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Auricular acupressure promotes uterine involution after cesarean section: A randomized controlled trial

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ABSTRACT

Background: Postpartum subinvolution of the uterus is a more common condition after cesarean section. Auricular acupressure (AA) is widely used for the treatment of postpartum diseases. However, few studies have explored the effects of AA as a treatment of uterine involution following cesarean section to date. This study aimed to assess the efficacy and safety of AA for uterine involution after cesarean section.

Methods: A total of 109 women who underwent cesarean section participated in this study. They were randomly allocated to either real AA or sham AA in a 1:1 ratio by a computer program. For 3 days, the real AA and sham AA groups received treatment 3 times daily. A series of assessments at 42 days after cesarean section, namely on the uterine size, the incidence of hydrometra, the first anal exsufflation time, bleeding volume at 6 hours, bleeding volume at 6–24 hours along with other general assessments were carried out.

Results: A total of 89 women completed the study. The uterine size at 42 days after a cesarean section was 6.3 cm smaller in the real AA group than in the sham AA group ($P < 0.01$). The incidence of hydrometra on day 42 postpartum was lower in the real AA group than in the sham AA group ($P < 0.01$). The lochia duration and the first anal exsufflation time after cesarean section were shorter in the real AA group than in the sham AA group ($P < 0.05$).

Conclusion: AA improves uterine involution after cesarean section.

Trial registration: ChiCTR1800015569.

1. Introduction

Uterine involution refers to the contraction and retraction of uterine muscle fibers after the delivery of a baby and its appendages. It entails the uterine volume and the attached part of the placental endometrium retreating to the non-pregnant state. The process takes approximately 6 weeks.[1] During the natural postpartum recovery process, over 70% of Chinese mothers have been reported to have varying degrees of incomplete uterine involution. This percentage has been increasing each year.[2] Incomplete uterine involution prolongs lochia by a duration of 3–10 days. This can also be accompanied by a slow decrease in the uterine fundus; intrauterine infection, such as fever, abdominal pain, lochia odor, uterine tenderness, or low back pain; or feeling of abdominal distension.[3] Moreover, the occurrence of complications affects maternal physical, mental health and quality of life.[4] The causes of uterine subinvolution include cesarean section, residual placental membrane, endometritis, pelvic infection, and uterine fibroids. Of these, the incidence of uterine subinvolution in cesarean section is

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the highest. Relevant data have shown that complications are 5–10 times more prevalent in cesarean section than in natural birth.[5]

Clinical observations show that AA can relieve postpartum pain[6] and improve postpartum anxiety and fatigue.[7, 8] It can also accelerate anal exhaust and defecation after cesarean delivery and promote recovery of gastrointestinal function.[9, 10] The results of previous clinical studies suggest that AA may contribute to uterine involution.[11, 12] The AA intervention is simple, convenient to implement, safe, and non-invasive.

High-quality evidence is needed to confirm the effect of AA. However, to date, no randomized controlled trials (RCTs) have been conducted on AA therapy for uterine involution. Thus, we designed a prospective clinical study with parallel randomized auricular and sham acupressure interventions to evaluate the efficacy and safety of AA on uterine involution after cesarean section.

2. Methods

2.1. Study design

This single-center, single-blind, RCT with a parallel-group design was conducted in Guangzhou, China from April 2018 to April 2019.

2.2. Ethical statement

The study was approved by the ethics committee of First Affiliated Hospital of Guangzhou University of Chinese Medicine (NO. ZYYECK [2017]071). Written informed consent was obtained from each participant.

2.3. Selection criteria

Prior to enrolment, all patients had signed the informed consent form and had been informed that they might be assigned to the real AA group or the sham AA group, and the efficacy of the treatment is uncertain. The researchers also performed blind evaluations of the patients after each treatment. The results of blind evaluation showed that there was no significant difference between the 2 groups.

