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EFFICACY OF CAPACITIVE RESISTIVE MONOPOLAR RADIOFREQUENCY IN THE PHYSIOTHERAPEUTIC TREATMENT OF CHRONIC PELVIC PAIN SYNDROME: A RANDOMIZED CONTROLLED TRIAL

CARRALERO MARTÍNEZ A[1], MUÑOZ PÉREZ MA[2], KAUFFMANN S[1], BLANCO RATTO L[1], RAMÍREZ GARCÍA I[1].
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[1] RAPbarcelona Physiotherapy Clinical Center, Barcelona, Spain [2] Department of Pediatrics, Obstetrics and Gynecology and Preventive Medicine. PhD program in Methodology of Biomedical Research and Public Health, Universitat Autònoma de Barcelona (UAB), Bellaterra, Spain

INTRODUCTION

Chronic pelvic pain syndrome (CPPS) has a prevalence ranging from 5.7% to 26.6% in women and 2.2% to 9.7% in men.[1,2] In addition to causing urinary and genital functional disability, this multifactorial condition can have a marked impact on quality of life (QoL).[3]

With respect to therapeutic approaches, there are various well-established physical options [4] including capacitive resistive monopolar radiofrequency (CRMRF). Even though this clinical approach has been common practice for the last two decades, reliable clinical data concerning its use are lacking. It has been observed that the electromagnetic field generated by the current leads to vasodilatation and an increase in cellular activity, which helps the connective tissue repair process, improves its elasticity, and increases the pain threshold as it reduces inflammation.[5,6]

Thermal stimulation affects pain reduction by suppressing ischemia and spasticity. Stimulation of the temperature receptors augments vasodilation and alleviates pain due to ischemia.[7,8] In addition, the bioelectrical effect encourages local pain sensory thresholds to recover to normal levels. Such an analgesic effect can be explained by the gate control theory.[9]

Despite the effectiveness of CRMRF in other musculoskeletal pathologies having been demonstrated,[5–7] there is scarce evidence of its benefits when applied as a pain and treatment management for CPPS.[10,11]

This study aims to evaluate the efficacy of CRMRF versus sham CRMRF treatment, both combined with pain education and physiotherapeutic techniques, with respect to pain reduction and QoL improvement in CPPS patients.

MATERIALS AND METHODS

This trial was made up of 81 consecutive patients with CPPS. Inclusion criteria were to be aged 18 years or more, and to present one of the following for at least the previous 6 months: endometriosis, adenomyosis, myofascial syndrome (Sd), levator ani Sd, bladder pain Sd, inflammatory prostatitis, pudendal nerve Sd, and nonspecific CPPS. Exclusion criteria were: (1) patients undergoing manual therapy, physical therapy, chiropractic massage, osteopathy, or any other conservative treatment throughout the study period; (2) having recently undergone oncological processes in the pelvic area, and surgery in the pelvic area in the previous 3 months; (3) pregnancy, chronic fatigue/fibromyalgia, severe psychological conditions, skin hypersensitivity, and neuromuscular diseases.

Sample size

The sample size calculation concluded that 40 patients were needed for each arm of the study.
The study was approved by the Vall d'Hebron Hospital Ethics Committee (PR(RAP)361/2018) and all participants signed an informed consent form.

Randomization

Study participants were randomly assigned to the control group (CG) and the intervention group (IG).

Four indications were taken into account to blind patients, physiotherapists, and the principal investigator to the assigned study group: (1) the screen visible to the CRMF team showed no parameter that could indicate whether or not the equipment emitted an electrical signal; (2) a 2% intensity parameter was established for all participants to prevent the IG from receiving any thermal effect; (3) to avoid any sensation, physiotherapists applied the CRMRF by manipulating it with the handle; (4) randomization and allocation sequences were concealed at all times until statistical analysis was performed on completion of the intervention.

Intervention

Treatment consisted of 10 CRMRF sessions (INDIBA®, 350 VA, and 100W at 448 kHz, INDIBA S.A.) once a week. All patients received CRMRF combined with simultaneous physiotherapeutic techniques and pain education, however CG participants received deactivated CRMRF.

