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Integrated Effect of Non-Invasive Neuromodulation on Bladder Capacity in Traumatic Spinal Cord Injury Patient: Single Case Report

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Objective: To evaluate the changes in bladder capacity and storage through non-invasive neuromodulation by application of repetitive Trans magnetic stimulation (rTMS) and genital nerve stimulation (GNS) in traumatic spinal cord survivors.

Design: A Single Case Study.

Method: The Patient was registered in trail with the clinical trial registry of India (CTRI/2022/05/042431). The Patient was interposed with rTMS on lumbar area, from T11-L4 vertebrae with 1 Hz and the intensity was 20% below that elicited local paraspinal muscular contraction for 13 minutes. GNS was placed over dorsum of the penis with the cathode at the base and anode 2 cm distally at 20 Hz, 200 microseconds, Continuous and biphasic current was delivered and amplitude of stimulation necessary to elicit the genito-anal reflex. For assessment, Neurological examination was done for peri-anal sensation (PAS), voluntary anal contraction (VAC) and bulbocavernous reflex (BCR), deep anal pressure (DAP), and American Spinal Injury Association Impairment Scale (ASIA scale). Outcome assessment was done using Urodynamics, Spinal Cord Independence Measure Scale Version-III (SCIM-III), American Spinal Injury Association Impairment Score (ASIA Score), Beck's Depression Inventory Scale (BDI). The baseline evaluation was taken on Day 0 and on Day 30.

Results: The pre-and post-data were collected through ASIA score, SCIM-III, BDI and Urodynamics test which showed significant improvement in bladder capacity and storage outcomes in the urodynamics study across the span of 4 weeks.

Conclusion: rTMS along with GNS showed improvement in bladder capacity & storage, on sensory-motor score, in functional independence of individual after SCI.

Key Words: Repetitive trans magnetic stimulation (rTMS), Genital nerve stimulation (GNS). American spinal injury association impairment scale (ASIA), Spinal cord injury independence measure- version III (SCIM-III)

Introduction

Injury to the spine refers to the damage to the neural elements of the spinal cord due to traumatic or non-traumatic lesions due to which Spinal Cord Injury (SCI) patients suffered from perceptual loss in motor and sensory ability [1]. SCI is categorized into complete or incomplete injury based on the degree of damage to the spine. In complete Spinal cord injury (ASIA-Grade A), damage to both motor and sensory function below the level of lesion resulting in paraplegia or quadriplegia. Individuals with SCI are challenged with various dysfunctions includes autonomic dysreflexia, bowel, bladder and sexual impairments, cardiovascular and respiratory consequences. These dysfunctions affect all the domains of the life and critically affect the health and survival of the individual after SCI.

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As per Global Burden Disease 2019, 0.9 million incident cases and 6.2 million of total Spinal cord injury survivors were Years Lived with Disability (YLD). Males had higher rate of incidence and prevalence with Age Standardized Incidence Rate (ASIR), Age Standardize Year Lived Disability Rate (ASYR) and prevalence, extent of chronicity, Years Lived with Disability increased with age. Spinal cord injury at higher level (cervical region) caused higher ASYR than injuries at thoracic, lumbar and sacral level [10]. In India, most commonly affected individuals were between 20-29 years of age and occur due to road traffic accidents followed by falls which lead to quadriplegia/paraplegia with complete or incomplete injuries [7]. Individuals with spinal cord injury, face barriers to social and economic participation due to high rate of unemployment for SCI survivors. SCI has devastating effect on the quality of life (QOL) with a significant involvement of bladder and bowel function, sexual function of affected individuals [8].

Voiding dysfunction results from any physiological or mechanical defects in which urinary sphincter unable to response appropriately to the increase or decrease of pressure of bladder. The neurogenic overactive bladder was consequences of damage to higher centre, autonomic nervous system and peripheral nervous system [12]. The symptoms of overactive bladder were frequency, urgency, urges incontinence and nocturia which affects performance of daily activities and social function such as sleep, physical exercise and sexual function and most likely predispose the individual to depression [14]. The negative impact of overactive bladder was on psychological and social domains, which affects quality of life and limits the social participation of individual [27]. The mismanaged bladder led to an over distended bladder and, a larger volume of urine output, resulting in the leakage of urine which is harmful to the bladder and to upper urinary tract system.

