Comparison of two methods of complementary medicine on postoperative pain and anxiety: A randomized clinical trial

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Abstract:

BACKGROUND: Postoperative pain and anxiety are unpleasant situations that are often experienced by women undergoing cesarean section. Since the routine methods of pain relief after surgery is still inadequate, the need for complementary treatments is felt. Foot Reflexology (FR) and Auricular Acupressure (AA) are two of the most popular and safe procedures of complementary and alternative medicine therapies. So, this study aimed to determine and compare the effectiveness of reflexology and AA on postoperative pain and anxiety.

MATERIALS AND METHODS: This three-group randomized clinical trial study was performed on 101 pregnant women, admitted to Mashhad Omolbanin hospital, for a cesarean section, in 2015. In the intervention groups, 2–3 h after the operation, AA or FR was performed for 20 min. Routine care was provided for the control group. Pain and anxiety were evaluated by VAS and Spielberger anxiety questionnaire before and 1 and 2 h after the intervention.

RESULTS: The results showed that immediately after the intervention, pain intensity was significantly lower in both AA and FR groups ($P < 0.001$) compared with the control group. In addition, 2 h after the interventions, pain intensity was significantly lower in the AA group compared with the control group ($P = 0.006$). However, no significant differences were observed between the FR and the control groups ($P = 0.095$). In addition, 1 and 2 h after the intervention, anxiety was significantly different between the three groups ($P = 0.033$ and $P = 0.018$), respectively. The results of the Tukey test showed that this difference was only between FR and control groups ($P = 0.025$ and $P = 0.017$), respectively.

CONCLUSION: AA is more effective in reducing post-cesarean pain while FR effectively reduces post-cesarean anxiety. Therefore, these complementary medicine treatments as easy and noninvasive methods are recommended to be used during labor for improving maternal outcomes.

Keywords:
Anxiety, auriculotherapy, complementary therapies, pain, reflexotherapy

Introduction

Today, cesarean section) CS (is one of the most common surgical procedures in women and cesarean rates have been rising rapidly in the last decades.[1,2] In some countries, CS is carried out in up to 60% of deliveries.[3] The prevalence of CS is also high in Iran and is estimated at 48%.[4] CS carries the risk of some maternal morbidity such as pain and anxiety.[5] Studies indicate that moderate-to-severe postoperative pain is experienced in 86% of the patients[6] and post-cesarean pain is more severe than those previously reported in the majority of cases.[4] On the other hand, postoperative anxiety is associated with postoperative pain.[7]

Poorly managed post-cesarean pain and anxiety may increase postoperative complications such as postpartum depression, persistent pain,[5] prolonged hospital stays,[6] greater opioid use, delayed functional recovery,[8] and limited breastfeeding.[9]

Despite receiving pain treatment, a large number of surgery patients suffer postoperative pain.[10,11] In addition, routine analgesic procedures in postoperative pain control are still inadequate[12] and can induce some adverse effects (AEs).[6] Therefore, there is a need for complementary and alternative medicine (CAM) treatments to improve the patient's quality of life, reduce postoperative pain and anxiety, and analgesic medication requirements and AEs.[6,13] There are several CAM methods for pain and anxiety management.[14] Recent studies have indicated that two of the most popular and safe procedures of CAM therapies are Auricular acupressure (AA) and foot reflexology (FR).[15,16] Reflexology is the stimulation of reflex points through deep massage on some parts of the body, which is often done on the feet.[16,17] Reflexologists believe that specific pressure on "reflex zones" would activate the healing power and positively affect the corresponding parts of the body[16,18] and can thus cause relaxation, preserve health, and reduce pain and anxiety.[17,18] Auriculotherapy is a branch of reflexology and also it is based on the traditional Chinese practice of acupuncture, which means stimulation of acupoints in the auricle (external surface of ear).[19] There are several methods of auricular stimulation such as using needles, lasers, moxibustion, magnetic or vaccaria seeds, and transcutaneous electrical and manual pressures.[6,20]

Auricular acupuncture can relieve various types of pain; especially postoperative pain.[20]

Auricular acupressure is a non-invasive intervention similar to acupuncture, which may be considered cost-effective, more acceptable to patients, and much easier to use compared with acupuncture.[21] Based on a systematic review and meta-analysis in terms of the efficacy of the various methods of auriculotherapy, the strongest evidence for pain relief is provided by AA and auricular acupuncture, respectively.[22]