Patients who underwent cesarean section were recruited by the co-first author (JCZ) in the postpartum ward of a tertiary medical cent providing maternity care. Patients were included in the study if they met the following criteria: cesarean section primipara, age $\geq$ 20 years and $\leq$ 40 years, single pregnancy, gave birth at $\geq$ 37 weeks of gestation, neonatal weight $\geq$ 2,500 g and $<$ 4,000 g, no obstetric complications from pregnancy through the intrapartum period, no medical or surgical disease history, and could breastfeed after birth. Patients were excluded if there were neonatal anomalies, genital malformations, or uterine abnormalities (such as uterine fibroids or adenomyosis), abnormal amniotic fluid, had received drugs to inhibit uterine contractions within 48 h before cesarean section, postpartum hemorrhage, or other high-risk complications. After explaining the aim of the study to eligible women face-to-face, the co-first author (JCZ) obtained written informed consent from those who had agreed to participate. Patients who did not complete the trial according to the design, and those who had obvious interventional factors affecting the determination of efficacy or safety, were excluded from the study.

2.4. Sample size calculation

The sample size was calculated based on the research team's previous findings. The sum of the three uterine diameters was 140.3 $\pm$ 14.5 mm in the real AA group and 147.8 $\pm$ 12.8 mm in the sham AA group. We set $\alpha = 0.05$ and $\beta = 0.2$ for statistical analysis of the study. PASS 11.0 software analyzed the experimental and control groups by comparing 2 independent means of the sample. The lost in follow-up rate was 20%. After calculation, the study required 51 cases in each group. Finally, a total of 128 patients were included in the study, with 64 patients in each group.

2.5. Randomization

Patients from the postpartum ward at First Affiliated Hospital of Guangzhou University of Chinese Medicine were randomly allocated into either the real AA or sham AA groups in a 1:1 ratio. Patients were allocated to either the real AA or sham AA group by randomization. A computer program was used to randomize the patients (according to the procedure predefined by Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine, Guangzhou, Guangdong Province, China). The study coordinator was responsible for allocating the randomization codes, which indicated the arms into the sequentially numbered and sealed envelopes. These envelopes were concealed from the investigators. In this study, both the analyst and the patients were blinded; however, the investigators were not blinded. The acupoint sticking tape (Beijing Zhongyan Taihe Medical Instrument Co. Ltd) used in the 2 groups was produced by a single manufacturer and the appearance was identical without any identifying features. A clinician (YFL) was responsible for screening qualified patients according to the admission criteria and assigning random numbers. The random allocation sequence was kept in an opaque sealed envelope in a locked drawer in the principal investigator's (GHL) office. Two acupuncturists (XZ and RZ) performed AA and sham AA interventions in the 2 groups. A research assistant (WLZ), blinded to the group allocation, was trained to collect data. The data analyst (LML) was also blinded to the patients' group assignments. Until the blinding was revealed after the trial, all patients were unaware of the subject grouping.

To evaluate the efficacy of the blinding, we performed a blind evaluation on the patients. Within 5 min after the end of each treatment, we asked the patients if they thought they were in the real AA group or the sham AA group. They were asked to provide their answers on a numerical scale. A score of 100 points meant that they were positive and were in the real AA group; 75 points meant that they thought they might be in the real AA group; 50 points meant they were unsure; 25 points meant they thought they might be in the sham AA group; and 0 points meant they were sure that they were in the sham AA group.

2.6. Interventions

Both groups received basic treatment after cesarean section, including routine intraoperative use of 10 U oxytocin myometrial injection, 10 U intravenous drip, perioperative antibiotics to prevent infection, and intravenous oxytocin injection (10 U qd) to promote uterine contraction for 3 days. The patients in both groups were no longer rooming-in, breastfeeding, and using other drugs to promote uterine contraction.

AA was provided by a senior physician (SXW) with 18 years of clinical acupuncture experience. The acupressure protocol included selecting 5 points (the monaural kidney, spleen, liver, internal genitalia, and central rim) (Supplement 1), embedding and taping the Wang Bu Liu Xing seed to the auricle at 2 hour postpartum, and applying acupressure for 1–2 min each time, 3 times daily. Treatment was administered every other day. During each treatment, both ears were pressed alternately, for a total of 2 treatments.

