

EFFECTS OF AURICULOTHERAPY ON LABOR TIME AND CESAREAN SECTION RATE: RANDOMIZED CLINICAL TRIAL

EFEITOS DA AURICULOTERAPIA NO TEMPO DE TRABALHO DE PARTO E TAXA DE CESÁREA: ENSAIO CLÍNICO RANDOMIZADO

EFFECTOS DE LA AURICULOTERAPIA EN EL TIEMPO DE TRABAJO DE PARTO Y TASA DE CESÁREA: ENSAYO CLÍNICO ALEATORIZADO

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ABSTRACT

Objective: to evaluate the effects of auriculotherapy on labor time and cesarean section rate. **Method:** this is a controlled, randomized, parallel and triple blind clinical trial. We selected 102 parturients with gestational age ≥ 37 weeks, cervical dilatation ≥ 4 cm and two or more contractions every 10 minutes. Parturients were randomly assigned to three groups at a university hospital in the countryside of the state of São Paulo, Brazil, to receive auriculotherapy, placebo or to participate as control group without intervention. Auriculotherapy was applied with crystal microspheres at four strategic points. The effects of the treatment were compared using the Kruskal-Wallis, Fisher's exact and chi-square tests. **Results:** the mean duration of labor was lower in the auriculotherapy group (607.8 versus placebo: 867.9 versus control: 694.7 minutes; p-value = 0.845); the rate of cesarean section was higher in the placebo group (55.9% versus auriculotherapy: 26.5% versus control: 20.6%, p-value = 0.0045). **Conclusion:** parturients who received auriculotherapy showed a lower cesarean rate compared to the placebo group and shorter labor time when compared to the other groups, but further studies are necessary. Registration: n° RBR-47hhbj.

Keywords: Auriculotherapy; Labor, Obstetric; Cesarean Section; Complementary Therapies; Obstetric Nursing.

RESUMO

Objetivo: avaliar os efeitos da auriculoterapia sobre o tempo de trabalho de parto e taxa de cesárea. **Método:** trata-se de um ensaio clínico controlado e randomizado, paralelo e triplo-cego. Foram selecionadas 102 parturientes com idade gestacional ≥ 37 semanas, dilatação cervical ≥ 4 cm e duas ou mais contrações em 10 minutos. As parturientes foram distribuídas aleatoriamente em três grupos em um hospital universitário do interior do estado de São Paulo, Brasil, para receber: auriculoterapia, placebo ou participar como controle, sem intervenção. A auriculoterapia foi aplicada com microesferas de cristal em quatro pontos estratégicos. A comparação dos efeitos do tratamento foi feita por meio dos testes: Kruskal-Wallis, exato de Fisher e qui-quadrado. **Resultados:** a média de duração do trabalho de parto foi menor no grupo de auriculoterapia (607,8 versus placebo: 867,9 versus controle: 694,7 minutos; p-valor = 0,845); a taxa de cesárea foi maior no grupo placebo (55,9% versus auriculoterapia: 26,5% versus controle: 20,6%; p-valor = 0,0045). **Conclusão:** as parturientes que receberam auriculoterapia mostraram menor taxa de cesárea em relação ao grupo placebo e menos tempo de trabalho de parto ao comparar com os demais grupos, porém novos estudos se fazem necessários. Registro: n° RBR-47hhbj.

Palavras-chave: Auriculoterapia; Trabalho de Parto; Cesárea; Terapias Complementares; Enfermagem Obstétrica.

