

Interferential electrical stimulation for improved bladder management following spinal cord injury

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Abstract. Patients with spinal cord injury (SCI) with neurogenic bladder (NB) represent a major medical problem, which initiated the search for a non-invasive and effective treatment that is easy to apply and without side effects. A study was performed using interferential medium frequency current electrical stimulation (IMFC ES) on 332 patients shortly after SCI diagnosed with NB dysfunction. All subjects received standard care and patients of the experimental group additionally received IMFC ES. Urinary management results included volitional control of voiding, intermittent catheterization, post-voidance residuum (PVR) quantity and quantity of urine lost (LOSS). Results were assessed based on the American spinal cord injury association impairment scale (AIS). The IMFC ES included two channels of medium frequency stimulation that were marginally different. Within the body, a low frequency field was generated through the interaction of the medium frequencies, which stimulated the urinary structures. In the IMFC ES group, interference stimulation was applied for 10 min with frequencies cycling from 0-100 Hz and back in 10 sec intervals. The strength of the low

frequency stimulation, achieved by the interference of the two medium-frequency fields, was adjusted to the patients' vibration sensation. The intensities triggering vibration sensation were between 20-80 mA for patients with AIS levels B, C and D. For patients with AIS level A intensities <20 mA were used for therapeutic effects without causing skin injuries. Safety of IMFC ES was based on occurrence of adverse events of which none were recorded in the experimental group. IMFC ES was effective in patients with AIS levels B and C, significantly decreasing PVR and LOSS compared with patients receiving standard care. No significant improvements in urinary management were observed following IMFC ES treatment of patients with AIS level A. Patients with SCI and NB classed as AIS levels B and C that exhibit preserved sensitivity were the best beneficiaries of IMFC ES therapy.

Introduction

In Romania, each year ~4,250 individuals are hospitalized with spinal cord injuries (SCIs) (1). SCI may generate severe and permanent impairment, including to voluntary motility, cutaneous sensitivity loss, micturition and/or defecation control, erection, ejaculation or fertility (2-5). Severe urological and gastro-intestinal medical conditions have been reported to occur following SCI (6,7). Bladder control is a major problem for patients with SCI (8,9).

SCI neurogenic bladder (NB) management can be classified under three main approaches: The preferred volitional voiding, intermittent catheterization (IC) and continuous catheterization (8,9). The effectiveness of these methods can be determined based on bladder control and incontinence episodes, and low pressure emptying of the bladder is an important goal (8-11). Foley catheters for draining the bladder are widely used in management of SCI NB (8,9). However, this method increases the risk of urinary tract infections (UTIs). IC utilizes small catheters that are inserted into the bladder via the urethra for drainage several times a day. Major problems

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Abbreviations: IMFC, interferential medium frequency current; ES, electrical stimulation; SCI, spinal cord injury; NB, neurogenic bladder; IC, intermittent catheterization; PVR, post voidance residuum; LOSS, quantity of urine lost; OCC, own customized clinical classification system; AIS, American spinal cord injury association impairment scale; UTI, urinary tract infection

Key words: neurogenic bladder, spinal cord injury, interferential medium frequency, electrical stimulation therapy

with this approach include difficulties when inserting catheter, incontinence between catheterizations and UTI (12). Bladder dysfunction medication is administered to reduce the risk of incontinence and UTIs (8,9). A recent change to the traditional management approaches was in the area of reflex and spontaneous voiding methods, where injection of botulinum toxin into the urethral sphincters has demonstrated to reduce voiding pressure and improve bladder evacuation (13-15).

Interferential medium frequency current (IMFC) electrostimulation (ES) is a non-invasive approach for the treatment of bladder incontinence first reported in 1985 by Dougall (16). By using interferential therapy in a controlled randomized comparative study with 75 male patients, Elgohary (13) demonstrated a significant difference for regaining bladder micturition control in patients with incontinence originating from different etiologies compared with patients receiving behavioral training, pelvic floor exercises with posterior tibial nerve stimulation. Rafaqat *et al* (14) reported that incontinence due to an over-reactive bladder condition was significantly improved by IMFC in a study with 40 patients, some of which were diagnosed with SCI NB. Kajbafzadeh *et al* (15) focused on the use of IMFC in the management of non-neuropathic underactive bladder dysfunction. The majority of recent studies described effects of IMFC ES on bladder incontinence and retention (15-18).

