Combined ultrasound and electric field stimulations improve pain and functional capacity in immediate cesarean delivery: a randomized clinical trial, double-blind, and placebo-controlled

Terapia combinada de estimulação elétrica por meio do ultrassom melhora a dor e a capacidade funcional no pós-parto imediato de cesariana: ensaio clínico randomizado, duplo-cego e placebo

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ABSTRACT

BACKGROUND AND OBJECTIVES: Wound complications and pharmacological pain relief methods used at the skin surgical site after cesarean delivery may result in women's physical and emotional burden. Thus, nonpharmacological treatments must be explored to avoid these complications and side effects on maternal health. The objective of this study was to investigate the effects of Combined Ultrasound and Electric Field Stimulation (CUSEFS) on cicatricial pain and functional capacity in immediate cesarean delivery.

METHODS: This study has a randomized clinical trial, double-blind, and placebo-controlled design. Thirty women (25.7±5.0 years) in immediate postpartum were randomly assigned to three groups: Control (CG, n:9), CUSEFS (TG, n:11), and Placebo (PG, n:10). CUSEFS was performed once for 20 minutes. Cicatricial pain (McGill Pain Questionnaire) and functional capacity (Functional Capacity Check) was assessed at baseline, after the intervention, and after 30 minutes. Cohen's (d) and Mixed-design analysis of variance were used to compare groups.

RESULTS: Immediately after the intervention, TG showed a decrease in cicatricial pain compared with CG in sensory (d:3.8 to 4.0), affective (d:4.0), and total categories (d:3.9). In functional capacity, TG had less difficulty than CG at walking (d:0.6) and lying down (d:1.1), and PG at rest (d: 0.9).

CONCLUSION: CUSEFS might be a resource for managing cicatricial pain and functional capacity in immediate cesarean delivery. Further studies with longer duration and different CUSEFS doses/parameters are required.

Keywords: Cesarean section, Combined modality therapy, Electric stimulation therapy, Pain, Ultrasonic therapy.

RESUMO

JUSTIFICATIVA E OBJETIVOS: As complicações na ferida e o uso de métodos farmacológicos de alívio da dor no local cirúrgico após a cesariana podem resultar em sobrecarga física e emocional para a mulher. Assim, tratamentos não farmacológicos devem ser explorados para evitar essas complicações e efeitos colaterais à saúde materna. O objetivo deste estudo foi investigar os efeitos da terapia combinada de estimulação elétrica por meio do ultrassom (CUSEFS) na dor cicatricial e na capacidade funcional no pós-parto imediato de cesariana.

MÉTODOS: Este estudo possui um desenho de ensaio clínico randomizado, duplo-cego e controlado por placebo. Trinta mulheres (25,7±5,0 anos) em pós-parto imediato de cesariana foram distribuídas aleatoriamente em três grupos: Controle (CG, n:9), CUSEFS (TG:11) e Placebo (PG, n:10). O CUSEFS foi realizado uma vez por 20 minutos. A dor cicatricial (Questionário de Dor McGill) e a capacidade funcional (Functional Capacity Check) foram avaliadas no início, após a intervenção e após 30 minutos. As análises de variância de design misto e Cohen (d) foram usadas para comparar os grupos.

RESULTADOS: Imediatamente após a intervenção, o TG apresentou diminuição na dor cicatricial em relação ao CG nas categorias sensorial (d:3,8 a 4,0), afetiva (d:4,0) e total (d:3,9). Na capacidade funcional, o TG apresentou menor dificuldade que o CG na marcha (d:0,6) e deitado (d:1,1), e que o PG em repouso (d:0,9).

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HIGHLIGHTS
- Combined Ultrasound and Electric Field Stimulation (CUSEFS) might be a resource in immediate cesarean delivery
- CUSEFS was successful for managing cicatricial pain in immediate cesarean delivery
- CUSEFS was effective in improving functional capacity in immediate cesarean delivery

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CONCLUSÃO: O CUSEFS pode ser um recurso para o manejo da dor cicatricial e da capacidade funcional imediatamente após a cesariana. Além disso, são necessários mais estudos com maior duração e diferentes doses/parâmetros de CUSEFS.
Descritores: Cesariana, Dor, Terapia combinada, Terapia por estimulação elétrica, Ultrassom.

INTRODUCTION

Cesarean delivery is now the most common obstetric surgery performed worldwide[1]. Wound complications at the surgical skin site, such as hyperemia, ecchymosis, hematoma, edema, cicatricial pain, and infection, occur in up to 16% of cesarean deliveries. These complications can lead to physical and emotional distress for women, less contact with the baby, prolonged hospital stay, readmission, delay in return to occupational functions, persistent cicatricial pain, increased opioid use, and increased health care costs[2,3]. Additionally, after cesarean delivery, it is common to observe deficits in range of motion and functional capacity in the immediate postpartum, facts that might impact the care offered to the newborn and self-care[4].

The American Pain Society guidelines for the management of postoperative pain list several options for nonpharmacologic therapies, including electrical therapy and thermotherapy[5]. Transcutaneous Electrical Nerve Stimulation (TENS) is a type of mild electrical current that involves delivering short electrical impulses from a battery-operated device via electrode pads attached to the skin close to the affected area, and it has been used to reduce postoperative pain[6,7] and improves functional capacity after cesarean section[6]. Likewise, High-frequency Ultrasound (HFU) therapy is also used in human dermal fibroblasts to accelerate wound healing[8]. Ultrasound has been found to stimulate wound recovery by increasing angiogenesis, fibroblast stimulation, collagen production, and macrophage responsiveness[9]. However, considering that electric current and ultrasound can be used to relieve pain after cesarean section and resolve the healing process, the combination of these two therapeutic modalities could enhance the effect of one modality alone.

