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PRACA ORYGINALNA
ORIGINAL PAPER

Bipolar pulsed radiofrequency neuromodulation of median nerve for treatment of carpal tunnel syndrome – a preliminary study

Neuromodulacja bipolarna nerwu pośrodkowego za pomocą pulsacyjnego prądu o częstotliwości radiowej w leczeniu zespołu cieśni nadgarstka – doniesienie wstępne

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ABSTRACT

INTRODUCTION: The results of direct surgical release of the median nerve in patients with carpal tunnel syndrome are frequently far from being satisfactory. Aim of the presented study is to assess the early results of bipolar pulsed radiofrequency (PRF) neuromodulation of the median nerve (MN) for treatment of carpal tunnel syndrome (CTS).
MATERIAL AND METHODS: Fifteen adult patients with CTS (10 women and 5 men, mean age 58.5 years) were treated. The bipolar technique of neuromodulation was applied, with confirmation of the correct electrode position by neurophysiological examination. The study protocol included the Boston Carpal Tunnel Questionnaire (BCTQ), Numerical Rating Scale (NRS) for pain assessment and tip pinch strength assessment performed before neuromodulation as well as 4 and 12 weeks after treatment. Moreover, the sensory nerve conduction velocity (SNCV) was assessed before and 12 weeks after the intervention.
RESULTS: A significant improvement in symptom severity (33.53 ± 8.25 at the baseline vs. 18.33 ± 11.06 and 25.67 ± 12.39 at 4 and 12 weeks) and functional status (21.0 ± 5.79 vs. 12.07 ± 7.20 and 17.73 ± 9.09) BCTQ subscores, as well as tip pinch strength (3.39 ± 1.68 vs. 5.86 ± 1.98 and 4.93 ± 2.22) were observed. A reduction in pain and improvement in SNCV were also found, but did not reach statistical significance.
CONCLUSIONS: Bipolar PRF neuromodulation of MN is a promising therapeutic tool for patients with CTS and could potentially be an alternative to direct surgical release of MN. A longer follow-up period is required to assess the longevity of clinical improvement after the treatment.

KEY WORDS

bipolar neuromodulation, carpal tunnel syndrome, median nerve, pulsed radiofrequency

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STRESZCZENIE

WSTĘP: Wyniki chirurgicznego odbarczenia nerwu pośrodkowego u części chorych z zespołem cieśni nadgarstka są niezadowalające. Celem pracy jest ocena wczesnych wyników leczenia zespołu cieśni nadgarstka (*carpal tunnel syndrome* – CTS) za pomocą bipolarnej neuromodulacji nerwu pośrodkowego (*median nerve* – MN) z użyciem prądu o częstotliwości radiowej w trybie pulsacyjnym (*pulsed radiofrequency* – PRF).
MATERIAŁ I METODY: Leczeniu poddano 15 dorosłych pacjentów z CTS (10 kobiet i 5 mężczyzn, średni wiek 58,5 roku). Zastosowano technikę bipolarnej neuromodulacji z użyciem prądu PRF. Prawidłowość położenia elektrod potwierdzano neurofizjologicznie. Protokół badania składał się z kwestionariusza objawów zespołu cieśni nadgarstka (Boston Carpal Tunnel Questionnaire – BCTQ), skali numerycznej NRS (Numerical Rating Scale) dla oceny bólu oraz oceny siły mięśniowej przed neuromodulacją oraz 4 i 12 tygodni po leczeniu. Ponadto oceniano szybkość przewodnictwa czuciowego w nerwie pośrodkowym (*sensory nerve conduction velocity* – SNCV) przed i 12 tygodni po interwencji.
WYNIKI: Stwierdzono znamienną poprawę w zakresie podskal BCTQ dotyczących ciężkości objawów (33,53 ± 8,25 przed zabiegiem vs. 18,33 ± 11,06 i 25,67 ± 12,39 po upływie 4 i 12 tygodni od zabiegu) oraz stanu czynnościowego (21,0 ± 5,79 vs. 12,07 ± 7,20 i 17,73 ± 9,09), a także poprawę siły mięśniowej (3,39 ± 1,68 vs. 5,86 ± 1,98 i 4,93 ± 2,22). Ponadto stwierdzono redukcję bólu i poprawę SNCV, jednak parametry te nie osiągnęły znamienności statystycznej.
WNIOSKI: Neuromodulacja nerwu pośrodkowego za pomocą prądu PRF przeprowadzona techniką bipolarną jest obiecującą metodą leczenia pacjentów z CTS i może być alternatywą dla chirurgicznego uwolnienia nerwu pośrodkowego. Dla oceny trwałości poprawy klinicznej po zastosowanym leczeniu konieczny będzie dłuższy okres obserwacji.

