Assessment of labor progress by ultrasound vs manual examination: a randomized controlled trial

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BACKGROUND: Assessment of labor progress via digital examination is considered the standard of care in most delivery rooms. However, this method can be stressful, painful, and imprecise, and multiple examinations increase the risk for chorioamnionitis. Intrapartum ultrasound was found to be an objective, noninvasive tool to monitor labor progression.

OBJECTIVE: This study aimed to investigate whether, among nulliparous women, the use of intrapartum ultrasound can reduce the rate of intrapartum fever by reducing the number of digital examinations.

STUDY DESIGN: This was a prospective, randomized controlled trial in term nulliparas admitted with prelabor rupture of membranes, induction of labor, or in latent phase of labor with a cervical dilation of <4 cm. Women were randomized into 1 of the following 2 arms: (1) labor progress assessed by ultrasound, avoiding digital examinations as much as possible; and (2) control group in which labor progression was assessed according to the regular protocol. Before the study, all labor ward physicians underwent training in intrapartum ultrasound.

RESULTS: A total of 90 women were randomized to the ultrasound group and 92 were randomized to the control group. When compared with the control group, the ultrasound group had significantly lower rates of intrapartum fever (11.1% vs 26.1%; P=.01), clinical chorioamnionitis (3.3% vs 16.5%; P>.01), and histologic chorioamnionitis (2.2% vs 9.8%; P=.03). The median number of digital examinations was significantly lower in the ultrasound group (5; interquartile range, 4–6) than in the control group (8; interquartile range, 6–10; P<.01). The median number of digital examinations per hour in the ultrasound group was significantly lower than in the control group (0.2 vs 0.4; P<.01). The induction rates, time from admission to delivery, mode of delivery, Apgar score at 5 minutes, and neonatal intensive care unit admission rates did not differ significantly between the groups.

CONCLUSION: The use of intrapartum ultrasound lessens the total number of digital examinations needed to be performed during labor and, consequently, the incidence of intrapartum fever and chorioamnionitis are reduced. No adverse effects on labor progression and short-term maternal or neonatal outcomes were noted.

Key words: delivery, digital exams, nulliparous, pregnancy, randomized controlled trial, transperineal ultrasound

Introduction

Clinical chorioamnionitis complicates about 5% to 10% of all term deliveries,[1,2] and most infections are caused by an ascending infection from the vaginal flora. Among other risk factors, such as nulliparity, prelabor rupture of membranes, an extended duration of labor, and group B *Streptococci* (GBS) colonization, multiple vaginal examinations have also been associated with an increased risk for labor-related infections.[2–4] In high-risk populations (nulliparous women with prolonged labors), the rates of intrapartum fever and chorioamnionitis are reported to be as high as 25% and 15%, respectively.[5–7] Nonetheless, the digital vaginal examination is still the standard method for evaluating the woman's cervical status and labor progression, although it is imprecise, subjective,[8] painful[9] and may induce anxiety.

EDITOR'S CHOICE

In recent years, there has been a substantial progress in the field of ultrasound (US) throughout labor. Numerous studies have shown that US in labor is a more accurate and objective tool for assessing fetal head station and position,[10–18] can be used to assess cervical status (effacement and dilation),[19,20] and assists in critical clinical decision-making during the second stage of labor.[20–27] Furthermore, transperineal US can reduce the perception of pain and anxiety when compared with routine vaginal examinations. Nonetheless, to the best of our knowledge, another important potential benefit of intrapartum US (IPUS), which is a reduction in the number of digital vaginal examinations required during labor and a consequent reduction in the rates of peripartum and puerperal infections, has been not studied before.

Thus, the aim of this study was to assess whether, in nulliparous women, the use of IPUS can reduce the rate of intrapartum fever and chorioamnionitis by reducing the total number of digital vaginal examinations that had to be performed during the process of labor.