The primary goal of rehabilitation of overactive bladder is to preserve urinary tract function as well as voiding function and to improve an individual's quality of life [24]. As per present evidence in the literature, a number of therapeutic interventions have been implemented for enhancing bladder function and on preventing complications and managing symptoms were electrical stimulation with electrical nerve stimulation-TENS [23], posterior tibial nerve stimulation, Kegel exercises, Clean Intermittent Catheterization (CIC) [15]. But these interventions unmet needed to provide the alternative therapy for restoring the function of bladder and suppress the unwanted detrusor contraction.

In the present arena, the treatment scenario has been modified significantly for bladder rehabilitation, educate SCI survivors regarding bladder and make them understand the importance of bladder. Bladder and Bowel rehabilitation strategies are more focused on the to improve symptoms of overactive bladder, restore the bladder function, and in enhance the quality of life. Non-invasive Neuromodulation therapy in terms of rTMS and genital nerve stimulation may improve an individual's quality of life. These neurmodulation techniques may provide alternatives to long-term pharmacological therapy and from invasive procedure for the symptomatic relief from overactive bladder in persistent or chronic conditions like SCI.

Repetitive Trans-Magnetic Stimulation (rTMS) is a non-invasive magnetic stimulation which modulate the function of nervous system [9]. The rTMS when applied in spinal cord injury leads to spinal cord plasticity and promote recovery by enhancing the collateral sprouting, axonal regeneration, remyelination and facilitate reorganization [19]. With the help of neuromodulation and genital nerve stimulation, the individuals after SCI could be able to self-urinate, gain a functionally independent life, and be free from emotional and psychological baggage due to bladder incontinence.

Under mentioned is the case of traumatic spinal cord injury intervened with repetitive transmagnetic stimulation, genital nerve stimulation along with conventional rehabilitation treatment in which after treatment outcomes were notified.

Methods

Patient representation

History of Present Illness

A 41-year-old male had a compression fracture of

T12-L1 after an object fell on his back. He was conscious at the time of injury and not able to move; there was no history of any open wound, or bleeding from the part at the time of injury. The patient had severe pain in his back after the incident and was not able to move his lower limb. The patient was taken to the nearby hospital from where he was referred to PGI, Chandigarh. MRI was done immediately and showed a fracture of the T12-L1 vertebrae. He was operated and fixation was done. ASIA scale was grade A.

Initial Neurological examination

The complete neurological evaluation of participant was done which includes detailed history, higher mental function assessment, sensory and motor examination, reflex examination. The neurological evaluation of the whole body according to dermatome level was done to obviate any contraindications for rTMS and genital nerve stimulation.

The patient had intact sensorium and higher mental function. The mini-mental status examination (MMSE) was used as the screening tool to assess the higher cortical function. On the basis of physical examination, the patient was found to be flaccid, hyporeflexive and sensory deficit below T12 was present in both lower limbs. On motor examination, patient had preserved range of motion in both upper limb but only passive full range of motion was preserved in lower limb and no active range of motion. Patient was wheelchair dependent and need maximum assistance for ambulation.

Intervention/Treatment Mediation

Selection Criteria of the Subject

The patient participated in clinical trial (CTRI/2022/05/042431). Patient was recruited as per inclusion criteria of the study. The eligibility criterion was spinal cord injury survivors between 20-50 years of age with spastic over-active bladder in both genders. The duration of injury should be more than 6 months, individual with no cognitive impairment MMSE > 26 and those who were willing to participate and give consent form. The individuals having non-traumatic spinal cord injury with hyporeflexia or areflexic bladder, with a history of any degenerative or brain diseases, with a history of psychological illness / disease, individuals with coexisting cauda equina with flaccid bladder and non-cooperative patients or cognitively impaired patients were not included in the study.

Ethical and Patient's informed consent

The patient was recruited in the study registered under the Institutional Ethical Committee of Punjabi University, Patiala with the reference number 14/36/IEC/PUP/2022 and the Clinical Trial Registry of India (CTRI/2022/05/042431). A written information was provided, in which he was informed about the objectives, procedures, potential hazardous, and / or expected outcome of the treatment intervention of the study. A written informed consent was obtained before the commencement of the present study. The confidentiality of the patient was maintained throughout the study.

