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Recent trends in applying functional electrical stimulation in the management of spastic paraplegia induced by spinal cord injury: a systematic review

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Abstract

Introduction. Functional electrical stimulation is one of the latest emerging trends in the field of electrotherapy in physiotherapy practice. It is nowadays used as an orthotic device for functional activity. The study aimed to determine the effectiveness of functional electrical stimulation in spasticity of lower extremity in spinal cord injury patients.

Methods. We conducted a qualitative systematic review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic literature search covered articles published in years 2000–2020. The databases considered for the literature search were PubMed, Cochrane, ScienceDirect, and Google Scholar. The Medical Subject Headings (MeSH) applied for the search included "functional electrical stimulation", "lower limb", "rehabilitation", "spasticity", "spinal cord injury". The records were assessed for the risk of bias with the RoB 2 Cochrane tool.

Results. The statistical evidence suggests functional electrical stimulation to be equivalent to other modes of treatment. The overall observation of the within-group results and the feedback from the patients indicate that functional electrical stimulation is superior to all other interventions in improving the functional activities of daily life.

Conclusions. From the evidence collected within the limitations of the present systematic review, it can be concluded that the effectiveness of functional electrical stimulation allows to apply it as an adjunct to the standard treatments available with more priority.

Key words: spinal cord injury, paraplegia, lower limb spasticity, functional electrical stimulation

Introduction

Functional electrical stimulation (FES) is an electrotherapy modality which occurs in numerous variations and constitutes an emerging trend in the field of rehabilitation. FES was first applied as a peroneal nerve stimulator to counteract hemiplegic foot drop in 1960. Since then, it has undergone many changes to be called today's FES [1–3]. FES is nowadays used as an orthotic device for functional activity. The changes enable the professional to set a new trend in physiotherapy practice. This paper deals with a collection of publications concerning FES which enhances function in paralyzed extremities. These uses of FES have much to contribute to the human being condition and this article would be a valuable aid to professionals who seek most satisfactory information regarding FES [4].

Kantrowitz and Schamaun [5] conducted a study to improve spastic bladder in paraplegics by using electrical stimulation and concluded that the method could enhance voiding in these patients [5]. Carnstam et al. [6] did a study on the improvement of gait after FES. They selected 7 patients with spastic paraplegia fitted with peroneal stimulators and assessed the changes in voluntary strength and proprioceptive reflex. After a 10-minute stimulation, they revealed a clear dorsiflexor strength and a decrease in Achilles reflex. Kralj et al. [7] performed a study on restoration of gait in paraplegics by using multichannel FES; 3 patients were involved and as a study result, 2 of them managed to walk in parallel bars and 1 walked independently with the help of a rollator. The authors therefore concluded that FES had a tremendous effect in improving gait in spinal cord injured patients. Gracanin [8] investigated the effect of FES for locomotor disorders and indicated that it helped in interneuron reorganization, adaptation of alternate neural pathways, and change in the morphology of central nervous system cells. Bajd et al. [9] used 2-channel FES to stimulate knee extensors and the peroneal nerve in spinal cord injured patients. They concluded that a 2-channel peroneal foot stimulator is a useful tool in spasticity inhibition, which in turn initiates a step. Taylor et al. [10] studied the effect of an FES-based Odstock dropped stimulator; 131 individuals with foot drop due to an upper motor neuron lesion were included in the study, which lasted for 4 months. The results implied a beneficial effect in the gait of 92.7% of the participants. Bajd et al. [9] applied FES to improve the gait in incomplete spinal cord injured patients. All subjects' hip/knee flexors and dorsiflexors were stimulated and the result suggested that FES-assisted walking improved the gait.

The present study provides a brief idea about FES to professionals in this field, particularly in India, where FES is not broadly used. It may help and establish a good foundation for further, more concentrated research. The collection of material in this study will be a useful guide for education and general reference to physiotherapy professionals. Clinically, FES is applied as a supportive device and a therapeutic strategy to facilitate recovery of voluntary movements. The aim of the study was to assess the effectiveness of FES in spasticity and in improving lower extremity function in spinal cord injury patients.