Various studies have confirmed the positive effects of AA or FR on pain and anxiety.[16,22-26]

However, some studies have ruled out the positive effects of these CAMs.[21,27,28]

Moreover, the result of a meta-analysis indicates that although auriculotherapy may be effective for postoperative pain management, further well-designed trials of the effect of auriculotherapy will be required.[29]

No sufficient scientific studies on AA have been conducted in Iran. Moreover, considering the doubts about the effectiveness of complementary medicine among the medical community and the lack of evidence for comparing these methods of CAM to determine the optimal method for the treatment of postoperative pain or anxiety, this study aimed to determine and compare the effectiveness of reflexology and AA on postoperative pain and anxiety.

Materials and Methods

Study design and setting
A randomized controlled trial was conducted on 117 pregnant women candidates for elective CS in Omolbanin hospital in Mashhad, Iran. The study was approved and supported by the Mashhad University of Medical Sciences. The trial was also registered in the Iranian Registry for Clinical trials (IRCT2014122920475N1).

Study participants and sampling
The eligibility criteria included singleton pregnancy, gestational age of over 37 weeks, labor pains not yet started, elective cesarean section planned before the onset of labor, using spinal analgesia for cesarean section, lack of medical conditions in mother (cardiac, respiratory, and hepatic or neurologic), the age range of 19 to 35 years, normal body mass index (18.5 < BMI < 30) in the first trimester of pregnancy, no history of infertility, lack of injuries and wounds at the feet or ears, no history of migraine, no history of FR or auriculotherapy, and no addiction to drugs, sedatives, and alcohol.

The exclusion criteria included lack of cooperation, non-transverse cesarean incision, and complications during and after surgery such as excessive bleeding, adhesions, fetal death, and prolonged duration of surgery (more than 1 h).

After the explanation of the aim and methodology of the study, written informed consent was signed by the subjects, who volunteered to participate in the study.

Having been enrolled, the patients were randomly allocated into three groups; namely, AA, FR, and control, according to block randomization, which consisted of six blocks. The baseline data were then collected using the socio-demographic questionnaire and Spielberger State-Trait Anxiety Inventory (STAI). The mothers completed the Spielberger State anxiety questionnaire and the pain visual analog scale (VAS) again before the intervention, immediately after interventions, and 1 and 2 h after the interventions [Figure 1].

The sample size was calculated by NCSS software based on the results of a similar study to compare the pain score
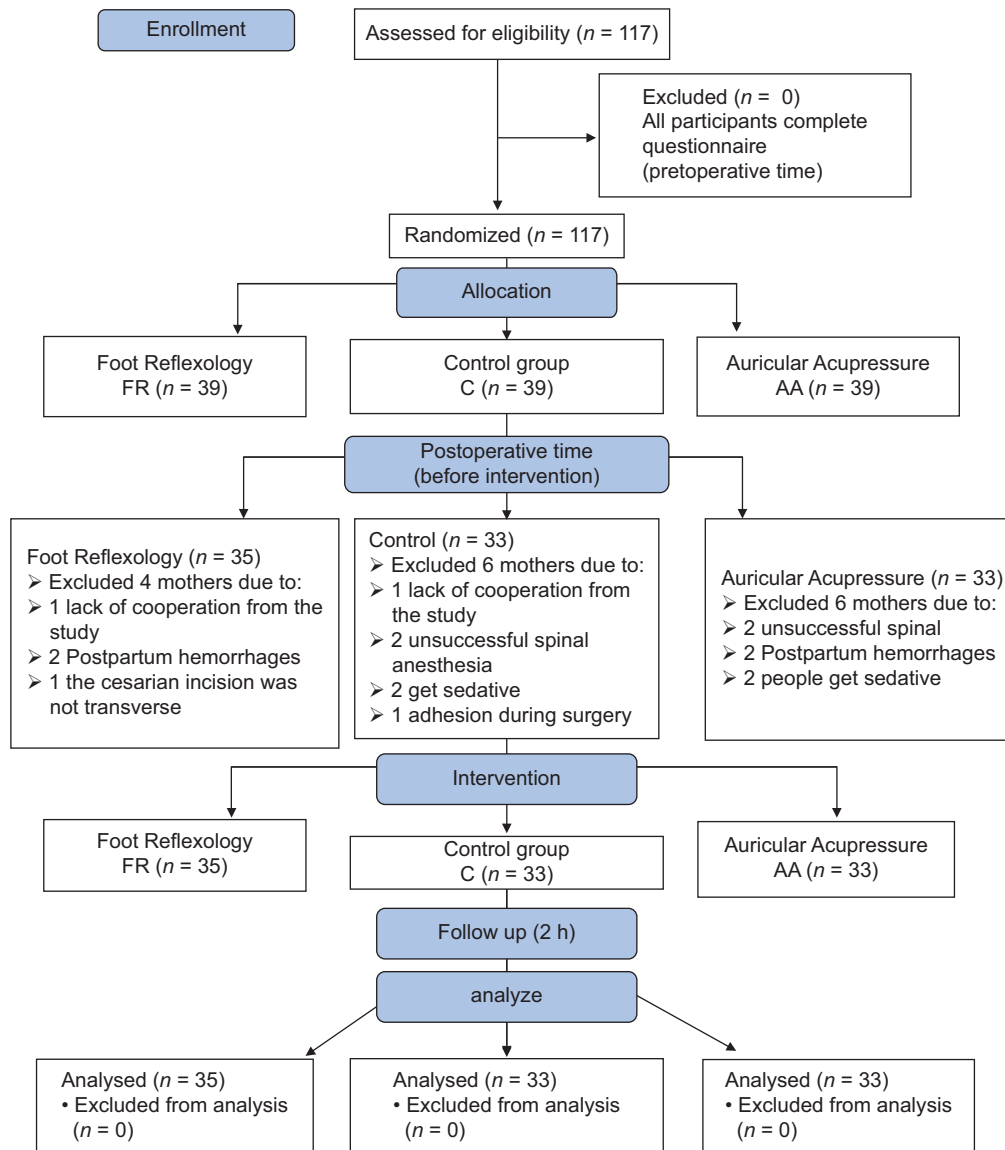
Figure 1: CONSORT flow diagram of participants

