

Conservative Management of Stress Urinary Incontinence/Pelvic Organ Prolapse

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INTRODUCTION

Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) represent common symptoms of pelvic dysfunction caused by aging, hypoestrogenism, or neuromuscular dysfunction. In 2002, The International Continence Society (ICS) defined SUI as the involuntary leakage of urine on effort or exertion, or on sneezing or coughing [1]. The severity of POP is determined by using the POP-Q quantitative system as adopted by the ICS in 1996 [2]. These symptoms are rarely life-threatening but may cause a negative impact on the quality of life including the physical, psychological, and social well being of the affected individuals. Treatment for these women should take into account the severity of the problem and also individual preferences and motivation. Healthcare professionals should be able to offer evidence-based information that is tailored according to the needs of the affected women. The affected women should also be given the opportunity to make their own informed decisions regarding the treatment of their conditions. The current treatment for SUI and POP includes surgical intervention and conservative management. There is a wide range of conservative management techniques for SUI including lifestyle interventions, physical therapies, behavioral therapies, drug therapies, non-therapeutic interventions and alternative therapies. Treatment modalities are often chosen according to the healthcare professional's preferences and experience. The effectiveness of conservative management has not been proven by an evidence-based systematic review of articles. Until now, there is no consensus on recommendations for clinical practice regarding the conservative management strategies for SUI or POP in Taiwan.

The National Institute for Clinical Excellence (NICE) offers guidelines for the management of urinary incontinence for women in England and Wales [3]. The NICE guidelines provide different grades (A, B, C, D) of recommendations for the clinical management of urinary incontinence based on available evidence. The level of evidence is cited according to the methodology of the study, the risk of bias, data analysis, and interpretation of the study (Table 1). This article will review the conservative management of SUI based on the NICE guidelines. The conservative management of POP is reviewed by an electronic search of articles on Pubmed, Medline, and the Cochrane library.

CONSERVATIVE MANAGEMENT OF SUI--LIFESTYLE INTERVENTIONS

There is a lack of good quality, prospective, controlled trials evaluating the effects of modifying lifestyle factors in women with urinary incontinence (UI). The assessment of the modification of fluid intake for the management of SUI is inconclusive and only randomized controlled studies (RCTs) of poor quality (EL=1-) exist. One RCT assessed the modification of daily fluid intake in women (n=32) with unspecified UI for five weeks [4]. The adherence to fluid intake protocol was poor and there were no significant changes in the reduction of leakage. Another three week RCT assessed the effect of fluid manipulation in women (n=84) with SUI or iDO [5]. The fluid manipulation protocol consisted of restricting caffeine for one week followed by either increasing or decreasing fluid intake and restricting caffeine for 2 weeks. The study found that reducing fluid intake significantly reduces leakage episodes, urgency, and frequency. Besides fluid modification, there is evidence that weight reduction in obese women is associated with relief of UI symptoms. There is also a three month RCT that assessed the outcome of a weight reduction program versus no intervention in overweight women (n=48) with UI [6]. The study reported that the reduction in weight and leakage episodes and the improvements in QOL were significantly greater in the group assigned to weight reduction (EL=1-).

Constipation and straining to defecate in early adult life may be associated with an increased tendency for pelvic organ prolapses and SUI. However, no evidence on the effects of modifying bowel habits and continence has been found. There is an observational study comparing the history of bowel function in women with uterovaginal prolapse (n=23), SUI (n=23), and a control group (n=27) [7]. There were significantly more women with prolapse and SUI who reported straining to defecate than in the control group (EL=2+). With regard to the effects of smoking in women with SUI, most observational studies show that smoking is associated with an increased risk of UI and overactive bladder (OAB). Again, there is no evidence citing smoking cessation in the management of these symptoms. A cohort study (EL=2+) reported a significantly increased incidence of SUI or OAB in current smokers compared with nonsmokers at 1 year [8].

Dietary habits may also be potential risk factors for the development of UI and OAB. A cohort study assessed the association between intake of certain foods, energy, minerals, and vitamins and the 1-year incidence of SUI or OAB in women (n=6424) aged 40 years or above [9]. The study reported that there is a reduced risk of new onset SUI with bread intake and an increased risk of new onset SUI with high fat, cholesterol, or vitamin B₁₂ intake (EL=2+). No studies were identified that assessed the effects of modifying dietary factors, including

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Table 1.

Levels of evidence	
1++	High quality metaanalyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted metaanalyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Metaanalyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies or High quality case control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Nonanalytic studies, eg case reports, case series
4	Expert opinion

alcohol, for the management of SUI.

Besides dietary modification, the quality of physical exercise and the prevalence of SUI has also been considered. A cohort study assessed the prevalence of SUI in women (n=104) who participated in long-term high impact exercise or low impact exercise [10]. No significant difference in the prevalence of SUI was identified (EL=2+). Another cohort study was conducted to assess the effects of physical activity in women (n=665) before and after the first childbirth [11]. The result revealed that pre-pregnancy high-impact activity may be associated with a risk of UI (EL=2+). The conflicting data may need further clarification.