Objective assessment

Baseline evaluation was done using American Spinal Injury Association Impairment (ASIA)-sensory and motor score, Spinal Cord Independence Measure Version-III (SCIM-III) and Urodynamics. ASIA is a standardized examination tool for SCI conditions, consisting of myotomal-based motor examination, sensory examination based on dermatomes, and anorectal examination [20].

The spinal cord independence measure (SCIM-III) is a scale used to assess the ADLs in Patients with spinal cord lesions. The SCIM-III consists of 3 subscales: self-care, respiration, bowel and bladder management and mobility. SCIM-III is found to be more accurate and reliable in SCI patients [13].

Urodynamics studies have a major tool in evaluating bladder dysfunction in patients with neurological conditions. This is the only method to objectify the dysfunction [21].

Intervention

This study was done for 4 weeks consecutively. The patient was intervened with rTMS over stimulation

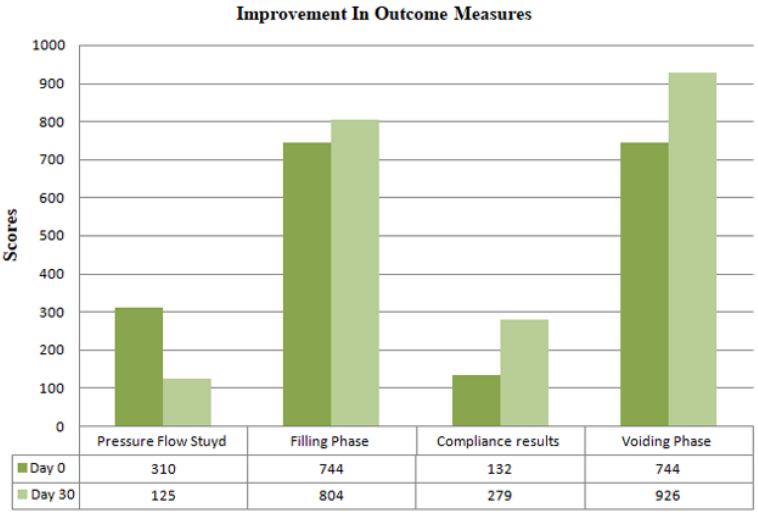

Figure 1. Improvement in outcome measures. Pressure flow study, filling phase, compliance results, and voiding phase in Urodynamics study

point was T-11 to L-4 vertebrae, the coil was centered along the midline during stimulation and each stimulation session consisted of 4 min continuous stimulation period of a total 13 minutes at 1 Hz. Placement of electrodes for the genital nerve stimulation was cathode at the base of the penis and anode 2 cm distal in males and in females, one electrode placed over clitoris and second at the medial aspect of thigh along with conventional physiotherapy. Both rTMS and genital nerve stimulation were applied to the patient. The intervention was given consecutively for 4 weeks (five sessions per week).

Results

The evaluation was done at Day 0 and Day 30 respectively to quantify the improvement in all outcome measures of the patient. The patient improvement was recorded in the urodynamics study (Figure 1). Detrusor pressure and vesicle pressure were improved with the change in pressure of the detrusor and

