Efficacy of Sacral Nerve Stimulation for Controlling Urinary Incontinence in Children with Spina Bifida

Hebatallah M. Kamal* and Mohamed M.Khalaf**
*Department of Physical Therapy for Disturbance of Growth and Development in Children and its Surgery, Faculty of Physical Therapy, Cairo University.
**Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University.

ABSTRACT

Background: *Urinary incontinence is defined as involuntary loss of urine. It is a common problem affecting children and interferes with style of life. Urinary incontinence is one of the complications of spina bifida.* ***Purpose:*** *This study was conducted to examine the efficacy of sacral nerve stimulation on controlling urinary incontinence in children with spina bifida.* ***Intervention:*** *Twenty spina bifida children with urinary incontinence were enrolled in this study, aged between 4 and 8 years. They were divided randomly into two groups. Group (A) which is the control group received medical care and standard urotherapy only. And Group (B) which is the study group received medical care and standard urotherapy in addition to sacral nerve stimulation. The children received 36 sessions over 12 successive weeks. 24-hour pad test was used to obtain the outcome measures for the groups.* ***Results:*** *The results showed a significant decrease in urinary loss before and after treatment for each group, also showed no significant difference between control and study groups after the treatment.* ***Conclusion:*** *It can be concluded that sacral nerve stimulation conducted through transcutaneous electrical nerve roots stimulation with the parameters used in this study has no role in controlling urinary incontinence in children with spina bifida.*

Key words: *Urinary incontinence, Sacral nerve Stimulation, Spina bifida, TENS.*

INTRODUCTION

Normal micturition involves passive, low pressure filling of the bladder during the urine storage phase while voiding requires coordination of detrusor muscle contraction with internal and external urinary sphincter relaxation. This micturition process is controlled by the central nervous system, which coordinates the sympathetic and parasympathetic nervous system activation with the somatic nervous system to ensure normal micturition with urinary continence[23].

Urinary incontinence is defined as any involuntary loss of urine. There is difficulty in treating urinary incontinence and neurogenic bladder which are common in children[5]. Urinary incontinence affects about 17% of children[8].

Bladder dysfunction is common in spina bifida, which affects approximately 1 per 1000 live births. Vesicoureteral reflux may occur in up to 40% of children with spina bifida by age 5, and up to 61% of young adults with spina bifida experience urinary incontinence[22].

The nonsurgical management of patients with spina bifida is predicated on maintaining a compliant bladder of adequate size or correcting detrusor sphincter dyssynergy that can lead to progressive bladder damage and ultimately upper tract changes. Pharmacologic management, targeted at the detrusor and/or external sphincter, can be done. Neuromodulation using transcutaneous approaches with interferential electro stimulation, sacral (S2-S3) roots stimulation via digital transcutaneous electrical nerve stimulation and percutaneous tibial nerve stimulation all suggested to have varied successes[3].

Sacral nerve stimulation with the InterStim implantable device has been used in adults for management of chronic urinary complaints. However, there are few data regarding the usefulness of sacral nerve stimulation in children[19].

Sacral neuromodulation (SNM) has been approved by the Food and Drug Administration (FDA) for the treatment of refractory voiding dysfunction since the late 1990s; urge incontinence (UI) since 1997, and urgency-frequency syndrome (U/F) and idiopathic, non-obstructive urinary retention (NOUR) since 1999[21].

A main goal of therapy should be to help the child gain continence with as little disruption in lifestyle as possible, in a manner

that allows the child to independently manage his/her self-care as early as possible.

The goal of this study is to test the ability of sacral nerve stimulation to control urinary incontinence in children with spina bifida.

MATERIALS AND METHODS

Subjects

Twenty spina bifida children (12 boys and 8 girls) with neurogenic bladder participated in this study. Their ages ranged from 4 to 8 years. Informed consent was provided for each child from their parents. They were treated in outpatient clinic, Faculty of Physical Therapy, Cairo University. Children were randomly assigned into two groups of equal numbers 10 patients each. Group (A) which is the control group received medical care and standard urotherapy only. Group (B) which is the study group received medical care and standard urotherapy plus sacral nerve stimulation. All children with spina bifida were recruited to the study after back closure. Full medical diagnosis was obtained for each child before participating in this study. Children were excluded if they had any neurological manifestation rather than spina bifida, any sign of urinary tract infection, or any implanted metal. A 24-hour pad test was used to measure cessation of urinary incontinence.

