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Efficacy of Biofeedback Training on Bladder Dysfunction and Quality of Life in Paraplegic Patients

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Abstract : Objectives: To evaluate efficacy of biofeedback training on treatment of bladder dysfunction and quality of life in paraplegic patients. **Methods:** Thirty male paraplegic patients within 6 to 18 months after injury, ages ranged from 20 to 35 years, participated in this study for a treatment period of six weeks; they were divided into two equal groups. Patients in group I were treated with pelvic floor exercises two times weekly, while patients in group II were treated with biofeedback training plus pelvic floor exercises two times weekly. All subjects were assessed for; 1) voiding cystometry, 2) EMG of pelvic-floor muscles, 3) QUALIVEEN questionnaire (short version). **Results:**There was significant improvement in group II and non-significant improvement in group I in values of an EMG biofeedback assessment of pelvic-floor muscles. There was highly significant improvement in group II in the bladder volume at the first desire to void and at maximum cystometric capacity, the detrusor pressure at maximum flow rate, the maximum flow rate, detrusor stability and significant improvement in bladder compliance while there was no significant difference in group I in the bladder volume at the first desire to void and at maximum cystometric capacity, the bladder compliance and detrusor stability & significant improvement the detrusor pressure at maximum flow rate & highly significant improvement in the the maximum flow rate. There was highly significant improvement in group II and non-significant improvement in group I in the Qualiveen questionnaire. **Conclusion:** Biofeedback training should be considered as valuable adjacent to conventional treatment in the control of bladder dysfunction & optimizing quality of life in paraplegic patients.

Introduction

Spinal cord injury (SCI) is not a notifiable injury. The estimated incidence of SCI worldwide is between 11 and 53 cases per million inhabitants. In general, road traffic accidents account for the largest number followed by falls, sports injuries and violence, although causes vary considerably according to the prevailing circumstances in the country in which they occur[1].

The effects of spinal cord transection include the initial state of spinal cord shock in which the bladder becomes overfilled and exhibits sporadic voiding. With time the voiding reflex is re-established but with no voluntary contraction. Bladder capacity is often reduced and reflex hyperactivity may lead to state called spastic neurogenic bladder. The bladder cannot empty completely resulting in residual urine[2].

Abnormal patterns of micturition and bowel function are common features of moderate to severe SCI. Disturbances of the bowel and bladder occur in myelopathy due to the loss of suprasegmental facilitatory and

inhibitory influences from the pontomesencephalic tegmentum via the reticulospinal tract. Corticospinal pathways also contribute inhibitory influences[3].

The loss of urinary function is one of the most important results of SCI. Specifically, neurogenic bladder often associated with SCI results from damage to the nerves controlling bladder function. A lesion above the sacral level of the spinal cord, which may or may not involve the brain, could affect how the bladder stores and empties urine. These upper motor lesions are most commonly seen after neurological diseases such as cerebrovascular accidents (stroke), SCI, multiple sclerosis, and also infections[4].

Urinary incontinence is known to have a detrimental effect on quality of life in patients with and without neurogenic bladder dysfunction. Consequently, in their study, patients with urinary incontinence had worse quality of life compared with patients who were continent. The incontinence in this cohort of patients, however, was mainly caused by detrusor overactivity[5].

The purpose of this study was to determine the efficacy of biofeedback training in the treatment of bladder dysfunction and optimizing quality of life for male paraplegic patients.

Patients and Methods

Thirty male patients suffered from bladder dysfunction (precipitancy overactive bladder) after traumatic partial spinal cord injury above T12 within 6 to 18 months after injury. Patients were divided randomly into two equal groups. Fifteen patients in the group I were subjected to the pelvic floor exercises only and other fifteen patients in the group II were subjected to biofeedback training plus the pelvic floor exercises.

Patients were randomly recruited from the neurology outpatient clinic at Kaser El Aini Teaching Hospital and Faculty of Physical Therapy, Cairo University. The patients were referred from urologist and neurologist with diagnosis of precipitancy overactive bladder due to partial spinal cord lesion. All participants provided informed consents prior to participation in the study.

