Urodynamic Parameters Response to Transvaginal Electrical Stimulation versus Trospium Hydrochloride in Women with Overactive Bladder Syndrome

Ali A. Thabet* and Mohamed M. Radwan**
*Department for Obstetrics and Gynecology, Faculty of Physical Therapy, Cairo University.
** Department of Obstetrics and Gynecology, Faculty of Medicine, Al Azhar University.

ABSTRACT

Background: *This study aimed to compare the urodynamic parameter response to transvaginal electrical stimulation versus trospium hydrochloride in women with overactive bladder syndrome.* ***Methods:*** *Forty patients were divided randomly into transvaginal electrical stimulation (Group A) and trospium hydrochloride (Group B). All patients were assessed before and after the end of the treatment course of 12 weeks according to urodynamic first sensation to void and bladder capacity.* ***Results:*** *Both groups (A and B), showed highly significant (P<0.0001) increase after the end of the treatment compared to the baseline regarding to first sensation to void, with no statistical significant differences (P>0.05) among both groups. Also, Comparing the results of the bladder capacity, showed that there was a highly significant (P< 0.0001) increase in both group (A and B) in the bladder capacity, while comparing the results of the bladder capacity among both group (A and B) showed that transvaginal electrical stimulation group (Group A) was statistically significant (P<0.05) when compared to trospium hydrochloride group (Group B).* ***Conclusion:*** *both of transvaginal electrical stimulation and trospium hydrochloride improve the urodynamic parameter in cases of overactive bladder syndrome. But still the transvaginal electrical stimulation seems to be more effective.*
Key Words: *trospium hydrochloride; transvaginal ES; Overactive Bladder; urodynamic parameter.*

INTRODUCTION

Overactive bladder (OAB) syndrome is defined as urgency, with or without urgency incontinence, usually with frequency and nocturia[7,8].

Overactive bladder syndrome affects individuals adversely, both physically and psychosocially, and worsens their quality of life. It also causes infection, sleeps disorders and depression and places a significant burden on health economics[19].

Overactive bladder syndrome is a common disorder, which can have a significant negative impact on quality of life, impairing several areas, including emotional well-being, productivity at home and at work, social relationships, sexual intimacy and physical functioning[14,15].

The estimated prevalence of overactive bladder syndrome among people aged 40 years and above is 15.6% and 17.4% in men and women, respectively, and one-third also experience urge urinary incontinence[1,24].

Overactive bladder syndrome affects individuals adversely, both physically and psychosocially, and worsens their quality of life. It also causes infection, sleeps disorders and depression and places a significant burden on health economics[7].

Pharmacological treatment comprises the main therapeutic modality in overactive bladder syndrome. However, the adverse effects of antimuscarinic therapy can influence a patient's quality of life and result in suboptimal dosing, poor patient compliance and even drug discontinuation[23].

Trospium chloride, which was approved for overactive bladder syndrome recently and is gaining popularity, improves urodynamic parameters and symptoms markedly with fewer side-effects (anticholinergic and central nervous system side-effects) than other anticholinergics[23].

The most commonly used non-drug treatment modalities include bladder training, pelvic floor muscle training and electrical stimulation. Electrical stimulation has been suggested to permit an effective inhibition of detrusor activity by stimulating the afferents of the pudendal nerve. It has been reported to be safe and effective for urinary incontinence[2,4].

The rationale behind the use of electrical stimulation (ES) to treat the symptoms of OAB is the observation that ES of the pelvic floor muscle reduces or inhibits detrusor activity, which contributes to the control of urgency sensation. In addition, our recent previous report has proved ES to be the best among ES, pelvic floor muscle training alone, and biofeedback-assisted pelvic floor muscle training in the treatment of OAB[26].

Electrical stimulation of the pelvic floor reduces symptoms of urinary urgency or frequency. The mechanism involves decreasing bladder overactivity by stimulating peripheral nerves that represent the same sacral area as the bladder. Three pathways are debated, at low bladder filling volumes by direct stimulation of the hypogastric nerve through activation of the sympathetic fibers, at maximal bladder filling by direct stimulation of the nuclei of the pudendal nerve in the spinal cord and due to a supra spinal inhibition of the detrusor[13].