Measurement procedure

The amount of urinary leakage was evaluated by using 24-hour pad test. Pad testing yields an objective measurement of fluid loss over a certain period[24].

Three pads were packed, each in a plastic bag and weighed by the investigators before and after use. The child's parents received a written instruction and were free to wear their child one, two or three pads. It was emphasized that the bag should be closed carefully every time a pad was changed to prevent evaporation. If the bags were open or less than three pads were returned, the test was excluded from evaluation. Pads were given to all children, to be worn for 24 hours preceding their appointment. The outcome of the 24-h pad test was recorded as the weight gain as measured by a verified spring balance. Weighing was done by the first or second author, within 3 days after the pad test was carried out. According to the literature, pads were assigned as wet if the total weight gain per 24 hours was $\geq$ 9 g.[20]. Diaper (Pampers) was used in this study. Firstly, the weight of pad was calculated then, the child wore it for 24 hours. The weight of absorbent pad was calculated and the difference expresses the amount of urine loss in grams. The test was performed before conducting sacral nerve stimulation and after 12 weeks of treatment.

Treatment procedure

Transcutaneous electrical nerve stimulation (TENS) unit (TENS 210 (T) manufactured by Duomef, inc., USA) was used to conduct sacral nerve stimulation[3,10]. Para-sacral TENS was performed for 20 minutes, 3 times weekly, with frequency of 10 Hz for 12 weeks[16]. Surface electrodes were placed at the level of sacral root S3.

Application of TENS was as follow

The child assumed prone lying position for application of TENS on sacral region. The skin where the electrodes were connected was cleaned with alcohol. Then, the skin was dried. The self-adhesive electrodes were used to help the electrical signals to activate the nerves under the skin. The electrodes were applied at the level of sacral nerve root S3. The pin connectors on the end of the electrode wire were hooked into the electrodes. The electrode wires were plugged into the TENS unit. The control knobs were slowly turned to the correct intensity causing comfortable sensation with no motor response.

Medical care

Medical care for children in both groups was controlled by their physicians and consisted of clean intermittent catheterization[7] and Oxybutynin[1,7]. Clean intermittent catheterization (CIC) was carried out by the parents. It was carried out by self-lubricating 8-F catheter. Child age determined the size of the catheter and the purpose was to use the catheter which was large enough to allow optimal bladder empty[4]. Oxybutynin dose was prescribed by the child's physician.

Standard urotherapy

1- Instructions were given to the parents for regular voiding habits through going to toilet every 2 to 4 hours for regular empty after removal of catheter.

2- Avoidance of drinking at least 2 hours before sleep.

3- The amount of water intake was divided through the whole day according to the child needs[18].

Data analysis

For analysis of data in the present study, SPSS software version 10 was used for data analysis in this study. Descriptive statistics was used to identify the mean and standard deviation for each variable. Paired t-test was used to test pre and post changes in each group of the study. Independent t-test was used to post test results between groups of the study. The level of significance used in this study was $P < 0.05$.

RESULTS

Descriptive statistics showed that the mean value of absorbent weighted pad pre-treatment for the control group was 161.50±6.25 grams, while post treatment, it was 156.50±5.29 grams. On the other hand, the mean value for the same measurement for the study group pre-treatment was 157.50±8.89 grams and post treatment; it was 152.50±8.84 grams as shown in table (1).

The results of the control group showed a significant decrease in pad weight after end of treatment with P=0.001. Also, there was a significant decrease in pad weight in the study group with P=0.000 as shown in table (1) and figure (1).

Table (1): Pad weight in grams pre and post treatment in each group.

Mean	Control group		Study group	
	Pre	Post	Pre	Post
	161.50	156.50	157.50	152.50
SD	±6.25	±5.29	±8.89	±8.84
t value	4.743		33.541	
P value	0.001		0.000	
Significance level	Sig.		Sig.	

SD= standard deviation, Sig= significant.

