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EFFECTIVENESS OF TRANSCUTANEOUS ELECTRICAL STIMULATION OF VAGUS NERVE AMONG POST STROKE URINARY INCONTINENCE

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ABSTRACT

BACKGROUND: One of the leading cause for disability and morbidity in India is Stroke.Among the stroke survivors, Urinary Incontinence (UI) is the most common condition that is more associated to disability and mortality. A study stated that among the continent stroke survivors 35% of them had an incidence of UI in a week.The "Vagus nerve stimulation" is a generalized term describing any method of stimulation of Vagus nerve. **OBJECTIVE:**To Find out the Effectiveness of Transcutaneous Electrical Nerve Stimulation of Vagus nerve in post stroke urinary incontinence . **METHODOLOGY:**The study design is experimental,study type was Single Blinded Randomized type, Sampling method was Random sampling Method with 30 subjects and Study duration was 8 weeks,Studysetting was SRM Medical College Hospital and Research Centre, Kattankulathur A total of 30 subjects were taken randomly ,Group-A subjects were given transcutaneous Vagus Nerve Stimulation (tVNS) and Kegel's exercise. Group-B control group was given Kegel's exercise alone. **OUTCOME MEASURES:**Barthel Index Score (BIS) and Overactive Bladder Symptom Score (OBSS) **RESULTS**: There is a significantly more improvement in the control of urinary bladder in Group-A than Group-B **CONCLUSION:** tVNS shows an increase in the bladder control in post stroke urinary incontinence patients.

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Key words: Transcutaneous Vagus Nerve Stimulation (tVNS), Urinary Incontinence, stroke, Kegel's exercise, pelvis floor muscles

INTRODUCTION

One of the leading cause for disability and morbidity in India is Stroke. The estimated prevalence rate of stroke range is aroundeighty four to two hundred sixty two per one lakh population in rural and three hundred thirty four to four hundred twenty four per one lakh population in urban areas. Based on the recent population based studies the incidence rate is around one hundred nineteen to one hundred forty five per one lakh population.[1]Among the stroke survivors, Urinary Incontinence (UI) is the most common condition that is more associated to disability and mortality. A study stated that among the continent stroke survivors 35% of them had an incidence of UI in a week.[2]

Young post stroke survivors with higher functional independence, have higher incidence of regaining continence. Cognitive impairment, communication ability, mobility and consciousness levels influences the continence in post stroke.[3]Urinary incontinence (UI) is the uncontrolled urine leakage, which is a prognostic risk factor. Thirty two percent to seventy nine percent of hospitalized stroke patients experience incontinence.[4]Signals are carried from the digestive system to the brain vice versa through the Vagus nerve. The tenth cranial nerve runs form the brain to the abdomen through the thorax. It is hence known as the "Wanderer nerve" due to its long pathway.[5]

The Vagus nerve exits the brainstem through the groove, between the medullary pyramid and Inferior cerebral peduncle and further from the skull it exits through the "Jugular Foramen".[6] The contraction of the smooth muscles at the small intestines and glandular secretions are being regulated by the Vagus nerve. The preganglionic neurons of the vagal efferent fibers of dorsal motor nucleus of Vagus

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nerve innervate the muscular and mucosal layers of the gut (in the lamina propria as well as muscularis externa). [7, 8&9]

The "Vagus nerve stimulation" is a generalized term describing any method of stimulation of Vagus nerve. In the 1880's the first observation for suppressing seizures through manual massage and carotid artery compression at the cervical region was carried out, it attributed to crude vagal nerve stimulation. In the 1930's and 1940's several studies were conducted researching the effect of the autonomic nervous system due to Brain modulation through Electrical Vagus Nerve Stimulation.[10]

PROCEDURE

The study got Institutional ethical committee clearance (1659/IEC/2019) initiallyThe Participants were explained about the procedure and the awareness of the study. The informed consent was obtained from the Participants who were willing to participate in the study according to inclusion criteriaSubject with post stroke UI.Subjects who were stable, cooperative, and could effectively communicate (to accomplish therapy). Subjects with urinary retention. And exclusion criteria

Subjects having various reasons for UI in the past (Parkinson's disease, spinal cord disease, dementia, urinary tract tumors, urolithiasis, unhealed urinary tract infections, or history of urinary tract surgery). Subjects with severe cognitive function disorders (Mini-Mental State Examination14-22 points).