In the last two decades successful maximal electrical stimulation (MES) of the pelvic floor has been reported in various type of urinary incontinence and various types of MES methods including anogenital long-term stimulation, short-term maximal stimulation, implantable stimulation and transcutaneous stimulation have been reported[11,16]. The therapeutic effects of these approaches were similar and the percentage of patients improved has been reported to be in the range of 50–90%[5,16]. MES of bilateral pudendal nerves by intravaginal electrodes has been claimed to inhibit involuntary detrusor contraction and represented a therapeutic alternative for urinary incontinence resulting detrusor instability[4,6,11,16,21].

Electrical stimulation induces fewer side-effects and is less costly than anticholinergic treatment though few studies exist that compare electrical stimulation and anticholinergic treatment[2,3,12].

The present study was carried out to determine the effectiveness of transvaginal electrical stimulation versus trospium hydrochloride on urodynamic parameters.

METHODOLOGY

Subjects

This study was carried out on forty volunteer's postmenopausal women, they were diagnosed with overactive bladder (urge incontinence), and they were randomly selected from Bab El Sharia University Hospital. Their age ranged between 47 to 59 years (Mean = 53.72 ±4.05), their body mass index not exceed 30 Kg/ m2. They were free from genito-urinary anomalies and infections, free from neurological problems, pelvic tumor, history of low back pain as well as, other types of urinary incontinence, also, free from diabetes, with no history of chronic relevant medical disease and none of them received medical treatment (except trospium hydrochloride for group B) during the study course. Patients were divided randomly into two groups (A and B) each group 20 patients. All patients were given a full explanation of the treatment protocol and informed consent form had been signed from each patient before participating in this study.

Materials

1) Weight-height scale was used for measuring the patient's body weight and height to calculate the body mass index.
2) DANTIC UD5000/5500 Urodynamic Investigation System A double-lumen cystometry catheter was used to fill the bladder with 0.9% saline solution at a rate of 20 ml/min. Volume at first desire to void and maximum bladder capacity were recorded before starting the study and at the end of the study (after 12 weeks).
3) ELPHA 2000 Conti: The ELPHA 2000 Conti was used to exercise the pelvic floor muscles by electrical stimulation, for strengthening the pelvic floor musculature and inhibiting the involuntary detrusor muscle contraction. Electrical stimulation was delivered by using a two-ring vaginal probe.
4) Jell was used for lubrication of the vaginal probe of the electrical stimulation.
5) Antiseptic solution was used for sterilization of the vaginal probe of the electrical stimulation.

Methods

1- Evaluation procedure:

Evaluation was done before starting the treatment and after the end of the treatment program for all patients participated in this study.

Urodynamic evaluation:

Urodynamic studies were carried by the Medical Staff of Urodynamic Unit, in Bab El Sharia University Hospital, to confirm the diagnosis of overactive bladder. It was used for measuring the first desire to void which revealed bladder sensation and the Bladder capacity. This procedure was done pre and post treatment at after 12 weeks.

2- Treatment procedure:

Subjects were divided randomly into two groups (A and B) and each group was included 20 patients.

Group A (Transvaginal electrical stimulation):

Consisted of 20 patients who received vaginal electrical stimulation for 12 weeks, three times a week, using a two-ring vaginal probe, biphasic symmetrical rectangular pulse with 5 Hz frequency, 0–80mA (the maximal current the patient could tolerate) for a total duration of 100 ms was applied for 20 minutes per session.

Group B (Trospium hydrochloride):

Consisted of 20 patients who were given trospium hydrochloride (Spasmex 30-mg tablet) for 12 weeks at a dose of 45 mg/day, 30 mg in the mornings and 15 mg in the evening.

Statistical Analysis

Statistical analysis of all the collected data was statistically analyzed using paired t-test for comparing each group before and after treatment and unpaired t-test to compare between the two groups. Also, descriptive statistics included mean (X), standard deviation (S.D) and percentage %. Significance level of 0.05 will be used throughout all statistical tests within this study; P-value< 0.05 will indicate a significant result.

