

Effects of capacitive and resistive electric transfer therapy in patients with painful shoulder impingement syndrome: a comparative study

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Abstract

Objective: Capacitive and resistive electric transfer therapy (CARE) reduces pain and improves quality of life for many orthopaedic degenerative and inflammatory disorders. The research aim was to determine the effects of CARE on painful shoulder. The outcomes were pain reduction and recovery of shoulder function.

Methods: A retrospective, observational case-control study was conducted. Participants were 46 patients (22 in the CARE group and 24 in the SHAM group). Clinical data, pain (visual analogic scale, VAS) and functional scale scores (Disabilities of the Arm, Shoulder and Hand scale, and Constant–Murley Scale) were measured at baseline T0 (before treatment), T1 (after treatment) and follow-up T2 (2 months after the end of the treatment).

Results: VAS scores in the CARE group improved from 7.23 ± 1.11 at baseline to 2.68 ± 0.99 at follow-up. The SHAM group did not experience any improvement. Similarly, functional scale scores improved in the CARE group compared with the SHAM group.

Conclusion: Considering the small number of sessions needed, low cost and long-term benefits, CARE could be a useful therapeutic option for the conservative management of shoulder pain to restore pain-free and powerful movement to the shoulder joint.

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Keywords

Diathermy, thermotherapy, shoulder pain, rehabilitation, capacitive and resistive electric transfer therapy, case-control study

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Introduction

Capacitive and resistive electric transfer therapy (CARE), an endogenous diathermic treatment, reduces pain and improves quality of life for several orthopaedic degenerative and inflammatory problems.¹ Its positive effects include greater blood circulation, which allows the removal of inflammatory catabolites.^{2,3} Bito et al.⁴ reported that CARE substantially improves blood circulation in the peritendinous region and increases haemoglobin saturation. In addition, CARE therapy warms deep tissue;⁵ the resulting greater vascularization promotes the relaxation of tissues (especially muscular tissue) and drainage of swelling (oedema and haematoma).

Based on these properties, CARE therapy is used in many orthopaedic pathologies, such as painful shoulder, before rehabilitation exercises are started. Despite the widespread use of CARE in the rehabilitative field, scientific evidence of its effectiveness for painful shoulder is limited and equivocal. Yokota et al.⁶ analysed the effects of CARE therapy (15 minutes of intervention) on muscle flexibility and lumbar-pelvic alignment after fatiguing exercise for other pathologies, such as back pain. They found good results for CARE compared with a control (15 minutes of rest).

Research using microwave diathermy, a form of physical therapy that uses endogenous heat (also known as hyperthermia), has also shown good efficacy for shoulder pathologies. For example, several groups

have demonstrated that microwave diathermy has positive effects on shoulder dysfunction and pain that are equivalent to those of subacromial corticosteroid injections, and is particularly effective for subacromial impingement syndrome without night pain.^{7,8} However, CARE therapy can be applied without heat, with mild heat and during hyperthermia. Thus, it is possible to use CARE for all pathological phases from acute to chronic. In contrast, microwave diathermy works only at high temperatures and is thus indicated preferentially for post-acute and chronic phases.^{1,9}

Rotator cuff tendinopathy is the most common painful non-traumatic shoulder condition, affecting approximately 20% of the population and increasing in prevalence with age.^{10,11} As the pain assumes the characteristics of an acute condition, CARE therapy could be a useful tool in the rehabilitation of this condition.

Rotator cuff-related shoulder pain is an overarching term that encompasses a spectrum of shoulder conditions, including subacromial pain (impingement) syndrome, rotator cuff tendinopathy, and symptomatic partial and full thickness rotator cuff tears. Patients with such problems present with pain on elevating the arm or when lying on the affected side. Moreover, shoulder pain is the third most common musculoskeletal complaint in orthopaedic practice.^{12,13} In light of these findings, the research aim was to determine the effects of CARE therapy on painful shoulder. The primary outcome was the assessment of pain reduction and the

secondary outcome was the recovery of shoulder function.

