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Cardiotocography alone vs. cardiotocography with ST segment analysis for intrapartum fetal monitoring in women with late-term pregnancy. A randomized controlled trial



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ABSTRACT

Objectives: Randomized studies have obtained conflicting results regarding the usefulness of fetal electrocardiographic (ECG) ST-segment analysis, possibly because these studies included non-homogeneous populations. We designed a study to determine whether this monitoring technique is potentially useful for populations at risk for fetal heart rate alterations during labor, i.e. groups of women who share late-term pregnancy as a risk factor.

Study design: This randomized clinical trial recruited women whose pregnancy had lasted more than 290 days. The participants were randomly assigned to continuous fetal cardiotocographic monitoring alone (CTG group) or with fetal ECG ST-segment analysis (ECG-F group). In the CTG group fetal heart rate was interpreted according to guidelines from the National Institute of Child Health and Human Development, whereas in the ECG-F group the tracings were interpreted according the original International Federation of Gynecology and Obstetrics (FIGO) guidelines. The primary outcome measure was neonatal outcome, evaluated as arterial blood pH in neonates after abdominal or vaginal operative delivery indicated because of nonreassuring fetal status.

Results: A total of 237 women were randomized, of whom 200 were included in the final analysis (100 in each group). The rate of cesarean delivery was the same in both groups (26%), and the rate of operative delivery due to nonreassuring fetal status did not differ significantly (38% in the CTG group vs. 39% in the ECG-F group). Regarding neonatal outcomes, there was no significant difference between groups in neonatal pH (7.27 [7.23–7.29] and 7.25 [7.21–7.27]).

Conclusions: In a population comprising only late-term pregnancies, fetal ECG monitoring had no benefits for the mother or fetus. Additional studies are needed of protocols for using ST waveform analysis in selected population groups.

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Introduction

Evidence of the benefits of continuous cardiotocographic monitoring (CTG) over intermittent auscultation remains inconclusive [1–4]. Now that fetal pulse oximetry has fallen into disuse, there is a greater need for better methods to evaluate intrapartum fetal well-being [5]. In their search for improved methods, Amer-Wahlin et al. published a randomized multicenter study in 2001 that found that CTG monitoring combined with automated analysis of the

ST segment from fetal electrocardiograms (ECG) provided better results than CTG alone, e.g. a lower rate of operative deliveries motivated by nonreassuring fetal status (NRFS) [6].

However, some subsequent studies failed to corroborate these results [7,8]. In addition, a recent metaanalysis by Schuit et al. [9] provided renewed support for the hypothesis that fetal ECG ST-segment analysis, when used together with CTG, could improve neonatal metabolic status. More recently (in 2015), Belfort et al. [10] published a study that randomized 11,108 women, and reported that fetal ECG ST-segment analysis failed to result in improved neonatal outcomes.

One explanation for the discrepancies among different studies lies in their methodological differences, as noted by Belfort et al.

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[10] However, it is also necessary to explore the target populations given that many studies to date have not been based on a homogeneous population. For example, studies published thus far have included labor and deliveries at both high and low risk for hypoxia, and disparate inclusion criteria regarding amniotomy, pathological CTG or high-risk pregnancy that required CTG monitoring [6–8,10,11].

For this reason a randomized study was designed with the aim of comparing the usefulness of ECG ST-segment analysis vs. conventional cardiotocography in a well-defined, homogeneous population of women with late-term pregnancy (LTP). Because these pregnancies should be considered at risk for fetal heart rate alterations during labor, we believed it necessary to perform a detailed analysis of cases in which operative delivery was indicated because of NRFS.

Patients and methods

This study was done at Virgen de las Nieves University Hospital in Granada, Spain between January 2013 and July 2016. Eligible patients were women with late-term pregnancy (gestational age between 291 and 294 days) with a singleton pregnancy and cephalic presentation in the active stage of labor. We did not include women with a prior cesarean delivery, fetal anomalies, genital bleeding, placenta previa or maternal genital infection.

The study design was an open randomized controlled trial with two arms. The population sample of women in active labor who met the inclusion criteria and had none of the exclusion criteria was distributed randomly to receive monitoring with conventional cardiotocography (CTG group) or cardiotocography and fetal ECG ST-segment analysis (ECG-F group). The research project was approved by the Virgen de las Nieves University Hospital Research Ethics Committee.