Recent publications encouraged the application of interferential therapy in bladder dysfunction, including neurogenic causes, both in incontinence and urinary retention (13-19). The objective of the current study was to use IMFC ES as an intervention in early SCI care. IMFC ES was applied with surface electrodes in pubic and abdominal areas to improve urinary management. The use of IMFC ES to treat NB after SCI described a non-invasive method of physiotherapy may be considered for treatment in the future.

Materials and methods

Study design. A total of 332 patients admitted to the Physical and Rehabilitation (Neuromuscular) Clinic Division at the Clinical Emergency Hospital 'Bagdasar Arseni' (Bucharest, Romania) between September 2006 and April 2011 were included in the present study. All patients were diagnosed with NB attributed to SCI and were enrolled 5-14 or 15-21 days after injury and categorized as sub- or post-acute, respectively (19,20).

Inclusion criteria for the study were as follows: i) ≥ 18 years, ii) diagnosed with NB caused by different pathological conditions, iii) SCI in sub- or post-acute state, iv) first admission to the Neuromuscular Department of Clinical Emergency Hospital 'Bagdasar Arseni' (Bucharest, Romania), and v) indwelling catheter at admission. SCI may have varying causes, this study included traumatic (T)-SCI and non-T-SCI caused by tumors, disc hernia or other. Exclusion criteria were as follows: i) History of other associated neurological diseases, including traumatic brain injury and stroke; ii) History of urinary tract infections; iii) IC after indwelling catheter removal not possible; iv) normal voluntary micturition control at admission; v) febrile pathology; vi) cachexia; vii) peace makers; viii) malign or benign tumors affecting health; ix) cutaneous pathology preventing electrode placement, including pressure sores, metallic osteosynthesis at lumbar vertebra 2 or the hip; and x) bladder stones.

Before being randomized into the two groups, the indwelling catheter was removed and all patients benefited by intermittent catheterization and standard care. A bladder ultrasonography examination was performed as described previously on all patients prior to grouping (21). All patients received an appropriate rehabilitation program, including medication and kinesiotherapy according to their medical condition and similar IC. The repartition of the patients in the two groups was performed randomly. A total of 162 patients additionally received IMFC ES therapy, while 170 patients only received standard care (control group). Furthermore, patients were classed using the American spinal cord injury association impairment scale (AIS) (22) and no urodynamic tests were performed in the current study.

IMFCES. The 5820 LIMFC stimulator (serial no. 5000-0381543) was obtained from BTL Industries Ltd. The apparatus is standardized and was authorized for medical use by the Romanian Ministry of Health (SR EN ISO 9001; certificate 5621C). The current study was approved by the Ethics Commission of the Clinical Emergency Hospital 'Bagdasar Arseni' (Bucharest, Romania; approval no. 7727).

In IMFC ES, an electrical interference is produced using two electrical circuits with constant amplitude at medium frequencies (3-10 kHz). The two of medium frequency channels varied by 100 Hz. Within the body, a low frequency field (0-100 Hz) was generated through interference of the medium frequencies, stimulating the urinary structures. This process is standardized and manufacturer-specific (15,23-25). Two electrodes are applied for each circuit and electrodes were 10x10 cm squares out of conductive silicone rubber with granite inserts, coated with a wet cellulose material. The interference stimulation was applied for 10 min and frequencies cycled from 0-100 Hz and back in 10 sec intervals (21,26,27). Vibration sensation is subjective for every patient with sensitivity in the targeted area. Patients classed as AIS level B, C and D received treatment with 20-80 mA intensities and patients with AIS level A received 20 mA treatments to achieve a therapeutic effect without causing skin injury. IMFC ES was applied immediately after IC to prevent voiding during stimulation or bladder-ureteral outflow.

Evaluation criteria. The following parameters were assessed: Age, sex and micturition control. The latter was defined by the following criteria and data were recorded daily: Post voidance residuum (PVR) quantity; amount of urine lost between IC or by voluntary micturition, including incontinence quantity and short-term quantity of urine lost (LOSS); number of voluntary micturition; number of ICs in 24 h.