Material and methods

Study design and population

This retrospective, observational case-control study was conducted to determine the efficacy of CARE therapy for the rehabilitation of shoulder pain and followed the Strobe guidelines.¹⁴ Fifty (N = 50) patients with shoulder pain were enrolled from the physical medicine and rehabilitation outpatient clinic of CUMS G. d'Annunzio University of Chieti-Pescara from September 2018 to December 2018.

The inclusion criteria were age 20 to 50 years; diagnosis of impingement syndrome (Neer stage 2 or 3) and shoulder pain (visual analogic scale, VAS) that had lasted less than 1 month (acute phase, VAS score >3);^{15,16} x-ray images of the anteroposterior, axillary, and outlet views and magnetic resonance imaging of the affected shoulder to complete the diagnosis. The exclusion criteria were patients who had undergone previous shoulder surgery or rehabilitative treatment in the last 3 months; inflammatory, neurological (systemic or local) or infectious disease; cognitive or psychiatric disorders; tumour; use of medications that could have affected shoulder pain; noncompliance; and pacemaker.

This study was performed according to the guidelines of the Helsinki declaration on human experimentation and was approved by the ethical committee of G. d'Annunzio University of Chieti (Italy). All patients gave written informed consent after receiving detailed information on the study aims and procedures. Clinical data were collected at baseline T0 (before treatment), T1 (after treatment) and follow-up T2 (2 months after the end of the treatment). We excluded patients receiving any other type of physiotherapy during the study period, restricting

treatment to exercise until follow-up to avoid evaluation bias regarding the effect of CARE therapy. The rehabilitative exercise, where necessary, was prescribed after the evaluation at the follow-up according to good clinical practices, but the results did not form part of this study.

Outcome measures

The VAS was used to measure shoulder pain outcomes. Patients were asked to mark the point that corresponded to their perceived pain intensity on a 10-cm line; 0 indicated the absence of pain and 10 reflected the most severe pain.¹³ The short form of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was used to estimate the physical ability and symptoms of the upper extremities and examine the impact of functional impairment and pain on daily living tasks, social and recreational activities, work and sleep. DASH scores ranged from 0 to 100 points; 0 reflected no disability and 100 corresponded to the most severe disability.^{17,18} The Constant–Murley Scale (CMS) was used to measure shoulder function. The CMS assesses subjective (sleep, work and recreational activities) and objective (range of motion and strength) components, adjusted for age and sex, according to normative values (Yian et al.);¹⁹ scores range from 0 (worst result) to 100 (best result).²⁰ Two experimenters administered the questionnaires, both of whom were blind to each patient's assigned group.

Rehabilitative treatment

Rehabilitative treatment using CARE therapy and SHAM was applied for 3 weeks (nine sessions, three times per week).

CareTherapy[®]

The CareTherapy[®] (compliant with Directive 93/42/CEE-EN60601, TecnoBody, Dalmine, Italy) treatment group received

20 minutes of shoulder treatment. Patients were treated passively in a comfortable sitting position.

The treatment started with an automatic capacitive energy transfer for 10 minutes. The active (capacitive) electrode (18×15 cm) was positioned near the proximal insertion of the biceps brachialis. The neutral rectangular steel electrode (20×11 cm) was positioned between the T1–T9 vertebrae (parallel to the long side of the spinous processes of the vertebrae above). Next, the capacitive plaque was pulled out and replaced by the resistive electrode, and the neutral electrode was fixed (Figure 1).

The entire treatment area was covered with a layer of high-conductivity cream, to ensure contact between the active electrodes (both capacitive and resistive) and the surface of the skin and thus better distribution of endogenous thermotherapy.