Outcome measures

Following guidelines from the International Continence Society (ICI) on assessing pain intensity, the VAS[12] score was used and a difference of at least two points was taken as the primary outcome measure. Additionally, the SF-12 health survey was used to assess QoL as a secondary outcome measure. Participants completed one assessment at baseline and two additional ones at 5 and 10 weeks after the first session.

After each treatment session, adverse events, if any, were noted. The most common adverse reaction to CRMRF, appears mainly at treatment commencement and consists of an increase in pain in the area lasting 2–3 days.

Statistical methods

Statistical analyses were performed with SPSS 24.0 software. A $p < 0.05$ significance level was established.

RESULTS

Baseline characteristics

Of the 82 eligible participants 1 was excluded due to pregnancy. Eighty-one patients (men, n = 26) took part in the study. Mean age was 43.6 years, and the mean duration of symptoms was 57.8 months ranging from 6 months to 25 years. Around half the patients presented myofascial syndrome (50.6%) and 44.4% had myofascial syndrome linked with other disorders. The majority were diagnosed with CPPS due to endometriosis (14.8%), bladder pain syndrome (14.8%), and prostatitis (11.1%).

Reduction in pain intensity

After 10 CRMRF treatment sessions, pain improved significantly (Table 1). End Protocol Analysis (PP) evaluation showed a significant reduction of 2.80 points in the IG mean values, whereas the CG showed a mean reduction of 1.22 points (p = 0.013). Figure 1A depicts the evolution of the VAS scores over time. The Intention-to-treat analysis (ITT) analysis presented a significant reduction of 2.74 points in the IG versus 0.95 points in the CG at treatment termination (p = 0.002). Furthermore, a significant mean reduction of pain (p = 0.020) of 1.59 points in the IG was observed at the fifth session, compared to a mean decrease of 0.29 points in the CG.

	ITT			PP		
	IG (*n*=41)	CG (*n*=40)	*p* Value	IG (*n*=38)	CG (*n*=32)	*p* Value
A. Visual analogic scale						
Baseline	5.93 (2.46)	4.87 (2.37)		5.95 (2.49)	4.83 (2.42)	
10 session	3.19 (2.78)	3.92 (2.76)		3.15 (2.78)	3.61 (2.79)	
Difference from baseline	-2.74 (-3.51: -1.92)	-0.95 (-1.70: -0.33)	**0.002**	-2.80 (-3.69: -1.96)	-1.22 (-2.10: -0.44)	**0.013**

Table 1. Parameter changes after 10 weeks of crmrf and sham treatments

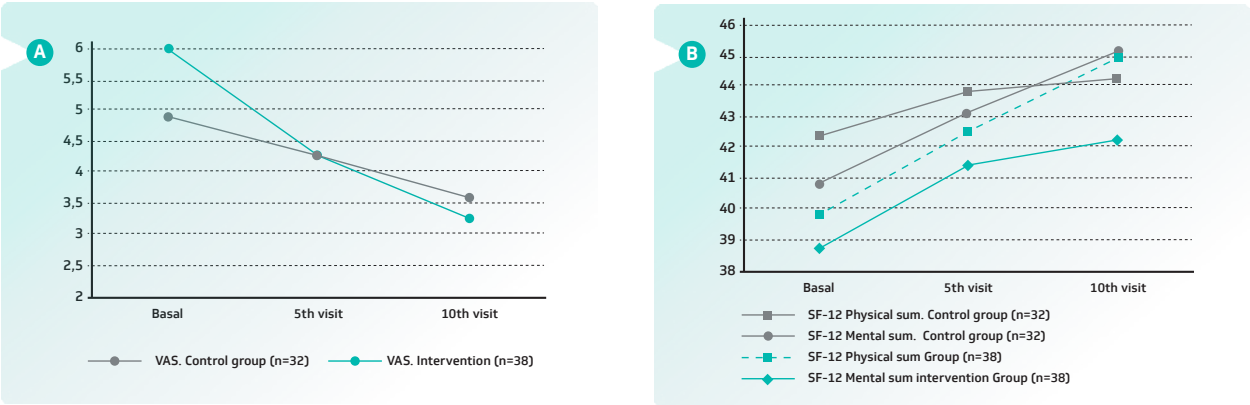

Figure 1. Intensity of pain (VAS) (A) and quality of life related to health (SF-12 survey) (B) values at baseline, 5 weeks, and end of treatment (Week 10). Per protocol analysis. VAS, visual analogue scale