in the three groups of 24 subjects (a total of 72)[28] and three groups of 32 subjects (a total of 96) with the effect size of δ = 0.8 and δ = 0.5, for the FR and AA groups, respectively, according to another study on the comparison of the anxiety level in the three groups.[30] Using a confidence level of 95% and power of 80% and allowing for 20% loss to follow-up, 39 participants were estimated to be required for each group (a total of 117 for this study).

In this study, 117 pregnant candidates for elective cesarean section participated, but 16 participants were excluded from the study (before the intervention) because of a lack of conditions for continued study [Figure 1].

Data collection tool and technique
Interventions were applied by one researcher with theoretical and practical training and certified by a faculty

member (Chinese Traditional Medicine Specialist) before and during the study (the same researcher did FR or AA). The researcher performed interventions only one time, 2–3 h after the operation and before the subjects received an analgesic drug for 20 min.

In the AA group, the five auricular points in both ears including the shenmen, subcortex, uterus, pelvic, and abdominal points, were stimulated for 20 min (circulating, 30 s pressure, four turns totally or 2 min for each point) using a manual pointer. Before the study, the precision of locating the desired points and using the correct technique was confirmed. The mean pressure was 1 to 2 kg (depending on the acupoint and participant's tolerance).

The patients in the FR group received FR massage in five reflex zones in both feet including solar plexus, CNS,

intestine, uterus, and pelvic for 20 min, each zone being massaged for 2 min. A non-aromatic oil (sesame oil) was used to reduce friction.

The patients in the control group only received routine care and the researcher was present in the room and answered their questions at the time of intervention for 20 min to eliminate the psychological effects of the presence and attention of the researcher. It should be noted that the participants in each group received routine pain relief (diclofenac 100 mg suppository) if necessary to observe ethical considerations.

STAI was used to evaluate anxiety. Trait anxiety was evaluated one time (before the operation) while stat anxiety was evaluated four times (before the operation, before the intervention, and 1 and 2 h after intervention).

The STAI was developed by Spielberger in 1970 as a self-administered questionnaire.[31] This inventory is made up of 40 questions divided equally into two subscales for State Anxiety (SA) and Trait Anxiety. The scores ranged from 1 to 4. Positive items scored from very low (4), low (3), high (2), to very high (1). Negative items had a reverse scoring from very low (1), low (2), high (3), to very high (4). The total score in each subscale was between 20 and 80. Scores in the ranges of 20 to 40, 41 to 60, and 61 to 80 indicated mild, moderate, and severe anxiety, respectively. The validity and reliability of this questionnaire for the Iranian population were confirmed by Mahram (1994).[32] In the current study, reliability values of $\alpha = 0.78$ and $\alpha = 0.84$ were obtained for the State and Trait Anxiety, respectively, using the calculation for Cronbach's alpha.

