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

Adam Krzywda¹, Agata Wypych-Ślusarska², Karolina Krupa-Kotara², Klaudia Oleksiuk², Joanna Głogowska-Ligus², Michał Skrzypek³, Jerzy L. Słowiński²,³, Klaudia Oleksiuk², Jerzy L. Słowiński²,³

¹Department of Orthopaedics, Sokołów Memorial Hospital, Wałbrzych, Poland
²Department of Epidemiology, Faculty of Health Sciences in Bytom, Medical University of Silesia, Katowice, Poland
³Department of Biostatistics, Faculty of Health Sciences in Bytom, Medical University of Silesia, Katowice, Poland
²Department of Neurosurgery, Sokołów Memorial Hospital, Wałbrzych, Poland

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
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-normaly 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.

| 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]  |                              |                  |                   |          |
| mild                          | n = 1                         | n/a              | n = 2             |          |
| moderate                      | n = 9                         | n/a              | n = 10            |          |
| severe                        | n = 5                         | n/a              | n = 3             | 0.0710   |
| 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 Sluijfer 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.

Funding
The project was funded by the Medical University of Silesia, Katowice, Poland, grant No. KNW-1-205/N/7/K.

Conflicts of interest
None declared

REFERENCES

1. Dec P., Zyluk A. Bilateral carpal tunnel syndrome – A review. Neurol. Neurochir. Pol. 2018; 52(1): 79–83, doi: 10.1016/j.gjnj.2017.09.009.
2. Kaplan J., Roth C., Metillo A., Koko E., Fuller D., Perry A. Analysis of surgical options for patients with bilateral carpal tunnel syndrome. J. Orthop. 2020; 22: 86–89, doi: 10.1016/j.jor.2020.03.060.
3. Patijn J., Valkjo R., Jansen M., Huygen F., Lataster A., van Kleef M. et al. Carpal tunnel syndrome: Pain Pract. 2011; 11(3): 297–301, doi: 10.1111/j.1533-2500.2011.00457.x.
4. Arouri S., Spence R.A. Carpal tunnel syndrome. Ulster Med. J. 2008; 77(1): 6–17.
5. Belze O., Remerand F., Laulan J., Augustin B., Rion M., Laffon M. et al. Chronic pain after carpal tunnel surgery: epidemiology and associated factors. Ann. Fr. Anesth. Reanim. 2012; 31(12): e269–274, doi: 10.1016/j.anfar.2012.08.009.
6. Haider N., Meckasha D., Chiravuri S., Wasserman R. Pulsed radiofrequency of the median nerve under ultrasound guidance. Pain Physician 2007; 10(6): 765–770.
7. Chen L.C., Ho C.W., Sun C.H., Lee J.T., Li T.Y., Shih F.M. et al. Ultrasound-guided pulsed radiofrequency for carpal tunnel syndrome: a single-blinded randomized controlled study. PLoS One 2015; 10(6): e0129918, doi: 10.1371/journal.pone.0129918.
8. Berger M.L., Dryer N., Anderson F., Towe A., Sedrakyan A., Normand S.L. Prospective observational studies to assess comparative effectiveness: the ISPOR good research practices task force report. Value Health 2012; 15(2): 217–230, doi: 10.1016/j.jval.2011.12.010.
9. Padua L., LoMonaco M., Gregori B., Valente E.M., Padua R., Tonali P. Neurophysiological classification and sensitivity in 500 carpal tunnel syndrome hands. Acta Neurol. Scand. 1997; 96(4): 211–217, doi: 10.1111/j.1600-0404.1997.tb00271.x.
10. Sluijter M.E., Cosman E.R., Rittman W.J., van Kleef M. The effects of pulsed radiofrequency fields applied to the dorsal root ganglion – a preliminary report. Pain Clin. 1998; 11: 109–117.
11. Facchini G., Spinnato P., Guglielmi G., Albisinni U., Bazzocchi A. A comprehensive review of pulsed radiofrequency in the treatment of pain associated with different spinal conditions. Br. J. Radiol. 2017; 90(1073): 20150406, doi: 10.1259/bjr.20150406.
12. Sluijter M.E., Imani F. Evolution and mode of action of pulsed radiofrequency. Anesth. Pain Med. 2013; 2(4): 139–141, doi: 10.5812/apm.10213.
13. Vanneste T., Van Lantschoot A., Van Boxem K., Van Zundert J. Pulsed radiofrequency in chronic pain. Curr. Opin. Anaesthesiol. 2017; 30(5): 577–582, doi: 10.1097/ACO.0000000000000502.
14. Chang M.C., Cho Y.W., Ahn S.H. Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain: A randomized controlled trial. Medicine (Baltimore) 2017; 96(9): e6236, doi: 10.1097/MD.00000000000006236.
15. Manual of RF techniques – a practical manual of radiofrequency procedures in chronic pain management. 3rd ed. Gucci C.A. [ed.]. CoMedical Ridderkerk 2011.

Author’s contribution
Study design – A. Krzywa, A. Wypych-Ślusarska, J.L. SŁowiński
Data collection – A. Krzywa, 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
Literature research – A. Krzywa, A. Wypych-Ślusarska, K. Krupa-Kotara, J.L. Słowiński

None declared