Ultrasound combined with electrical therapy, also called "Combined Ultrasound and Electric Field Stimulations" (CUSEFS)[9], consists of the therapeutic application of an electric current through the ultrasound transducer, and both treatments are applied simultaneously[10]. There is convincing evidence of the effects of CUSEFS on fibromyalgia-related pain[11], foot ulcers[9], and knee osteoarthritis[10]. Research also suggests that CUSEFS can also be used to accelerate acute wound healing[9,12]. In contrast, there is still a lack of evidence for CUSEFS[13,14], and its utility in surgical incisions is sparse and unclear in humans[12,13]. Additionally, previous studies have shown that the use of pharmacological pain relief methods led to residual discomfort and adverse side effects, including residual pain, negative encounters with healthcare providers and the baby, affecting not only physical aspects (e.g., nausea and sedation) but also emotional like sense of failure and depression[15]. Considering these assumptions, this study aimed to evaluate the effect of CUSEFS (TENS and HFU) on cicatricial pain and functional capacity in immediate cesarean delivery.

METHODS

The present study had a randomized, double-blind (investigator and participants in all evaluations and procedures), and placebo-controlled clinical trial design. The investigator and participants were blinded to group assignments. To ensure the blinding of the evaluation and protocols, there was no contact between the evaluators and the researchers who performed the experimental procedures and there was no information exchange between the evaluator and the participant. In this way, there was a guarantee that all stages of evaluation and participation in this study were blinded.

The eligibility criteria were as follows: (a) women aged 18-40 years; (b) a minimum of 8 hours and a maximum of 40 hours after cesarean delivery; (c) immediate cesarean delivery cicatricial pain; (d) no immediate postpartum adverse events (bleeding, infection, febrile anesthesia complications, and chest incidences), epilepsy diagnoses, demyelinating diseases, spinal cord injury, tumors, diabetes mellitus and arterial hypertension; (e) no use of pacemakers or implanted electronic devices; (f) absence of signs of local drainage system; and (g) absence of self-reported irritation or intolerance to the use of TENS or HFU.

Initially, 55 women were recruited by spontaneous demand in a public hospital from Curitiba – Brazil, and the assessments were performed between April to December 2017. After applying the eligibility criteria, 30 women were randomly allocated into three groups: control (CG), CUSEFS (TG) and placebo (PG). For the allocation into groups, the women were placed on a list, with a random draw being carried out for distribution among the groups. The allocation ratio was 1:1:1. More details of the group allocation in figure 1. No participant dropped out of the intervention.

The sample size was calculated *a priori* by the G*Power program and was based on a study[9] that showed an effect size of 0.77 in the "limitation because of physical health" domain after the CUSEFS intervention. In addition, the following parameters were considered: (1) F test (analysis of variance [ANOVA]); (2) a 95% confidence level; (3) a sampling error of 3%; (4) power analysis of 80%; (5) number of groups = 3; (6) number of measures = 3 (T0, T1 and T2 evaluations); and (7) a 10% margin for possible losses. Therefore, the initial sample estimated 26 women (Power of 86%) was allocated into three groups. Thus, 30 participants completed all procedures (CG, n = 9, 29.0 ± 6.2 years; TG: n = 11, 26.7 ± 4.9 years; PG: n = 10, 21.4 ± 3.9 years;). Figure 1 shows the group allocation and experimental design.

The same physiotherapist treated both groups (TG and PG) with the same procedures (skin preparation, electrode placement and stroking technique). TG received CUSEFS for 20 minutes, while at PG the devices remained on to simulate application but delivered no electrical stimulus. CG performed only routine nursing care in the hospital. To ensure that the participants did not know about their allocation groups, all women performed the same routine nursing care in the hospital and there was no contact bet-

