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Znaczenie systematycznej rehabilitacji na przestrzeni 45 lat pacjentki z rozwojową dysplazją stawu biodrowego

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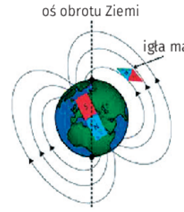

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Effect of transcranial magnetic stimulation on functional outcome in patients with incomplete spinal cord injury: A randomized controlled study

Wpływ przezczaszkowej stymulacji magnetycznej na wyniki czynnościowe u pacjentów z niecałkowitym uszkodzeniem rdzenia kręgowego: randomizowane badanie kontrolowane

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Abstract
Background. Incomplete spinal cord injury is a common disorder leading to sensory or motor function loss.
Objective. This study aimed to investigate the effect of repetitive transcranial magnetic stimulation therapy (rTMS) on functional outcome in patients with incomplete spinal cord injury.
Design. A prospective randomized controlled trial. Setting. Agouza Rehabilitation Hospital Out clinic.
Methods. Forty male patients with chronic traumatic incomplete spinal cord injury aging from 25 to 45years. Patients were randomly divided into two equal groups (group A and group B). Group A was the study group that received rTMS in addition to traditional physical therapy program including BWST training and Group B was the control group that received the same traditional physical therapy program including BWST training. The functional gait was assessed using walking index for spinal cord injury (WISCI II) and gait speed was assessed using 10 m walk test. Measurements were performed before and after treatment and three months after end of the treatment as follow up.
Results. There was a statistically significant improvement in WISCI II and 10m walk test at post treatment and follow up compared with that pre-treatment in study group ($P < 0.05$). There was no statistically significant improvement in all outcome variables at post treatment and follow up compared with that pretreatment in control group ($P > 0.05$).There was a statistically significant improvement in patients who received rTMS with BWST compared with patients received BWST only in WISCI II and 10 m walk test at post treatment ($p = 0.01$ and $p = 0.001$ respectively) compared to pre treatment. The gained effect was lost at follow up measurement compared to post treatment in WISCI II and the gained effect was maintained at follow up measurement compared to post treatment in 10m walk test score.
Conclusion. It was proven that rTMS add a valuable effect for restoring function in patients with incomplete spinal cord injury, particularly in cases when the effect of BWST has reached a plateau.

Keywords
incomplete spinal cord injury, repetitive transcranial magnetic stimulation (rTMS), walking index for spinal cord injury (WISCI II), 10 m walk test, functional outcome

Streszczenie
Informacje wprowadzające. Niecałkowite uszkodzenie rdzenia kręgowego jest częstym zaburzeniem prowadzącym do utraty funkcji czuciowych lub motorycznych.
Cel. Badanie to miało na celu zbadanie wpływu powtarzanej przezczaszkowej stymulacja magnetycznej (rTMS) na wyniki czynnościowe u pacjentów z niecałkowitym uszkodzeniem rdzenia kręgowego.
Metody. W badaniu wzięło udział czterdziestu pacjentów płci męskiej z przewlekłym urazowym niecałkowitym uszkodzeniem rdzenia kręgowego w wieku od 25 do 45 lat. Pacjenci zostali losowo podzieleni na dwie równe grupy (grupa A i grupa B). Grupa A była grupą badaną, która była poddawana rTMS i realizowała zaprojektowany program fizykoterapii, w tym trening BWST, a grupa B była grupą kontrolną, która realizowała ten sam zaprojektowany program fizykoterapii, w tym trening BWST. Chód funkcjonalny oceniono za pomocą wskaźnika marszu dla uszkodzenia rdzenia kręgowego (WISCI II), a prędkość chodu za pomocą testu marszu na 10 m. Pomiary wykonano przed i po interwencji oraz trzy miesiące po zakończeniu leczenia w ramach wizyty kontrolnej.
Wyniki. Wystąpiła statystycznie istotna poprawa w teście WISCI II i teście marszu na 10 m po interwencji i w okresie obserwacji w porównaniu z okresem przed interwencją w grupie badanej ($P < 0,05$). Nie zaobserwowano statystycznie istotnej poprawy we wszystkich zmiennych wynikowych po interwencji i podczas wizyty kontrolnej w porównaniu z badaniem przed interwencją w grupie kontrolnej ($P > 0,05$). Wystąpiła statystycznie istotna poprawa u pacjentów, którzy byli poddawani rTMS i BWST w porównaniu z pacjentami, którzy byli poddawani tylko BWST w teście WISCI II i teście marszu 10 m po interwencji (odpowiednio $p=0,01$ i $p=0,001$) w porównaniu z okresem przed interwencją. Uzyskany efekt utracono w pomiarze kontrolnym w porównaniu do wyniku po interwencji w teście WISCI II. Uzyskany efekt utrzymywał się w pomiarze kontrolnym w porównaniu z wynikiem testu marszu na 10 m po interwencji.
Wniosek. Wykazano, że rTMS daje korzystne rezultaty przy przywracaniu funkcji u pacjentów z niecałkowitym uszkodzeniem rdzenia kręgowego, szczególnie w przypadkach, gdy efekt BWST stabilizował się.

