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The effect of auricular acupressure on short-term postoperative pain intensity after cesarean section: A three-arm randomized controlled trial

Running title: Auricular finger acupressure for post-cesarean pain intensity

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Abstract

Introduction: Pain control after a cesarean section remains a challenge for healthcare professionals and both pharmacological and non-pharmacological treatment methods can be used to reduce this pain. The present study evaluated the effect of auricular acupressure (applied using the finger) combined with routine care on the short-term pain severity compared to sham acupressure or routine care alone.

Methods: A randomized controlled clinical trial with three parallel groups was conducted between April and May 2021. Participants were pregnant women aged 18-35 years, of gestational age 37-40 weeks who underwent cesarean section according to the anesthesia protocol provided in Imam Ali Hospital, Amol, Mazandaran, Iran. Using the balanced blocks randomization method, participants were randomly allocated into three study groups. Participants (N=180) were randomly assigned to either routine care with auricular acupressure (n=60), routine care with sham control (n=61), or routine care only (n=59). The intervention (auricular acupressure) was performed by a trained nurse three times (three, five, and seven hours after surgery) on ear acupoints including Shen Men, Point Zero, Pelvic, abdomen, Endocrine, and Uterus points, in both ears. The primary outcome was pain severity assessed using the Visual Analog Scale (VAS) at eight time points (i.e., before the intervention, and then 15, 30, and 60 minutes after the intervention, and 3, 6, 12, and 24 hours after the intervention). Patients and outcome assessors were blind.

Results: The pain intensity in the three groups was not significantly different until 6 hours after the intervention. The level of pain in the intervention group receiving auricular acupressure was significantly lower than the sham group at 6 hours (MD: -1.06 [95% CI: -1.83; -0.30]), 12 hours (MD: -1.24 [95% CI: -1.96; -0.52]), and 24 hours (MD: -1.21 [95% CI: -1.96; -0.47]) after the intervention. Also, the pain intensity in the intervention group was significantly lower than the control group at 6 hours (MD: -0.80 [95% CI: -1.53; -0.08]), 12 hours (MD: -0.98 [95% CI: -1.67; -0.30]) and 24 hours (MD: -1.00 [95% CI: -1.70; -0.29]) after the intervention. Moreover, no adverse outcomes were observed related to auricular acupressure.

Conclusion: Auricular acupressure might be an effective adjuvant complementary treatment for post-operative cesarean pain in controlling pain and reducing the need for analgesics with no adverse effect.

Trial registration: Registered prospectively in the Iranian Registry of Clinical Trials (Decree code: IRCT20130822014436N1).

Funding: Mazandaran University of Medical Sciences.

Keywords: auricular acupressure, postoperative pain, intensity, cesarean section

Introduction

Cesarean section is very common globally [1]. More than 1.3 million cesarean sections are performed annually in the United States [2]. The prevalence of cesarean section in Iran (where the present study was carried out) is 48% [3], which is higher than the global average of 21% [4, 5]. Cesarean section is one of the major abdominal surgeries with many complications and problems including pain [6]. Severe postoperative pain results in unfavorable outcomes such as overuse of opiate drugs, difficulty in sleeping and resting, delayed maternal recovery, delayed onset of activities such as sitting, getting up, delayed breastfeeding, and persistent pain in the first days after birth [6, 7]. Therefore, effective pain management and reduction is one of the main and important challenges in cesarean section [8]. There are various methods, both pharmacological and non-pharmacological, to control postoperative pain [9]. The use of analgesics to relieve patients' pain after cesarean section is the most common therapeutic measure [10, 11].

In pharmacological treatment, narcotic drugs (morphine, pethidine, etc.) and non-steroidal anti-inflammatory drugs (NSAIDs) are mostly used, each of which have their own side effects [10, 11]. For example, NSAIDs are associated with many side effects such as gastrointestinal problems, nephrotoxicity, blood disorders, headaches, and drowsiness [12, 13]. Side effects of pharmacological treatments have resulted in a tendency to use non-pharmacological methods. One of the non-pharmacological methods used to relieve pain is auricular acupressure [14].

Auricular acupressure is a 2500-year-old Chinese complementary medicine method. Since 1957, the scientific community has been made aware that the outer part of the ear, the auricle, is like an inverted fetus and a view of the internal organs of the body [14, 15]. Auricular acupressure involves the connection of the ear to the body's energy lines (energy channels and meridians) and the muscular areas of the whole body according to the reflexology theory [16, 17]. This theory states that when a symptom or disease occurs in the body, its anatomical points can be tracked at a specific point in the ear [17].

Auricular acupressure is performed by various methods such as electrical stimulation, using needles, lasers, cupping or granular labels (including magnetic grains and plant grains such as Vaccaria) and manual pressure of the ear, etc. [14, 18]. Although the results of systematic review studies have indicated that auricular acupressure may be effective in relieving a variety of pain disorders, including postoperative pain, further studies are needed to examine the effect of auricular acupressure on postoperative pain management among clinical patients [15, 19]. Moreover, although previous studies have investigated the impact of auricular acupressure on pain, most studies have investigated the impact of this type of treatment with regards to normal labor pain [20], and the impact of auricular acupressure on pain severity after cesarean section has not been sufficiently investigated. Therefore, the present study evaluated the effect of auricular acupressure combined with routine care on the short-term pain severity compared to sham finger acupressure or routine care alone.

