Neonatal Outcomes of Continues Fetal Heart Rate Monitoring in Low-Risk Pregnant Women During Labor

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Abstract- Various methods are used in order to describe the heart rate patterns of the fetus. The use of electronic monitoring during labor is widely accepted today. The aim of this study was to compare the neonatal outcomes of continuous Fetal Heart Rate (FHR) monitoring to intermittent auscultation among low-risk pregnant women during labor. This randomized clinical trial was conducted among 900 low-risk pregnant women who met inclusion criteria and were admitted to maternity wards of academic hospitals of Mashhad University of Medical Sciences for labor. They were randomly divided into two groups: the intermittent auscultation group and the Continuous FHR monitoring group. The pregnancy and neonatal outcomes were compared in two groups; data were processed in SPSS16 software. P less than 0.05 was considered as significant level. In this study, the first and fifth minutes Apgar scores, the rate of NICU admission, advance resuscitation requirement, neonatal seizure incidence, and the neonatal or fetal death did not differ significantly between two groups (P>0.05). In the Continues monitoring group, the rate of cesarean section due to fetal distress and operative vaginal delivery was significantly higher rather than the other group (P=0.001). The results of this study showed that continuous FHR monitoring in low-risk pregnancies during labor increases the risk of cesarean and instrumental delivery without improving neonatal outcomes.

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Keywords: Pregnancy outcome; Auscultation; Fetal heart rate; Fetal monitoring

Introduction

Perinatal mortality is incredibly high worldwide, with up to seven million perinatal deaths annually (1). Hypoxia is believed to be one of the main preventable reasons for perinatal deaths (2,3). Continuous electronic fetal monitoring (EFM) was introduced in the 1960s and 1970s with the idea that by early diagnosing of fetal hypoxia, it would prevent perinatal mortality and morbidity. EFM was mainly used in complicated pregnancies when introduced for the first time, but it was gradually used extensively in most pregnancies before gathering scientific evidence to support such widespread application, insofar as it is used in more than 85% of all live births in the United States to date (4,5).

There are a variety of methods to assess fetal wellbeing during labor; however, Fetal Heart Rate (FHR) monitoring remains the most common method for intrapartum fetal assessment (6). Intermittent auscultation and continuous FHR monitoring, using an Electronic fetal heart rate monitoring machine that prints a paper showing FHR and uterine contractions called a cardiotocograph (CTG) are two widely used FHR monitoring methods (7). Intermittent auscultation (IA) is operated by listening to the fetal heart using either a fetal stethoscope or a hand-held Doppler ultrasound device (Sonicaid). Each auscultation is performed after a contraction, at least for 60 seconds (4). In continuous FHR monitoring, the patient’s mobility is restricted, but more measurable parameters of FHR pattern are obtained that provide recordable legal evidence. However, the complexity of the FHR pattern makes its interpretation problematic in many situations (8).

The term EFM (Electronic Fetal Monitoring) refers to a group of electronic methods to monitor the fetus, including internal and external cardiotocography, fetal...
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This randomized clinical trial was conducted in three academic hospitals in Mashhad, from November 2016 to December 2017. Ethical approval for this trial was obtained from the ethical committee of the Mashhad University of Medical Sciences (IR.MUMS.FM.REC.1395.163), and we registered this RCT on Iranian Registry of Clinical Trials (IRCT2017010731725N1).

Inclusion criteria for this study were all women with term cephalic singleton pregnancies without any of the following conditions; diabetes mellitus, hypertensive disorders, intrauterine growth retardation, placenta Previa or placental abruption, cardiopulmonary or neurologic disorders, connective tissue diseases, previous cesarean section, chorioamnionitis or sepsis, pre-term or post-term pregnancy, misoprostol or oxytocin application or meconium-stained amniotic fluid before enrollment.

Exclusion criteria in this study were; misoprostol or oxytocin augmentation requirement, meconium-stained amniotic fluid after enrollment, dilation or descent arrest, and the patient’s unwillingness to continue the trial.

Oral and written informed consents were taken from all the participants after the aims and objectives of the study had been explained to them. "An admission CTG was done for 20 min after taking a detailed history, to document vital signs and also the obstetric examination was made to confirm reactive fetal heart rate, the fetal lie, presentation, station, cervical dilatation and status of membranes. Those with category one traces were randomly allocated to continuous monitoring group or intermittent auscultation group. A gynecology resident on duty filled out a patient's checklists. Due to the nature of the interventions, masking participants, or research staff to the allocation was not possible.

