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PREVENTION & REHABILITATION: Randomised Study

Effect of one session of tDCS on the severity of pain in women with chronic pelvic pain

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ABSTRACT

Aim: The present study aimed to investigate the effects of tDCS on pain score in women with Chronic Pelvic Pain (CPP).**Materials & methods:** A total of 16 women with CPP participated in the present double-blind sham-controlled cross-over study. Each participant received a 20-min 0.3 MA of trans Cranial Direct Stimulation (tDCS) with a current density of 0.1 mA/cm². In addition to the pain intensity, the Quality of Life (QOL), disability, and depression statuses were assessed prior to and one week after the treatment. Shapiro-Wilks goodness-of-fit test for normality, dependent *t*-Test, and Wilcoxon Signed-Rank Test were used for data analysis. Values of *p* < .05 were considered statistically significant.**Findings:** Active tDCS treatment was effective in the reduction of pain (*p* = .0001), improving QOL (208.938 > 193.313, *P* = .025), and the disability (22.375 < 30.375, *P* = .025). The results showed no effect of active or sham treatment on the depression (*p* ≥ .05).**Conclusion:** The positive effects of active tDCS on CPP suggest the need to study the effect of this method on other types of chronic pain.

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1. Introduction

Chronic Pelvic Pain (CPP) is described as any pelvic pain with no relevance to pregnancy, menstruation, and intercourse that lasts for six months or more. The etiology is often unclear; it may result from complex interactions between the gastrointestinal, urinary, gynecologic, musculoskeletal, neurologic and endocrine systems, as well as the influence of psychological and socio-cultural factors (Zondervan et al., 2001; Howard, 2003; Sedghimehr et al., 2017). CPP has an adverse impact on women's Quality of Life (QOL), daily activities (Arnold et al., 2006; Whitaker et al., 2016; Harvey et al., 2017), and general well-being (Latthe et al., 2006; Savidge and Slade, 1997), which can cause a drastic increase in anxiety and

depression rate (Arnstein, P. et al.; Brawn, J. 2014). It has an alarming prevalence rate ranging from 1.2%–39% in different countries varying the characteristics of the studied population and research methodology (Latthe et al., 2006; Ahangari, 2014). The prevalence of CPP has previously been estimated in Iran in two cross-sectional studies at 10.2% (Dehghan et al., 2009) and 17.7% (Dehghan et al., 2014).

In spite of billions of dollars being spent on diagnosis and treatment of CPP, there are few evidence-based treatment protocols. Therefore, both patients and health professionals feel disappointed when dealing with conventional treatments (Engeler et al., 2013; Simis et al., 2015).

Recent studies have reported that dysfunction of the limbic system and hypothalamic-pituitary-adrenal axis dysfunction may be responsible for the CPP (Fenton et al., 2009; Brawn, J. 2014; Simis et al., 2015). They hypothesized that CPP is associated with central sensitization as well as functional and structural changes in the brain (Brawn et al., 2014; Kaya et al., 2013). It seems as if treatment procedures which focus on the pelvic organs are not effective in

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producing long-lasting management of the limbic dysfunction. Therefore, during recent years, non-invasive brain stimulation methods in term of Transcranial Direct Current Stimulation (tDCS) and Transcranial Magnetic Stimulation (TMS) are proposed (Zaghi et al., 2009; Simis et al., 2015). Generally, tDCS is more affordable and effective than TMS; it is also cheaper, with fewer complications and side effects. (Zaghi et al., 2009). Transcranial direct current stimulation (tDCS), as a form of noninvasive brain stimulation, has been proven to be very promising in treating chronic pain conditions. This direct electrical current, with low doses delivered to the brain via electrodes placed directly on the scalp, induces changes in the neuronal activity of the cortex by increasing excitability in the areas under the anode and decreasing it in the areas under the cathode (Rostami et al., 2015).

Recent studies have shown the positive effects of tDCS on the central nervous system function (Giordano et al., 2017; Sankarasubramanian et al., 2017) and the reduction of chronic pain (Vaseghi et al., 2014; Silva et al., 2017; Kanotkova, 2017).

Determining the proper parameters of tDCS to increase cortical excitability are one of the issues that need to be addressed (O'Connell et al., 2010). One of these important parameters is applying tDCS over M1 and DLPFC. It is claimed that the simultaneous stimulation of these two regions increase the excitability of the motor cortex up to three times as compared with the conventional one; therefore, speeds up the process of pain relief (Vaseghi et al., 2015a,b). The present study aimed to investigate the potential effect of a one-session of a-tDCS_{UHDS} (M1 and DLPFC) on pain intensity, QOL, disability, and depression status of women with CPP.