Method

Study design and participants

This was a randomized clinical trial conducted between April to May 2021. Participants were individuals at gestational age of 37-40 weeks, were aged 18-35 years, and had a cesarean section with a similar anesthesia protocol. Patients were excluded from the study if they had a history of diabetes, hypertension, kidney, liver and cardiovascular disease, neurological disease, taking narcotic drugs, cigarette smoking or alcohol consumption and/or having a history of ear disease treatment in the past six months. The study process is shown in the CONSORT diagram (Figure 1).

Figure 1. CONSORT Flow Diagram

Sample size estimation

The sample size in the present study was estimated based on the study conducted by Khaloo Bagheri et al. [21]. Considering the Cohen's *d* effect size of 0.459 (equal to *f* effect size of 0.24), a type I error of 0.01, a type II error of 0.05, having three groups with eight measurement outcome times using *G-Power* software, the sample size was estimated to be 150 individuals. Due to possibility of sample dropout during follow-up with a 10% attrition rate, 61 individuals were invited to participate in each group.

Recruitment

The study setting was Imam Ali Hospital in Amol city which is affiliated to Mazandaran University of Medical Sciences, Mazandaran, Iran. It is the largest specialized hospital in Amol with 300 beds in 20 different wards. It is the only referral center for women and children in Amol district (Amol city and five other cities). To identify eligible individuals, the research team reviewed the women on the cesarean section list. desired. After transferring patients to the clinic ward, and based on the pre-prepared allocation sequence, each person was randomly allocated into one of the three groups (treatment group, control group or placebo group).

Randomization

The balanced blocks randomization method was used for random allocation. Since there were three groups (routine care with auricular acupressure, routine care with sham control, or routine care only), a nine-block method was used to randomly allocate the participants. The allocation sequence was determined by a person outside the research team using online random allocation sequence generation software. To conceal the allocation sequence, the papers identifying the group of individuals in the order of generated allocation sequence, were placed in sealed pockets, and coded in the same order from 1 to 183. Accordingly, a questionnaire with the same code was completed for the person who received the intervention code 1.

Blinding

The present study was a patient and outcome assessor blinded clinical trial. The participants were selected using convenience sampling and randomly divided into three groups: intervention, placebo, and control. Participants were blinded to their assigned study group. Participants were informed (when providing informed consent) that they would be randomly assigned to one of study groups. The specific group was not mentioned to them. Only the person who was responsible for carrying out the acupressure was informed about which group the participant was in. This person was not responsible for either outcome assessment or analysis. The outcome assessor and the data analyst were unaware of the grouping of the participants in the study.

Procedure

All patients in the present study underwent spinal anesthesia with same protocol (bupivacaine half a percent, 2.5 cc to 3cc, and total dose of 12 to 15 milligrams), and were operated by a single surgeon with the same type of surgical transverse incision. After surgery, all participants were cared for in post-surgery recovery until they became conscious, and then transferred to the women's surgery ward. Routine care was provided to all groups including control of vital signs, control of bleeding, and post-surgery training, as well as pro re nata (PRN or taken as needed) administration of an intra-rectal diclofenac suppository of 100 mg to relieve the pain of all patients. Participants received auricular acupressure or sham intervention besides routine care or only routine care based on allocation sequence. The starting time of intervention (auricular acupressure or sham intervention) was set three hours after receiving a Diclofenac suppository. As part of routine care, intra-rectal Diclofenac suppository is used to relieve the pain of patients after cesarean section. This time interval considered as the maximum time of complete effect of the suppository is one hour and the peak effect is one to three hours [22].

Auricular acupressure (applied using finger): In the intervention group, auricular finger acupressure was applied on the ear acupoints of Shen Men, Point Zero, Pelvic, Abdomen, Endocrine, and Uterus points in both ears symmetrically as presented in Figure 2 [19, 23]. The skin of the auricular area was cleaned with 70% alcohol and a cotton swab. Then, the selected ear acupoints were pressed with the responsible person from research team with thumb and forefinger for one minute. They applied mild pressure to the extent that the bed of the researcher's fingernails turned white [17, 23]. Auricular acupressure was performed at 3, 5, and 7 hours after surgery.

Sham finger acupressure: In the sham group, the researcher touched the same ear acupressure with a cotton ball for one minute. A cotton ball was placed on the ear without pressure. Sham intervention was conducted at the same time points as auricular acupressure.

The auricular finger acupressure and the sham intervention were conducted by a trained member of research team. She was working as a nurse in postpartum care ward. To conduct auricular acupressure, she was trained in an educational training course teached by a Chinese medical specialist in auriculotherapy sponsored by the Iran Scientific Association of Midwifery.

Routine control: In the control group, no intervention was performed except for routine hospital care.

