Aims: To assess the role of transcutaneous electrical nerve stimulation (TENS), alone or in combination with anticholinergic drugs in the management of neurogenic bladder (NB) in spina bifida (SB).

Materials and Methods: All the consecutive patients, visiting outpatient clinic between July 2017 and December 2018, who were toilet trained and at least 1 year post-SB surgery with clinical and/or urodynamic evidence of NB, were included in the study. Out of 65 patients, 40 fulfilled the inclusion criteria and were randomised into: group A (ten patients, placebo TENS with anticholinergic agents), Group B (14 patients, TENS therapy with placebo medications) and Group C (16 patients, TENS therapy with anticholinergic medications). All the patients maintained a voiding diary and underwent assessment before and after the intervention. The study was approved by the Institutional Ethics Committee.

Results: The presenting symptoms were urinary incontinence (100%), increased frequency (45%), straining during micturition (22.5%), urgency (22.5%), and hesitancy (30%). The demographic parameters were comparable in all the groups. After group specific intervention, the wet episodes/day significantly improved in Group C ($P=0.001$). Similarly, the mean wet days/week also improved significantly in Group C (6.5–4.37 days/week, $P=0.01$). Out of 40 patients, 29 had abnormal findings on ultrasonography before the start of the therapy. Following intervention, only two patients in Group C showed normalization of findings. On Urodynamic studies, detrusor pressure (Pdet max) decreased in all the groups; however, the patients in Group C, showed the maximum reduction (56.6 ± 11–30 ± 6.7 cm H$_2$O). Similarly compliance (9.4 to 14.5 cm H$_2$O, $P=0.02$) and bladder capacity (68%–88% of EBC, $P=0.001$) also improved significantly in Group C as compared to other 2 groups Overall, nine patients (Group A, B, and C = 1, 3, and five patients, respectively) showed detrusor instability, while post therapy, only one patient (Group B) had unstable bladder. Maximum decrease in postvoid residue (mean) was also observed in Group C (77–41 ml, $P=0.01$).

Conclusions: The application of TENS in NB secondary to SB is effective and its application led to improvement in symptoms, decrease in the wet episodes/day, maximum detrusor pressure, instability, bladder compliance, and capacity. TENS therapy in combination with anticholinergic agents had a better outcome as compared to monotherapy with either of the two modalities.

Keywords: Transcutaneous, neurogenic, spina bifida, voiding diary

Spina bifida (SB) is one of the most common anomalies responsible for various structural and functional departments of Pediatric Surgery, 1Physical and Rehabilitation Medicine and 2Radio-Diagnosis, Advanced Pediatric Centre, Postgraduate Institute of Medical Education and Research, Chandigarh, India
morbidity in the affected child.\textsuperscript{[1]} More than 90% of the children with SB present with varying degrees of neurogenic bladder (NB) dysfunction depending upon the level and the severity of the lesion.\textsuperscript{[2]} In patients other than those with completely areflexic or paralytic bladder, there is a risk of upper renal tract damage from raised intravesical pressures. Clean intermittent catheterization (CIC) and anticholinergic medications remain the mainstay of therapy to decrease the intravesical pressure but are limited by the side effects of the drugs and inconvenience associated with repeated catheterisations.\textsuperscript{[3,4]} Besides anticholinergic agents, \(\alpha_1\) adrenergic agonists, benzodiazepines, botulinum toxin have also been used in the treatment of NB dysfunction. They mainly target the receptors in the bladder or its outlet. Around 4% of the children have been shown to suffer from the side effects of the medications which may lead to cessation of the concerned drug.\textsuperscript{[5]} There is continuous search for alternatives which may be free from adverse effects, easy to apply, convenient for caregivers and the patients with a limited physical mobility.\textsuperscript{[3]}

Electrical stimulation has been used since many years as a substitute treatment for the lower urinary disorders. Stimulation of pudendal and tibial nerve, sacral neuro modulation and transcutaneous electrical nerve stimulation (TENS) have all been considered in the children.\textsuperscript{[6,7]} The sacral nerve roots (S2-S4) provide principle motor supply to the bladder; specifically, the S3 root, which mainly innervates the detrusor muscle and is the main target of neuromodulation. Transcutaneous nerve stimulation has been used in overactive bladder in adults as well as children. However, there is scarcity of literature using neuromodulation in NB secondary to SB. The children with partial neurological lesions in SB may have varying amounts of residual conduction and might benefit from the external electrical stimulation of these nerve roots.

