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GENERAL GYNECOLOGY

Auricular acupuncture as effective pain relief after episiotomy: a randomized controlled pilot study

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Abstract

Purpose Previously, pain treatment following episiotomy has relied on non-steroid anti-inflammatory drugs as analgesics, whose use during breastfeeding remains controversial due of their transfer to the child.

Methods This was a pilot randomized parallel single-center study aiming to evaluate the effects of auricular acupuncture on pain relief after episiotomy. The primary outcome was reduction of pain intensity using visual analogue scale (VAS) scores during the first three postpartum days. The patients were allocated to either of the groups by using a heads–tails binary result coin toss method and the allocation was not masked. The study was completed after including 60 healthy women that underwent mediolateral episiotomy performed during vaginal delivery, with 29 receiving acupuncture therapy and 31 not receiving acupuncture therapy for pain relief. Oral analgesic therapy was made available per request for all patients.

Results This study showed that subjective experience of pain was significantly reduced in the acupuncture group on the second and third postpartum days ($P=0.004$, $P=0.005$, $P=0.22$). There were no adverse effects of acupuncture noted.

Conclusions Our findings confirm that auricular acupuncture therapy may be a valuable adjunct to analgesic therapy in patients undergoing episiotomy during vaginal delivery. The results prompt a question whether our current 'best practice' may yet be improved.

Keywords Auricular acupuncture · Episiotomy · Acupuncture · Pain relief · Analgesic therapy

Introduction

Episiotomy is an obstetric surgical procedure performed in the second stage of labor to prevent major birth canal injury and to enable faster delivery. This is the most common surgical procedure performed during vaginal delivery and can cause significant pain and discomfort lasting for weeks and even months [1]. The perineum and the vagina are surgically cut using either scissors or a scalpel and at the end of the delivery, sutured back to its previous form. It is not recommended as a routine procedure, but only when a clear indication is present. Regardless of indication criteria, there are still differing incidences worldwide based on published literature (between 2.5 and 100%) [2, 3]. The procedure itself is not without controversy, including proper pain management after it has already been performed [4]. Proper suturing techniques and pain management are essential, having in mind that the early days of motherhood should allow a woman to dedicate herself to her child's care with a minimum of distraction and encourage a positive attitude toward delivery [5]. It is necessary to minimize the pain caused by the episiotomy and to enable the mother to confront the challenges of motherhood with confidence [6]. The pain after episiotomy is often poorly treated, with insufficient evidence supporting an optimal course of treatment and over 50% of patients reporting pain-related issues after the procedure [7]. Pharmacological treatment is frequently used, but the number of drugs that can be used during lactation is limited because of possible adverse drug reactions in neonates. Published data about non-pharmacological methods of pain

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management after episiotomy are sparse. Acupuncture is one of possible alternative therapies that has already gained recognition in several obstetric indications [8–13]. Acupuncture therapy involves inserting thin steel needles through the skin at special points to exert its therapeutic effect. The positive effect of acupuncture on pain has been confirmed in many clinical studies, but only few have investigated its effect on pain relief after episiotomy [14, 15].

The aim of this study was to evaluate the effect of acupuncture on pain relief after episiotomy. The primary objective of the study was to determine the pain intensity in the first 2 h after episiotomy and during the first 3 days of hospital stay both in rest and during physical activity. Secondary goals were oriented toward noting the amount of analgesics received and the frequency of their use, observing wound-healing progression, strength of uterine contractions, the presence of abnormal bleeding, patient satisfaction with acupuncture therapy and procedural follow-up (pain at acupuncture site, allergic reaction to needles, subjective opinions about the impact of acupuncture on mobility and breastfeeding).