Outcomes and measurements

The main outcome of the present study was pain severity after cesarean section. The patients' subjective pain experience was assessed using the Visual Analogue Scale (VAS). This scale is a 10 cm ruler in which 0 represents no pain and 10 represents the most severe pain that a person might experience [24]. The validity and reliability of this tool have been confirmed in multiple previous studies [25]. Pain severity was assessed once before the intervention and 15, 30, and 60 minutes after the intervention, and then 3, 6, 12, and 24 hours after the intervention [23]. For the control group with routine care, the same timing was used with start point of three hours after surgery (which was the start time for intervention and sham group).

The secondary outcome of the present study was the total number of Diclofenac suppositories received for pain relief, which was recorded at the end of the intervention according to the patient's record. In addition, a demographic information questionnaire and a medical and surgical checklist were prepared. This questionnaire included questions such as age, education, occupation, average family income, residence (city or village), gestational age, number of pregnancies and deliveries, satisfaction with the gender of the fetus, gender of neonate, pregnancy status, marital satisfaction, and body-mass index. The medical and surgical checklist and registration form for the use of analgesics included a complete list of analgesics used in the operating room and recovery, as well as after surgery, the time of the first breastfeeding, and the time the patient got up from the bed and started walking. In this checklist, the number of times each of these analgesics was used and their dose after surgery and in the operating room and recovery for each person participating in the study were recorded.

Ethical consideration and informed consent

The present study was approved by the Institutional Review Board and the Ethics Committee of Mazandaran University of Medical Sciences, Mazandaran, Iran (approval code: IR. MAZUMS.REC.1399.7708). Participants were informed about the study aim, their freedom to participate in or withdraw from the study, and the confidential management of their data. Then, the written informed consent of each participant was acquired. Study interventions were provided by one of the researchers.

Trial registration

Trial was registered in the Iranian Registry of Clinical Trials under decree code of Registration code: IRCT20130822014436N1 prospectively.

Treatment fidelity

To conduct the intervention, the first author underwent an acupressure training course under the supervision of a traditional medicine specialist. After confirming the accuracy of the implementation method, the intervention was performed on the participants. In addition, to ensure the correct implementation of the techniques, the first 10 interventions were performed under the supervision of the traditional medicine specialist.

Data analysis

SPSS (version 24) was used to analyze the data. The normal distribution of the main outcome (pain score based on VAS) was examined using the Shapiro-Wilk test for the indicators of central tendency, dispersion, and histogram diagram. Intergroup comparisons were performed to evaluate the distribution of variables based on the proposed Imbens and Rubin method, taking into account the standardized mean difference criteria of <0.25 for continuous quantitative variables and <10% risk difference index for qualitative variables [26]. Given the normal distribution of the data, analysis of variance (ANOVA) for repeated measures was used to compare the changes in the mean score of pain score between study groups at different time points. In each case, the prerequisites for performing ANOVA for repeated measures including sphericity test and homogeneity of variance were checked. Due to the lack of sphericity default, the results were reported with Greenhouse-Geisser correction. In cases where the ANOVA result was significant for repeated measures, a Sidak post hoc test was used to determine the differences. Moreover, an analysis of covariance was performed to compare the groups according to the corrected pain score so that the effect of the average pain score at baseline can be controlled. Bonferroni corrections for multiple comparisons were performed. The effect sizes of the mean difference (MD) and the standardized mean difference (SMD) were calculated based on Cohen *d*. A Cohen's *d* effect size of 0.2-0.5 was considered as a small effect size; 0.5-0.8 was considered as medium effect size; and greater than 0.8 was interpreted as large effect size [27]. The mean difference was examined for minimal clinically important difference (MCID) which was reported to be 0.9cm change in VAS pain scores [28]. The significance level of all tests was $p< 0.05$.

Results

A total of 183 mothers participated and 180 individuals completed the study procedure. One of the participants in the intervention group dropped out due to her unwillingness to continue the intervention, and two dropped out from the sham group due to postpartum hemorrhage. The mean age (and standard deviation) of mothers was 30.23 years (SD=5.52). Most mothers had university education (42.8%) and were housewives (81.7%). Other demographic and clinical data are reported in Table 1. In the present study, mothers were allocated into three groups: intervention (n=60), sham (n=59) and control (n=61). The frequency of demographic and clinical variables by treatment group is also reported in Table 1. The variables of baseline pain severity, age, gestational age, and number of pregnancies, neonate gender, and the number of analgesics

received were not equally distributed in the groups, which were controlled as covariates in the RM ANOVA-ANCOVA model.

Table 1. Descriptive information of demographic and clinical variables of mothers in the three groups

The results of the ANOVA for repeated measures before and after correction of the effect of covariates (age) are shown in Table 2 and Figure 2. The corrected results showed that the level of pain among the three groups lasting up to six hours after the intervention was not significantly different from each other. The level of pain in the auricular acupressure intervention group that was obtained 12 and 24 hours after the intervention was significantly lower than the VAS pain reports in the sham and control groups.