RESUMEN

Objetivo: evaluar los efectos de la auriculoterapia sobre el tiempo de trabajo de parto y la tasa de cesárea. **Método:** se trata de un ensayo controlado aleatorizado, paralelo y triple ciego. Se seleccionaron 102 parturientas con edad gestacional ≥ 37 semanas, dilatación cervical ≥ 4 cm y dos o más contracciones en 10 min. Las parturientas fueron divididas aleatoriamente en tres grupos en un hospital universitario del interior del Estado de São Paulo, Brasil, para recibir auriculoterapia, placebo o participar como control, sin intervención. La auriculoterapia se aplicó con microesferas de cristal en cuatro puntos estratégicos. Los efectos del tratamiento fueron comparados por medio de las pruebas: Kruskal-Wallis, exacto de Fisher y chi cuadrado. **Resultados:** la media de duración del trabajo de parto fue menor en el grupo de auriculoterapia (607,8 versus placebo: 867,9 versus control: 694,7 minutos, p-valor = 0,845); la tasa de cesárea fue mayor en el grupo placebo (55,9% frente a la auriculoterapia: 26,5% frente al control: 20,6%, p-valor = 0,0045). **Conclusión:** las parturientas que recibieron auriculoterapia mostraron menor tasa de cesárea en relación al grupo placebo y menor tiempo de trabajo de parto al comparar con los demás grupos; sin embargo, son necesarios nuevos estudios. Registro: n° RBR-47hhbj

Palabras clave: Auriculoterapia; Trabajo de Parto; Cesárea; Terapias Complementarias; Enfermería Obstétrica.

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INTRODUCTION

The interventionist and medicalized model of childbirth has generated numerous discussions and reflections among obstetric professionals both in the humanization of care and in the identification of routine practices in some institutions which are considered obstetric violence.¹ A retrospective North American study analyzed 7,296,363 deliveries in three States between 1995 and 2009 and revealed that more than 4% of full-term births occurred before the start of labor (L) and without medical indication, including cases of induction and/or cesarean section.² Another study³, conducted in Brazil, showed that cesarean sections are performed in 52% of births, and in the private sector the number increases to 88%. However, the recommendation of the World Health Organization (WHO) is that only 15% of deliveries be performed through this surgical procedure.

Women can be assisted during labor in a way they are the protagonists, considering that gestation is a physiological and natural event of their reproduction. Some authors have proposed integrative and complementary practices (ICP)^{4,5} aiming to rescue the humanization of childbirth care and comfort to parturient women, ensuring the good obstetric practices recommended by WHO.⁶

In Traditional Chinese Medicine (TCM), some therapies replace conventional medical treatment or are used in a complementary way to it. Acupuncture, auriculotherapy and acupressure are some of these therapies. Auriculotherapy is used in the treatment of different dysfunctions of the body and for analgesia, through stimuli in reflex points of the ear. This therapy aims to harmonize the functions of organs and viscera and physical and mental illnesses from the reflex that the stimulus in its points exerts on the central nervous system.⁷

Some studies have evaluated the effects of auriculotherapy in chronic pain, as a systematic review showed.⁸ In the results presented, auriculotherapy decreased pain intensity, especially chronic low back pain and chronic tension-type headache. Another review⁹ sought evidence of the use of auriculotherapy with vaccaria seeds or rigid microspheres in the treatment of insomnia. This study showed that auriculotherapy is beneficial in the treatment of primary insomnia, with improvement in sleep time and quality. However, these literature reviews^{8,9} suggest that more methodological rigorous randomized controlled trials (RCTs) are needed to assess the efficacy of such therapy.

Auriculotherapy has some points described for the treatment of obstetric dystocia, induction of labor, and reduction of expulsion time,^{7,10} and may be an alternative to the qualified care of parturients. However, the scarcity of studies in this population limits the establishment of this therapy in obstetric practice. In this context, this study aimed to evaluate noninvasively the effects of auriculotherapy on labor time and cesarean section rate.

METHOD

This is a randomized, parallel, controlled clinical trial performed from April 2015 to June 2016. This study is part of a larger project that had as secondary outcomes of auriculotherapy the duration of labor and cesarean section rate. The participants were 102 pregnant women admitted for delivery at a public tertiary and teaching hospital located in the countryside of the state of São Paulo, Brazil. To be included in this study, the women should: be of any age or parity; have 37 weeks of gestation; be on spontaneous, induced and/or guided labor, with dilation ≥ 4 cm and two or more contractions every 10 minutes; have integral skin in the auricular pavilion, and with a fetus that was alive, in vertex cephalic presentation and with good conditions of vitality. Cases with dilatation ≥ 7 cm, severe preeclampsia, placenta previa, previous cesarean section, or immediate indication of this surgical procedure were excluded.