RESULTS

The results of this clinical study were represented as follows:

1) The first desire to void was measured before starting the treatment, after twelve week of the treatment for all the patients in both groups (A and B).
2) The bladder capacity was measured before starting the treatment and after twelve week of the treatment for all patients in both groups (A and B).

As observed in table (1) and figure (1), in the group (A), there was highly significant (P<0.0001) increase in the first desire to void in response to transvaginal electrical stimulation and the percentage of improvement in first desire to void in group (A) was 46.00%. And also, in group (B), there was highly significant (P<0.0001) increase in the first desire to void in response to trospium hydrochloride and the percentage of improvement in first desire to void in group (B) was 36.18%.

Table (1): The comparison between the pre and post mean values and percentage of improvement of the first desire to void between both groups (A and B).

		Pre treatment	Post treatment	MD	Imp. %	t-value	P-value	Significance
Group (A)	Mean	103.00	150.00	47.00	46.00%	27.097	<0.0001	Highly significant
	SD	7.54	11.29					
Group (B)	Mean	103.20	140.20	37.00	36.00%	8.547	<0.0001	Highly significant
	SD	6.69	19.93					

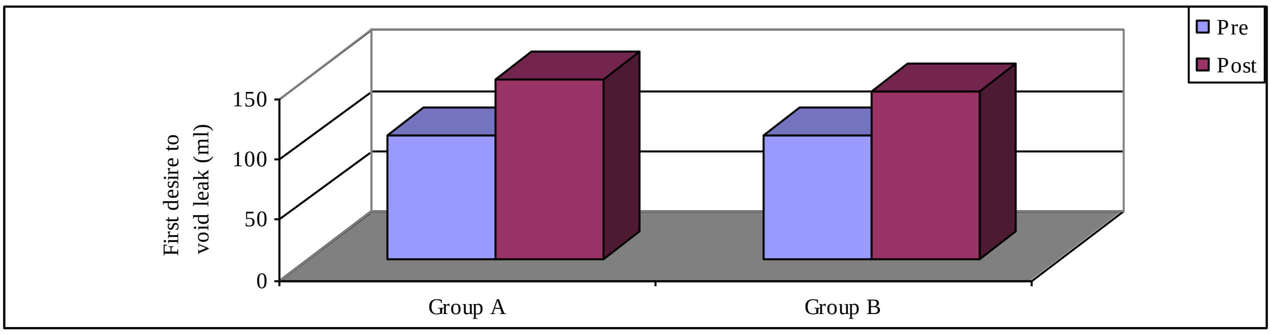

Fig. (1): The mean values of pre & post of the first desire to void in both groups (A and B).

As observed in table (2) and figure (2), comparing mean value of first desire to void at the end of the treatment course for transvaginal electrical stimulation group (Group A) and trospium hydrochloride group (Group B) revealed no statistical significant differences (P>0.05) among both groups.

Table (2): The comparison between pre and post mean values of the first desire to void between both groups (A and B).

		Group (A)	Group (B)	MD	Imp. %	t-value	P-value	Significance
Pre treatment	Mean	103.00	103.20	00.20	00.0%	0.122	0.904	Non Significant
	SD	7.54	6.69					
Post treatment	Mean	150.00	140.20	9.80	6.88%	1.934	0.068	Non Significant
	SD	11.29	19.93					