Table 2. Mean (standard deviation) of pain score at measurement times by groups and their comparison

Figure 3. Mean pain score during the measurement times by groups. Figure A is based on the results of the uncorrected model and Figure B is based on the results of the corrected model

Since the minimum clinically significant difference for pain is 0.9 units of change in the VAS, the difference between mean pain scores in the auricular acupressure group 12 and 24 hours after the intervention as compared to the sham group (-1.21, -1.24) and the control group (-0.98, -1) was statistically and clinically significant. However, given the effect size of the standardized mean difference, the moderate to significant effect of this intervention in the auricular acupressure group was compared to the sham group and started from three hours after the intervention. The effect size gradually increased 6, 12 and 24 hours after the intervention (i.e., 0.43, 0.68, 0.83, 0.73).

The moderate to significant effect of auricular acupressure compared to the control group started six hours after the intervention and gradually the effect size increased 12 and 24 hours after the intervention (i.e., 0.53, 0.69, and 0.66). Figure 3 shows the trend of changes in the mean pain score in two uncorrected and corrected models separately for the three groups. The results of the study on the secondary outcomes are shown separately in Table 3. The mean number of analgesics received in the first 24 hours after delivery was significantly lower in the intervention group than the sham and control groups. However, there was no difference among the intervention and sham and control groups in terms of breastfeeding time and walking duration on the first day after surgery.

Table 3. Comparison of secondary outcomes in study groups

Adverse outcomes: During intervention and follow-up assessments, no participants reported any adverse effects or reactions related to auricular finger acupressure.

Discussion

The present study evaluated the effect of auricular acupressure on pain severity after cesarean section among three groups given either auricular acupressure, sham or control interventions. The results showed that this method was significantly effective for reducing pain after cesarean section. These findings are consistent with the results reported by Chen et al. [29] and Wei et al [30]. Chen et al. [29] studied the effect of acupressure on nausea, vomiting, anxiety and pain among post-cesarean section women in Taiwan, comparing acupressure (experimental group) with routine postoperative nursing instruction (control group). Acupressure significantly reduced post-cesarean anxiety and pain among the experimental group compared to the control group [29]. Wei et al reported the pain-relieving effect of electroacupuncture of different frequencies on the point of Sanyinchiao for women who underwent cesarian section surgery under spinal anesthesia [30]. However, different results were reported by Hinze [31] who assigned 48 healthy women to one of four different study groups (i.e., therapeutic touch, acupressure, placebo attention with mock transcutaneous electrical nerve stimulation [TENS], and no treatment control group). Participants' anxiety and pain distress ratings were not significantly different among groups but in therapeutic touch and acupressure, a higher perception of effectiveness was reported. In terms of mechanism of action, auricular acupressure is thought to balance the levels of hormones and neurotransmitters in the brain, thereby reducing pain [32]. Also, by stimulating the acupoints including ear acupoints, meridian channel that exists in the body will be activated, it transmits energy throughout the body passing through the ear, and the energy of the whole body can be regulated [17, 33, 34].

The results showed that auricular acupressure at the Shen Men, Points Zero, Pelvic, Abdomen, Endocrine, and Uterus points can reduce the severity of pain after cesarean section. Previous studies have indicated that stimulation of the Shen Men point is highly effective in reducing anxiety, mental disorders, emotional instability, and pain, and has anti-inflammatory properties [35], and stimulation of the Zero point has antispasmodic, analgesic, and sedative effects [35, 36]. Stimulation of the Master Endocrine point has been shown to be effective in treating endocrine disorders, hypothyroidism, hyperthyroidism, diabetes, gynecological diseases, rheumatoid arthritis [35]. Stimulation of the Pelvic and Uterus points is effective in reducing labor pain [23, 36], and stimulation of the Pelvic, and Abdomen points can reduce the pain in abdomen and lower back [37].

The present study showed that the effect of intervention in the auricular acupressure group compared to the sham group started three hours after the intervention and gradually the effect size increased 6, 12 and 24 hours after the intervention. The moderate to significant effect of auricular acupressure compared to the control group started six hours after the intervention and gradually the effect size increased 12 and 24 hours after the intervention. This time-lag between the commencement of intervention and its' effectiveness might be due to the fact that applying auricular acupressure activates some physiological response in different neural pathways [16, 17, 19, 38]. Consequently, passing time is needed for these responses to have a desired effect**,** such

as alleviating pain. Despite an extensive review of the literature, no previous study has ever investigated the effect of auricular acupressure on pain after cesarean section, although some studies have investigated the effect of auricular acupressure on various types of acute and chronic pain.

The results of existing studies have reported inconsistent evidence concerning the effect of auricular acupressure on different types of pain. Any negative findings might be due to reasons such as low sample size, selective patterns for stimulating points on the ear, the source of pain, and the degree of participants' adherence to auricular acupressure protocol. The positive effects of auricular acupressure include managing acute pain in conditions such as dysmenorrhea [12, 39], temporomandibular disorders [40, 41], postoperative pain [19, 42], hip fracture [43], before and after musculoskeletal surgery and trauma [35], and chronic pain, such as chronic back pain [44], and various types of chronic musculoskeletal pain [35, 45].