SŁOWA KLUCZOWE

neuromodulacja bipolarna, zespół cieśni nadgarstka, nerw pośrodkowy, prąd pulsacyjny o częstotliwości radiowej

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most frequent human compression neuropathy, with a prevalence of 3–5% in the general population [1,2]. The male/female ratio is estimated to be 1:3.6 [3]. If left untreated, compression of the median nerve (MN) can lead to chronic pain and paraesthesias, hand dysfunction and neurological deficits. Mild cases usually benefit from non-surgical treatment, while moderate and severe cases frequently require surgical intervention – open or endoscopic carpal tunnel release (CTR) [4].
Surgical treatment carries a risk of complications, occurring approximately in 25% of cases, with hand numbness, hematoma and wound infection being the most frequent [2]. Moreover, the pain persists in 12%, while 22% of patients develops a new type of pain one year after CTR – so-called chronic postoperative pain [5]. Other, less invasive interventional modalities like pulsed radiofrequency (PRF) neuromodulation of MN could potentially fill the gap between conservative and surgical treatment. Unipolar pulsed radiofrequency of MN was first applied by Haider et al. [6] in a patient with recurrent CTS after previous surgery, in whom a 70% symptom reduction was achieved after PRF. In this particular case, the radiofrequency electrode was positioned on the median nerve at the level of the cubital fossa under ultrasound guidance. This site of PRF was dictated by post-surgical scarring at the wrist.
A randomized clinical trial performed by Chen et al. [7] in patients with CTS showed significantly better results of unipolar PRF of MN in comparison with conservative treatment (wrist splinting). In the cited study the electrode was positioned at the level of the wrist. The purpose of our study was to assess the early results of bipolar PRF neuromodulation of the median nerve for the treatment of CTS.

MATERIAL AND METHODS

A prospective observational study was conducted with a single-group pretest/posttest design, according to the classification by Berger et al. [8].
Fifteen adults with CTS (10 women and 5 men, the mean age 58.53 ± 10.38 years) were treated. The bipolar technique of neuromodulation was applied, with neurophysiological confirmation of the correct electrode position. The procedure was performed with a G4 Radiofrequency Generator (Cosman Medical, Burlington, Mass., USA). Two cannulas (22G, length 50 mm, active tip 4 mm) were arranged in parallel, and introduced perpendicular to the skin surface, above the course of MN in the forearm, between the tendons of the flexor carpi radialis and the palmaris longus muscles. The first cannula was introduced 4 cm proximally from the first bracelet (Rascette) line, and the second was 1 cm proximal to the previous cannula. The cannulas were navigated towards MN under electrophysiological guidance; sensory (50 Hz, up to 0.45 V) and motor (2 Hz, up to 1 V) stimulation was performed via the RF electrode, for each cannula separately. After an injection of 0.5 ml 0.9% saline through each cannula, the bipolar PRF was performed (4 cycles, 2 min each, 2 Hz, 20 ms, 45 V, temperature not to exceed 42°C). After the procedure, the puncture sites were dressed in a sterile manner. The PRF procedures were performed by two surgeons (A. Krzywda and J.L. Słowiński).

The examination protocol consisted of the Boston Carpal Tunnel Questionnaire (BCTQ) with the Symptom Severity Scale (SSS) and Functional Status Scale (FSS) subscale scores, the Numerical Rating Scale (NRS) for pain intensity assessment, and tip pinch strength – all performed at 0, 4 and 12 weeks after treatment. A neurophysiological examination, including measurement of the sensory nerve conduction velocity (SNCV) in the median nerve was performed before and 12 weeks after the PRF procedure.

Ethical approval of the project was obtained from the Bioethical Committee of the Medical University of Silesia, Katowice, Poland.

Statistical analysis

Continuous variables with normal distribution were presented as the mean and standard deviation, and those with non-normal distribution – as the median as well as lower and upper quartiles. Categorical variables were expressed as counts and percentages. The differences between three consecutive time points were compared using the repeated measures analysis of variance or the Friedman test for normally or non-normally distributed data, respectively. Bearing in mind the aim of the study, we compared only the first and the last time point after repeated measures tests, using a paired samples t-test or the Wilcoxon signed-rank test for normally or non-normally distributed data, respectively, purposely without any corrections for multiple comparisons. The normality of the distribution was assessed using the Shapiro-Wilk test. A p-value less than 0.05 was considered statistically significant. Analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

The results of this study are summarized in Table I.