Both groups were treated for 3 days. At a fixed time of each day in the morning, during the middle of the day, and in the evening, the physician invited each patient from the 2 groups to the treatment room and pressed the auricle with the same force. If the pa-

tient realized that it was intolerable, the intervention was halted in time. The interaction time was equal between the 2 groups.

The treatment and operation methods for the sham AA group were the same as those for the real AA group, but the Wang Bu Liu Xing seeds were not stuck to the adhesive tape in the control group.

2.7. Single-blind

Two groups of acupoint sticking tape were the same. The real AA group's tape had Wang Bu Liu Xing seeds, and the sham AA group's tape had none. The amount of stimulation after pressing was significantly different between the 2 groups. The stimulation of real AA group was larger. The patients felt swelling, fever, or even pain in the areas where acupressure was, while the sham AA group did not experience these sensations. Because Wang Bu Liu Xing seeds are small in size, and we used uniform skin-colored tape, there was not much difference in appearance. The patients were also evaluated blinded after each treatment.

2.8. Outcome measures

2.8.1. Primary outcome

Uterine size on day 42 postpartum

The transverse, long, and anterior and posterior diameters of the uterus were measured by Color Doppler ultrasound to calculate the sum of the 3 diameters.

2.8.2. Secondary outcomes

1) Incidence and number of cases of hydrometra on day 42 postpartum,
2) Sum of the distance of uterine fundus drop for the first 3 days after delivery and the cumulative height of uterine fundus drop every day.

The same researchers were responsible for measuring and recording the parameters each time to reduce errors caused by different operators. The height of uterine fundus drop per day (cm) was determined by the height of the fundus uteri on the previous day (cm)minus the height of the fundus uteri on the present day (cm). The dropping height on the first day after delivery was replaced by a, the total dropping height on the second day after delivery was replaced by B', the dropping height on the second day after delivery was replaced by b, the total dropping height on the third day after delivery was replaced by C', and the dropping height on the third day after delivery was replaced by c. The relationship was as follows: B' = a + b, C' = a + b + c.

1) The first anal exsufflation time after cesarean section
2) Lochia duration, followed up to 42 days postpartum, with clean lochia as an indicator.
3) Bleeding volume (prenatal and postnatal volume difference of single-use maternity kit, calculated by a designated nurse) at 6 hours and 6–24 hours after cesarean section.
4) Changes in hemoglobin and red blood cell count in the blood analysis 48 hours after surgery compared to the levels before surgery.

The occurrence of adverse events was recorded throughout the study.

2.9. Statistical analysis

The analyses were performed on the intention-to-treat (ITT) population, defined as those patients who had completed baseline assessment and at least 1 evaluation after treatment. Group differences at each measuring time point were examined using 2 independent sample *t*-tests. The repeated measurements analysis of variance was used for comparison before and after treatment. Categorical variables, including categorical baseline variables and incidence of adverse events, were analyzed using the chi-square ($\chi 2$) test or the Fisher's exact test. Grade data was expressed as a composition ratio, and the 2 groups were compared using a Wilcoxon rank sum test. If part of the data for uterine size or uterine effusion were missing, we used multiple interpolation to perform interpolation and set the missing data to be randomly missing. We used the meta-analysis method to combine the multiple imputation results and calculate the final results. All statistical analyses were performed using SPSS 20.0 (IBM SPSS Inc., Armonk, New York, USA). We conducted bilateral tests, and $P < 0.05$ was considered statistically significant. Review Manager 5.3 software was used to combine and analyze the dataset results produced by multiple interpolation.

In the past 42 days, postpartum Color Doppler ultrasound data was missing for 21 (19.3%) cases, multiple imputation methods were used for statistical analysis in the experimental group, and a total of 5 imputations were performed. The outcomes in Supplement 2 and Supplement 3 represent the data for the uterine size at 42 days postpartum and incidence of hydrometra, obtained after conducting 5 interpolations. In order to show the similarity of the results after multiple imputations, the results of the 5 imputations and the un-imputed results have been displayed in the form of a forest diagram for mutual comparison.

