## **OBSTETRICS**

# Efficacy of Music Therapy on Immediate Postpartum Episiotomy Pain: A randomized controlled trial

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#### **ABSTRACT**

**Objectives:** To evaluate the effectiveness of music therapy in alleviating immediate postpartum episiotomy wound pain.

Materials and Methods: A randomized controlled trial was conducted to evaluate the efficacy of music therapy in alleviating immediate pain from an episiotomy wound. Uncomplicated singleton vaginal delivery women with the second degree or less episiotomy wound at Delivery and Postpartum Inpatient Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Srinakharinwirot University, Thailand were enrolled into the study. Visual analog scale (VAS) scoring was used for comparing pain levels.

**Results:** One hundred postpartum women were enrolled in our study. Baseline characteristics such as age, degree of episiotomy wound tear were similar between both groups. The median pain VAS score was statistically significantly lower in the music group than in the control group at the end of the 2<sup>nd</sup> hour after finish of episiotomy wound repairing process [24.0 millimeters (8.3-41.5) and 36.5 millimeters (20.0-53.3), p < 0.001]. The median pain VAS score was statistically significantly lower in the music group than in the control group at the end of 6th hour after finish of episiotomy wound repairing process [12.0 millimeters (3.0-21.0) and 22.0 millimeters (15.0-38.0), p < 0.001]

**Conclusion:** Music therapy is effective for reducing the perceived immediate postpartum pain of an episiotomy wound.

**Keywords:** episiotomy pain, music therapy, singleton pregnancy.

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ประสิทธิภาพของดนตรีบำบัดในการบรรเทาความรู้สึกเจ็บปวดจากแผลฝีเย็บช่วงหลัง คลอดทันที: การศึกษาแบบสุ่มและมีกลุ่มควบคุม

รวิตา ซัยชนะลาภ, วิภาดา เหล่าสุขสถิตย์, กิตติพงษ์ คงสมบูรณ์, ธารางรัตน์ หาญประเสริฐพงษ์

# บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพของดนตรีบำบัดต่อการบรรเทาความรู้สึกเจ็บปวดจากแผลฝีเย็บช่วงหลังคลอดทันที
วัสดุและวิธีการ: การศึกษาแบบสุ่มและมีกลุ่มควบคุมเพื่อประเมินประสิทธิภาพของดนตรีบำบัดต่อการบรรเทาความรู้สึก
เจ็บปวดจากแผลฝีเย็บช่วงหลังคลอดทันที หญิงหลังคลอดทางช่องคลอดซึ่งได้รับการตัดฝีเย็บระดับ 2 หรือน้อยกว่า โดยไม่มี
อาการแทรกซ้อนของการคลอด ที่ห้องคลอดและหอผู้ป่วยในหลังคลอดของภาควิชาสูติศาสตร์นรีเวชวิทยา คณะแพทยศาสตร์
มหาวิทยาลัยศรีนครินทรวิโรฒ ซึ่งได้รับคำเชิญให้ร่วมในการศึกษานี้ โดยใช้มาตรวัดความเจ็บปวดด้วยสายตาเปรียบเทียบระดับ
ความปวดระหว่างกลุ่มศึกษาและกลุ่มควบคุม

ผลการศึกษา: หญิงหลังคลอด 100 คน ได้รับเชิญให้เข้าร่วมในการศึกษานี้ ลักษณะพื้นฐานของผู้เข้าร่วมการศึกษาเช่น อายุ ระดับความรุนแรงของการฉีกขาดแผลฝีเย็บเหมือนกันในทั้งสองกลุ่มผู้เข้าร่วมการศึกษา ค่ามัธยฐานของระดับความเจ็บปวด วัดโดยใช้มาตรวัดความเจ็บปวดด้วยสายตา ณ. เวลา 2 ชั่วโมงหลังสิ้นสุดการเย็บแผลฝีเย็บของกลุ่มศึกษาต่ำกว่ากลุ่มควบคุม อย่างมีนัยสำคัญทางสถิติ [24.0 มิลลิเมตร (8.3-41.5) และ 36.5 มิลลิเมตร (20.0-53.3) ตามลำดับ, ค่า p < 0.001] ค่ามัธยฐาน ของระดับความเจ็บปวดวัดโดยใช้มาตรวัดความเจ็บปวดด้วยสายตา ณ. เวลา 6 ชั่วโมงหลังสิ้นสุดการเย็บแผลฝีเย็บของกลุ่ม ศึกษาต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ [12.0 มิลลิเมตร (3.0-21.0) and 22.0 มิลลิเมตร (15.0-38.0) ตามลำดับ, ค่า p < 0.001]