Patients and methods

The study was designed as a proof of concept study on a limited number of participants. It was designed as a pilot randomized parallel longitudinal single-center study to evaluate the effects of auricular acupuncture on pain relief after episiotomy conducted in the Department of Gynecology and Obstetrics, University Hospital Center Sestre milosrdnice, Zagreb, Croatia. This institution performs up to 3100 deliveries per year. Episiotomy is performed in 30% of them. The study was approved by the Hospital Board of Ethics (E.P. number: 14280/16-4), according to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and as amended most recently by the 64th World Medical Assembly, Fontaleza, Brazil, October 2013. Written informed consent was obtained from all of the patients enrolled in the study. It was registered with the German Clinical Trials Register (www.drks.de), DRKS-ID: DRKS00014691 and ClinicalTrials.gov (Identifier: NCT03534869). Prospective data were collected from November 2016 to April 2017. The study included healthy pregnant women over 18 years of age and a minimum of 36 weeks' gestation who underwent mediolateral episiotomy during vaginal delivery. Out of the total 78, the protocol excluded 18 patients. Six patients were excluded due to illness during pregnancy, and 12 patients declined to participate in the study. Standard treatment (golden standard) was to perform an episiotomy and supply oral analgesics per request.

In this study, auricular acupuncture was used as a comparator treatment group. The acupuncture treatment consisted of three acupuncture needles on the dominant ear according to French auriculotherapy guidelines—internal genital area, external genital area and Shen Men point that is used to increase the anaesthetic effect according to both French and Chinese traditions [16–18]. Acupuncture needles were stimulated by manual rotation of the needle to evoke needle sensation De Qi. No electrostimulation was used. Sterile 0.2×1.4 mm press needles were used. The needles were inserted within 6–8 h after childbirth by a certified acupuncturist. The points for auriculotherapy were identified using an auriculoacupuncture atlas and an electropoint detector [17]. The needles were left in place until the hospital discharge of the patient on the third postpartum day and were removed by a certified acupuncturist.

Additional oral analgesics (NSAID) could be supplied at any time upon patients' request during hospitalization. Oral ibuprofen was given as first-line therapy, while oral paracetamol was given as second-line therapy.

Primary outcome measures were pain intensity immediately after birth, 2 h after birth and during the first 3 days, at rest and with activity. Secondary outcome measures were the need for analgesics, the amount of given analgesics and the number of analgesic repetitions during the day (Fig. 1).

In addition, subjective experiences of postpartum bleeding and pain due to uterine contractions were recorded. For those who had received acupuncture therapy, pain levels at the acupuncture site, analysis of acupuncture-related experience including discomfort during sleep, other contacts with acupuncture previously and likelihood of recommending the method to a friend were noted. After leaving the hospital, women in the acupuncture group were asked to fill out a questionnaire on acupuncture treatment satisfaction. All patients signed an informed consent. Inter-group comparisons were performed based on the patient status at the time of hospital admission and during hospital stay. Input parameters were: age, education level and number of previous deliveries. Characteristics of delivery were noted as: the time of birth, the duration of the labor, the subjective experience of the labor and the application of epidural analgesia.

If labor started before 8 AM, it was considered as the 1st day of hospitalization, and if labor started later than 8 AM, the 1st day of hospitalization was documented as the next day.

We evaluated pain using the visual analog scale score. VAS score is scaled from 1 (smallest pain) to 10 (strongest pain). VAS score higher than 3 was the cutoff point for analgesic administration. We divided the patients into two groups based on their education level; the first group encompassed women who had finished high school and the other women who held a university degree.