3. Results

3.1. Patients characteristics

Of the recruited 128 primiparas who underwent cesarean section, 120 met the criteria. These 120 patients were randomly assigned to either the AA group (60 cases) or the sham AA group (60 cases), of which 109 patients (90.8%) completed the entire treatment and 89 patients (74.2%) completed the entire trial. Reasons for withdrawal are shown in Fig. 1. Data were missing for 21 patients (10 in the real AA group and 11 in the sham AA group), including eight women who refused to return to the designated hospital for follow-up Color Doppler ultrasound and 13 felt no discomfort during the telephone follow-up and refused to return to the designated hospital for review on time. For missing data of these patients, we used multiple interpolation. There was no difference in baseline data between the 2 groups (Table 1).

There was no difference between the real AA group and the sham AA group in terms of baseline characteristics (Table 1).

3.2. Outcome measures

3.2.1. Primary outcome

Forty-two days after cesarean section, uterus size in the real AA group was 6.3 cm smaller than that of the control group (95% confidence interval (CI) -11.6 to -0.9, $P < 0.01$). The 5 interpolation results were consistent (Supplement 2).

3.2.2. Secondary outcomes

-Secondary outcome 1

Incidence and number of cases of hydrometra. There were 2 patients in the real AA group had hydrometra on day 42 postpartum, which was far less than the 13 patients in sham AA group. There was a significant difference between the 2 groups, the difference was significant difference (P=0.007 < 0.01). Additionally, the 5 interpolation results were consistent (Supplement 3).

-Secondary outcome 2

The changes in the height of the uterine fundus drops at different time points before and after delivery as shown in Table 2. The height of uterine fundus drop in 2 groups after delivery increased

