



## Full length article

## Does vaginal estriol make urodynamic changes in women with overactive bladder syndrome and genitourinary syndrome of menopause?



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## ABSTRACT

**Objectives:** OAB is a common finding in postmenopausal women. Hypoestrogenism is the root cause of many signs and symptoms of Genitourinary Syndrome of Menopause (vaginal dryness, atrophy, dyspareunia, urinary disorders, etc.). As such the aim of this study was to evaluate the urodynamic effects of ultralowdose estriol vaginal gel formulation to treat women with Genitourinary Syndrome of Menopause and Overactive Bladder Syndrome.

**Study design:** This open-labeled, single center, prospective study involved 37 women with OAB recruited in our Urogynecological Unit between January and July 2016. They received estriol 50 mcg/g vaginal gel, one applicator-dose per day for 3 weeks followed by one dose twice a week for 12 weeks. Objective and subjective parameters were evaluated before and after treatment through the urodynamic examination, Overactive Bladder symptom score and Short Form Health Survey-36 questionnaires.

**Results:** Vaginal atrophy symptoms and signs as well as the overactive bladder subjective symptom parameter improved significantly. Urodynamic evaluation showed significant improvement in first desire to void and maximum cystometric capacity after estriol usage. Patients who had detrusor overactivity did not show any improvement for this parameter after treatment. The voiding function parameters did not significantly change. Short form-36 showed a better quality of life after treatment especially for the emotional role, as well as mental and general health.

**Conclusions:** A local ultra-low dose concentration of estriol could be effective in women with vaginal atrophy and Overactive Bladder Syndrome for improving both subjective symptoms and urodynamic parameters of storage function not affecting voiding function.

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## Introduction

Overactive bladder syndrome (OAB) consists of urinary urgency, with frequency and nocturia, with or without urge incontinence [1]. OAB can affect the quality of life (QoL) of women who have a significant impairment of physical, social, emotional, and sexual functions [2].

In some patients OAB is associated with detrusor overactivity (DO), a condition characterized by uncontrolled contraction of the detrusor muscle. However, only half of the women with OAB present DO. Furthermore, up to 50% of patients presenting with DO on urodynamics do not experience clinical symptoms [3].

The prevalence of OAB increases with age and occurs in approximately 30% of women over the age of 65 years. There are about 50–100 million OAB sufferers world-wide and is more prevalent in postmenopausal women with Genitourinary Syndrome of Menopause (GSM) [4]. GSM presents a variety of signs and symptoms, linked to hypoestrogenism and atrophy such as vaginal dryness, burning, dyspareunia, and urinary dysfunctions (nocturia, pollakiuria, urgency) whose etiology is attributable to reduced estrogen receptors in some tissues such as vaginal epithelium and trigone of the bladder [5] and are related to genitourinary atrophy. Estrogen deficiency, in fact, can cause irritative urinary symptoms because of the increased contact of sensitive nerve endings with urine due to the thinning of the bladder [6]. The aim of OAB therapy is primarily to reduce the frequency and urgency suffered. Antimuscarinic drugs are the first-line medical treatment for OAB symptoms [7]. However, the bladder, urethra, pelvic floor musculature and vagina have great

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affinity for oestrogens [8]. Oestrogens deficiency during postmenopause can impact the genital structures, the lower urinary tract and pelvic floor structures. Estrogen deficiency in the genitourinary tract results in vaginal dryness, itching, burning, dyspareunia and sexual dysfunction, as well as urinary incontinence, frequency, urgency, nocturia and infections. Estrogen therapy results in maturation of vaginal epithelium and improves blood flow; moreover, it maintains the acid pH of the vagina fostering lactobacilli proliferation [9]. Women with GSM may benefit from treatment with an ultra low dose estriol vaginal gel formulation (0.005% concentration) [10–12]. Some authors have shown that the local estriol in association with antimuscarinics for treatment of OAB syndrome was more effective than antimuscarinics alone [13,14].

Studies concerning changes in urodynamic parameters and clinical symptoms after OAB treatment are limited. The aim of this study was to investigate the changes of urodynamic parameters and urinary symptoms after treatment with ultra low dose estriol vaginal gel formulation in women with both GSM and OAB. We adopted the clinical and urodynamic evaluation used by Matsukawa et al. [15].

## Materials and methods

This pre- and post-treatment open-labeled study was performed at the Gynecological Clinic, University Hospital “Policlinico-Vittorio Emanuele”, Catania. The study protocol was approved by the Institutional Review Board of the Department and conformed to the ethical guidelines of the 1975 Helsinki Declaration. Informed written consent was obtained from each woman before entering the study, and they did not receive any monetary payment. Patients were recruited from January to July 2016.

Postmenopausal women with GSM, having urgency episodes  $\geq 1$  per week, OAB symptom scores (OABSS) of  $\geq 3$ , maximum urinary flow rate ( $Q_{max}$ )  $> 15$  mL/s with a voiding volume  $\geq 100$  mL, and post-void residual urine volume (PVR)  $< 150$  mL were included in the study.