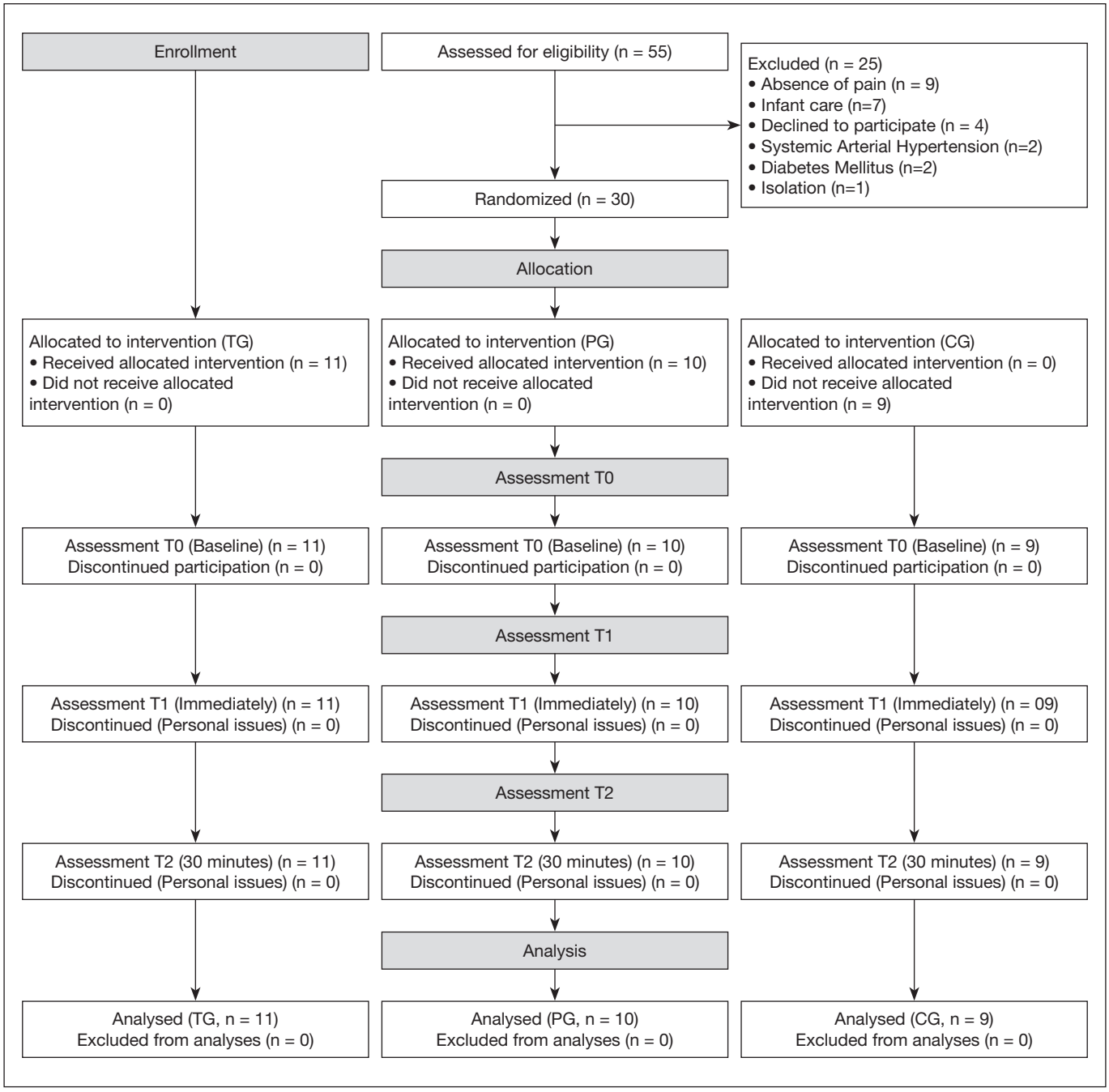

Figure 1. Flowchart of the study and participants allocation in control (CG), CUSEFS (TG), and placebo (PG) groups

ween them, thus the participants did not identify which procedures were performed with their peers. This study was approved by Health Sciences Research Ethics Committee of the Health Sciences, at Federal University of Paraná (*Universidade Federal do Paraná* - Opinion Number: 2.027.597), and was registered at the Brazilian Clinical Trials Registry (*Registro Brasileiro de Ensaios Clínicos* - RBR-6wq24d) and adhered to the CONSORT guidelines[16]. All subjects gave written informed consent prior to study participation.

The technique of transverse incision of the lower segment was used in all sample for cesarean section. No dressing was used at the incision site and the area was kept dry. The surgical wound was cleaned during bathing or, if necessary, with sterile gauze soaked in saline. After delivery, patients were transferred to the obstetric ward which was part of rooming-in. For immediate cesarean delivery treatment, dipyrone (500mg 6/6h), ketoprofen (100mg 8/8h), diclofenac (50mg 8/8h) and acetaminophen (500mg 6/6h) were administered during the first 24 hours. Additional analgesics or anti-inflammatory drugs were administered if the patient desired. Patients were encouraged to get up early after delivery and do their normal daily activities without restrictions.

The assessment was performed at baseline (T0), immediately after the procedure (T1) and after 30 minutes of procedure application by a blinded rater (T2); each assessment was performed

in the participant's bed lasting approximately 15 minutes, and in case of need for breastfeeding the assessment was momentarily interrupted and was continued after the end of breastfeeding. The initial evaluation followed the methodology proposed by a study[17] which considers the minimum interval of eight hours after delivery to avoid acute disruption of postanesthetic recovery, while the maximum time of 40 hours is related to the acute phase of the injury and the peak of the inflammatory process. Participants were interviewed, in a single session of 15 minutes, in the following order: an initial screening with personal and clinical characteristics collected from medical records, qualitative aspects of cicatricial pain (McGill Pain Questionnaire)[18] and functional capacity (Functional Capacity Check)[19]. In summary, the participant was assessed at T0 (baseline), the intervention was applied for 20 minutes, then T1 assessment occurred and after 30 minutes of completion of the intervention the participant was last evaluated in T2.

The McGill Pain Questionnaire (MPQ) was used to measure cicatricial pain quality and intensity. The Brazilian-Portuguese MPQ was found to be reproducible, valid, and responsive for the assessment of pain[18]. The questionnaire consists of 78 pain words representing four dimensions (sensory, affective, evaluative, and miscellaneous). The scoring system is calculated as follows: (1) Pain Rating Index (PRI): sum of word rank values chosen by the participant; (2) Number of Words Chosen (NWC): sum of the words chosen; and (3) Present Pain Intensity (PPI): the combination of the numerical score with quality of cicatricial pain to determine the intensity of global pain. Higher scores indicate more severe cicatricial pain. The Functional Capacity Check, developed by a study[19] and adapted with a 10 point-Likert scale, was used to assess functional capacity. Participants were asked to perform activities of daily living (resting, sitting, standing, walking, and lying down) and specify which item best described their difficulty in performing each activity (zero = no difficulty, 10 = unable to perform the activity).

In the intervention program, TG underwent CUSEFS with TENS and HFU performed by the Sonophasys device (KLD Biosystems, Brazil). This device emits an electric current through the ultrasound transducer, generating simultaneously sound pulses and electric current flow. For dosing, each parameter was selected based on previous scientific findings[12]. The parameters of TENS were set to highly modulated frequency pulses (100 Hz), with a phase duration of 100 microseconds and an asymmetric biphasic waveform with a continuous pattern. The intensity was set at the sensory level (strong numbing sensation, maximally tolerable but without muscle contraction or pain). HFU was set with a 3MHz transducer, an effective radiating contact area of 5 cm^2, a beam nonuniformity ratio BNR of <5.6, a pulsed mode (100 Hz), a duty cycle of 20%, a spatial and temporal average intensity of 0.5 W/cm^2 and 0.1 W/cm^2, respectively, and a therapeutic dose of 6 J/cm^2.

CUSEFS was performed for 20 minutes by direct contact with water-soluble gel around the wounded area. Manual linear sliding of the HFU with constant transverse motion (velocity approximately 1cm^2/second) was performed in parallel 1cm below and above the cesarean section, but not below. In addition, a TENS conductive silicone electrode (5 x 5 cm) with water-soluble gel was wrapped in the left hemidium, 4 cm above the iliac crest (figure 2). During the experimental protocol, women remained supine with their knees extended and in a neutral hip position. All asepsis procedures were performed according to hospital guidelines.

