



EFFECT OF TRANSCUTANEOUS STIMULATION OF POSTERIOR TIBIAL NERVE ON OVERACTIVE BLADDER : A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Urinary incontinence (UI) is the involuntary leakage of urine. It is Common health problems among women of old ages with prevalence ranging from 10% to 34% in India. UI affects the women physically and psychosocially and worsen their quality of life. Overactive bladder is defined as urgency, with or without incontinence, usually with increased frequency and nocturia. To investigate the effects of Transcutaneous Nerve Stimulation (TENS) of Tibial Nerve on frequency, quality of life, and urgency in women with overactive bladder. In this Randomized Controlled trial, 30 women having overactive bladder problem with age between 35-70 years were selected. Women with pelvic surgery, any neurological problem, pregnancy were excluded. Subjects were divided into 2 groups randomly: Group A (experimental n=15) and Group B (control n=15). Outcome measures were frequency and volume of urination, Visual Analogue Scale for urgency of micturation and King's health questionnaire for quality of life. Conventional TENS was given on posterior tibial nerve for unilateral leg trice a week for 4 weeks and re-assessment was done at the end of 4th weeks. Statistically significant difference in pre-post frequency of micturation was noted as Gr. A had mean frequency of 2.10 and gr. B had 1.06. Volume of Urine showed significant reduced in Group A (24.29 ml) than group B (9.39 ml). Statistically significant improvements was seen in group A in urgency of micturation and quality of life than group B after 4 weeks of treatment. This study concluded that TENS improves the overactive bladder problems and thus improves the quality of life. TENS on Tibial nerve is cost effective and non invasive technique which can be easily utilized by many women for their treatment without feeling embarrassed.

KEYWORDS: TENS , Urinary Incontinence, Overactive bladder, Tibial Nerve



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INTRODUCTION

According to the International Continence Society (ICS), Incontinence of urine is defined as the involuntary loss of urine which is a social or hygiene problem. Involuntary urinary leakage may be a symptom of which the patient complains or a sign seen on examination, which may be urethral or extraurethral leakage. In women, urinary leakage may need to be distinguished from sweating or vaginal discharge.¹ Symptoms tends to become worse with age, especially in women reaching postmenopausal years. Generally only 1 in 10 women will seek professional services for incontinence.² A survey by Lewis *et al* (1993) indicated that 75% women subjects with incontinence had remained silent for 3 or more years before taking consulting help.³ This problem frustrates and depresses the individual.⁴ With prevalence ranging from 10% to 34% in India,⁵⁻⁶ the condition is usually under reported as many women hesitate to seek help or report symptoms to doctors due to the embarrassing and culturally sensitive nature of this condition.⁷ It is most common health problems among women of old age, with an increase in prevalence of aging.⁸ It is reported that 25% to 45% of women, of different ages and throughout the world suffer from involuntary urine leakage while 9% to 39% of women over 60yrs of age report daily urinary leakage.⁹ In Brazil studies indicate that between 26.2% and 35% of post menopausal women suffer from UI.¹⁰ Most studies report some degree of UI in 25%-45% of women; 7%-37% of women aged 20-39 years report some UI; "daily UI" is reported by 9%-39% of women aged > 60 years. Prevalence of UI in men is approximately half of that in women: UI is seen in 11%-34% of older men, with 2%-11% reporting daily UI.¹¹⁻¹² Women experience incontinence twice as often as men, with 15% to 30% of women in all ages group affected. Among middle-aged women, research indicates that 58% reported some urine loss, but only 25% took treatment. Among non-institutionalised women older than 60, it was found that 37.7% suffered from incontinence. A new study showed that transcutaneous posterior tibial nerve stimulation is safe and acceptable with evidence of potential benefits for bladder dysfunction in elders.¹³ Some studies reported that transcutaneous nerve stimulation (TENS) could be used as a worldwide treatment for neurological patients with urinary symptoms.¹⁴ TENS is a relatively convenient, cheap and non-invasive therapy and it is also free from pharmaceutical side effects. Few studies done on percutaneous tibial nerve stimulation (PTNS) on overactive bladder. It was effective and also cost effective. This studies were done by using a Urgent percutaneous stimulation which had two electrode: one needle and another surface electrode. The most common side-effects with PTNS treatment are temporary and minor, resulting from placement of needle electrode. They include minor bleeding, mild pain and skin inflammation. There have been very few studies done on TENS in overactive bladder. It is believe that the electrical stimulation can penetrate the skin delivering tibial nerve stimulation. Hence the objective of this study was to find the effectiveness of TENS on overactive bladder as it is cost-effective and doesn't harm the subject as it has both surface electrodes

