Effectiveness of Repetitive Peripheral Magnetic Stimulation for Treatment of Mild to Moderate Carpal Tunnel Syndrome: A Randomized Controlled Trial

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ABSTRACT

Objective: This study aimed to evaluate the effectiveness of active repetitive peripheral magnetic stimulation (rPMS) compared to sham rPMS on symptoms severity and functional status among patients with mild to moderate carpal tunnel syndrome.

Materials and Methods: A randomized controlled trial was conducted. Participants were randomly allocated (1:1) to either intervention (active rPMS) or control (sham rPMS) groups. Both groups received rPMS (A20 mode of OPTIMUS Pro) for 10 min, once a week for four weeks (four sessions). Symptom severity scales (SSS) and functional status scales (FSS) of Boston Carpal Tunnel Questionnaire were measured at baseline (before session one) and at the end of treatment (after session four). The relative changes in SSS and FSS scores were calculated as a clinical outcome.

Results: Forty-two participants were enrolled and randomly allocated to either the intervention (n = 21) or control group (n = 21). There were no statistically significant differences in the median (interquartile range) of relative changes in SSS [0.05 (0.15) vs 0 (0.27), P = 0.41] or FSS [0 (0.25) vs 0 (0.11), P = 0.97] between the intervention and control groups.

Conclusion: Active rPMS did not improve clinical outcome compared to sham rPMS among patients with mild to moderate CTS. A greater number of subjects and treatment sessions might be required for the future study.

Keywords: Repetitive peripheral magnetic stimulation; carpal tunnel syndrome; median neuropathy at the wrist; non-surgical treatment (Siriraj Med J 2023; 75: 488-493)

INTRODUCTION

Carpal tunnel syndrome (CTS) or median neuropathy at the wrist is the most common compressive neuropathy with a prevalence of 2-3% in the general population.[1] Patients with CTS might have hand numbness or pain along the median nerve distribution. In severe CTS, thenar weakness and/or atrophy can be found. Although CTS can normally be diagnosed by symptoms and physical examinations, nerve conduction studies (NCS) can provide a diagnostic test for CTS in cases where patients have uncertain presentations.[2] Furthermore, NCS can determine the severity of CTS based on electrophysiological findings.[3]

In patients with mild to moderate CTS, non-surgical treatment options such as a neutral wrist splint, corticosteroid injection should be considered. In cases of severe CTS associated with axonal loss, or patients that have not

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responded to non-invasive treatments, surgical release of the transverse carpal ligament is indicated.[4]

Repetitive peripheral magnetic stimulation (rPMS) is a novel physical modality that uses pulsed high-intensity magnetic field to stimulate muscles or nerves. The advantages of rPMS include that it is painless, easy to administer, and allows non-invasive deep tissue penetration.[5] The clinical applications of rPMS in the literature encompass treatment of pain conditions (e.g., myofascial pain, chronic low back pain, neuroma/nerve entrapment) and sensorimotor impairments (e.g., stroke, traumatic brain/spinal cord injury, traumatic brachial plexopathy).[5-7]

Although rPMS is used to treat neuropathy or plexopathy,[8] its clinical evidence as a non-surgical treatment specifically for CTS is limited. There was a preliminary study that evaluated the effectiveness of rPMS (8 wrists) compared to transcutaneous electrical nerve stimulation (TENS; 7 wrists).[9] Both rPMS and TENS were applied for 20 min once a day, three days a week for four weeks. This previous study found that rPMS was not more effective compared to TENS. However, the sample size of this study was too small to derive conclusive results, and no sham stimulation was performed as a control. Hence, the present study aimed to determine whether active rPMS improves clinical outcomes compared to sham rPMS.

MATERIALS AND METHODS

Participants and study design

This study was a randomized, sham-controlled trial conducted at Phramongkutklao Hospital in Bangkok, Thailand, from August 2020 to February 2022. Thai adults (20 to 79 years) who had signs and symptoms of CTS and electrophysiological findings of mild (peak sensory latency > 4.0 ms with normal motor study of median nerve) to moderate (motor latency > 4.5 ms with normal amplitude of compound muscle action potential and preserved sensory action potential of median nerve) degree of CTS were eligible to participate in the present study. If the participants had bilateral CTS, the most affected side was chosen. However, patients who had contraindications to rPMS, such as the use of a cardiac pacemaker; other neurological diseases such as cervical radiculopathy, polyneuropathy; and cognitive impairments were excluded.

Randomization

A computer-generated randomization list in a block of four was generated by an independent researcher before the beginning of enrollment. The random allocation sequence was concealed by an opaque envelope. Participants who met eligibility criteria were randomly assigned 1:1 to receive either active (Intervention group) or sham (Control group) rPMS.