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Subjects and methods

Literature search strategy and study eligibility criteria

We conducted a qualitative systematic review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic literature search covered articles published in years 2000–2020. The databases considered for the literature search were PubMed, Cochrane, ScienceDirect, and Google Scholar. The Medical Subject Headings (MeSH) applied for the search included "functional electrical stimulation", "lower limb", "rehabilitation", "spasticity", "spinal cord injury". In the screening process, both full text articles and abstracts were involved in the review. The investigated types of study were randomized controlled trials, cohort studies, case control studies, case reports. The selection criteria included (i) problem of research question: spinal cord injury; (ii) FES; (iii) control group with standard treatment as a comparator; (iv) the outcome variable: functional ability in the activity of daily life tasks. Data extraction was performed by using the participants/problem (P), intervention (I), comparison (C), and outcome (O) format on the basis of the selection criteria. Participants included adults with spinal cord injury for original studies or animal models as a study population that matched the research question, FES was the intervention, comparison could be either a control group with standard treatment or the same group with results presenting the pre- and post-intervention test values of the outcome variables. The outcome variables involved the test that assessed the functional ability of activity of daily life. We excluded articles with the following elements: (i) paralysis caused by a higher centre lesion; (ii) upper limb injury. The articles retrieved were distributed to the reviewers for screening for their eligibility through title screening, abstract screening, and full text screening. The feedback and comments from the reviewers were discussed and resolved.

Data extraction

The records were collected after the study eligibility screening processes for data extraction. The relevant data extracted from the records included were updated in a data extraction sheet. Disagreements were resolved after discussions on the reviewers' opinions. The elements included for data extraction were: (i) author and year of the study; (ii) study design; (iii) population/problem; (iv) sample size; (v) inclusion criteria; (vi); intervention; (vii) comparison status; (viii) outcome measures.

Risk of bias assessment

The risk of bias of the articles included in the systematic review was assessed by using the risk-of-bias assessment tool RoB 2 for randomized controlled trials [11]. The risk assessment domains included pre-intervention domains, namely (i) bias due to randomization; (ii) bias due to deviations from intended interventions; (iii) bias due to missing outcome data; (iv) bias due to measurement of outcome; (v) bias due to reported result; and overall risk of bias. The judgment for each article was given as low risk, some concerns, high risk.

Results

Literature search results

We performed a data search using the PRISMA guidelines. We retrieved records from different databases, including 3 records from PubMed database, 9 trials from the Cochrane database, 1960 from the Google Scholar database; 1972 records were extracted in total and screened for their eligibility for the study. The extraction process involved title screening, abstract screening, and full text screening. After the screening process, the records that did not satisfy the study eligibility criteria were eliminated and 5 full text articles were selected for the study. The reasons for the elimination of records in the study included: (i) the study design not matched; (ii) outcome measures not matched; (iii) duplication of articles; (iv) study population not matched with the inclusion criteria (Figure 1).