In obstetrics, the effect of auricular acupressure on episiotomy pain has been investigated in some studies, but none of these showed a significant effect of auricular acupressure on episiotomy pain [46-48]. The positive effect of auricular acupressure for reducing labor pain has been confirmed in various previous studies [20, 23, 49]. However, the results were not statistically significant due to their low sample size. In a systematic review investigating the effect of acupuncture on pain relief, Liu et al. reported that the use of acupuncture in combination with other interventions better reduced severity of acute pain compared to chronic pain and needed shorter treatment time [50]. The results of the present study also showed that the need for analgesics in the intervention group was significantly lower in the auricular acupressure group than in sham and control groups, which was probably a reflection of less pain in this group. Vahedi et al. also reported lower pain severity in the auricular acupressure group compared to a mefenamic acid group [12].

Limitations

The present study had several limitations, including pain assessment using a self-report scale, and the lack of follow-up of patients after 24 hours. Absence of blinding in the routine-care alone group might be a source of bias which may have over-estimated or under-estimated the mean differences between the real acupressure group and the routine care group. A participant may have reported the pain more seriously than the real/sham acupressure group due to the awareness of being assigned in the group with no additional intervention group. Participants may have reported less pain if they felt their condition was not so serious as deserving additional intervention.

Conclusion

Based on the findings, auricular acupressure might be an effective adjuvant complementary treatment for post-operative cesarean pain in controlling pain and reducing the need for analgesics. Moreover, no adverse outcomes were observed related to auricular acupressure.

Author Contributions: ZHM, ZA & TO contributed to the conception and design of the study, ZHM & MA contributed to intervention and data collection; ZA, AH & HDK contributed in data analysing and interpretation of data; ZHM, ZA, TO drafted the manuscript; MDG & ZA provided contributions to the literature review and discussion and prepared the final version of the manuscript. MDG revised the manuscript and copy-edited the manuscript. All authors revised the manuscript, agreed to be fully accountable for ensuring the integrity and accuracy of the study, and read and approved the final version of the manuscript to be published. All the authors met the criteria for authorship, and they are listed as co-authors on the title page.

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Declaration of Competing Interest: The authors have no conflicts of interest to declare.

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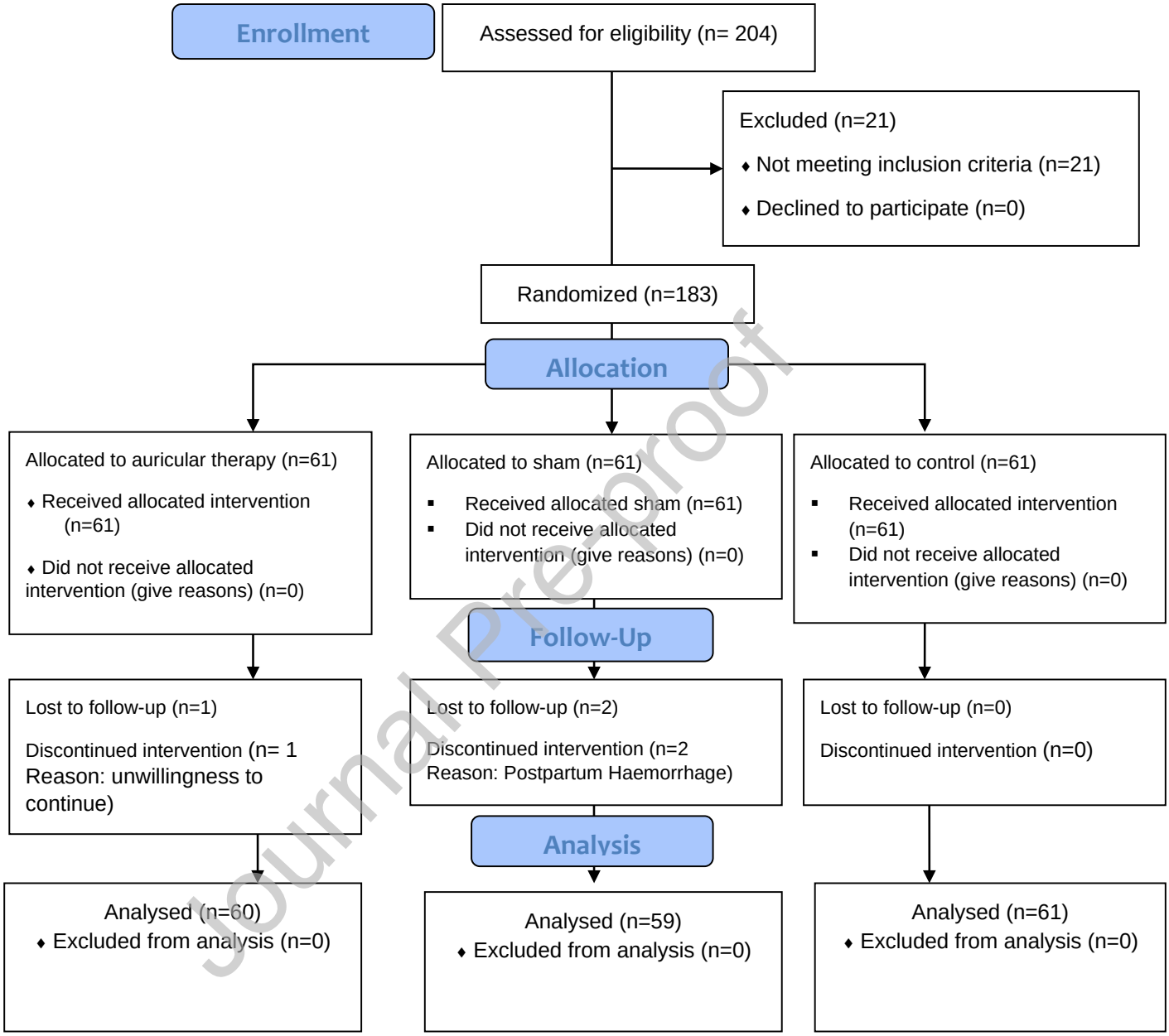
Figures legends:

Figure 1. CONSORT Flow Diagram

Figure 2- Ear acupoints stimulated in present study

Figure 3- Mean pain score during the measurement times by groups. Figure A is based on the results of the uncorrected model and Figure B is based on the results of the corrected model

Figure 1. CONSORT Flow Diagram



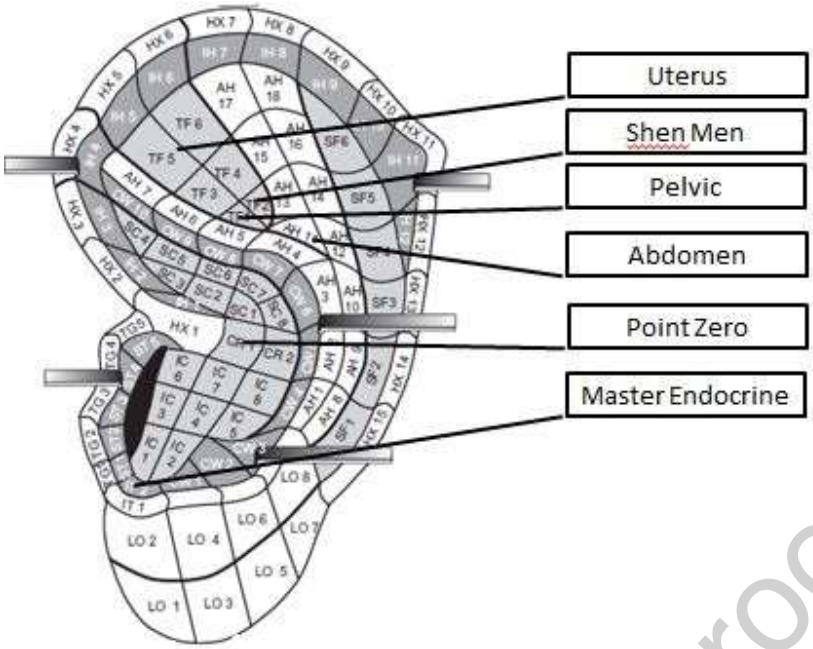
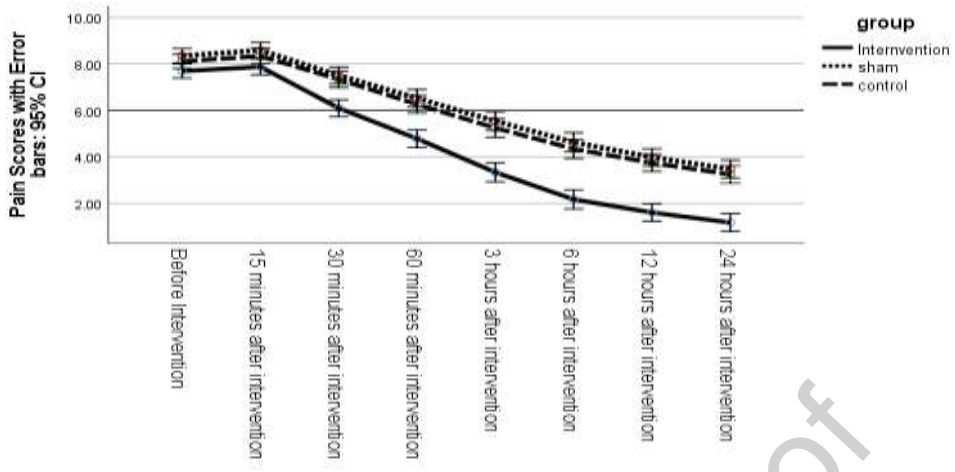
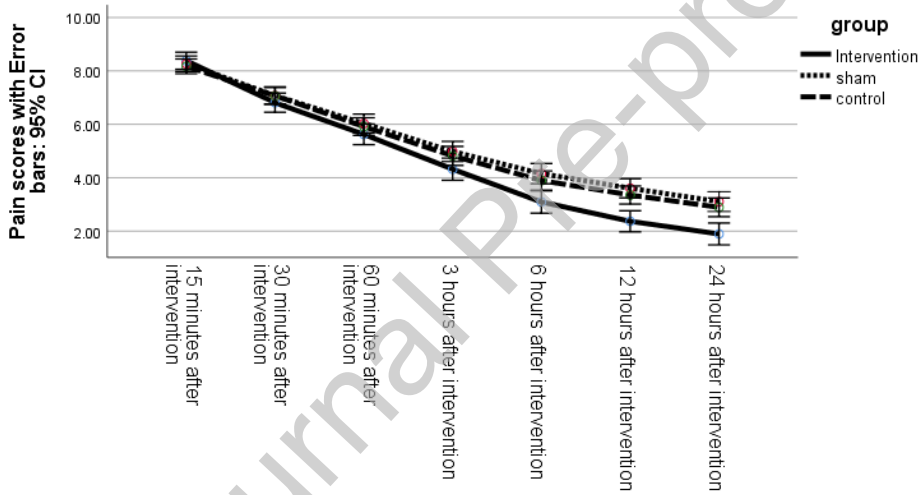