Ethical Consideration

The trial protocol was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Number R174h/63) and was registered in the Thai Clinical Trials Registry (TCTR20210209012). All participants gave their written informed consent before participating in the study.

Interventions

The rPMS machine in the present study was OPTIMUS Pro (REMED, Gyeonggi-do, South Korea) which has magnetic flux density of three Tesla. All participants received 10 min electromagnetic stimulation in A20 mode once a week for four consecutive weeks (four sessions).[10] The round coil rPMS transducer was placed horizontally on the volar side of the affected wrist for the intervention group, but it was applied vertically for the control group, as shown in Fig 1. The intensity of rPMS was gradually increased to the highest level that the patient could tolerate for the intervention group, while it was adjusted to 20% to make the sound of stimulation for the control group. Furthermore, all participants in both groups were advised to avoid hyperflex/extension of the wrist and use a night splint if possible and were allowed to receive cointerventions as desired.

Outcome measure

The outcome measure was the Boston Carpal Tunnel Questionnaire (BCTQ). It is a self-administered questionnaire consisting of two scales: the Symptom Severity Scale (SSS; 11 questions) and the Functional Status Scale (FSS; 8 questions). Each question is rated on the Likert scale from 1 (no) to 5 (the worst) with a higher score indicating greater severity/difficulty. The mean score for each scale was calculated. The Thai version of BCTQ showed good internal consistency for both SSS (Cronbach's alpha of 0.86) and FSS (0.84).[11] BCTQ was evaluated at baseline (before session one) and at the end of treatment (after session four). The relative changes [(pre-treatment score – post-treatment score)/pre-treatment score] in the mean SSS and FSS score were used as clinical outcomes. Participants who had relative changes of ≥ 0.3 were defined as responders to rPMS treatment.[12]

Statistical analysis

With a significant level of 5% and a power of 80%,

Fig 1. Coil position/orientation for each group.

32 participants (16 participants for each group) were required to detect a 0.1 difference in the mean of the relative changes in the SSS or FSS score with a variance of 0.01 between two groups. Estimating a dropout rate of 20%, the target sample size was 40 participants (20 participants per group).

Categorical variables including age group, gender, affected side, severity of CTS, BMI, and treatment result were reported as number and percentage, while continuous variables such as SSS and FSS score at baseline were described as median (min – max). To determine statistical difference in variables between treatment groups, Fisher's exact test was used for categorical data, while the Mann-Whitney test was used for continuous data. Statistical significance was considered where $P < 0.05$. All statistical analyses were based on the intention-to-treat principle.

RESULTS

A total of 50 patients were eligible to participate in the present study. However, three patients were excluded due to radiculopathy, polyneuropathy, and a history of wrist fracture. Two patients refused to participate in this study due to transportation difficulties. From the remaining patients, 42 completed follow-ups for a 4-week period, with 21 patients in the intervention group and 21 patients in the control group (Fig 2).

Of these 42 participants, 90.5% were female; 52.4% were categorized within the age group of 40-59 years; and 73.8% were graded as having moderate CTS. There were no statistically significant differences in age, gender, CTS severity, body mass index (BMI), or pre-treatment SSS or FSS scores between both groups ($P > 0.05$). These details are provided in Table 1.

After the four-week program, there were no statistically significant differences in the median (interquartile range) of relative changes in the SSS [0.05 (0.15) vs 0 (0.27), $P = 0.41$] or FSS score [0 (0.25) vs 0 (0.11), $P = 0.97$] between the intervention and control groups (Fig 3). According to the relative changes in the SSS score, only five participants (11.9%) were categorized as responders: two participants (9.5%) in the intervention group and three participants (14.3%) in the control group ($P = 1$), while no participants were classified as responders based on the relative changes in the FSS score. Furthermore, in the subgroup analysis of participants who had pre-treatment SSS score of at least 2 (eight in the intervention group and seven in the control group), no statistically significant differences were found in the median (interquartile range) of pre-treatment SSS score [2.3 (0.4) vs 2.5 (0.4), $P = 0.22$] and relative changes in the SSS score [0.04 (0.26) vs 0.07 (0.32), $P = 0.82$] was found between the intervention and control groups. Lastly, adverse effects were not found or reported from any of the study participants.