To calculate the number of pregnant women needed for our study sample, we used as the main outcome variable arterial blood pH in neonates after abdominal or vaginal operative delivery indicated because of NRFS. A pilot study was done based on pH measurements in a group of 15 patients who were monitored with fetal ECG and ST-segment analysis and whose babies were born by operative delivery because of NRFS ($\text{pH } 7.2866 \pm 0.0208$), and in a separate group of 15 women who were monitored with CTG only ($\text{pH } 7.2575 \pm 0.06849$). To detect differences between the results and the null hypothesis $H_0: \mu_1 = \mu_2$ at 80% power with a two-sided Student's *t* test for two independent samples and a significance level of 5%, 38 patients in each group were needed, for a total of 76 study participants.

Patients were assigned randomly to either group until the predetermined sample size was reached.

All women who were selected for possible participation were informed by a physician verbally and in writing of the characteristics of the study, and were asked to provide their informed consent to take part in the study. After written consent was provided, the women were assigned by simple random sampling to either the ECG-F or CTG group, according to a random sequence of numbers generated with specially-designed software. The allocation ratio was 1:1 to ensure that both groups had the same number of participants. Allocation concealment was ensured by using serially numbered opaque envelopes, each containing a folder with the woman's group allocation. The envelopes were stored securely and opened by an independent physician in an office at the hospital. Participant allocation was not changed after the envelope was opened.

After cervical effacement when dilation had reached 2.5 cm, CTG tracings were observed for 30 min. When the tracing was considered normal, monitoring was continued according to the group assignment. In the CTG group fetal heart rate (FHR) was

observed with an external Doppler system to record heart movements (Philips Avalon FM30, Boblingen, Germany), and clinical decisions were made by the medical team in the delivery room in light of the CTG interpretation according to guidelines produced by the National Institute of Child Health and Human Development workshop report on electronic fetal monitoring [12] (NICHD) and the usual protocols at our center. In the ECG-F group, to comply with the recommendation to begin ST monitoring while the fetus is well oxygenated and the CTG is not pathological [13], we waited until FHR signals were normal for 30 consecutive minutes until amniotomy was done if the membranes had not ruptured spontaneously, and then inserted a Goldtrace fetal scalp electrode to obtain FHR data, which were recorded and analyzed with a STAN S31 CTG monitoring system (Neovinta Medical, Mölndal, Sweden). Evaluation of the fetal ECG and decision-making based on this information were done in accordance with the manufacturer's recommendations, which refer to the specific guidelines developed for CTG interpretation based on the original International Federation of Gynecology and Obstetrics (FIGO) guidelines of 1987, together with specific CTG+ST criteria for taking clinical action [14,15]. The delivery room staff at our center were trained in the use and interpretation of fetal ECG ST-segment analysis, a technology that has been used at our center since 2005, initially with a STAN 21 system and more recently with a STAN S31 system.

In both groups the indication for using pH to confirm intrapartum fetal well-being was at the discretion of the physician in charge of the delivery.

On delivery, neonatal assistance included Apgar score check and collection of umbilical artery and vein blood samples for pH and blood gas testing. Both cord vessels were sampled to ensure accurate results.

The primary outcome was arterial blood pH in neonates after abdominal or vaginal operative delivery indicated because of NRFS, and the secondary outcomes were type of delivery and indications for each type.

Statistical analysis

Descriptive statistics are reported here as absolute and percentage frequencies for qualitative variables, and as means with standard deviation and maximum and minimum values for continuous numerical variables. Normal distribution of the data was verified with the Kolmogorov-Smirnov test. The rates of cesarean delivery, indications for intervention due to NRFS, and the percentage of infants with neonatal acidosis in each group were compared with the chi-squared test or Fisher's test. Comparisons of the means were done with Student's *t* test if the data were distributed normally (data reported here as the mean \pm standard deviation), or with the Mann-Whitney test otherwise (data reported here as the median and interquartile range [P25-P75]). The level of significance was set at 0.05, and all data were analyzed with IBM SPSS v. 19.0 software.

Results

To attain the calculated sample size of 38 women in each group in whom operative delivery was indicated because of NRFS, a total of 298 women were recruited during the study period as meeting all eligibility criteria; of this group 41 declined to participate and 257 were included in the study. After 21 cases of precipitous labor were excluded, 237 women were randomly allocated to one group or the other, and the final number of cases included in the analysis was 100 in each group (Fig. 1).