METHODOLOGY

In this experimental study design, 30 female subjects were included who have Overactive bladder problems (urge incontinence) from the age of 30 to 70 yrs. Random allocation of subjects by lottery method were done in 2 groups: Group A (experimental n=15) and Group B (control n=15). Ethical clearance was taken from Institutional Sub-Ethics committee with Reference No. DYPCPT/297-A/28/2015 Dated 22/08/2015. Informed written consent was taken from the subjects. Pre assessment was taken for outcome measures. They were excluded if they had Pelvic surgery, Neurological deficit or peripheral neuropathy that may cause neurogenic bladder, Pregnancy or suspicious of pregnancy, Genitourinary infection or haemorrhage and deterioration in cognitive or intellectual functions, Females taking medicine like anticholinergics and antidepressants, No physiotherapy treatments received before for incontinence, Local tropic lesion on site of stimulation, Contraindications for TENS, No history of kidney failure. In group A the patients were treated with posterior tibial nerve stimulation for 4 weeks, 3 days a week, for 30 minutes and pelvic floor muscle strengthening exercise. Transcutaneous posterior tibial nerve stimulation was applied unilaterally with 2 surface electrodes: Negative electrode placed behind the medial malleolus and Positive electrode 10cms proximal. Stimulation protocol was fixed frequency of 10Hz, pulse width 200ms for 30 minutes. The amplitude is slowly increased until the large toe starts to curl or toes start to fan. If the large toe does not curl or pain occurs near the application site, the stimulation device is switch off and the procedure is repeated. In group B, with placebo treatment the patients were treated. Posterior tibial nerve stimulation for 4 weeks, 3 days a week, for 30 minutes and pelvic floor muscle strengthening exercise. Nerve stimulation was applied unilaterally with 2 surface electrodes: Negative electrode placed behind the lateral malleolus and Positive electrode 10cms proximal. Stimulation protocol was fixed frequency of 10Hz, pulse width 200ms for 30 minutes.

Outcome Measures were as follows

Voiding Diary - Before each assessment, patients were asked to fill in a three day voiding diary that included daily voiding frequency (n/day) and frequency of urgency before voiding (n/day). A frequency volume chart with three days columns with 3 subdivision on it i.e. F= Fluid intake U= Urine passed W=Wet (leakage). A plastic measuring mug with 500ml marking done on it was given to patients. Visual analogue scale (VAS) for severity of urine - A 10 cm visual analogue scale (VAS) was used to assess the severity of urgency in patients where a horizontal line with 'no urgency' at the starting and 'maximum urgency of urination' at the end was marked. Patient were instructed to place a mark on the line that corresponds to their severity of urgency. Quality of life using King's Health Questionnaire - The researcher had given the patients the questionnaire and asking about it. The researcher mark on the questionnaire. Post outcome measures were taken after four weeks and data was collected and analysis was done.

RESULT

Statistical Analysis was done using Primer of Biostatistics Software. Comparison between pre and post treatment within the groups were tested by Paired test whereas between the groups were tested by t-test. Analysis of co variant (ANCOVA) was used for comparing difference between the group for quality of life

Table 1
Comparison of Age in Both Groups

Group	Mean	SD	t value	P value
Group A	43.13	17.56	1.528	0.138
Group B	53.27	18.75		

Table 2
Comparison of TENS in group A and group B

	Group	Pre	post	Diff in Pre & Post	SD	P value	P & t values
Frequency of urine	Gr.A	9.63	7.5	2.10	0.7471	0.00	P<0.001
	Gr.B	9.2	8.13	1.06	0.9377	0.00	t =5.045
Volume of Urine	Gr.A	216.7	241	24.29	24.24	0.002	P = 0.03
	Gr.B	236.3	245.7	9.39	7.23	0.000	t =2.281
Urgency of Mictu-ration	Gr.A	7	1.06	7.20	2.752	0.000	P<0.001
	Gr.B	7.6	4.3	3.26	0.8837	0.000	t=11.397

Table 3
Effect of TENS on Group A and B on Quality of life of the patients

Ques No	Group A				Group B			
	pre mean	post mean	Diff of pre & post	SD	pre mean	post mean	Diff of pre & post	SD
1	70	33.3	36.11	12.47	43.8	11.6	32.22	13.69
2	68.8	33.3	35.53	8.624	51	2.22	48.84	17.2
3	71	32	38.89	24.95	49.9	0	49.96	17.81
4	64.8	31.08	33.77	32.42	39.9	0	39.97	18.68
5	67.3	28.12	39.23	22.16	46.9	0	46.99	15.82
6	27.7	16.6	11.11	17.43	14.4	3.3	11.11	20.57
7	74.7	33.3	41.41	18.98	40.1	1.84	38.26	12.78
8	85.5	32.1	53.34	14.39	55.6	20.8	34.83	20.99
9	67.2	22.7	44.44	14.31	36	1.17	34.89	9.81

Significant change between the pre and post treatment value in Quality of life in treatment of Group A as value of ($p < 0.001$), except domain 6 i.e personal relationship which is not statistically significant. There is also significant change between the pre and post treatment values in Quality of life in Group B as value of ($p < 0.001$),, except domain 6 i.e. personal relationship which is statistically not significant. When both groups were compared using ANCOVA test for the post values using pre values as covariate, Domain 1 showed not significant difference. In domain 2, 3, 4, 7 & 9 showed significant differences, mean scored showed more improvement in group A than group B. Domain 5, 6 & 8 could not analysed as post values were 0.