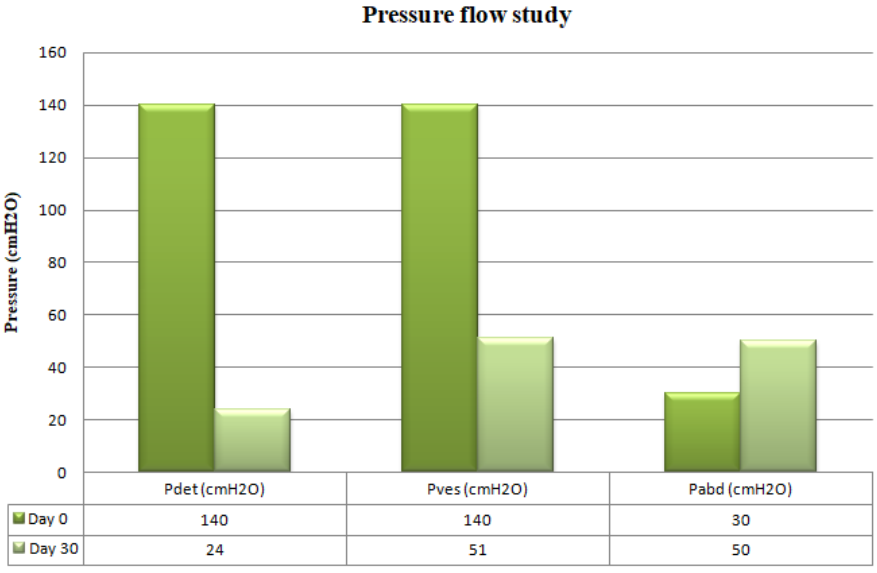

Figure 2. Improvement in pressure flow score in urodynamics study

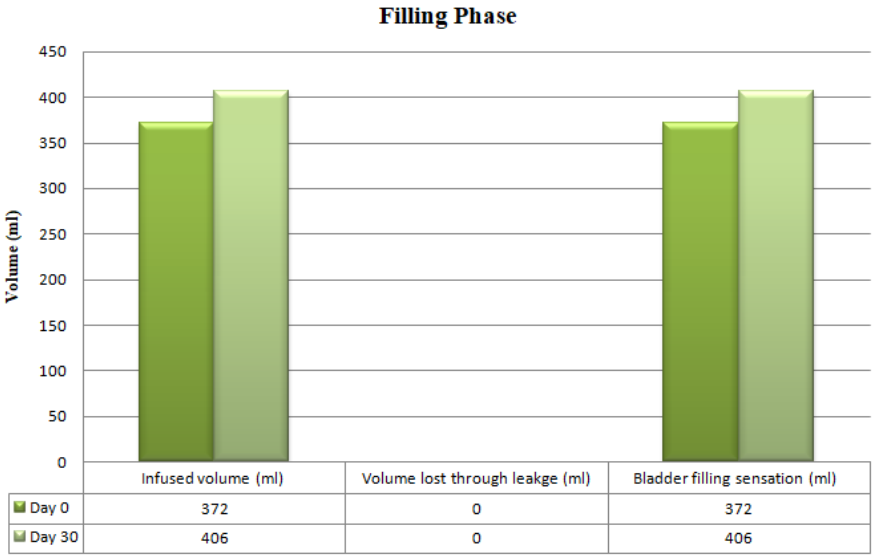

Figure 3. Improvement in filling phase score of the bladder in urodynamics study

vesicle. The Pdet (pressure of detrusor) lowered from 140 CmH_2O to 24 CmH_2O, Pves (pressure of vesicle) lowered from 140 CmH_2O to 51 CmH_2O and Pabd (pressure of abdomen) increased from 30 CmH_2O to 50 CmH_2O during cough (Figure 2). Similarly, improvement was also observed in the filling phase, infused volume in the bladder increased from 372 ml to 406 ml, volume lost through leakage was 0, and bladder filling sensation increased from 372 ml to 406 ml (Figure 3).

Urodynamics also showed improvement in voiding phase study, results showed that total bladder capacity increased from 372 ml to 407 ml, Delay time was not present in the first urodynamics but during the second, it was 112 sec. However, detrusor pressure at peak flow, time to peak flow, void volume and void time were not able to be measured because Patient was not able to void (Figure 4). The compliance results showed that Pves (ml/CmH_2O) improved from 15 to 125, and Pdet (ml/CmH_2O) improved from 15.4 to 52.1 (Figure