In this study, we investigated the effect of sacral TENS on bladder function of these patients alone or in combination with the pharmacotherapy.

Materials and Methods

This was an interventional prospective study with random allocation from July 2017 to December 2018 including all the operated patients of SB with NB. The study comprised of patients in the toilet trained age group of 4–15 years, who were at least 1 year post SB surgery. The patients with clinical or urodynamic evidence of high pressure, small capacity and low compliance bladder with or without detrusor instability were included in the study.

The patients with urinary tract infections during the previous 4 weeks, associated lower urinary tract defects, flaccid/areflexic bladder on baseline urodynamic assessment and those undergoing any operative intervention for bladder were excluded from the study.

All the patients were clinically and radiologically evaluated for the presence of bladder dysfunction. The clinical criteria consisted of a detailed history, symptom complexes as per the ICCS criteria (Urgency, frequency, nocturia etc), and history of recurrent urinary infections. The neurological examination was performed for the presence or absence of neurological deficit. All these patients underwent renal and bladder ultrasound (RBUS) evaluation to see the renal morphology, hydronephrosis, ureteric dilatation and post void residual urine. Patients further underwent voiding cystourethrogram (VCUG) to rule out the presence of vesicoureteric reflux (VUR). Only patients with clinical or radiological abnormality were subjected to radionuclide Di-mercapto-succinic acid (DMSA) scan to assess for the presence of renal scars, if any.

The patients, who had clinical or radiological abnormalities suggestive of bladder dysfunction, underwent a urodynamic study. Children with normal urodynamic parameters were excluded from the study, while those with abnormal urodynamic findings were randomised into three groups with the use of online random number generators (URL: http://www.randomizer.org/form.htm) and were assigned to receive intervention as per the group as follows:

- **Group A**: Anticholinergic medication + Placebo TENS
- **Group B**: TENS + Placebo Anticholinergic medication
- **Group C**: Combination of TENS and Anticholinergic medication

All the patients were blinded to their group of allocation. Parents were also asked to maintain a voiding diary for 3 days in week to analyses their voiding pattern before start of the therapy and until 1 month after completion. The Visual Analog Scale score used to evaluate results of the therapy by the parents with 0 meaning “no improvement in voiding” and 10 meaning “the complete resolution of symptoms.” The intervention period for each group consisted of 16 weeks. In addition, two more visits were made by the patient; at the start of the study and at 1-month follow up in the outpatient clinic.

The urodynamics study (UDS) was performed at first visit for selection of the patients and 1 month after the last treatment session. It was performed on the Medical Measurements System B. V (Netherlands) machine and included assessment of cystometric parameters bladder.
compliance, expected bladder capacity (EBC), detrusor pressure at maximum cystometric capacity and the leak point pressure. Cystometry was done via a 6Fr double lumen catheter introduced into bladder via the urethra. The bladder was filled at a slow rate of 5 ml/min and gradually increased up to 10 ml/min (10% of the EBC for age). EBC was calculated with the formula $[(\text{age (years)} +2) \times 30]$.

The TENS therapy was given by placing the electrodes on the skin at parasacral region on either side of the spine at S2/3 level [Figure 1]. The patients receiving placebo TENS (Group-A) received no electrical stimulation, however the electrodes were attached at the same place. The accuracy of the position of the electrodes was assessed by the perception of paraesthesia on the pathway of the nerve roots. A 5–20-Hz (low) frequency with a 200 s (microseconds) continuous stimulation for a minimum 30 min in each cycle, was applied every week for 12 weeks. The children were asked to indicate the tolerable intensity from 5 mA onwards up to a maximum of 30 mA.

