Archives of Gynecology and Obstetrics
https://doi.org/10.1007/s00404-020-05475-9

MATERNAL-FETAL MEDICINE

Effect of music on labor and delivery in nulliparous singleton pregnancies: a randomized clinical trial

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Received: 31 October 2019 / Accepted: 22 February 2020

Abstract

Background Women's experience of pain during labor varies greatly, and pain control is a major concern for obstetricians. Several methods have been studied for pain management for women in labor, including drug and non-drug interventions.

Objective To test the hypothesis that in nulliparous women with singleton pregnancies at term, listening to music would reduce the pain level during labor.

Methods Parallel group non-blinded randomized clinical trial conducted at a single center in Italy. Nulliparous women in spontaneous labor with singleton pregnancies and vertex presentation admitted in labor and delivery room between 37 0/7 and 42 0/7 weeks of gestation for active phase of labor were eligible, and were randomized in a 1:1 ratio to receive music during labor or no music during labor. Music in labor was defined listening to music from the randomization until the delivery of the baby. The primary endpoint was the pain level during the active phase of labor, recorded using the visual analogue scale (VAS) for pain, ranging from 0 (no pain) to 10 (unbearable pain). The effect of music use during labor on each outcome was quantified as the mean difference (MD) with 95% confidence interval (CI).

Results During the study period, 30 women agree to take part in the study, underwent randomization, and were enrolled and followed up. 15 women were randomized in the music group, and 15 in the control group. No patients were lost to follow up for the primary outcome. Pain level during the active phase of labor was scored 8.8 ± 0.9 in the music group, and 9.8 ± 0.3 in the control group (MD −1.00 point, 95% CI −1.48 to −0.52; $P < 0.01$). Music during labor and delivery was also associated with a decreased pain at 1 h postpartum (MD −2.40 points, 95% CI −4.30 to −0.50), and decreased anxiety level during active phase of labor (MD −19.90 points, 95% CI −38.72 to −1.08), second stage of labor (MD −49.40 points, 95% CI −69.44 to −29.36), and at 1 h postpartum (MD −27.00 points, 95% CI −47.37 to −6.63).

Conclusion In nulliparous women with singleton pregnancies at term, listening to music reduces the pain level, and the anxiety level during labor.

Trial registration: Clinicaltrials.gov NCT03779386.

Keywords Birth · Neonatal · RCT · Pregnancy · Delivery · Labor · Women's health

Introduction

Women's experience of pain during labor varies greatly, and pain control is a major concern for obstetricians. Several methods have been studied for pain management for women in labor, including drug and non-drug interventions. Jones et al. in a Cochrane review, assessed 18 reviews of different interventions for reducing pain in labor [1]. Most methods of non-pharmacological pain management are non-invasive and appear to be safe for mother and baby, including immersion in water, relaxation, acupuncture, and massage. However, their efficacy is unclear, and based mostly on

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Published online: 03 March 2020

non-randomized studies. On the other hand, there are strong data to support the efficacy of pharmacological methods, including epidural analgesia, which improves pain relief but may also increase the incidence of operative deliveries [1–3].

A recent meta-analysis aimed to examine the effects of mind-body relaxation techniques for pain management in labor on maternal and neonatal well-being, including relaxation, yoga, mindfulness, music, and audio analgesia [2]. The authors showed that when comparing music to control there was lower pain intensity in the latent phase of labor, and no clear benefit in the active phase of labor [2].

Objective

The hypothesis of this trial was that in nulliparous women with singleton pregnancies at term, listening to music would reduce the pain level during labor.

Methods

Study design and participants

This was a single-center open-label parallel group randomized clinical trial of women with singleton pregnancies and spontaneous labor at term, conducted from January 2019 to July 2019.

The trial was approved by the local ethics committee. All participants in the trial provided written informed consent.

Eligible women were nulliparous women with singleton pregnancies and vertex presentation admitted in labor and delivery room between 37 0/7 and 42 0/7 weeks of gestation for active phase of labor. Exclusion criteria were: multiparous women, multiple gestation, preterm labor, post-term labor, preterm premature rupture of membranes, prior cesarean section, induction of labor with either oxytocin or cervical ripening, and high-risk pregnancies, including hypertensive disorders of pregnancies, diabetes, intrauterine growth restriction, fetal abnormalities. Women were enrolled at the time of diagnosis of active phase of labor. We included both women with spontaneous premature rupture of membranes (PROM) and those with unruptured membranes at the time of enrollment.