PHYSICAL THERAPIES

Physical therapies for SUI include pelvic floor muscle training, vaginal cones, biofeedback, electrical stimulation, transcutaneous electrical nerve stimulation (TENS), posterior tibial nerve stimulation, and magnetic therapy. Physical therapy studies are heterogenous in terms of the treatment programs, duration of the treatment and /or follow up, and treatment outcome measurements. Pelvic floor muscle training (PFMT) involves repeated voluntary contractions of the levator ani muscles to increase their strength with the resultant being an increase in urethral closure pressure. Evidence-based studies include six RCTs [12-17], which state that daily PFMT is an effective treatment for stress or mixed UI compared with no treatment over the short-term (EL=1+). The duration of the PFMT in these studies included 1 week, 8 weeks, 3 months, and 6 months. In these studies, the PFMT programs ranged from 8-12 contractions three times a day to 20 contractions four times a day. There were occasional cases of pain or discomfort during PFMT, but no other adverse effects were noted. According to NICE guidelines, women with stress or mixed UI, should perform PFMT for at least 3 months and this regimen should be recommended as first-line treatment. Studies with a higher-intensity of PFMT regimens reported a greater subjective cure or improvement rate than lower-intensity regimens after a one year follow up [18,19]. A good quality RCT (EL=1++), including women (n=747) with stress, urge, or mixed UI 3 months postpartum, assessed the effect of different PFMT regimens after 1 year and at 6 years [19]. The study compared PFMT which included

individualized instruction and a target of 80-100 contractions/day with standard postnatal care. At 6 years, 69% of the women were in the follow-up, and there were no significant differences in UI prevalence, leakage episodes, or UI severity. Over the long term, the differences between these groups were not sustained. There is a lack of evidence for optimum training regimens for PFMT.

Vaginal cones are cone-shaped appliances of various weights. Passive and active contraction of the pelvic floor muscles will prevent the vaginal cones from slipping out of the vagina. Repetitive training will strengthen the pelvic floor muscles with the result being a reduction in leakage episodes. In women with SUI, vaginal cones are more effective than no treatment over the short-term [12]. When compared with the effect of PFMT, there is no evidence of a difference in effectiveness between cones and PFMT [20,21]. However, compared with PFMT, vaginal cones are associated with more of a compliance problem. Vaginal cones are inappropriate for use in some circumstances, such as moderate to severe prolapse, too narrow or too capacious a vagina causing difficulty with insertion or displacement of the cone, untreated atrophic vaginitis, vaginal infection, during menstruation or pregnancy (EL=4).

Biofeedback can enhance the awareness, motivation, and voluntary control of the pelvic floor muscles through visual, auditory, or tactile stimulation. A few good quality RCT studies compared the effectiveness of biofeedback-assisted PFMT with PFMT alone in women with SUI, with the treatment duration ranging from 4 weeks to 6 months [16, 22-25]. Most studies found no significant differences in the outcomes measured including objective or subjective cure rates, QOL (BFLUTS), or social activity index scores (EL=1+). Biofeedback-assisted PFMT is more costly than PFMT alone and therefore is not cost-effective with the lack of evidence of additional benefit.

Electrical stimulation can increase the urethral pressure through pudendal nerve stimulation and cause a direct pelvic floor muscle contraction. Through the spinal cord, reflex pelvic nerve stimulation causes an inhibition of detrusor muscle activity. The outcomes of electrical stimulation were compared with PFMT alone in 3 good quality RCTs [12,26,27]. The participants included women with SUI (n=18 to 51) and the treatment duration ranged from 6 weeks to 12 months. The objective cure rate ranged from 10 to 54% for PFMT alone and 4 to

40% for electrical stimulation. There were no significant differences between the groups. A study has also been designed to evaluate the effectiveness of electrical stimulation in combination with PFMT in the treatment of women with SUI [28]. When compared with PFMT alone, electrical stimulation did not result in additional benefits as noted in the outcome measurements such as self-reported cure or improvement rates or pad test evaluation (EL=1+). Some studies report adverse effects with the application of electrical stimulation. These include vaginal irritation in 12%-22% of women and pain in 6%-9% of women, and there have been cases of fecal incontinence, discomfort, tenderness, and bleeding as well [12,27]. Regarding the management of SUI with transcutaneous electrical nerve stimulation (TENS), posterior tibial nerve stimulation, and magnetic therapy, there is limited data with reported case series and their role in the treatment of SUI is unclear.

DRUG THERAPIES

Duloxetine is a serotonin and noradrenaline reuptake inhibitor that acts chiefly in the sacral spinal cord. The resultant increase in pudendal nerve activity increases the urethral sphincter contraction and closure pressure. There are a few double blind RCTs evaluating the effectiveness of duloxetine in the treatment of women with moderate to severe SUI [29-32]. The women in these studies reported at least 4 to 7 leakage episodes/week. Three short-term studies (12 weeks) [29-31] reported that the use of duloxetine is associated with a reduction in leakage episodes, an increase in voiding intervals, and improvement of quality of life (EL=1+). However, one study with 9 months of treatment [32] did not report any significant differences in quality of life between the treatment group and the placebo group (EL=1+). A quarter of the patients had dropped out of the study at the study endpoint. Across these studies, there were significantly more women in all of the duloxetine dosage groups (20 mg, 40 mg, 80 mg) who discontinued the treatment due to adverse effects compared with the placebo groups (range 13% to 46% vs. 0 to 6%). Nausea was the most common symptom accounted for in the withdrawals from the Duloxetine studies [31]. Other side effects included dry mouth, constipation, fatigue, insomnia, dizziness, increased sweating, vomiting, and somnolence. An economic model, constructed for the purposes of the NICE guidelines, suggests that PFMT is more cost-effective than duloxetine alone as the first-line of treatment for SUI.