Data analysis. Data were collected over the duration of this 30 days study. PVR was classified as follows: i) Minimal, ≤ 40 ml PVR; ii) slight, 41-100 ml PVR; iii) moderate, 101-200 ml PVR; iv) severe, 201-400 ml PVR and > 6 CI daily or indwelling catheterization; and v) massive, > 400 ml PVR and indwelling catheter. Incontinence and LOSS stages were defined as follows: i) Minimal, ≤ 25 ml urine; ii) slight, 26-50 ml urine and required use of absorbent devices; iii) moderate, 51-100 ml urine and required use of absorbent devices; iv) severe, 101-250 ml urine and required use of absorbent devices; and v) massive, > 250 ml urine and required use of absorbent devices.

As presented in Table I, the customized clinical classification (OCC) of micturition control was based on the following five stages: (I) Full, no or minimal ≤ 40 ml PVR and/or ≤ 25 ml incontinence and LOSS between voidances; (II) acceptable, 1-2 ICs within 24 h and 41-100 ml PVR and/or 26-50 ml incontinence and LOSS; (III) partial, mandatory IC (3/day) for moderate 101-200 ml PVR and/or 51-100 ml LOSS; (IV) practically abolished, mandatory IC (4-6/day), severe 201-400 ml PVR and low 101-250 ml LOSS; and (V) abolished, mandatory IC (>6 /day), high >400 ml PVR and >250 ml LOSS, and level of incontinence suggesting the use of indwelling catheters. IC did not contribute to OCC.

The number of IC needed per patient was recorded on a daily basis. Patients were further classed by bladder dysfunction causes, namely mixed NB type, including incontinence and urinary retention (28) and retention NB type, only with urinary retention. The regain of normal control of voiding was assessed using the above mentioned classifications; for retention NB type, with no PVR at IC and for mixed NB type, with no PVR at IC and no LOSS. Additionally, for both NB type voluntary voiding was further recorded. Fully regained bladder control was classed as no need of IC, no PVR, no LOSS and declared voluntary voiding.

Potential adverse effects of IMFC ES were monitored, including local tegument reactions (erythema and erosion) and general effects, such as discomfort of any nature, variations of the blood pressure, pulse, temperature, palpitations, dizziness and weakness.

Statistical analysis. Data was compared using unpaired Student's t-test or χ^2 -test. Initial PVR data (ml) were not normally distributed (Gaussian), according to the Kolmogorov-Smirnov normality test (29). In order to obtain normally distributed data and pass the normality test, the square roots of initial PVR data were calculated, thus limiting the data range to 0-45. One-way analysis of variance was performed to compare multiple groups using the least significant difference test as post hoc test. Statistical analysis was performed using SPSS version 24.0 (SPSS, Inc.). $P < 0.05$ was considered to indicate a statistically significant difference.

Results

Demographic data. No significant difference between the control and the IMFC ES group were determined with regards to the age and sex of the patients (Table II). The mean age was 39.96 ± 17.58 and 39.63 ± 17.06 years for the control and IMFC ES groups, respectively, and 74 and 67% of the patients were male, respectively.

Distribution of SCI NB etiology. Patients in the control group presented with the following causes of SCI: 141 cases of T-SCI, 20 cases of SCI caused by tumors, including 8 primary tumors (5 meningiomas, 2 hemangioblastomas and 1 ependimoma) and 12 of secondary tumors (11 prostate adenocarcinoma metastases and 1 breast cancer metastases), and 9 cases of SCI caused by disc herniation. Patients of the IMFC ES groups presented the following etiology: 150 cases of T-SCI, 7 cases of SCI caused by myelopathy and 5 cases of SCI caused by disc herniation.

Table I. OCC stage and clinical degree of micturition control based on PVR and LOSS.

OCC stage	Micturition control	PVR (ml)	LOSS (ml)
I	Full	≤ 40	≤ 25
II	Acceptable	41-100	26-50
III	Partial	101-200	51-100
IV	Practically abolished	201-400	101-250
V	Abolished	>400	>250

PVR, post voidance residuum; LOSS, quantity of urine lost; OCC, own customized clinical classification system.