The statistical analysis was done using SPSS version 20 IBM SPSS Version 20 (IBM Corp., Armonk, N.Y., USA). Quantitative variables were determined using measures of central location (mean) and measures of dispersion like standard deviation and standard error using Student’s $t$-test for comparison of groups. For multiple comparisons amongst the groups and within a group, ANOVA was used while a $P < 0.05$ was considered significant.

**RESULTS**

A total of 65 patients of lumbosacral meningomyelocele (MMC) who had undergone excision were examined. Out of 65 patients, 25 were excluded from the study on the basis of urodynamic assessment; flaccid/areflexic bladder with continuous dribbling of urine, (13) not co-operative enough for urodynamic study/TENS(3) and high grade bilateral VUR.(1) Four patients did not turn up for the follow up after the initial urodynamic study. Another three patients were lost to follow up after few weeks of TENS therapy (2 from Group A and 1 from the Group B). Another one patient had features of myogenic failure, whose bladder capacity was more than 150% of the expected. Remainder of the 40 patients with abnormal urodynamics were randomized into three groups (A, B and C).

The patients included in the study had urinary incontinence (40, (100%)), increased frequency of micturition (18,(45%)) straining at micturition (9, (21.4%)), urgency (9,(22.5%)) and hesitancy (12,(30%)). Most of the patients were having more than one symptom at presentation. Out of 40 patients, 17 (42.5%) had neurological deficit in one or both lower limbs and hydrocephalus was seen in 14 (35%) patients. Faecal incontinence was seen in 11 (27.5%) patients. The demographic parameters were comparable among all the groups [Table 1].

All the patients included in study had normal renal function tests. Among 40 patients, 2 were having hydronephrosis before therapy and no change was seen after completion of the therapy. Twenty three (57.5%) patients were having thickened bladder prior to start of the therapy and it was present in 19 (47%) patients after treatment. Twenty-two patients showed significant postvoid residue (PVR) on RBUS and only 14 patients had significant PVR after completion of the treatment. Eleven patients had normal VCUG whereas 13 children showed features of trabeculated bladder and another 9 had a small capacity bladder. One patient in Group A and two patients in Group C showed a trabeculated bladder with VUR. DMSA scan showed scars in 2 out of 19 patients.

The voiding diary charts were analysed for wet episodes (urine leak) per day and wet days per week. In

| Table 1: Demographic data |
|--------------------------|
| Group A | Group B | Group C | $P$ |
| (n=10) | (n=14) | (n=16) |
| Age | 6.7±2.0 | 6.14±2.1 | 6.18±2.4 | 0.495 |
| Sex (male: female) | 5:5 | 11:3 | 12:4 | 0.275 |
| Urinary incontinence | 10 | 14 | 16 | 0.21 |
| Urgency | 1 | 3 | 5 | 0.55 |
| Straining | 3 | 2 | 3 | 0.812 |
| Hesitancy | 1 | 4 | 5 | 0.07 |
| On CIC therapy | 3 | 5 | 5 | 0.72 |
| Fecal incontinence | 2 | 4 | 4 | 0.817 |
| Lower limb weakness | 4 | 6 | 6 | 0.821 |
| Hydrocephalus | 3 | 5 | 6 | 0.614 |

CIC: Clean intermittent catherization

**Figure 1:** Parasacral transcutaneous electrical nerve stimulation
Group A mean wet episodes per day prior to therapy were 10.4 (range 10–14) which decreased to 9.6 (range 7–10) after therapy (P = 0.121), however in Group B, the wet episodes decreased from 12 to 9.4 episodes per day (P = 0.01). In Group C, the mean wet episodes were 12.6±2.1 before therapy which decreased to 8.2 (range 6–10) after the therapy and the difference was highly statistically significant (P = 0.001). The wet days per week were in 6.4 days (mean) prior to therapy and 5.7 days after completion of the therapy. The Group B had similar findings and the difference in both the groups was statistically insignificant. However, in Group C, the mean wet days were 6.5 days/week before therapy which decreased to 4.37 days/week (2–7 days) (P = 0.001) [Table 2].