Visual analog scale) VAS) was used four times (before the intervention, immediately after interventions, and 1 and 2 after the interventions) to evaluate pain intensity. VAS is a 10-cm horizontal or vertical line, ranging from "No Pain" to "Intolerable Pain." The patients were asked to mark the number, which reflected their pain severity, where "0" indicated the absence of pain and "10" indicated the presence of very severe pain. The vertical line is assumed to be easier to understand in general.[33] In the current study, Cronbach's α internal consistency coefficient was found to be 0.76 for the VAS.

Statistical analysis
The SPSS statistical software (v. 16) was used for data analysis. Normalization of the data was first measured using the Shapiro–Wilk and Kolmogorov–Smirnov tests. The analysis was carried out using the Chi-square test, Fisher exact test, one-way Analysis of variance (ANOVA), Tukey's *post hoc*, non-parametric Kruskal–Wallis test, and paired samples *t*-test.

ANOVA was used to compare the groups for the pain intensity and total anxiety score, followed by Tukey's *post hoc* test to compare the groups two-by-two. Moreover, ANOVA was performed for repeated measures with the between-subject factor GROUP (AA, FR, and control) and within-subject factor TIME (measurement time points). In the current study, $P < 0.05$ was considered statistically significant.

Ethical considerations
This study was approved and supported by the Mashhad University of Medical Sciences, in 2015 (Ethics Committee code IR.MUMS.REC.1394.261). The authors certify that they have obtained the appropriate patient consent form. In the form, the patients have given their consent for clinical information to be reported in the journal. The patients understand that their names and initials will not be published.

Results

Baseline characteristics
All 101 participants, who completed the study, were married and live with their spouses. None of the participants smoked. There were no significant differences in baseline characteristics (socio-demographic data) such as age, gravida, parity, gestational age, weight, BMI, mothers' and fathers' educational status, income level, occupation, living area, marital satisfaction, gender of the baby, and satisfaction with the gender of the baby ($P > 0.05\%$). Table 1 shows some of the results.

In addition, there were no significant differences among the groups in terms of the duration of operation and hospitalization, and fasting before intervention ($P > 0.05\%$).

Results for Spielberger state-trait anxiety inventory
One-way ANOVA indicated that there were no significant differences among the three groups at preoperative state-trait anxiety and postoperative (before intervention) state anxiety ($P > 0.05\%$). Furthermore, the average anxiety score was significantly different among the three groups at 1 and 2 h after the intervention ($P = 0.033$ and $P = 0.018$), respectively). The results of Tukey's test showed that this difference was only between FR and control groups ($P = 0.025$ and $P = 0.017$, respectively) [Table 2].

Results for pain (VAS)
One-way ANOVA indicated that there were no significant differences among the three groups at postoperative pain score (before intervention) ($P > 0.05\%$). In addition, the average pain score was significantly different among the three groups immediately after intervention ($P < 0.001$).

Tukey's *post hoc* test indicated that both AA and FR were significantly lower than the control group (P < 0.001).

The results showed that no significant differences between the three groups 1 h after the intervention. Moreover, 2 h after the intervention, there were statistically significant differences in pain between the three groups (P = 0.007). *Post hoc* (Tukey) test showed that this difference was between the AA and control groups (P = 0.006). In particular, repeated measure analyses indicated that the interaction effect of GROUP*TIME significantly increased in FR and control groups (P < 0.001) [Table 3 and Figure 2].

Moreover, in both experimental groups, the request for receiving the first analgesic was made significantly later than in the control group (P < 0.001).

Discussion

In this randomized clinical trial, the effects of two methods of CAM (FR and AA) on post-cesarean pain and anxiety were compared and investigated. Since the routine methods of pain relief after surgery are still inadequate, the need for interventions and complementary treatments is felt. These CAMs are well accepted by most of the participants, can be implemented easily in clinical practice, and appear safe with respect to potential side effects and complications. These therapies are aimed at harmonizing the functions of body organs and physical and mental problems.[34] FR involves the application of deep pressure by the thumb and forefinger in specific areas of the feet.[16]

AA can be performed by several techniques such as using a finger, acupressure with a manual device, and magnetic or vaccaria seeds.[19,35] In this study, the manual acupressure method was used.