The obstetric characteristics of the population sample and type of onset of labor are shown in Table 1.

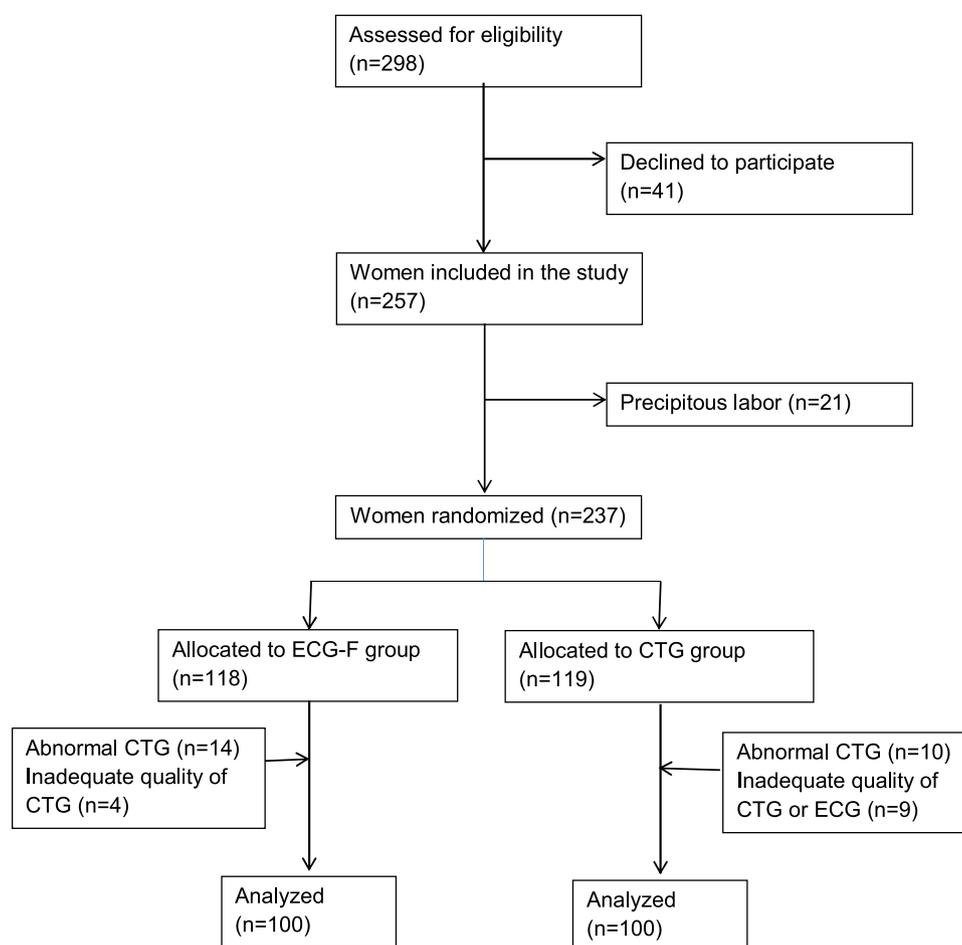


Fig. 1. Enrollment, randomization and follow-up of the study participants.
CTG: continuous cardiotocographic monitoring.
ECG: fetal electrocardiographic ST-segment analysis.

The percentage of nulliparous women was higher in the ECG-F group, and cervical dilation at the moment of inclusion was slightly greater in this group. However, these differences did not translate into differences between groups in cervical condition or prognosis of labor, given that there was no difference in the percentage of women with a Bishop score lower than 7 (94% vs. 96%). The frequency of alterations in the CTG recordings, based on the classification proposed by Amer-Wahlin et al. for interpreting fetal ECG ST segments,¹⁵ was similar in both groups: abnormal in 9% of the CTG

group and 20% of the ECG-F group, and suspicious in 65% and 52% respectively. These data may be associated with the frequency of cord abnormalities, i.e. nuchal cord or loop around the chest, in 29% of the CTG group vs. 34% of the ECG-F group. We measured pH on the fetal scalp in 5 cases in the CTG group and 3 cases in the ECG-F group, and in all cases the value recorded was >7.25.