Słowa kluczowe
niecałkowite uszkodzenie rdzenia kręgowego, powtarzalna przezczaszkowa stymulacja magnetyczna (rTMS), wskaźnik chodu dla urazu rdzenia kręgowego (WISCI II), test marszu na 10 m, wynik czynnościowy

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Introduction

About 2.5 million people worldwide have sustained a spinal cord injury (SCI), which may cause significant impairment owing to impaired sensory and motor functions. Incomplete spinal cord damage describes the loss of sensory or motor function at the base of the spinal column as a consequence of trauma or degenerative processes (iSCI). There is substantial evidence linking it to deteriorating health and diminished autonomy. This has been shown to be the case [1].

According to the (WHO) report in 2009, there was 746, 138 spinal cord injured cases were registered from Egyptian Ministry of Health Hospitals, of which 71.01% were males and 28.9% were females. The report revealed that leading causes of injury was road traffic injuries and the highest distribution of injuries occurred in ages 20 years to less than 30 year [2].

Spinal cord injury (SCI), whether it is caused by trauma or not, is a serious medical condition. While SCI will always have an impact on a person's life, it should not prevent them from leading happy and full lives. Using the American Spinal Injury Association (ASIA) grading system, neurological outcomes are often assessed 72 hours following the injury in clinical care of SCI. This point in time has been found to provide a more accurate evaluation of neurological deficits after SCI. Whether the damage was full or partial is a key factor in predicting functional recovery. Over time, some spontaneous motor and sensory function recovery occurs in SCI patients [3].

Repetitive transcranial magnetic stimulation (rTMS) rehabilitation methods have been shown to enhance neurological recovery and functional capacities. Some of these methods include following predetermined protocols designed to activate just certain regions of the brain (CNS). The main motor cortex (M1), spinal cord, and corticospinal tract are all stimulated by applying biphasic magnetic pulses to the same cortical region repeatedly. This induces neuronal remodeling [4].

The excitability of neuronal circuits has been altered using rTMS protocols, with beneficial effects at the stimulation site or transsynaptically at other locations, like spinal cord circuits.Long-term potentiation-like changes in synaptic plasticity, changes in network excitability, the activation of feedback loops, and activity-dependent metaplasticity are all effects of high-frequency rTMS (i.e. 5Hz) [5].

By significantly facilitating motor responses, high frequency rTMS across the primary motor cortex (M1) delivered at frequencies of five to 20 Hz causes an increase in corticospinal excitability [6].

It affected how well my muscles worked. Kinematic recording may be used to evaluate these changes. The majority of motor cortical regions are simple to reach with TMS. This is notably true for the lateral premotor cortex and primary motor cortex (M1) [7].