Clinical evaluations including; neurological, musculoskeletal, and urinary were performed to all patients. Inclusion criteria were patients 20 to 35 years old with precipitancy overactive bladder dysfunction due to partial spinal cord lesion. Diagnosis was confirmed by clinical and radiological assessment through urologist and neurologist. All patients were medically fit to participate in the study. Patients with SCI below T12, with history of bladder dysfunction before the SCI, severe psychological disorder, pre-existing lung diseases, cardiac diseases, major neurological, musculoskeletal or metabolic disorders were excluded from the study.

Methodology

Assessment Procedure:

All patients were subjected to the following procedures before starting the study and after completing the 6 week treatment regimen:

1. Cystometry
2. Pelvic-floor muscles activity measurement
3. Qualiveen questionnaire (short version)

Cystometry was assessed with a DANTIC UD 5000/5500 Urodynamic Investigation System (Megamed, Germany). All patients were subjected to multichannel cystometry before starting the study and at the end of 6-week treatment[6]. The following parameters are measured volume at first desire to void, maximum cystometric capacity, maximum flow rate (Qmax) and detrusor pressure at Qmax.

Electromyography activity (EMG) of pelvic-floor muscles was measured using Toennies Neuro Screen Plus System EMG biofeedback device [7].Two parameters were assessed; Amplitude per time (A/T) and upper centile amplitude (UCA).

Qualiveen questionnaire was developed as a disease specific quality of life measure for individuals with SCI who have urinary disorder that could be used in international multi-center trials. The tool was developed by

a multi-disciplinary group of experts and the questions were derived based on the literature and individuals with SCI. There are four scales: limitations, constraints, fears, and feelings. The Qualiveen questionnaire can be administered by interviewer or be self- administered. The questionnaire is based on a five points Likert scale [8].

Therapeutic Intervention:

Treatment regimen was done on 12 sessions two times per week for six weeks. The group I was managed by Pelvic floor exercises only. The Group II was managed with biofeedback training plus the pelvic floor exercises using The Electromyography (EMG) Biofeedback Device (Toennies Neuro Screen Plus System EMG biofeedback device, model 1998 made by Germany).

Treatment Procedures

1. **Pelvic floor exercises:** for all patients (n = 30). The patients were taught how to tighten and lift the pelvic floor muscles as if they are interrupting the flow of urine midstream. Initial contractions were 5-10 seconds with a 10 to 20 seconds rest, with 12-20 repetitions. Endurance exercise focused on maintaining muscle contraction in at 65-75% of maximum strength and holding for 20-30 seconds with 8-10 repetitions. Speed was achieved by sets of quick repetitive contractions in a 10 seconds span with a 20 seconds rest. Purposeful control involved gradual recruitment to maximal contraction with a 5 seconds hold and a slow release with a rest period of 15-30 seconds[9]. The patients were asked to perform 30 contractions in the morning, afternoon, and evening at home.

2. **PFBFB Session:** With an empty bladder, the patient contact the pelvic floor muscles in in fowler lying position. With the EMG Biofeedback Device; the site of positive electrode (red) was marked by a marker at the base of the penis one centimeter lateral to the median line of the perineum on the right side, and the site of negative electrode (black) was marked at the bulk of pelvic-floor muscles especially ischiocavernosus and bulbospongiosus muscles about three centimeters from the positive electrode site and one centimeter lateral to the median line of the perineum also on the right side. The positive and negative electrodes were filled with gel and were connected to the marked site, and it was fitted by adhesive plaster. The patients were asked to perform short (a second) and long (6-10 seconds) contractions of target muscles. They were asked to look at the screen of the computer to watch the EMG biofeedback activities during muscle contraction and also the patient was asked to listen to the sound of the loudspeaker caused by contraction of the pelvic floor muscles. The same procedure was conducted on the left side of the perineal muscles[10].

Statistical analysis:

Data was analyzed using IBM SPSS Advanced Statistics version 22.0 (SPSS Inc., Chicago, IL). All assessment variables were tested for normality of distribution (Shapiro-Wilk test); all variables were found to be not normally distributed. Thus, two-way analysis was not done. Comparison between two groups was done using Mann-Whitney test. Wilcoxon Signed Ranks Test was used to compare pre- and post-test measures in each group separately. A p-value < 0.05 was considered significant.

