), use of reinforcement techniques, and the nature of clinician/patient interactions.

Is bladder training (BT) better than no treatment, placebo, or control treatments? No new trials were added to the previous five published trials. Current trials are small and of variable quality. There is only minimal evidence that BT is an effective treatment for SUI, UUI, and MUI (Level of Evidence: 1).[2]

Recommendation: BT may be an appropriate first-line treatment for UI (Grade of Recommendation A).[2]

Is BT better than other treatments? One new trial[22] was added to the two previously published trials. In the previous review, no statistically significant differences were found between PFMT and BT (Level of Evidence: 2) in women with SUI and/or DO or UI. In contrast, in the recent trial of women with SUI[22] symptoms, leakage episodes and QoL were statistically significantly better in the PFMT group (Level of Evidence: 2).

Recommendation: For women with UUI or MUI, PFMT and BT are recommended effective first-line conservative therapies (Grade of Recommendation: B). For women with SUI, PFMT is better than BT as a first-line conservative therapy (Grade of Recommendation: B).

There are no new trials comparing BT to drug therapy. It remains unclear whether BT is more effective than drug therapy for women with DO or UUI (Level of Evidence: 1). This is consistent with the Cochrane review,[23] which concluded that there was insufficient evidence to determine whether first-line therapy should be BT or anticholinergic drugs.

Recommendation: Either BT or anticholinergic drugs for women with DO or UUI may be effective (Grade of Recommendation: B). BT may be preferred by some because it does not produce the side effects and adverse events associated with drug therapy (Grade of Recommendation: D).

2. Pelvic Organ Prolapse (POP)

POP is characterised by a variety of pelvic floor symptoms. They include dragging in the vagina, feeling of a lump in the vagina, urinary symptoms, bowel symptoms, and discomfort during intercourse. The degree of uterine descent can be graded by the POPQ staging system and is based on the position of the most distal portion of the prolapse during the Valsalva maneuver.

Treatment depends on the severity of the prolapse and its symptoms, and the woman's general health. Conservative treatment is generally considered for those with a mild degree of prolapse, those who wish to have more children, the frail, or those unwilling to undergo surgery. Conservative treatment for POP includes lifestyle interventions, physical therapies, and pessaries.

(2.1) Lifestyle interventions for POP symptoms

Lifestyle interventions include weight loss, reducing activities that strain the pelvic floor and treating constipation; the objective is to avoid further exacerbation of the prolapse by decreasing intra-abdominal pressure.

Is lifestyle intervention effective in the prevention of POP? There are no prospective studies of lifestyle interventions to prevent a prolapse. However, additional observational studies were identified.

Association between POP and occupation: Three new studies, which support an association between a women's current employment in heavy occupational lifting and prolapse, were found;[24-26] however, the odds ratio in one study was only marginally significant.

Association between POP and bodyweight: Four new studies addressed obesity and prolapse,[24, 26-28] and support the findings from the previous review that obesity and prolapsed may be linked.

Association between POP and bowel function: Four new studies were identified: one relating to irritable bowel and prolapse[29] and three addressing defaecatory dysfunction problems.[24, 30, 31] The findings of the four new studies are similar to previous studies. There were significant associations with the prolapse symptoms but none with the prolapse stage.

Association between POP and nutrition: In the ICI 4th edition, one study was found that suggested anaemia was associated with increased odds of having a prolapse.[32] A new study[33] found that vitamin D levels were not associated with prolapse.

Recommendation: Being overweight or engaged in occupations involving heavy lifting or hard physical labour may play a role in the development of POP (Level of evidence: 3).

Is lifestyle intervention effective in the treatment of POP? Previously, no studies evaluating the effectiveness of lifestyle interventions in the treatment of women with POP were identified. Currently, this is still the case.

(2.2) Physical Therapies for POP

Is physical therapy effective in the prevention of POP? Currently, there is no evidence from intervention studies regarding the role of PFMT or other physical therapies in the prevention of POP. However, one trial is now underway (<http://clinicaltrials.gov/ct2/show/NCT01171846>). Based on 3 new observational studies,[26, 34, 35] better PFM function may be associated with a lower risk of prolapse (Level of Evidence: 3).

Is physical therapy effective in the treatment of POP? Evidence is growing for the role of PFMT in the treatment of POP, both as a treatment in itself and as an adjunct to surgery. Three new trials[36-38] and a pilot study,[39] were added. All three reported significantly fewer prolapse symptoms in the PFMT group compared to the control group at follow-up. Two of three reported significantly more women with decreased POP-Q stage in the intervention group compared to control;[38, 39] while the third trial also found a trend in this direction.[36]

Based on previous studies and new evidence from four new trials, PFMT may improve the symptoms of prolapse and the anatomical defects (Level of Evidence: 1).

Recommendation: PFMT can improve prolapse symptoms and reduce the severity (Grade of Recommendation: A).

(2.3) Pessaries and POP

Pessaries offer a non-surgical option for the treatment of POP. A range of vaginal pessaries exist which can be broadly divided into two categories: support and space-filling.

Are pessaries effective in the treatment of POP? Evidence for the effectiveness of pessaries can be obtained from a large number of observational studies and two RCTs,[40, 41] one of which is new.[40] The oldest trial[41] compared two types of pessaries: the Gellhorn and the ring with

support. Study results showed that there were statistically and clinically significant improvements in the majority of the symptoms, as well as on the QoL scales, for both types of pessaries and no significant differences between the two (Level of Evidence: 2). The most recent RCT compared PFMT with a Colpexin sphere to PFMT alone.[40] Both groups saw an improvement in PFM function after 16 weeks of training; however, there was no significant added effect noted for the Colpexin sphere.