Specifically, we used a power of 100 W for the capacitive mode and 200 W for the resistive mode to induce a biostimulating effect with increased consumption of adenosine triphosphate (ATP) and oxygen. This produces an analgesic effect owing to minimum thermal increase, which reduces nociceptor activity, and a slight thermal effect that increases tissue metabolism.²¹ A super-low-frequency output of 100 Hz was provided in pulsed mode to allow better dissipation of the induced heat using a duty cycle. This cycle represents the quotient of the total active time of the emitted signal and the sum of the pauses; it is expressed as a percentage of the application time.

The control group underwent the same procedures as the CARE group at the same time but with the CareTherapy® medical device turned off.

Statistical analysis

The sample size was calculated with pain intensity (VAS score) as the primary outcome. A power analysis of 90% and alpha

level of 0.05 were considered, with a difference of 2 points (cm), assuming a standard deviation of ± 1.5 for VAS score in relation to the minimal clinically important difference between groups after treatment.²² Thus, the analysis yielded 16 patients per group; based on a 20% potential dropout rate, we included 22 patients per group.

Data were collected at T0, T1 and T2 to determine whether the conditions improved in treated and untreated patients. Differences in the mean values of CMS, DASH and VAS scores at these time points in each group were evaluated using two-way analysis of variance (ANOVA) for repeated measures, followed by Tukey's post-hoc test. The normality of the data distribution was tested using the Jarque–Bera test, and the covariance sphericity was analysed using the Mauchly test. The variables violated the normality and sphericity assumptions; thus, the data were transformed. We found an exponent, λ , for which the assumptions were respected. λ was 0.15 for VAS, 0.6 for DASH and 0.15 for CMS scores. Before the parametric analysis, descriptive statistics were used to describe the sample. The χ^2 test was used to test the independence between treatment groups and sexes. Differences were evaluated for P -values < 0.05 . The tests were performed in R (R Foundation for Statistical Computing, Vienna, Austria).

Results

Four patients were excluded: three did not meet the inclusion criteria and one declined to participate. Finally, 46 patients were randomized into two groups (sample randomization 1:1): 22 in the CARE therapy experimental group (cases) (9 women and 13 men) and 24 in the SHAM group (controls) (12 women and 12 men).

Table 1 shows the descriptive statistics for each variable for the two groups. P -values for comparisons of baseline