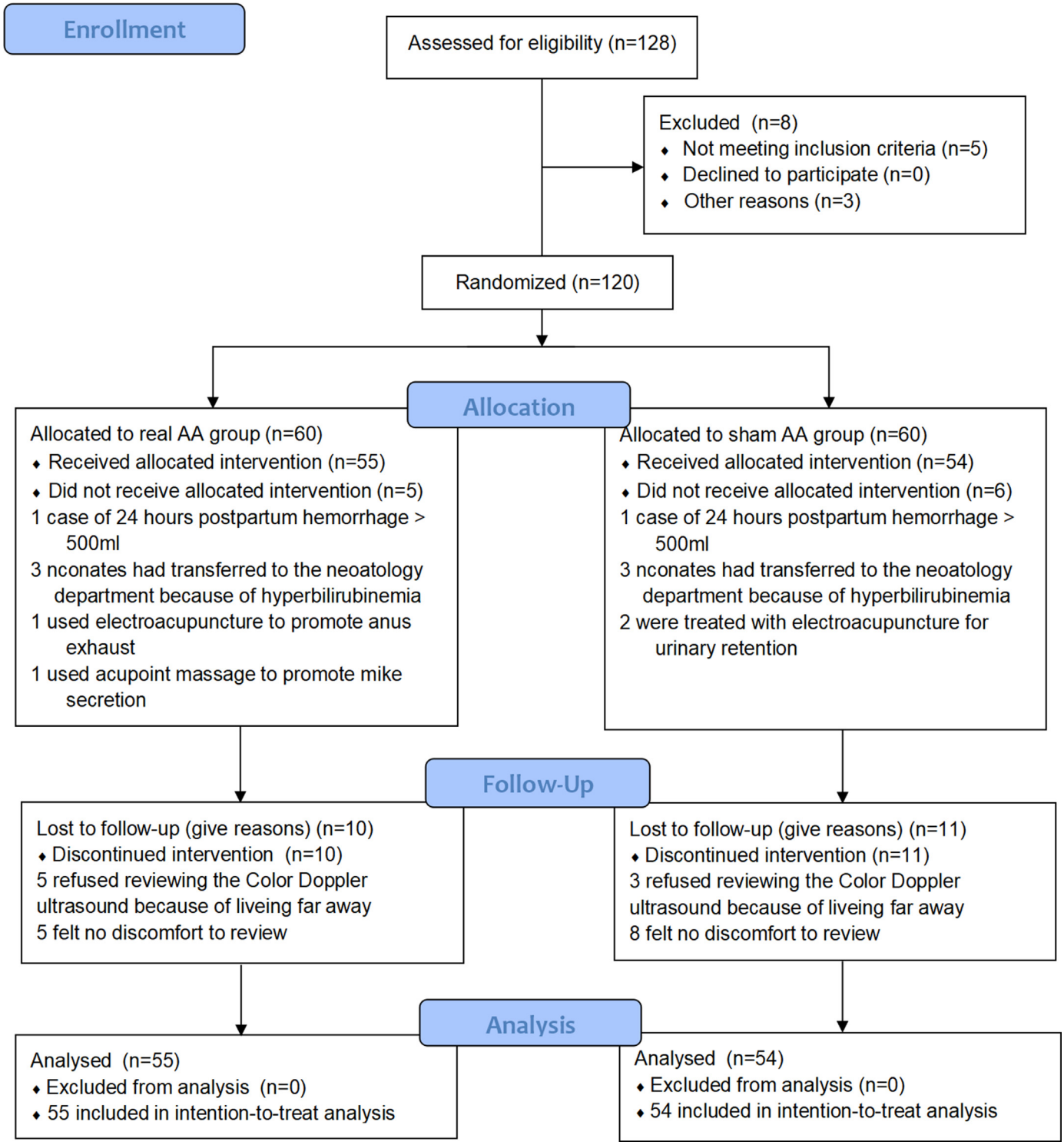

Fig. 1. CONSORT diagram: flow of patients through the study.

with time on the first and second day and decreased on the third day ($P < 0.01$). The sum of the height of uterine fundus drop of 2 groups after delivery increased with time. Compared with the sham AA group, the difference of real AA group on the first, second, and third day after delivery was higher than sham AA group ($P < 0.01$).

The first anal exsufflation time after cesarean section in the real AA group was shorter than that of the sham AA group ($P < 0.05$, Table 2). The are no significant differences in amount of bleeding and hemoglobin and red blood cell count between real AA group and the sham AA (Table 2)

Since the follow-up time of study was 42 days after delivery, a total of eight patients were not clean after the duration of lochia exceeded 42 days; therefore, the mean value was not calculated according to measurement data. Lochia can be cleaned within a month in most women, so the duration of lochia was divided into 3 groups: < 30 days, 30-42 days, and > 42 days. Lochia dura-

Table 1
Patients baseline characteristics.

Variable	Total, n=109, (%)	Real AA, n=55, (%)	Sham AA, n=54, (%)	t or $\chi 2$	*p*
Age (yr)	28.0 (3.6)	27.6 (3.0)	28.5 (4.1)	-1.3	0.2
Uterine height (cm)	158.9 (4.2)	158.4 (3.9)	159.4 (4.6)	-1.2	0.2
Body temperature, ℃	36.5 (0.3)	36.5 (0.3)	36.5 (0.3)	0.4	0.7
Week of delivery, W	39.6 (1.0)	39.6 (1.0)	39.6 (1.0)	Z 0.2	0.8
Amount of bleeding, ml	298.8 (44.0)	293.6 (48.0)	304.1 (39.2)	-1.3	0.2
Amniotic fluid, ml	684.2 (201.0)	674.2 (188.0)	694.4 ± 214.9	-0.5	0.6
Preoperative red blood cells (× 1012/L)	4.0 (0.4)	4.0 (3.4, 5.3)	3.9 (3.2, 4.5)	1.9	0.1
Preoperative hemoglobin, g/L	120.8 (11.5)	120.6 (11.4)	121.1(11.7)	-0.2	0.8
Newborn weight, kg	3.4 (0.4)	3.4 (0.4)	3.3 (0.3)	1.0	0.3
Dysmenorrhea	6.0 (5.5)	5.0 (9.1)	1.0 (1.9)	2.7	0.1
History of vaginal trial-production	16.0 (14.7)	9.0 (16.36)	7.0 (13.0)	0.3	0.6
History of spontaneous abortion	8.0 (7.3)	4.0(7.3)	4 (7.4)	2.0	0.3
Newborn sex	-	-	-	-	-
Male	55 (50.5)	32 (58.2)	23 (42.6)	1.5	0.2
Female	54 (49.5)	23 (41.8)	31 (57.4)		

Table 2
Outcomes.