On assessing UDS parameters, overall maximum detrusor pressure value (Pdet max) before intervention was 57 ± 14 which decreased to 30 ± 12 cm of H_2O after intervention. In group A, the mean Pdet max was 57 ± 21 cm which decreased 48 ± 16 cm of H_2O after the therapy. In Group A, Pdet max of two patients was above 80 cmH_2O, although it decreased but never reached the normal range. In group B, the mean Pdet max was 48.5 ± 6.9 and 38.4 ± 12 cm of H_2O respectively, before and after the intervention. In Group C, the mean Pdet max reduced from 56.6 ± 11 cm to 30 ± 6.7 cm of H_2O, which was significant when compared to the pressure reduction in other two groups. The compliance was calculated from the cystometry curve using linear regression method. Overall, 62.5% (25) of the patients had poor compliance (<10 cm H_2O) before therapy, which decreased to 20% after the therapy. In Group C, the maximum improvement was seen and the compliance improved from 9.4 to 14.5 cmH_2O (P = 0.02). Out of 40 patients, 9 (22.5%) showed features of detrusor instability. Group A had one patient with detrusor instability at initial UDS, which became normal posttreatment. While Group B had 3 (21.4%) patients, out of which 2 showed improvement post therapy, while one patient continued to have symptoms. In Group C, 5 (31%) patients with incontinence and urgency had detrusor instability on UDS and all the five patients showed resolution after the completion of the treatment.

Overall, the mean bladder capacity of these patients was 162 ml (65% of EBC) which improved to 201 ml (80% of EBC) after the treatment. In Group A, the mean bladder capacity was 167.8 ml (65% of EBC) prior to therapy, while after the therapy, mean bladder capacity improved to 189 ml (74% of EBC). In Group B, the mean bladder capacity was 151 (62% of EBC) and 160 ml (75% of EBC) respectively before and after therapy. Mean bladder capacity in Group C before treatment was 169 ml (68% of EBC) and it increased to 217 ml (88% of EBC) after completion of the treatment (P = 0.001). PVR was calculated in patients after voiding via a clean catheter. In Group A, the PVR slightly increased from 44 to 47.9 ml (mean) (P = 0.6) while in Group B PVR decreased 49–39 ml (P = 0.7) from the decrease in PVR was maximum in Group C (77–41 ml) (P = 0.01) [Table 3].

In multi comparison analysis, Group C showed better results for wet episodes/day, wet days/week, detrusor pressure, PVR and detrusor instability as compared Group A and B. whereas for bladder capacity and compliance, Group C showed significant improvement as compared to Group A, but not so in relation to Group B [Table 4].

**DISCUSSION**

MMC is the most common cause of paediatric NB and lower limb weakness in children. Urological dysfunction is seen in more than 90% of children with MMC depending upon the level of the lesion and the extent of involvement of spinal cord. The primary goals in the management of paediatric NB are to normalize vesical pressure, preserve renal function and achieve social continence.[8] The mainstay of management of NB continues to be clean intermittent catheterization (CIC) with or without anti-cholinergic medications. TENS is nonpharmacological modality modulating the pelvic nerves. Urinary bladder is supplied by the sympathetic hypogastric plexus, which when stimulated, relaxes the detrusor muscle, inhibiting urinary voiding.
Opposite effect is observed on stimulation of pelvic parasympathetic plexus. At the spinal as well as supraspinal level, pudendal nerve innervation of the pelvic floor is quite complex involving various pathways and interactions.\[6\] Posterior tibial is a mixed nerve containing fibres from L5-S3 segments, originating from the same spinal segments as the parasympathetic innervations to the bladder (S2-S4).