Women using oral anticholinergic agents,  $\beta$ -3 agonists,  $\alpha$ -1 blockers, antidepressants, or antianxiety agents before urodynamic evaluation; or had a diagnosis of neurogenic bladder dysfunction, bladder calculi, or active urinary tract infection; or with endometrial thickness  $\geq 4$  mm measured by transvaginal ultrasound, and/or abnormal uterine bleeding, or with hormone-dependent malignancies; with a history of thromboembolic disease, liver and renal disease, and/or hormone therapy usage for less than three months, were excluded.

A total of 40 women (mean age  $\pm$  SD,  $68.2 \pm 11.4$ ) who met the aforementioned criteria were enrolled in this prospective study and received estriol 50 mcg/g vaginal gel, one applicator-dose per day for the first three weeks of treatment before going to bed, then only one dose twice a week until 12 weeks.

The OABSS questionnaire is obtained using a questionnaire, summing the scores of four items that refer to day frequency, night frequency, urgency, and urgency incontinence; each single score ranging from zero to 15. A total score of  $\leq 5$ , 6–11, and  $\geq 12$  corresponds to mild, moderate or severe symptoms, respectively [16].

Vulvo-vaginal atrophy (VVA) symptoms, including vaginal dryness and dysuria, were evaluated. The severity of each symptom was self assessed and rated on a four-point scale (0, none; 1, mild; 2, moderate; 3, severe). At baseline and end of treatment, participants were instructed to rate each of the VVA symptoms as not present, mild, moderate, or severe. Change in severity was used to evaluate symptomatic improvement.

The QoL was measured by the Short Form Health Survey-36 (SF-36) self-administered questionnaire. It evaluates the following eight physical and mental health areas: physical function, physical role, emotional role, vitality, mental health, social function, body pain, and general health [17].

Each of the eight areas is scored on a scale of 0–100, where a higher score indicates better health, subjectively. Thereafter, we determined the sum of four items of each category.

Mean values were assessed based on individual items within a given category, and eight scale scores were obtained with higher scores denoting better functioning.

Women also underwent an urodynamic study (UDS) to evaluate their objective urinary symptoms by measuring uroflowmetry, cystometrogram (CMG) and pressure flow study (PFS). The maximum cystometric capacity (MCC), presence of detrusor overactivity (DO) and first desire to void (FDV), were evaluated as parameters of storage function.  $Q_{max}$ , postvoid residual urine volume (PVR), and detrusor pressure at  $Q_{max}$  (Pdet $Q_{max}$ ) were evaluated as parameters of voiding function. A disappearance of DO was considered as an improvement in DO.

A single operator performed both the clinical and instrumental diagnostic procedures to enroll the women (MGM). CMG and PFS were performed based on the standard methods defined by the International Continence Society [18].

Intravesical pressure was monitored by a 7 Fr air-charged catheter, with filling lumen (T-Doc, Mediwatch) transurethrally inserted into the bladder. In addition, to measure abdominal pressure a 7 Fr air-charged catheter was inserted into the anus (T-Doc, Mediwatch). A UDS was performed in the sitting position. After emptying the bladder, physiological saline was injected into the bladder at 50 mL/min, increasing to 100 mL/min after filling 100 mL. When the woman felt a maximal desire to void, she was invited to empty her bladder with the catheters kept inside simultaneously measuring the intravesical pressure, abdominal pressure, detrusor pressure, and urinary flow. UDS parameters were analyzed independently by two clinicians (GV, GS).

All assessments were collected at baseline and at the 12th week of follow-up.

All statistical values are represented as mean standard deviation. The Wilcoxon rank-sum test, Student's *t*-test, and the chi-square test were performed to evaluate changes in subjective symptoms, including OABSS and objective symptoms, based on CMG and PFS. All tests were two sided, and a *P* value  $< 0.05$  was considered statistically significant. The Primer of Biostatistics statistical computer package (Glanz SA, New York: McGraw-Hill, Inc.1997) was used to perform the statistical analysis.

## Results

The analysis included 40 women with a mean age of 68.2 years (range, 50–82 years). Two of them (5%) discontinued treatment due to burning and one (2.5%) refused to undergo UDS after estriol administration at 12 weeks. The baseline characteristics of the women are shown in Table 1.

The majority of women (24, 60%) had moderate symptoms at OABSS, six women (15%) were diabetic and 18 women (45%) were receiving pharmacotherapy for hypertension.

Symptoms and signs of vaginal atrophy significantly improved at final visit compared with baseline. In fact, at baseline, two women (5%), four women (10%), and 34 women (85%) in the study group reported mild, moderate, and severe vaginal dryness, respectively. On the 12th week of follow-up, 33 women (89.2%) reported no symptoms, and four women (10.8%) reported mild vaginal dryness ( $p < 0.001$ ). Moreover, at baseline one woman (2.5%), two women (5%), and 37 women (92.5%) were affected by mild, moderate, and severe dysuria, respectively. After 12 weeks of

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