Materials and Methods

Study design, participants, and randomization

This was a prospective, randomized controlled trial conducted at the Kaplan Medical Center between August 2019 and August 2020. Nulliparous women who met the inclusion criteria were randomized into 1 of the following 2 groups: (1) the study group in which progression of labor was assessed mainly by transperineal sonography, avoiding digital vaginal examinations as much as possible; and (2) the control

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AJOG MFM at a Glance

Why was this study conducted?

The purpose of this study was to investigate whether the use of intrapartum ultrasound can reduce the rate of intrapartum fever by reducing the number of digital examinations.

Key findings

Using intrapartum ultrasound to assess labor progress markedly reduced the number of digital examinations, intrapartum fever, and chorioamnionitis.

What does this add to what is known?

This study demonstrates that assessment of labor progress via ultrasound is feasible, it can reduce the number of digital vaginal examinations, and, consequently, is associated with lower rates of intrapartum fever and chorioamnionitis.

group in which the progression of labor was assessed using routine digital vaginal examinations. Nulliparous women with a singleton pregnancy at term (37 +0 to 42+0 weeks' gestation) and a live vertex fetus presenting with either 1 of the following were eligible to be included in the study: (1) prelabor rupture of membranes (PROM); (2) induction of labor; or (3) in latent phase of labor with a cervical dilation of <4 cm. Women were excluded if they presented in active labor, were admitted directly to the delivery suits, had a contraindication for a vaginal delivery, had a known active infection (other than being a GBS carrier), or were under immunosuppressive therapy.

After signing an informed consent form, participants were randomly assigned in a 1:1 ratio to either the control or the study groups. Randomization was achieved by choosing an envelope from a mixed stack of equal number (200 in total) of sealed opaque envelopes containing a paper marked with one of the allocation groups ("PV" for the control group and "US" for the study group). The content of each envelope was blinded to the recruiting researchers. A pop-up message appeared each time the woman's file was opened, reminding the staff that she is participating in the study and if she is part of the study or control group.

Definitions and study procedures

Intrapartum fever was defined as a body temperature of ≥38°C measured at least once during labor or delivery. In our delivery ward, the diagnosis of clinical chorioamnionitis is based on the American College of Obstetricians and Gynecologists committee definition from 2017,[28] which includes a maternal temperature of ≥39.0°C or 38.0°C to 38.9°C with 1 additional clinical risk factor present such as maternal leukocytosis, purulent cervical drainage, or fetal tachycardia. Once the diagnosis of chorioamnionitis was suspected, blood, urine, and vaginal-rectal cultures were taken from the woman and a complete blood count was conducted and empirical treatment with intravenous antibiotics (usually cefuroxime unless there is a known allergy) was initiated. All placentas of women with intrapartum fever were routinely sent for a pathologic evaluation.

Similar to most delivery units throughout the world, in our labor ward we assess labor progress via digital examinations. The frequency at which digital examinations are preformed is according to the different stages of labor and its progression. In accordance with the National Institute for Health and Care Excellence guidance,[29] a digital vaginal examination is performed every 2 to 4 hours (depending on labor progress) during the first stage of labor and at least hourly during the second stage.

Ultrasound assessment

To ensure that the staff was familiar with IPUS and can use it to assess labor progression during all shifts and weekdays, all residents and attending physicians responsible for care of laboring women underwent a constructed frontal and hands-on training in US in the delivery room before the initiation of the study. In addition, to be qualified, they had to produce at least 20 images of fetal position and station, as well as cervical dilation and effacement, to the satisfaction of the senior investigator (R.L.).

The US assessment in the study group was performed using a portable 2-dimensional machine equipped with a 2- to 5-MHz transabdominal, 2-dimensional convex transducer (Voluson P6, GE Medical Systems, Zipf, Austria). The US was used to assess fetal head position (transabdominal), cervical dilation and effacement, angle of progression, and head perineal distance (transperineal). For the transperineal US, the abdominal probe was covered with a sterile latex glove and was placed between or horizontally to the labia.