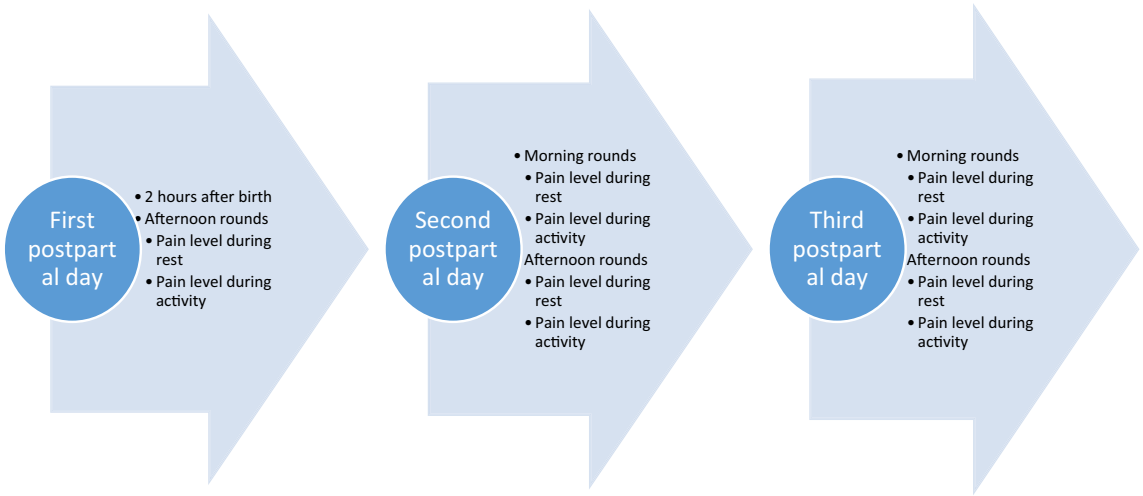

Fig. 1 Diagram showing the time course of VAS pain scoring and possible intervals of analgesic administration

Statistical analysis

In line with the pilot trial recommendations, this study did not require a sample power calculation [19]. The patients were allocated either of the groups by using a heads–tails binary result coin toss method. The results were expressed as a number for categorical variables and as a median value (25–75th interquartile range) for continuous variables. The data were tested with the Smirnov–Kolmogorov test for normal distribution. Of all the variables, only the pain VAS score on the first postpartum day and the pain VAS score on the second postpartum day having a normal distribution were identified. Variables were compared using the Mann–Whitney *U* test and Kruskal–Wallis test (the non-parametric alternative to ANOVA). All statistical tests were two tailed, and P values < 0.05 were considered statistically significant. Statistical analysis was performed using MedCalc software (Version 11.2.1 © 1993–2010. MedCalc Software bvba Software, Broekstraat 52, 9030 Mariakerke, Belgium) and SPSS (Version 22.0., 2013. IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.) using standard descriptive statistics and frequency tabulation as indicated.

Results

Sixty patients were included in the study. All of the patients had mediolateral episiotomy performed during vaginal delivery, out of which 29 received acupuncture therapy and 31 did not receive acupuncture therapy for pain relief. The allocation ratio was 0.94. In both groups, administration of oral analgesics per request was recorded. Table 1 shows the characteristics of patients recorded at hospital admission, during delivery and within the first 2 h after delivery. Patient groups

Table 1 Patient characteristics at hospital admission, during and within first 2 h after delivery

	No acupuncture $N=31$	Acupuncture $N=29$	P value
Age (years)	30 (29–34)	32 (28–33)	0.584
Education			
Finished high school	8 (26)	4 (14)	0.337
Graduated	23 (74)	25 (86)	
Birth no.			
Primipara	25 (81)	21 (72)	0.680
Secundipara	6 (19)	8 (28)	
More than two	1 (0)	0	
Time of the day when birth occurred			
In the morning (7–15)	16 (52)	11 (38)	0.660
In the afternoon (15–23)	10 (32)	14 (48)	
At night (23–7)	5 (16)	4 (14)	
Duration of birth			
Up to 4 h	10 (32)	12 (41)	0.381
4–8 h	11 (35)	10 (34)	
8–12 h	8 (26)	6 (21)	
More than 12 h	2 (7)	1 (4)	
Epidural analgesia			
Yes	15 (48)	16 (55)	0.616
No	16 (52)	13 (45)	
Subjective experience of birth			
Easy	17 (55)	21 (72)	0.188
Difficult	14 (45)	8 (28)	
Intensity of pain within first 2 h after delivery (VAS score)	3 (2–6)	4 (2–5)	0.918

Results are presented as median (25–75th interquartile range), or as number (%); variables were compared using Mann–Whitney *U* test, Kruskal–Wallis test

did not significantly differ in age, education, number of prior deliveries, time of the day when birth occurred, duration of delivery, administration of epidural analgesia, subjective birth experience and intensity of pain within the first 2 h after delivery (according to VAS scores). Since both groups contained patients that had epidural analgesics administered during the first 2 h after delivery, it was not considered as a confounding factor. The follow-up rate at the end of the study period was 100%.