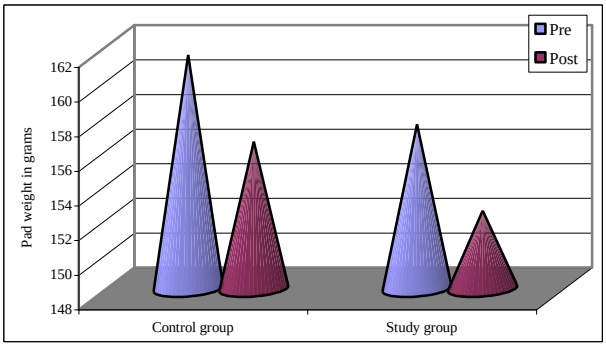

Fig. (1): Pad weight in grams pre and post-treatment for each group.

For testing the possibility of sacral nerve stimulation to control the urinary incontinence between both groups, independent t test showed that, there was no significant difference after end of treatment between the study and control groups with P=0.236. There was also, no significant difference exists pre-treatment between both groups with P=0.260 as shown in table (2) and figure (2).

Table (2): Pad weight in grams pre and post- treatment and the mean difference in both groups.

Time	Pre-treatment		Post-treatment	
Groups	Control	Study	Control	Study
Mean	161.50	157.50	156.50	152.50
Mean difference	4.00		4.00	
t value	-1.163		-1.227	
P value	0.260		0.236	
Significance level	Non sig.		Non sig.	

Non sig. = non significance.

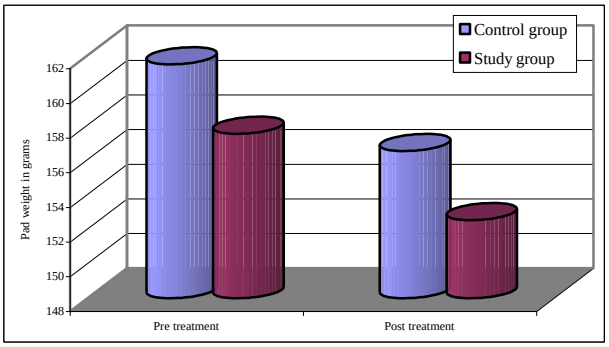

Fig. (2): Pad weight in grams pre and post-treatment of the two patients groups.

DISCUSSION

Urinary incontinence is a common problem in pediatric practice[6]. Many patients with underlying neurological disease often develop neurovesical voiding dysfunction and present clinically with overactive bladder (OAB) symptoms of urgency, frequency, and/or urge incontinence. These lower urinary tract symptoms in patients with a known neurologic condition are due to disturbances of the neurological control mechanisms and are often referred to as neurogenic overactive bladder[13].

In patients with spina bifida, detrusor over activity combined with sphincter over activity is seen in almost 40% of the cases. The cause of over activity is thought to be a defect in supraspinal management of urine storage and bladder emptying due to myelodysplasia at the level of the anatomical malformation[7].

The objectives in the urological management of patients with spina bifida are (1) preservation of renal function; (2) quality of life, preferably with urinary dryness by school age; and (3) independence at an older age with respect to bladder and bowel management (4) The 24-h pad test is almost certainly more representative to the patients' day-to-day experiences and is more likely to correlate with self-reported symptoms[17].

Oxybutynin is best started together with CIC immediately after closure of the back. Other antimuscarinic agents have not yet been registered for pediatric use[4].

Pharmacotherapy is the first-line treatment for overactive bladder, but many patients discontinue drug therapy because of intolerable side effects, expense, or lack of long term adherence. Alternative treatments are needed for patients who are unable to tolerate pharmacotherapy or who do not derive the desired benefits. Sacral nerve stimulation therapy has evolved into one of the most widely accepted treatment modalities in the arena of neurourology. Sacral nerve stimulation activates or "resets" the somatic afferent inputs that play a pivotal role in the modulation of sensory processing for micturition reflex pathways in the spinal cord[15].

Manipulation of S3 activity (PTNS, sacral implantation, sacral rhizotomy) has been employed effectively for facilitating bladder storage. However, a more invasive approach requires general anesthesia and is associated with risks such as infection, erosion, or neuronal injury. Transcutaneous stimulation has been used in children. This involves placement of surface electrodes to stimulate the sacral root (S3). Several stimulation frequencies have been used, and stimulation of 2 Hz seems to be sufficient. Researchers have not yet determined the optimal length of neither each stimulation during a treatment session nor how many sessions the treatment should continue[14].