Patients' assessments: QoL scores

There was no difference between each study group in PP analysis after treatment termination. Figure 1B shows the evolution of the values obtained through the SF-12 questionnaire over time. Even though the IG and CG achieved a mean increase in the physical and mental domains, suggestive of a minor impact on lower urinary tract dysfunction on the perceived QoL, these changes were not significant.

The ITT analysis indicated a significant difference (p = 0.034) in the physical SF-12 summary at the end of treatment of 4.70 (SD 6.40) points for the IG compared to 1.33 (SD 7.68) points for the CG. The mental SF-12 summary was unchanged between treatments and at termination.

In both analyses, a significant improvement was noticed in the physical functioning domain (p < 0.037), where an increase in QoL > 5 points was observed in the IG compared to 0.99 points in the CG. An enhancement was noted in all the other domains of the questionnaire at the end of the treatment, these differences, however, were not statistically significant.

Side effects and adherence

No serious adverse events were reported. Overall adherence to treatment was 86.4% (70/81 patients).

DISCUSSION

This is the first time that CRMRF procedure been assessed by means of a randomized controlled trial (RCT). Our results show that the response to CRMRF therapy (IG) was superior to that reported for the CRMRF sham one (CG) in the treatment of myofascial syndrome, and in a similar manner to other painful disorders.[5,13-15]

Only two previous studies have investigated its efficacy in reducing pelvic perineal pain. One of them was the RCT by Bretelle et al.[11] conducted in postpartum women. They concluded that applying CRMRF to the perineum on the first day following delivery reduced discomfort when walking and decreased paracetamol consumption. The second was a quasi experimental study by Fernández Cuadros et al.[10] They observed a reduction in pain and an improvement in muscle strength after eight sessions of manometric biofeedback followed by CRMRF.

Whilst our study participants differ from those in the trial by Bretelle et al.[11] they are similar to those in the study by Fernández Cuadros et al.[10] The latter, however, was a quasi experimental/before after study which employed neither randomization nor blinding procedures leading to a possibly higher risk of participant selection. Moreover, two therapies were simultaneously applied. In contrast, the present study was designed as a RCT with a greater number of patients and thus providing a stronger and better evidence.

The significant VAS decrease by almost 3 points in the IG group was similar to other findings using CRMRF in various musculoskeletal disorders. [10,14,5] Moreover, it was higher than the minimal clinical important difference described in other chronic pelvic pain populations.[16]

Despite a lower scoring (1 point in the VAS), our CG also showed a reduction in pain intensity which could have been due to the myofascial therapy applied in parallel with sham CRMRF therapy as described by FitzGerald et al.[174]

Before RF, deep thermotherapy, ultrasound, and diathermy were frequently used. Such therapies improve hemoglobin saturation and increase deep tissue temperature more than superficial thermotherapy. Currently, however, they are infrequently used to treat CPPS due to the risk of periosteal inflammation. Moreover, most diathermy devices with frequencies of 8–14 MHz produce excessive heat during treatment which can cause skin burns if a cooling system is not employed.[7–8] CRMRF at 448 kHz does not require of a cooling system as it does not cause excessive heat, making it safer to use than other devices.[5–8,13]

Limitations

Comparing baseline pathologies, there was homogeneity for both groups, except for the characteristic gynecological surgery. Even though, according to the CONSORT statement, it could be understood that any difference might be the result of chance and not a selection bias, we consider we have properly covered this issue as a limitation. On the other hand, we did not take into account this variation between both groups because, in most cases, such interventions had been performed several years before commencement of the pain. Moreover, they did not appear to be either the etiology or trigger of the pain experienced by the patient.

