Posterior Tibial Nerve Stimulation for Treating Neurologic Bladder in Women: a Randomized Clinical Trial

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Abstract- Overactive bladder (OAB) is a disabling disorder. Treatment of cases with OAB includes behavioral, pharmacological, surgical interventions and peripheral electrical stimulation. The goal of this study was to determine effects of posterior tibial nerve stimulation on sexual function and pelvic disorders in women with Overactive bladder (OAB). Fifty women were randomly assigned to PTNS (posterior tibial nerve stimulation) plus tolterodine or tolterodine alone treatment. Tolterodine group received 4 mg tolterodine daily for three months while the other group received this treatment plus percutaneous tibial nerve stimulation for 12 consequence weeks. Two in PTNS group and 8 in the control group withdrew from the study. Age, education level, and occupation status were not significantly different between two groups. Mean total FSFI and its subscales were not significantly different before and after treatment between two groups. Urine leakage associated with a feeling of urgency and loss of stool or gas from the rectum beyond patient's control became significantly different after treatment between two groups. Posterior tibial nerve stimulation could help urinary problems in women with a neurologic bladder.

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Introduction

Overactive bladder (OAB) is a disabling disorder characterized by urinary urgency with or without urge incontinence, frequency and nocturia in the absence of underlying pathology (1). Overactivity of the bladder detrusor muscle, unprovoked contractions of the detrusor and urethro-vesical dysfunction may cause OAB symptoms. OAB affects near 16% of adults in America during its incidence increases with age advancing (2-3). OAB affects social, psychological, occupational, domestic, physical, and sexual functioning of all affected cases (4). Low self-esteem, embarrassment, depression and increase in the number of falls and fracture are among consequences of OAB(5-6).

Treatment of cases with OAB include behavioral, pharmacological, surgical interventions and peripheral electrical stimulation(7).

Peripheral electrical stimulation has been considered for treating urinary disorders for many years (8-9). Different methods such as chronic perineal muscles stimulation, acute perineal nerve stimulation (dorsal nerve of the penis), chronic electrical stimulation of perineal skin/ sacral dermatomes and posterior tibial nerve stimulation were applied to treat different urinary disorders (8-10).

Amarenco *et al.,* showed that posterior tibial nerve stimulation increased detrusor contraction volume and maximum cystometric capacity (11).

The goal of this study was to determine the effects of posterior tibial nerve stimulation on sexual function and pelvic disorders in women with Overactive bladder (OAB).

Materials and Methods

In this randomized clinical trial which conducted in Imam Hospital (affiliated hospital of Tehran university of medical sciences) between September 2012 and

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September 2013, 50 women with confirmed neurologic bladder (by means of urodynamic test) enrolled. By means of computer generated numbers, cases were assigned to PTNS plus tolterodine or tolterodine alone treatment. Tolterodine group received 4 mg tolterodine daily for three months while the other group received this treatment plus percutaneous tibial nerve stimulation for 12 consequence weeks.

Every session lasted for 30 minutes while a 34 gauge needle placed 5 cm near internal malleolus. All cases asked to fill informed consent forms from the studies that had been approved by local ethics committee. All cases filled FSFI (Female sexual function Index) and a questionnaire assessing pelvic problems. Nor the patients nor the physician were blinded to the patient's group.

All data were analyzed using SPSS software version 18.0 (SPSS Inc., Chicago, IL, USA).

Student's t-test and paired sample t-test was used to compare continuous variables and *chi*-square used to compare categorical variables.

P-value less than 0.05 was considered as significant.

Results

Before the study beginning, 2 in PTNS group and 8 in the control group withdrew from the study.

Age, educational level, and occupation status were not significantly different between two groups (Table 1).

Mean total FSFI and its subscales were not significantly different before and after treatment between two groups.

Repeated measure ANOVA showed that mean FSFI and its subscales were significantly different before and after treatment in each group ($P<0.001$) (Table 2).

Pelvic disorders were not significantly different before treatment between two groups (Table 3).

Urine leakage associated with a feeling of urgency and loss of stool or gas from the rectum beyond patient's control became significantly different after treatment between two groups (Table 4).