Accordingly, a total number of 1395 low-risk pregnant women who were admitted for labor were assessed, though 293 women did not meet the inclusion criteria, and 52 of cases refused to enter the study. The remaining 1050 women were randomly assigned to: the continuous monitoring group (intervention group n=525) or the intermittent auscultation group (control group n=525), using a computer-generated sealed envelope method. Some cases were excluded from the study during allocation, follow-up, and analysis, as shown in detail in Figure 1.

Materials and Methods

Sampling and study design
Intervention method

Those randomized to the control group (n=450) received intermittent auscultation immediately after each contraction and between contractions in each 30 minutes interval during the first stage of delivery and each 15 minutes interval during the second stage of delivery for the duration of at least 60 seconds using a Sonicaid (FonoonTeb & co, Iran). A trained midwife or a trained gynecology resident performed auscultations. If abnormal auscultation was detected, the FHR was monitored continuously for 20 minutes. If normal FHR pattern was identified, intermittent auscultation would continue; otherwise, the patient would be excluded from the study. During the intervention, one midwife was assigned solely to each patient allocated in this group.

Those randomized to the intervention group (n=450) received continuous FHR monitoring using an external cardiotocography (Bionet & co, South Korea) that simultaneously recorded fetal heart rate and uterine contractions. A trained gynecology resident evaluated the traces every 30 minutes during the first stage and every 15 minutes during the second stage of the delivery. Unconfirmed or abnormal traces were diagnosed based on the ACOG Practice Bulletin 2013 Guidelines. Emergency cesarean delivery or instrumental vaginal delivery planned for category 3 FHR tracing. For category 2 (non-reassuring traces), conservative treatment was performed depending on the patient’s condition in both groups. The conservative treatment consists of changing the patient’s position, administration of 6 lit O2/m by face mask, and infusion of 500 ml ringer lactate solution in 1 hour. The monitoring was discontinued only for short periods when the patient wanted to go to the toilet.

Outcome measures

The first and fifth minute neonatal Apgar scores were defined as the primary outcome in this study, and advance resuscitation requirement (intubation or chest compression or any drug administration requirement to resuscitate the neonate), the incidence of infant seizures, and NICU admission as secondary outcomes. We also assessed the delivery method (spontaneous vaginal delivery, cesarean section, or operative vaginal delivery).

Sample size determination and data analysis

Collected data were analyzed using SPSS software version 16 (SPSS Inc., Chicago, IL, USA). All
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qualitative data are reported as percentages, analyzed using the Chi-square test, while quantitative data are reported as mean (±standard deviation), and analyzed using Fisher or T-test since they were normally distributed. P≤0.05 was considered statistically significant.

Results

Data of 900 patients (450 cases in each group) were analyzed, and the women’s baseline characteristics of age, parity, gravidity, amniotic sac condition, and gestational age were similar in both groups (Table 1).

The first and fifth minute Apgar scores were defined as primary outcomes in this study that no statistical difference existed between two groups in view of neonatal first and fifth minute Apgar scores (P>0.5). thirty cases in the control group (6%) and 35 cases in the intervention group (6.3%) had a first minute Apgar score of lower than 7, and also, 15 cases in the control group and 20 cases in the intervention group had a fifth-minute Apgar score of lower than 7 (3% and 4%, respectively).

Instrumental vaginal delivery and cesarean section (due to fetal distress (category 3 FHR tracing)) were significantly higher in the intervention group rather than the control group (13% vs. 4%, P=0.001). 15 neonates in the control group and 20 neonates in the intervention group were admitted to NICU (P=0.47), and all of them required advanced resuscitation or intubation. In this study, no case of neonatal death or seizure happened in the neonatal period (first 28 days of life), and all the neonates were discharged from the hospital in good general condition.