Patient characteristics related to pain management during the first 3 days after delivery are shown in Tables 2, 3 and 4. The groups did not significantly differ during all 3 days in total analgesic consumption, type of analgesics and number of daily doses of analgesics. There were no statistically significant differences between the groups in pain intensity at rest and during activity during the 1st day. However, on the 2nd day, patients in the acupuncture group had a statistically lower VAS score during rest and activity ($P=0.034$, $P=0.043$, Mann–Whitney U test, Kruskal–Wallis test, Table 3). On the third day, a lower VAS score was noted both during activity and rest in the acupuncture group ($P=0.039$, $P=0.022$, Mann–Whitney U test, Kruskal–Wallis test, Table 4).

Table 2 Patient characteristics during the first postpartum day

	No acupuncture $N=31$	Acupuncture $N=29$	P value
Intensity of pain in rest (VAS score)	5 (4–7)	5 (4–6)	0.584
Intensity of pain in activity (VAS score)	7 (5–8)	6 (5–8)	0.607
Analgesics			
Yes	27 (87)	25 (86)	0.781
No	4 (13)	4 (14)	
Number of taken analgesics			
0	4 (13)	4 (14)	0.317
1	21 (68)	23 (79)	
2	6 (19)	2 (7)	
Analgesics			
Paracetamol	4 (13)	4 (14)	0.392
Ibuprofen	27 (87)	25 (86)	0.780
Ketoprofen	1 (0)	1 (0)	
Diclofenac	2(0)	1 (0)	
Total amount of analgesic(s) during the day (mg)			
Ibuprofen	600 (600–1200)	600 (600–1200)	0.382
Number of daily doses of analgesics			
1	14 (45)	14 (48)	0.289
2	6 (19)	8 (28)	
3	5 (16)	3 (10)	
4	2 (1)	0	

Results are presented as median (25–75th interquartile range), or as number (%); variables were compared using Mann–Whitney U test, Kruskal–Wallis test

Table 3 Patient characteristics during the 2nd postpartum day

	No acupuncture $N=31$	Acupuncture $N=29$	P value
Intensity of pain at rest (VAS score)	4 (3–6)	3 (2–5)	0.034
Intensity of pain with activity (VAS score)	6 (5–7)	5 (3–6)	0.043
Analgesics			
Yes	26 (84)	24 (83)	0.817
No	5 (16)	5 (17)	
Number of taken analgesics			
0	5 (16)	5 (17)	0.826
1	23 (74)	20 (69)	
2	3 (10)	4 (14)	
Analgesics			
Paracetamol	4 (13)	5 (17)	0.914
Ibuprofen	24 (77)	20 (69)	0.654
Ketoprofen	1 (0)	1 (0)	
Diclofenac	0	2 (0)	
Total amount of analgesic(s) during the day (mg)			
Ibuprofen	600 (600–1700)	1200 (600–1800)	0.590
Number of daily doses of analgesics			
1	12 (39)	10 (34)	0.794
2	5 (16)	8 (28)	
3	8 (26)	6 (21)	
4	1 (0)	1 (0)	

Results are presented as median (25–75th interquartile range), or as number (%); variables were compared using Mann–Whitney U test, Kruskal–Wallis test

Table 5 shows the patients' characteristics during hospital stay. There was no statistically significant difference between subjective experience of postpartum bleeding and pain due to uterine contractions in the first, second and third postpartum days. Although there were no statistically significant differences in pain intensity due to contractions on the 3rd day, pain intensity in patients in the acupuncture therapy group was still lower.

Table 6 shows patients' characteristics in the group treated with acupuncture. Ninety-three percent of women had a positive experience related to acupuncture. Only two patients (7%) had a negative experience related to acupuncture. The pain during the procedure was perceived as middle intensity in 10% of patients. None of them had previous contact with acupuncture therapy. Ninety percent of women would recommend acupuncture as a procedure for pain relief after episiotomy.

