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ORIGINAL ARTICLE

The Effect of Lumbosacral Neuromodulation Stimulation in Functional Recovery to Spina Bifida Patients

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ABSTRACT

Background: *Lumbosacral neuromodulation is a therapeutic technique that involves electrical stimulation to a lumbosacral nerve root to modulate a neural pathway.*
Objective: *To evaluate the effectiveness of lumbosacral neuromodulation in the management of lower limb weakness, sensory disorders, and urinary and bowel incontinence in patients with spina bifida.*
Patients and methods: *A clinical therapeutic interventional trial study was conducted in Al Arabi Private Hospital, Baghdad, Iraq during the period from the 1st of January to the 1st of December 2023. A convenient sample of 40 patients who presented with spina bifida were enrolled in the current study. Inclusion criteria included patients aged 4-6 years who were presented with lower limb weakness, sensory disorders, urinary incontinence, and bowel incontinence. The intervention included sensory nerve stimuli, motor nerve stimuli, and pulse radiofrequency for two sessions at three-month intervals.*
Results: *A total of 40 patients were enrolled in the current study. Among patients with Medical Research Council grading system grades 2, 3, and 4, there were a significant proportion of patients who had improvement in muscle power after the first session (P-values were 0.049, 0.002, and 0.004, respectively). After the second session, a significant proportion of patients with all grades had improvement (P-values were 0.001, 0.014, 0.001, and 0.001, respectively). After the first session, a significant proportion of patients had improvement in bowel and urinary incontinence (P-values=0.001), these proportions were significantly increased after the second session (P-values=0.001). After the first session, a significant proportion of patients had improvement in sensory disorders (P-value=0.001), this proportion was significantly increased after the second session (P-value=0.001),*
Conclusion: *There was variable improvement in sensory and motor in the lower limbs and there was a significant improvement in both sphincters after the second section.*

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Keywords: ***Pulsed radiofrequency, Neuromodulation, spina bifida***

1. INTRODUCTION

An open neural tube defect can occur at the cranial level (anencephaly), the spinal level (myelomeningocele or spina bifida), or both (craniorachischisis) if the neural tube fails to fuse during the third week of gestation (1). Spina bifida is a congenital spine deformity in which the meninges and a portion of the spinal cord are visible through a gap in the backbone with associated susceptibility to infection and cerebrospinal fluid leakage (2). The deficiency commonly arises in the lumbosacral region, namely between the S1 and S2 (3) vertebrae. Spina bifida is a prevalent congenital anomaly of the central nervous system, affecting about one in every thousand newborns(4). Nevertheless, the occurrence rate of spina bifida at birth differs among various populations. In Iraq, constituted 8.62 of congenital abnormalities according to a study done in Baghdad in 2020(5). In spina bifida, Insufficient development of the lower spinal cord results in impaired bladder and bowel function (1, 2). In many cases, muscles in the lower extremities can be weakened or paralyzed. With increasing severity, spina bifida weakens the plantar flexor, gluteal, and quadriceps muscles (6). Neurosurgical care for the majority of infants born with spina bifida commences promptly after delivery by closing the spinal defect and assessing the necessity of hydrocephalus management. The closure techniques have undergone minimal changes across multiple generations, namely in surgically delineating the joined layers that have occurred in the embryonal defect. Once formed, these layers are utilised to seal the spinal defect (7). Nevertheless, there is no singular medicinal or surgical intervention that may fully alleviate or restore the combination of symptoms and impairments linked to spina bifida. Multiple therapies are necessary to enhance the quality of life for these individuals (8). Approximately 4% of the youngsters have been demonstrated to experience adverse effects from the drugs. Hence, there is an ongoing quest for alternatives that are devoid of negative consequences, simple to administer, and comfortable for carers and patients with restricted physical mobility (9). Neuromodulation refers to the modification of neuronal and synaptic characteristics either by neurons themselves or by chemicals that are released by neurons (10). It incorporates an array of non-invasive, minimally invasive, and surgical electrical therapies. Invasive therapies include stimulation of the deep brain and motor, stimulation of the peripheral nerve, and non-