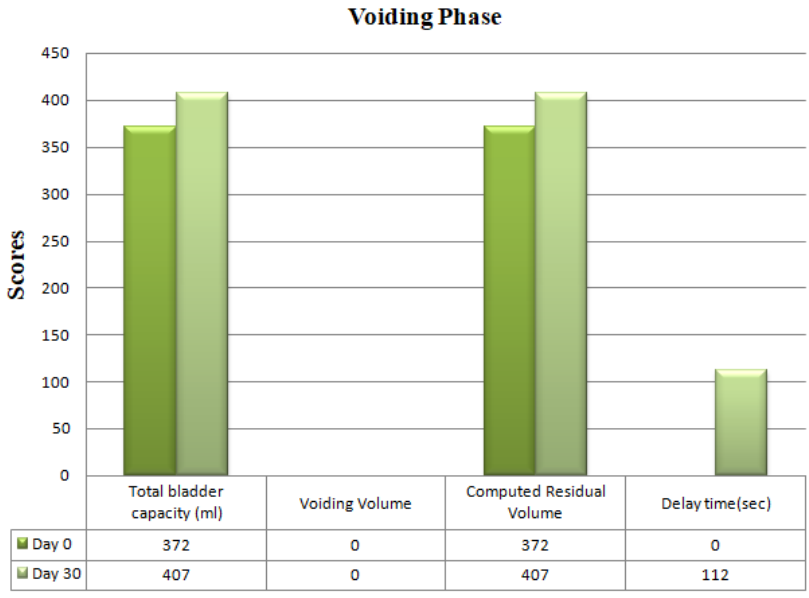

Figure 4. Improvement in voiding phase scores in urodynamics study

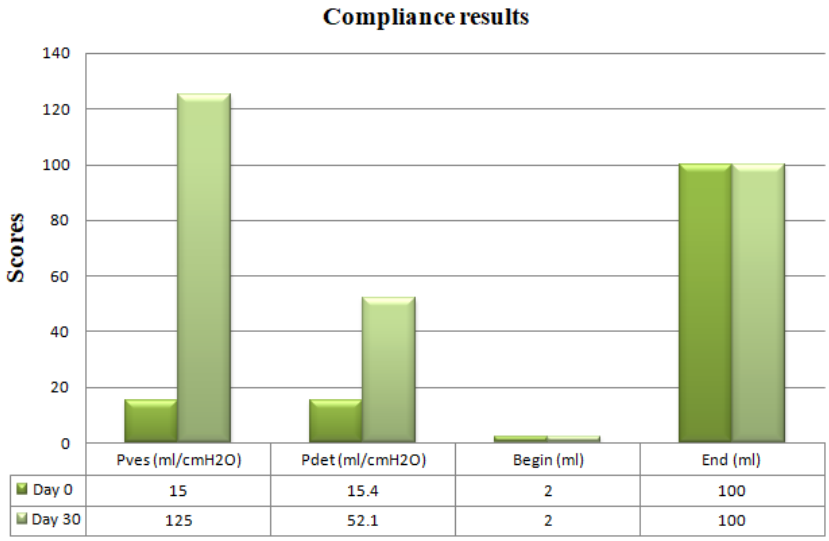

Figure 5. Improvements observed in Compliance of bladder in urodynamics study

5). The Patient and his caregiver also found an increase in the urine output volume after CIC, increased bladder capacity, and decreased risk of neurogenic overactive bladder, and the patient was in safe storage. SCIM-III was also improved form score 54 to 66 and there was no change in the ASIA score.

Discussion

In SCI, alteration in urinary bladder and urethra function is the most important consequence. The main focus for the management of neurogenic overactive bladder was to improve storage of bladder by decreasing pressure, reduce urinary incontinence/leakages, preserve upper urinary tract, and enhance the quality of life of individuals [26]. Even with advances in urological treatment, individuals with chronically catheterized bladder remain at risk. The main objective of treatment is to have a low-pressure, good compliance bladder and bladder emptying with low urethral pressure timely [25].

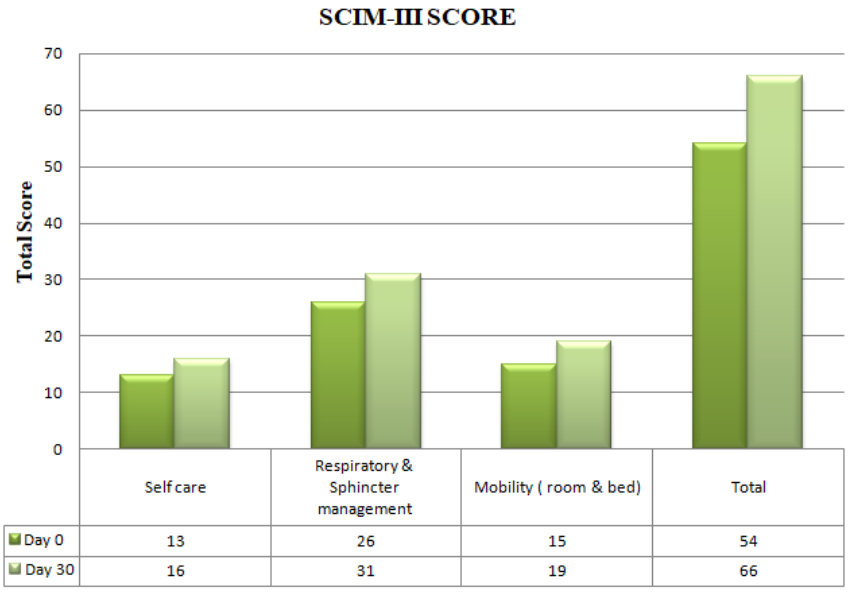

Figure 6. Improvement in Spinal Cord Independence Measure (SCIM-III)

