Maturitas 66 (2010) 101–106

Contents lists available at ScienceDirect

Maturitas

journal homepage: www.elsevier.com/locate/maturitas

Brief communication

The use of oestradiol therapy in postmenopausal women after TVT-O anti-incontinence surgery

A. Liapis [a,*], P. Bakas [a], C. Georgantopoulou [b], G. Creatsas [c]

[a] Department of Urogynaecology and Pelvic Floor Disorders, 2nd Department of Obstetrics & Gynaecology of the University of Athens, Aretaieion Hospital, N. Paritsi 9A, 15451 Neo Psychiko, Athens, Greece
[b] Obstetrician & Gynaecologist, Obstetric & Gynaecology Unit and Research Centre of the University of Athens, Evgenideion Hospital, Greece
[c] 2nd Department of Obstetrics & Gynecology of the University of Athens, Aretaieion Hospital, Greece

ARTICLE INFO

Article history:
Received 9 September 2009
Received in revised form 21 January 2010
Accepted 27 January 2010

Keywords:
Stress incontinence
Menopause
Urgency
Frequency
Urinary symptoms
TVT-O
Oestrogens

ABSTRACT

Objective: To investigate whether patients who were treated with TVT-O procedure for urodynamic stress incontinence had a significant improvement in their urodynamic findings and their post-operative symptoms (frequency, urgency, nocturia) if they were treated post-operatively with vaginal oestradiol for 6 months compared to the non-treated group.
Methods: Prospective randomised study. 190 patients were asked to participate in our study. Finally, a total of 92 patients in group 1 and 91 patients in group 2 completed the study. In group 1, which was the treatment group, patients having the TVT-O procedure for urodynamic stress incontinence were instructed to use post-operatively oestradiol tablets, 25 micrograms (Vagifem, Novo Nordisk) vaginally, once daily, nocte, for 2 weeks and then twice weekly for 6 months. The patients in group 2 (control group) had the TVT-O procedure only. All patients were reviewed in 2 months and again in 6 months time.
Results: There was no statistically significant difference between the two groups concerning pre-operative and post-operative haemoglobin, operative time, hospital stay or return to work. The within group analysis did not show significant differences between pre-operative and post-operative urodynamic data in both groups. Patients treated with vaginal estradiol post-operatively showed a statistically significant reduction in relation to the symptoms of urgency and frequency but not in relation to nocturia and urge incontinence compared to the non-treated group. There is no difference in relation to the efficacy of TVT-O procedure between the groups at 6 months follow-up.
Conclusion: It appears that vaginal oestradiol treatment could be offered to postmenopausal patients after a TVT-O procedure having the symptoms of frequency and urgency provided they are aware of the lack of evidence regarding long term benefit.

© 2010 Published by Elsevier Ireland Ltd.

1. Introduction

The menopause, with its oestrogen withdrawal, signals major changes in the lower urinary tract. The urethra, the trigone, the pelvic floor, all carry oestrogen receptors [1]. Thus, the postmenopausal urogenital atrophy affects the histology and the function of all the structures of the urogenital tract. The urethra and its sphincteric mechanisms, the bladder function, the pubococcugeous muscle, the alpha-adrenergic tone are all altered.

Stress Urinary Incontinence (SUI) is the most common type of incontinence encountered in women. It is treated surgically with suburethral slings, the Tension free Vaginal Tape (TVT) being the first of a series of slings. In 2003, De Leval [2] described a new sling – the Tension Free Vaginal Tape-Transobturator (TVT-O) – which passes through the obturator foramina. Suburethral slings although highly efficient in treating stress incontinence will not cure urge symptoms such as frequency, urgency, nocturia. They may even aggravate these symptoms and are known to lead to de novo detrusor overactivity in up to 26% of cases. De novo urgency, urge symptoms or detrusor overactivity are recognised post-operative problems. In 2003, a Cochrane review [3] concluded that oestrogen can improve urinary incontinence but conceded that the quality of evidence was poor. Two further placebo-controlled studies [4,5] which used vaginal oestrogens to treat urogenital symptoms concluded that the symptoms of frequency, nocturia, dysuria, urge or stress incontinence improved in the treated group. Although there is no definitive consensus, there is a considerable body of evidence suggesting that local hormone replacement therapy may alleviate the "urge" symptoms associated with oestrogen deficiency and atrophy.

* Corresponding author. Fax: +30 210 6712188.
E-mail address: eurotas@panafonet.gr (A. Liapis).

0378-5122/$ – see front matter © 2010 Published by Elsevier Ireland Ltd.
doi:10.1016/j.maturitas.2010.01.020

Table 1
Baseline demographic and clinical characteristics of each group.

Characteristic	Group 1 = 95	Group 2 = 94	*p*-Value
Age (years)	59.5 ± 5.7	60.3 ± 7.2	0.14
Body mass index (m^2)	26.1 ± 1.2	25.8 ± 1.5	0.42
Parity	1.6 ± 1.1	1.5 ± 1.2	0.21
Menopause	100%	100%	

Objective of the study was to investigate if local oestradiol therapy could have therapeutic role in the treatment of women who are postmenopausal and undergo the TVT-O procedure (Gynecare, Johnson & Johnson) for the management of stress urinary incontinence by reducing the post-operative bladder symptoms such as frequency, urgency, nocturia or detrusor overactivity.