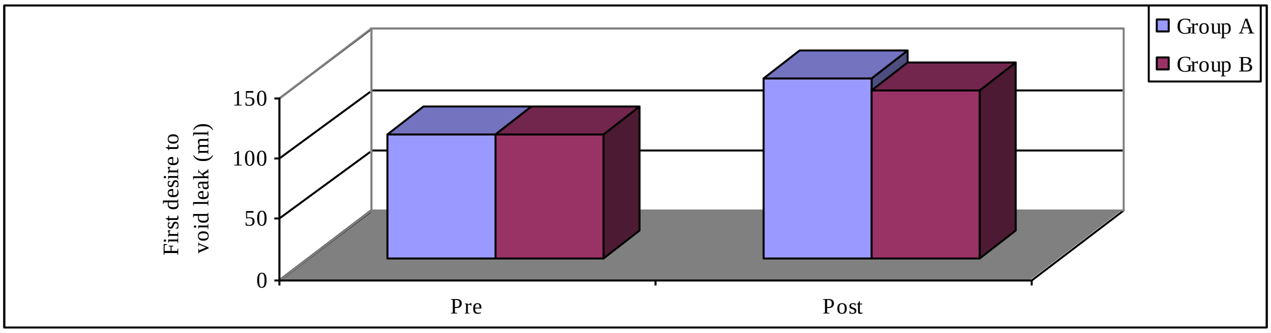

Fig. (2): The comparison between pre and post mean values of the first desire to void between both groups (A and B).

As observed in table (3) and figure (3), in group (A), there was a highly significant (P<0.0001) increase in the bladder capacity in response to transvaginal electrical stimulation after the end of the treatment course and the percentage of improvement in bladder capacity in group (A) was 20.00%. Also, in group (B), there was a highly significant (P<0.0001) increase in the bladder capacity in response to trospium hydrochloride after the end of the treatment course and the percentage of improvement in bladder capacity in group (B) was 13.40%.

Table (3): The comparison between the pre & post mean values and percentage of improvement of the bladder capacity between both groups (A and B).

		Pre treatment	Post treatment	MD	Imp. %	t-value	P-value	Significance
Group (A)	Mean	238.22	285.58	47.40	20.00%	14.673	<0.0001	Highly significant
	SD	18.80	18.81					
Group (B)	Mean	238.00	269.85	31.85	13.40%	7.503	<0.0001	Highly Significant
	SD	13.86	23.75					

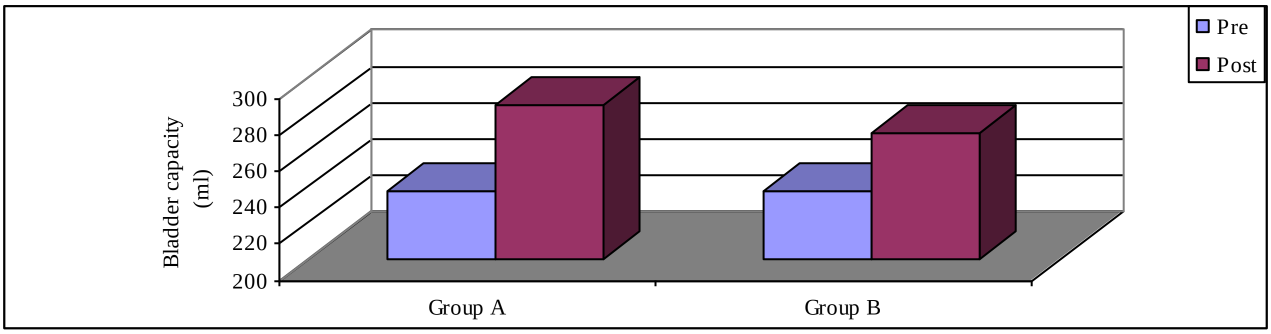

Fig. (3): The mean values of pre & post of the bladder capacity in both groups (A and B).

As observed in table (4) and figure (4), comparing mean value of bladder capacity at the end of the treatment course for transvaginal electrical stimulation group (Group A) and trospium hydrochloride group (Group B) showed that transvaginal electrical stimulation group (Group A) was statistically significant (P<0.05) when compared to trospium hydrochloride group (Group B).

Table (4): The comparison between pre and post mean values of the bladder capacity between both groups (A and B).

		Group (A)	Group (B)	MD	Imp. %	t-value	P-value	Significance
Pre treatment	Mean	238.22	238.00	00.22	00.0%	0.017	0.986	Non Significant
	SD	18.80	13.86					
Post treatment	Mean	285.58	269.85	15.73	5.82%	2.50	0.022	Significant
	SD	7.11	9.69					