According to the authors, there is no previous study that revealed the effect of rTMS in relation to Body weight supported treadmill (BWST) on spinal cord injury patients. Previous studies showed the effect of TMS only on spinal cord injury patients or the effect of TMS with program of resisted exercises only [8], also previous studies that studied TMS with locomotor training were for short term effect [9].

This study's goal was to examine the short and long-term effects of TMS in relation to BWST on functional outcomes and quality of life (QOL) on patients with incomplete spinal cord injury. This study determined the effect of rTMS in relation to BWST training on functional performance after SCI to enable physiotherapist to use new technology in rehabilitation and treatment.

Materials and methods

Participants

This randomized controlled study was conducted at Agouza Rehabilitation Hospital Out clinic from February 2020 to January 2022.

Patients who were diagnosed as having a chronic traumatic incomplete spinal cord injury at mid thoracic level based on careful clinical assessment by a neurosurgeon and radiological investigations including computed axial tomography or magnetic resonance imaging of the spinal cord were initially screened. Thoracic level (T_6–T_{12}) was determined according to American Spinal Injury Association (ASIA) scale motor and sensory for lower limb [3].

Ethical considerations

The study protocol was explained in details for each patient before the initial assessment and enrollment in the study and all patients signed an institutionally approved informed consent form which was approved by the Ethics Committee of the Faculty of Physical Therapy, Cairo University (P.T.REC/012/004381). The study was registered on Pan African Clinical Trial Registry database and the registration number was PACTR 202302883669762.

Procedures

After the screening process, patients were eligible to participate in the study if they had (i) age ranged from 25 and 45 years; (ii) duration of illness ranged from three months to one year; (iii) muscle tone of affected lower limb was not more than grade 2 according to the Modified Aschowrth scale (MAS) [10]; (iv) muscle power of paretic lower limb muscles wasn't less than (grade 2) according to group muscle test (not less than ASIA B according to ASIA scale). Patients were excluded if they exhibited any of the following criteria: (i) other causes of spinal cord disorders e.g: Neoplastic, Multiple Sclerosis, infected disorder of spinal cord, amyotrophic lateral sclerosis, T.B. or myelopathy; (ii) Cardiac pacemaker

Study design and randomization

A total of 53 male patients with traumatic incomplete spinal cord injury were assessed for eligibility. Eight patients were excluded as they did not fulfill the inclusion criteria and five patients were excluded as they refused to participate in the study. A randomization process was performed for 40 patients using sealed envelope.

A diagram of patients retention and randomization throughout the study is shown in Fig. 1. Patients were randomly assigned to one of the following two groups: Study group received rTMS and (traditional physical therapy program including BWST training),it included 20 patients and control group received the traditional physical therapy program including BWST training, it included 20 patients. Both groups had BWST training for about 60 minutes three days/week for 12 weeks and a physical therapy program for 60 minutes three days/week for 12 weeks.