Table II. Demographic data.

Characteristic	Control	IMFC ES	P-value
N	170	162	
Age (years)			0.866
Mean	39.96 ± 17.58	39.63 ± 17.06	
Median	36.5 (18-82)	34.5 (19-89)	
Sex			0.171
Male	126 (74%)	109 (67%)	
Female	44 (26%)	53 (33%)	

Data are presented as the mean \pm standard deviation, median (range) or n (%). IMFC ES, interferential medium frequency current electrical stimulation.

Data adjustment and grouping. Due to lack of normality of initial numeric values, square root computing was applied. The PVR ranges obtained after square root adjustment are presented in Table III and aim to allow putting the results into clinical context. The square root for each PVR value for all patients were determined. Efficiency of IMFC ES, defined as the micturition control recovery, was determined by analyzing the mean of the square roots. Lower square root values indicated a gain in micturition control; micturition control regain micturition control was defined by square root values below 7.07 (Table III).

Association between SCI location and severity based on PVR evaluation. The analyses of IMFC ES efficiency on NB were made by comparing the level of micturition control of patients with SCI at the same AIS level. Table IV shows the patient distribution based on SCI location (C1-C8 and T1-S1) and severity (AIS levels A-D). For the following assessment, 16 subgroups were established based on SCI location (C1-C8 and T1-S1) and severity (AIS levels A-D), 8 for the control and the IMFC ES group, with the squared root values presented in Table V.

For patients classed as AIS level A in either SCI location, no statistical differences in PVR values were determined between the IMFC ES and the control group at day 30, with 29.40 ± 6.24 vs. 30.14 ± 7.41 for C1-C8 and 29.46 ± 6.22 vs. 30.28 ± 6.79 for T1-S1 (Table V).

Table III. Conversion of PVR to the square root adjusted output.

PVR (ml)	Square roots
<50	<7.070
50-199	7.071-14.140
200-399	14.141-20.00
400-599	20.01-24.49
≥600	≥24.5
PVR, post voidance residuum.	

Patients in both neurological level groups classed as AIS level B or C exhibited significant differences in PVR values between the control and the IMFC ES group (Table V). For patients with AIS level B, at SCI location C1-C8 significant differences between the IMFC ES and the control group (21.10 ± 6.24 vs. 29.76 ± 7.58 ; $P=0.003$) were observed and at SCI location T1-S1 PVR values between these groups were also significantly different (15.79 ± 6.14 vs. 28.15 ± 6.46 ; $P<0.001$). For patients with AIS level C in the IMFC ES and the control group significant differences in PVR values were determined at C1-C8 (11.36 ± 6.07 vs. 16.49 ± 7.64 ; $P=0.004$) and T1-S1 (9.19 ± 6.08 vs. 16.07 ± 6.25 ; $P<0.001$).

Patients with AIS level D in the IMFC ES and the control group exhibited no significant differences in PVR values at SCI location C1-C8 (8.57 ± 3.16 vs. 7.83 ± 3.29) and SCI location T1-S1 (6.48 ± 3.43 vs. 12.26 ± 5.79).

A global evaluation of the means of square root values for PVR was performed for the IMFC ES and the control group revealing 14.95 ± 11.95 and 21.79 ± 12.70 ; respectively (data not shown; $P<0.001$).

Effects of IMFC ES on regaining bladder control and OCC staging. The number of patients who regained normal bladder control at the end of the study was evaluated, revealing 37 patients from IMFC ES group completely regained intentional control of voiding and 13 patients from the control group (data not shown).

Further investigation was based on patients grouped according the NB type, namely retention NB type or mixed NB type. The comparison for patients of the IMFC ES and the control group with retention NB type are presented in Table VI and results for mixed NB type are included in Table VII. The assessment included mean quantities of PVR and LOSS, as well as the daily number of ICs.