Subjects with concurrent systemic disorders. . Further the demographic data was collected, then the patient were asked to fill in the "Modified Barthel Index" and the Overactive Bladder Symptom Score (OBSS) questionnaire before the treatment commenced to check their current control of the urinary bladder.

The subjects were divided in to two groups, the Group A(Experimental group) and the Group B (Control group) with each group of 15 patients.

The Group A did the Kegel's exercise and also underwent Vagus nerve stimulation using TENS with the clip electrodes placed at the Auditory Meatus and Concha

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(Cymba conchae and Cavum conchae) at the left ear (continuous 0.25ms pulses, 25Hz) for 60 minutes once a day for 60 days., in the general medicine ward in presence of a senior physiotherapist and emergency medical care.

The Group B was taught and asked to perform Pelvic floor muscles strengthening through Kegel's exercise, where in the exercises involve the conscious contraction and relaxation of the Pubococcygeus muscle, with the goal of increasing the resting tension of the sphincter components for 60 days.

OUTCOME MEASURES

1. Overactive Bladder Symptoms Score
2. Barthel Index Score sheets

RESULTS

According to Table 1 The table shows significant result increase in Overactive Bladder Symptom Score for Group A (experimental group) value between pre-test and post- test at $p<0.001$ level.

According to Table 2, The table shows significance in Barthel Index Score for Group A (experimental group) value between pre-test and post- test at $p<0.001$ level.

According to Table 3, The table shows non-significant results in Overactive Bladder Symptom Score Score for Group B (Control group) value between pre-test and post- test at $p<0.001$ level.

According to Table 4, The table shows non-significant results in Barthel Index Score for Group B (Control group) value between pre-test and post- test at $p<0.001$ level.

According to Table 5, The table shows non-significant results in Overactive Bladder Symptom Score and Barthel Index Score for Group A(Experimental group) and Group B (Control group) value in post- test at $p<0.001$ level.

DISCUSSION

There is a relaxation of the detrusor muscles, sphincter closing and bladder filling through the reduced activation of the "Sympathetic Nervous System" (SNS). The urge sensation to void is sent to the brain through spinal cord, as the urine volume in the bladder reaches two hundred to four hundred milliliters. The voluntary urination or micturition depends on the parasympathetic and voluntary somatic nervous system. Signals from these systems and corresponding somatic neuro activities, results in detrusor muscle contraction and relaxation of sphincter respectively .[11]

International Continence Society has defined urinary incontinence as an " involuntary urination". It is a common condition of public health in elderly population impacting their quality of life. Localized brain injuries causes pelvic muscle weakness and bladder hypersensitivity. Urinary tract infections, fungal dermatitis and nephritis are a few potential symptoms caused by urinary incontinence. It also causes decrease of self esteem, isolation from social activities and depression which in turn impacts the therapy, concentration and period of treatment.[12]

According to Homma Y et al., the Overactive Bladder Symptoms Score was intended to collectively evaluate the symptoms of Overactive Bladder. The score has the sum of four symptoms namely, morning time frequency, nocturnal frequency, urgency and urgency incontinence. Despite several measures available for evaluating the Overactive bladder as Primary Over Active Bladder Symptom Questionnaire, Urgency Questionnaire, etc. All the questionnaires measures only health related quality of life instead of the symptoms. Though it does not intend to neglect the symptoms. Hence the Overactive Bladder Symptom Score was intended to describe the symptoms for treating the Overactive bladder.[13]

Barthel index is for measuring the Activities of Daily Living performance and is mainly intended to individuals with stroke and other neuromuscular or

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musculoskeletal disorders. The bladder control has 0 to 10 (0= incontinence, 5= occasional accident and 10=continent), usually the Barthel index assessing is evaluated over preceding 24 to 48 hours, but occasionally longer periods will be relevant.[14]

The objective of this study was to find out the effectiveness of Transcutaneous Vagus nerve stimulation among post stroke Urinary Incontinence patients along with Kegel's exercise.