Active phase of labor was defined as the presence of a contractile pressing activity, regular for intensity and duration, 2–4 contractions in 10 min, felt by the woman as painful, associated with a cervical dilatation from / above the 4 cm. Second stage of labor was defined as the part of labor from the full dilatation of the cervix until the delivery of the baby.

All women received one-to-one support by a midwife during labor. Artificial rupture of membranes and augmentation of labor with oxytocin were performed at physicians discretion. Women in both groups received physical exam every 3–4 h.

Randomization and masking

Eligible participants were randomly allocated in a 1:1 ratio to either music during labor or control group. Women were randomized by a web-based system (randomization.com) to receive intervention or control. The trial coordinator did not have access to the randomization sequence. The allocation code was disclosed only after the patient's initials was confirmed. The trial was open-label, but the data analyst was blind to the allocated treatment group until the entire analysis was completed.

Intervention

Women in the intervention group was offered music in labor, defined listening to music via speakers from the randomization until the delivery of the baby. Women had the possibility to select the songs at their discretion. Women in the control group received the same obstetrical care during labor and delivery as those in the intervention group, with no music during labor or delivery.

Outcomes

During the labor, and in the post-partum period, women received specific questionnaires for the evaluation of pain, and anxiety level. Assessment of anxiety and pain level was carried out at the end of each hour during labor, starting from the randomization until the delivery of the baby. In the post-partum period, women were evaluated for pain and anxiety at 1 h, 24 h, and 48 h post-partum.

Pain level and anxiety level were self-reported and recorded using the visual analogue scale (VAS). VAS for pain ranged from 0 (no pain) to 10 (unbearable pain). VAS for anxiety ranged from 0 (not at all anxious) to 100 (extremely anxious).

The primary outcome was the mean pain level during the active phase of labor, assessed by VAS for pain.

The secondary outcomes were:

1. mean pain level during the second stage, and at post-partum, assessed by VAS for pain;
2. mean anxiety level during the active phase of labor, second stage, and at post-partum, assessed by VAS for anxiety;
3. incidence of episiotomy, and of vaginal lacerations;
4. use of analgesics; and