2. Materials & methods

Between October 2016 and January 2017, from among the patients who referred to a pelvic floor clinic in Yas Hospital, affiliated to Tehran University of Medical Sciences, 25 patients were assessed for eligibility and 16 non-postmenopausal women with CPP were recruited. The sample size was estimated with a 95% confidence interval and a test power of 80% (Fenton et al., 2009). The selection and referral of the CPP patients was conducted by a team specialised in Female Pelvic Medicine and Reconstructive Surgery, according to the definition provided by American College of Obstetrician and Gynecologists (ACOG Practice Bulletins, 2004).

Exclusion criteria included: genitourinary diseases, neurologic bladder dysfunction, self-reported alcohol or drug abuse over the past six months, taking medications like Carbamazepine, severe depression, neurological disorders, history of head injury resulting in temporary unconsciousness, and medication for pain reduction (Vaseghi et al., 2015a,b). The age range of participants was 21–50 years and BMI ranged between 19.72 and 45.79 (31.7 ± 7.27) kg/cm². To stimulate the dominant hemisphere, only right-handed subjects were selected (Vaseghi et al., 2015a,b).

Before starting the study, all patients completed the written consent form.

The study was approved by the Research Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran.

After collecting demographic information, the following reliable and valid instruments were used to measure the outcomes: VAS pain score, WHOQOL-BREFE Questionnaire to assess QOL (Nedjat et al., 2008), Oswestry Disability Index (Baradaran et al., 2016; Mousavi et al., 2006), and the short form of Beck Depression Inventory (Hojat et al., 1986; Dadfar and Kalibatseva, 2016). The tDCS device used in the study was from the Active Dose Company, Thailand.

After selection and referral of patients, the study was carried out in two main phases with a one-week interval between them. Both phases consisted of three parts: pretreatment assessment of all

outcome measures, a treatment phase, and a post treatment assessment (Vaseghi et al., 2015a,b). All participants were their own controls and randomly received both active and sham treatment (Fenton et al., 2009; Vaseghi et al., 2015a,b). Randomization was performed by a blinded therapist using a sealed envelope for each woman. All participants and assessors were blinded to the intervention group. The following flowchart shows the stages of the study (See Fig. 1).

Completion of questionnaires and tDCS treatment was performed by an experienced physiotherapist, who had already passed the tDCS course.

2.1. tDCS

A direct current was applied over the M1 and DLPFC concurrently through two active saline-soaked surface sponge electrodes (1.5×2 cm). The small size of the electrodes produced a highly focused direct current over the target areas (Vaseghi et al., 2015a,b). Two reference electrodes (2×6 cm) were placed over the contralateral supraorbital area (Vaseghi et al., 2015a,b). The size of the reference electrodes was four times that of the active electrode, and this reduced their neuromodulator effects (Vaseghi et al., 2015a,b). The t-DCS simulators were set to deliver a 0.3 MA direct current for a period of 20 min. The required current intensity (0.3 MA) allowed the use of small active electrodes (Vaseghi et al., 2015a,b). The location of the electrodes is shown in Fig. 2.

To maintain safety, the current density was kept in a safe range (0.1 mA/cm^2) (Poreisz et al., 2007; Vaseghi et al., 2015a,b; Brunoni et al., 2011). Two tDCS devices were used for stimulation of the target areas in a-tDCS_{UHDS} conditions.

The international 10–20 system was followed to determine the target spots for stimulation. In the current study, the anode electrodes were placed over C3 and F3, the locations of left M1 and DLPFC respectively (Fig. 2) (Vaseghi et al., 2015a,b). In the sham group, only 30 s of stimulation was applied to mimic the itching associated with actual stimulation (Munjee et al., 2016). Then, the device remains silent on the patient's head until the end of the 20-min treatment (Vaseghi et al., 2015a,b). Participants were informed they could leave the study at any stage, but none of the patients left the trial due to side effects in either active or sham treatment.

Adverse effects were monitored immediately after each treatment and one week after the treatment. The most frequent reported side effects were mild tingling and itching without any sense of burning and pain beneath the anode electrodes after active or sham treatment only immediately after treatment, compared with one week later. Two patients perceived that one session of their treatment was sham, whereas others could not distinguish between the sessions.

Data were analyzed using SPSS statistical software (v. 21). Shapiro-Wilks goodness-of-fit test was used to assess the distribution of quantitative variables. Based on the results of this test, the matched *t*-test or Wilcoxon Signed-Rank Test was used to compare variables before and after sham or active intervention. A significant level was considered as $p < .05$ with a power of 80%.

2.2. Findings

Table 1 presents the values of the outcomes before and after the intervention (See Table 1).

Table 2 shows the results of the comparison of the averages before and after the intervention (See Table 2).