TENS is a noninvasive method which is without any major adverse effects. However, mechanism of action of TENS is not clearly known. Recently Netto et al. studied action of parasacral transcutaneous electro neural stimulation (p TENS) on central nervous system via magnetic resonance image connectivity analysis which showed anterior cingulate cortex (ACC) is a major site of activation during pTENS and there is an increased connectivity between ACC and dorsal lateral prefrontal cortex (DLPFC). This connection between these sites may allow for proper balancing of the sympathetic (ACC) and parasympathetic (DLPFC) stimulus to the bladder.\[9\]

There is lack of data regarding use of TENS in children especially, so in NB secondary to SB. In our study, gender distribution and the location of defects, presentation and spectrum of urological dysfunction was similar to that reported in the literature.\[10,11\] On analysing the voiding diary, our study showed that the wet episodes/day decreased with treatment in all the groups. While improved results were seen in TENS monotherapy (Group B) but significant results were seen only in patients undergoing combination therapy of TENS with oxybutynin (Group C). Similar significant results were seen for wet-days per week in the combination group. Recently Borch et al. concluded that TENS, when combined with oxybutynin in children with urge incontinence, was superior compared to both TENS and oxybutynin used as monotherapy.\[5\]

### Table 3: Urodynamic parameters before and after the therapy

| Urodynamic parameters | Groups (n) | Mean±SD | P |
|-----------------------|-----------|---------|---|
| Pdet max (H₂O)        | A (10)    | 57.0±21 | 0.032 |
|                       | Baseline  | 57.0±21 |     |
|                       | Post     | 48.8±16 |     |
|                       | B (14)    | 48.5±6.9 | 0.014 |
|                       | Baseline  | 48.5±6.9 |     |
|                       | Post     | 38.4±12 |     |
|                       | C (16)    | 56.6±11 | 0.0001 |
|                       | Baseline  | 56.6±11 |     |
|                       | Post     | 30.0±6.7 |     |
| Bladder capacity (ml) | A (10), EBC=255 | 167.8±38 | 0.01 |
|                       | Baseline  | 167.8±38 |     |
|                       | Post     | 189.5±43 |     |
|                       | B (14), EBC=240 | 151.7±50 | 0.61 |
|                       | Baseline  | 151.7±50 |     |
|                       | Post     | 160.0±43 |     |
|                       | C (16), EBC=245 | 169.4±30 | 0.001 |
|                       | Baseline  | 169.4±30 |     |
|                       | Post     | 217.0±38 |     |
| Compliance            | A (10)    | 9.0±3.6 | 0.1 |
|                       | Baseline  | 9.0±3.6 |     |
|                       | Post     | 10.2±3.8 |     |
|                       | B (14)    | 8.7±3.5 | 0.06 |
|                       | Baseline  | 8.7±3.5 |     |
|                       | Post     | 12.5±4.5 |     |
|                       | C (16)    | 9.38±5.4 | 0.02 |
|                       | Baseline  | 9.38±5.4 |     |
|                       | Post     | 14.5±5.8 |     |
| PVR (ml)              | A (10)    | 44.2±15 | 0.605 |
|                       | Baseline  | 44.2±15 |     |
|                       | Post     | 47.9±13 |     |
|                       | B (14)    | 49.5±23 | 0.70 |
|                       | Baseline  | 49.5±23 |     |
|                       | Post     | 39.5±22 |     |
|                       | C (16)    | 77.5±33 | 0.01 |
|                       | Baseline  | 77.5±33 |     |
|                       | Post     | 41.4±38 |     |

SD: Standard deviation, PVR: Postvoid residue, EBC: Expected bladder capacity, Pdet max: Maximum detrusor pressure