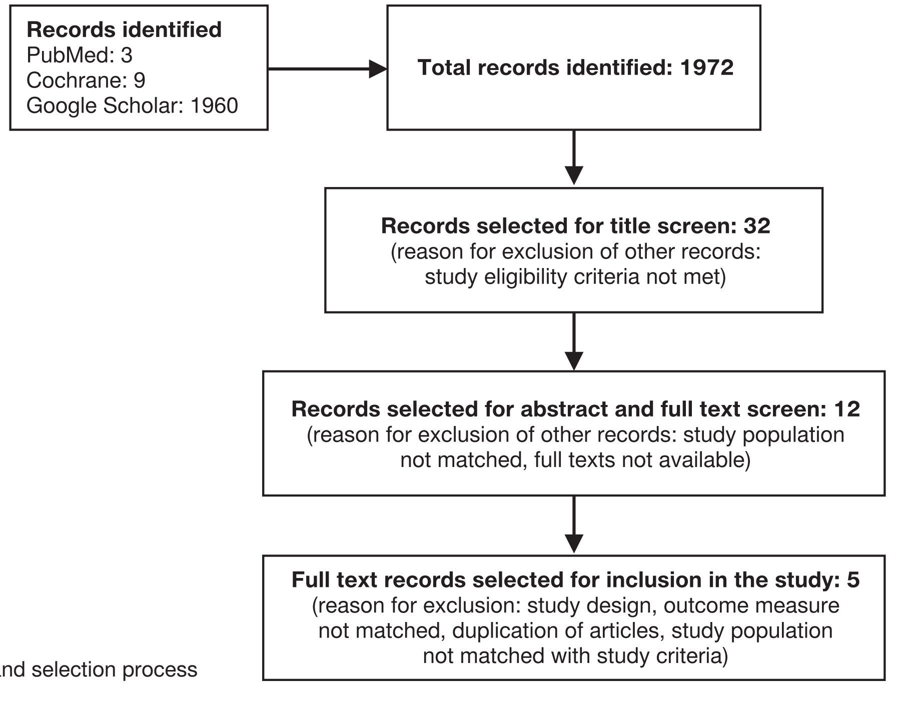

Figure 1. Literature search and selection process

Characteristics of included studies

Sivaramakrishnan et al. [12] conducted a randomized double-blinded crossover trial with participants exhibiting spinal cord injury with lower limb hypertonicity. They assessed the role and efficacy of FES and compared its effects with those of transcutaneous electrical nerve stimulation. The intervention was administered for the spasticity of plantar flexors, hip adductors, and quadriceps. A MEGA XP (CyberMedic, Korea) device with an 8-channel stimulator was applied, which provides biphasic rectangular pulses at a pulse rate of 35 Hz and pulse width of 300 μs. The treatment lasted for 30 minutes and the evaluation involved the use of a spinal cord assessment tool for spastic reflexes, with the measurement varying between 0 (minimum) and 9 (maximum). Ralston et al. [13] performed a 5-week crossover randomized trial in which the participants received both the intervention and the control phase. The study included 2 weeks of an experimental period and 2 weeks of a control period with a 1-week washout period in between. The intervention consisted in FES cycling for about 30–45 minutes. The key test muscles involved quadriceps, hamstrings, and glutei. The outcomes were leg circumference and hypertonicity measured with the modified Ashworth scale and the Patient-Reported Impact of Spasticity Measure (PRISM). An additional secondary outcome measure, the Patient Global Impression of Change, was gathered from the participants at the end of the study. Kapadia et al. [14] conducted a parallel randomized controlled trial. Subjects were selected who could not walk or walked independently with the help of assistive devices. The intervention included 45-minute therapy sessions, 3 days per week. The therapy duration was 16 weeks. The key muscles for assessment involved quadriceps, hamstrings, dorsiflexors, and plantar flexors. The outcome measures were spasticity, muscle atrophy, bone loss, and satisfaction with daily living. Yaşar et al. [15], in a prospective single-arm study, investigated the effect of FES cycling on later stage functional recovery of lower extremity spasticity in gait measurements while walking in participants with incomplete spinal cord injury. Patients with long-term incomplete spinal cord injury who walked with assistive devices without hip-knee-ankle-foot orthoses took part in the study. Giangregorio et al. [16] conducted a parallel-group randomized trial on FES-assisted walking in incomplete spinal cord injury as compared with a non-FES exercise protocol. Individuals who had been affected by incomplete spinal cord injury for 18 months were assigned for FES-assisted walking, aerobic and resistance exercise training classes 3 days a week for 16 weeks (Table 1).

Risk of bias assessment

We used the Cochrane risk of bias assessment tool RoB 2 to assess the risk of bias of the randomized controlled and crossover trials that were shortlisted for inclusion. A total of 77% of the included studies were at a low risk of bias arising from the randomization process, 60% were at a low risk of bias due to the intended intervention, 100% were at a low risk of bias due to missing outcome data, bias due to measurement of outcome, and bias in the selection of the reported result. As for the overall risk of bias of the included reports, 60% were at a low risk of bias, 20% aroused some concerns, and 20% represented a high risk of bias.

FES in reducing spasticity of lower extremity in spinal cord injury patients

In their report, Sivaramakrishnan et al. [12] evidenced no significant difference between the groups for the key muscles, namely hip adductors, knee extensors, and plantar flexors. The assessment was carried out at different stages of the study period: at 1 hour, 4 hours, and 24 hours. The study revealed a significant within-group difference in the muscles, namely hip adductors and knee extensors, after the intervention, with a value of $p < 0.001$. No statistically significant differences were observed in the modified Ashworth scale records of plantar flexors. Ralston et al. [13] evidenced a mean score difference between the groups for lower limb swelling of –0.1 cm, for lower limb spasticity as evaluated with the modified Ashworth scale, and for PRISM reports. The different spasticity scale results support FES cycling. Additionally, most of the participants reported to have obtained more benefit from FES cycling when compared with standard treatment and 2 study subjects indicated a moderate improvement on the Patient Global Impression of Change scale. Kapadia et al. [14] found no statistically significant difference in the total spinal cord independence measure between the groups. Both groups experienced an increase in the total spinal cord independence scores at 12 months during the follow-up period as compared with the baseline scores. The post-intervention value at 12 months was 21.33 for the experimental group. A significant difference was evident for the experimental group and not for the control group. The 10-m walk test revealed no significant change over time. Yaşar et al. [15], in a prospective single-arm study, reported that the alterations in gait measurements reached no significant difference, with a value of $p > 0.05$. The evidence suggests that FES cycling may provide some functional improvements in the later period of spinal cord injury. Giangregorio et al. [16], in a parallel-group randomized trial, measured the lower extremity cross-sectional area, the fat cross-sectional area to assess the whole body, leg lean, and body fat mass. The readings were taken at baseline and at 4 and 12 months. The intervention lasted for 4 months. The results reported no significant changes in the body composition at the post-intervention stage but long-term follow-up proved muscle mass maintenance.