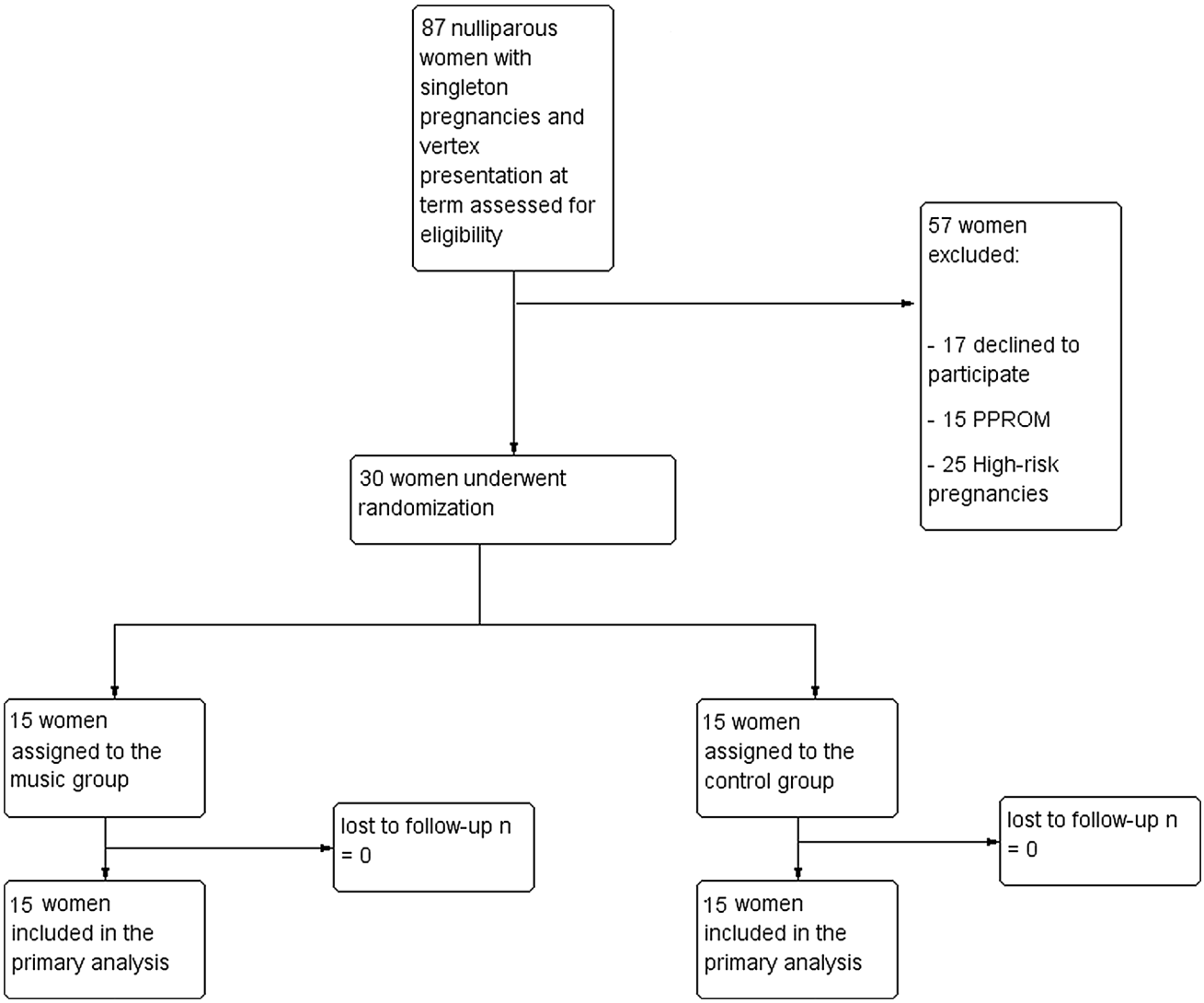

Fig. 1 CONSORT Study flow-chart. PPROM, preterm premature rupture of membranes

5. neonatal outcomes

Sample size calculation

Calculation of the sample size was based on detecting an effect that produces a difference in 1.2 cm/points on VAS pain with 1.1 SD [2]. We determined that a sample size of 30 patients (15 per group) would provide a power of 80%, with a two-sided type 1 error of 5%.

Statistical analysis

Data are shown as mean values, or as number (percentage). Univariate comparisons of dichotomous data were performed with the use of the Chi-square test with continuity correction. Comparisons between groups were performed with the use of the *T* test to test group means by assuming equal within-group variances. The primary analysis was an intention to treat comparison of the treatment assigned at randomization. The effect of music use during labor on each outcome was quantified as the unadjusted relative risk (RR) or as the mean difference (MD) with 95% confidence interval (CI). No interim analyses were planned.

A two-sided *P* value less than 0.05 was considered significant.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc.).

Table 1 Characteristics of the enrolled women

	Music group ($N=15$)	Control group ($N=15$)	P value
Age (years)	28.7 ± 3.3	31.1 ± 6.6	0.98
BMI	24.8 ± 0.7	25.1 ± 1.2	0.40
Race			0.49
Caucasian	15 (100%)	14 (93.3%)	
Other		1 (6.7%)	
Membranes at the time of randomization			
Ruptured	4 (26.7%)	8 (53.3%)	0.14
Gestational age at randomization (weeks)	39.4 ± 1.3	39.5 ± 1.1	0.82

Data are presented as number (percentage), or as mean ± standard deviation

BMI body mass index

Results

Trial population

During the study period, 30 women agree to take part in the study, underwent randomization, and were enrolled and followed up (Fig. 1). No patients were lost to follow up for the primary outcome, and no data were missing. 15 women (50.0%) were randomized in the music group (i.e. intervention group), and 15 women (50.0%) were randomized in the control group.

Table 1 shows the baseline demographic and clinical characteristics for each group. All women were nulliparous, singleton gestations, with spontaneous labor at term, and were enrolled at the time of active phase of labor. None of them were smokers. Twelve women had PROM at the time of randomization, 4 (26.7%) in the intervention group, and 8 (53.3%) in the control group.

Obstetric outcomes

Overall, 27/30 (90.0%) women delivered by spontaneous vaginal delivery. Six women in the intervention group (40.0%) and 5 (33.3%) in the control group received episiotomy. None of the included women received epidural analgesia. No differences were found in the mode of delivery, including rate of spontaneous vaginal delivery and of operative delivery, but the trial was not powered for these outcomes (Table 2). All cases of operative deliveries were performed for fetal bradycardia.