2. Methods

The patients participating in the study were recruited amongst postmenopausal patients with urodynamic stress urinary incontinence attending the Urogynaecology Unit of the 2nd Department of Obstetrics & Gynaecology, in Aretaieio Hospital. Ninety-two patients were included in group 1 (treatment group) and ninety one patients were included in group 2. Patients in group 1 had anti-incontinence surgery followed by oestrogen treatment. The patients in group 2 (control group) had anti-incontinence surgery only. Inclusion criteria were the presence of urodynamic stress incontinence. Exclusion criteria were presence of urge or mixed incontinence and cystocele greater than stage II. Also, patients with comorbidities were excluded that could affect the therapeutic outcome. Thus, patients with health problems aggravating their incontinence, such as neurological disease, diabetes mellitus, and congestive heart failure were excluded.

All patients had to complete a 3-day bladder diary and to undergo uroflow, filling and voiding cystometry and urethral profilometry pre-operatively and at 2 and 6 months follow-up. In addition, patients of group 1 at 6 months follow-up had a transvaginal ultrasound to assess endometrial thickness. Endometrial thickness less than 5 mm was considered normal. All patients were required to have a normal mammogram within the last year. As menopausal have been considered the patients having lack of menstruation for 1 year or more with concomitant significant elevation of gonadotropines.

Primary outcome measures were the incidence of post-operative symptoms (frequency, urgency, nocturia) compared to the non-treated group. Secondary outcome measures were the urodynamic parameters of maximum flow rate, maximum cystometric capacity, maximum urethral closure pressure, maximum urethral length, detrusor pressure at maximum flow, maximum detrusor pressure and post-void residual.

Subjective cure was considered the absence of urine leaking with coughing, sneezing, weight lifting, etc., as it was stated by the patients. The anti-incontinence procedure performed was insertion of a Tension Free Vaginal Tape-Transobturator (TVT-O). The TVT-O was performed under epidural anaesthesia. The patients in group 1 were instructed to use estradiol tablets, 25 micrograms (Vagifem, Novo Nordisk) vaginally, once daily, nocte, for 2 weeks and then twice weekly for 6 months. The patients in group 2 (control group) had the TVT-O procedure only. We reviewed the patients in 2 months and again in 6 months time. Sample size was estimated on the basis that in order to demonstrate a reduction from 26% of overactive bladder symptoms (which is the highest quoted estimate of overactive bladder post-suburethral sling) to 10%, with an 80% power, we had to recruit 90 patients in each arm of the study. The patients were randomized as follows: patients had to put their names in a waiting list of the outpatient gynecology department. When they were called to come in to the hospital for the operation, were randomly allocated in to one of the two groups from the staff of the outpatient department in an alternate fashion. The definitions used were based on the International Continence Society Standardisation of Practice Guidelines. Approval of hospital ethical committee and informed consent was obtained from all patients.

The findings of the urodynamic investigations between the two groups were analysed by Student's *t*-test. We also used paired *t*-test to compare the urodynamic findings within groups (before any treatment and at 2 and 6 months). The differences in post-operative symptoms between the two groups were also calculated and analysed by *z*-test. A $p < 0.05$ was considered statistically significant.

3. Results

Between February 2004 and January 2009, 190 patients were asked to participate in our study. Two patients declined, so 188 patients were enrolled. The follow-up period was completed by July 2009. 94 patients were randomly assigned in each group. In group 1, which was the treatment group, one patient did not receive the allocated treatment (Vagifem tablets) and two patients were lost to follow-up. In group 2, which was the control group, one patient did not receive the allocated treatment (TVT-O) and three further patients were lost to follow-up. A total of 92 patients in group 1 and 91 patients in group 2 were included in an intention to treat analysis.

Table 2
Urodynamic findings before treatment and at 6 months.

	Group 1 (95 pts)			Group 2 (94 pts)		
	Before	6 months	*p*-Value	Before	6 months	*p*-Value
Maximum flow rate (ml/s)	19.2 ± 10.4	17.3 ± 11.8	0.0876	18.8 ± 8.2	17.7 ± 7.1	0.1164
Maximum cystometric capacity (ml)	425.4 ± 165.2	392.3 ± 155.2	0.2763	430.2 ± 170.1	395.1 ± 150.3	0.1211
Maximum urethral closure pressure (cm H20)	76.4 ± 30.8	74.2 ± 29.8	0.2623	75.2 ± 30.9	74.7 ± 28.9	0.3774
Functional urethral length (mm)	22.8 ± 4.7	24.9 ± 5.2	0.0717	23.4 ± 5.0 ± 4.8	25.3 ± 5.6	0.1696
Detrusor pressure at maximum flow (cm H20)	15.2 ± 17.3	17.3 ± 19.4	0.1036	14.8 ± 16.2	16.8 ± 18.5	0.1395
Maximum detrusor pressure (cm H20)	26.7 ± 10.3	27.8 ± 10.8	0.3260	26.2 ± 10.7	27.7 ± 12.4	0.819
Post-void residual	13.22 ± 16.8	22.58 ± 20.8	0.0564	14.31 ± 15.7	23.7 ± 17.3	0.1795

Download English Version:

https://daneshyari.com/en/article/1918088

Download Persian Version:

https://daneshyari.com/article/1918088

Daneshyari.com