DISCUSSION

The objective of this study was to determine the effectiveness of rPMS for the treatment of CTS. The present study found that active rPMS did not improve

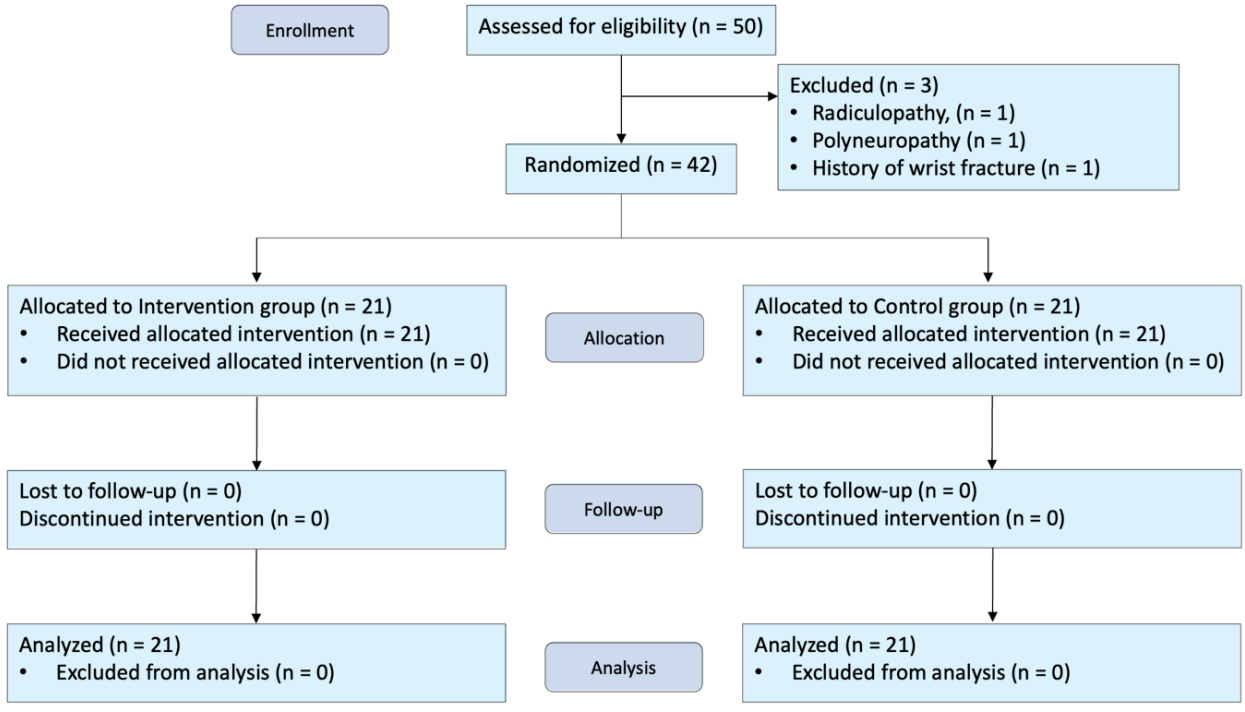

Fig 2. CONSORT diagram of the present study

TABLE 1. Demographic data of participants.

Variables	Intervention group (n=21)	Control group (n=21)	P-value
Age group, n (%)			
40 – 59	10 (47.6)	12 (57.1)	0.76
60 – 79	11 (52.4)	9 (42.9)	
Gender, n (%)			
Male	0 (0)	4 (19)	0.11
Female	21 (100)	17 (81)	
Affected side, n (%)			
Left	5 (23.8)	4 (19)	1.00
Right	16 (76.2)	17 (81)	
CTS Severity, n (%)			
Mild	3 (14.3)	8 (38.1)	0.16
Moderate	18 (85.7)	13 (61.9)	
BMI, n (%)			
< 27	20 (95.2)	18 (85.7)	0.61
≥ 27	1 (4.8)	3 (14.3)	
BCTQ-SSS, median (min – max)	1.8 (1.3 – 2.9)	1.7 (1.3 – 2.7)	0.89
BCTQ-FSS, median (min – max)	1.1 (1 – 2.4)	1 (1 – 1.9)	0.13

Abbreviations: CTS, Carpal tunnel syndrome; BMI, Body mass index, BCTQ, Boston Carpal Tunnel Questionnaire; Symptom Severity Scale, SSS; FSS, Functional Status Scale.