**สรุป**: ดนตรีบำบัดมีประสิทธิภาพในการบรรเทาความรู้สึกเจ็บปวดจากแผลฝีเย็บช่วงหลังคลอดทันที

คำสำคัญ: เจ็บปวดแผลฝีเย็บ, ดนตรีบำบัด, หญิงตั้งครรภ์เดี่ยว

#### Introduction

Episiotomy is a common obstetric procedure which is often performed during a vaginal delivery in Thailand. Benefits of the episiotomy include decreasing third-degree vaginal tearing, prevention of pelvic floor muscle relaxation, and they are easier to repair and heal better than spontaneous lacerations<sup>(1)</sup>. However, pain and edema in the episiotomy area following the birth can cause discomfort and interfere with ambulation, breastfeeding, slower resumption of normal sexual function and defecation and urination functions<sup>(2)</sup>. Many modalities have been introduced for reducing episiotomy pain, such as administration of local anesthetics (lidocaine gel, spray or injection, oral or intravenous pain killer)(3-4). However all of these methods involve adverse effects such as rash, gastrointestinal tract disturbance or allergic reactions.

Music therapy is an alternative medicine which has been found to be effective in reducing in many medical situation, including laparoscopic cholecystectomy and open heart surgery<sup>(5-6)</sup>. Music therapy functions to control pain via the pain gate control theory, which states that pain fibers from injured tissue activate the pain gate at the spinal gating system of the spinal cord. Music closes the pain gate and therefore inhibits pain signals from being transmitted from the wound site to the brain. Furthermore, it is hypothesized that music therapy activates the anterior pituitary gland to release endorphins which relieve pain. Relaxation music without lyrics included synthesizer, harp, piano, orchestra and jazz with slow beat 60-80 beats per minute were used post-operative for 60 minutes and pain was reduced approximately 30 percent(7-9). However, to date there have no study which have evaluated the effectiveness of music therapy in alleviating the pain arising from an episiotomy in immediate postpartum period. Thus, we conducted this study which aimed to analyze the efficacy of music therapy on episiotomy wound pain in uncomplicated vaginal deliveries.

#### **Materials and Methods**

#### Subjects

A prospective randomized controlled study was conducted at the Delivery and Postpartum Inpatient Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Srinakharinwirot University, Thailand between March and December 2016. At our institute, all pregnant women were delivered in private room one by one. Uncomplicated singleton vaginal delivery women with the second degree or less episiotomy wound were enrolled into our study. The exclusion criteria were women who received anesthesia more than a local infiltration of xylocaine such as a pudendal nerve block, the presence of birth passage hematoma, cervical tearing requiring surgical suturing, third or fourth degree episiotomy tearing, hearing deficit or impaired balance and allergic to acetaminophen.

#### Study procedure

The study was approved by the institute ethics committee (SWUEC/E-048/2559) and the Thai Clinical Trials Registry (TCTR 20160325001). During the early active phase of labor, we explained about our study to all singletons which possible to success their deliveries through the vaginal route including how to assess the pain VAS score. Intrapartum management was performed as usual. Immediately after delivery (including placenta), if the physician found a second degree vaginal tear which needed suturing, we asked the patient if she would agree to participant in our study, if she would give her informed consent. Then the participants were randomized into two groups using a computerized block of four. Concealment of allocation was ensured by using serially numbered, sealed opaque envelopes. The envelopes were opened after the informed consent was received by the nurse who prepared the music but was not involved the pain score measurements. The participants' demographic data were collected. Participants were classified into high risk and low risk groups by antenatal history. "High risk" was defined as being complicated with a medical condition such as diabetic