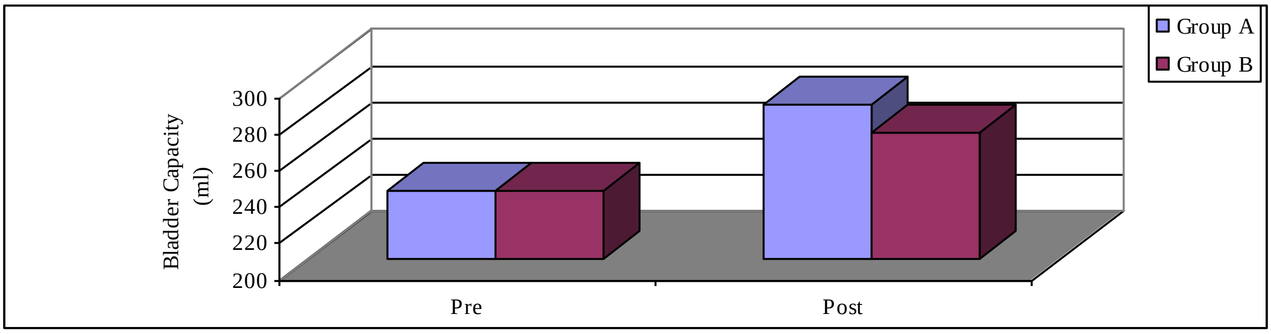

Fig. (4): The comparison between pre and post mean values of the bladder capacity between both groups (A and B).

DISCUSSION

The main goal of overactive bladder syndrome is to inhibit detrusor overactivity and thus to increase functional bladder capacity. Few studies have explored the effects of electrical stimulation on urodynamic parameters, and these studies presented evidence that it causes improvements[1,7,28].

This study was designed to determine the effectiveness of transvaginal electrical stimulation versus the trospium hydrochloride in urodynamic parameters in cases of overactive bladder.

The results of our study revealed improvements in urodynamic parameters, with treatment in both groups. While comparing the results of the bladder capacity among both group (A and B) at the end of this study showed that transvaginal electrical stimulation group (Group A) was statistically significant (P<0.05) when compared to trospium hydrochloride group (Group B).

So, In the present study, we found that both transvaginal electrical stimulation and trospium hydrochloride improved urodynamic parameters, but there was statistically significant difference regarding bladder capacity for the transvaginal electrical stimulation group.

These results agreed with previous study reported that vaginal ES had the greatest success rate of 58.4% and was the most effective of the three treatments for OAB. Oxybutynin was more effective than placebo[25].

The obtained results also agreed with study reported that Maximal electrical stimulation could offer a safe, non-invasive and effective treatment for patients with detrusor instability who respond poorly to other conservative therapies[27].

The obtained results also agreed with those reported that a significant difference between cystometric bladder capacity before and after application of maximal pelvic floor stimulation in idiopathic detrusor instability[10].

Also, these results were supported by previous study that found thirty-two of the 45 patients (71%) with idiopathic detrusor dysfunction improved both urodynamically and subjectively after the electrostimulation treatment.[17] And also, our results were in agreement with those few previous studies on the effect of pelvic floor electrical stimulation for the treatment of idiopathic detrusor instability[5,13,20,28].

Also, these results were supported by previous studies found lowering of the detrusor pressure after the transvaginal electrical stimulation[9,20,28].

These results were supported previous study found that detrusor instability became stable in 89% of women with detrusor instability using transvaginal electrical stimulation[7].

These results also agreed with previous study reported that electrical stimulation was useful in treating urinary incontinence due to detrusor instability with 70% cure rate[28].

These results also agreed with previous Studies that compared the effects of intravaginal electrical stimulation and anticholinergic treatment (propantheline, oxybutynin) on urodynamic parameters found no significant change in urodynamic parameters[27].

Zinner and colleagues' 12-week, placebo-controlled study with trospium hydrochloride reported significant improvement after treatment in the IIQ-7 total score in patients who used trospium hydrochloride[29].

In contradiction, previous study using a single vaginal or anal electrode device for short term home treatment reported a 30% cure rate and 22% at one year follow up based on questionnaires[17].

In another study that compared perianal transcutaneous electrical stimulation with oxybutynin, the authors showed that oxybutynin improved urodynamic parameters better than electrical stimulation[22].