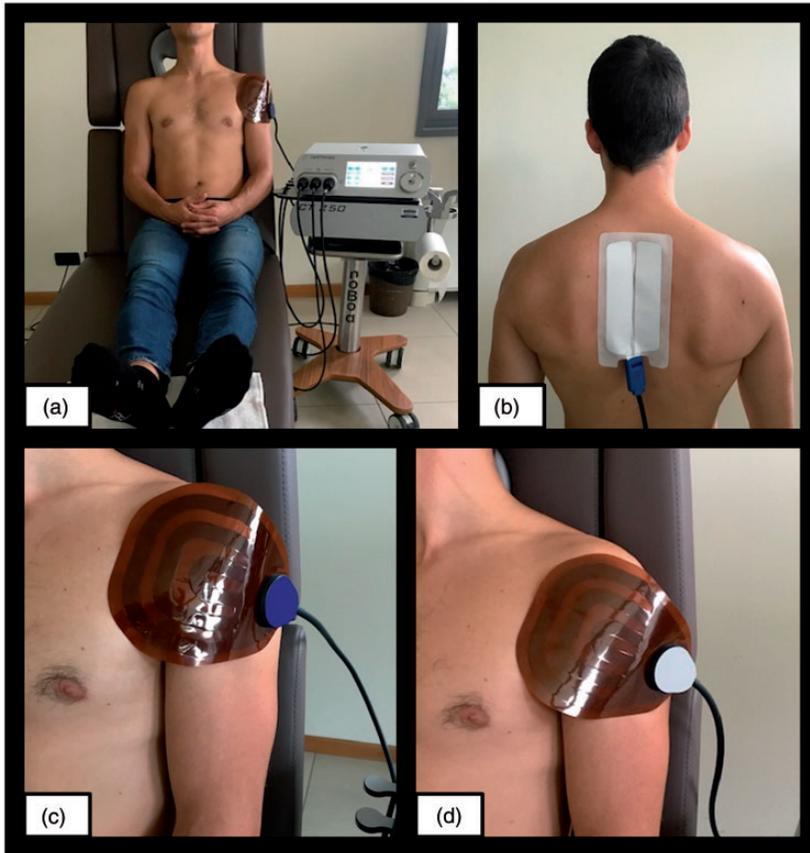


Figure 1. CareTherapy[®] treatment. (a) The patient is seated in a comfortable position during the therapy. (b) Positioning of the neutral rectangular steel electrode (20×11 cm). (c) Positioning of the capacitive static electrode (Kapton-coated copper, dimensions 18×15 cm) on the shoulder to be treated. (d) Positioning of the static resistive electrode (silver, dimensions 18×15 cm) on the shoulder to be treated.

differences and for comparisons of scores over time are shown. The experimental group showed significant decreases on scores for each variable (VAS: $P=0.045$; DASH: $P=0.055$; CMS: $P=0.046$) whereas the control group scores remained constant compared with baseline (Figures 2, 3 and 4). VAS scores for the CARE group dropped from 7.23 ± 1.11 at baseline to 2.68 ± 0.99 at follow-up.

Table 2 shows the results of the two-way ANOVA, which confirmed a between-group difference in variables over time.

There was a statistically significant main effect for group and time (all $P < 0.001$, except the between-group difference in DASH scores of $P < 0.05$) and a significant interaction between group and time (all $P < 0.001$).

Discussion

The study aim was to assess the effects of CARE therapy versus SHAM treatment for painful shoulder. Our results are encouraging. Considering pain reduction as the main

Table 1. Descriptive data for the two groups

Descriptive Statistics			
Variables	CARE group (N = 22) Mean \pm SD	SHAM group (N = 24) Mean \pm SD	P-values for baseline differences
AGE (years)	52.45 \pm 19.60	45.75 \pm 18.28	0.234
Height (m)	1.66 \pm 0.08	1.68 \pm 0.08	0.425
Weight (kg)	67.73 \pm 8.91	65.12 \pm 11.79	0.559
BMI (kg/m ²)	24.56 \pm 2.00	23.14 \pm 3.46	0.117
VAS (cm) T0	7.23 \pm 1.11	6.62 \pm 1.06	0.045
VAS (cm) T1	2.09 \pm 1.51	6.33 \pm 1.27	
VAS (cm) T2	2.68 \pm 0.99	6.58 \pm 1.1	
DASH T0	47.70 \pm 25.78	33.49 \pm 19.85	0.055
DASH T1	18.02 \pm 12.02	34.05 \pm 19.50	
DASH T2	16.77 \pm 12.72	34.23 \pm 19.82	
CMS T0	31.63 \pm 11.55	38.50 \pm 11.10	0.046
CMS T1	66.05 \pm 22.11	37.75 \pm 10.84	
CMS T2	64.95 \pm 21.40	37.75 \pm 10.84	
SEX	Male 13 Female 9	Male 12 Female 12	0.750

SD: standard deviation; BMI: body mass index; VAS: visual analogic scale; DASH: Disabilities of the Arm, Shoulder and Hand; CMS: Constant–Murley Scale.