Results:

The two groups were comparable regarding age, height, weight and body mass index (BMI) as shown in table 1. Table 2 shows cystometric measurements in the two studied groups before and after treatment. Before treatment there was no significant difference in bladder volume at first desire to void ($p= 0.990$), maximum bladder capacity ($p = 0.259$) and maximum flow rate ($p = 0.294$), but the detrusor pressure at maximum flow rate was significantly higher in the group II ($p = 0.018$). After treatment, there was no significant difference between the two groups except for detrusor pressure at maximum filling ($p = 0.008$).

Table 1: Demographic and clinical characteristics of the two studied groups

	Group I n=15	**Group II n=15**	**p value**
Age (years)	28.33 ± 5.09	28.13 ± 5.42	0.918
Height (cm)	167.3 ± 7.38	166.6 ± 8.23	0.799
Weight (kg)	72.20 ± 8.07	69.47 ± 10.61	0.434
Body mass index (kg/m^2)	25.87 ± 3.18	25.00 ± 3.30	0.467

Data presented as mean±SD

Table 2: Cystometric measurements in the two studied groups before and after treatment

	Group I n=15	**Group II n=15**	**p value**
Volume at first desire to void (ml)			
Before Treatment	264.6±102.5	264.1±89.8	0.990
After Treatment	266.7±103.7	299.7±93.5	0.367
Maximum cystometric capacity (ml)			
Before Treatment	267.1±92.8	235.1±54.5	0.259
After Treatment	270.5±90.0	261.9±56.8	0.758
Detrusor pressure At Qmax (cmH_2O)			
Before Treatment	55.0±28.9	79.8±24.8	0.018
After Treatment	59.1±31.6	90.3±28.2	0.008
Maximum flow rate (mL/s)			
Before Treatment	6.6±1.9	5.8±2.2	0.294
After Treatment	7.2±1.9	7.9±2.1	0.321

Data presented as mean±SD

Table 3 shows EMG measurements of the pelvic floor muscles in the two studied groups before and after treatment. Before treatment there was no significant difference in the strength of the muscles between the two groups. After treatment, the strength of the muscles on both sides was significantly higher in group II. Similarly, Qualiveen questionnaire (SH-8) score was comparable before treatment (p = 0.202) and after treatment (p = 0.000) (Table 3).

Table 3: EMG measurements of the pelvic floor muscles in the two studied groups before and after treatment

	Group I n=15	**Group II n=15**	**p value**
Amplitude per time, RT (mV)			
Before Treatment	0.19±0.05	0.22±0.06	0.098
After Treatment	0.19±0.05	0.26±0.04	0.000
Amplitude per time, LT (mV)			
Before Treatment	0.19±0.05	0.23±0.06	0.049
After Treatment	0.19±0.05	0.25±0.05	0.001
Upper centile amplitude, RT (mV)			
Before Treatment	0.28±0.06	0.31±0.11	0.361
After Treatment	0.28±0.07	0.35±0.10	0.016
Upper centile amplitude, LT (mV)			
Before Treatment	0.28±0.06	0.31±0.10	0.434
After Treatment	0.28±0.06	0.34±0.10	0.031
Qualiveen SH-8			
Before Treatment	3.18±0.62	2.93±0.41	0.202
After Treatment	3.08±0.58	2.13±0.40	0.000

RT: on the Right side, LT: on the left side, Data presented as mean±SD

Discussion

This controlled randomized study was conducted to determine the effectiveness of biofeedback training on bladder dysfunction and optimizing quality of life in male patients with partial spinal cord injury.

The present study revealed that, biofeedback training was more effective than pelvic floor exercises alone, in improving the bladder control and quality of life in male patients with partial spinal cord injury. This study is the first one to interest in bladder and quality of life complications of patient with spinal cord injury in Egypt.

In the present study the biofeedback training of the pelvic floor muscles had been aimed to regain voluntary control of the pelvic floor musculature aiming to initiate voiding. The biofeedback training was performed twice weekly for six weeks with duration of 40 min. Decrease in leaking episodes, use of diapers and number of intermittent self-catheterizations per day reflected positively on quality of life as well as objective improvement in the bladder volumes, detrusor pressures, and maximum flow rate gained through urodynamic measurement.