Non-invasive spine stimulation becomes evident method to induce neural synaptic plasticity. Magnetic stimulation, modulate the function of the nervous system by using magnetic energy. Among such methods, repetitive trans-magnetic stimulation and Transcranial direct current stimulation (tDCS) are most commonly choice of treatment in the field of basic neuroscience. However, this study is distinct in its implementations of the rTMS along with genital nerve stimulation, rehabilitation for 4 weeks and their effect on overall recovery especially on bladder and autonomic nervous system, in the traumatic spinal cord injury survivors.

The clinical applicability of rTMS along with genital nerve stimulation on individual with SCI, targeting the sympathetic as well as somatic nervous system was developed from the fact that detrusor pressure increases which reduces the bladder capacity and causes symptoms of overactive bladder after SCI causing devastating impact on SCI survivor well-being. The authors of the study concluded that transcutaneous electrical stimulation of the dorsal genital nerves can reduce detrusor over activity. The application of peripheral stimulation in the form of genital nerve stimulation was to inhibit detrusor over activity and increased the bladder capacity. The bladder capacity was significantly improved by the application of GNS in the study conducted by Bros et al., [6], and Bourbeau et al., [5].

The result in the current patient showed that there is improvement in the pressure flow study which showed, there was a significant decrease in detrusor pressure (Pdet) from 140 CmH_2O to 24 CmH_2O and decreased vesical pressure (Pves) from 140 CmH_2O to 51 CmH_2O. During the filling phase, the infused volume as well as bladder filling volume was increased from 372 ml to 406 ml and the bladder filling sensation started at 405 ml. A significant improvement showed in the voiding phase also, total bladder capacity increased from 372 ml to 407 ml but there is no voiding volume. The Ice Water Test (IWT) was also negative which means there was no over activity of detrusor muscle. The first urodymanics study diagnosed the patient had neurogenic detrusor over activity with decreased bladder capacity but after the completion of 4 weeks of intervention again urodynamics study was done which showed bladder was in safe storage, and there was no over activity of the detrusor.

Yeh et al., [25], conducted a study on the effects of genital nerve stimulation amplitude on bladder capacity in spinal cord injured Patients and concluded that GNS was effective in improving bladder capacity and inhibiting bladder over activity. Doherty et al., [11] conducted a study on a urodynamic comparison of neural targets for transcutaneous electrical stimulation to inhibit detrusor contractions and compare dorsal genital nerve stimulation, tibial nerve stimulation, sacral nerve stimulation, and spinal stimulation on neurogenic detrusor over activity in spinal cord injury individuals, by this comparison the author concluded that dorsal genital nerve stimulation (DGNS) acutely inhibit the detrusor over activity and increased bladder capacity. In addition, Wheeler, Walter & Zaszczurynski, 1992 [24] found that surface dorsal genital nerve stimulation was effectively inhibit the detrusor over activity and increased the micturition threshold in SCI Patients.

There is enormous dearth of literatures regarding the clinical efficacy of rTMS on bladder function in spinal cord injury survivors. The current case can be a primary support as opportunity for administers this protocol to large population of SCI to set up the quality of evidence in bladder rehabilitation. This single case study provided us with evidence of rTMS and genital nerve stimulation in spinal cord injury patients on bladder function even so a large sample trial shall be sufficient to provide with the quality of evidence.

Limitations & Conclusion

The findings of this study cannot be specified since this is a single case study and no comparison has been done to establish the effectiveness of rTMS. However, an integrated approach of the rTMS has provided an add-on effect concerning the improvement in bladder function. Large sample size for further trials is required to establish the efficacy of rTMS and genital nerve stimulation in SCI survivors.

To conclude, that the application of rTMS and genital nerve stimulation-induced improvement in

bladder capacity, and decreased detrusor pressure in neurogenic detrusor overactive bladder in SCI patients but the Patient still doing clean intermittent catheterization (CIC) and was not able to void. There is no urinary incontinence/leakage and the patient is in safe storage of the bladder.

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Conflict of interest

The author declared no potential conflicts of interest concerning the authorship and/or publication of this article.

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