The statistical results has shown the Experimental group (Group A) of 15 subjects with Transcutaneous Vagus nerve stimulation and Kegel's exercise showed more significant increase in both Barthel Index Score and Overactive Bladder Symptom Score. According to the statistical results the experimental group has shown an increase in mean value from 1.93 to 5.0 between pre- test and post- test for Barthel Index Score and an increase in mean value from 8.33 to 12.80 between pre- test and post- test atp<0.001 level.

In an experimental study lead by Eleni Franogos et al., revealed the relation between the auricular branch of the Vagus nerve and the urinary bladder control. According to the study while stimulating the vagus nerve through left cymba conchae there were activities noticed at the contralateral Locus coeruleus and bilateral paracentral lobules. Literatures states the cortical regions that regulates the voluntary control of the bladder functions includes the Paracentral lobule.[15] A study by Anna P Malykhina revealed that moments before urinating, there is rapid increase in less frequencied neuron of the Locus Coeruleus match closely to that neurons at medial Prefrontal Cortex (mPFC).

The changes help in urinating, by increasing the attention by increased arousal through filled bladder. The neurological physiology behind urination is the "medial Prefrontal Cortex (mPFC)" located anteriorly in the cortex, Pontine Micturation Center (PMC) and Locus Coeruleus (LC) at pons of brainstem send and receive signals within one another. Bladder signals reach LC through spinal cord, further passed to other parts of the brain including PMC. PMC signals back to the bladder through spinal cord. Then PMC consist neurons that are "Corticotrophin Releasing Hormone (Crh+)" which involve in the commencement of the urination

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and other type of neuron without this hormone is Crh- that are potentially believed to help in urine storage.[16]

The Control group (Group B) of 15 subjects who were taught and asked to practice Kegel's exercise alone, without the Transcutaneous Vagus nerve stimulation has shown a statistically lesser significance than the Experimental group in Barthel Index Score and Overactive Bladder Symptom Score. The control group increase in mean value from 1.93 to 2.66 between pre and post –ctest for Barthel score index and increase in mean value from 13.0 to 12.6 between pre and post – test for Overactive Bladder Symptom Score atp<0.001 level.

According to Shin and his team, urinary incontinence has been impacted by pelvic floor strengthening exercise, depending on the method applied. Both group were given pelvic muscle training, fifty minutes, thrice a week for eight weeks. The pelvic floor muscle training consist of educating all the participants about urinary incontinence and role of pelvic floor muscles. Further the participants were asked to contract their pelvic floor muscles by leaning forward and backward, while contracting the pelvic floor muscles and pulling in the coccyx; through erect sitting over the couch for pulling the ischium for strengthening mucles.

The participants also contracted the abdominal muscles and muscles of pelvic floor together through "sit ups". Auklee and team in their study reported that muscle activities of pelvic floor increased significantly through muscle training of pelvic floor with biofeedback among mild aged female population. Kim and team in their study reported that muscle training of pelvic floor region after child birth under therapist supervision had more effect urinary incontinence than those who were not supervised by therapist. [18]

There are several studies stating the influence of the Vagus Nerve controlling the urinary bladder and several text supporting the incidence of Urinary incontinence in Vagus Nerve injury.

Thus this study concluded that there is an increase in the bladder control through transcutaneous stimulation of the Vagus nerve along with Kegel's exercise.

It is also evident that there are many different types of continence problems that can occur (sometimes in combination) as a result of stroke.These include

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functional incontinence, stress incontinence, overflow incontinence and urge incontinency.

CONCLUSION

The study concludes that the experimental group with Kegel's exercise and Transcutaneous Vagus nerve stimulation showed a statistical significantincrease in the urinary bladder control in subjects with post stroke urinary incontinence.

The control group showed statistically lesser significance in the urinary bladder control as they were taught and asked to follow Kegel's exercise alone, no transcutaneous stimulation was given.

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest

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TABLE-1

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COMPARISON OF PRE AND POST TEST VALUE OF OBSS FORGROUP A (EXPERIMENTAL GROUP)

Test	Pre test mean	Post test mean	Mean value	Standard deviation	T value	significance
OBSS	8.33	12.80	-4.46667	2.13363	-8.108	.000

The above table reveals the mean, standard deviation, t-test, p value of Overactive Bladder Symptom Score (OBSS).

The Overactive Bladder Symptom Score has shown a decrease in mean value from 8.33 to 12.80 between pre- test and post- test.