Longer follow-up studies are warranted. Further research determining the most cost-effective way of applying the CRMRF technique is called for, as more prospective studies are required to evaluate response to CRMRF procedure in a larger population, including improvement of the protocol of application.

CONCLUSIONS

The CRMRF technique compared to the same sham technique and demonstrate its superiority in decreasing pain intensity in CPPS patients. In addition, the differences observed in the other patient-reported outcomes, such as health related QoL, denote statistically significant advances.

Both technique applications ameliorated symptoms and to a large extent QoL even though the perception of improvement differed between the two groups. These results, and the ease of use of CRMRF, should encourage more frequent prescription of this procedure.

REFERENCES

1. Ahangari A. Prevalence of chronic pelvic pain among women: an updated review. Pain Physician. 2014;17(2):e141□e147.
2. Grinberg K, et al. A common pronociceptive pain modulation profile typifying subgroups of chronic pelvic pain syndromes is interrelated with enhanced clinical pain. Pain. 2017;158(6):1021□1029.
3. Engeler D et al. Guidelines on chronic pelvic pain. European Association of Urology. 2016.
4. Klotz SGR , Ketels G, Löwe B, Brünahl CA. Myofascial findings and psychopathological factors in patients with chronic pelvic pain syndrome. Pain Med. 2020; 21(2):e34-e44.
5. Kumaran B, Watson T. Treatment using 448kHz capacitive resistive monopolar radiofrequency improves pain and function in patients with osteoarthritis of the knee joint: a randomised controlled trial. Physiotherapy. 2019;105(1):98-107.
6. Yokota Y, et al. Effect of capacitive and resistive electric transfer on tissue temperature, muscle flexibility, and blood circulation. J Nov Physiother. 2017;7:325.
7. Tashiro Y, et al. Effect of capacitive and resistive electric transfer on hemoglobin saturation and tissue temperature. Int J Hyperthermia. 2017;33(6):696-702.
8. Hernández-Bule ML, et al. In vitro stimulation with radiofrequency currents promotes proliferation and migration in human keratinocytes and fibroblasts. Electromagn Biol Med. 2021;40(3):338-352.
9. Melzack R, Wall PD. Pain mechanisms: a new theory. Science. 1965;150(3699):971-979.
10. Fernández-Cuadros ME, et al. [Effectiveness of multimodal rehabilitation (biofeedback plus capacitive-resistive radiofrequency) on chronic pelvic pain and dyspareunia: prospective study and literature review] (Spanish). Rehabilitacion (Madr). 2020;54(3):154-161.
11. Bretelle F, et al. Capacitive-resistive radiofrequency therapy to treat postpartum perineal pain: a randomized study. PLoS One. 2020;15(4):e0231869.
12. Hanno P, et al. Bladder pain syndrome. In: Abrams P, Cardozo L, Wagg A, Wein A, eds. Incontinence. 6th ed. International Consultation on Incontinence; 2017:2203–2301.
13. Notarnicola A, et al. Short term efficacy of capacitive-resistive diathermy therapy in women with low back pain: a prospective randomised controlled trial. J Biol Regul Homeost Agents. 2017;31:509-515.
14. Diego IMA, et al. Analgesic effects of a capacitive-resistive monopolar radiofrequency in patients with myofascial chronic neck pain: a pilot randomized controlled trial. Rev Assoc Med Bras (1992). 2019;65(2):156-164.
15. Duñabeitia I, et al. Effects of a capacitive-resistive electric transfer therapy on physiological and biomechanical parameters in recreational runners: a randomised controlled crossover trial. Phys Ther Sport. 2018;32:227-234.
16. Gerlinger C, et al. Defining a minimal clinically important difference for endometriosis-associated pelvic pain measured on a visual analog scale: analyses of two placebocontrolled, randomized trials. Health Qual Life Outcomes. 2010;8:138.
17. Fitzgerald MP, et al. Urological pelvic pain collaborative research network. Randomized multicenter feasibility trial of myofascial physical therapy for the treatment of urological chronic pelvic pain syndromes. J Urol. 2013;189(1, suppl):S75-S85.