The difference between groups in the rate of operative delivery (vaginal and cesarean) was not significant. When we analyzed these variables according to NRFS as the indication for operative delivery, the difference between groups was again not significant (Table 2).

Table 1
Obstetric characteristics and characteristics of labor.

| | CTG Group n: 100 (50%) | ECG-F Group n: 100 (50%) | p |
|---------------------------------|---------------------------|-----------------------------|--------|
| Nulliparous | 63 (63%) | 79 (79%) | 0.013 |
| Bishop score <7 on inclusion | 94 (94%) | 96 (96%) | 0.516 |
| Onset of labor | | | 1 |
| Spontaneous onset of labor | 6 (6%) | 6 (6%) | |
| Induced onset of labor | 94 (94%) | 94 (94%) | |
| Meconium-stained amniotic fluid | 23 (23%) | 31 (31%) | 0.203 |
| Epidural analgesia | 91 (91%) | 95 (95%) | 0.268 |
| Intrapartum fever | 15 (15%) | 13 (13%) | 0.684 |
| Cord abnormality | 29 (29%) | 34 (34%) | 0.447 |
| Gestational age (days) | 292 [291–292] | 292 [291–292] | 0.638 |
| Dilation on inclusion (cm) | 3 [2.5–3.5] | 4 [2.5–5] | <0.001 |
| Duration of active labor (min) | 330 [210–480] | 360 [190–480] | 0.930 |
| Duration of second stage (min) | 90 [30–180] | 120 [45–170] | 0.420 |

Intrapartum fever was defined as a maternal temperature of $\geq 38^{\circ}\text{C}$.
Data are expressed as n (%) or the median [P25–P75].

Table 2
Characteristics of delivery.

| | CTG Group n: 100 (50%) | ECG-F Group n: 100 (50%) | p |
|---------------------|---------------------------|-----------------------------|---------|
| Type of delivery | 100 (100%) | 100 (100%) | 0.48 |
| Spontaneous | 52 (52%) | 45 (45%) | |
| Operative (vaginal) | 22 (22%) | 29 (29%) | |
| Cesarean | 26 (26%) | 26 (26%) | |
| Indication: NRFS | 38 (38%) | 39 (39%) | 0.117 |
| Cesarean | 20 (52.6%) | 14 (35.9%) | |
| Operative (vaginal) | 18 (47.4%) | 25 (64.1%) | |
| Other indications | 10 (10%) | 16 (16%) | 0.664 † |
| Cesarean | 6 (60%) | 12 (75%) | |
| Operative (vaginal) | 4 (40%) | 4 (25%) | |

Data are expressed as n (%).

Fisher's test (†).

NRFS: nonreassuring fetal status.

Table 3
Neonatal outcomes.

| | CTG Group n: 100 (50%) | ECG-F Group n: 100 (50%) | p |
|--|---------------------------|-----------------------------|-------|
| Weight (g) | 3556 ± 378 | 3457 ± 382 | 0.068 |
| pH | 7.26 [7.22-7.30] | 7.25 [7.21-7.29] | 0.446 |
| pO ₂ (mmHg) | 21.4 ± 6.9 | 21.7 ± 6.6 | 0.817 |
| pCO ₂ (mmHg) | 49.7 ± 10.2 | 50.9 ± 8.6 | 0.318 |
| HCO ⁻³ (mmol/L) | 20.9 ± 2.6 | 21.7 ± 2.8 | 0.069 |
| Base deficit (mmol/L) | -4.9 ± 2.6 | -4.9 ± 2.9 | 0.959 |
| pH in operative delivery because of NRFS | 7.27 [7.23-7.29] | 7.25 [7.21-7.27] | 0.210 |
| Apgar 1 min <4 | 0 (0%) | 1 (1%) | 1† |
| Apgar 5 min <7 | 1 (1%) | 1 (1%) | 1† |
| Neonatal endotracheal intubation | 4 (4%) | 7 (7%) | 0.268 |
| Neonatal admission | 16 (16%) | 19 (19%) | 0.577 |
| Days of neonatal admission | 2 [1–3] | 2 [1–2] | 0.255 |

NRFS: nonreassuring fetal status.

Data are expressed as the mean ± SD, n (%) or median [P25–P75].

Fisher's test (†).