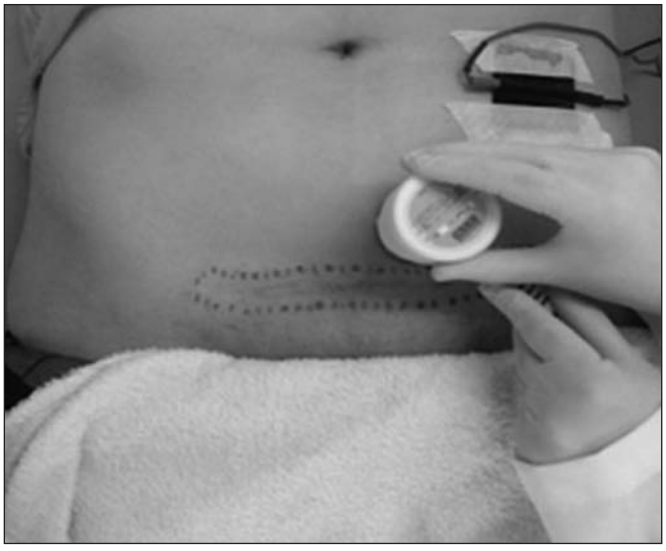

Figure 2. Combined ultrasound and electric field stimulation schematic representation

Statistical analysis

Descriptive statistics (mean and standard deviation for continuous data and frequency and percentage for categorical data) were performed to characterize the groups. Data normality, sphericity and homogeneity of variance were tested using Kolmogorov-Smirnov, Mauchly, and Levene tests. Categorical data were analyzed with Pearson's Chi-squared to examine the differences between groups (CG, TG vs. PG). Mixed-design analysis of variance and Bonferroni *post hoc* tests were used to compare between groups (CG, TG vs. PG) and assessment time points (T0, T1 and T2). In addition, Cohen's effect size (d) was calculated to check the magnitude of the observed effects. A small (d < 0.50), medium (0.50 to 0.79), large (0.80 to 1.29) and huge effects (d >1.29) were assumed. Statistical procedures were performed using SPSS software, version 22, and the significance level was set at $p<0.05$.

RESULTS

The examined population consisted of 30 women (25.7±5.0 years). Most of the women were married (CG: 16.7%; TG: 20%) or single (PG: 16.7%), with secondary incomplete/complete (CG: 23.3%; TG: 20%; PG: 16.7%), employed (CG and PG: 26.7%; TG: 13.3%), without smoking or alcohol habits. In the gestational characteristics, most of them were primiparous, with an unplanned pregnancy, without risk pregnancy, with slight overweight, similar gestational age (39 weeks), delivery duration and newborn weight. No significant differences were found in sociodemographic and clinical characteristics ($p>0.05$). A detailed description of the groups is presented in table 1.

Table 1. Sociodemographic and clinical characteristics of the participants (n = 30)

Variables	CG (n = 9) n(%)	TG (n = 11) (n(%)	PG (n = 10) (n(%)
Marital Status			
Married	5 (16.7)	6 (20.0)	4 (13.3)
Single	4 (13.3)	5 (16.7)	5 (16.7)
Separated	0 (0.0)	0 (0.0)	1 (3.3)
Schooling level			
Primary incomplete/complete	1 (3.3)	4 (13.3)	3 (10.0)
Secondary incomplete/complete	7 (23.3)	6 (20.0)	5 (16.7)
College incomplete/complete	1 (3.3)	1 (3.3)	2 (6.7)
Occupational status			
Employed	8 (26.7)	4 (13.3)	8 (26.7)
Housewife	1 (3.3)	5 (16.7)	2 (6.7)
Student	0 (0.0)	2 (6.7)	0 (0.0)
Lifestyle			
Smoking habits	1 (3.3)	1 (3.3)	0 (0.0)
Alcohol consumption	4 (13.3)	0 (0.0)	3 (10.0)
Gestational characteristics			
Primiparous	4 (13.3)	8 (26.7)	5 (16.7)
Planned pregnancy	5 (16.7)	2 (6.7)	2 (6.7)
Risk pregnancy	4 (13.3)	2 (6.7)	1 (3.3)
	Mean (SD)	Mean (SD)	Mean (SD)
Gestational BMI (kg/m^2)	31.0 ± 3.8	31.0 ±4.3	29.9 ±5.2
Gestational age (weeks)	39.2 ±1.3	39.6 ± 1.5	39.0 ± 1.2
Delivery duration (min)	61.3 ± 16.4	58.5 ± 26.2	40.8 ± 12.3
Newborn weight (grams)	3381 ± 579.6	3619 ± 465.1	3241 ± 525.6

BMI = Body mass index; CG = Control Group; TG = CUSEFS Group (CUSEFS: Combined Ultrasound and Electric Field Stimulations); PG = Placebo Group; Categorical data: Chi-squared test; Continuous data: One-Way Anova.

There was no difference in the technique of skin approximation after cesarean (p = 0.953), indicating the similarity between the groups. In T0, cicatricial pain (NWC, PRI and PPI) was similar between groups (p>0.05), except for the PPI baseline analysis for the sensory dimension. The interaction effect between cicatricial pain and group was statistically significant, in NWC total [F(4, 54) = 2.64, p = 0.04] and Sensory PRI [F(4, 54) = 2.85, p = 0.03]. *Post-hoc* comparisons using Bonferroni test in T1, indicated that TG decreased the mean scores in PRI for the sensory dimension compared to CG (7.1 vs. 16.3 points, d = 4.0, p = 0.03) and in NWC for the total (7.2 vs. 15.5 points, d = 3.9, p = 0.03), in sensory (3.7 vs. 7.7 points, d = 3.8, p = 0.04) and in affective (1.8 vs. 4.0 points, d = 4.0, p = 0.04) dimensions. In T2, only TG showed lower scores in NWC for the affective dimension than CG (1.8 vs. 4.0 points, d = 4.9, p = 0.01). In the comparison of CG and TG with PG there were no differences (p<0.05), reinforcing the results found in the treatment group. The detailed information is presented in table 2.