The sample was calculated in order to compare the groups in relation to the variable labor time. ANOVA models were used. The estimates of means of labor time for each of the groups and the standard deviation of the mean square of the error of the model was based on a previous study⁵ on the effects of acupressure on the labor time; a difference of 407.04 min in labor time. Moreover, a significance level of 5% and test power of 80% were assumed in sample calculations. The calculation resulted in a sample of 33 individuals per group, out of 99 individuals.

Blind allocation was used to distribute the participants in the treatments. To this end, opaque, sealed envelopes, sequentially numbered with aid of the site <http://www.randomization.com> were distributed in three groups: auriculotherapy with microspheres of 1,5 mm polished crystals (Intervention Group - IG); auriculotherapy with (low cost) glass microspheres (Placebo Group - PG); and control group (CG). The envelopes were opened by the principal investigator after inclusion of the parturient in the study. This was done in the presence of two workers of the unit who were not participating in the study and who did not provide care to the parturients. The study used the triple-blind method, that is, neither the IG and PG parturients nor the team of five evaluators (nursing technicians) who recorded the results of the study, nor the professionals who provided care and who could influence the outcomes of labor (induction/conduction or delivery method), were aware of the group to which each participant belonged. However, in the third group that received usual care (CG), it was not possible to blind the participants, due to the characteristics of the study.

For the collection of sociodemographic and clinical data, an instrument submitted to analysis of content validation was created by five judges with experience in the area of Obstetrics and/or TCM. The questionnaires were later identified with a number and their respective groups with a letter, maintaining the blinding for the analyses conducted by a statistician.

The following points were used in the IG according to the Chinese auricular map: i) *shenmen*, which predisposes the brainstem and the cortex to receive, condition and encode atrial reflexes; ii) *uterus*, which is indicated for gynecological and obstetric changes, induction of labor, reduction of expulsion time, and reduction of pain in the postpartum; iii) *neurasthenia*, indicated for the treatment of anxiety; iv) *endocrine*, which regulates the functions of endogenous secretory glands, and is used in gynecological disorders, among others. These points were based on clinical practice and previous studies^{7,10}, as illustrated in Figure 1 (highlighted in white).

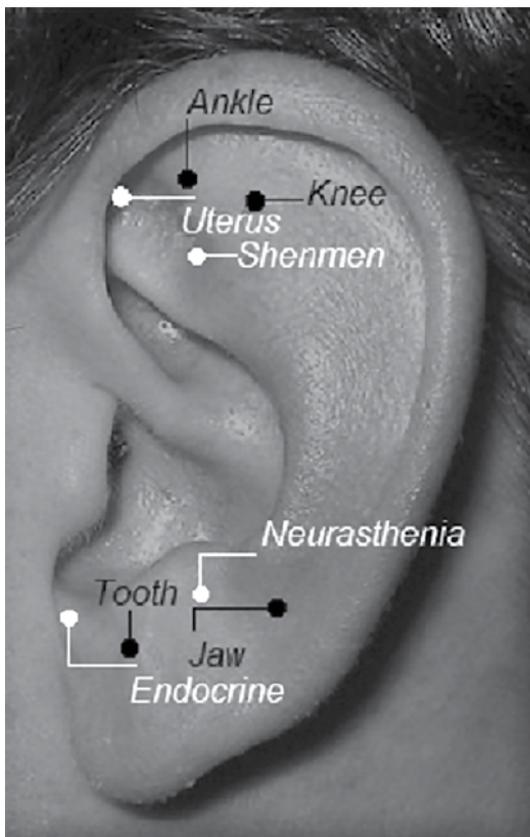


Figure 1 - Location of auricular points used in the study. Campinas, 2016. Source: <https://pt.wikipedia.org/wiki/Orelha>

Antisepsis of the external ear was made with 70° ethyl alcohol before the therapy. The points were searched with pressure exerted by a point probe stimulator and defined near the topography indicated in the "point map" as more painful to palpation. As the point was located, the crystals were fixed with adhesives on the IG parturients, being individually pressed for one minute or even causing bearable pain to induce the stimulus. In the PG, the point probe was used to indicate the location and fix the glass microspheres at *sham* points (not indicated and reducing possible effects for the proposed treatment): ankle, knee, tooth and jaw, without pressure stimuli in any moment of the study, as illustrated in Figure 1 (highlighted in black).