Digital vaginal examinations

The decision whether to perform a digital examination in the control and study groups was at the discretion of the physicians and midwives in the delivery ward according to their clinical judgment. If a midwife suspected that a digital examination was warranted in the study group, she was instructed to consult with the attending physician or resident. However, prespecified circumstances that mandated a digital vaginal examination in both study arms included a nonreassuring fetal heart rate, need for membranes sweep, for an amniotomy, for placing a scalp transducer, when it was difficult to determine the cervical status with an US, and in the decision-making process of an operative or cesarean delivery.

Outcome measures

The primary outcome of the study was the rate of intrapartum fever. Secondary outcomes included the number digital vaginal examinations and the incidence of clinical and histologic chorioamnionitis. Maternal outcomes, including mode of delivery, postpartum fever,

maternal antibiotic administration, and positive blood cultures, and neonatal outcomes, including Apgar scores (at 5 and 10 minutes), neonatal intensive care unit (NICU) admissions, neonatal antibiotics administration, positive cultures, and mortality, were also assessed. In addition, a 2-week follow-up survey via a phone call (or by assessing the medical records if phone was unanswered) was completed to detect additional cases of readmissions, postpartum fever, or endometritis after the initial hospital discharge. All digital vaginal examinations in the study group were evaluated to analyze why and when during labor they were performed.

The study protocol was approved by the institutional review board (0118-17-KMC) and the trial was registered at ClinicalTrials.gov (NCT04651309; AssessmentofLabourProgressByIntrapartumUltrasound). All participants provided a written informed consent before randomization.

Statistical analysis

We calculated that at least 178 women would need to be included in the study (89 in each arm) to provide a power of 80% to detect a reduction in the rate of intrapartum fever from 25% in the control group to 10% in the study group with a 1-tail α-error of 0.05. The assumptions for this power analysis were based on local data obtained from a previous study[18] in which the rate of intrapartum fever was up to 20% in nulliparous women. However, because the study population to be included in our study (nulliparous women with an anticipated longer time to delivery) was assumed to have an even higher risk for intrapartum fever, we assumed a 25% rate of intrapartum fever in the control group for the sample size calculation. Although not ideal, because we anticipated that in routine clinical practice it will hard for the managing staff to strictly adhere to the study protocol for the entire length of labor with several shift changes and because the possibility of an increased intrapartum fever rate in the study group seemed to be extremely unlikely, a 1-tailed test was chosen to minimize as far as possible the required sample size. Comparisons of proportions were performed using the Pearson chi square test for categorical variables and the Mann-Whitney U test for continuous variables. A P value <.05 was considered statistically significant. Data were analyzed using IBM SPSS Statistics (version 21.0) (IBM Corp, Armonk, NY), and the power analysis was calculated using G Power (version 3; Kiel, Germany).

Results

Trial participants

Overall, 186 women were recruited and randomly assigned to the control and study group. Four women chose to be withdrawn from the study after randomization because they did not wish to be examined solely via US, and a total of 182 women were included in the final analyses with 90 in the study group and 92 in the control group (Figure).

Demographic and baseline characteristics were similar between the 2 study groups (Table 1). Table 2 presents the clinical data of the 2 study groups. There were no marked differences between the 2 groups in the mode of delivery, time from admission to delivery, or the use of epidural analgesia. Of note, the mean interval hours from ruptured membranes to delivery (15.3±11.5 vs 11.7±11.7; P=.01), as well as the oxytocin use rate (87.6% vs 71.7%; P=.008), was significantly higher in the US group than in the control group.

Outcomes

The primary outcome of the study, the rate of intrapartum fever, was significantly lower in the study group than in the control group (11.1% vs 26.1%; P=.01). Accordingly, the study group had a significantly lower rate of clinical chorioamnionitis (3.3% vs 16.3%; P=.003), as well as histologic chorioamnionitis (2.2% vs 9.8%; P=.03), than the control group (Table 2).