### Table 4: Multiple comparison analysis between the groups

| Dependent variable | Mean difference (I-J) | SE | P |
|--------------------|-----------------------|----|---|
| Wet days/week      | A                    | B  | 0.12857 | 0.06869 | 0.834 |
|                    | C                    | −1.48750 | 0.59262 | 0.017 |
|                    | B                    | C  | −1.61607 | 0.53801 | 0.005 |
| Bladder capacity   | A                    | B  | −12.65714 | 8.33629 | 0.137 |
|                    | C                    | −25.92500 | 8.11630 | 0.003 |
|                    | B                    | C  | −13.26786 | 7.36831 | 0.080 |
| Compliance         | A                    | B  | −7.07143 | 1.72511 | 0.001 |
|                    | C                    | −8.99375 | 1.67958 | 0.001 |
|                    | B                    | C  | −1.92232 | 1.52479 | 0.215 |
| P det (max)        | A                    | B  | −7.87143 | 4.04317 | 0.059 |
|                    | C                    | −18.42500 | 3.93647 | 0.001 |
|                    | B                    | C  | −10.55357 | 3.57369 | 0.05 |

Pdet max: Maximum detrusor pressure, SE: Standard error
In our study, a reduction in the bladder capacity <80% of the EBC, compliance <10 ml/cm H2O, peak detrusor pressures >40 cm of H2O were considered as abnormal urodynamic parameters and such bladders were termed as NBs. In our patients 11%, 13% and 20% improvement in mean bladder capacity was seen in Group A, B and C respectively. Borch et al. noticed a rise of 11% in the mean voided volume in over active bladder patients, while Borch et al. concluded that therapy with TENS had no effect on bladder capacity when evaluated with maximal voided volume or average voided volume in urge incontinence patients.5,12

All the three groups (A, B, and C) showed a decrease in the Pdet max, but the combination therapy (Group C) showed better results as compared to either, the Group A or B. Although, the PVR increased post therapy (mean 44–47.9 ml) in Group A which may be due to the effect of anticholinergic agents on the detrusor muscle but in Group C, it showed a significant decrease. Borch et al. also found a synergistic effect of combining TENS to oxybutynin. On comparative analysis, we noticed that the Group C patients had fared better with detrusor instability and high PVR as compared to the patients in Group A and B.

TENS therapy being simple and noncomplex, can be easily applied at home. However, most of our patients were from poor socioeconomic background and preferred to visit hospital for therapy. There are no fixed protocol or schedules for usage of TENS therapy in pediatric age group in terms of site, intensity, and duration. Barroso et al. concluded based on parental perception, parasacral TENS is more successful than posterior tibial nerve stimulation.12 A few studies showed better outcomes with daily or thrice weekly TENS therapy but we followed once weekly therapy due to limited resources and patient preferences. De Paula et al. in their study concluded that once a week parasacral TENS significantly decreased the urgency in overactive bladder patients.13 A standard dosing schedules for TENS may become available in future.

Electrical nerve stimulation has already proven its benefits in patients of spinal cord injury, by promoting recovery of neural connectivity within the damaged spinal cord via the afferent pathways commencing in the periphery and ending at the cortical regions of the brain. The transcutaneous spinal cord stimulation causes excitation of the spinal nerve dorsal roots that in turn transmit action potentials along the internuncial neurons within the spinal cord. The excitation propagates via the anterior horn along the total area of stimulation, thereby causing multi-segmental excitation of motor nerve fibers, leading to spontaneous muscle contraction. It can be postulated that a similar mechanism may work in the operated cases of SB with NB, by stimulating S1-S3 segment for excitation of detrusor muscle.14

We noticed flushing sweating and constipation in a few patients, who were taking anti-cholinergic medications; however, none of them discontinued the treatment and all could be managed medically. None of the patients who underwent TENS therapy had any side effects.

**Conclusions**

TENS is a noninvasive, nonpharmacological therapy which improves voiding and urodynamic parameters in NB secondary to SB. TENS therapy when combined with anticholinergic agents had a better outcome when compared to the monotherapy with either of them.

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**Conflicts of interest**

There are no conflicts of interest.

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