Figure 2. Ear acupoints stimulated in present study



A



B

Figure 3. Mean pain score during the measurement times by groups. Figure A is based on the results of the uncorrected model and Figure B is based on the results of the corrected model

Table 1. Descriptive information of demographic and clinical variables of mothers in the three groups				
		Intervention (N=60)	Sham (N=59)	Control (N=61)
		Mean (SD)	Mean (SD)	Mean (SD)
Age (year)		31.62 (4.66)	29.07 (5.45)	30.00 (6.12)
BMI		31.64 (8.47)	30.91 (4.42)	30.80 (5.78)
Gestational age (weeks)		38.23 (1.05)	38.56 (1.39)	37.79 (1.86)
Surgical time (minutes)		63.67 (24.85)	66.61 (21.66)	67.70 (22.76)
		N (%)	N (%)	N (%)
Number of parity	1	23 (38.3)	35 (59.3)	30 (49.2)
	2	23 (38.3)	14 (23.7)	22 (36.0)
	3	13 (21.7)	9 (15.3)	5 (8.2)
	4	1 (1.7)	1 (1.7)	4 (6.6)
Educational status	Under Diploma	18 (30.0)	17 (28.8)	16 (26.2)
	Diploma	18 (30.0)	14 (23.7)	20 (32.8)
	Academic	24 (40.0)	28 (47.5)	25 (41.0)
Job	House Wife	56 (93.3)	49 (83.1)	42 (68.9)
	Employed	4 (6.7)	10 (17)	19 (31.1)
Residency	Town	32 (53.3)	30 (50.8)	32 (52.5)
	Village	28 (46.7)	29 (49.2)	29 (47.5)
Income level	Less than the cost of living	20 (33.3)	17 (28.8)	16 (26.2)
	equal for the cost of living	30 (50.0)	41 (69.5)	41 (67.2)
	More than the cost of living	10 (16.7)	1 (1.7)	4 (6.6)
Having health insurance	Yes	56 (93.3)	51 (86.4)	55 (90.2)
	No	4 (6.7)	8 (13.6)	6 (9.8)
Neonate gender	Male	26 (43.3)	41 (69.5)	34 (55.7)
	Female	34 (56.7)	18 (30.5)	27 (44.3)

Table 2. Mean (standard deviation) of pain score at measurement times by groups and their comparison