doi.org/10.56984/8ZG0DF2F4

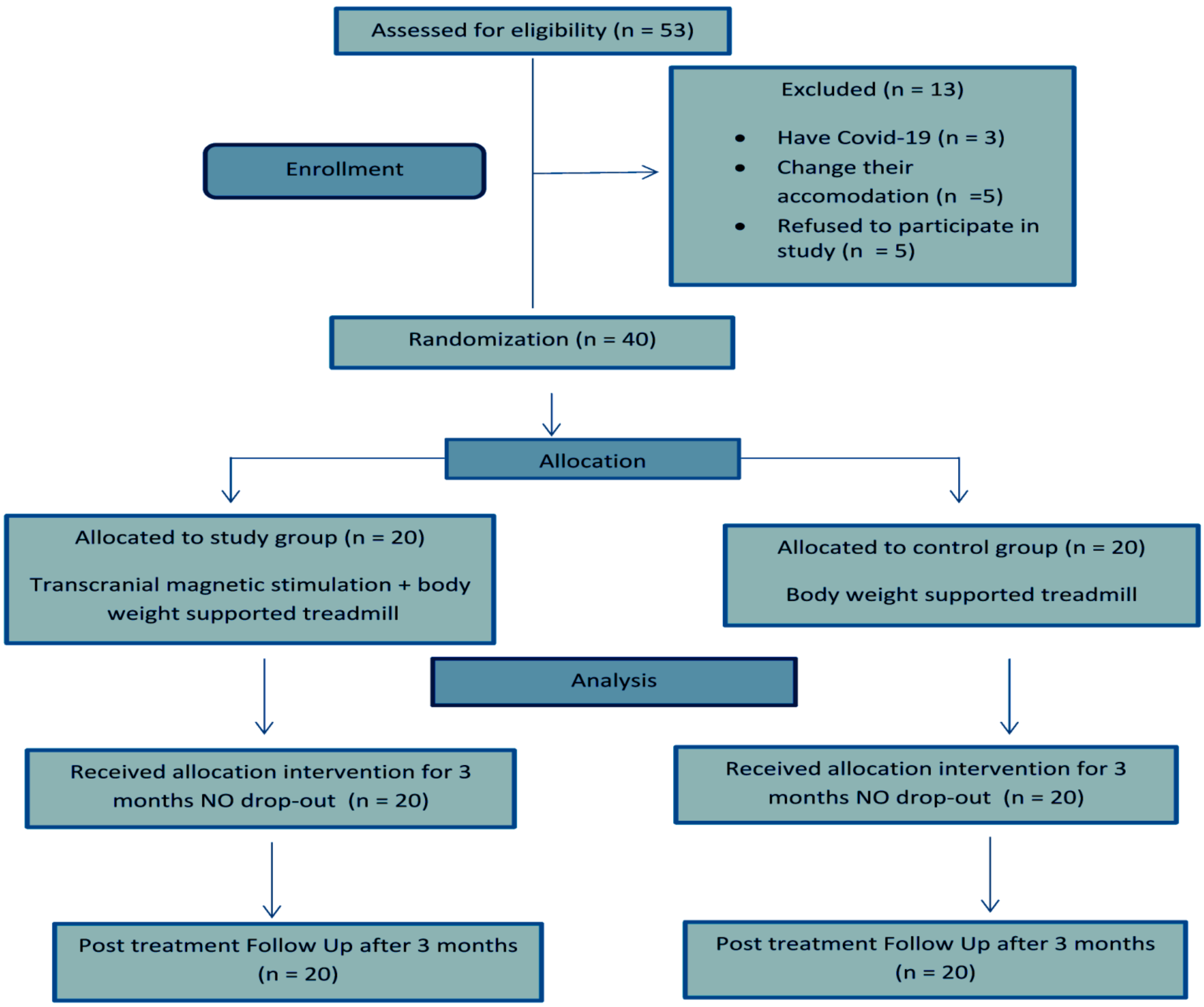

Figure 1. Flow chart of study participants

Outcome measures

The outcome measures were carried out for each patient individually before, after treatment and three months after end of treatment as a follow up by the same outcome assessor. Outcome measures include 1) walking Index for spinal cord injury (WISCI II). In selecting a level, we choosed the level at which the patient is safe with patient's comfort level described [11].

The time needed to administer the WISCI II may vary from 5 minutes in the acute phase to 15 minutes in a follow up assessment. The duration of the assessment depends on the subject's self selected WISCII level [12] and 2) 10 m Walk Test, Each patient was asked to ambulate10 meters and time take was calculated by a stop watch. A "flying start" is used where the subject may accelerate 2 meters before entering the timed 10-meter distance and 2 meters to decelerate afterwards [13].