For patients with AIS level A and retention NB type, no significant difference in PVR values was determined between the IMFC ES and the control group ($1,282 \pm 303$ vs. $1,332 \pm 324$ ml; Table VI). Similarly, for patients with AIS level A and mixed NB type no significant differences between the IMFC ES and the control group were determined for PVR (644 ± 112 vs. 612 ± 153 ml) or LOSS (752 ± 109 vs. 795 ± 155 ml; Table VII). OCC stages for patients with AIS level A and retention or mixed NB type were consistent in the IMFC ES and the control group.

Table IV. Patient distribution based on AIS score and SCI location.

A, Control group (n=170)			
AIS level	SCI location (n)		
	C1-C4	C5-C8	T1-S5
A	7	44	23
B	0	12	22
C	1	26	19
D	4	5	7

B, IMFC ES group (n=162)

AIS level	SCI location (n)		
	C1-C4	C5-C8	T1-S5
A	7	19	28
B	0	7	30
C	4	28	24
D	0	6	9

IMFC ES, interferential medium frequency current electrical stimulation; SCI, spinal cord injury; AIS, American SCI association impairment scale.

For patients with AIS level B and retention NB type, the number of ICs required per day was 1.3 ± 0.5 in the IMFC ES and 2.1 ± 0.9 in the control group, the PVR values were significantly decreased in IMFC ES compared with the control group (526 ± 205 vs. 872 ± 308 ml; $P<0.001$; Table VI). Determined OCC stages were the same in the IMFC ES and the control group for this subset of patients. For patients with AIS level B and mixed NB type LOSS and PVR significantly decreased in the IMFC ES compared with the control group (LOSS, 41 ± 12 vs. 171 ± 40 ml; $P=0.020$; PVR, 116 ± 85 vs. 178 ± 71 ; $P=0.020$; Table VII). With regards to LOSS, the IMFC ES group was classified as OCC stage II and the control group received an inferior classification of with stage IV (Table VII), no difference was observed in OCC stages with regards to the PVR volumes.

For patients with AIS level C and retention NB type, the number of ICs required per day was 0.6 ± 0.4 in the IMFC ES and 1.1 ± 0.6 in the control group. PVR significantly decreased in the IMFC ES compared with the control group (262 ± 146 vs. 451 ± 234 ml; $P<0.001$; Table VI). Based on the PVR volumes, patients in the control group were classed as OCC stage V and patients in the IMFC ES groups were classed as OCC stage IV. For patients with AIS level C and mixed NB type, LOSS and PVR significantly decreased in the IMFC ES compared with the control group (LOSS, 71 ± 15 vs. 267 ± 58 ml; $P<0.001$; PVR, 29 ± 16 vs. 105 ± 56 ml; $P<0.001$; Table VII). With regards to LOSS, the IMFC ES group was classified as OCC stage III and the control group received an inferior classification of with stage IV (Table VII). A similar difference was observed in the

Table V. Square root PVR values for patients classed by AIS level and SCI location.

A, SCI location C1-C8.

		Square root PVR value		
AIS level	N	Mean ± SD (SEM)	95% CI	Range
IMFC ES				
A	26	29.40±6.24 (1.22)	26.97-32.01	22.36-42.43
B	7	20.10±6.24 (2.35) ^a	14.32-25.87	12.14-29.36
C	32	11.36±6.07 (1.07) ^b	9.17-13.55	3.16-27.32
D	6	8.57±3.16 (1.29)	5.24-11.89	4.47-13.16
Control				
A	51	30.14±7.41 (1.03)	28.05-32.22	6.32-44.72
B	12	29.76±7.58 (2.18)	24.94-34.58	14.49-39.43
C	27	16.49±7.64 (1.47)	13.46-19.51	5.48-30.00
D	9	7.83±3.29 (1.09)	5.30-10.37	4.47-12.25

B, SCI location T1-S1.