Discussion

On the basis of the evidence collected, FES was found to be beneficial when compared with other treatment modalities in reducing the spasticity of the lower extremity in spinal cord injury patients. Though the statistical evidence suggests FES to be equivalent to other modes of treatment, the overall observation of the within-group results and the feedback from the patients imply that FES is superior to all other interventions in improving the functional activities of daily life.

Recently, FES has been used as one of the active rehabilitation strategies. FES is a therapeutic technique that produces functional movements in paraplegics. Currently, the rehabilitation of the voluntary movements in paralyzed patients is enhanced by the latest neurophysiological understanding of the mechanisms behind the voluntary motor function recovery.

For the rehabilitation of patients with spinal cord injury and stroke, the concept of neuroplasticity in neurorehabilitation offers promising results. Neuroplasticity is the capacity of the central nervous system to restructure the acquisition, memory

Table 1. Characteristics of the included studies

Author, year	Type of study	Population	Sample size	Inclusion criteria	Intervention	Comparison	Outcome measures
Effects on spasticity							
Sivaramakrishnan et al., 2018 [12]	Randomized crossover trial	Population with lower limb spasticity after spinal cord injury	10	Age of 39 ± 13.6 years C1–T11 level of injury 1–26 months after spinal cord injury Lower limb spasticity	FES	Electrical stimulation – transcutaneous electrical nerve stimulation	Key muscles involved: hip adductors, knee extensors, and ankle plantar flexors. Spasticity level assessed with modified Ashworth scale. Spinal cord assessment tool applied for spastic reflexes at baseline and immediately and 1, 4, and 24 hours after treatment
Ralston et al., 2013 [13]	Randomized crossover trial	14 participants with a recent motor complete spinal cord injury	14	Upper motor neuron lesion Spinal cord injury in the preceding 6 months Current in-patient rehabilitation Age > 16 years AIS score of A, B, or C with 5/50 lower limb strength Tolerance of FES for 20 minutes within 1-hour period Deemed medically fit by the treating medical consultant	During the experimental period of study, selected participants received FES cycling therapy for 2 weeks; each week comprised 4 sessions	Within-group with a 1-week washout period between interventions	Modified Ashworth scale for assessing spasticity of key muscles. Patient-Reported Impact of Spasticity Measure. Open-ended feedback questions to all participants to evaluate the therapy effectiveness
Effects on gait and spasticity							
Kapadia et al., 2014 [14]	Randomized controlled trial	Participants with long-duration incomplete traumatic spinal cord injury	27	Traumatic incomplete spinal cord lesion Level of lesion between C2 and T12 (AIS neurological impairment grade C or D) 18 months after injury Inability to walk or walking with assisting devices	FES-assisted walking sessions for 16 weeks, 3 days per week	Control group with standard treatment protocol	Gait parameters, balance, spasticity, and functional activity levels at baseline and at 4, 6, and 12 months
Giangregorio et al., 2012 [16]	Randomized trial	Participants with chronic spinal cord injury	34	Traumatic spinal cord injury More than 18 months after spinal cord injury Level of injury: C2–T12	FES-assisted walking or aerobic 3 times weekly for 16 weeks	Resistance training	Whole body, leg lean, whole body fat mass measured with dual-energy X-ray absorptiometry. Lower limb muscle cross-sectional area and fat cross-sectional area assessed with peripheral computed tomography at 4 and 12 months
Yaşar et al., 2015 [15]	Single-arm study	Participants with chronic incomplete spinal cord injury	10	More than 2 years after incomplete spinal cord injury Ability to be ambulant for at least 10 minutes or with assistance of cane or walker (no hip-knee-ankle-foot orthosis)	1-hour FES cycling 3 times a week for 16 weeks	No control group	Functional Independence Measure. Modified Ashworth scale for knee spasticity, temporal spatial gait parameters assessed at baseline and at 3 and 6 months

AIS – American Spinal Injury Association Impairment Scale, FES – functional electrical stimulation retention, and consolidation of motor skills. One of the interventions that can accomplish neuroplasticity is FES [17, 18], a type of neuromuscular electrical stimulation. The electrical stimulation is aimed to induce purposeful functional movements of the extremities. The functional movements like bringing a bottle of water to the mouth, picking food to the mouth, lifting an object from one place to another can be achieved by using FES. FES that permits a specific movement is referred to as neuroprosthesis. The neuroprostheses for the lower extremity are applied for standing, walking, and reaching [19–21].