Table 1. Demographic characteristics between two groups

		PTNS group	Control group	*P*-value
Age (mean ±SD)		47±13.1	49.5±10.3	0.5
Level of education	**Educated**	18	13	0.7
	Not educated	5	4	
Occupation status	**Occupied**	6	7	0.4
	Not occupied	17	10	
Previous delivery	**Yes**	21	17	0.2
	No	2	0	

Table 2. FSFI and its subscales before and after treatment in each group

	PTNS group	Control group	*P*-value
Desire before treatment	2.7±1.7	2.2±1.4	0.4
Desire after treatment	2.9±1.5	2.5±.1	0.3
Arousal before treatment	2.6±1.7	2.4±1.5	0.7
Arousal after treatment	3±1.6	2.3±1.7	0.1
Lubrication before treatment	3.1±2	2.5±2.1	0.3
Lubrication after treatment	3.4±2.1	2.5±1.8	0.1
Orgasm before treatment	2.8±2	2.2±1.8	0.3
Orgasm after treatment	3.4±2.3	2.3±1.5	0.06
Satisfaction before treatment	3±1.8	2.2±1.8	0.1
Satisfaction after treatment	3±1.9	2.2±1.4	0.1
Pain before treatment	3.8±2.3	2.9±2.2	0.2
Pain after treatment	4.2±2.2	3.2±2.2	0.1
Total FSFI score before treatment	18.1±10.7	14.6±10.5	0.3
Total FSFI score after treatment	20.2±11.2	15.2±8.7	0.1

Table 3. Pelvic disorders before treatment between two groups

		PTNS group	Control group	*P*-value
1. Do you usually experience urine leakage related to coughing, sneezing or laughing?	**Yes**	18	7	
	No	5	10	
If yes, how much does it bother you?	**Rarely**	5	3	0.07
	Somewhat	4	1	
	Moderately	5	0	
	Quite a bit	4	3	
2. Do you usually experience frequent urination during the day or awaking during the night for urination 2 times or more?	**Yes**	14	12	
	No	9	5	
If yes, how much does it bother you?	**Rarely**	3	1	0.2
	Somewhat	0	3	
	Moderately	4	2	
	Quite a bit	7	6	
3. Do you usually experience a strong sensation of needing to go to the bathroom for urination?	**Yes**	21		
	No	2		
If yes, how much does it bother you?	**Rarely**	5	2	0.8
	Somewhat	7	6	
	Moderately	9	8	
	Quite a bit			
4 .Do you usually experience urine leakage associated with a feeling of urgency?	**Yes**	18	14	
	No	5	3	
If yes, how much does it bother you?	**Rarely**	3	2	0.3
	Somewhat	4	2	
	Moderately	7	2	
	Quite a bit	4	8	
5. Do you usually experience difficulty emptying your bladder?	**Yes**	7	5	
	No	19	12	
If yes, how much does it bother you?	**Rarely**	3	4	0.5
	Somewhat	1	0	
	Moderately	1	1	
	Quite a bit	2	0	
6. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	**Yes**	12	8	
	No	11	9	
If yes, how much does it bother you?	**Rarely**	4	3	0.5
	Somewhat	1	3	
	Moderately	3	1	
	Quite a bit	4	1	
7. Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?	**Yes**	10	6	
	No	13	11	0.7
If yes, how much does it bother you?	**Rarely**	5	1	
	Somewhat	3	3	
	Moderately	1	1	
	Quite a bit	1	1	
8. Do you usually lose stool or gas from rectum beyond your control?	**Yes**	11	2	
	No	12	15	
If yes, how much does it bother you?	**Rarely**	6	1	0.1
	Somewhat	4	1	
	Moderately	0	0	
	Quite a bit	1	0	
9. Are you sexually active?	**Yes**	12	11	
	No	11	6	
If yes, how much does it bother you?	**Rarely**	0	4	0.1
	Somewhat	3	3	
	Moderately	6	3	
	Quite a bit	3	1	
10. Do you usually experience vaginal noise?	**Yes**	5	2	
	No	18	15	
If yes, how much does it bother you?	**Rarely**	4	1	0.5
	Somewhat	0	0	
	Moderately	1	1	
	Quite a bit	0	0	