invasive treatments including transcranial direct current stimulation, repetitive transcranial magnetic stimulation, and transcutaneous electrical nerve stimulation (11). Lumbosacral neuromodulation is a therapeutic technique that involves electrical stimulation to a lumbosacral nerve root to modulate a neural pathway (12). The precise mechanism by which lumbosacral neuromodulation works is not yet fully understood. However, it appears to involve the modulation of spinal cord reflexes and brain networks through the influence of peripheral afferents. This conclusion is based on findings from various studies in the fields of neurophysiology, electroencephalography, positron emission tomography, and magnetic resonance imaging (13). The main indications of lumbosacral electrical neuromodulation are urinary incontinence, retention, polyuria, and faecal incontinence. However, at present, it is accepted as an effective method in the treatment of pelvic pain syndromes and constipation as in multiple sclerosis and partial cord damage (14). Pulse radiofrequency uses a radiofrequency current comprising alternatively repeated electrical stimulation with a short duration and resting phase (15). The utilisation of pulsed radiofrequency treatment for chronic pain involves a minimally invasive approach to reduce the impulses transmitted by pain-causing nerve fibers (16). Pulsed radiofrequency does not cause neural damage and if happens, it is reversible (17)

2. METHODOLOGY

Study design and setting: A clinical therapeutic interventional trial study was conducted in Al Arabi Private Hospital, Baghdad, Iraq during the period from the 1st of January to the 1st of December 2023.

Sampling method and inclusion criteria: A convenient sample of 40 patients who presented with spina bifida were enrolled in the current study.

Inclusion criteria:

1. Patients aged 4-6 years.

2. Patients with lower limb weakness, sensory disorders, urinary incontinence, and bowel incontinence.

Exclusion criteria:

1. Coagulopathy with INR > 1.5 and platelet counts < 50,000 per mm^3 are absolute contraindications.
2. Patients with metastases involving more than one organ or tumour positioned close to essential structures, such as bowel, gallbladder, major bile duct, ureter, spinal cord, nerve or major blood vessels.
3. Patients with a grade of 0 on the Medical Research Council grading system.
4. Patients who were denervated and proved by neurologist and electromyography.

Intervention and data collection

Before the intervention, the medical history was taken from the parents including the frequency of urinary and bowel incontinence, clinical sensory examination, and muscle strength was assessed through the Medical Research Council grading system.

Under heavy sedation, the lumbosacral nerve was targeted under ultrasound guidance with a needle which served as an electrode for a current passing. Sensory stimulation was applied in 5-10 hits for to three times before the motor stimulation procedure, after the first motor stimulation procedure, and after the second motor stimulation procedure. Motor stimulation was applied for 10 minutes two times per session. Pulsed radiofrequency was applied at a temperature of 42°C for 4 minutes. These procedures were repeated for two sessions in three month intervals. Another assessment was done for the patients after the first and second sessions, another assessments were done including the frequency of urinary and bowel incontinence, clinical sensory examination, and muscle strength were assessed through the Medical Research Council grading system. Medical Research Council grading system provides the following grades: 0, paralysis; 1, only a trace or flicker of muscle contraction is seen or felt; 2, muscle movement is possible with gravity eliminated; 3, muscle movement is possible against gravity; 4, muscle strength is reduced, but movement against resistance is possible and 5, normal strength (18).

Statistical analysis:

The data that had been collected was then analysed using the Microsoft Excel software. The descriptive analysis mostly concentrated on the frequencies and percentages. The categorical data were expressed as proportions, and the chi-square test and t-test were

employed to assess the disparity between the two proportions. A P-value below 0.05 was deemed statistically significant.

3. RESULTS

A total of 40 patients were enrolled in the current study. Among patients with Medical Research Council grading system grades 2, 3, and 4, there were a significant Motor improvement and muscle power after the first session (P-values <0.05) where a total of 25 patients had improved out of the 40 patients distributted across the 4 grades 11/20 in grade 1, 9/14 in grade 2, ¾ in grade 3 and both patients with grade 4 were improved, the overall improvement rate after the first session was 62.5%.

Nine of the remaining 15/40 patients who did not improve at the first session, were improved at the second session; of the 5 with grade1, 3 grade 2 and 1 of grade 3. Giving an overall improvenet at the second session of 60%. However, the total improved cases in both sessions were 34/40, giving an overall improvement rate of 85%, these findings are shown in (**Table 1, Table 2 and Figure 1**).

