Acceptability of Intrapartum Ultrasound Monitoring - Experience from a Romanian Longitudinal Study

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ABSTRACT: Objectives: To assess the acceptability of intrapartum ultrasound (IPUS) labor monitoring in unselected Romanian women attending a tertiary maternity unit and the patients’ experience of the examination (i.e. the perceived difficulty regarding the evaluation protocol). Methods: The research was a prospective longitudinal observational study on unselected low-risk women that delivered in our unit. IPUS monitoring of active labor was proposed for observational purposes in low-risk population. Transabdominal and transperineal scans were performed hourly in the first stage of labor and at every 15 minutes in the second stage. The second day after birth, consenting women were invited to take part in a questionnaire survey with features regarding the patient’s impression about the ultrasound monitoring scans during labor, and the acceptability of having an IPUS protocol for labor monitoring in the future. Results: From 200 parturient women questioned, 98% of them agreed to IPUS investigation protocol. The demographic characteristics did not influence the acceptance. However, due to the small number of women declining IPUS we were not able to compare the characteristics and perceptions of women who declined the scan with those who accepted it. Most of the women (93% of accepters and 75% of decliners) had little difficulty deciding whether or not to have the scan protocol. All laboring women who had the IPUS scan found it an acceptable experience; 21% of women without epidural anesthesia rated the perceived difficulty as “mild” or “discomforting”. Women rated having the IPUS scan as being significantly less difficult than having a cervical smear, transvaginal scan or having a digital clinical evaluation. 67% of the studied patients expressed increased confidence while being able to follow along the medical personnel the progression of the labor on the ultrasound screen. 97% of the consenting women who had the IPUS scans and all the 4 decliners said they would definitely or probably agree such ultrasound monitoring in a future labor, if this technique is proven useful for the labor outcome. Conclusions: IPUS protocol for labor monitoring was overwhelmingly acceptable in our population of women, despite the fact that they were learning about the procedure for the first time. The demographic characteristics did not influence acceptance, but due to the high rate of acceptance, predictors of acceptance could not be analyzed. More than two thirds of the patients expressed increased confidence while being able to follow along the medical personnel the progression of the labor on the ultrasound screen and almost all the participants were willing to have the procedure again in future, further reinforcing their favorable attitude to the procedure.

KEYWORDS: intrapartum ultrasound, labor, maternal fetal medicine, transperineal ultrasound

Introduction

Since the introduction of medical ultrasonography, it has evolved into an essential evaluation in obstetrical practice [1]. The necessity of intrapartum use of sonography is highlighted in previous studies, because the current clinical digital vaginal estimations of fetal head position, station and progression in the pelvic canal are intrusive, uncomfortable, unreliable, poorly reproducible, associated with infection and therefore insecure, particularly in clinical situations when obstetrical interventions are more likely to be needed [2-22]. Unlike clinical evaluation, US determinations are less experience-dependent, easier to learn, and allows the medical personnel to capture and store images with objective recordable measurements. Thus, IPUS could improve the outcome of labor because of the potential major consequences in the birth prognostic and decision of the delivery mode [23-29]. Given the increasing evidence regarding the advantages offered by the US use in labor, it emerged the concept to develop an objective partogram, based on the US measurements - the sonopartogram [32], in order to enhance or replace the traditional clinical labor monitoring represented by Leopold manoeuvres and vaginal digital evaluation.

However, there is little information in the literature regarding the ultrasonographic monitoring of the entire active labor mechanism [30-33] and until present we do not have data regarding the acceptability for such a sonographic protocol.
We conduct a longitudinal study regarding the sonographic assessment of active labor in unselected parturient at term in order to establish nomograms for the ultrasound monitoring of labor. As part of this study, we aimed to investigate the acceptability of an IPUS protocol with repeated scans in unselected parturient women and patients’ experience of the examination.

**Methods**

This is a prospective longitudinal observational study, which took place in a Romanian tertiary maternity hospital (University Emergency Clinical County Hospital Craiova). The main objective was to investigate the acceptability of intrapartum transabdominal and transperineal ultrasound monitoring in low-risk women in labor at term, with singleton eutrophic cephalic presentation pregnancies. This is a novel, non-intrusive, combined transabdominal and transperineal ultrasound technique to assess the fetal head position and progression. Secondary, we aimed to evaluate the experience of the examination in women who accepted the procedure and the presence of psychological morbidity (anxiety, pain) associated with IPUS scans.

All pregnant women admitted in active labor at term were considered eligible for the study. They were consecutively included in the study, depending on the availability of the US operators involved. The cases planned for elective caesarean section, with imminent intention to deliver, involving non-cephalic presentation, intra-uterine death, or multiple pregnancies were excluded from the study. Additionally, we excluded women either younger than 18 years or considered in the opinion of the physicians by virtue of language or learning impairment.

During their usual consultation in the labor ward, in eligible cases the physician on duty provided brief information about the IPUS study. If the patient showed interest in the study and met the inclusion criteria, the ultrasound operator presented the scan protocol (Fig.1). The details of the study, the safety of the procedure and its potential benefits were explained to the patient. It was explained that laboring women may experience a slight discomfort when the probe is placed, although this should be less than the discomfort experienced with vaginal examinations.

It was made clear to all participants that the ultrasound protocol is only observational, without any obstruction for the clinical manoeuvres. The management of labor and delivery was made exclusively based on the traditional clinical evaluation, by senior physicians.
Consenting women and decliners were questioned if their decision was easy to make. Labor characteristics were recorded: mode and time of delivery, neonatal Apgar score and birth weight, whether labor was spontaneous or induced, use of oxytocin or epidural anesthesia, occipital position at delivery. Maternal characteristics are retrieved from the hospital records: maternal age, gestational age, parity, height, weight, provenience (rural or urban residence), marital status, education, ethnicity, religion.