Table 4. Pelvic disorders before treatment between two groups

		PTNS group	Control group	*P*-value
1. Do you usually experience urine leakage related to coughing, sneezing or laughing?	**Yes**	16	8	
	No	7	9	
If yes, how much does it bother you?	**Rarely**	5	3	0.3
	Somewhat	7	1	
	Moderately	2	2	
	Quite a bit	1	1	
2. Do you usually experience frequent urination during the day or awaking during the night for urination 2 times or more?	**Yes**	12	12	
	No	11	5	
If yes, how much does it bother you?	**Rarely**	3	6	0.3
	Somewhat	5	2	
	Moderately	1	1	
	Quite a bit	2	3	
3. Do you usually experience a strong sensation of needing to go to the bathroom for urination?	**Yes**	21	16	
	No	2	1	
If yes, how much does it bother you?	**Rarely**	8	4	0.2
	Somewhat	9	4	
	Moderately	2	5	
	Quite a bit	1	3	
4 .Do you usually experience urine leakage associated with a feeling of urgency?	**Yes**	18	14	
	No	5	3	
If yes, how much does it bother you?	**Rarely**	9	3	0.03
	Somewhat	7	3	
	Moderately	1	6	
	Quite a bit	0	2	
5. Do you usually experience difficulty emptying your bladder?	**Yes**	6	4	
	No	17	13	
If yes, how much does it bother you?	**Rarely**	3	3	0.7
	Somewhat	3	1	
	Moderately	0	0	
	Quite a bit	0	0	
6. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	**Yes**	12	8	
	No	11	9	
If yes, how much does it bother you?	**Rarely**	6	1	0.1
	Somewhat	1	5	
	Moderately	1	1	
	Quite a bit	3	1	
7. Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?	**Yes**	8	6	
	No	15	11	
If yes, how much does it bother you?	**Rarely**	4	0	0.1
	Somewhat	4	3	
	Moderately	0	2	
	Quite a bit	0	1	
8. Do you usually lose stool or gas from rectum beyond your control?	**Yes**	11	2	
	No	12	15	
If yes, how much does it bother you?	**Rarely**	9	0	0.01
	Somewhat	3	2	
	Moderately	0	0	
	Quite a bit	0	0	
9. Are you sexually active?	**Yes**	12	11	
	No	11	6	
If yes, how much does it bother you?	**Rarely**	1	6	0.06
	Somewhat	3	3	
	Moderately	4	2	
	Quite a bit	4	0	
10. Do you usually experience vaginal noise?	**Yes**	2	2	
	No	18	15	
If yes, how much does it bother you?	**Rarely**	3	0	0.4
	Somewhat	1	1	
	Moderately	1	1	
	Quite a bit	0	0	

Discussion

The result of the current study showed that PTNS is effective for improving urine leakage associated with a feeling of urgency and controlling stool or gas lost from rectum. The result showed that these items improved significantly after treatment in PTNS group than tolterodine group. We also found no significant difference between two groups regarding FSFI score and its subscales.

In a previous study conducted by Peters *et al*., twenty-nine patients with neurogenic bladder were treated with PTNS method for 36 months. The result of their study showed that mean urination at night reached 1.7 at the end of the study in comparison to 2.7 at the beginning. Urinary urgency had decreased to 0.3 in comparison to 3.3. At the end of study, all items of quality of life had improved(12). In another study conducted by Peters *et al*., in 2009, 100 patients with frequency urination randomly received either PTNS for 12 weeks or 4mg tolterodine. They found that frequency had been improved in 79% in PTNS group and 54% in the other group(13).

By applying 12 weeks PTNS for patients with OAB, Scott *et al.,* investigated that after 6 and 12 months, 94% and 96% of patients responded to the treatment (14).

Amarenco *et al*., treated 44 patients with OAB with PTNS and reported detrusor contraction volume cystometry as 162.9 ml at the beginning of the study while it became 232.1 ml during PTNS. Their findings showed that PTNS significantly improved first involuntary detrusor contraction volume (11).

These findings could show that PTNS in effective in treating urinary symptoms.

Behavioral modifications such as bladder training, pharmacological and surgical interventions have been considered as treatment modalities for cases with OAB.

Cases with detrusor instability or hyperreflexia usually are treated with anticholinergic drugs while they have no efficacy for urinary symptoms in some patients. On the other hand, cases suffer from side effects of these medications and most of the cases quit the treatment. Dry mouth, constipation, blurring eyes, hesitancy or urinary retention are among adverse effects of these medications (11).

A different method of electrostimulation has been regarded to improve bladder storage capacity. For instance, literature shows that sacral anterior root stimulation and S3 neuromodulation was effective for treating bladder over-activity but needed surgical implantation and a test period (15).

Previnaire *et al.,* used dorsal penile or clitoris nerve surface electrodes for patients with spinal cord injury and investigated significant increase in bladder capacity (10).

By means of vaginal electrode or surface electrode on dorsal part of penis in cases with detrusor overactivity, Yamanishi *et al*., reported significant increase in bladder and cystometric capacity (16).

Our results showed that PTNS is effective for improving urine leakage associated with a feeling of urgency and controlling stool or gas lost from rectum.

By depolarizing somatic sacral and lumbar afferent fibers, PTNS prevents bladder activity (17). Stimulation of afferent fibers will result in central inhibition of the

preganglionic bladder motor neurons in the sacral cord (8).

PTNS is a minimally invasive technique which could suppress detrusor instability or hyperreflexia and increase bladder capacity (11). As it is not invasive, it could be used in clinical practice but multi-centric studies with larger sample sizes are needed. Also, patients with urinary problems and different underlying diseases should be enrolled in the study.

Conclusion: posterior tibial nerve stimulation could help urinary problems in women with neurologic bladder.

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