Table 2. Comparison of pain by McGill Pain Questionnaire total score (mean and standard deviation) and dimensions (sensory, affective, evaluative, and miscellaneous) at the different evaluation times adjusted by the confidence interval (95% CI) and effect size (Cohen's d) between groups

Dimension		CG (n = 9)	TG (n = 11)	PG (n = 10)	CG vs. TG (95%CI)	Cohen's d	CG vs. PG (95%CI)	Cohen's d	TG vs. PG (95%CI)	Cohen's d
Total	NWC	F (4, 54) = 2.64, p = 0.043*, partial eta squared = 0.164								
	T0	16.4 (1.3)	14.0 (1.2)	16.3 (1.2)	-2.4 (-7.0 – 2.2)	1.9	-0.1 (-4.9 – 4.6)	0.0	-2.3 (-6.8 – 2.2)	0.7
	T1	15.5 (2.2)	7.2 (2.0)	9.1 (2.1)	-8.2 (-16.1 – -0.4)*	3.9	-6.4 (-14.4 – 1.5)	2.2	-1.8 (-9.0 – 5.7)	0.6
	T2	15.5 (2.0)	8.6 (1.8)	13.6 (1.9)	-6.9 (-13.8 – 0.04)	3.6	-1.9 (-9.0 – 5.1)	0.6	-4.9 (-11.7 – 1.8)	1.7
	PRI	F (4, 54) = 2.39, p = 0.062, partial eta squared = 0.151								
	T0	33.4 (3.7)	29.8 (3.3)	38.2 (3.5)	-3.6 (-16.5 – 9.2)	1.0	4.7 (-8.4 – 17.9)	1.7	-8.3 (-20.9 – 4.1)	2.9
	T1	29.2 (4.7)	14.0 (4.2)	17.6 (4.4)	-15.2 (-31.5 – 1.0)	3.4	-11.7 (-28.3 – 4.9)	4.0	-3.5 (-19.3 – 12.3)	1.2
	T2	29.3 (8.3)	15.6 (7.5)	39.3 (7.8)	-13.6 (-42.3 – 14.9)	1.7	9.9 (-19.2 – 39.2)	3.4	-23.6 (-51.4 – 4.1)	8.1
	PPI	F (4, 54) = 0.43, p = 0.782, partial eta squared = 0.031								
	T0	2.6 (0.7)	3.7 (0.6)	4.0 (0.6)	1.1 (-1.3 – 3.6)	1.7	1.3 (-1.2 – 3.9)	0.4	-0.2 (-2.6 – 2.2)	0.1
	T1	2.4 (0.5)	2.6 (0.5)	2.7 (0.5)	-0.2 (-1.6 – 2.1)	0.4	0.3 (-1.6 – 2.1)	0.1	-0.09 (-1.9 – 1.7)	0.1
	T2	2.4 (0.5)	2.4 (0.4)	2.9 (0.5)	0.06 (-1.7 – 1.9)	0.0	-0.4 (-2.2 – 1.3)	0.1	0.5 (-1.3 – 2.3)	0.1

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Table 2. Comparison of pain by McGill Pain Questionnaire total score (mean and standard deviation) and dimensions (sensory, affective, evaluative, and miscellaneous) at the different evaluation times adjusted by the confidence interval (95% CI) and effect size (Cohen's d) between groups – continuation