Women allocated to the CG were followed up for the same period and evaluated as in the other groups.

The duration of labor was calculated from the beginning of the rhythmic and painful contractions referred by the parturients to the treatment, from the treatment to birth, and the sum of the two variables.

The induction or mechanical or pharmacological conduction of labor is a routine practice in the obstetric unit. Labor induction occurs when the cervix is favorable and the *Bishop* index ≥ 6 . Cervical preparation of pregnant women with an unfavorable cervix is done using prostaglandin or a *foley* catheter (balloon inserted above the internal bore of the cervical canal, inflated with 30 50 mL of distilled water). In pregnant women who initiate cervical prostaglandin preparation and obtain a good response, the conduct is maintained in the first 24 hours or until the establishment of free labor: 25 mcg dosage every 6 hours (up to the maximum dose of 100 mcg, if necessary, in 24h). In cases of labor induction with oxytocin, the protocol¹¹ establishes intravenous infusion of 5 mIU/min and double dose every 30 min until the establishment of effective labor.

The researcher responsible for the application of auriculotherapy underwent training of the technique in two short courses, totaling 64h.

Comparisons of the quantitative variables between groups were performed using the Kruskal-Wallis test. For the associations between the groups and the categorical variables, the chi-square test or Fisher's exact test were used. The analyses were performed using the Statistical Analysis System (SAS), 9.4.

This study was approved by the *Comitê de Ética em Pesquisa da Universidade Estadual de Campinas, SP* (Opinion 855.496 / CAAE: 35671514.6.0000.5404). All the participants signed the Informed Consent Term.

RESULTS

A total of 102 parturients participated in this study. They were equally distributed in the three groups (Figure 2). There were no losses after randomization; only parturients submitted to cesarean section were excluded from the analyses related to the labor time (from the allocation at birth), due to the surgical interruption of their progress.

Table 1 presents the general and obstetric characteristics of the parturients according to the allocation group. The mean age was higher in the PG; in terms of schooling and marital status, values were similar. The majority of the parturients had completed high school (IG: 88.2%; PG 91.2%; and CG 82.6%, *p*-value = 0.6594, Fisher's exact test); there were no illiterate women in the sample. The other parturients were either attending or had completed higher education.