Variable		Group		Difference (95% CI)	ES	*p*
		Real AA Mean (SD)	Sham AA Mean (SD)			
Decrease uterine height	Day1	1.1(1.1)	0. 8(0.7)	0.4 (-0.1 to 0.8)	0.4[0.0,0.7]	0.24
	Day2	1.9(1.7)	1.0(1.0)	0.9 (0.4 to 1.4)	0.9[0.4,1.4]	0.00
	Day3	1.1 (1.2)	1.0(1.1)	0.2 (-0.3 to 0.6)	0.2[-0.4,0.7]	0.90
Tatal decrease uterine height	Day1	1.1(1.1)	0. 8(0.7)	0.4 (-0.2 to 1.0)	0.4[-0.0,0.8]	0.44
	Day2	1.9(1.7)	1.0(1.0)	1.2 (0.7 to 1.8)	0.2[-0.1,0.6]	0.00
	Day3	4.2(2.1)	2.8(1.4)	1.4 (0.8 to 2.0)	0.8[0.4, 1.2]	0.00
The first anal exsufflation time (h)		24.1 (14.7)	30.33 (12.84)	-6.25 (-11.50,-1.01)	-0.45 [-0.83, 0.07]	0.02
Bleeding volume at 6 hours, ml		58.09 (16.62)	56.30 (18.02)	1.79 (-4.79, 8.38)	0.10 [-0.27, 0.48]	0.59
Bleeding volume at 6-24 hours ml		34.00 (12.78)	32.22 (12.31)	1.78 (-2.99,6.54)	0.14 [-0.24, 0.52]	0.46
Red blood cells × 10^{12}/L		0.33 (0.33)	0.30 (0.26)	0.03 (-0.08,0.15)	0.10 [-0.28, 0.48]	0.58
Hemoglobin d, g/L		9.09 (9.56)	9.69 (8.36)	-0.59 (-4.01,2.82)	-0.07 [-0.44, 0.31]	0.73

tion in real AA group was shorter than that of the sham AA group ($P < 0.01$).

One adverse event occurred in each group, which was characterized by ear itching symptoms, but with no skin damage. It was determined that the ear itching symptoms occurred because of the AA tape's adhesion. Symptoms disappeared after switching to desensitizing tape (produced by Jiaozuo Union Medical Materials Co. Ltd). The incidence of adverse events related to AA for both groups was 1.7%.

3.3. Blinding test

In order to evaluate the effect of patient blinding, we perform blind evaluation on patients. Within 5 minutes of the end of each treatment, ask the patient to answer that it is 100 points in the AA group, possibly 75 points in the AA group, 0 points in the sham AA group, and 25 points in the sham AA group, 50 points for no idea.

For the first blind score, the real AA group (60.0 ± 28.4) and the sham AA group (59.9 ± 27.9) had a difference of 0.12 points. However, this difference was not statistically significant within a 95% CI (-11.8,12.1), $P > 0.05$. For the second blind score, the real AA group (60.0 ± 25.8) and the sham AA group (60.5 ± 30.0) had a difference of -0.47 points. This difference was also not statistically significant within a 95% CI (-13.3,11.4), $P > 0.05$.

4. Discussion

Patients received AA experienced shorter uterine involution times than in the sham AA group at day 42 after cesarean section. Furthermore, the AA intervention reduced uterine effusion occurrence, lochia duration, and the first anal exsufflation time for post-cesarean section patients during the early postpartum period. However, AA did not affect the amount of bleeding at 6 hours and 6–24 hours after the patients' cesarean sections. The study had 74.2% completion rate. No serious adverse events occurred during the whole study period.

There are few studies on the effect of ear acupoint pressure on uterine involution. Two previous studies have suggested that AA may help uterine involution. Chen et al.[11] studied the effect of AA combined with traditional Chinese medicine foot bath on uterine involution after cesarean section, but the study did not describe the course of AA treatment, and only the name of AA and the method of pressing were mentioned. Zheng et al.[12] studied the combination of AA and oxytocin to reduce postpartum hemorrhage and promote uterine involution, but the study did not include women who had undergone cesarean section. Therefore, it is temporarily impossible to directly compare the results of this study with the existing literature.