		Square root PVR value		
AIS level	N	Mean ± SD (SEM)	95% CI	Range
IMFC ES				
A	28	29.46±6.22 (1.09)	27.21-31.70	22.36-42.43
B	30	15.79±6.14 (1.10) ^c	13.53-18.04	3.16-31.62
C	24	9.19±6.08 (1.24) ^d	6.61-11.75	3.16-22.36
D	9	6.48±3.43 (1.14)	3.84-9.12	3.16-14.14
Control				
A	23	30.28±6.79 (1.41)	27.34-33.22	22.36-42.43
B	22	28.15±6.46 (1.37)	23.01-28.74	11.62-37.42
C	19	16.07±6.25 (1.43)	13.06-19.09	4.47-28.36
D	7	12.26±5.79 (2.19)	6.90-17.63	4.47-18.97

^aP=0.003 vs. control (C1-C8, AIS level B); ^bP=0.004 vs. control (C1-C8, AIS level C); ^cP<0.001 vs. control (T1-S1, AIS level B); and ^dP<0.001 vs. control (T1-S1, AIS level C). IMFC ES, interferential medium frequency current electrical stimulation; SCI, spinal cord injury; AIS, American SCI association impairment scale; SD, standard deviation; SEM, standard error of the mean; CI, confidence interval.

OCC stages with regards to the PVR volumes with stages I and III, respectively (Table VII).

For patients with AIS level D and retention NB type, the number of ICs required per day was 0.2 \pm 0.1 in the IMFC ES and 0.4 \pm 0.3 in the control group. PVR significantly decreased in the IMFC ES compared with the control group (111 \pm 12 vs. 128 \pm 11 ml; P=0.003; Table VI). For patients with AIS level D and mixed NB type, PVR significantly decreased in the IMFC ES group compared with the control (24 \pm 12 vs. 28 \pm 11 ml; P=0.030); for LOSS this decrease between the groups was not significant (16 \pm 9 vs. 21 \pm 11 ml; Table VII). OCC stages for patients with AIS level D and retention or mixed NB type were consistent in the IMFC ES and the control group.

During the current study, no significant adverse reactions to IMFC ES were observed in the patients.

Discussion

The OCC measure for urinary function was developed and validated recently and was used in this study to communicate results regarding the effects of IMFC ES on NB after SCI in clinical terms (30). After using IMFC ES for NB caused by SCI for over a decade, micturition control regaining was observed, with the most marked results recorded for patients classed AIS level B or C.

IMFC ES covers a wide range of frequencies that are active on different types of muscles involved in the urinary tract activity, both denervated and not, and IMFC ES has good chance to stimulate all these muscles (15,17,21,28,31,32). At 0-5 Hz, the IMFC endogenous field causes skeletal muscles with innervation to contract (16,26-28) and 5-10 Hz may

Table VI. Patient data associated with retention NB classed by AIS level.

AIS level	Retention (n)	PVR (ml)	P-value	IC (n/day)	OCC stage
A			0.279		
Control	36	1,332±324		3.3±1.1	V
IMFC ES	22	1,282±303		3.0±0.9	V
B			<0.001		
Control	30	872±308		2.1±0.9	V
IMFC ES	14	526±205		1.3±0.5	V
C			<0.001		
Control	28	451±234		1.1±0.6	V
IMFC ES	28	262±146		0.6±0.4	IV
D			0.003		
Control	9	128±11		0.4±0.3	III
IMFC ES	7	111±12		0.2±0.1	III

Data are presented as the mean ± standard deviation or n. IMFC ES, interferential medium frequency current electrical stimulation; SCI, spinal cord injury; AIS, American SCI association impairment scale; PVR, post voidance residuum; OCC, own customized clinical classification.

Table VII. Patient data associated with mixed NB type classed by AIS level.

AIS level	Mixed NB (n)	PVR (ml)	P-value	OCC stage	LOSS (ml)	P-value	OCC stage
A			0.16			0.12	
Control	38	612±153		V	795±155		V
IMFC ES	32	644±112		V	752±109		V
B			0.02			0.02	
Control	4	178±71		III	171±40		IV
IMFC ES	23	116±85		III	41±12		II
C			<0.001			<0.001	
Control	18	105±56		III	267±58		IV
IMFC ES	28	29±16		I	71±15		III
D			0.03			0.2	
Control	7	28±11		I	21±11		I
IMFC ES	8	24±12		I	16±9		I

Data are presented as the mean ± standard deviation or n. IMFC ES, interferential medium frequency current electrical stimulation; SCI, spinal cord injury; AIS, American SCI association impairment scale; PVR, post voidance residuum; OCC, own customized clinical classification; LOSS, quantity of urine lost.

further cause contracting of skeletal muscles without innervation. At 11-35 Hz, smooth muscles are stimulated and furthermore (21,28,31,32), 36-80 Hz can also activate smooth muscles without innervation (21,28,31-34). For 80-100 Hz, the stimulation field relaxes both smooth and skeletal muscles and IMFC ES can affect contracting and relaxing structures (21,28,31-34). Thus, IMFC ES may improve the neural muscular control in the main types of NB.

