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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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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pulse oximetry, fetal electrocardiography, and electronic uterine monitoring; which the last one is the most novel equipment for this purpose (9). However, in this study, external cardiotocography is the intended form of EFM.

Some studies demonstrated that electronic fetal monitoring is associated with recent declines in neonatal mortality (5,10,11). On the other hand, some researchers believe that not only continuous fetal monitoring could not decrease the rate of cerebral palsy or fetal death, but also it has increased the rate of cesarean section and instrumental vaginal deliveries (8,12,13). Obviously, these trials are underpowered to evaluate differences in major outcomes for the reason that they were conducted in the 1970s to early 1990s, where different equipment and interpretation criteria were used comparing to current practice (14). Hence, conducting new trials using current obstetric guidelines in FHR interpretation and current monitoring devices seems to be necessary.

Moreover, some researchers claim that because of the very poor positive predictive value of electronic fetal monitoring for fetal death in labor and cerebral palsy, such monitoring has failed as a public health screening program (15). Therefore, continuous FHR monitoring application in appropriate patients seems to be an important matter that requires further investigation.

Despite the lack of evidence regarding the benefit of continuous monitoring and despite the fact that intermittent auscultation is more cost-effective, continuous monitoring is still the most routine intrapartum fetal wellbeing assessment method in practice (5,8,16,17).

Although, nowadays, continuous FHR monitoring has become a standard intrapartum fetal monitoring method in high-risk pregnancies, using it in low-risk pregnancies (healthy women with uncomplicated pregnancies) remains a controversy among clinicians and using intermittent auscultation instead seems more reasonable (7,8,18-20). In spite of that, continuous FHR monitoring is still used in low-risk patients routinely in practice (21). The aim of this study is to compare the neonatal outcomes of intermittent auscultation and continuous fetal heart rate monitoring among low-risk pregnant women during labor.

Materials and Methods

Sampling and study design

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 laborwere 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.

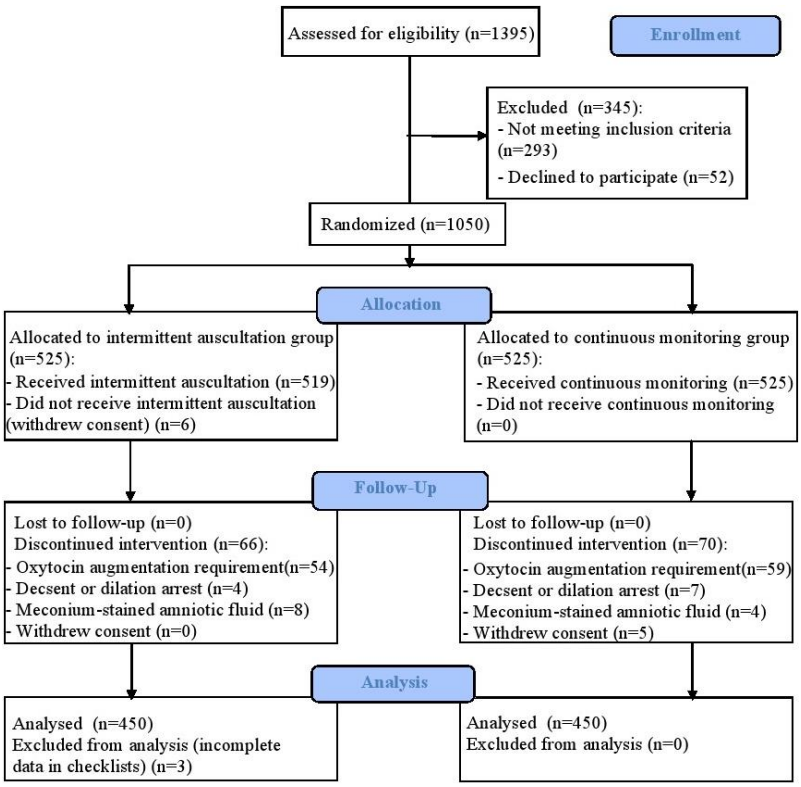

Figure 1. Consort Diagram for the participants involved in the trial

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. In the event that 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 O^2/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

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. $P \leq 0.05$ 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*
Variable	Maternal Age (years) (mean±SD)	27.76±5.8	27.60±5.9	0.69
	Gestational Age (weeks) (mean±SD)	39.18±0.76	39.26±0.82	0.11
	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
Type of parity n (%)	Nulliparous	135 (30)	157 (34)	0.11
	Multiparous	315 (70)	293 (66)	
Type of Gravidity n (%)	Primigravida	124 (27.6)	131 (29.1)	0.11
	Multigravida	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	430 (96)	390 (87)	0.001
Delivery method n (%)	Cesarean section or operative vaginal delivery	20 (4)	60 (13)	
First minute Apgar Score n (%)	>7	420 (94)	415 (93.7)	0.41
	<7	30 (6)	35 (6.3)	
Fifth minute Apgar Score n (%)	>7	435 (97)	430 (96)	1
	<7	15 (3)	20 (4)	
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 believe 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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References