| Table 1. Baseline clinical characteristics of the control and intervention group |
|-------------------------------|-------------------------------|--------|
|                               | Control group (n=450)        | Intervention group (n=450) | P   |
| Maternal Age (years)          | 27.76±5.8                    | 27.60±5.9 | 0.69  |
| (mean±SD)                     |                               |                    |      |
| Gestational Age (weeks)       | 39.18±0.76                   | 39.26±0.82 | 0.11  |
| (mean±SD)                     |                               |                    |      |
| Intact amniotic sac n (%)     | 367 (81.6)                   | 354 (78.8) | 0.27  |
| Labor Pain at admission n (%) | 426 (94.7)                   | 408 (90.7) | 0.02  |
| Nulliparous                   | 135 (30)                     | 157 (34)  | 0.11  |
| Type of parity n (%)          |                               |                    |      |
| Multiparous                   | 315 (70)                     | 293 (66)   |       |
| Multigravida                  | 124 (27.6)                   | 131 (29.1) | 0.11  |
| Type of Gravidity n (%)       | 236 (72.4)                   | 319 (70.9) |       |
| Previous history of abortion n (%) | 75 (16.7)  | 92 (20.4)  | 0.14  |

| Table 2. Comparison of study outcomes between the control group and the intervention group |
|-------------------------------|-------------------------------|--------|
|                               | Control group (n=450)        | Intervention group (n=450) | P   |
| Variable                      | Spontaneous vaginal delivery |                   |      |
| Delivery method n (%)         | 430 (96)                     | 390 (87)   | 0.001 |
| Cesarean section or operative |                               |                    |      |
| vaginal delivery              | 20 (4)                       | 60 (13)    |       |
| First minute Apgar Score n (%)| >7                            | 420 (94)   | 0.41  |
| Score n (%)                   | <7                            | 30 (6)     |       |
| Fifth minute Apgar Score n (%)| >7                            | 435 (97)   | 1     |
| Score n (%)                   | <7                            | 15 (3)     |       |
| NICU admission requirement n (%) | 15 (3)                    | 20 (4)    | 0.47  |

Discussion

This study demonstrated no significant difference in neonatal outcomes between continuous monitoring and intermittent auscultation method, even though continuous monitoring method was associated with more cesarean or operative vaginal deliveries in low-risk patients. The same results were reported in multiple studies (20,22,23).

In a systematic review by Alfirevic et al., which included 13 trials comparing continuous cardiotocography with intermittent auscultation or...
monitoring, it was concluded that continuous CTG increases the cesarean sections and instrumental vaginal births but reduces rates of neonatal seizures (8). A study by Thacker et al., also demonstrated the same results (24). In our study, however, no case of neonatal seizure was reported that might be due to our smaller sample size. Moreover, only low-risk pregnancies were included in our study that might have had an impact on the incidence of neonatal seizures.

Our study showed that continuous FHR monitoring in low-risk patients has no superiority over intermittent auscultation. In fact, the FHR monitoring value and necessity in improving neonatal outcomes have been doubted recently (8,25,26). In a study by Clark et al., which was aimed to examine FHR monitoring limits in the prevention of neonatal metabolic acidemia, it was shown that only one-half of infants who are born with metabolic acidemia could be identified and perform expedited delivery even under ideal circumstances. Moreover, 20% of fetuses who are born with significant metabolic acidemia do not show any abnormal features in their traces that mandate any intervention (27). FHR monitoring is known to have a very poor positive predictive value (15).

However, these findings even challenge our archaic assumptions on the sensitivity of continuous FHR monitoring. Although some researchers believe that using a strictly standardized system in the interpretation of FHR traces can be predictive of umbilical artery acid-base status at delivery (28), it seems that even using the computerized interpretation of cardiotocographs during labor cannot reduce the likelihood of metabolic acidosis or poor neonatal and maternal outcomes (29,30).

Previous trials comparing continuous EFM with intermittent auscultation were mostly conducted 2 or 3 decades ago (8,12,13). This study aimed at low-risk patients exclusively, using modern EFM devices and recent diagnostic criteria to monitor cases during labor. In spite of that, our study results were much the same as the old studies and continuous EFM in low-risk cases, appears to have no improving effect on neonatal outcomes. This result is valuable when the doctor and the patient are making decisions on monitoring methods during labor. Moreover, a lot of clinicians and health care providers need to change their archaic belief in continuous monitoring, especially in low-risk patients.

One of the strengths of the current study was evaluating the low-risk pregnancies, which are a more challenging issue on the implication of continuous monitoring in obstetrical care. Another strength is that it is a multicentric study by clinical trial design. The potential weakness of this study was different decision making on abnormal tracing patterns by the different attending physician (inter-observer interpretation), which may affect the rate of cesarean section in the continuous FHR monitoring group.

This trial demonstrated no significant statistical difference in neonatal outcomes between the low-risk laboring women monitored by continuous EFM or intermittent auscultation. However, continuous EFM appeared to increase the risk of cesarean section or instrumental vaginal delivery.

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