The median number of vaginal examinations in infected and not infected women was 11 and 8, respectively, in the vaginal examinations group. In the US group, the median number of vaginal examinations was 5 in those not infected, and in the 3 infected women, there were 5, 6, and 11 vaginal examinations, respectively.

The median number of digital vaginal examinations performed in the study group was significantly lower than in the control group (5; interquartile range [IQR], 4−6 vs 8; 6−10; P<.001). However, the overall median total number of examinations (digital and sonographic) did not differ significantly between the 2 groups (Table 3).

Table 4 depicts the indications for a digital examination violation in the study group. Overall, most of these violations were during the latent phase (51%) or the second stage of labor (34%), commonly because of a lack of adherence to the study protocol (partially by midwifes who were not trained in preforming US), difficulties in assessing cervical status by US, or for a nonreassuring fetal heart rate.

Postpartum maternal and neonatal adverse outcomes

Women in the study group had a significantly lower rate of postpartum antibiotics administration (P=.02) and there was a trend (P=.08) toward a lower readmission rate (Table 2). No significant differences in the rates of postpartum fever (while still being admitted to the hospital) or length of hospital stays were noted. Regarding neonatal complications, the Apgar scores, NICU admission rates, and antibiotics administration rates did not differ significantly between the groups. (Table 2)

Discussion

Principal findings

This randomized controlled trial demonstrated that assessing labor progression mainly by US is feasible and is associated with a marked reduction in the rates of intrapartum fever and clinical and histologic chorioamnionitis assumed to be mainly as a consequence of a reduction in the total number of digital vaginal examinations that needed to be performed during the labor process. These findings are also summarized in the video below.