As seen in Table 2, there was a reduction of 2.94 (49%) points in the mean pain intensity for the active stimulation while this value was 0.56 (0.001%) for the sham treatment. Also, active treatment resulted in a significant decrease of 31.67% in the mean level of

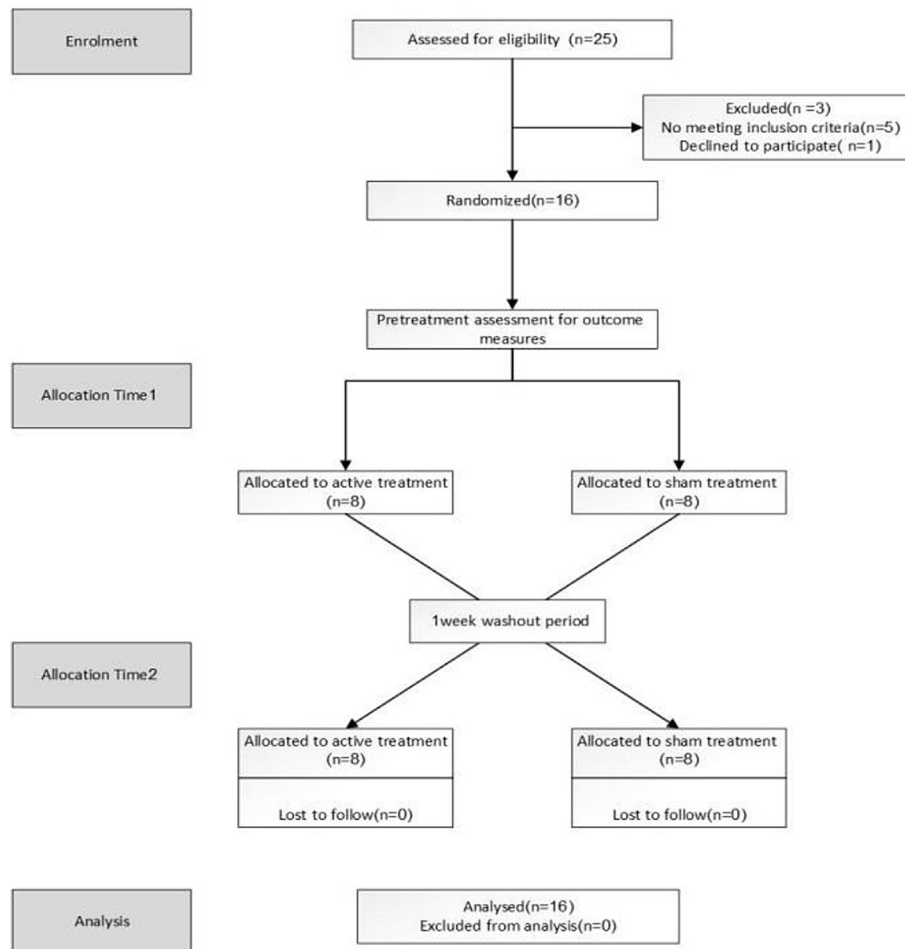


Fig. 1. Steps followed in the present research.

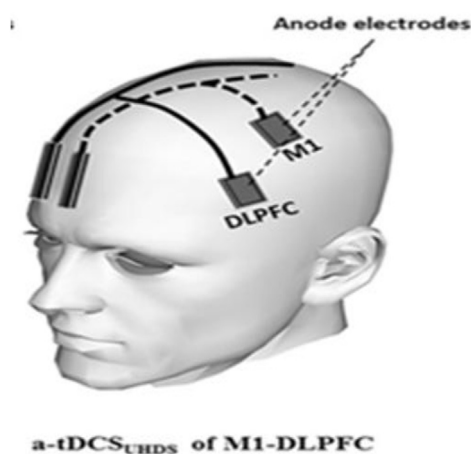


Fig. 2. Locations of electrodes (Vaseghi et al., 2015a,b).

3. Discussion

The present study showed that the Active-DLPFC-M_1 a-tDCS (UHCDs) technique, compared to the sham technique, decreases pain severity and improves the QOL and disability status in women with CPP.

The reduction in pain intensity was consistent with some previous studies (Cecilio et al., 2008; Fenton et al., 2009; Vaseghi et al., 2015a,b; Silva et al., 2017; Kanotkova, 2017; Rostami et al., 2015). In these studies commonly the tDCS (M1) technique was used but in the study by Cecilio et al, in addition to the M1, the S1 region was also stimulated unintentionally. Contrary to the previous studies in which the number of treatment sessions was 2–10 or more (Cecilio et al., 2008; Fenton et al., 2009; Vaseghi et al., 2015a,b; Silva et al., 2017; Kanotkova, 2017; Rostami et al., 2015), in the current study only the effects of one session were investigated.