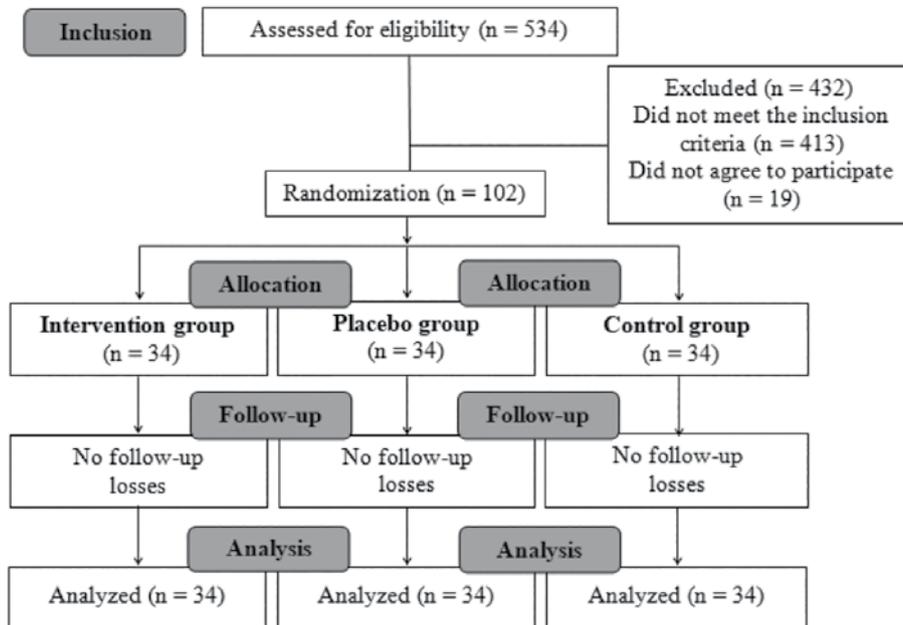


Figure 2 - Flowchart of recruitment and grouping of participants. Campinas, 2016.
Source: <http://www.consort-statement.org/consort-statement/flow-diagram>, adapted to Consort.

Table 1 - Distribution of general characteristics, obstetric characteristics and study groups of parturients. Campinas, 2016

Variable	Study group			p-value
	Intervention (n = 34)	Placebo (n = 34)	Control (n = 34)	
Age (years), mean (SD)	23,9 (5,8)	25,1 (7,0)	22,7 (5,3)	0,3503 ^w
Schooling (years of study), mean (SD)	10,7 (3,1)	9,9 (2,4)	10,7 (3,1)	0,4567 ^w
Marital status, n (%)				
With partner	29 (85.3)	33 (97.1)	32 (94.1)	
Without partner	5 (14.7)	1 (2.9)	2 (5.9)	0.2674 ^f
Number of pregnancies, mean (SD)	1.6 (1.0)	1.6 (1.0)	1.7 (1.1)	
Parity, n (%)				
Nulliparous	27 (79.4)	25 (73.5)	25 (73.5)	0.8090 ^o
Multiparous	7 (20.6)	9 (26.5)	9 (26.5)	
Before treatment				
Amniotic membranes, n (%)				
Integral	25 (73.5)	21 (61.8)	19 (55.9)	
Artificial rupture	3 (8.8)	6 (17.7)	3 (8.8)	0.3378 ^f
Spontaneous rupture	6 (17.7)	7 (20.5)	12 (35.3)	
Cervical dilatation (cm), mean (SD)	4.6 (0.9)	4.8 (0.8)	4.5 (0.8)	0.3915 ^w
Number of contractions, mean (SD)	3.1 (0.9)	3.2 (0.7)	3.3 (0.9)	0.5986 ^w
Duration of contractions (sec), mean (SD)	45.8 (7.7)	43.6 (8.0)	46.6 (8.1)	0.0853 ^w
Intensity of contractions, n (%)				
Mild	2 (5.8)	6 (17.6)	0 (0.0)	
Moderate	16 (47.1)	17 (50.0)	22 (64.7)	0.0634 ^f
Strong	16 (47.1)	11 (32.4)	12 (35.3)	

Continue...

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Table 1 - Distribution of general characteristics, obstetric characteristics and study groups of parturients. Campinas, 2016

Variable	Study group			p-value
	Intervention (n = 34)	Placebo (n = 34)	Control (n = 34)	
After treatment				
Amniotic membranes, n (%)				
Artificial rupture	17 (50.0)	16 (47.1)	13 (38.2)	0,4895 ^f
Spontaneous rupture	4 (11.8)	1 (2.9)	4 (11.8)	
Other (cesarean section or previous rupture)	13 (38.2)	17 (50.0)	17 (50.0)	

Source: prepared for purposes of this study. Notes: *Kruskal-Wallis test, ^fFisher exact test, ^QChi-square test; p < 0.05.