Recommendation: In a choice between the Gellhorn and the ring with support pessaries, either may improve prolapse symptoms and reduce their impact (Grade of Recommendation: B).

DISCUSSION

The 5th ICI Update provides additional support for conservative management of female UI and POP. For UI, there are no prevention trials on lifestyle interventions. Although limited, there are a few new intervention trials of lifestyle interventions involving weight loss and fluid intake with improved levels of evidence and grade of recommendation. Outside of pre- and post-natal PFMT trials for the prevention of female UI, there is a dearth of PFMT prevention trials for women with UI. PFMT remains the first-line treatment for female UI with high levels of evidence and grade of recommendation. The best PFMT program remains to be defined, however. Bladder training level of evidence and grades of recommendation are maintained. For POP, new evidence supports the effectiveness of physiotherapy in the treatment of POP and there are now improved levels of evidence and grades of recommendation.

CONCLUSION

There are clearly positive outcomes for the implementation of PFMT in the treatment of UI and POP. However, outside this area, there is an absence of research on the prevention of female UI and POP, the benefit of lifestyle interventions in prevention trials and adjunct interventions such as biofeedback, vaginal cones, electrical stimulation, and lifestyle interventions. Such trials are complex and can be costly, such that researchers need to prioritise the research needs based on input from women themselves as well as cost–benefit issues. No trials have addressed the economics of treatment or the cost of not treating. The research priorities identified by the review should provide direction to researchers, policy makers, and health care agencies.

ACKNOWLEDGMENTS

The editors of the Incontinence book: Fifth Edition 2013, Paul Abrams, Linda Cardozo, Saad Khoury, and Alan Wein.

APPENDIX

Areas for future research

Lifestyle interventions:

- Weight loss and prevention of weight gain should receive high research priority.

- Larger RCTs to assess the effect of caffeine and other dietary factors.
- Studies are required to establish whether heavy exertion or straining are etiologic factors in the pathogenesis of UI and whether changes in exertion levels can alleviate established UI.
- Effect of smoking cessation on UI needs investigation.
- Impact of lifestyle interventions on nocturia, diurnal frequency, urgency, and UUI to delineate whether interventions affect different areas of OAB.

Pelvic floor muscle training (PFMT):

In antenatal and postnatal women:

- Antepartum PFMT on preventing postpartum UI in multiparous women.
- Long-term effect (5+ years) of postpartum PFMT programs (suitable exercise dose and supervision intensities).

In all women:

- Different PFMT programs should be compared. In addition to clinical effectiveness, this is an important question because of resource implications.
- Effect of biofeedback in subgroup of women, such as those with weakened PFMs or those experiencing difficulty contracting PFMs in isolation.

Vaginal cones (VC)

- VC as an overload progression as part of active PFM strengthening exercises in subgroup of women (those with a demonstrated minimum-PFM-strength level).

EStim

- The purpose and biological rationale for EStim in different diagnostic groups so that these can then be tested and compared in clinical trials.

Scheduled voiding regimes: Bladder training (BT)

- BT variables to be investigated include: instructional approach, supervisory intensity, urgency control strategies, scheduling parameters, length of treatment, and use of adjunctive treatments.
- BT versus another active treatment such as PFMT or drug therapy.
- Benefits of BT+/- anticholinergic/antimuscarinic drug treatment.
- Habit training in ambulatory, cognitively intact women with a consistent UI pattern.

POP in females

Lifestyle interventions:

- Studies are needed to fully investigate the association between POP and factors such as occupation and heavy lifting, bodyweight, and constipation. These studies should ensure that:

- Occupation, physical activity, bowel function and diet are rigorously assessed, using instruments with sound psychometric properties.
- Potential confounding variables are considered.
- Attempts are made to overcome some of the research obstacles, such as recall bias inherent in assessing lifetime occupational history or healthy worker bias which is a problem when attempting to compare POP in women currently employed in heavy-labor jobs versus others.

Only when the links between various lifestyle factors and POP have been more clearly established can good RCTs be set up to investigate the effects that changes in these lifestyle factors can have on preventing POP.

Physical therapy

Studies are needed to fully investigate the role of physical therapies in the prevention of POP. Such studies should:

- Consider the exact nature and timing of any physical therapies.
- Ensure that the effects of lifestyle factors and other potential confounding variables are taken into account.

Further trials are needed to add to the evidence regarding:

- the effectiveness of PFMT on different stages and types of prolapse;
- the role of PFMT as an adjunct to prolapse surgery.

Pessaries

- There remains a pressing need for well-designed RCTs to examine the effects of using the variety of pessaries in the treatment of POP. Such studies need to:
- Address optimal pessary effectiveness, including the symptomatic and therapeutic benefits of pessaries as well as the indications for use, pessary fit, replacement, and care.
- Adopt consistent protocols regarding the optimal choice of a pessary.
- Allow sufficient follow-up periods.

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This is the accepted version of the following article: Dumoulin C, Hunter KF, Moore K, Bradley CS, Burgio KL, Hagen S, Imamura M, Thakar R, Williams K, Chambers T. (2016). Conservative management for female urinary incontinence and pelvic organ prolapse review 2013: Summary of the 5th International consultation on incontinence. *Neurourology and Urodynamics*. 2016 Jan; 35(1): 15-20., which has been published in final form at <http://onlinelibrary.wiley.com/doi/10.1002/nau.22677/epdf>