The neonatal outcomes are summarized in Table 3. We found no differences between groups in any of the variables. When we analyzed cord artery blood pH in cases for which operative delivery was used because of NRFS, the difference between groups was again not significant. There were no cases of neonatal metabolic acidosis according to the definition of Amer-Wahlin et al. [6]

Because the sample size needed to test the usefulness of ST-segment analysis was calculated based on NRFS as the indication for operative delivery, the characteristics of this population are shown in Table 4. In contrast to the results presented in Table 1, our analysis of the subset of deliveries with NRFS showed no differences between the CTG group and ECG-F group.

Among the operative deliveries that were indicated because of NRFS, there were 18 (47.4%) vaginal and 20 (52.6%) cesarean deliveries in the CTG group, compared to 25 (64.1%) vaginal and 14 (35.9%) cesarean deliveries in the ECG-F group (p = 0.139).

Comparison of the neonatal outcomes in the CTG group and the ECG-F monitoring group disclosed no statistically significant differences (Table 5).

Discussion

The usefulness of ST waveform analysis in fetal ECG tracings is currently being questioned, as shown by the publication in 2015 of a trial in the USA which concluded that “ECG-F used as an adjunct to conventional intrapartum electronic fetal heart-rate monitoring did not improve perinatal outcomes or decrease

Table 4
Obstetric characteristics and characteristics of labor and delivery in the NRFS group.

| | CTG Group n: 38 (49.4%) | ECG-F Group n: 39 (50.6%) | p |
|---------------------------------|----------------------------|------------------------------|--------|
| Nulliparous | 32 (84.2%) | 36 (92.3%) | 0.310† |
| Bishop score <7 on inclusion | 36 (94.7%) | 38 (97.4%) | 0.615† |
| Onset of labor | | | 0.240† |
| – Spontaneous onset of labor | 2 (5.3%) | 0 (0%) | |
| – Induced onset of labor | 36 (94.7%) | 39 (100%) | |
| Meconium-stained amniotic fluid | 14 (36.8%) | 18 (46.2%) | 0.407 |
| Epidural analgesia | 37 (97.4%) | 37 (94.9%) | 1† |
| Intrapartum fever | 5 (13.2%) | 5 (12.8%) | 1† |
| Cord abnormality | 9 (23.7%) | 17 (43.6%) | 0.065 |
| Gestational age (days) | 292 [291–292] | 292 [291–293] | 0.730 |
| Dilation on inclusion (cm) | 3 [2.5–3.5] | 3 [2.5–4] | 0.212 |
| Duration of active labor (min) | 400 [327–566] | 330 [180–490] | 0.052 |
| Duration of second stage (min) | 180 [60–195] | 160 [35–190] | 0.612 |

Intrapartum fever was defined as a maternal temperature of ≥38 °C.

Data are expressed as n (%) or the median [P25–P75].

Fisher's test (†).

Table 5
Neonatal outcomes in the NRFS group.

| | CTG Group n: 38 (49.4%) | ECG-F Group n: 39 (50.6%) | p |
|----------------------------------|----------------------------|------------------------------|-------|
| Weight (g) | 3502 ± 346 | 3375 ± 366 | 0.125 |
| pH | 7.27 [7.23-7.29] | 7.25 [7.21-7.27] | 0.210 |
| pO ₂ (mmHg) | 18.66 ± 5.85 | 21.19 ± 5.76 | 0.060 |
| pCO ₂ (mmHg) | 49.68 ± 8.54 | 50.00 ± 6.83 | 0.823 |
| HCO ⁻³ (mmol/L) | 21.55 [19.37-23.02] | 20.09 [19.1-23] | 0.771 |
| Base deficit (mmol/L) | -5.13 ± 2.86 | -5.22 ± 2.43 | 0.883 |
| Apgar 1 min <4 | 0 (0%) | 0 (0%) | |
| Apgar 5 min <7 | 0 (0%) | 0 (0%) | |
| Neonatal endotracheal intubation | 2 (5.3%) | 3 (7.7%) | 1† |
| Neonatal admission | 7 (18.4%) | 10 (25.6%) | 0.445 |
| Days of neonatal admission | 3 [1–3] | 2 [2–3] | 0.431 |

NRFS: nonreassuring fetal status.

Data are expressed as the mean ± SD, n (%) or median [P25–P75].

Fisher's test (†).

operative-delivery rates”, [10] and the subsequent publication in 2016 of a metaanalysis by Saccone et al. [16] that reached similar conclusions.