Labor time was calculated among women with vaginal delivery in three established periods (Table 2). Mean labor time in the IG was 91.1 min less than the PG, and 99.4 min less than the CG after intervention. Spontaneous labor time was higher among the IG patients (IG: 73.5% versus PG: 47.1% versus CG: 55.9%, p-value = 0.0781, chi-square test), but there was no statistical difference as well as in the pharmacological conduction of labor with: prostaglandin (IG: 7 (20.6%); PG: 10 (29.4%), CG: 11 (32.4%), p = 0.52373, chi-square test) and oxytocin (IG: 18 (52.9%), PG: 16 (47.1%), CG 21 (61.8%), p = 0.4725, chi-square test). The total volume of oxytocin solution 5 IU in the groups is described in Table 2.

The cesarean section rate was higher in the PG (55.9%) followed by the IG (26.5%) and the CG (20.6%). The Apgar score, the most used method for immediate evaluation of the newborn's state at birth, showed no differences between the means presented in the first and fifth minutes of life (Table 3).

The parturients were questioned if they knew auriculotherapy as an alternative and complementary treatment to several types of symptoms/diseases. However, few patients reported knowing or having used this therapy before (IG: 5.9% versus PG: 8.8% versus CG: 2.9%, p-value = 0.7375, Fisher's exact test).

Table 2 - Differences in labor time among parturients with vaginal delivery and use of oxytocics between groups. Campinas, 2016

Variável	Study group						p-value
	Intervention (n = 25)		Placebo (n = 15)		Control (n = 27)		
	Mean	SD	Mean	SD	Mean	SD	
Duration of labor (min)							
Until treatment	357.6	235.9	485.5	327.1	349.4	200.0	0.2167
From treatment to birth	269.2	154.8	360.3	252.5	368.6	208.0	0.1871
Total labor time	607.8	333.1	867.9	414.4	694.7	328.5	0.0845
Oxytocin solution							
(SG5% 500 mL + 1 ampoule oxytocin 5 IU) (mL)	231.9	312.5	342.2	387.3	179.9	296.7	0.1242

Source: prepared for purposes of this study.

Notes: Kruskal-Wallis test; p < 0.05

Table 3 - Type of delivery and Apgar score among parturient groups. Campinas, 2016

Variable	Study group						p-value
	Intervention (n = 34)		Placebo (n = 34)		Control (n = 34)		
	n	%	n	%	n	%	
Type of birth							
Vaginal	25	73.5	15	44.1	27	79.4	0.0045 ^Q
Cesarean	9	26.5	19	55.9	7	20.6	
Apgar Values							
1 st minute	9.1	1.1	8.3	1.8	8.7	1.9	0.0879 ^w
5 th minute	9.8	0.5	9.7	0.7	9.7	1.6	0.5711 ^w

Source: prepared for purposes of this study. Notes: ^Qchi-square test; ^wKruskal-Wallis test; p < 0,05.

DISCUSSION

Auriculotherapy is a treatment used worldwide and studied for pain relief, relaxation, insomnia, among other dysfunctions, but there is little evidence of its use in obstetric clinic. Some authors¹² sought use magnetic resonance imaging (MRI) to evaluate the effects of auriculotherapy in central areas of the brain by stimulating semipermeable needles at two auricular points (*thumb* and *brainstem*). MRI revealed extensive activation of the right, primary and secondary sensory motor cortex (M1, SI and SII) with maximal activity in the precentral gyrus when stimulating the *thumb* point. The *brainstem* point, according to its therapeutic effect, activated mainly cortical and limbic regions that are part of the pain matrix. These authors concluded that the responses to the two points tested may be linked to the respective therapeutic indications in auriculotherapy, instigating studies in other auricular sites.

In this study, most parturients were unaware or had never used auriculotherapy before. The obstetric characteristics that could influence the progress of labor such as rupture of the amniotic sac and uterine dynamics (number, intensity and time of contractions) were similar among parturients in the groups of the study.