Although neuromodulation is used more commonly in adults, this treatment approach has been used in children in whom behavioral and pharmacologic therapy fails. The exact mechanism by which neuromodulation affects detrusor over activity is not fully understood. Sacral nerve stimulation may induce reflex-mediated inhibitory effects on the detrusor through afferent and/or efferent stimulation of the sacral nerves. In addition, stimulation of the somatic fibers of the nerves may activate the pelvic floor muscles, causing further detrusor inhibition[12].

Bower et al.,[2] illustrated that home application of TENS in children is successfully feasible in children. The reported changes with neuromodulation include: significantly increased bladder capacity, decreased severity of urgency, improved continence, and decreased frequency of urinary tract infections. Recently a prospective randomized controlled study showed significantly better outcome compared to sham stimulation[16].

Hagstroem et al.,[10] reported that, sacral transcutaneous electrical nerve stimulation for 4 weeks of 2 hours of daily application seems superior to placebo for refractory daytime incontinence in children with overactive bladder. This effect does not seem to be a consequence of improved bladder reservoir function.

Hoebeke et al.,[11] tested home para-sacral TENS in 15 girls and 26 boys with overactive bladder. The frequency of 2 Hz was used. Stimulation conducted for 2 hours, for a period of 6 months. Thirteen (32%) children did not respond to the treatment. After year, the rate of complete resolution of daytime incontinence was 51%.

Our results agreed with one study of Guys et al.,[9] who reported that, although some improvement was noted in patients treated with sacral neuromodulation, there was no significant difference noted between study and control groups regarding sacral neuromodulation for neurogenic bladder dysfunction in children.

Our results showed that, although there was a significant improvement before and after treatment in the study and control groups, there was no significant improvement was observed between the groups of this study after end of treatment. This can be attributed to several factors, one of these is that, the improvement observed before and after treatment in each group was due to medical care and urotherapy and improper parameters of sacral stimulation used in this study as the studies of Hagstroem et al.,[10] and Hoebeke et al.,[11] conducted for longer time which was 2 hours of stimulation. Another factor is the small sample size used in this study. Also, no type on neurogenic bladder dysfunction is likely to remain the same over time and the age and speed at which bladder deterioration can occur is very variable. Furthermore, the severity of the neurogenic lesion, as well as the site of the lesion does not appear to correlate with the degree of neurogenic dysfunction[4].

Conclusion

Although many studies supported the ability of sacral nerve stimulation on improving urinary incontinence in children, our results cannot confirm this work. The sacral nerve stimulation with the parameters used in this study cannot be used for treatment of spina bifida children complaining from urinary incontinence.

Recommendations

We recommend that, other trials should be conducted with large numbers of cases to show the effect of this modality in solving such problem. Also we recommend using different parameters with different groups to show the most effective parameter of sacral nerve stimulation for controlling urinary incontinence in spina bifida children.

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الملخص العربي

فاعلية التنبيه العصبي العجزي علي التحكم في التبول اللاإرادي في الأطفال المصابين بالشوك المشقوق

أجريت هذه الدراسة علي عدد عشرين طفلا مصابين بالشوك المشقوق والذين يعانون من التبول اللاإرادي . وقد تراوحت أعمارهم من أربعة إلى ثمانية سنوات. قسم الأطفال عشوائيا إلى مجموعتين : المجموعة الأولى وهي المجموعة الحاكمة وقد تلقت العلاج الطبي فقط والمجموعة الثانية وهي مجموعة الدراسة وقد تلقت العلاج الطبي بالإضافة إلى التنبيه العصبي العجزي. تلقي الأطفال عدد ستة وثلاثون جلسة علي مدار اثنا عشر أسبوعا . وقد استخدم اختبار ضمادة الأربعة وعشرون ساعة لقياس كمية البول المفقود في المجموعات . وقد أظهرت النتائج تحسن ذو دلالة إحصائية عند المقارنة قبل وبعد العلاج . ولم تظهر النتائج تحسن ذو دلالة إحصائية عند القياس بين المجموعتين بعد العلاج . وعلي هذا فان التنبيه العصبي العجزي باستخدام التنبيه الكهربائي عبر الجلد بالمعايير المستخدمة في هذا البحث ليس له دور فعال علي التحكم في التبول اللاإرادي عند الأطفال المصابين بالشوك المشقوق .