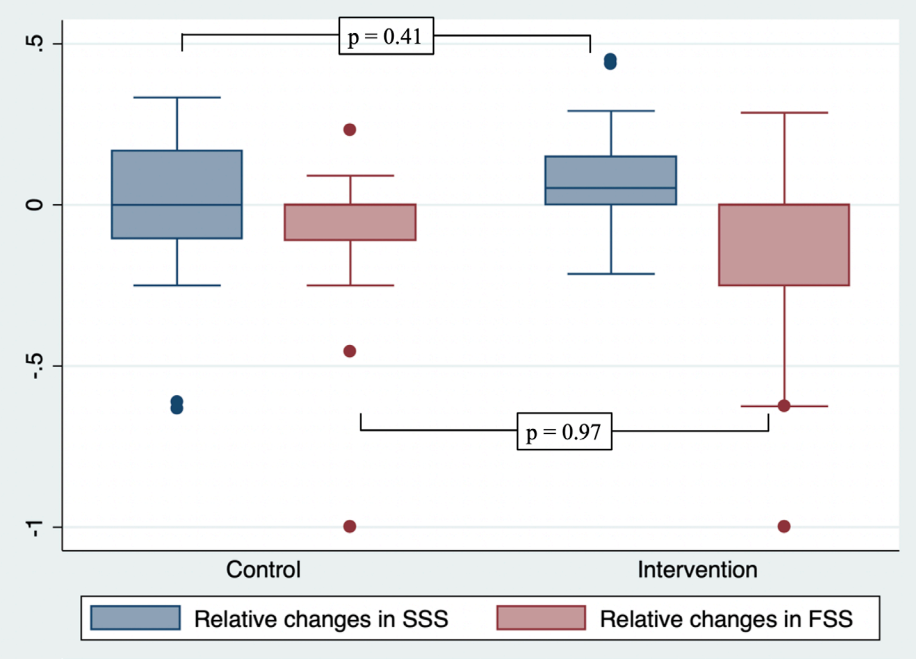

Fig 3. Relative changes in the Symptom Severity Scale (SSS) and the Functional Status Scale (FSS) of both groups

clinical outcomes compared to sham rPMS at the end of 4-week treatment in patients with mild to moderate CTS in both overall and subgroup analyses. To compare with previous studies, so far, no sham-controlled trials have been conducted to determine the effectiveness of rPMS in patients with CTS. However, a small clinical trial was conducted (11 patients) in Korea to determine the effectiveness of rPMS (8 wrists) compared to TENS (7 wrists). The result of this previous study showed that the change in BCTQ score after treatment between these two modalities was not significantly different ($p = 0.97$).[9]

Based on the comparison of SSS scores between active and sham rPMS in this study, it appears that rPMS is an ineffective physical modality to reduce the clinical symptoms of CTS. This result may be because rPMS is used primarily to treat pain conditions. However, most patients with mild to moderate CTS have no or minimal pain but usually present with numbness or tingling. Moreover, although rPMS could have a temporary positive effect for patients with CTS due to eliciting excitability of muscles and nerves under the transducer leading to changes in neuronal functions and neuroplasticity,[13] it was unable to correct the pathophysiology of CTS caused by a compression mechanism resulting in local swelling and dysfunctions of the median nerve in the wrist.[14] Therefore, it could not have the therapeutic (long-term) effect in cases of compressive neuropathy. Furthermore, most of the participants did not have functional problems with their hands, with a median FSS score of 1, as seen in Table 1. This is possibly a key reason why an improvement in the FSS score was not observed in this study.

The present study used the A20 mode with a preset frequency of 8-25 Hz as advised from the manufacturer's recommendation for the control of neuropathic pain. The recommended duration of treatment for this mode was 10-20 min. Hence, in this study, treatment duration for both groups was 10 min, while average (standard deviation) duration of treatment across previous studies was 13.4 (8.8) min.[5] However, the present study was unable to calculate the total number of stimuli because the manufacturer did not provide the details of the duty cycle and the duration of ON/OFF periods of the A20 mode.

In clinical trials for rPMS, standard protocols of sham stimulation have not been established. The orientation of the transducer at a 90 degree angle to the body surface (vertical) was able to reduce the effects of rPMS applied to the target sites.[15] The vertical orientation of the transducer with low stimulation intensity was used in the present study; thus, the sham group should not receive the effects of rPMS even though a real transducer was used. Moreover, two clinical trials evaluating the effects of rPMS on pain among patients with lumbosacral spondylosis or low back pain used this control protocol.[16,17]

Several limitations of this study should be considered. With a relatively small sample size, the results must be interpreted with caution because of the low power of the statistical tests. Most of the participants also had a very mild symptom that might be the reason for the negative results of this study. For this reason, the subgroup analysis was conducted, and it seemed to be similar to the results from the overall analysis. The immediate effect of rPMS on clinical outcomes was not evaluated after

each treatment session. Furthermore, there was only one outcome measure (BCTQ) in this study. Evaluation of objective outcomes, such as grip strength, could be useful in determining the positive effect of rPMS. Lastly, the present study provided rPMS to participants only once a week for four weeks, which might not be enough to improve the clinical symptoms of CTS patients.

CONCLUSION

Active rPMS with preset frequency of 8-25 Hz for 10 min, once a week for four weeks, did not improve clinical outcomes compared to sham rPMS among patients with mild to moderate CTS. However, a greater number of participants and treatment sessions might be considered for future work.

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