The results of this study showed that although FR and AA both showed significantly better results than the control group for pain intensity during the study time, the best results were observed in AA. Regarding anxiety, in the present study, a significant decrease in the postoperative state anxiety score was found only in the FR group.

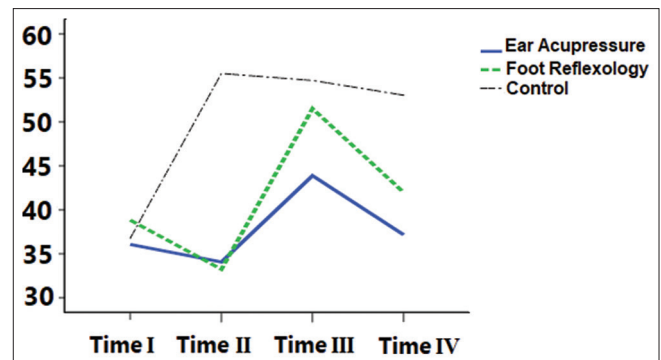In congruence with the current study, Masoudi *et al.*[36] (2022) showed that acupressure reduced mothers'

Table 1: Some baseline characteristics of participants

	Ear acupressure n (%)	Foot reflexology n (%)	Control n (%)
Educational status			
Primary school	6 (18.2)	5 (14.3)	11 (3.3)
Secondary school	7 (21.2)	16 (45.7)	7 (21.2)
Diploma	17 (51.5)	11 (34.4)	12 (36.4)
University	3 (9.1)	3 (8.6)	3 (9.1)
Working conditions			
Unemployed	31 (93.9)	34 (97.1)	31 (93.9)
Employee	2 (6.1)	1 (2.9)	2 (6.1)
Gravida			
First	1 (3.0)	2 (5.7)	0 (0)
Second	27 (81.8)	26 (74.3)	22 (66.7)
Third and more	5 (15.2)	7 (20.0)	11 (33.3)
Parity			
First	1 (3.0)	2 (5.7)	3 (9.1)
Second	32 (97.0)	33 (94.3)	30 (90.9)
Pregnancy planning			
Yes	21 (63.6)	28 (80.0)	21 (63.6)
No	12 (36.4)	7 (20.0)	12 (36.4)
Maternal feeling			
Very happy	14 (42.4)	19 (54.3)	10 (30.3)
Happy	17 (51.5)	16 (45.7)	21 (63.6)
Not happy nor sad	2 (6.1)	0 (0)	2 (6.1)
Satisfaction with the gender of the baby			
Yes	24 (72.7)	30 (85.7)	27 (81.8)
No	3 (9.1)	0 (0)	0 (0)
It doesn't matter	6 (18.2)	5 (14.3)	6 (18.2)

Figure 2: Postoperative pain, measured in patients who received ear acupressure (EA), foot reflexology (FR), and routine care (control) before interventions or at a comparable time in the control group (time I), immediately after the intervention (time II), 1 h after intervention (time III), and 2 h after intervention (time IV) using VAS pain. P < 0.001 time II: (EA and control) and (FR and control). P = 0.006 time IV: (EA and control)

Table 2: Postoperative state anxiety

State anxiety	Mean±SD			ANOVA
	Ear acupressure	Foot reflexology	Control	
Before intervention	38.69±7.87	37.85±7.49	40.66±9.34	P=0.362
1 h after intervention	39.84±7.51	37.37±6.69	42.54±9.65	P=0.033
2 h after intervention	37.30±7.66	36.00±7.64	41.30±8.05	P=0.018
	P=0.134	P=0.269	P=0.276	

Table 3: Severity of postoperative pain (VAS)