Reagrding the improvement in the bowel and urinary incontinence after intervention, a significant improvement was reported in both; For the bowel incontinence, 14/40 (35%) were improved after the first session, and other 19/40 (47.5%) improved after the second, therefore a total of 33/40 cases were improved in both sessions giving an overall improvement rate of 82.5%, (P<0.001, significant). Similar trend was found regarding the improvement in the urinary incontinence where the total improved cases after both sessions was 36 giving an overall improvement rate of 90%, (p<0.001). For the sensory disorders, a significant proportion of patients had improvement in sensory disorders after the first session and this proportion was significantly increased after the second session, with an overall improvement rate of 97.5% (P.value=0.001), all these findings are shown in (**Table 3 and Figure 2**)

Table 1. Motor improvement after the First session of intervention (N=40)

Grades	No. of cases	Improved		Not Improved	
		No.	%	No.	%
Grade 1	20	11	55.0	9	45.0
Grade 2	14	9	64.3	5	35.7
Grade 3	4	3	75.0	1	25.0
Grade 4	2	2	100.0	0	0.0
Total	40	25	62.5	15	37.5
P. value = 0.022					

Table 2. Motor improvement after the second session of intervention (N=15)

Grades	No. of cases	Improved		Not Improved	
		No.	%	No.	%
Grade 1	9	5	55.6	4	44.4
Grade 2	5	3	60.0	2	40.0
Grade 3	1	1	100.0	0	0.0
Grade 4	0	0	0.0	0	0.0
Total	15	9	60.0	6	40.0
P. value = 0.040					

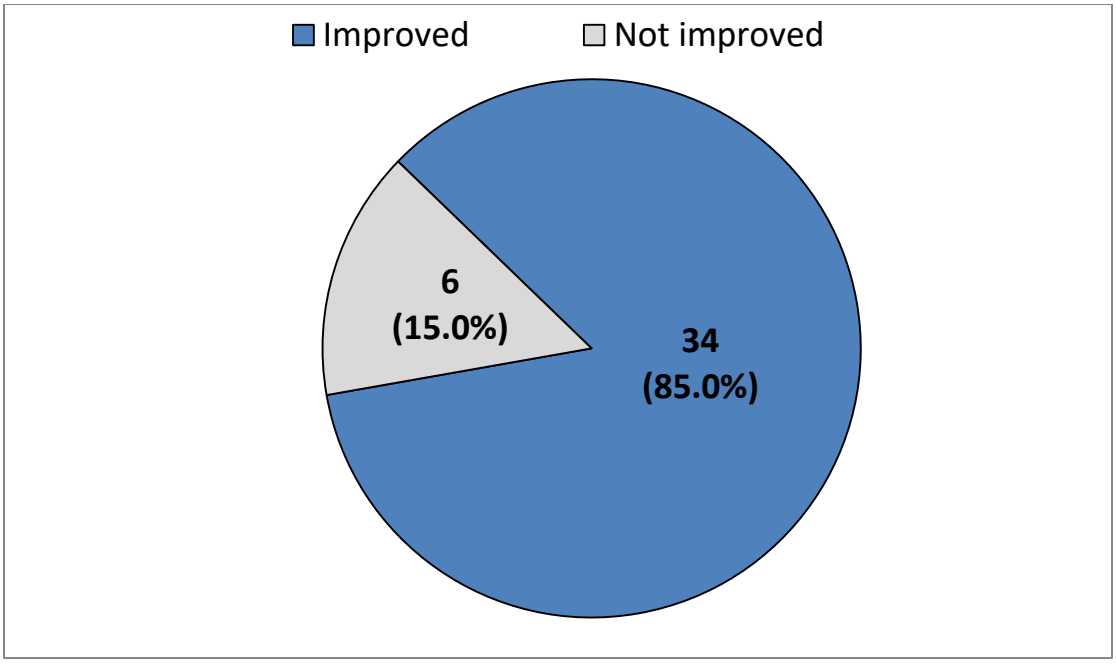

Figure 1. Overall Motor improvement after the first and second sessions of intervention

Table 3. Improvement in urinary incontinence , bowel incontinence and sensory disorders after intervention among the studied group

	Bowel incontinence	Urinary incontinence	Sensory disorders
Baseline total cases	40	40	40
Improved after first session	14	17	30
Improved after Second session	19	19	9
Total improved cases in both sessions	33	36	39
Overall Improvement rate	82.5%	90.0%	97.5%
P. value	<0.001	<0.001	<0.001