The table shows significant result increase in Overactive Bladder Symptom Score forGroup A(experimental group) value between pre-test and post- test at $p<0.001$ level.

GRAPH-1

COMPARISON OF PRE AND POST TEST VALUE OF OBSS FOR GROUP A (EXPERIMENTAL GROUP)

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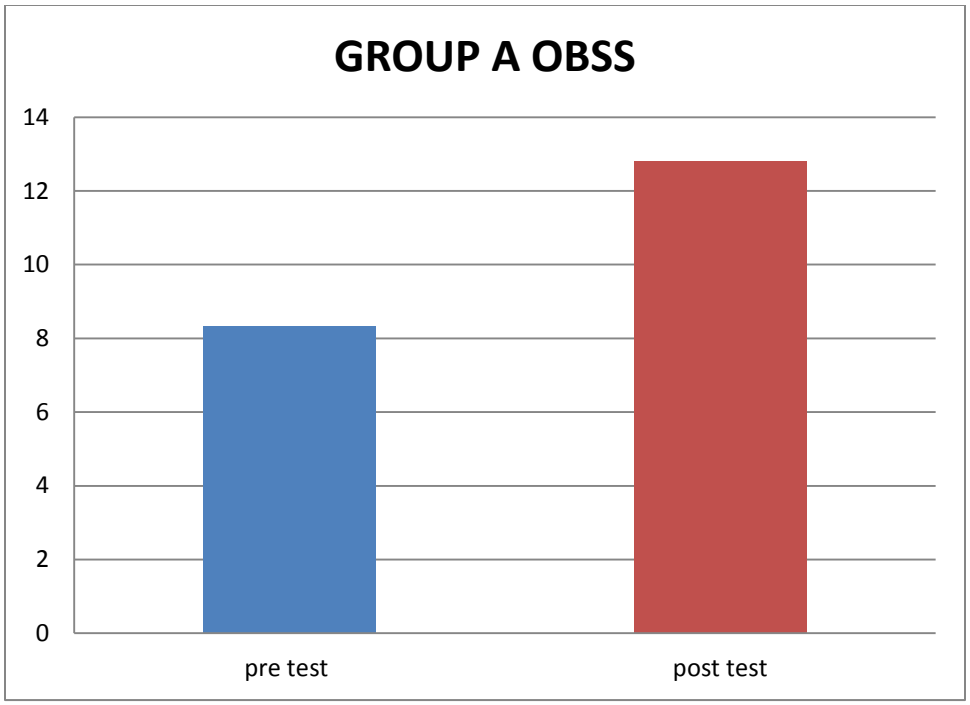

TABLE-2

COMPARISON OF PRE AND POST TEST VALUE OF BARTHEL INDEX SCORE FOR GROUP A (EXPERIMENTAL GROUP)

Test	Pre test mean	Post test mean	Mean value	Standard deviation	T value	Significance
BIS	1.93	5.00	-3.06667	1.70992	-6.946	.000

The above table reveals the mean, standard deviation, t-test, p value Barthel Index Score (BIS) between pre-test and post- test of the Group A (experimental group). Barthel index score has shown an increase in mean value from 1.93 to 5.00 between pre and post test.

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The table shows significance in Barthel Index Score forGroup A(experimental group) value between pre-test and post- test at $p<0.001$ level.

GRAPH 2

COMPARISON OF PRE AND POST TEST VALUE OF BARTHEL INDEX SCORE FOR GROUP A (EXPERIMENTAL GROUP)