State anxiety	Mean±SD			ANOVA
	Ear acupressure	Foot reflexology	Control	
Before intervention	36.06±15.40	38.29±13.87	37.27±16.31	P=0.834
Immediately after intervention	34.06±21.01	33.14±13.83	56.27±18.82	P<0.001
1 h after intervention	43.88±20.02	51.60±20.46	54.70±21.56	P=0.096
2 h after intervention	37.15±20.65	42.50±19.66	52.82±19.93	P=0.007
	P=0.088	P<0.001	P<0.001	

anxiety. Research by Valiani *et al.*[37] (2018) conducted to determine the effect of auriculotherapy on the severity and duration of labor pain showed that auriculotherapy reduces the severity of labor pain. In the study of Wan LS *et al.*[24] (2013), the AA by auricular-plaster therapy alleviates postoperative pain and is partially consistent with the results of several studies, which indicated that FR was significantly better than the control group for postoperative pain and anxiety.[22,23] However, AA was inconsistent with the findings of Kwan *et al.*'s[27] study (2013), which indicated no significant differences between AA and placebo for postpartum pain, perhaps the differences in the population of the study or AA techniques have led to differences in results. So that, in their study, AA was performed using vacaria seeds, while in the present study, we used the manual acupressure method. Moreover, in their study, postpartum perineal pain after vaginal delivery was evaluated; while we evaluated post-cesarean pain. Therefore, maybe the difference in the type and nature of the pain caused the difference in the results; post-caesarean pain is an incision pain, in addition to uterine contractions. According to another study, although AA can significantly reduce analgesic drug usage, there were no differences in pain scores between the intervention and control groups. Inconsistent with the present study, Vakilian *et al.*[38] (2022) conducted a study on the effect of Auriculotherapy on Labor Anxiety, and they reported that auriculotherapy was effective to reduce anxiety pain. Perhaps the differences in the method of auriculotherapy have led to differences in results. Because in their study, auriculotherapy was performed using electrical stimulation.

Various studies have confirmed the positive effects of FR on pain and anxiety.[16,23,39,40] Levy, S. *et al.*[41] (2020) showed that FR had a positive short-term anxiolytic effect during labor with moderate-to-severe anxiety pain. Navaee *et al.*[42] (2020) showed the positive effect of reflexology massage on pre-cesarean anxiety in primiparous women. However, Hafizi *et al.*[43] (2021) reported that despite the positive effect of FR on post-cesarean pain, it cannot reduce post-cesarean anxiety. Maybe the differences in scale have led to differences in results; we used STAI, while in their study anxiety was evaluated by VAS.

In the present study, AA was more effective in reducing post-cesarean pain while not positively affecting

postoperative anxiety. Juan Rodríguez *et al.*[44] (2014) showed that AA and massage therapy yielded better results in the control group in terms of the pain and anxiety of the elderly. Better results were specially obtained in AA. This may be because reflexology is more superficial and differs from massage therapy.[16] In general, these complementary medicine methods, by resulting in the reduction of adrenaline, noradrenaline, and increasing endorphin, opens the blocked paths of energy channels, which leads to the free flow of energy in the body and causes the body to regain its health and balance.

Limitations
The main limitations of this study were the short follow-up period after treatment. Moreover, participants in this study were women with CS, which might limit the generalizability of our findings to women giving vaginal birth.

In the end, to confirm the effectiveness of these complementary methods, long-term follow-up and using other auricular points or reflex zones are recommended. Moreover, in further study, comparing these methods with other complementary medicine methods should be considered

Conclusions

Although AA and FR showed better results than the control group in post-cesarean pain, AA is more effective. Moreover, FR is more effective in reducing post-cesarean anxiety. Therefore, the application of AA and FR to relieve pain and anxiety, respectively, is recommended in post-cesarean care.

List of abbreviations
Foot Reflexology (FR), Auricular acupressure (AA), Cesarean Section) CS(, Complementary and Alternative Medicine (CAM), Adverse Effects (AEs), Spielberger State-Trait Anxiety Inventory (STAI), Visual Analog Scale (VAS).

Declarations
Ethics approval and consent to participate: The study was approved by the Ethics Committee at the Mashhad University of Medical Sciences (MUMS) and was carried out with the financial support of the Deputy of Research.

The researchers obtained written informed consent from each participant as one of the criteria for them to join the study. The consent form outlined that participation is voluntary, participant anonymity will be protected, and participants may withdraw their participation whenever they desire with no repercussions. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication
Not applicable.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions
FSM: conception and design of the study. Analyzed and interpretation of data and drafted the manuscript. NG: helped with the literature search prepared the proposal and design the study, revising the article. HBT: acupuncturist. Revising the article. MV: revising the article and interpretation of data. FR: drafted the manuscript and data gathering. AS: data analysis. All authors have read and approved the final manuscript.

Conflicts of interest
There are no conflicts of interest.

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