A significant improvement in the SSS and FSS BCTQ subscores and tip pinch strength were observed. A reduction in pain and improvement in SNCV were also found, but did not reach statistical significance.

At baseline, one patient met the criteria of mild CTS, nine moderate and five severe CTS according to the neurophysiological grading elaborated by Padua et al. [9]. At the 12 week follow-up, the grade of three patients improved, but the difference was not statistically significant. There were no complications or side effects from the PRF procedure.

Table I. Summary of results in cohort of fifteen CTS patients treated with median nerve bipolar PRF
Tabela I. Podsumowanie wyników leczenia grupy 15 pacjentów z CTS leczonych za pomocą neuromodulacji nerwu pośrodkowego prądem PRF

Variable	Baseline	4 weeks after PRF	12 weeks after PRF	p – value
BCTQ-SSS	33.53 ± 8.25*	18.33 ± 11.06*	25.67 ± 12.39*	< 0.0001
BCTQ-FSS	21.0 ± 5.79*	12.07 ± 7.20*	17.73 ± 9.09*	0.0006
NRS	6.00 (4.00–7.00)**	3.50 (0.50–4.50)**	3.00 (0.00–5.00)**	0.0596
Tip pinch strength (kg)	3.39 ± 1.68*	5.86 ± 1.98*	4.93 ± 2.22*	0.0017
Padua's et al. classification [9] (No. of cases is provided)				
mild	n = 1	n/a	n = 2	0.0710
moderate	n = 9	n/a	n = 10	
severe	n = 5	n/a	n = 3	
SNCV (m/s)	31.50 (0–40.50)**	n/a	35.10 (28.00–42.20)**	0.2095

BCTQ – Boston Carpal Tunnel Questionnaire; SSS – Symptom Severity Scale; FSS – Functional Status Scale; CTS – carpal tunnel syndrome; NRS – Numerical Rating Scale for pain assessment; PRF – pulsed radiofrequency; SNCV – sensory nerve conduction velocity; SD – standard deviation; n/a – not applicable; * mean ± SD; ** median, lower and upper quartiles

DISCUSSION

Pulsed radiofrequency was first applied in the interventional treatment of pain by Sluijter et al. [10] in the 1990s. Over the next two decades, a wide spectrum of clinical applications for PRF emerged, e.g. radicular pain, facet pain, trigeminal neuralgia, occipital neuralgia, shoulder pain, knee pain and other pain syndromes [11,12,13]. It was recently found that bipolar PRF could be more effective in pain treatment compared with unipolar PRF. This is probably due to the larger and denser electrical field between a closely spaced pair of electrodes [14].

The bipolar PRF of MN for the treatment of CTS was pioneered by Ruiz-Lopez (Ruiz-Lopez R. Treatment of carpal tunnel syndrome with pulsed radiofrequency. Lecture at the Invasive Procedures in Motion Conference. Swiss Paraplegic Center, Nottwil, Switzerland, January 18–19, 2008). He performed the procedure at the wrist, with two electrodes arranged colinearly and coming from opposite directions (personal communication). This was actually the first ever application of bipolar PRF for pain management [15].

Since then, there have been no other reports describing the application of bipolar PRF in CTS. Our study demonstrates the effectiveness of bipolar PRF of MN in a cohort of 15 patients with CTS. Improvement both

in terms of clinical symptoms and tip pinch strength was observed. The placement of electrodes in the forearm proved to be technically straightforward and clinically effective.

This brief clinical report has inherent limitations. A small number of patients was recruited and we did not perform a long-term follow-up. A longer-term follow-up will show whether the benefit of bipolar PRF is maintained over time.

CONCLUSIONS

The favourable early results of bipolar PRF of the median nerve in patients with CTS encourage a wider application of this approach by neurosurgeons, orthopaedists, hand surgeons or pain management specialists.

Importantly, as a minimally invasive procedure, PRF can be performed in an outpatient setting. Furthermore, PRF can be offered to patients awaiting surgical release of carpal tunnel.

A longer follow-up and recruitment of a larger group of patients is needed to determine the longevity of clinical improvement after PRF.

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Conflicts of interest

None declared

Author's contribution

Study design – A. Krzywda, A. Wypych-Ślusarska, J.L. Słowiński
Data collection – A. Krzywda, A. Wypych-Ślusarska, K. Oleksiuk, J. Głogowska-Ligus, M. Skrzypek
Data interpretation – K. Krupa-Kotara, J.L. Słowiński
Statistical analysis – M. Skrzypek
Manuscript preparation – K. Oleksiuk, J. Głogowska-Ligus, M. Skrzypek, J.L. Słowiński
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