The uterine involution rate after cesarean section is slower than that of natural delivery, and the amplitude is smaller as well. This may be a reason the incidence of uterine subinvolution is higher for cesarean section than for natural delivery.[13] Uterine subinvolution after cesarean section may occur because of multiple reasons. First, the cesarean section cuts the uterine muscle bundle and cuts off the blood vessels between the muscle walls. Even if sutured, its continuity is interrupted. Poor blood supply affects uterine contraction, which weakens the hemostasis caused by blood vessel compression in the muscular layer during uterine contraction.[14] Second, the uterine incision diminishes the integrity of the uterus, and affects the symmetry and polarity of uterine contractions. This results in increased intrauterine bleeding.[15] Increased postpartum bleeding further inhibits uterine contraction. Third, newborn sucking nipples can promote uterine contraction, reduce postpartum hemorrhage, and promote uterine recovery. However, fasting and drinking before cesarean section, increased blood loss during surgery, and slow recovery of gastrointestinal function after

surgery affect the nutritional supply. At the same time, inconvenience and wound pain delay the first time the infant sucks the nipple. These factors cause mothers to miss the best window for lactation reflex, thus affecting uterine involution.[16] Finally, mental health factors after cesarean section may affect the pituitary and hypothalamus function, reduce prolactin secretion, decrease lactation, and reduce breastfeeding rates.[17]

In this study, compared with the sham AA group, the duration of lochia and the time of first anal exhaust after cesarean section in the AA group were significantly shortened. The reduction of postpartum hemorrhage is conducive to uterine contraction after cesarean section. The reduction of the first anal exhaust time after cesarean section is beneficial to the recovery of gastrointestinal function[18] and increases the absorption of nutrients. Spleen and liver acupoints can also promote lactation.[19] These combined effects may be the reason why AA enhances uterine contractions.

This study has several limitations. First, we did not measure maternal uterine size before pregnancy. This is because most pregnant women do not visit the hospital for treatment and establish corresponding files until 20 weeks into their pregnancies. Prior to this stage, many pregnant women have yet to have a uterine ultrasound. Therefore, it is impossible to obtain comprehensive data on maternal uterine size before pregnancy. Thus, conducting a before and after comparison would be unrealistic. In addition, according to the Chinese habits, the purpura is usually recuperating at home within 42 days after delivery. Women will not go to the hospital for any examination unless feeling any specific discomfort. There is no data available to explain the usual timeline of how the size of the uterus changes within 42 days of delivery among women undergoing cesarean section. Second, only the amount of bleeding within 24 hours after birth was registered and calculated. Subsequent bleeding amounts were not registered, and postpartum bleeding was not thoroughly evaluated. Third, AA treatment was performed only within 3 days of hospitalization after cesarean delivery. From discharge to 42 days after delivery, there are still many confounding factors that cannot be ruled out. This may have affected the results. Fourth, we did not evaluate health economic indicators.

In conclusion, this RCT showed that AA promotes uterine contractility in patients undergoing cesarean section, compared with a sham AA group. It was also found to reduces the incidence of uterine effusion and shortens the first anal exsufflation time and lochia duration, thus promoting uterine involution after cesarean section. Therefore, AA is an effective and safe therapy for uterine involution after cesarean section.

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Author contributions

Conceptualization: SXW, JCZ and GHL; methodology: JCZ and LML; acupuncturists: SXW, XZ and RZ; software: YFL; validation: TL and ZJR; investigation: WLZ and YFL; data curation: WLZ and YFL; data analysis: LML; writing–original draft: RJZ and ZJC; writing–review & editing: SXW and ZJL; supervision: YLL; project administration: SXW and GHL; funding acquisition: GHL.

Conflict of interest

The authors report no conflicts of interest in this work.

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Ethical statement

This research was approved by the ethics committee of First Affiliated Hospital of Guangzhou University of Chinese Medicine (NO. ZYYECK [2017]071).

Data availability

The data will be made available upon reasonable request.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2021.100724.

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