Interventions

Patients in both the study group (n = 20) and control group (n = 20) received traditional physical therapy program including BWST training . The traditional physical therapy program was for 60 minutes, three days/week for four weeks, the program was: gait training between parallel bars, weight bearing exercises, balance training , standing on wall bar. Body weight supported treadmill training BWST with setup and take-down consuming an average of 10 to 15 minutes of this time. Patients were scheduled to train 60 minutes for three days/week for four weeks. Prior to and following training all patients had a battery of tests including a short-bout (6- meter) walk and a long-bout (2-minute) walking test. For all walking-related tests, patients were allowed to self-select their preferred walking speed as we believe this most accurately reflects the individuals' actual everyday performance. The level of BWS was therefore adjusted within and between sessions as needed based on these criteria. However,BWS was maintained at or below 30% of body weight as this level of support has been shown to be associated with gait kinematics that resemble walking without support. The patients in study group only received repetitive transcranial magnetic stimulation (rTMS) for about "20" minutes, three sessions per

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week, for four weeks. Application of rTMS was applied to an angulated figure-eight coil over the lower-limb motor area localized in M1 (in order to stimulate both lower limbs), with the handle of the coil parallel to the interhemispheric midline (pointing occipitally).

Sample size

To avoid a type II error, a preliminary power analysis [power (1−α error P) = 0.8, α = 0.05, effect size = 0.9266] determined a sample size of 20 for each group (40 total subjects for study groups). This effect size was calculated according to Kumru et.al. (2016) study on 30 patients complaining from partial spinal cord energy using post treatment difference between groups (rTMS group and sham rTMS group). The power analysis was carried out by G*Power 3.1.9.2 software, using test family as T-tests and statistical test as mean difference between two independent groups [14].

Data analysis

Patients characteristics were compared between both groups using t test. Normal distribution of data was checked using the Shapiro-Wilk test for all variables. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. Mixed MANOVA was conducted to compare the mean values of walking index for spinal cord injury and 10 meter walk test between study and control group and between pre and post treatment in each group. Partial squared eta was considered as the effect size. Posthoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysiswas conducted through the Statistical Package for Social Studies (SPSS) version 19 for windows (IBM SPSS, Chicago, IL, USA).

Results

Patients' characteristics

Table 1 showed the mean ± SD of patient's characteristics and duration of illness in both groups. There was no statistically significant difference between both groups regarding the mean age, weight, height, body mass index (BMI) and duration of illness ($p > 0.05$).

Table 1. Comparison of demographic characteristics and duration of illness between both group

	Study group Mean ± SD	Control group Mean ± SD	MD	t- value	p-value	Sig
Age [years]	35.05 ± 6.34	33.45 ± 6.61	1.6	0.78	0.44	NS
Weight [kg]	84.55 ± 10.76	86.75 ± 11.07	−2.2	−0.63	0.52	NS
Height [m]	169.6 ± 7.31	170.2 ± 6.81	−0.6	−0.26	0.79	NS
BMI [kg/m^2]	30.03 ± 4.06	29.48 ± 4.07	0.55	0.42	0.69	NS
Duration of illness [months]	7.6 ± 2.5	6.7 ± 2.2	0.9	1.21	0.23	NS

SD: Standard deviation; MD: Mean difference; t value: Unpaired t value; p value: Probability value; NS: Non significant

Effect of treatment on walking index score

Within group comparison

Study group

The result of this study revealed a statistically significant increase in the mean value of walking index score at post treatment and follow up compared with that pretreatment ($p = 0.001$ and $p = 0.001$ respectively). The gained effect was lost at follow up in walking index score compared with that post treatment ($p = 0.01$).

Control group

The result of this study revealed no statistically significant difference in the mean value of walking index score at post treatment and follow up compared with that pre treatment ($p = 0.17$ and $p = 1$ respectively). The mean difference in walking index score between post treatment and follow up was 0.35 and the percent of change was 3.72%. There was no statistically significant difference in walking index score between post treatment and follow up ($p = 0.06$).

