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Efficacy of *Boswellia serrata* L. and *Cyperus scariosus* L. plus pelvic floor muscle training in stress incontinence in women of reproductive age

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A B S T R A C T

Introduction: To determine the efficacy of combining of *Boswellia serrata* L. resin and the root of *Cyperus scariosus* L. plus PFMT in reproductive age women with stress urinary incontinence.
Methods: A prospective, single-blind, placebo-controlled, randomized trial was conducted. The patients were randomized to receive orally either combination of equal quantity of *B. serrata* and *C. scariosus* (2g) ($n = 30$) or placebo ($n = 30$) respectively twice daily for 8 weeks in addition to pelvic floor muscle training in both groups. The outcome was one hour pad test. The results were analyzed using parametric and nonparametric test.
Results: The improvement in the test and control group was 60% and 37% respectively. Between the group comparison was statistically significant ($P = 0.035$). The intra group comparison of one hour pad test was statistically significant in both groups ($P < 0.001$). No adverse effects were noted.
Conclusion: The test group was more effective than control group in women with SUI.

1. Introduction

Urinary incontinence (UI) is an under-reported, undiagnosed, and often untreated medical condition that significantly impacts on quality of life for women of all ages [1,2]. Of the six major types of UI, stress urinary incontinence (SUI) is the most common, reported by approximately 50% of incontinent women [3]. It is frequently reported by women of childbearing age [4].

Stress urinary incontinence (SUI) is a major health problem with significant personal, family and economic costs that has substantial and important effects on health-related quality of life [5]. Other adverse effects of SUI include social isolation, loneliness and sadness, psychiatric illness including depression and embarrassment which affects activities of daily living, stigmatises, affects sexual relationships and disturbs sleep [4,5]. SUI is defined as the involuntary loss of urine that occurs with physical exertion and rise in abdominal pressure (coughing, sneezing, straining, jumping, and running) [3,6]. The prevalence of urinary incontinence is expected to increase as a result of demographic change and the increasing elderly population [5]. Pathophysiologically, SUI can be the result of bladder neck/urethral hypermobility and/or neuromuscular defects (intrinsic sphincter deficiency) [3,6]. Internal sphincter deficiency (ISD) can be defined as damage to the urethral sphincteric mechanism, regardless of etiology. The urethra might be damaged owing to fixation (as in cases of spina bifida), prior surgery, denervation or muscle damage during childbirth. Internal sphincter deficiency and hyper mobility can exist concomitantly as well as alone [7]. Despite its high prevalence, its association with adverse health outcomes and the fact that there are evidence-based treatment options available, many health-care practitioners do not routinely screen for SUI [8]. There are broad varieties of therapies for the treatment of stress urinary incontinence (SUI) in adult women, ranging from physiotherapy to surgical interventions [9]. Therapies include medical management, Kegel exercises, biofeedback, and electrical stimulation. All of these treatments are established methods used in urinary incontinence [5]. The pharmacological treatment of SUI includes α-adrenoceptor (α-AR) agonists, β-AR agonists, estrogens and tricyclic antidepressants (TCAs) have been used off-label. However, the effectiveness of these drugs from randomized controlled trials (RCTs) shows little or no evidence and several of them may cause significant adverse effects. Imipramine, a TCA, is used occasionally to treat SUI. This drug inhibits the re-uptake of

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noradrenaline and serotonin in adrenergic nerve endings, which might increase the contractile effects of noradrenaline on urethral smooth muscle. No good-quality RCTs have investigated the efficacy of imipramine. Adverse effect of TCAs includes orthostatic hypotension, dry mouth, constipation, retention, and falls. Serotonergic agonists generally suppress parasympathetic activity and enhance sympathetic and somatic activity in the lower urinary tract, which, together, promote urine storage [3]. In a systematic literature review, the Cochrane Incontinence Group concluded that pelvic floor muscle training should be offered as first-line conservative management to women [10]. A subsequent Cochrane review also concluded that PFMT is effective for women with SUI and is superior to no treatment [11].

In the Unani system of medicine oleo-gum-resin of *Boswellia serrata* (*kundur*) and root of *Cyperus scariosus* (*nagarmotha*) have been used traditionally to treat urinary incontinence. These plant products have astringent property and tone the muscles [12]. These herbs are also known for their effects on the nerves, astringent antidepressive, sedative and analgesic properties. In animal studies no toxicity has been reported for both herbs in therapeutic doses [13,14].

Although these herbs are mentioned in classical texts and are frequently used, however, documentations are not available. Combination of these two Unani herbs was selected to validate their efficacy in reproductive age women with SUI. The research question was whether the use of *B. serrata* and *C. scariosus* plus PFMT was effective in ameliorating SUI in women of reproductive age. The aim of this study was whether the combination of *B. serrata* and *C. scariosus* plus PFMT compared with placebo plus PFMT would be effective in improving SUI.