Even with an empty bladder, patients from the IMFC ES group reported an urgent micturition sensation during the IMFC ES procedure, which was associated with the vibration sensation of the applied current. During the procedure, patients learned to associate a specific vibration with need to

void allowing them to train their cortical perception to do so. Patients further stated that this mental association helped them to regain micturition control. It is possible that IMFC ES activates certain sensory C fibers, bypassing above lesion levels and transmitting information to the spinal-thalamic tracts and then the cortex (10,11,35-37). This observation concerns only patients with AIS levels B, C and D. Another hypothesis is that electrical stimulation of the abdominal wall and pelvic floor may generate conscientious excitatory effects in patients with incomplete SCI (10,11,35-37).

The distribution showed that a larger number of patients affected at the dorsal and sacral vertebra T1-S5 level participated in the current study, although a large amount of patients

recruited to the control group were affected at C1-C8. It is possible that this can be explained by patients affected at the dorsal and sacral vertebra T1-S5 being more stable immediately after SCI compared with patients affected at C1-C8, which required more assistance (38). More male than female patients were recruited to the control and the IMFC ES groups. It is well established that SCI is more frequent in men compared with women (4:1 occurrence) and the patient distribution observed here followed these patterns (10).

The fact that no urodynamic evaluation was performed is a limitation of the current study and a follow-up study to consolidate this may be performed in the future. Furthermore, patients at post- and sub-acute stages of SCI are often in spinal shock (39). The design of the current study did not allow discriminating between contributions of the spontaneous recovery from the spinal shock and those attributed to IMFC ES. However, by choosing similar patient distributions in the control and IMFC ES groups, the influence of spinal shock recovery may be similar in both groups. As the regain of micturition control was significantly improved in the IMFC ES group, it was suggested that this limitation did not affect the validity of the presented results. IMFC ES was performed immediately after bladder catheterization and on an empty bladder and therefore IMFC ES did not generate any bladder-ureteral outflow.

During the study, no significant adverse reactions to IMFC ES were encountered, suggesting that this non-invasive electrical stimulation method may be safe. There are other studies using IMFC ES to improve bladder control with different disease causes, including multiple sclerosis (32), myelomeningocele (33,34) spina bifida (40) and enuresis (41), performed in children (33) or elderly (42) patients. This strengthens the observations that IMFC ES is safe, effective and a well-tolerable therapy. The aim of this study was to determine the potential of using IMFC ES in adults with SCI and NB, both the retention and mixed types, similar to previous studies (13-19).

In summary, the results emphasize the IMFC ES was not significantly better than the control treatment in patients with AIS level A, for retention and incontinence NB types. For patients with AIS levels B and C, IMFC ES provided significantly improved results, helping patients to regain micturition control in patients with incontinence and retention problems. For patients with AIS level D, this non-invasive electrical stimulation showed no significant improvement mixed NB types.

In conclusion, the current study was a preliminary study for using IMFC ES in the treatment of NB following SCI in adults. It may be important in the future to recommend the use of IMFC ES when treating NB to patients with preserved skin sensitivity that are still able to experience sensation. Future studies may be performed with increased technical support and patient numbers to further the knowledge in this specific research area.

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Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

The study was conducted and designed by GO. CD analyzed the data, assessed all medical information and participated in the statistical analysis of the data. The results were analyzed and interpreted by CD and AMB. CDB and CC contributed to analyzing the patient data and performed AIS classification. AMB participated in editing and reviewing the article. All authors read and approved the final version of the manuscript.

Ethics approval and consent to participate

This study was approved by the Hospital's Ethics Commission (Clinical Emergency Hospital 'Bagdasar Arseni', Bucharest; approval no. 7727). Written informed consent was obtained from all participants included in the study.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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