Primary and secondary outcomes

Pain level during the active phase of labor was scored 8.8 ± 0.9 in the music group, and 9.8 ± 0.3 in the control group (MD − 1.00 point, 95% CI − 1.48 to − 0.52; $P<0.01$). Music during labor and delivery was also associated with a decreased pain at 1 h postpartum (MD − 2.40 points, 95% CI − 4.30 to − 0.50), and decreased anxiety level during active phase of labor (MD − 19.90 points, 95% CI − 38.72 to − 1.08), second stage of labor (MD − 49.40 points, 95% CI − 69.44 to − 29.36), and at 1 h postpartum (MD − 27.00 points, 95% CI − 47.37 to − 6.63). There was no significant between-group difference in pain level during second stage of labor (Table 3).

Neonatal outcomes

No cases of neonatal death, necrotizing enterocolitis (NEC), intraventricular hemorrhage (IVH), respiratory distress syndrome (RDS), bronchopulmonry dysplasia (BPD), retinopathy of prematurity (ROP), or sepsis were recorded. No neonates were admitted to neonatal intensive care unit.

Trial adverse events

No cases of maternal death, or serious injuries during the study period were reported.

Discussion

Main findings

This randomized clinical trial showed that in nulliparous women with singleton pregnancies at term, listening to music resulted in a statistically significant lower pain level than no music. Music during labor and delivery was also associated with a decreased anxiety level. Pain and anxiety level were self-reported and recorded using the VAS.

In our trial use of music in labor was associated with a trend for benefits for all outcomes, except for anxiety level at 48 h postpartum which is higher in the music compared to the control group (Table 3).

Limitations of our trial included the open-label nature of the trial that could have affected medical decision making, and findings of the study. Second, the numerous secondary endpoints with no adjustment for multiple comparisons could have led to type 1 error. Third, the single center nature of the trial, and the small sample size, raises the question of the external generalizability of the findings.

Our trial did support earlier findings of a recent Cochrane review, that showed that when comparing music to control interventions there was evidence of lower pain intensity in

Table 2 Obstetric outcomes

	Music group ($N=15$)	Control group ($N=15$)	RR or MD (95% CI)
Use of oxytocin for augmentation of labor	5 (33.3%)	6 (40.0%)	0.75 (0.17 to 3.33)
Operative vaginal delivery	0	3 (20.0%)	0.12 (0.01 to 2.45)
Spontaneous vaginal delivery	15 (100%)	12 (80.0%)	8.68 (0.41 to 184.28)
Episiotomy	6 (40.0%)	5 (33.3%)	1.33 (0.30 to 5.91)
Vaginal laceration (2nd degree)	9 (60.0%)	7 (46.7%)	1.71 (0.40 to 7.29)
Vaginal laceration (3rd degree)	1 (6.7%)	0	3.21 (0.12 to 85.20)
Total length of labor[a] (min)	288.4 ± 138.9	231.3 ± 84.1	57.10 min (− 25.07 to 139.27)
Length of the second stage of labor (min)	49.6 ± 32.2	47.5 ± 30.9	2.10 min (− 20.48 to 24.68)

Data are presented as number (percentage), or as mean ± standard deviation

RR relative risk, *MD* mean difference, *CI* confidence interval

[a]From randomization to delivery

Table 3 Primary and secondary outcomes

	Music group ($N=15$)	Control group ($N=15$)	RR or MD (95% CI)
Pain level during active phase of labor[a]	8.8 ± 0.9	9.8 ± 0.3	**− 1.00 (− 1.48 to − 0.52)**
Pain level during second stage of labor[a]	9.0 ± 1.7	9.5 ± 0.9	− 0.50 (− 1.47 to 0.47)
Pain level at 1 h postpartum[a]	3.6 ± 2.7	6.0 ± 2.6	**− 2.40 (− 4.30 to − 0.50)**
Pain level at 24 h postpartum[a]	3.1 ± 2.6	3.8 ± 2.4	− 0.70 (− 2.49 to 1.09)
Pain level at 48 h postpartum[a]	1.7 ± 2.2	2.0 ± 1.4	− 0.30 (− 1.62 to 1.02)
Anxiety level during active phase of labor[a]	53.9 ± 27.9	73.8 ± 24.6	**− 19.90 (− 38.72 to − 1.08)**
Anxiety level during second stage of labor[a]	45.3 ± 37.2	94.7 ± 13.6	**− 49.40 (− 69.44 to − 29.36)**
Anxiety level at 1 h postpartum[a]	10.7 ± 20.9	37.7 ± 34.4	**− 27.00 (− 47.37 to − 6.63)**
Anxiety level at 24 h postpartum[a]	7.3 ± 15.8	16.3 ± 21.8	− 9.00 (− 22.62 to 4.62)
Anxiety level at 48 h postpartum[a]	10.0 ± 20.7	3.0 ± 6.5	7.00 (− 3.98 to 17.98)