Labor conduction was frequent in all three groups, according to the routine of the unit and presented data. The mean total oxytocin 5 IU solution administered was higher in the PG. Despite of this, labor time after admission in the study was higher in this group in relation to the IG, and similar to the CG. The mean labor time was lower among parturients who received auriculotherapy (IG), but there was no statistical significance. No previous studies evaluating the use of auriculotherapy on the progress of labor were found. However, some therapy scholars have shown that stimuli at auricular points were able to activate the autonomic nervous system with predominance of the sympathetic nervous system¹³, responsible for uterine contractions, distension of the lower segment of the uterus and cervix, which may have reduced labor time in the IG. Cochrane review¹⁴ on acupuncture in labor induction showed no evidence regarding a shorter labor time, but there were alterations in cervical emptying among patients who received acupuncture compared to placebo: mean difference (MD) 0.40, 95% confidence interval (CI) 0.11-0.69, in a study with 125 women; and when compared to the usual treatment: MD 1.30, CI 0.11-2.49, in another study with 67 women.

Meta-analysis¹⁵ showed that acupressure, a therapy performed by finger or hand pressure on acupuncture points, showed promising results in reducing by 1.310 hours (95% CI 1.738 -0.882, $p < 0.001$) the active phase of labor, and by 5.808 minutes (95% CI 1.615 - 0.807, $p < 0.001$) the expulsion time, a tendency also observed in the results of this RCT.

There was a significant difference in cesarean section rate between groups. There was a higher incidence of this surgical

procedure in the PG, which was above the rate of 47.2% recorded in the collection site in 2015.¹⁶ However, the delivery route was similar in the IG and the CG, mostly vaginal delivery. A study¹⁷ with five pregnant women with previous cesarean sections and one with ovarian cyst surgery evaluated auriculotherapy associated with electrostimulation on the birth canal. The authors reported that auriculotherapy may reduce conditions involving dystocic labor and possibly reduce the cesarean rate. This surgery occurred only in one participant in that study. In a meta-analysis¹⁵ with nine studies, acupressure increased the chance of vaginal delivery when compared to placebo and usual care (odds ratio 2,329, 95% CI, 1.348 - 4.024, $p = 0.002$, risk difference 8.9%, CI 95 % 2.7% - 15.0%, $p = 0.005$). However, other studies with acupuncture did not find statistically significant differences of delivery route¹⁴, nor clear effects of auriculotherapy on the outcome of childbirth were found in our results.

A study in three public maternity hospitals in Brazil¹⁸ showed that vaginal delivery was more efficient and showed better effectiveness for primiparous women in three of four outcomes: avoided maternal morbidity, avoided admission to neonatal ICU, and avoided neonatal death. For the outcome avoided maternal death, elective caesarean section presented little additional effectiveness. Vaginal delivery also had a lower cost (BRL 1,709.58; USD 518.05) than cesarean section (BRL 2,245.86; USD 680.56). In another study¹⁹ the main causes of maternal mortality associated with cesarean sections in Turkey were hemorrhage (20%), hypertension (18.2%), embolism (10.3%), cardiovascular diseases (9%), infection (5%), among others (10.4%). ICPs may favor the labor progress and, consequently, vaginal delivery, thus improving obstetric indicators and reducing the costs of childbirth care, as proposed in this study.

Regarding the Apgar score, there were no differences in the present study, showing that the type of treatment for each group did not change this indicator.

A limitation of this study is related to the study site; the study was conducted at a university hospital, a regional reference for high-risk pregnancies. This may have contributed to high rates of interventions in childbirth care. Another limitation is related to parturients of the third group (CG), because they did not receive the microspheres in the external ear, and only the IG and PG groups were blind; this may cause bias in the study.

CONCLUSION

In this study, all three groups received routine care in the obstetric unit and during hospitalization for the same period. Among the participants, women submitted to auriculotherapy (IG) showed shorter labor time. Cesarean section rates were similar to the CG, and the effects of auriculotherapy were not clear. However, this intervention did not worsen the indicators, show-

ing no adverse reactions from its use during parturition. Nevertheless, further studies with larger samples and/or conducted in environments that promote the physiological progress of labor, with fewer interventions such as amniotomy and oxytocin use, may result in different data from those found in this trial.

Auriculotherapy is one of the ICPs for which there is good evidence of use and that can be studied and legally used by nurses, obstetrician nurses and trained midwives in their work environments in order to increase the alternatives of care for parturients.

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