Conclusion

In conclusion, both vaginal electrical stimulation and trospium hydrochloride were effective in women with overactive bladder syndrome, and thus the continuation of these two treatments is important. Still the transvaginal electrical stimulation seems to be more effective than the trospium hydrochloride in treating overactive bladder that represent conservative treatment which is cheap, simple to handle, non invasive safe, non toxic, free of adverse events and non pharmacological type.

REFERENCES

1- Alhasso, A., McKinlay, J., Patrick, K. and Stewart, L.: Anticholinergic drugs versus non-drug active therapies for overactive bladder syndrome in adults. Cochrane Database Syst Rev. 4: CD003193, 2006.

2- Amaro, J., Gameiro, M., Kawano, P. and Padovani, C.: Intravaginal electrical stimulation: a randomized, double-blind study on the treatment of mixed urinary incontinence. Acta Obstet Gynecol Scand. 85: 619-622, 2006.

3- Arruda, R., Castro, R., Sousa, G., Sartori, M. and Baracat, E.: "Prospective randomized comparison of oxybutynin, functional electrostimulation, and pelvic floor training for treatment of detrusor overactivity in women. Int Urogynecol J Pelvic Floor Dysfunct ", 19: 1055-1061, 2008.

4- Berghmans, L., Hendriks, H. and De Bie, R.: Conservative treatment of urge urinary incontinence in women: a systematic review of randomized clinical trials. BJU Int. 85: 254-263, 2000.

5- Bo, K.: Effect of electrical stimulation on stress and urge urinary incontinence. Clinical outcome and practical recommendations based on randomized controlled trials. Acta Obstet Gynecol Scand. 168: 3-11, 1998.

6- Bratt, H., Salvesen, K., Eriksen, B. and Kulseng-Hanssen, S.: Long-term effects ten years after maximal electrostimulation of the pelvic floor in women with unstable detrusor and urge incontinence. Acta Obstet Gynecol Scand. 168: 22-24, 1998.

7- Brubaker, L., Benson, J. and Bent, A.: Transvaginal electrical stimulation for female urinary incontinence. Am J Obstet Gynecol. 177: 536-540, 1997.

8- Cardozo, L., Coyne, K. and Versi, E.: Validation of the urgency perception scale. BJU Int. 95: 591-596, 2005.

9- Carlson, B., Dedkov, E., Borisov, A. and Faulkner, J.: Skeletal muscle regeneration in very old rats. J. Gerontol. A Biol. Sci. Med. Sci. 56, B224–B233, 2001.

10- Erickson, D., Herb, N., Ordille, S., Harmon, N. and Bhavanandan, V.: A new direct test of bladder permeability. J Urol. 164: 419, 2000.