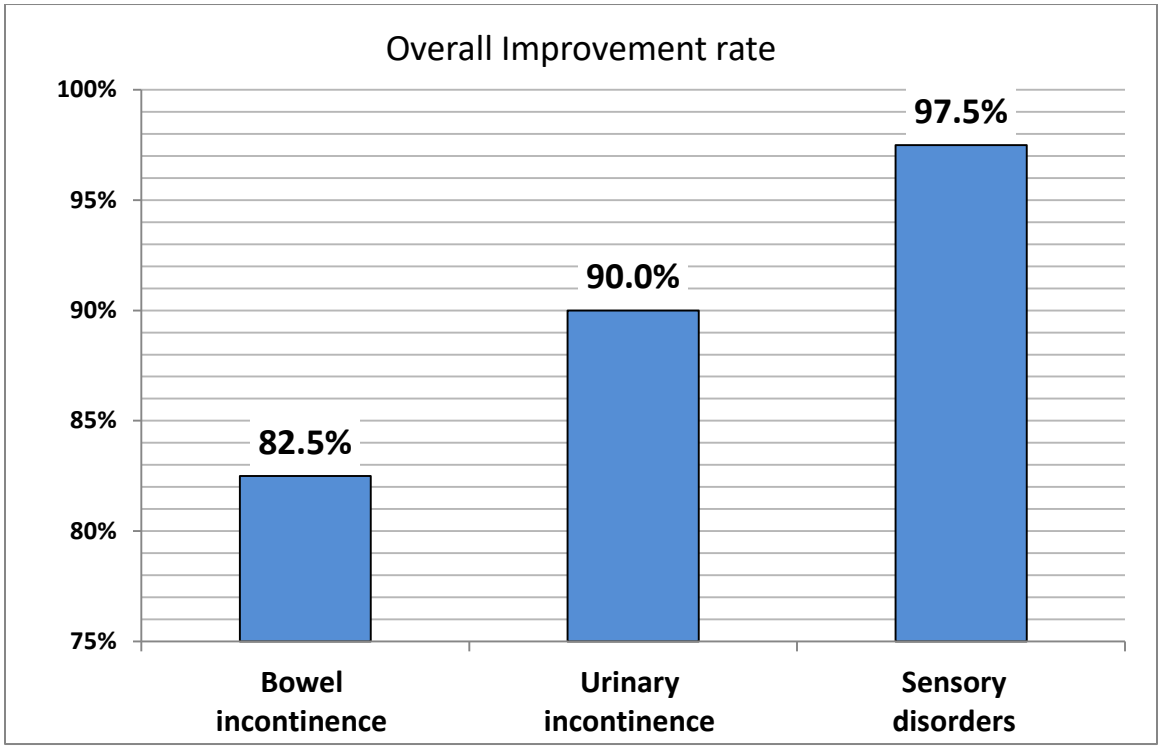

Figure 2. Overall improvement rates in urinary incontinence , bowel incontinence and sensory disorders after intervention

4. DISCUSSION

Surviving patients with spina bifida experience motor disability, bowel and bladder problems, and neurological sequelae (19). To the best of our understanding, this study in Iraq was the first to evaluate the efficacy of sensory stimulation, motor stimulation, and pulse radiofrequency in treating individuals with spina bifida. The main finding of the current study was that there were proportions of patients who had variable improvement in muscle power after the first and second sessions. In a separate study conducted by Enrico et al., the objective was to examine the impact of lumbosacral spinal cord epidural stimulation on standing ability in individuals with complete paralysis. The findings suggest that it is more practical to manipulate the physiological condition of the lumbosacral spinal circuitry in order to allow individuals to actively control incoming sensory information and facilitate standing (20). Another finding of the current study was that there were significant proportions of patients who had improvement in urinary and bowel incontinence after the

first and second sessions. In agreement, Farzaneh Sharifiaghdas et al. conducted another study to evaluate lumbosacral neuromodulation in children with lumbosacral defects with neurogenic lower urinary tract symptoms and concluded positive results in short-term follow-up (21). The same results were obtained in another study that was done by Khodorovskaya et al. which concluded that most pediatric patients had good and satisfactory results in the treatment of urinary and bowel dysfunction by lumbosacral neurostimulation (22). In agreement, similar results were obtained in another study which was done by Kenneth et al (23). Regarding sensory improvement, a significant proportion of patients had sensory improvement after the first session, and the proportion of those patients significantly increased after the second session. The same results were obtained in another study that was done by Gerti et al (24). This agreed with the results of the study that was done by Kenneth et al (23).

5. CONCLUSIONS

there was variable improvement in sensory and motor in the lower limbs and there was a significant improvement in both sphincters after the second section.

Ethical Approval:

The research was approved by the Scientific Council of Anaesthesia and Intensive Care of the Arab Board of Medical Specializations. Written consent was obtained from each patient before the recruitment. All ethical issues were approved by the author in accordance with Declaration of Helsinki of World Medical Association , 2013 for the ethical principles of researches involving human.

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