Krishnan and Guad[11] described the neurophysiologic basis of bladder inhibition in response to pelvic floor stimulation; a long lasting reflex discharge unaffected by changes in intravesical pressure or by micturition was evoked in the hypogastric nerves, which also provided a powerful central inhibition of efferent activity in the pelvic nerves. Therefore neural stimulation could exert a beneficial effect through modulation of the sphincteric activity and stabilization of the reflexes which are responsible for this behavior.

The results of present study consistent or supported by the work reported by: Spinal cord injury is devastating and produces profound changes in the life style of the individual and his family. It is difficult to predict bladder and sphincter behavior on the basis of clinical somatic neurological deficits. Aggressive management of neurogenic bladder dysfunction is a crucial component of the rehabilitation program for spinal cord injury patients. Repeated urodynamic studies are an essential aid in managing the evolving nature of the bladder dysfunction. Meticulous bladder management protocol can prevent upper urinary tract complications[12].

The urodynamic findings that distinguish upper from lower motor neuron bladder dysfunction in spinal cord injured patients to evaluate the benefit of medications used to treat their voiding disorders. Management of the urinary tract dysfunction in spinal cord injured individuals should be based on urodynamic principles and findings in addition to the neurologic history and physical examination[13].

Biofeedback techniques use a manometric or electromyographic device to relay visual and/or auditory evidence of pelvic floor muscle tone to improve muscle awareness and to assist the patient in the performance of pelvic floor exercises. This treatment is indicated in bladder hyperactivity and incontinence. This is often used in addition to pelvic floor exercises. Biofeedback can also be used for the treatment of spasticity of pelvic floor muscles and has been shown to improve voluntary control of muscles[14].

Biofeedback is a self-regulation training technique derived from well-established principles of human learning. Biofeedback is a technique, not a stand-alone treatment, which is one component of a behavioral training program to facilitate acquisition of pelvic floor muscle control and other continence skills[15].

Biase et al.[16] showed that treatment involving EMG biofeedback significantly increased voluntary EMG responses from pelvic-floor muscles in individuals with spinal cord injuries. The use of EMG biofeedback in the rehabilitation of patients with incomplete spinal cord injuries has already shown significant motor improvement.

Pelvic floor muscle training also known as Kegel exercise is considered a cornerstone in behavioral treatment. Pelvic floor muscle training is a program of repeated voluntary pelvic floor muscle contractions taught and supervised by a health care professional. These work by increasing the strength and tone of the pelvic floor muscles, which in turn increases the urethral closure force. It is also useful for urge incontinence as the detrusor contractions can be reflexively or voluntarily inhibited by tightening the pelvic floor. The success of Pelvic floor muscle training depends on the patient's ability to perform the exercise correctly and the motivation to actually practice it regularly[17].

Porru et al.[18] reported that pelvic floor muscle re-education produces a quicker improvement of urinary symptoms and of quality of life in patients, and its early practice reduces urinary incontinence.

The Qualiveen scales concerning fears and feelings were significantly worse in patients with suboptimal bladder function compared with those patients with treatment success. The results of our study have demonstrated that a treatment regimen leading to favorable urodynamic data and continence correlates with better quality of life[19].

Although one purpose of assessing quality of life is to evaluate the effects of treatment, quality of life can be influenced by diverse factors such as family support, adjustment and coping, productivity, self-esteem, financial stability, education, and the physical and social environment. These factors should also be evaluated in future studies to assess whether the management of neurogenic bladder might improve the quality of life in those patients. Potentially, identifying and characterizing factors related to quality of life in those patients with SCI might accelerate the development of preventive, diagnostic and therapeutic strategies for improving quality of life in those patients[20].

Limitations of this study: include lack of patients seeking medical help, which were due to difficulties in recruiting patients who were able and willing to undergo two months biofeedback training. Besides, urodynamic examination is highly expensive. However, it could be confirmed that, all patients in the two groups were training precisely.

Finally and within the obtained results, preliminary evidence was provided to highlight the role of biofeedback training in bladder dysfunction and optimizing quality of life in spinal cord injury. Therefore this modality must be recommended in the rehabilitation program for patients with spinal cord injury having bladder dysfunction.

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