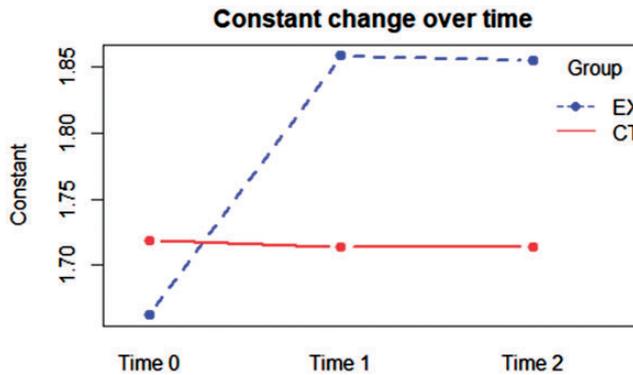


Figure 2. CMS score change over time for experimental (Ex) and control (CT) groups. CMS: Constant–Murley Scale.

outcome, the CARE group responded positively to the treatment. Their VAS scores decreased from 7.23 ± 1.11 at baseline to 2.68 ± 0.99 at follow-up, a statistically significant improvement that was within the

minimal clinically important difference.²² In contrast, the SHAM group showed unchanged pain values at T0 and follow-up, indicating no improvement (and not even a placebo effect).²³ For this acute

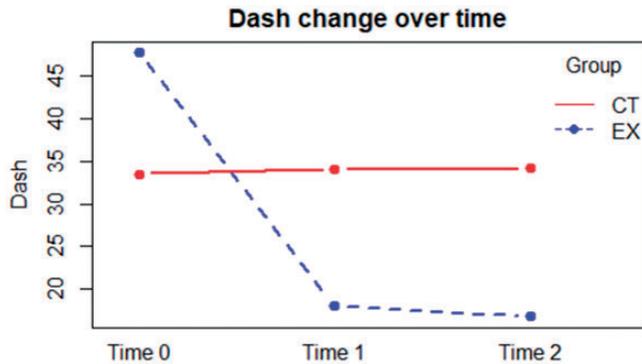


Figure 3. DASH score change over time for experimental (EX) and control (CT) groups. DASH: Disabilities of the Arm, Shoulder and Hand.

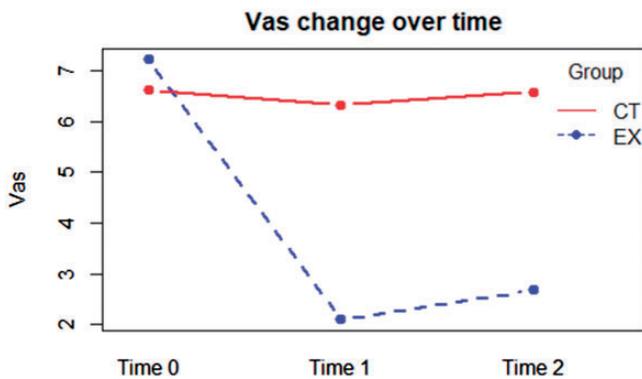


Figure 4. VAS score change over time for experimental (EX) and control (CT) groups. VAS: visual analogic scale.

pain condition, we did not observe any fluctuating symptoms typical of chronic painful conditions, such as exacerbation, remission and recurrence.²⁴ The mitigation of shoulder pain, which paralleled the improvement in function, prepared the patient for rehabilitative exercise: manual therapy reduces the signs and symptoms of extrinsic subacromial shoulder impingement more if the pain before rehabilitative treatment is not high.²⁵

The innovative technical characteristics of CARE therapy allow the transfer of high energy levels without causing significant temperature increases, thus achieving

excellent results, even for acute pain associated with shoulder impingement syndrome. The typical characteristics of shoulder impingement in Neer stage I are reversible lesions with oedema and haemorrhage. In stage II, chronic inflammation or repeated episodes of impingement lead to histomorphological changes, such as fibrosis and thickening of the supraspinatus, the long biceps tendon and subacromial bursae. In stage III, rotator cuff tears, rupture of the biceps tendon and bony changes may be observed, accompanied by significant tendon degeneration following a long history of refractory tendinitis.²⁶ Pain and

Table 2. Analysis of variance results for between- and within-group comparisons

Two-way ANOVAs			
Factors	P-value (effect size – eta squared)		
	CMS	DASH	VAS
Group	<0.001 (0.11)	<0.05 (0.03)	<0.001 (0.26)
Time	<0.001 (0.13)	<0.001 (0.12)	<0.001 (0.24)
Group × Time	<0.001 (0.16)	<0.001 (0.13)	<0.001 (0.23)