Bajd et al. [22] did a study on the symmetry of FES responses in lower limbs of paraplegic participants. They selected 10 paraplegic patients who received FES training programs. The outcome measures used for the assessment included recruitment curve, fatigue index, and twitch delay. Overall, an average of 80% similarity was found in all evaluated variables, permitting a reduction in the complexity of control protocols for FES ambulatory aids [22, 23]. Granat et al. [24] conducted a study to verify the effect of FES in gait. They administered FES to 6 patients with spinal cord injury and trained them for standing and then for walking. It was observed that FES-assisted walking was feasible in individuals with incomplete spinal cord injury even with severe motor loss [24–26]. Kralj et al. [23] performed a statistical survey in Slovenia on the usage of FES and revealed over 1500 new cases of FES administration per million inhabitants in 1980s. They indicated that single-channel FES was applied in the rehabilitation program in 60% of cases, dual-channel FES in 30%, multichannel FES in 10%. Granat et al. [25] examined the role of FES in the rehabilitation of patients affected with incomplete spinal cord injury and observed that the method induced a decrease in the tone of the quadriceps muscle, an improvement in voluntary muscle strength, a reduction in physiological gait parameters, and an enhancement of stride length.

Maležič and Hesse [27] did a study on restoration of gait with FES. They selected 4 spinal cord injured patients and treated them for 10–17 days by FES, concluding that the modality had a beneficial effect in improving gait [27–29]. Kobetic et al. [30] performed a study to find the effect of FES on muscles engaged in ambulation. They used 16-channel and 8-channel FES to stimulate such muscles as erector spinae, gluteus maximus, adductor magnus, hamstring, tensor fasciae latae, sartorius, vastus muscles, tibialis anterior, and peroneus longus; 16-channel FES produced satisfactory results to improve gait. Veltink and Donaldson [31] proved good results of FES in training for standing among paraplegics.

Kamnik et al. [32] conducted a study on the effect of FES on sit-to-stand transfer in paraplegics and concluded that FES could play a major role in rehabilitating these patients in their transfer activities. Banaroti et al. [33] compared the effect of a knee-ankle-foot orthosis and FES on ambulation and upright mobility in an 11-year-old boy with T10 level spinal cord injury, implying that FES was far better than the orthosis as an ambulatory support. Kobetic et al. [30] examined the effect of 16-channel FES on standing and walking in 10 paraplegics. As a research result, they suggested that FES was an essential means to help the participants walk and stand [32–36].

The presented systematic review and meta-analysis evaluated the effectiveness of electrical stimulation on the volume of voluntary muscle and spasticity in spinal cord injury patients. The 5 studies involved 95 patients with complete or incomplete spinal cord injury. One study evidenced the use of electrical stimulation on muscle cross-section in the lower extremities; the overall result was statistically significant in participants with acute spinal cord injury, with a value of $p < 0.04$. In the 4 studies that investigated the effect of electrical stimulation on the spasticity of the lower extremity, the overall effect was non-significant, with a value of $p > 0.21$. Electrical stimulation was suggested to be a useful therapy for improving muscle volume in spinal cord injury patients, but exerted no effect on spasticity. Further analysis is recommended to identify the effect of electrical stimulation on spasticity in spinal cord injury [37–42].

Strengths, limitations, and recommendations

The evidence collected through this systematic review helps to uncover the lacuna existing in this field of research and to open up the hidden science behind the approach for patient mobilization in spinal cord injury. In spite of the provided evidence, still a number of limitations persist in the systematic review in identifying the effectiveness of FES to reduce spasticity and improve gait among patients affected with lower limb spasticity in spinal cord injury. Though the results prove beneficial associations, evidence to support the versatile role of FES is lacking. We recommend future studies in a large scale to explore the effectiveness of FES in improving the functional mobilization of patients with paraplegia.

Conclusions

The evidence collected within the limitations of the present systematic review indicates that the effectiveness of FES is equal to that of the standard treatments available. At the same time, within-group analysis reported a significant difference between FES and other treatment modalities in reducing spasticity and improving functional mobility among patients with spinal cord injury. With the available sources and the review, it may be concluded that FES can be used as an adjunct to standard physiotherapy protocols for early functional recovery.

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Ethical approval

The conducted research is not related to either human or animal use.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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