DISCUSSION

The purpose of the study was to examine the effect of Transcutaneous Posterior Tibial Nerve Stimulation on frequency, volume of urination, severity of urgency and quality of life in women with overactive bladder syndrome. Group A patients had mean age 43.13 ± 17.56 and Group B had 53.27 ± 18.75 . After conducting the study for 3 days/week for 4 weeks, significant

improvement in group A in which TENS was found. Studies done by Leslie saltzstein Woodridge and Joanne Booth et al have shown the effects of posterior tibial nerve electrical stimulation on urodynamic parameters, frequency and volume of urination and these studies presented evidence that it cause improvement. S_2 - S_4 nerve roots provide the principal motor supply to the bladder and S_3 root mainly innervates the destrusor muscle. The posterior tibial nerve is a mixed nerve containing L_5 - S_3 fibres, originating from the same spinal segments as parasympathetic innervations to the bladder. The physiological effects of this treatment may be explained by the presence of posterior tibial nerve afferent fibres in same sacral projection of the bladder innervations. In this way, the stimulation of posterior tibial nerve afferent fibre would produce a neuromodulation in the region, inhibiting destrusor muscle afferent fibres, thereby reducing the urge sensation.¹⁵ Posterior tibial nerve electrical stimulation was chosen as a alternative physiotherapeutic method for the treatment of overactive bladder, which is effective and without any side effects. This study showed significant improvement in quality of life (QOL) in group A by using King's Health

Questionnaire. There is a negative impact on quality of life among patients suffering from overactive bladder. To reduce this impact, they choose to change their lifestyles like adjust their travel plans, look for places with easy access to bathrooms and often restricted their fluid intake. Hence, when incontinence was improved, QOL was better.¹⁶ There are similar studies done on overactive bladder with percutaneous posterior tibial nerve stimulation by Michael R van Balken et al, Miguel Angel Arrabal-Polo et al, Martin Slovak et al showed a significant improvement in symptoms after overactive bladder syndrome after PTNS treatment.^{17, 18, 19} Group B was treated with TENS on lateral aspect of lower limb and pelvic floor strengthening exercise. The result showed improvement in reduction in urgency of micturition, volume and frequency of urination and quality of life, can be due to the pelvic floor muscle strengthening exercises given three times for 4 weeks. Pelvic floor muscle contraction can inhibit the detrusor muscle contraction. During urine storage there is an increased pudendal nerve outflow response to the external urethral sphincter, increasing intraurethral pressure. Micturition centre excitatory loop switches on when bladder pressures are between 5 and 25mm Hg, while the inhibitory loop is predominantly active above 25mm Hg. Inhibition involves an automatic (unconscious) increase in tone for both the pelvic floor muscle and the urethral striated muscle. Thus, voluntary pelvic floor muscle contractions may be used to control urgency and urge incontinence.²⁰ A similar study done by Marianne de S'eze et al, on multiple sclerosis patients, suffering from overactive bladder. Their results, showed improvement in symptom like urgency, reduce frequency and urge urinary incontinence and had a positive impact on QoL. The clinical efficacy of TPTNS

occurs independently of the cystometric effect may argue for a predominant action non TPTNS on the afferent pathway of the micturition reflex. This sensitive action on TPTNS is of particular interest in patients presenting with urgency and irritative symptoms linked to sensitization of bladder afferent pathways, as observed in MS.²¹ A similar study was done using TENS in the treatment of patients with post stroke urinary incontinence. There was significant improvement in daily micturition, nocturia, urgent urination, and urge urinary incontinence compared to the control group. Thus TENS improved incontinence symptoms, enhanced quality of life, and decreased adverse effects.²² The limitation of this study was less sample size, men were not included in the study. This study was confined to comparatively lesser age group even though OAB was prevalent in old age people

CONCLUSION

This study concluded that transcutaneous posterior nerve stimulation is effective in treating the overactive bladder symptoms and improving quality of life of these patients.

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CONFLICT OF INTEREST

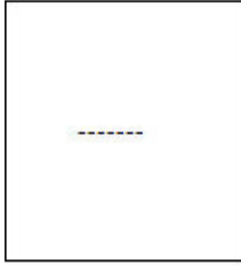
Conflict of Interest declared None

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