Oestrogens may affect autonomic innervations, especially adrenergic nerves or receptor density on the lower urinary tract, or help to maintain the normal function of the urethra through changes in the vascular or connective tissue element of the urethral wall. However, there is still controversy over their use especially in postmenopausal women when weighing the risks and benefits. Short-term studies of intravaginal oestrogens suggest some improvement in symptoms of incontinence and frequency in postmenopausal women who have urogenital symptoms secondary to vaginal atrophy [33,34]. Three RCTs compared the effectiveness of systemic oestrogen with a placebo for the treatment of SUI [35-37]. The oral estrogens evaluated were conjugated equine oestrogen (CEE) with medroxyprogesterone acetate (MPA), estradiol, and estrone. There were no significant differences in any outcomes across the studies including leakage episodes, pad tests, frequency, QOL, and perception of improvement (EL=1+). There were two RCTs designed to evaluate the benefits and risks of HRT and they also analyzed the continence outcome in the subjects [38,39]. In the

'HERS' study [38], there were significantly more women in the HRT group who reported a worsening of UI symptoms after 4 years of treatment (CEE+MPA). In women who did not have UI at the baseline, the risk of reporting any type of UI at the end of the study was significantly higher in the HRT group (EL=1++). In the WHI study [39], the relative risk of incidental UI of any type was significantly higher in the CEE+MPA and CEE groups at 1 year. The relative risk of UI worsening, evaluated by leakage quantity and episodes, limitations of daily activity, and a bother factor was also significantly higher with HRT (EL=1++).

BEHAVIOURAL THERAPIES

Women with SUI often void more frequently in the belief that they can pre-empty their bladder and decrease the frequency of UI associated with a rise in abdominal pressure. Behavioural therapy involves the modification of previous voiding patterns or a re-establishment of new voiding behaviors according to the patient's symptoms and cognitive function. Bladder training activities (bladder retraining, bladder drills, bladder re-education, bladder discipline) involve patients fulfilling the goal of increasing intervals between the desire to void and actual voiding. One RCT (EL=1++) reported that the combination treatment of bladder training with PFMT may provide short-term benefits to women with stress, urge, or mixed UI [40]. Other studies evaluated the efficacy of multi-component behavioural therapy including a wide range of training programs and regimens in women with stress, urge, or mixed UI [41-43]. These studies showed improvements in leakage episodes over those in comparison (no active treatment, written instructions) within 6 weeks to 6 months (EL=1+).

CONSERVATIVE MANAGEMENT OF POP

Conservative treatment is considered for patients with mild POP, women of child bearing age, patients who are not good candidates for an operation, or patients who are unwilling to undergo an operation. Conservative management of POP includes physical therapies and lifestyle modification. Lifestyle modification includes weight loss, reducing exertion that will cause an increase in abdominal pressure, and treating constipation. There are few studies evaluating the outcome of conservative management in patients with POP. Hagen et al [44] conducted a single blind randomized controlled trial that included 47 women with grade 1 or grade 2 prolapse of any type. The women were randomized into an intervention group and a control group. The participants in the intervention group received 5 physiotherapy sessions over 16 weeks where PFMT techniques were taught and 6 sets of exercises per day was recommended. Participants in both the control group and intervention group were given a lifestyle advice leaflet. The outcomes were measured with a postal questionnaire at baseline, 20, and 26 weeks follow-up. This study reported a better outcome in the intervention group as demonstrated in the decrease in prolapse severity at 20 weeks. Another single blind randomized controlled trial was conducted by Jarvis et al [45] in 2005 which included 60 women who were scheduled to undergo surgery to correct prolapse or incontinence. After randomization, 30 women were included in the intervention group. These women were requested to perform an individually tailored PFMT program preoperatively and also postoperatively. The report describes an improvement in urinary symptoms, pelvic floor muscle function, and a reduction in diurnal frequency in the intervention group. Piya-Anant

et al [46] described a trial of PFMT and advice on reducing constipation in 654 community-dwelling Thai women aged over 60 years, who were assessed for the presence of anterior wall POP. Three hundred and thirty women were randomized into the intervention group. However, the author did not describe the method of randomization, blinding, and whether the women without prolapse were excluded from the study. Follow-up was conducted at 6, 12, and 24 months. The women in the intervention group were reported to be less likely to have worsening of prolapse at the 24 month follow up than those in the control group. In conclusion, the limited evidence available is not sufficient to assess the value of conservation treatment in women with POP.

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