11- Eriksen, B., Bergman, S. and Eik-Nes, S.: Maximal electrostimulation of the pelvic floor in female idiopathic detrusor instability and urge incontinence. Neurourol Urodyn. 8: 219-230, 1989.
12- Kabay, S., Mehmet, Y. and Sahin, K.: "Acute urodynamic effect of percutaneous posterior tibial nerve stimulation on neurogenic detrusor overactivity in patients with multiple sclerosis" urology 71: 641-645, 2008.
13- Klinger, H., Pycha, A. and Marberger, M.: "Use of peripheral neuromodulation of S3region for the treatment of detrusor over activity:a urodynamics based study". Urology 56: 766-771, 2000.
14- Klotz, T., Bru¨ ggenju¨ rgen, B., Burkart, M. and Resch, A.: The economic costs of overactive bladder in Germany. Eur Urol. 51: 1654-1663, 2007.
15- Monz, B., Chartier-Kastler, E. and Hampel, C.: Patient characteristics associated with quality of life in European women seeking treatment for urinary incontinence: results from PURE. Eur Urol. 51: 1073-1082, 2007.
16- Okada, N., Igawa, Y. and Nishizawa, O.: Functional electrical stimulation for detrusor instability. Int Urogynecol J Pelvic Floor Dysfunct. 10: 329-335, 1999.
17- Plevnik, S., Homan, G. and Vrtacnik, P.: Short-term maximal electrical stimulation for urinary retention. Urology 24: 521-523, 1984.
18- Primus, G. and Kramer, G.: Maximal external electrical stimulation for treatment of neurogenic or non-neurogenic urgency and/or urge incontinence. Neurourol Urodyn. 15: 187-194, 1996.
19- Richard, F. and toozs-hobson, P.: detrusor overactivity. obstetrics, gynaecology and reproductive medicine, 17(9): 255-260, 2007.
20- Siegel, S., Richardson, D. and Miller, K.: Pelvic floor electrical stimulation for the treatment of urge and mixed incontinence in women. Urology 50: 934 -940, 1997.
21- Smith, J.: Intravaginal stimulation randomized trial. J Urol. 155: 127-130, 1996.
22- Soomro, N., Khadra, M., Robson, W. and Neal, D.: A crossover randomized trial of transcutaneous electrical nerve stimulation and oxybutynin in patients with detrusor instability. J Urol, 166: 146-149, 2001.
23- Staskin, D.: Trospium chloride: Distinct among other anticholinergic agents available for the treatment of overactive bladder. Urol. Clin. North Am. 33: 465–73, 2006.
24- Stewart, W., Van Rooyen, J. and Cundiff, G.: Prevalence and burden of overactive bladder in the United States. World J Urol. 20: 327-336, 2003.
25- Wang, A., Chih, S. and Chen, M.: Comparison of electric stimulation and oxybutynin chloride in management of overactive bladder with special reference to urinary urgency: a randomized placebo controlled trial. Urology, 68: 999–1004, 2006.
26- Wang, A., Wang, Y. and Chen, M.: Single-blind, randomized trial of pelvic floor muscle training, biofeedback assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. Urology, 63: 61-66, 2004.
27- Yalcin, O., Hassa, H., Sarac, I.: Int J Gynaecol Obstet. Short-term intravaginal maximal electrical stimulation for refractive detrusor instability Dec. 79(3): 241-244, 2002.
28- Yamanishi, T., Yasuda, K., Sakakibara, R., Hattori, T. and Suda, S.: Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity. Urology 55: 353-357, 2000.
29- Zinner, N., Gittelman, M., Harris, R., Susset, J. and Kanelos, A.: Trospium Study Group. Trospium chloride improves overactive bladder symptoms: a multicenter phase III trial. J Urol, 171: 2311-2315, 2004.

الملخص العربي

استجابة قياسات ديناميكية البول للتنبية الكهربائي عبر المهبل مقابل عقار تروسبيام هيدروكلوريد في متلازمة فرط نشاط المثانة

أجريت هذه الدراسة لتحديد مدي أستجابة قياسات ديناميكية البول للتنبيه الكهربائي عبر المهبل مقابل عقار تروسبيام هيدروكلوريد في متلازمة فرط نشاط المثانة . وقد شاركت أبعون سيدة في هذه الدراسة ، وقد تم تقسيمهن إلى مجموعتين (أ ، ب) . المجموعة (أ) تم علاجهن بالتنبيه الكهربائي عبر المهبل ، والمجموعة (ب) تم علاجهن بعقار تروسبيام هيدروكلوريد . لمدة 12 أسبوع بواقع ثلاث جلسات أسبوعياً . وقد استخدمت قياسات ديناميكية البول قبل وبعد العلاج . وقد أكدت نتائج هذ ه الدراسة على تحسن قياسات ديناميكية البول للمثانة بالتنبيه الكهربائي عبر المهبل واستخدام عقار تروسبيام هيدروكلوريد في متلازمة فرط نشاط المثانة . وقد أوضحت النتائج أن هناك تحسن ذو دلالة إحصائية في قياسات ديناميكية البول الدالة على سعة المثانة في المجموعة (أ) بالمقارنة بالمجموعة (ب) وهكذا يمكن أن نستخلص أن التنبيه الكهربائي عبر المهبل كان أكثر تأثيراً وفاعلية بالمقارنة باستخدام عقار تروسبيام هيدروكلوريد في متلازمة فرط نشاط المثانة .

الكلمات الدالة : التنبيه الكهربائي- تروسبيام هيدروكلوريد - ديناميكية البول – متلازمة فرط نشاط المثانة .