mellitus, hypertension, etc. If none of any complication, we defined as "Low risk". Administration of an analgesic drug during the active 1st stage of labor was recorded. The physician who delivered the baby and sutured the episiotomy wound was blinded to the study. At our hospital, the obstetrician locally injects 1% lidocaine with adrenaline just before performing an episiotomy. Additional injections can be provided during the episiotomy repair at the patient's request because of breakthrough pain. Total lidocaine usage in each participant was recorded. Polyglactin 910 sutures (Vicryl) were used for suturing the episiotomy in all participants. A continuous suturing technique is normally used, although an interrupted suturing technique can be done as indicated for hemostasis. The duration of the episiotomy repair was timed from the first needle puncture until the suture-check rectal examination was finished. The music was introduced as the suturing was finished.

A Yellow Brick Cinema-relaxing piano music with rhythm of 70 beats per minute was used in our study. The music was played through a two-earphone device for the participant in the study groups and the earphones were removed just only for short periods of time (~1 minute) for the participant to complete the VAS evaluations. The music was continued for a full 6 hours postpartum. The compliance of the patient in terms of music listening was monitored by the nurse and number of times the patient discontinued listening more than 30 seconds was recorded. All the participants in both groups received oral acetaminophen 500 milligrams after evaluated pain VAS score at the end of the 2nd hour. If a participant asked for more pain killer than protocol, the episiotomy wound was evaluated and the participant removed from the study.

All participants were asked for a pain VAS assessment at the end of the 2<sup>nd</sup> and 6<sup>th</sup> hour after the music started by a nurse who was blinded for the intervention About breast feeding, all pregnant women in our hospital were counseled about breast feeding during the antenatal period, and told that breast feeding should begin as soon as possible following delivery.

During the study, all neonates started breast feeding and room-in with mother after delivery as soon as possible, but following this initial feeding, all participants were asked to delay further breast feeding until after the study ended, 6 hours postpartum. Questions about the level of pain were concentrated on pain at the episiotomy area as much as possible.

#### Sample size

The study was designed to compare two-independent means formula. From a pilot study, mean  $\pm$  SD pain VAS were 15.52  $\pm$  16.5 millimeters (mm) and 28.8  $\pm$  21.28 mm in music therapy and control group, respectively. To achieve 80% power, with an alpha equal 0.05, assuming at least 60% retention at the end of the study and a sample ratio between the two groups of 1:1, the sample size required for each group was at least 50 subjects or 100 in total.

#### Statistical analysis

The statistical analysis was performed with R 2.10.0 software (freeware distributed by the R Development Core Team). The data collected and its distribution was analyzed by Kolmogorov-Smirnov test. Descriptive statistics including number, percentage, median, range, mean, standard deviation (SD) and 95% confidence interval (95% CI) as well as the independent t-test and Mann-Whitney U test were used to detect differences between the VAS scores of the two groups at the end of the 2<sup>nd</sup> and 6<sup>th</sup> hours postpartum. A probability value (p value) of < 0.05 was considered significant.

#### Results

One hundred participants were enrolled in the study, 50 in each group. The participants' baseline characteristics are shown in Table 1. Maternal age, body mass index (BMI), education, parity, gestational age at delivery, degree of episiotomy wound tearing, antenatal risk classification, volume of 1% lidocaine usage, duration of episiotomy wound repairing, history of 1st stage analgesic administration, fetal birth weight and neonatal NICU requirement between the two groups

were not statistically significant. Fortunately, none of our participants needed more pain killer than our

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protocol or found postpartum hemorrhage or episiotomy wound complication after randomization (Fig. 1).