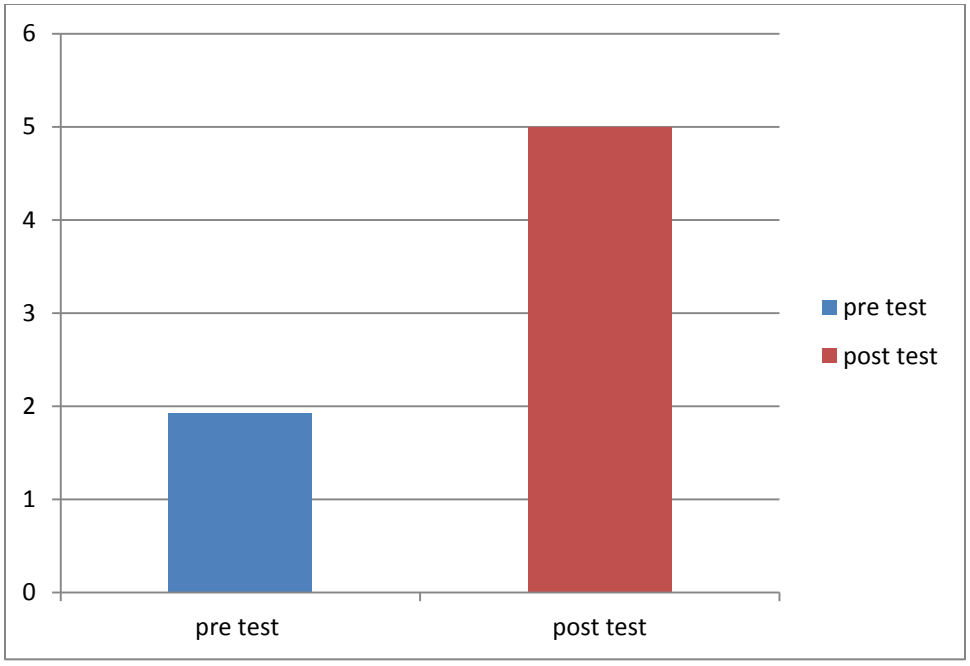

TABLE-3

COMPARISON OF PRE AND POST TEST VALUE OF OBSS FOR GROUP B (CONTROL GROUP)

Test	Pre test mean	Post test mean	Mean value	Standard deviation	T value	significance
OBSS	13.0	12.6	.46667	4.71876	.383	.707

The above table reveals the mean, standard deviation, t-test, p value of Overactive Bladder Symptom Score (OBSS) between pre-test and post- test of the Group B (control group).

The Overactive Bladder Symptom Score has shown a decrease in mean value from 13.0 to 12.6 between pre- test and post- test.

The table shows non-significant results in Overactive Bladder Symptom Score Score for Group B(Control group) value between pre-test and post- test at $p<0.001$ level.

GRAPH-3

COMPARISON OF PRE AND POST TEST VALUE OF OBSS FOR GROUP-B (CONTROL GROUP)

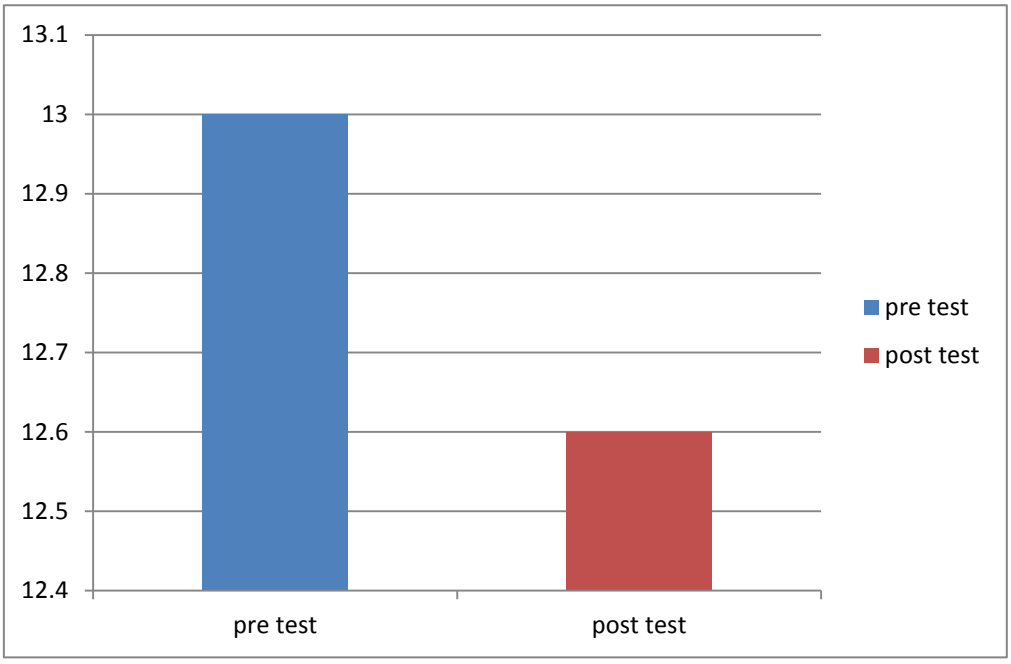

TABLE 4

COMPARISON OF PRE AND POST TEST VALUE OF BARTHEL INDEX SCORE FOR GROUP B (CONTROL GROUP)