FIGURE
Flowchart of the study population randomized to control or intervention

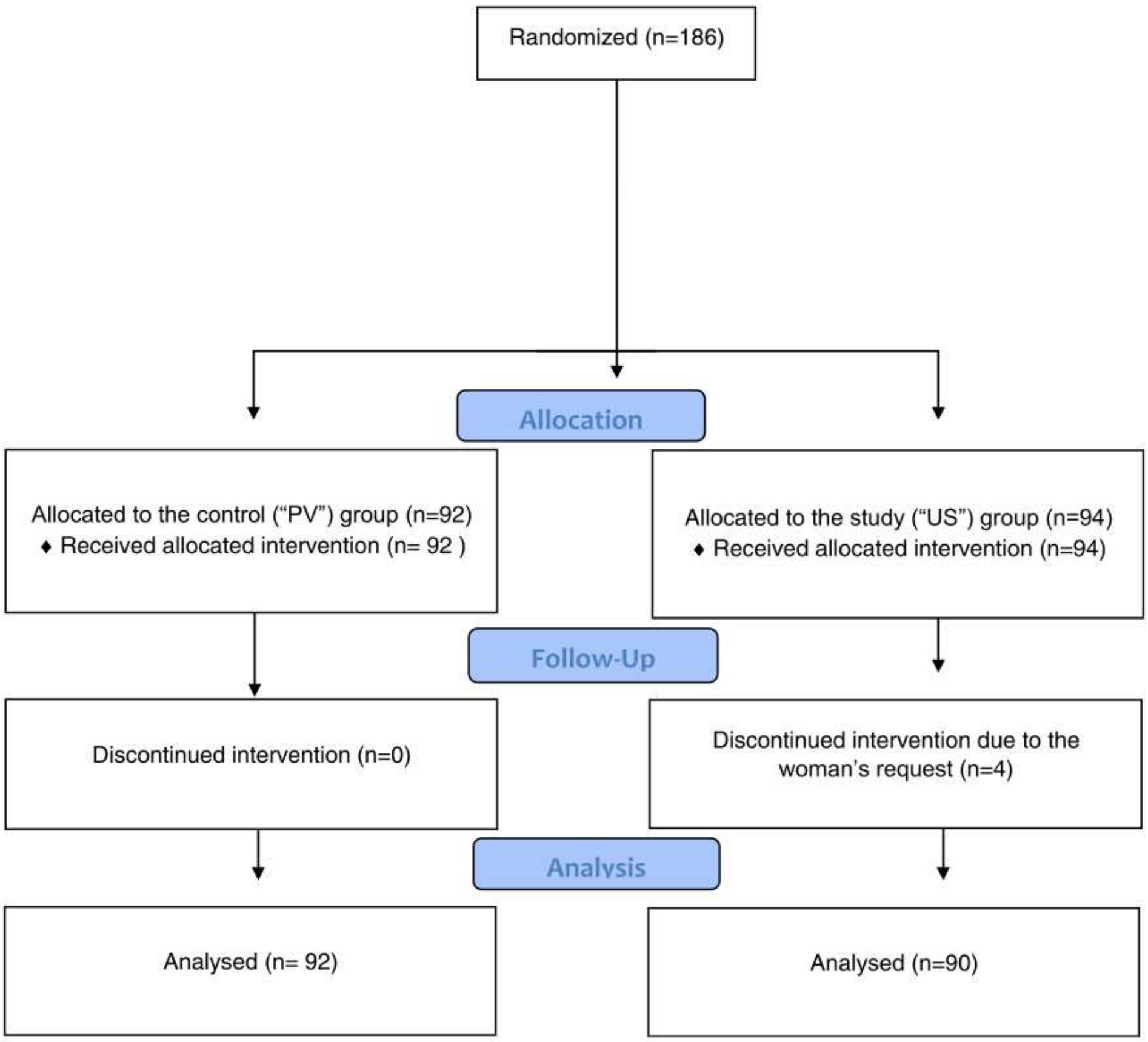

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TABLE 1
Demographic and baseline characteristics of the study population according to their randomization group

Characteristics	Study group (US) (n=90)	Control group (PV) (n=92)
Maternal age (y)	27.2±4.2	27.5±4.1
Body mass index (kg/m^2)	24.3±5.1	24.1±4.8
Gestational age at delivery (wk)	39.8±1.2	40.0±1.0
GBS carriers	12 (13.3)	10 (10.8)
Induction of labor	29 (32.2)	29 (31.5)

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

GBS, group B Streptococcus; *PV*, per vagina; *US*, ultrasound.

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Results

Numerous studies have focused on comparing the reliability and accuracy of intrapartum US examinations with routine digital vaginal examinations, meaning that women usually underwent both examinations.[13,30,31] This study was a randomized study attempting to assess labor progression via US, replacing at least part of the digital examinations.

The use of US to assess labor progression led to a reduction in the number of digital vaginal examinations, however, it did not reduce the overall number of examinations, implying that a substantial number of digital examinations can be replaced by an US examination,

TABLE 2
Clinical characteristics and maternal and neonatal outcomes of the study population according to the randomization group

Outcome	Study group (US) (n=90)	Control group (PV) (n=92)	*P*
Admission to delivery time (h)	30.5±24.3	26.3±19.0	.18
Ruptured membranes to delivery time (h)	15.3±11.5	11.7±11.7	.01
Oxytocin use	78 (87.6)	66 (71.7)	.008
Epidural (continuous with top-ups as needed)	88 (97.8)	88 (95.7)	.42
Intrapartum fever ≥38°C	10 (11.1)	24 (26.1)	.01
Clinical chorioamnionitis	3 (3.3)	15 (16.3)	.003
Histologic chorioamnionitis	2 (2.2)	9 (9.8)	.03
Intrapartum antibiotics (other than GBS indicated)	14 (15.6)	25 (27.2)	.056
Mode of delivery			
Normal vaginal delivery	70 (77.8)	70 (76.1)	.79
Vacuum extraction	14 (15.6)	13 (14.1)	.79
Cesarean delivery	6 (6.7)	9 (9.8)	.45
Postpartum admission (d)	2.8±1.3	2.7±0.8	.5
Postpartum antibiotics administration	11 (12.2)	24 (26.1)	.02
Readmission after discharge	0	3 (3.3)	.08
Neonatal outcomes			
Birthweight (g)	3189±431	3222±602	.17
Apgar 5 min, median (range)	9 (9-9)	9 (9-9)	.4
NICU admission	0	2 (2.2)	.5
Neonatal antibiotics administration	3 (3.3)	3 (3.3)	1.0

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

GBS, group B *Streptococcus*; *NICU*, neonatal intensive care unit; *PV*, per vagina; *US*, ultrasound.