ANOVA: analysis of variance; VAS: visual analogic scale; DASH: Disabilities of the Arm, Shoulder and Hand; CMS: Constant–Murley Scale.

inflammation have been traditionally conflated, but lack of consistent nomenclature for histopathologic findings has limited progress in understanding the pathologic basis of tendinopathies, which are characterized by absence of inflammatory cells and a tendency for poor healing.^{27,28} The resistive-capacitive energy transfer generation effect of CARE therapy has a thermal and non-thermal effect on tissues, although there is more research validation of thermal effects than of non-thermal effects.³ As CARE therapy exploits the heat effect, it can be assumed that its biological effect is related to hyperthermia, as used in different forms of thermotherapy. Increased tissue temperature causes arteriolar and capillary dilatation, and consequent greater blood flow to tissues, leading to higher cellular metabolism and greater tendon and muscle flexibility; in fact, heat improves the contractile performance of muscle, as it increases adenylypyrophosphatase (ATPase) activity and changes the mechanical properties of collagen in tendons.²⁹ As Giombini et al. have discussed, hyperthermia treatment is associated with an increase in nutrients and oxygen in the heated region. In particular, nutrients and oxygen are critical for all anabolic processes, and (together with pH normalization) are necessary for tissue repair.^{30,31}

Another property of CARE therapy is attributed to the classical resistive-capacitive energy transfer generator of

pulse width modulation (PWM) technology.³² This creates a square wave with a constant repetition frequency and variable duration (duty cycle), which allows very precise control of the power absorbed by an electrical load by varying the duty cycle. The emitted PWM signal is over-modulated with a low-frequency signal (100–200–300 Hz), which facilitates the respiratory mechanisms of cells, increasing metabolic reactions and releasing substances (fibroblasts) that stimulate tissue repair processes.³³ This association substantially reduces the dissipated power, allowing the heat that is generated to be controlled at tolerable levels for the patient without limiting the average power that is supplied.

Further, although CARE therapy is delivered in a static mode, it has a substantial muscle-relaxing effect, which facilitates shoulder rehabilitative exercises.^{5,6} In particular, the use of static electrodes avoids the bias caused by differences in operator skill and training. The massage that the therapist performs with the hand piece in classical diathermy renders the treatment operator-dependent, which may cause bias.

Notably, no side effects were reported during CARE therapy for either group. Positive effects on shoulder pain have been found for other similar physical therapy modalities. For example, one study showed that pulsed yttrium aluminium garnet (YAG) laser combined with exercise

was more effective for treatment of rotator cuff tendinopathy than sham laser treatment with exercise.³⁴ Future randomized controlled trials should examine the combined effects of CARE and exercise, as most studies have shown no difference in outcome between impingement syndrome patients randomized to surgical decompression or conservative management.³⁵ Thus, it is always desirable to start with conservative rehabilitation treatment, administering surgical treatment only in select cases. The optimal treatment for shoulder impingement syndrome remains unknown,²⁶ and exercise is still the most important treatment component for this disorder.

Limitations

Exercise alone can improve shoulder pain; however, we did not include a third exercise group as comparison, as the main study focus was to address the research gap on the effectiveness of CARE therapy. Therefore, further studies are needed to compare the effects of CARE therapy with other treatment modalities.

Strengths

This research is the first attempt to determine the effects of CARE therapy on acute shoulder pain using low-frequency fields.

Conclusion

Considering the small number of sessions needed, low cost and long-term benefits, CARE is a useful therapeutic option for the conservative management of shoulder pain to restore pain-free and powerful movement to the shoulder joint. Moreover, conservative treatment with CARE provides an opportunity for recovery and increases the function and quality of life in patients with shoulder impingement syndrome. Further research with long-term follow-up is needed to confirm our results.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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