Model	Time	Intervention (N=60)	Sham (N=61)	Control (N=59)	Intervention vs. Sham		Intervention vs. Control		Sham vs. Control	
					MD [95% CI]	SMD [95% CI]	MD [95% CI]	SMD [95% CI]	MD [95% CI]	SMD [95% CI]
Crude*	Baseline	7.70 (1.50)	8.36 (1.09)	8.11 (0.95)	-0.66 [-1.19; -0.13]	0.33 [-0.03; 0.69]	-0.41 [-0.94; 0.11]	0.50 [0.14; 0.87]	0.24 [-0.29; 0.77]	0.25 [-0.12; 0.60]
	15 m	7.88 (1.38)	8.59 (1.31)	8.34 (1.29)	-0.71 [-1.30; -0.12]	0.34 [-0.02; 0.71]	-0.46 [-1.05; 0.12]	0.53 [0.16; 0.89]	0.25 [-0.34; 0.84]	0.20 [-0.16; 0.60]
	30 m	6.10 (1.35)	7.51 (1.44)	7.34 (1.44)	-1.41 [-2.03; -0.78]	0.89 [0.51; 1.26]	-1.24 [-1.86; -0.62]	1.01 [0.63; 1.39]	-0.16 [-0.46; 0.79]	0.12 [-0.24; 0.45]
	1 h	4.78 (1.30)	6.53 (1.53)	6.26 (1.59)	-1.74 [-2.40; -1.08]	1.02 [0.64; 1.40]	-1.48 [-2.13; -0.83]	1.23 [0.84; 1.62]	0.26 [-0.39; 0.92]	0.17 [-0.19; 0.53]
	3 h	3.33 (1.41)	5.54 (1.65)	5.25 (1.70)	-2.21 [-2.92; -1.50]	1.30 [0.84; 1.62]	-1.91 [-2.61; -1.21]	1.44 [1.04; 1.84]	0.30 [-0.40; 1.00]	0.17 [-0.19; 0.53]
	6 h	2.17 (1.25)	4.63 (1.57)	4.34 (1.92)	-2.46 [-3.17; -1.75]	1.73 [1.31; 2.15]	-2.18 [-2.88; -1.47]	1.34 [0.94; 1.74]	0.28 [-0.43; 0.99]	0.17 [-0.19; 0.52]
	12 h	1.60 (0.85)	3.98 (1.43)	3.74 (1.91)	-2.38 [-3.03; -1.73]	2.02 [1.58; 4.46]	-2.14 [-2.78; -1.49]	1.45 [1.05; 1.85]	0.24 [-0.40; 0.89]	0.14 [-0.22; 0.50]
	24 h	1.17 (0.49)	3.47 (1.64)	3.25 (1.92)	-2.31 [-2.97; -1.65]	1.9 [1.47; 2.33]	-2.08 [-2.73; -1.42]	1.48 [1.08; 1.89]	0.23 [-0.43; 0.89]	0.12 [-0.24; 0.48]
Adjusted**	15 m	8.38 (1.24)	8.27 (1.16)	8.17 (1.09)	0.11 [-0.47; 0.70]	-0.09 [-0.45; 0.27]	0.21 [-0.34; 0.76]	-0.18 [-0.54; 0.18]	0.10 [-0.38, 0.57]	0.09 [-0.27; 0.45]
	30 m	6.81 (1.40)	7.07 (1.32)	7.07 (1.24)	-0.27 [-0.92; 0.39]	0.19 [-0.17; 0.55]	-0.26 [-0.88; -0.37]	0.20 [-0.16; 0.56]	0.01 [-0.52; 0.54]	0 [-0.36; 0.36]
	1 h	5.62 (1.55)	6.03 (1.40)	5.92 (1.32)	-0.41 [-1.11; 0.30]	0.28 [-0.08; 0.64]	-0.29 [-0.96; 0.38]	0.21 [-0.15; 0.57]	0.12 [-0.45; 0.69]	0.08 [-0.28; 0.44]
	3 h	4.32 (1.63)	4.98 (1.47)	4.82 (1.40)	-0.67 [-1.42; 0.09]	0.43 [0.06; 0.79]	-0.50 [-1.23; -0.22]	0.33 [-0.03; 0.69]	0.17 [-0.44; 0.78]	0.11 [-0.25; 0.47]
	6 h	3.10 (1.63)	4.15 (1.47)	3.90 (1.40)	-1.06 [-1.83; -0.30]	0.68 [0.31; 1.04]	-0.80 [-1.53; -0.08]	0.53 [0.16; 0.89]	0.26 [-0.36; 0.88]	0.17 [-0.18; 0.53]
	12 h	2.37 (1.55)	3.60 (1.40)	3.35 (1.32)	-1.24 [-1.96; -0.52]	0.83 [0.46; 1.21]	-0.98 [-1.67; -0.30]	0.69 [0.32; 1.06]	0.25 [-0.33; 0.84]	0.18 [-0.18; 0.54]
	24 h	1.89 (1.63)	3.11 (1.47)	2.89 (1.40)	-1.21 [-1.96; -0.47]	0.78 [0.41; 1.15]	-1.00 [-1.70; -0.29]	0.66 [0.29; 1.02]	0.22 [-0.39, 0.82]	0.15 [-0.21; 0.51]

Statistical results:
* Crude model: Repeated measure ANOVA: Effect of time: F= 1093.99, p<0.001; Effect of Group: F= 37.52, p<0.001; Effect of Group*Time: F=13.34, p<0.001
**Adjusted model: Repeated measure ANOVA-ANCOVA: Effect of Time: F= 0.48, p=0.71; Effect of Group: F=3.98, p=0.02; Effect of Group*Time: F=5.00, p<0.001
Covariates=Baseline pain scores (p<0.001), Age (p=0.43), Gestational age (p=0.41), Parity (p=0.009), Neonatal gender (p=0.71), Number of received painkillers (p<0.001)

Table 3. Comparison of secondary outcomes in study groups

Secondary outcome variables	Intervention (N=60)	Sham (N=61)	Control (N=59)	MD; 95% CI			
				Intervention vs. Sham	Intervention vs. Control	Sham vs. Control	ANOVA statistics
Number of received Diclofenac suppositories	2.30 (1.17)	4.51 (1.14)	4.34 (1.42)	-2.21 (-2.76; -1.65)	-2.04 (-2.59; -1.49)	0.16 (-0.39; 0.72)	F= 57.94; P<0.001*
Walking time on the first day after surgery (minutes)	34.75 (11.26)	35.97 (9.83)	31.16 (7.01)	-1.21 (-5.43; 3.00)	3.59 (-0.60; 7.77)	4.80 (0.60; 9.00)	F= 4.15; p=0.02**
Breastfeeding time (minutes)	122.83 (42.86)	128.98 (44.59)	135.74 (44.48)	-6.15 (-25.64; 13.34)	-12.90 (-32.23; 6.42)	-6.75 (-26.17; 12.66)	F=1.30; p=0.27

* Intervention group differed significantly from Sham and Control group.

** Sham group had significantly higher scores compared to Control group.

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