Vaseghi et al. (2014) reported that a-tDCS on the DLPFC region had a greater effect than a-tDCS on M1 (Vaseghi et al., 2015a,b). In another study, authors suggested that simultaneous stimulation of these two regions would increase the excitability of the motor cortex, which is an important factor in reducing pain (Vaseghi et al., 2015a,b).

In the present study, simultaneous stimulation was performed on both of these areas and perhaps this was a factor influencing the effectiveness of a single treatment session. A-tDCS M1 leads to

disability, while the sham treatment showed no significant change ($p > 0.05$). Moreover, there was no significant difference between the two treatment conditions in terms of the depression level ($p > 0.05$).

Table 1

Average Values of clinical data before and after the intervention.

Group Variables	Pre-test		Post-test	
	Active	Sham	Active	Sham
number	16	16	16	16
Pain Score	6.12 ± 2.15	4.93 ± 3.043	3.06 ± 1.95	4.37 ± 2.52
QOL	193.3 ± 87.49	206.7 ± 80.43	208.93 ± 89.24	200.93 ± 78.70
Depression	10.43 ± 8.06	8.62 ± 8.21	10.06 ± 9.14	8.75 ± 7.96
Disability Status	30.37 ± 19.18	26.12 ± 13.99	22.37 ± 13.10	25 ± 12.81

Table 2

Between groups differences in main outcomes before and after interventions

Groups Variables	Active		Sham	
	Mean ± SD	P value	Mean ± SD	P value
pain Score	3.06 ± 1.69	0.0001*	0.56 ± 1.26	.95
QOL	−15.62 ± 20.4	.02*	.81 ± 38.51	.55
Depression	0.37 ± 3.8	.7	−0.12 ± 2.15	.8
Disability Status	8 ± 12.7	.02*	1.12 ± 9.58	.64

inhibition of pain by increasing the irritability of the M1, inhibiting external thalamic activity, controlling the somatosensory cortex, and increasing the level of opioids (Maeoka et al., 2012; Lauro et al., 2014; Parker et al., 2016; Cortese et al., 2017). Because of the relationship between the peripheral cortex of the left hemisphere and limbic structures, it could be effective in controlling the emotional aspect of pain. (Maeoka et al., 2012; Cortese et al., 2017). Anatomical based studies have also shown that the posterior part of the peripheral cortex passes a message to the M1 and the spinal cord receives input from the DLPFC (Kaya et al., 2013; Brawn et al., 2014).

Compared to the M1 stimulation, accompanying of the M1 and DLPFC (a-tDCS UHCDS M1 & DLPFC) stimulations may activate the DLPFC-premotor-primary motor path, increase M1 excitability and also reduce the GABAergic interneurons inhibitory function (Vaseghi et al., 2014; Vaseghi et al., 2015a,b; Silva et al., 2017; Kaya et al., 2013).

However, one study suggested that using both tDCS and TENS did not show a significant difference compared to TENS alone on pain score in patients with CPP or abdominal pain (Harvey et al., 2017). It is likely that the low number of samples and lack of a sham group are the possible reasons for this difference. Nevertheless, the recently published guidelines emphasizes caution in extensive use of this therapeutic method (Lefaucheur et al., 2017).

Similar to a previous study, our study revealed that one treatment session of the a-tDCS UHCDS (M1-DLPFC) improved the QOL in patients with CPP (Rostami et al., 2015). According to one study, the use of a-tDCS resulted in decreasing pain and improving QOL in people with fibromyalgia syndrome (Lefaucheur et al., 2017). This finding is compatible with those of other studies (Rostami et al., 2015; Mendonca et al., 2016; Mori et al., 2010). This has probably been the result of the effect of the treatment on the patients' pain level (Simis et al., 2015). However, Simis et al. reported no significant effect on the QOL among their CPP patients.

The severity of pain is closely associated with disability (Tripoli et al., 2011; Romão et al., 2009; Arnstein et al., 1999). Therefore, the application of a-tDCS UHCDS (M1 and DLPFC) can result in a decrease in the pain level and improves the disability status.

There was no significant difference between the depression index between two shams and active treatment groups. This finding confirms the previous studies (Fenton et al., 2009). Since there are changes in the brain in the event of depression over time, there may be a need for more therapeutic sessions. (Liu et al., 2016).

The lack of using functional MRI to assess possible changes in

the brain and long-term follow-up were the main limitations of the present study. More trials are needed to compare the potential effects of the present method with that of conventional tDCS. In conclusion, one session of the -tDCS UHCDS (M1 and DLPFC) has a significant effect on pain score in patients suffering from CPP. Also, the stimulation of M1 and DLPFC of the same hemisphere with two separated tDCS devices seems a safe method for the management of CPP.

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