Comparison between groups

Pre treatment

The result of this study revealed no statistically significant difference in the mean value of walking index score between both groups pre treatment ($p = 0.26$) (Table 2).

Post treatment

The result of this study revealed a statistically significant increase in the mean value of waking index between both groups post treatment ($p = 0.01$) (Table 2).

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Table 2. Comparison of mean value of walking index score between study & control group before, after and three months after end of treatment (follow up)

Walking index score					
Study group, Mean ± SD			Control group, Mean ± SD		
Pre treatment	Post treatment	Follow up	Pre treatment	Post treatment	Follow up
10.1 ± 2.91	12.05 ± 3.05	11.6 ± 3.25	9 ± 3.27	9.4 ± 3.42	9.05 ± 3.23

Within group comparison (time effect)					
		MD	% of change	p-value	Sig
Study group	Pre vs post treatment	−1.95	19.31	0.001	S
	Pre treatment vs Follow up	−1.5	14.85	0.001	S
	Post treatment vs Follow up	0.45	3.73	0.01	S
Control group	Pre vs post treatment	−0.4	4.44	0.17	NS
	Pre treatment vs Follow up	−0.05	0.56	1	NS
	Post treatment vs Follow up	0.35	3.72	0.06	NS

Between group comparison (group effect)				
		MD	p-value	Sig
Study vs control	Pre treatment	0.01	0.49	NS
	Post treatment	0.068	0.001	S
	Follow up	0.065	0.001	S

Effect of treatment on 10 m walk test score

Within group comparison

Study group

The result of this study revealed a statistically significant increase in the mean value of 10 m walk test score at post treatment and follow up compared with that pre treatment (p = 0.001 and p = 0.001 respectively). The gained effect was maintained at follow up in 10 m walk test score compared to post treatment. (p = 0.56) (Table 3).

Control group

The result of this study revealed no statistically significant difference in mean value of 10 m walk test score at post treatment and follow up compared with that pretreatment (p = 1 and p = 1 respectively). The mean difference in 10 m walk test score between post treatment and follow up was 0.005 and the percent of change was 4.31%. There was no statistically significant difference in 10 m walk test score between post treatment and follow up (p = 1) (Table 3).

Comparison between groups

Pre treatment

The result of this study revealed no statistically significant difference in the mean value of 10 m walk test score between both groups pretreatment (p = 0.49) (Table 3).

Post treatment

The result of this study revealed a statistically significant increase in the mean value of 10 m walk test score between both groups post treatment (p = 0.001) (Table 3).

doi.org/10.56984/8ZG0DF2F4

Table 3. Comparison of mean value of 10 m walk test score between study & control group before, after and three months after end of treatment (follow up)

10 m walk test score [m/sec]					
Study group, Mean ± SD			Control group, Mean ± SD		
Pre treatment	Post treatment	Follow up	Pre treatment	Post treatment	Follow up
0.124 ± 0.047	0.184 ± 0.069	0.176 ± 0.062	0.114 ± 0.045	0.116 ± 0.049	0.111 ± 0.046

Within group comparison (time effect)					
		MD	% of change	p-value	Sig
Study group	Pre vs post treatment	−0.06	48.39	0.001	S
	Pre treatment vs Follow up	−0.052	41.94	0.001	S
	Post treatment vs Follow up	0.008	4.35	0.56	NS
Control group	Pre vs post treatment	−0.002	1.75	1	NS
	Pre treatment vs Follow up	0.003	2.63	1	NS
	Post treatment vs Follow up	0.005	4.31	1	NS

Between group comparison (group effect)				
		MD	p-value	Sig
Study vs control	Pre treatment	0.01	0.49	NS
	Post treatment	0.068	0.001	S
	Follow up	0.065	0.001	S

Discussion

This study was conducted to investigate the effect of rTMS on functional outcome of patients with iSCI. The results of this study showed a statistically significant increase in the mean value of walking index and 10 m walk test score in study group that received rTMS at post treatment and follow up.The results of this study also showed significant improvement in functional gait and gait speed in study group compared with control group that received the traditional physical therapy program including BWST at post treatment and follow up.