1. Y VY Global, regional and national perinatal and neonatal mortality. J perinatal med 2003;31:376-9.
2. Allanson ER, Muller M, Pattinson RC. Causes of perinatal mortality and associated maternal complications in a South African province: challenges in predicting poor outcomes. BMC pregnancy childbirth. 2015;15:37.
3. Lawn JE, Cousens S, Zupan J. 4 million neonatal deaths: when? Where? Why? Lancet 2005;365:891-900.
4. Cunningham FG, Leveno KJ, Bloom SL. Intrapartum Assessment. In: Cunningham FG, Leveno KJ, Bloom SL, Dashe JS, Hoffman BL, Casey BM, et al., eds. Williams Obstetrics. 25th ed. United States: NY: McGraw-Hill Education,2018:457-84.
5. Ananth CV, Chauhan SP, Chen HY, D'Alton ME, Vintzileos AM. Electronic fetal monitoring in the United States: temporal trends and adverse perinatal outcomes. ObstetGynecol 2013;121:927-33.
6. Alfirevic Z, Stampalija T, Gyte GM. Fetal and umbilical Doppler ultrasound in high-risk pregnancies. Cochrane Database Sys Rev 2013:11;Cd007529.
7. Ayres-de-Campos D, Spong CY, Chandraharan E. FIGO consensus guidelines on intrapartum fetal monitoring: Cardiotocography. Int J GynaecolObstet 2015;131:13-24.
8. Alfirevic Z, Devane D, Gyte GM, Cuthbert A. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 2017;2:Cd006066.

9. Ashwal E, Shinar S, Aviram A, Orbach S, Yogev Y, Hiersch L. A novel modality for intrapartum fetal heart rate monitoring. J Matern Fetal Neonatal Med 2017;2:1-7.
10. Philopoulos D. [Electronic fetal monitoring and its relationship to neonatal and infant mortality in a national database: A sensitivity analysis]. J GynecolObstetBiolReprod (Paris) 2015;44(5):451-62.
11. Chen HY, Chauhan SP, Ananth CV, Vintzileos AM, Abuhamad AZ. Electronic fetal heart rate monitoring and its relationship to neonatal and infant mortality in the United States. Am J ObstetGynecol 2011;204:491.e1-10.
12. Vintzileos AM, Nochimson DJ, Guzman ER, Knuppel RA, Lake M, Schifrin BS. Intrapartum electronic fetal heart rate monitoring versus intermittent auscultation: a meta-analysis. ObstetGynecol 1995;85:149-55.
13. MacLennan AH, Thompson SC, Gecz J. Cerebral palsy: causes, pathways, and the role of genetic variants. Am J ObstetGynecol 2015;213:779-88.
14. Heelan L. Fetal monitoring: creating a culture of safety with informed choice. J Perinat Educ 2013;22:156-65.
15. Grimes DA, Peipert JF. Electronic fetal monitoring as a public health screening program: the arithmetic of failure. ObstetGynecol 2010;116:1397-400.
16. Schulten PS, Suppelna JP, Dagres T, Noe G, Anapolski M, Reinhard J, et al. [Comparison of International Guidelines For the Application of Cardiotocography]. Z GeburtshilfeNeonatol 2018;222:66-71.
17. Graham EM, Petersen SM, Christo DK, Fox HE. Intrapartum electronic fetal heart rate monitoring and the prevention of perinatal brain injury. Obstetgynecol 2006;108:656-66.
18. Liston R, Crane J, Hamilton E, Hughes O, Kuling S, MacKinnon C, et al. Fetal health surveillance in labour. J obstetgynaecol Can2002;24:250-76.
19. ACOG. ACOG Practice Bulletin No. 106: Intrapartum fetal heart rate monitoring: nomenclature, interpretation, and general management principles. Obstetgynecol 2009;114:192-202.
20. Herbst A, Ingemarsson I. Intermittent versus continuous electronic monitoring in labour: a randomised study. Br J ObstetGynaecol 1994;101:663-8.
21. Smith V, Begley CM, Clarke M, Devane D. Professionals' views of fetal monitoring during labour: a systematic review and thematic analysis. BMC pregnancy childbirth 2012;12:166.
22. VelimalaRatna K, Indiramani I, Chakravarthy K, Anitha A. A comparative study of perinatal Outcome in low risk pregnancies with CTG monitoring and intermittent Ascultation. J Evol Med Dent Sci 2015;4:17038-42.
23. Kelso IM, Parsons RJ, Lawrence GF, Arora SS, Edmonds DK, Cooke ID. An assessment of continuous fetal heart rate monitoring in labor. A randomized trial. Am J ObstetGynecol 1978;131:526-32.
24. Thacker SB, Stroup D, Chang M. Continuous electronic heart rate monitoring for fetal assessment during labor. The Cochrane Database Syst Rev 2001;2:Cd000063.
25. Sartwelle TP, Johnston JC. Cerebral palsy litigation: change course or abandon ship. J Child Neurol 2015;30:828-41.
26. Nelson KB, Sartwelle TP, Rouse DJ. Electronic fetal monitoring, cerebral palsy, and caesarean section: assumptions versus evidence. BMJ 2016;355:i6405.
27. Clark SL, Hamilton EF, Garite TJ, Timmins A, Warrick PA, Smith S. The limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia. Am J ObstetGynecol 2017;216:163.e1-.e6.
28. Soncini E, Paganelli S, Vezzani C, Gargano G, Giovanni Battista LS. Intrapartum fetal heart rate monitoring: evaluation of a standardized system of interpretation for prediction of metabolic acidosis at delivery and neonatal neurological morbidity. J Matern Fetal Neonatal Med 2014;27:1465-9.
29. Group IC. Computerised interpretation of fetal heart rate during labour (INFANT): a randomised controlled trial. Lancet 2017;389:1719-29.
30. Nunes I, Ayres-de-Campos D, Ugwumadu A, Amin P, Banfield P, Nicoll A, et al. Central Fetal Monitoring With and Without Computer Analysis: A Randomized Controlled Trial. Obstetgynecol 2017;129:83-90.