Test	Pre test mean	Post-test mean	Mean value	Standard deviation	T value	Significance
BIS	1.66	2.66	-1.00000	1.51186	-2.562	.023

The above table reveals the mean, standard deviation, t-test, p value of Barthel Index Score (BIS) between pre-test and post- test of the Group B (control group). While Barthel index score has shown an increase in mean value from 1.66 to 2.66 between pre and post - test.

The table shows non-significant results in Barthel Index Score for Group B(Control group) value between pre-test and post- test at $p<0.001$ level.

GRAPH 4

COMPARISON OF PRE AND POST TEST VALUE OF BARTHEL INDEX SCORE FOR GROUP B (CONTROL GROUP)

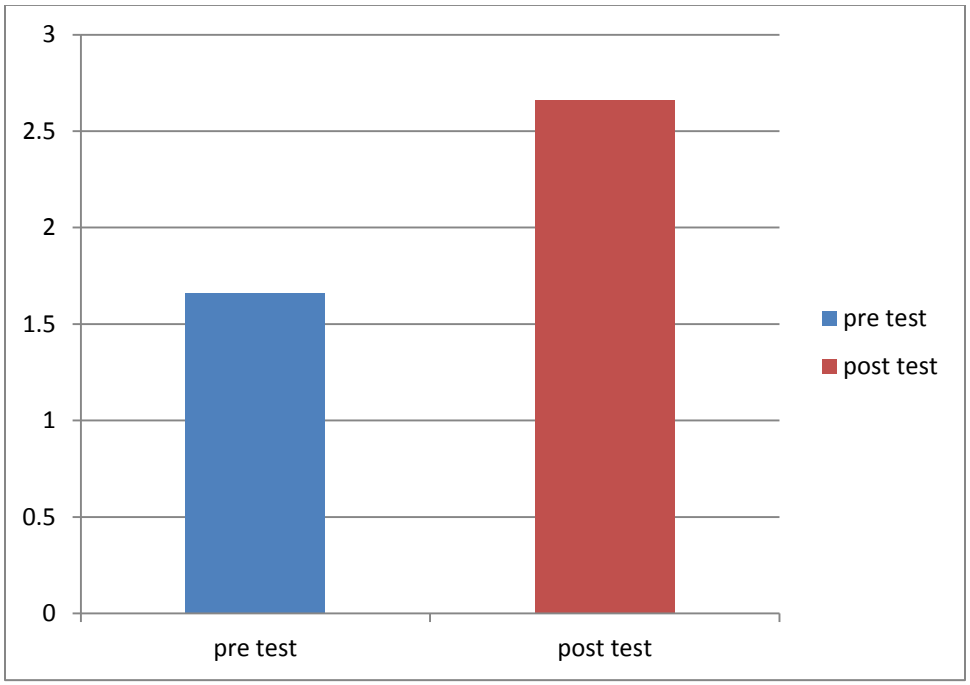

TABLE-5

COMPARISON BETWEEN POST TEST OF GROUP A (EXPERIMENTAL GROUP) AND GROUP B (CONTROL GROUP)

Test	Mean		T Value	Significance
	Group A	Group B		
OBSS	12.8	12.6	-374	.712
BIS	5.0	2.6	-2.73	.011

The above table reveals the mean, standard deviation, t-test, p value of Overactive Bladder Symptom Score (OBSS) and Barthel Index Score (BIS)in post- test of the Group A (experimental group) and Group B (control group).

The Overactive Bladder Symptom Score has shown a greater mean value in Group AthanGroup B in post- test. While Barthel index score has also shown a greater mean value in Group A than Group B in post- test.

The table shows non-significant results in Overactive Bladder Symptom Score and Barthel Index Score for Group A(Experimental group) and Group B(Control group) value in post- test at $p<0.001$ level.

GRAPH-5

COMPARISON BETWEEN POST TEST OF GROUP A (EXPERIMENTAL GROUP) AND GROUP B (CONTROL GROUP)