2. Material and methods

2.1. Study design

A prospective, parallel, single centre, single-blind, simple randomized, placebo-controlled study was conducted at the outpatient department of the National Institute of Unani Medicine (NIUM), Bangalore, India between March 2012 and February 2013. The Institutional Ethical Committee of NIUM (Memo No.: NIUM/IEC/2010-11/23/ANQ/05) approved the protocol and all the patients gave written informed consent. The study was performed in accordance with the Declaration of Helsinki and GCP guidelines issued by the AYUSH Dept, Ministry of Health, Government of India. The trial is registered in clinical trial registry-India (ICMR) with ref no. REF/2014/01/006298. A total of 60 patients presenting with stress urinary incontinence for at least six months who fulfilled the inclusion criteria were recruited.

2.2. Participants

2.2.1. Inclusion and exclusion criteria

Parous and menstruating women aged 18–55 years having symptom of predominant SUI with or without grade 1, 2 and 3 genital prolapse, an average daytime voiding interval >2 h, a nocturnal voiding frequency ≤2 per day and a positive cough stress test (supine full bladder) observed on physical examination at visit 1 were included. Hematological and biochemical parameters within normal range and willing to sign the informed consent were included. Patients were excluded if they were on pharmacological treatment for symptoms of urinary incontinence in preceding one month and continence surgery within 6 months, enuresis, continuous leakage of urine, pelvic pathology (fibroid, malignancy, fistula), systemic and endocrine diseases (asthma, tuberculosis, diabetes mellitus, uncontrolled hypertension or any psychiatric disorders), pregnant women or nursing mothers, obstruction of urethra, cognitive and psychiatric impairment and drug treatment for depression [15].

2.3. Study procedure

During the selection procedure, all patients underwent assessment including urogynecological history, physical examination, a cough stress test, a 1-h pad test, and investigations. Clinical variables were also collected; how long they had the complaint of stress urinary incontinence, incontinence frequency episodes [Never (0); About once a week or less often (1); Two or three times a week (2); About once a day (3); Several times a day (4) and All the time (5)], amount of leakage (whether you wear protection or not)? [None (0); A small amount (2); A moderate amount (4) and A large amount (6)], pad usage (yes or no) and number of pads (1-2, 3-4, or >4 units/day) [16], leakage on sitting to standing, difficulty in emptying the bladder, and pain or discomfort in the lower abdomen or genital area or pain in the middle of abdomen as bladder fills.

To evaluate mental status, simple observation of the patient's orientation, speech, memory, level of consciousness and comprehension was performed. In complete pelvic examination, stress test, pelvic floor muscular strength (PFMS), genital prolapse, per speculum and per vaginal examination was performed. For stress test, patient was asked to perform a valsalva maneuver or cough repetitively and leakage from the urethra was observed. PFMS was noted by vaginal palpation [17]. Genital prolapse was graded using the Baden–Walker classification system [18]. Routine investigations like complete blood picture, erythrocyte sedimentation rate (ESR), random blood sugar and routine urine examination were done to exclude general diseases. Baseline (visit 1) and post treatment (visit 5), complete blood picture, ESR, random blood sugar, alkaline phosphatase SGOT, SGPT, serum creatinine and blood urea were done to assess the safety of test drugs. The specific investigations such as thyroid profile, urine culture and pelvis ultra sonography test were done to exclude, thyroid dysfunction, urinary tract infection and uterine fibroid, and malignancy respectively.

2.4. Assessment tools

All patients underwent standardized 1-hr pad test as per the International Continence Society to assess incontinence in the present study [19].

2.4.1. Standardized one hour pad test

In the present study, pre and post pad weight at baseline (visit 1) and post treatment (visit 5) was determined using digital electronic precision balance scale with accuracy $d = 0.01$ g and capacity 600 g (model: FR-H). Pad weight increase of1g/h or greater was considered abnormal [19]. The pad test is used for an objective quantification of urinary incontinence. Versi et al. found a positive predictive value of 92% and a negative predictive value of 53% of it when screening for lower urinary tract dysfunction [20]. Lose and Versi used the same test for diagnosing genuine stress incontinence in patients who had no other urodynamic abnormality, the positive and negative predictive values were 91% and 72% respectively [21].

2.5. Follow up and assessment

Follow-up visits were scheduled every fortnightly during treatment of 8 weeks and one follow up after a month without treatment. The patients were asked about improvement or worsening of their symptoms at each visit and 1-hr pad test was