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TABLE 3
Distribution of digital vaginal examinations and transperineal sonographic assessments according to the randomization group

Digital exams	Study group (US) (n=90)	Control group (PV) (n=92)	*P*
Number of digital examinations	5 (4–6)	8 (6–10)	<.001
Number of digital examinations per hour	0.2 (0.2–0.3)	0.4 (0.3–0.6)	<.001
Number of ultrasound examinations	5 (3–7)		
Total number of examinations	11 (9–14)	11 (8–14)	.99
Total number of examinations per hour	0.5 (0.3–0.6)	0.6 (0.3–0.7)	.07

Data presented as median (interquartile range) or mean±standard deviation.

PV, per vagina; *US*, ultrasound.

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thereby sparing women from a possible intrapartum infection and all of its consequences.

Overall, 18.6% of the study population had an intrapartum fever, 26% in the control group and 11% in the study group. Most studies have estimated intrapartum fever rates of between 5% to 10% in a heterogenic study population that included both nulli- and multiparous women,[4,32,33] although the risk is known to be higher among the former. The intrapartum fever rate in our study is in accordance with a previous study from our department[18] and reflects the relatively higher risk our study population had for this complication because women who came during active labor were not included in the study.

Our study is also in accordance with previous reports that demonstrated an intrapartum fever rate of 20% to 25% in specific high-risk populations, such as nulliparas undergoing induction of labor[5] or nulliparas who underwent a late amniotomy,[6] or a 15% rate of chorioamnionitis in high-risk populations, such as women with admission after a delivery interval of >24 hours, women undergoing induction of labor, or women with arrest of dilatation.[7,34]

It is uncertain whether intrapartum fever and infections in primiparous women are more common because of the prolonged labor itself and a longer duration of being susceptible to ascending infections or because of the multiple digital examinations during the process; perhaps it is a combination of both factors. Multiple digital examinations as a risk factor for chorioamnionitis has been debated across several studies.[2,3,32,35] One retrospective study that included nulli- and multiparous women claimed that the rate of intrapartum fever was not related to the number of vaginal examinations.[35] This study, however, did concur that nulliparity and a lower Bishop score and induction of labor with extended length of delivery were all risk factors for intrapartum fever. In our study, the entire study population was nulliparous women and there was no marked difference in either the length of labor or

TABLE 4
Indication for digital vaginal examinations in the study (US) group

Indication	%[a]
Lack of adherence to the study protocol	34
Difficulty in assessing cervical status via US Second stage of labor (50%) Latent phase (35%) Active phase (8%) Upon deciding on an epidural anesthesia or entering the delivery room (7%)	17
Deceleration	15
Insertion or extraction of PG or balloon catheter	10
Unknown	10
Amniotomy and membrane sweep	9
Scalp stimulation and others	5

US, ultrasound.

[a] Percentage of digital examinations of all the digital examinations preformed in the study (US) group.

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the induction rates between the groups. In contrast, large prospective studies concluded that multiple digital examinations are a substantial risk factor for intrapartum infection, although a crucial specific number of examinations has not been agreed upon.[2,3,36,37] The results of our study support the notion that fewer digital vaginal examinations are associated with lower intrapartum infection rates. Thus, although there are situations that mandate a digital vaginal examination, all efforts should be made to minimize the number of these examinations and to replace the others by US assessment, especially in high-risk populations for intrapartum infections such as nulliparous women.