Data are presented as as mean ± standard deviation. Boldface data, statistically significant

Pain level during active phase of labor, primary outcome of the trial

RR relative risk, *MD* mean difference, *CI* confidence interval

[a]Assessed by VAS

the latent phase for women receiving music. However, the authors found no clear benefit in the active phase of labor [2].

Implications

Several methods have been studied for pain management for women in labor [1, 2, 4–13]. These include both non-pharmacological interventions and pharmacological interventions. Downe et al. showed that self-hypnosis training sessions did not significantly reduce intra-partum epidural analgesia use [4]. Among other non-pharmacological interventions, massage, ambulation, and positions, are associated with a reduction in epidural analgesia and a higher maternal satisfaction with childbirth [5]. Immersion in water is the one of most popularized over the past several decades. Among randomized trials included in a 2018 Cochrane systematic review that addressed immersion in water in the first stage of labor, results were inconsistent with regard to maternal benefits, and there were insufficient data on which to draw conclusions regarding benefits and risks during the stage of labor and during delivery [6].

Among pharmacological interventions, inhaled analgesia, opioids, non-opioids drugs, local anesthetic nerve blocks, epidural and intrathecal injections of local anesthetics or opioids have been studied [1]. Neuraxial analgesia for labor and delivery (e.g. spinal, epidural, and combined spinal epidural), is the most effective and most commonly used therapy for pain relief during labor and delivery. These techniques provide excellent analgesia with minimal risks, and are appropriate for laboring women regardless of parity, cervical dilation, and fetal station [7]. Level-1 data showed that epidural analgesia is more effective in reducing pain during labor and increasing maternal satisfaction with pain relief

than non-epidural methods [3, 8, 9]. However, these techniques increase the risk of operative vaginal delivery, and cesarean section [8, 9]. For this reason, studying an approach to relief pain with no risk of women and fetuses, such as listing to the music, is a major goal for obstetricians.

Prior trials evaluated the effect of music in labor and delivery [2, 14, 15]. Gedde-Dahl et al. studied relaxation, music, and guided imagery in the third trimester and during labor [14]. They showed that intervention was associated with better score on total wellbeing, as measured by the ESAS Edmonton Scale [14]. Kimber et al. performed a randomized trials in which women were randomized in three groups: massage with relxation techniques, music with relaxation techniques, and usual care. They found a trend towards more positive views of labor preparedness and sense of control in the two intervention groups, compared with the control group [15].

Conclusion

In summary, in nulliparous women with singleton pregnancies at term, listening to music reduces the pain level, and the anxiety level during labor.

Author contributions AB: study conception, study design, patients' enrollment, data collection. GS: study conception, study design, methods supervision, data analysis, manuscript preparation, whole study supervision. MM: study conception, study design, patients' enrollment, data collection. AR: study conception, study design, methods supervision, data analysis, manuscript preparation, whole study supervision. LDM: study conception, study design, patients' enrollment, data collection. LeDM: study conception, study design, patients' enrollment, data collection. PT: study conception, study design, patients' enrollment, data collection. AT: study design, methods supervision, data analysis, manuscript preparation. RZ: study conception, methods supervision, whole study supervision. MD: study conception, methods supervision, whole study supervision. FZ: study design, methods supervision, whole study supervision. ML: study conception, methods supervision, whole study supervision.

Funding No financial support was received for this study.

Compliance with ethical standards

Conflict of interest The authors report no conflict of interest.

Ethical approval This study was approved by the local IRB of the University of Naples Federico II, number 287/18.

Informed consent All participants in the trial provided written informed consent.

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