Table 4 Patient characteristics during the third postpartum day

	No acupuncture $N=31$	Acupuncture $N=29$	P value
Intensity of pain at rest (VAS score)	3 (2–5)	2.5 (1–4)	0.022
Intensity of pain with activity (VAS score)	4 (3–6)	4 (2–5)	0.039
Analgesics			
Yes	18 (58)	11 (38)	0.193
No	13 (42)	18 (62)	
Number of taken analgesics			
0	13 (42)	18 (42)	0.089
1	16 (58)	11 (48)	
2	1 (0)	0	
Analgesics			
Paracetamol	4 (13)	1 (0)	0.392
Ibuprofen	15 (48)	14 (48)	0.803
Ketoprofen	0	0	
Diclofenac	0	0	
Total amount of analgesic(s) during the day (mg)			
Ibuprofen	600 (600–1200)	700 (600–1200)	0.886
Number of daily doses of analgesics			
1	14 (45)	14 (48)	0.278
2	3 (10)	1 (0)	
3	1 (0)	0	
4	0	0	

Results are presented as median (25–75th interquartile range), or as number (%); variables were compared using Mann–Whitney U test, Kruskal–Wallis test

Discussion

According to traditional Chinese medicine, different specialized forms of acupuncture exist, such as auriculoacupuncture or cranialacupuncture. In modern medicine, compared to other pain treatment methods, acupuncture is considered to be a valid alternative, and in some cases, a method of choice for pain treatment therapy. The needles inserted into specific points on the body or the ear increase endogenous opioid peptide production (endorphine) in the central nervous system, which is then responsible for the analgesic effect of acupuncture [20].

Interpretation

The results of this study show that pain intensity VAS scores are lower on the 2nd day in the group of patients with acupuncture compared to the group without acupuncture at rest and with activity. The 3rd day also showed a positive result of acupuncture (VAS score was lower during rest and activity in the acupuncture therapy group—VAS score 2.5 versus 3, $P=0.022$). Our findings suggest that acupuncture therapy is a useful method for postpartum pain relief therapy in patients undergoing episiotomy during vaginal delivery. The effect seems to be additive with standard oral analgesic therapy. As today's incidence of epidural analgesia is high (in our department in 37% of all vaginal deliveries), published literature raises questions of residual epidural analgesia effects in the first two postpartum hours [21, 22]. Our research showed that there were no differences in the groups that would affect the VAS score. The possible mechanism of action underlying adjunct auriculoacupuncture as an analgesic treatment may be a cascade event, whereby an initial intervention during labor facilitates subsequent interventions to manage the effects of the prior intervention and is associated with outcomes [13, 23]. We studied the influence of acupuncture on the subjective amount of bleeding according to the patients' appraisals of postpartum bleeding and found no difference between the examined groups. In all women, bleeding ceased within 2 days, which is consistent with known data [24]. The advantages of auriculoacupuncture in comparison to full body acupuncture, reducing the discomfort of postpartum patients were utilized, illustrated by the overall VAS reduction in the acupuncture group both during

Table 5 Patient characteristics during hospital stay

	No acupuncture $N=31$	Acupuncture $N=29$	P value
Subjective experience of postpartum bleeding			
Scarce	3 (10)	2 (7)	0.579
Flush	6 (19)	8 (27)	
Normal	22 (71)	19 (66)	
Pain due to contraction on 1st day	4 (2–7)	3 (2–6)	0.147
Pain due to contraction on 2nd day	4 (3–6)	4 (2–5)	0.133
Pain due to contraction on 3rd day	3 (2–5)	2 (1–3)	0.092

Results are presented as median (25–75th interquartile range), or as number (%); variables were compared using Mann–Whitney U test, Kruskal–Wallis test

Table 6 Patient characteristics with acupuncture ($N=29$)

Subjective experience of acupuncture	
Positive	27 (93%)
Negative	2 (7%)
Pain during the procedure	
Easy	26 (90%)
Middle	3 (10%)
Strong	0
Pain in the ear during the hospitalization	
Yes	4 (14%)
No	25 (86%)
Earlier contacts with acupuncture	
Yes	0
No	29 (100%)
Recommendation for acupuncture	
Yes	26 (90%)
No	3 (10%)