Dimension		CG (n = 9)	TG (n = 11)	PG (n = 10)	CG vs. TG (95%CI)	Cohen's d	CG vs. PG (95%CI)	Cohen's d	TG vs. PG (95%CI)	Cohen's d
Sensory	NWC	F (4, 54) = 1.99, p= 0.108, partial eta squared = 0.129								
	T0	8.1 (0.8)	6.9 (0.7)	8.3 (0.7)	-1.2 (-3.9 – 1.5)	1.6	0.1 (-2.6 – 3.0)	0.07	-1.3 (-4.1 – 1.3)	0.4
	T1	7.7 (1.1)	3.7 (1.0)	4.9 (1.0)	-4.0 (-7.9 – -0.1)*	3.8	-2.8 (-6.8 – 1.0)	0.9	-1.1 (-4.9 – 2.6)	0.4
	T2	7.7 (1.0)	4.6 (0.9)	6.9 (1.0)	-3.1 (-6.8 – 0.5)	3.2	-0.8 (-4.6 – 2.8)	0.2	-2.2 (-5.8 – 1.3)	0.7
	PRI	F (4, 54) = 2.85, p = 0.032*, partial eta squared = 0.174.								
	T0	17.1 (2.1)	15.6 (1.9)	20.2 (2.0)	-1.4 (-8.8 –5.8)	0.7	3.0 (-4.4 – 10.5)	1.0	-4.5 (-11.6 – 2.5)	1.5
	T1	16.3 (2.4)	7.1 (2.2)	9.6 (2.3)	-9.1 (-17.6 – -0.6)*	4.0	6.7 (-15.4 – 1.9)	2.3	-2.4 (-10.6 – 5.8)	0.8
	T2	16.3 (2.4)	9.0 (2.2)	14.6 (2.3)	-7.3 (-15.7 – 1.0)	3.1	-1.7 (3-6.8 – 10.3)	0,5	-5.6 (-13.7 – 2.5)	1.9
	PPI	F (4, 54) = 3.96, p = 0.007*, partial eta squared = 0.227								
	T0	2.2 (0.6)	4.4 (0.5)	3.1 (0.5)	2.1 (0.1 – 4.3)*	0.3	0.9 (-3.1 – 1.2)	0.3	1.2 (-0.8 – 3.3)	0.4
	T1	2.4 (0.7)	3.2 (0.6)	2.0 (0.7)	0.8 (-1.8 – 3.4)	1.2	-0.3 (-3.0 – 2.2)	0.1	1.1 (-1.3 – 3.7)	0.4
	T2	2.4 (0.7)	3.1 (0.6)	3.1 (0.7)	0.7 (-1.8 – 3.3)	1.0	0.7 (-1.9 – 3.3)	0.2	0.03 (-2.4 – 2.5)	0.0
Affective	NWC	F (4, 54) = 2.01, p = 0.106, partial eta squared = 0.130								
	T0	4.2 (0.4)	3.6 (0.4)	4.2 (0.4)	-0.5 (-2.2 – 1.0)	1.5	-0.02 (-1.6 – 1.6)	0.0	-0.5 (-2.1 – 1.0)	0.2
	T1	4.0 (0.6)	1.8 (0.5)	2.2 (0.5)	-2.1 (-4.3 – -0.2)*	4.0	-1.8 (-4.0 – 0.4)	0.6	-0.3 (-2.4 – 1.7)	0.1
	T2	4.0 (0.5)	1.8 (0.4)	3.0 (0.5)	-2.1 (-3.9 – 0.3)*	4.9	-1.0 (-2.8 – 0.8)	0.3	-1.1 (-2.9 – 0.5)	0.4
	PRI	F (4, 54) = 0.84, p = 0.505, partial eta squared = 0.059								
	T0	8.5 (1.3)	7.4 (1.2)	9.2 (1.2)	-1.1 (-5.7 – 3.5)	0.8	0.6 (-4.1 – 5.4)	0.2	-1.7 (-6.3 – 2.8)	0.6
	T1	6.4 (1.1)	3.1 (1.2)	4.0 (1.2)	-3.1 (-7.9 – 1.4)	2.8	-2.4 (-7.2 – 2.3)	0.8	-0.8 (-5.4 – 3.7)	0.3
	T2	6.4 (1.1)	3.0 (1.0)	4.9 (1.1)	-3.3 (-7.4 – 0.7)	3.2	-1.5 (-5.7– 2.6)	0.5	-1.8 (-5.7 – 2.1)	0.6
	PPI	F (4, 54) = 2.24, p = 0.076, partial eta squared = 0.143								
	T0	2.6 (0.4)	3.5 (0.3)	3.6 (0.4)	0.9 (-0.5 – 2.4)	2.5	0.9 (-0.5 – 2.5)	0.3	-0.03 (-1.5 – 1.4)	0.03
	T1	2.7 (0.6)	2.0 (0.5)	1.9 (0.5)	-0.6 (-2.7 – 1.4)	1.2	-0.8 (-3.0 – 1.3)	0.2	0.1 (-1.8 – 2.2)	0.0
	T2	2.7 (0.5)	2.2 (0.5)	2.7 (0.5)	-0.4 (-2.4 – 1.5)	1.0	0.01 (-2.0 – 2.0)	0.0	-0.4 (-2.4 – 1.4)	0.1
Evaluati-ve	NWC	F (4, 54) = 1.18, p =0.327, partial eta squared = 0.081								
	T0	1.0 (0.3)	1.3 (0.2)	0.9 (0.3)	0.3 (-0.7 – 1.4)	1.2	-0.1 (-1.2 – 1.0)	0.03	0.4 (-0.6 – 1.5)	0.1
	T1	0.8 (0.3)	1.0 (0.2)	0.6 (0.2)	0.2 (-0.8 – 1.2)	0.8	-0.2 (-1.3 – 0.7)	0.07	0.4 (-0.5 – 1.5)	0.1
	T2	0.8 (0.1)	0.5 (0.1)	0.9 (0.1)	-0.3 (-0.8 – 0.1)	3.0	0.01 (-0.4 – 0.4)	0.03	-0.3 (-0.8 – 0.1)	0.1
	PRI	F (4, 54) = 2.76, p = 0.036*, partial eta squared = 0.170								
	T0	2.0 (0.4)	1.8 (0.3)	3.2 (0.4)	-0.1 (-1.6 – 1.3)	0.5	1.2 (-0.3 – 2.7)	0.4	-1.3 (-2.8 – 0.06)	0.4
	T1	2.1 (0.4)	1.1 (0.4)	1.2 (0.4)	-0.9 (-2.5 – 0.7)	2.5	-0.9 (-2.6 – 0.7)	0.3	-0.01 (-1.6 – 1.5)	0.0
	T2	2.1 (0.4)	0.9 (0.4)	2.1 (0.4)	-1.2 (-2.8 – 0.4)	3.0	-0.01 (-1.6 – 1.6)	0.0	-1.1 (-2.7 – 0.3)	0.4
	PPI	F (4, 54) = 3.61, p = 0.011*, partial eta squared = 0.211								
	T0	2.8 (0.5)	3.7 (0.5)	2.9 (0.5)	0.8 (-1.0 – 2.7)	1.8	0.01 (-1.9 – 1.9)	0.03	0.8 (-1.0 – 2.6)	0.2
	T1	2.5 (0.6)	2.0 (0.5)	1.7 (0.6)	-0.4 (-2.7 – 1.7)	0.9	-0.8 (-3.1 – 1.4)	0.2	0.3 (-1.7 – 2.5)	0.1
	T2	2.5 (0.5)	1.5 (0.5)	2.7 (0.5)	-1.0 (-3.0 – 1.0)	2.0	0.1 (-1.9 – 2.2)	0.07	-1.1 (-3.1 – 0.8)	0.4
Miscella-neous	NWC	F (4, 54) = 1.41, p =0.239, partial eta squared = 0.095								
	T0	3.0 (0.3)	2.6 (0.2)	3.0 (0.3)	-0.3 (-1.4 – 0.6)	1.6	0.0 (-1.0 – 1.0)	0.0	-0.3 (-1.3 – 0.6)	0.1
	T1	2.8 (0.8)	2.0 (0.7)	2.8 (0.8)	-0.8 (-3.7 – 2.0)	1.0	-1.2 (-4.2 – 1.6)	0.0	0.4 (-2.4 – 3.2)	0.2
	T2	2.8 (0.7)	2.3 (0.7)	2.8 (0.7)	-0.5 (-3.2 – 2.2)	0.7	-0.08 (-2.8 – 2.7)	0.0	-0.4 (-3.1 – 2.2)	0.2
	PRI	F (4, 54) = 0.68, p = 0.605, partial eta squared = 0.048								
	T0	5.7 (0.7)	4.9 (0.6)	5.7 (0.6)	-0.8 (-3.3 – 1.6)	1.2	-0.07 (-2.6 – 2.4)	0.0	-0.7 (-3.2 – 1.6)	0.2
	T1	4.4 (1.7)	3.9 (1.6)	3.0 (1.6)	-0.5 (-6.6 – 5.5)	0.3	-1.4 (-7.6 – 4.7)	0.4	0.9 (-5.0 – 6.8)	0.3
	T2	4.4 (1.6)	3.9 (1.5)	4.6 (1.6)	-0.5 (-6.3 – 5.3)	0.3	0.1 (-5.8 – 6.1)	0.1	-0.6 (-6.3 – 4.9)	0.2
	PPI	F (4, 54) = 1.81, p = 0.140, partial eta squared = 0.118								
	T0	2.9 (0.4)	3.7 (0.4)	3.2 (0.4)	0.8 (-0.7 – 2.4)	0.2	0.2 (-1.3 – 1.9)	0.1	0.5 (-1.0 – 2.0)	0.1
	T1	2.2 (0.5)	1.2 (0.5)	2.0 (0.5)	-1.0 (-3.0 – 1.0)	0.3	-0.1 (-2.2 – 1.9)	0.07	-0.8 (-2.8 – 1.1)	0.2
	T2	2.2 (0.5)	1.9 (0.4)	2.7 (0.5)	-0.2 (-2.1 – 1.6)	0.1	0.5 (-1.3 – 2.4)	-0.1	-0.7 (-2.6 – 1.0)	0.2