Interestingly, although the US group had a trend toward longer deliveries and a markedly longer mean interval time from ruptured membranes to delivery (by almost 4 hours), the rate of intrapartum fever was lower. The shorter deliveries in the control group may be attributed to the possibility that during a digital vaginal examination, an undeliberate digital stripping or sweeping of the fetal membranes may have been performed or an accidental rupture of the membranes may have occurred, all things that can potentially shorten the length of the latent phase or the first stage of labor.[38,39] However, despite the longer duration of labor, the study group still had lower rates of intrapartum fever and chorioamnionitis with similar rates of operative or cesarean deliveries.

Reasonably, reduced rates of chorioamnionitis should be associated with lower adverse maternal and neonatal outcomes. Indeed, in our study, we noticed a lower postpartum antibiotics administration rate and a trend toward a lower postpartum readmission rate; however, our study was underpowered to adequately address this issue and larger randomized clinical trials are needed. In contrast, it seems unlikely that a strategy, such as that applied in the study group will unexpectedly lead to higher adverse outcomes rates.

Strengths and limitations

The main strength of our study is the study design, which was a randomized controlled trial including a homogenous study population of nulliparous women who were at the highest risk for intrapartum infection. In addition, the prestudy training of all staff members allowed adherence to the study protocol throughout the entire day and on all weekdays.

Our study was not without limitations. First, as stated in the methods, the assumption was for a possible unidirectional effect of a lower infection rate in the study group, thus a 1-tailed assumption was made for sample size calculation. However, it may be more appropriate to use a 2-tailed test but this would have required a larger sample, which we felt at the time of initiation of the study will be hard to complete because of the complexity of adherence to the study protocol. Thus, although the rate of intrapartum fever was lower in the study group, we do not claim for a change in clinical practice but rather to set the ground for larger randomized clinical trials in different labor wards settings.

Another important limitation is the lack of blinding of the clinical staff to the women's study arm. However, the diagnoses of intrapartum fever and clinical and histologic chorioamnionitis were based on objective measures, including body temperature, fetal and maternal tachycardia, blood tests, and histologic examination of the placenta. During the study, we have noticed a learning curve, with a better adherence to the protocol in the study group at the end of the study than at the beginning, probably because of increased confidence in the US assessment. Thus, it may be possible to further decrease the perceived necessary digital vaginal examinations as personal experience and confidence in IPUS is gained. Furthermore, part of the unnecessary digital vaginal examinations in the study group were performed by midwives who were without expertise in US examinations. Thus, to further decrease the number of digital examinations during labor, midwives should be encouraged to participate in IPUS training programs to be able to use this modality as well.

Another limitation was the lack of blinding of the pathologist to the clinical notes and their free access to the woman's file. Our protocol was to send the placentas for pathologic examination in all cases of intrapartum fever, preeclampsia, preterm delivery, small for gestational age neonates, suspected placental abruption, or in any delivery with a neonate with an Apgar score of ≤7 at 5 minutes. However, it should be

noted that in all cases of intrapartum fever without clinical chorioamnionitis, histologic chorioamnionitis was not diagnosed, whereas histologic chorioamionitis with vilitis was diagnosed in 61% of women with clinical chorioamnionitis.

Potentially, the noticeable decrease in the rate of chorioamnionitis in our study may be attributed to our delivery suite policy of allowing prolonged deliveries with a relatively low rate of operative interventions. Thus, we recognize that the impact of the strategy employed in our study group may be more modest in delivery rooms with a less conservative approach.

Conclusion and research implications

The results of our study indicate that the routine use of US for the assessment of labor progression is feasible, can reduce the needed number of invasive digital vaginal examinations, and, consequently, is associated with lower rates of intrapartum fever and chorioamnionitis. Larger randomized controlled trials are needed to confirm our findings and to adequately address the issue of a potential reduction in the maternal and neonatal adverse outcomes rates. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2022.100817.

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