In view of these important publications two issues need to be raised. On one hand, there were substantial methodological differences between the study by Belfort et al. and trials carried out in Europe, as widely shown in the publications by Amer-Wahlin et al. [17] and Bloom et al. [18] In addition, a metaanalysis by Olofsson et al. in 2014 clearly documented the perinatal benefits of the European protocol comprising CTG plus ECG-F [19].

Most previous trials included only women with either abnormal CTG findings or meconium, [8] or only women with high-risk pregnancies, [6,11,20]. In contrast, two other trials [7,10] included low-risk pregnancies. In light of the clear effect of selection criteria on the conclusions of different studies, the present study was designed to select a sample of the at-risk population in which the risk was homogeneous across all participants with LTP. Late-term pregnancy should be considered an at-risk situation because of its association with increased perinatal morbidity and mortality [21,22], with an increased risk of cesarean delivery after week 40, and with the presence of meconium in the amniotic fluid [23].

The sample of cases selected for the present study comprised women in whom labor was induced in 94% of the cases in both groups, with a high proportion of nulliparous women in both the CTG (63%) and ECG-F groups (79%). This means that NRFS during labor was highly likely to occur in the group of women in our study.

In our study population we observed no decrease in the rate of operative vaginal deliveries in our ECG-F group compared to women who were monitored with CTG alone. In this regard our results are consistent with earlier randomized controlled trials (RCT) [7,8,11], although the 2016 metaanalysis by Blix et al. [24] and a 2015 Cochrane Review [25] did report that operative vaginal deliveries were less frequent when ECG and ST-segment analysis were used. The rate of operative delivery in the present study was high: vaginal and cesarean deliveries together accounted for 48% of all deliveries in the CTG group and 55% in the ECG-F group.

Studies designed to test any fetal monitoring procedure should take into account the indication for operative delivery motivated by NRFS and in this regard the results in our sample of women with LTP failed to demonstrate that monitoring with ECG-F was able to decrease the frequency of operative delivery for this indication. Once again, our results differ from those of earlier studies.

Westgate et al. [20] found that the use of ECG monitoring led to a significant decrease in cesarean delivery motivated by NRFS and the study by Amer-Wahlin et al. [6] reported a significant decrease

in operative deliveries motivated by fetal distress. However, a recent metaanalysis by Blix et al. [24] emphasized that no decrease could be demonstrated in the rate of interventions motivated by NRFS. The situation may be summarized in the light of the 2014 metaanalysis by Olofsson et al. [19], which amended misapprehensions identified in previous metaanalyses and noted the differences between protocols used in the USA and Europe. Olofsson et al. concluded that CTG+ST-segment monitoring achieved a significant decrease in vaginal operative deliveries but had no effect on the rates of cesarean delivery or interventions motivated by fetal distress.

In the present study we were unable to demonstrate a significant decrease in the need for intrapartum pH determination in our group with fetal ECG monitoring. The study by Olofsson et al. [19] showed that CTG+ST monitoring significantly reduced fetal scalp blood sampling usage, a finding consistent with a recent Cochrane Review [25].

With regard to neonatal outcomes, fetal ECG monitoring in the present study was not superior to CTG alone for any of the variables we analyzed. Current debates on the efficacy of fetal ST-segment monitoring appear to focus most intensively on its capacity to reduce the frequency of neonatal metabolic acidosis. Olofsson et al. [19] recognized that it can lead to a significant decrease in the rate of metabolic acidosis, whereas the subsequent RCT published by Belfort et al. [10] failed to find differences between groups. More recent metaanalyses yielded contradictory conclusions, with Blix et al. finding a significant decrease in neonatal metabolic acidosis [24], whereas Saccone et al. [16] were unable to demonstrate this effect.

As a potential limitation of this study, we note that fetal heart rates were recorded with different classification systems in the two groups compared here. However, this was done in accordance with actual clinical practice at the center where the study was carried out: the NICHD classification is normally used for monitoring and clinical decision-making in cases with NRFS, whereas in the study group with ST segment monitoring, the STAN system, based on the FIGO classification, is used.

In conclusion, the present study shows that in a population of pregnant women with LTP, monitoring with fetal ECG had no benefits for the fetus or mother. Further research is needed on the outcomes obtained with protocols that call for ST waveform analysis, particularly when these protocols are used in selected populations.

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