NWC = Number of words chosen; PRI = Pain rating Index; PPI = Present pain intensity; CG = Control Group; TG = CUSEFS Group; CUSEFS = Combined Ultrasound and Electric Field Stimulations; PG = Placebo Group; * p<0.05

Table 3. Comparison of functional capacity activities (resting, sitting, standing, walking, and lying down) at the different evaluation times adjusted by the confidence interval (95% CI) and effect size (Cohen's d) between groups

Activities		CG (n = 9)	TG (n = 11)	PG (n = 10)	CG vs. TG (95%CI)	Cohen's d	CG vs. PG (95%CI)	Cohen's d	TG vs. PG (95%CI)	Cohen's d
Rest	T0	5.6 (0.7)	6.3 (0.6)	5.5 (0.7)	0.6 (-1.9 – 3.3)	0.4	-0.1 (-2.8 – 2.5)	0.03	0.8 (-1.6 – 3.4)	0.2
	T2	4.2 (0.7)	2.0 (0.6)	4.7 (0.7)	0.4 (-2.2 – 3.1)	0.7	-0.4 (-3.1 – 2.2)	0.1	2.7 (0.1 – 5.2)*	0.9
Sitting	T0	5.8 (0.5)	6.6 (0.4)	7.0 (0.5)	0.7 (-1.1 – 2.6)	0.2	1.1 (-0.8 – 3.0)	0.4	-0.3 (-2.2 – 1.4)	0.1
	T2	4.8 (0.7)	3.5 (0.7)	4.9 (0.7)	-1.3 (-4.0 – 1.3)	0.4	0.01 (-2.7 – 2.7)	0.0	-1.3 (-3.9 – 1.2)	0.4
Standing	T0	6.3 (0.6)	7.5 (0.5)	7.6 (0.5)	1.2 (-0.8 – 3.2)	0.4	1.2 (-0.8 – 3.3)	0.4	-0.05 (-2.0 – 1.9)	0.03
	T2	4.3 (0.8)	4.8 (0.7)	5.9 (0.8)	0.4 (-2.5 – 3.4)	0.1	1.5 (-1.4 – 4.6)	0.5	-1.0 (-3.9 – 1.8)	0.3
Walking	T0	7.4 (0.4)	7.1 (0.4)	7.8 (0.4)	-0.2 (-1.8 – 1.3)	0.1	0.3 (-1.2 – 1.9)	0.1	-0.6 (-2.1 – 0.9)	0.2
	T2	5.8 (0.5)	3.8 (0.4)	4.8 (0.5)	-2.0 (-3.9 – -0.1)*	0.6	-1.0 (-3.0 – 0.8)	0.3	-0.9 (-2.8 – 0.8)	0.3
Lying down	T0	6.3 (0.6)	6.2 (0.6)	6.2 (0.6)	-0.06 (-2.4 – 2.2)	0.0	-0.1 (-2.5 – 2.2)	0.0	0.07 (-2.2 – 2.3)	0.0
	T2	5.7 (0.8)	2.4 (0.7)	4.9 (0.7)	-3.3 (-6.1 – -0.4)*	1.1	-0.8 (-3.7 – 2.0)	0.2	-2.4 (-5.2 – 0.3)	0.8

CG = Control Group; TG = CUSEFS Group; CUSEFS = Combined Ultrasound and Electric Field Stimulations; PG = Placebo Group; * p<0.05.

All groups had similar difficulties in functional activities before the intervention (table 3), indicating sample homogeneity. However, in T2, the TG had less difficulty than the CG in walking (d = 0.6, medium effect, p = 0.04) and lying down (d = 1.1, large effect, p = 0.03) and the PG in resting (d = 0.9, large effect, p = 0.03).

DISCUSSION

This is the first study to examine the acute effects of CUSEFS in immediate cesarean delivery. The literature indicates that the delivery way interferes with the immediate post-partum, especially the cesarean delivery. In this delivery type, the impacts on activities of daily living were higher, not only because of the highest cicatricial pain intensity but also because of the lower range of motion, worse functional capacity, and limitations[4]. The results of this research showed that CUSEFS was able to improve cicatricial pain and functional capacity in immediate cesarean delivery. The information showed in the present study suggests that CUSEFS can be used as a complementary therapy to reduce cicatricial pain in immediate cesarean delivery and optimize functional recovery.