The results of this study regarding a significant increase in WISCI II score in the study group post treatment compared with pre treatment came in agreement with the finding that WISCI II was improved in patients with SCI after transcranial magnetic stimulation [15].

Also, these results regarding WISCI II agreed with the findings revealed an increase in WISCI II score after rTMS in patients with SCI [16].

High frequency rTMS may enhance 10 metre walk test (10MWT) in patients with SCI after the final session, and the effect was sustained over the 2weeks follow up period [9].

Significant improvement in functional gait and gait speed in the study group might be attributed to several mechanisms, the first was physiological effect of rTMS, applying high frequency rTMS at frequency of five to twenty hz over the primary motor cortex causes increase in cortical excitability as shown by a significant facilitation of motor responses,it persuaded changes in motor performance in patients with SCI [6].

The impact of rTMS on the 10-meter walk test may be because rTMS directly activates supraspinal regions relevant to gait by rTMS. Voluntary motor acts frequently need corticospinal drive to be accompanied by activity in subcortical structure (vestibulospinal, reticulospinal) for stabilization and balance. Walking results from an interaction between central program and feedback mechanisms at spinal cord, like central pattern generator and supraspinal levels [17].

After treatment, patients' gait function improved. Improving neurophysiological results and voluntary motor output in individuals with motor disorders may be related to high-frequency rTMS's capacity to modify corticospinal projections by boosting motor cortex excitability (20hz) via long-term potentiation-like synaptic plasticity, network excitability changes, feedback loop activation, and activity-dependent metaplasticity [18].

The second explanation was the increases in neural plasticity and regeneration that play a role in the beneficial effects of rehabilitation techniques like repetitive transcranial magnetic stimulation (rTMS) and others based on protocols that selectively stimulate specific pathways along the central nervous system (CNS) on neurological recovery and functional improvement [19].

Numerous rTMS sessions, as opposed to single, discontinuous ones, are more successful in eliciting CNS plasticity. Following this lead, clinically focused rTMS trials have standardised on a 5-session weekly schedule [20].

Our results showed improvement on functional gait and gait speed in study group that received rTMS in relation to BWST and the improvement maintained in the follow up period,suggesting that rTMS may itself prove valuable for restoring function in the SCI population, particularly in cases when the effect of physical exercise has reached a plateau.

The result of current study showed that there was no effect of BWST training on WISCI II score in control group post treatment compared to pretreatment. This finding is consistent with the findings of examined effectiveness of treadmill training with over-the-ground gait training for people with spinal cord

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injuries. The WISCI score improved after the intervention, compared to before treatment [21].
The result of current study showed that there was no effect of BWST training on 10 m walking test score in control group post treatment compared with pretreatment. This result was consistent with the findings that compared the efficacy of step training with BWST for 12 weeks on a treadmill with overground in patients with incomplete spinal cord injury with reported no significant differences between treatment groups in walking speed and distance [22].
Also, this result regarding 10 m walk test was in line with the findings that compared the effectiveness of body-weight-supported treadmill training and robotic-assisted gait training with overground gait training and traditional physiotherapy in patients with SCI. The authors showed that body-weight-supported treadmill training and robotic-assisted gait training do not increase walking speed more than overground gait training and other forms of physiotherapy do [23].
The current study showed loss of gained effect in the WISCI score at follow up comparing to post treatment score.This in agreement with revealed Improvement in lower extremity motor score, walking speed, The high frequency rTMS treatment of motor incomplete SCI patients led to the development of WISCI. After 15 days of therapy, the active rTMS group had a significant improvement in their symptoms and it lasted at 2 weeks during the follow up period [8].

Conclusion

It was proven that rTMS add a valuable effect for restoring function in patients with incomplete spinal cord injury, particularly in cases when the effect of BWST has reached a plateau.

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