Results are presented as numbers (%)

rest and activity, showing a negligible amount of discomfort related to needle insertion. After examining the results of our research, we believe that they suggest a beneficial effect of combined auricular acupuncture and oral analgesic therapy that may be used to maximize their individual effects. Our patients had no previous contact with acupuncture therapy, minimizing their pre-treatment bias, and a vast majority claimed that they were satisfied with its effects and keen on recommending this method of treatment further. Since the potential transfer of oral therapy through breastfeeding has become common knowledge in the patient population, acupuncture is viewed as an acceptable alternative or complementary method of pain relief.

Generalizability

This study did not show a significant reduction of oral analgesic use in the group of patients treated with auriculoacupuncture. We cannot draw firm conclusions on whether acupuncture is effective as an independent treatment method or as a possible adjunct treatment, but published meta-analyses suggest that acupuncture may be equally effective as a primary pain control modality in parturient women compared to pethidine and a control group without any analgesic intervention [11, 15, 17]. These results support our claims that auriculoacupuncture is effective in reducing postprocedural pain. Furthermore, auriculoacupuncture was administered alongside oral analgesic therapy and used as a comparator treatment group, which was described in a select few previously published studies citing similar results in intrapartum pain reduction, increased rates of normal vaginal delivery and increased average Apgar score at 1 and 5 min after birth [9]. Since both groups received oral analgesic therapy, they differed in only one key variable, supporting the strength of our findings. The advantages of acupuncture treatment are further accentuated by the potential transfer of oral therapy to the newborn through breastfeeding that has become common knowledge in the patient population [15, 17]. When body acupuncture is used for pain management after episiotomy, remarkably positive results have been suggested.

Limitations

This pilot study was performed on a small number of patients. We wanted to compare the standard treatment (gold standard—episiotomy and oral analgesics per request) with a novel approach based on a possible additive effect of auricular acupuncture. Also, due to a limited number of patients, it was difficult to form another group with placebo acupuncture treatment. It is very difficult to discern between the placebo effect driving the analgesic therapy effect in the oral analgesic group versus acupuncture as well [25]. This question may be better suited to a larger study, whereas our principal question of interest was to evaluate the clinical usefulness of offering acupuncture to our patients in addition to oral analgesics. A potential pitfall of our data collection strategy was the introduction of bias that could occur, as patients might have responded differently to self-administered questionnaires, rather than the ones filled out by medical professionals. A large number of patients requested analgesic therapy preemptively from fear of possible pain emergence later on during the day. While a positive attitude recorded in our patient population might also be a source of placebo, it is also important to note that 12 patients declined to participate in the study. Their reasons for non-participation included unwillingness to try novel treatment, prohibitory religious beliefs and fear of acupuncture needles. This illustrates the point that the benefits of acupuncture treatment may be reserved for patients with a positive attitude toward alternative treatment, which may also be a source of bias due to the placebo effect stemming from positive expectations in the patient group that was treated with acupuncture [24].

Conclusions

Adequate postpartum pain relief methods are very important. This study showed that pain intensity was significantly reduced in the acupuncture therapy group according to VAS scores on the second and third postpartum days. Acupuncture is a safe and well-tolerated procedure for pain relief. Auricular acupuncture for pain relief after episiotomy used in this study was very effective in conjunction with oral analgesic therapy and prompts a question whether our current ‘best practice’ may yet be improved.

Author contributions KKJ: protocol/project development, data collection or management, data analysis, manuscript writing/editing. TMT: protocol/project development, data collection or management, data analysis, manuscript writing/editing. M: protocol/project development, data collection or management, data analysis, manuscript writing/editing. ID: protocol/project development, data collection or management, data analysis, manuscript writing/editing. VK: protocol/project development, data collection or management, data analysis, manuscript writing/editing. AK: protocol/project development, data collection or management, data analysis, manuscript writing/editing.

Compliance with ethical standards

Conflict of interest This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The authors have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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