Effective cicatricial pain relief is a top priority for women undergoing cesarean section and pain management could improve maternal mobility and facilitate rapid recovery[3,20], with minimal risks or side effects and allow breastfeeding of the newborn[21]. Additional findings showed that even women who received drugs for pain relief had residual discomfort and had adverse side effects in immediate cesarean delivery, which suggests that they were not enough for analgesia and women who used drugs were more likely to have negative encounters with healthcare providers and the baby, and a sense of guilt and/or failure[15]. Guidelines for the management of postoperative cicatricial pain refer to the use of nonpharmacologic therapies, including electric therapy and thermotherapy[5], which is consistent with the results of the present study demonstrating the efficacy of using CUSEFS for cesarean deliveries section. Additionally, other studies found similar results on pain and functionality in patients with fibromyalgia[11], foot ulcers[9] and knee osteoarthritis[10].

The simultaneous use of two modalities has been suggested because the benefits of both can be achieved at the same time, making therapy time more efficient for the patient and therapist. In addition, it is suggested that the combination of electrical therapy and ultrasound is thought to enhance the therapeutic effect of one therapy on the other. It seems that HFU increases the permeability of cell membranes (sodium and calcium ions), which favors the effect of electrical currents on nervous tissue[11,12]. This may be related to the physical properties of TENS to modulate pain by activating descending inhibitory pathways. Nociceptive input at the spinal cord level may reduce input through the ascending spinothalamic tract by TENS activating δ-opioid and gamma-aminobutyric acid receptors, thereby alleviating cicatricial pain[22]. Previous studies evaluating the TENS analgesic effect after cesarean section found that electroanalgesia provided effective cicatricial pain relief[6,23]. These effects of TENS can also be explained by the theory in which the endogenous bio-electric system activates crucial contributors to the wound healing process, such as macrophages, neutrophils, and fibroblasts[9].

Additionally, cicatricial pain relief has been related to the physical properties of HFU, particularly the non-thermal effects and the reduction in compression of pain-sensitive structures due to the resolution of the inflammatory process[8,9]. Through acoustic cavitation and microstreaming, HFU has been promoting wound healing by stimulating fibroblasts and collagen production, increasing angiogenesis and nitric oxide levels, along with enhancing macrophage responsiveness[9]. These pieces of information justify the findings of the present study and reinforce the applicability and safety of CUSEFS to reduce cicatricial pain in immediate cesarean delivery.

Non-healing cesarean section wounds have implications for health service resources in the treatment of chronic conditions and acute/secondary care setting readmissions[24]. Therefore, it can be a source of anxiety, low quality of life, and negative impact on the mother-child relationship and self-care that could impact women's life and their functional activities, emphasizing the importance of improving the healing process[1,24]. In the present study, the functional activities showed medium to high scores in the initial evaluation, indicating difficulty to perform daily activities, which is compara-

ble with other studies that focused the period after abdominal and pelvic surgery[25,26]. In this scenario, CUSEFS was also effective in improving functional capacity. This finding may be related to the reduction of local inflammation and cicatricial pain from electrical therapy and ultrasound intervention[12]. CUSEFS has been shown to accelerate acute wound healing that can impact in functionality[9,12]. Furthermore, a study[12] suggested that combined therapy may alter the activity of the innate and adaptive immune system, which promotes the healing process and attenuates the inflammatory response. The respective benefits of TENS and HFU in wound healing complement and supplement each other, and therefore it seems reasonable to combine both therapies[9].

These findings suggest that CUSEFS could be considered a complementary therapy to conventional treatment of cicatricial pain and functional capacity associated with cesarean delivery to reduce the use of analgesics and minimize tolerance and adverse effects. In addition, individuals with less pain and higher functional capacity may be more willing to increase their physical activities level, which may further reduce cicatricial pain.

The placebo effect found in the present study can be explained by the interaction between the professional and the participant, the natural regression of symptoms and the body's self-healing abilities[27]. There is evidence that psychological characteristics play a role in therapeutic effects, including hopefulness, expectations, and beliefs. Placebos can induce biochemical and cellular changes in the patient's brain within a set of sensory and social stimuli that can simulate and enhance positive responses to pharmacological agents[27,28].

One of this study's strengths was the maintenance of the standard hospital nursing routine in the immediate postpartum period after caesarean section, following the drug guidelines recommended to prevent surgical site infections[29] and reduce pain during childbirth[30]. The lack of modifications allowed this study to show that CUSEFS could be replicated in clinical practice without changes to hospital routines, highlighting a great potential for practical applicability. Future studies could analyze the impact of this intervention and the use of drugs in immediate cesarean delivery.

This study had some limitations. First, in relation to the sample size, therefore, further studies with a larger sample size and longer follow-up periods are needed. Secondly, the intervention was performed only once for 20 minutes because of the local routine. Future studies might examine the long-term effects of CUSEFS on immediate postpartum cicatricial pain and functional capacity in immediate cesarean delivery. Thirdly, only a specific dose of parameters was assessed in postpartum; therefore, the results cannot be extrapolated to conditions in which other parameters and/or other forms of electrical stimulation may be used. Finally, functional capacity was evaluated only in T0 and T2 due to pain complaints and newborn care, as well as the protocol authorized by the hospital for carrying out this research. This study suggest that future researches could evaluate the different moments to allow a more detailed analysis of the variables. These limitations do not reduce the impact of the present study's findings but indicate caution in the general data extrapolation and indicate opportunities for future studies.

The present study's results provide some relevant practical considerations regarding the effects of combination therapy on acute cicatricial pain and functional recovery in immediate cesarean delivery, and suggest that CUSEFS might be used as a complementary therapy to conventional treatment. Women are an important part of the family and society, and their well-being depends on meeting their socioeconomic and health needs. In addition, women with less severe cicatricial pain and greater functional capacity may have a higher quality of life and physical activity level, which have the benefits well documented in the literature.

CONCLUSION

CUSEFS can manage cicatricial pain and improve functional capacity in immediate cesarean delivery. Despite the results shown in this study, further research with longer duration and different CUSEFS doses/parameters are required to investigate the relief of cicatricial pain and functional capacity recovery in immediate cesarean delivery.

AUTHORS' CONTRIBUTIONS

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