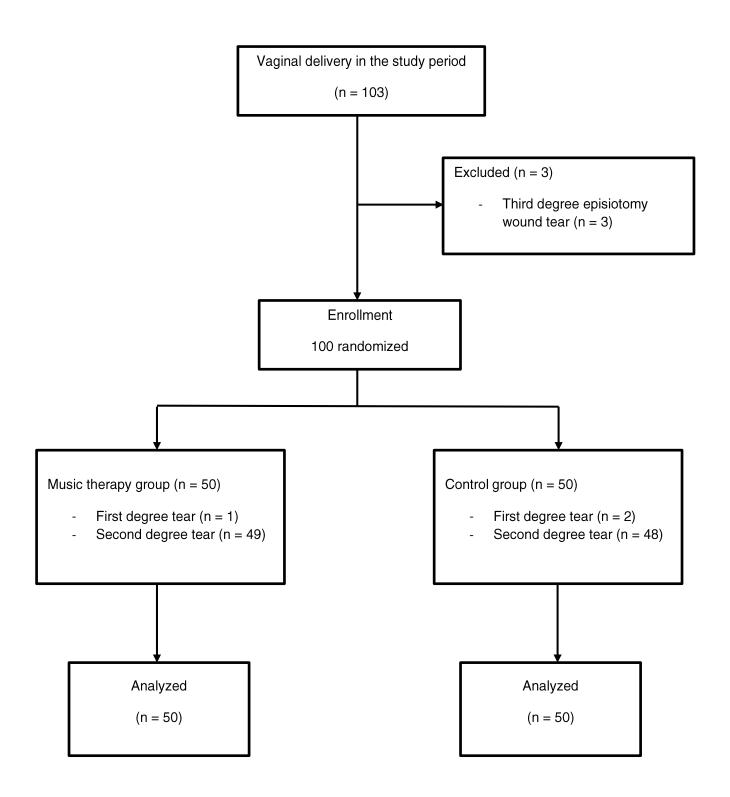


Fig. 1. Randomization.

 Table 1. Baseline Characteristics.

Variable	Group	
	Music therapy	Control
	n = 50	n = 50
Age (years), mean ± SD	$25.9 \pm 5.5$	$25.4 \pm 6.2$
BMI, kg/m², mean ± SD	$26.2 \pm 4.6$	$25.9 \pm 3.6$
Education		
High school and below	36 (72%)	37 (74%)
Bachelor degree and above	14 (28%)	13 (26%)
Parity, n (%)		
Nulliparous	15 (30%)	25 (50%)
Multiparous	35 (70%)	25 (50%)
Gestational age (weeks), mean ± SD	$38.8 \pm 1.4$	$30.6 \pm 1.5$
ANC risk		
Low-risk	36 (72%)	36 (72%)
High-risk	14 (28%)	14 (28%)
1 <sup>st</sup> stage analgesic administration	1 (2%)	2 (4%)
Degree of episiotomy wound tear, n (%)		
First degree	1 (2%)	2 (4%)
Second degree	49 (98%)	48 (96%)
Type of Episiotomy wound		
Median	6 (12%)	5 (10%)
Mediolateral	44 (88%)	45 (90%)
1% lidocaine volume, ml, median (interquartile range)	10 (9-10)	10 (9-10)
Duration of repair episiotomy wound, minutes,	30 (20-40)	30 (20-35)
median (interquartile range)		
Fetal birth weight, grams, mean ± SD	3009.2 ± 352.8	3033.6 ± 403.9
Neonatal NICU admission, n (%)	5 (10%)	3 (6%)

**Table 2.** VAS after repair episiotomy.

Pain score	Group		p value
	Music therapy	Control	_
	n = 50	n = 50	
Two-hours after	24.0	36.5	< 0.001
repair episiotomy,	(8.3-41.5)	(20.0-53.3)	
(mm), median (interquartile range)			

Table 2 presents the median and interquartile ranges pain VAS scores at the end of the 2<sup>nd</sup> hour and 6<sup>th</sup> hour after the repairing process was finished. A median pain VAS scores at the 2<sup>nd</sup> hour was statistically significantly lower in the music group than in the control group [24.0 mm (8.3-41.5) and 36.5 mm (20.0-53.3), respectively]. A median pain VAS score at the 6<sup>th</sup> hour was statistically significantly lower in the music group than in the control group [12.0 mm (3.0-21.0) and 22.0 mm (15.0-38.0), respectively].

#### **Discussion**

Our study found that the median pain VAS score at the end of 2<sup>nd</sup> and 6<sup>th</sup> hour after the repairing process were significant lowered in music therapy using groups. Immediate postpartum pain and discomfort is a quite complex phenomenon. It comprises perineal pain, uterine contraction pain, fatigue and feelings of exhaustion. Perineal pain arises from birth passage trauma and/or following an episiotomy. A higher degree of perineal pain was linked to postpartum dyspareunia and delayed wound healing(10). Both pharmacologic and non-pharmacological methods have been used for relieving episiotomy pain. Ibuprofen and acetaminophen with codeine can reduce episiotomy wound pain but there were side effects<sup>(3)</sup>. Cryotherapy using icepacks and epifoam are non-pharmacological methods that have been tried with some success. Icepacks, however, can cause some discomfort because it must directly apply to the perineal area. Music therapy have been found to be an effective alternative treatment for reducing pain in many medical situations such as colonoscopy and burn pain(11, 12). However, there has been no studied examining the effectiveness of music therapy on reducing postpartum episiotomy wound pain. Thus, our study is the first study conducted with the objective of controlling any factors that might influence the degree of pain following an episiotomy and measuring the pain level by a standard objective method (VAS). The VAS score is an objective tool which is used to measure the degree of pain by asking the participant to indicate a point along a 10 centimeter horizontal line (0 = no pain and 10 = worst possible pain). The VAS has been proven to be an accurate tool for assessing pain in many studies<sup>(13)</sup>. We found that music therapy was an effective modality for alleviating immediate postpartum episiotomy wound pain at the end of two and six hours post-delivery.

Music can also act as a distraction from pain<sup>(11,12)</sup>. We believe the main advantage of music therapy over cryotherapy is that there is no need to apply anything directly at the perineum area, which is sensitive from the wound, thus the patient feels more comfortable than with cryotherapy. Unfortunately, a limitation of our study was that we did not assess the patients' satisfaction with the use of music therapy. Moreover, we postulate that both of these mechanisms for reducing pain by music therapy may reduce overall postpartum pain and the discomfort which arises from uterine contractions and anxiety about the new experience in the new mother's life. Also, music has no adverse effects which may accompany pharmacological methods of pain control. Thus, it is a good alternative choice for patients who feel only mild to moderate degrees of pain and want to avoid using pain-relief drugs.

However, our participants were not included severe degree of episiotomy wound. Thus, it limited to confirm about effectiveness. Thus, we plan to evaluate the effectiveness of music therapy on 4th degree episiotomy wounds and also episiotomy wounds with complications such as hematoma or re-suturing. The effectiveness of music therapy in controlling pain longer than 6 hours postpartum should also be investigated, and patients' satisfaction with this form of therapy. Moreover, the method for applying music therapy needs to be investigated, as earphones may be uncomfortable to use and thus lead to lower compliance, and a low level of music in the patient's room may be more suitable for some patients. We also postulate that music may reduce stress and anxiety for other family members, including the newborn him/herself, as a previous study found that music altered the behavior, neural effects. pain response, B-endorphin and cortisol concentrations beginning in the fetal period and carried forward to the newborn period in both term and preterm babies(14-16).

Moreover, we did not confirm the baseline VAS scores before the intervention because we believed that it should be approximately equal by randomization. Thus, it may be a weakness of our study. Compare to previous study which evaluate the pain VAS score after using music for reducing pain in the management of chronic pelvic pain. It found that music could be a more significant reduction in VAS pain between study and control group (3  $\pm$  1.7 VS 4.6  $\pm$  1.7, respectively) and reducing both anxiety/depression(17). Even the level of pain VAS score before and after using the intervention are not very different but the pain is a complex feeling. Thus the authors believe that decreasing of pain at any level make the patients feel better.

#### Conclusion

In conclusion, music therapy is an effective alternative modality for alleviating during the first 6 hours postpartum episiotomy pain without side effects.

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### Potential conflicts of interest

The authors declare no conflict of interest.

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