In order to evaluate the acceptability of IPUS monitoring, we examined the rate of uptake of ultrasound protocol during labor. The day after birth, consenting women were invited to take part in another questionnaire survey by the project research manager. Women were assured that their questionnaire would not be seen by physicians involved in the US scan. The questionnaires contained no identifying information other than a code number. It was completed with features regarding the patient’s impression about the ultrasound monitoring scans during labor. The final questions concerned the willingness of having again an IPUS protocol for labor monitoring in the future. We examined the “second day” responses to individual questions on:

-whether the IPUS scan was a difficult experience (rating scale 0 = not a difficult experience at all, 5=a very difficult experience);
-how they felt about the IPUS scan compared to other medical procedures (digital vaginal examination, pap smear procedure);
-increased confidence while being able to see the progression of the labor on the ultrasound screen (yes, don’t know, no);
-whether women would have a IPUS monitoring for a future labor (definitely, probably, don’t know, probably not, definitely not);

The study design stated that in the cases when ultrasound manoeuvres during labor were perceived as a difficult experience, a questionnaire had to be addressed 4-6 weeks after the birth with the intention to assess the longer term impact of the protocol.

**Statistical analysis**

Explanatory variables were to include the demographic characteristics, while outcome variables were to be their acceptance of, tolerance for, and perceived future acceptance of the procedure. The statistical analyses was performed by IBM SPSS Statistics for Windows, Version 22.0. (Armonk, NY: IBM Corp.)

**Reporting of adverse events**

All adverse events reported spontaneously by patients or observed by the obstetricians were to be recorded. The patients were informed that, at their will, the sonographic protocol could be terminated at any time. The physicians were instructed to take all necessary and appropriate measures to ensure the safety and comfort of the patient.

**Ethical considerations**

Ethics approval of the study protocol was obtained from the Ethics Committees of the university and hospital. The intrapartum ultrasound trial is registered in the ClinicalTrials.gov Registry: NCT02326077.

**Results**

During the study period, 200 unselected women in labor were invited to participate in the IPUS study, and agreed to fill the acceptability questionnaire. 196 (98%) of them agreed to IPUS investigation protocol. Only 4 women (2%) declined to have IPUS.

The demographic characteristics did not influence the acceptance. However, due to the small number of women who declined IPUS we were not able to compare the characteristics and perceptions of women who declined the scan with those who accepted.

Most women had little difficulty deciding whether or not to have the IPUS scan protocol. 93.37% (183/196) of accepters and 75% (3/4) of decliners reported that the decision was quite or very easy to make.

Regarding the physical discomfort during the IPUS scan, none of the patients related extreme discomfort to cause the interruption of the sonographic protocol. All laboring women who had the IPUS scan found it an acceptable experience. None of the women with epidural analgesia related any discomfort at all, and approximately one fifth (21%) of women without epidural anesthesia rated the perceived difficulty as “mild” or “discomforting”. Only one patient found the scan more painful, or “distressing”. None of the women reported higher levels of pain, as “intense” or “excruciating”. Women rated having the IPUS scan as being significantly less difficult than having a cervical smear (Wilcoxon Z=-8.39, P<0.001), transvaginal scan (Wilcoxon Z= -8.34,P<0.001) or having a digital clinical evaluation (Wilcoxon Z= -8.45,P<0.001) irrespective of age, parity, and epidural analgesia (Table 1).
Table 1. Wilcoxon analysis regarding the perceived difficulty related by the labouring patients without epidural analgesia compared to other medical procedures (cervical smear, transvaginal scan and digital clinical evaluation).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Median</th>
<th>Za</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrapartum ultrasound protocol</td>
<td>0.0</td>
<td>-8.341b</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transvaginal ultrasound</td>
<td>1.0</td>
<td>-8.451b</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vaginal digital examination</td>
<td>2.0</td>
<td>-8.389b</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cervical smear</td>
<td>2.0</td>
<td></td>
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</tr>
</tbody>
</table>

About two thirds (66.84%, 131) of the studied patients expressed increased confidence while being able to follow along the medical personnel the progression of the labor on the ultrasound screen; 24 patients (12.24%) considered that their confidence was not influenced positively by the live visualization of fetal progression on the screen, and the rest of 41 (20.92%) were not able to offer a definite answer (“don’t know”). The level of education was significantly correlated positively with the interest and confidence in this novel imagistic technique aimed to assess the labor evolution.

Almost all consenting women (97.44%, 191/196) who had the IPUS scans said they would definitely or probably agree such ultrasound monitoring for a future labor, if this technique is proved useful for the labor outcome. The 4 patients which declined IPUS expressed their willingness for the procedure if the ultrasound monitoring would be proved helpful and considered for the labor management.

Discussion

Adequate counselling helps patients make informed decisions, especially when bringing new services to them. It had been anticipated that a significant number of laboring women would prefer to have a more familiar clinical examination. However, this study has demonstrated that IPUS monitoring protocol is an acceptable procedure for laboring women regardless of their initial acceptance and most would willingly have it again in a future birth, if such a technique is proven useful for the outcome of labor. Also, most patients expressed increased confidence while being able to follow along the medical personnel the progression of the labor on the ultrasound screen.

We could not search for factors which differentiate parturient women who decline IPUS scan from those who accepted it, because only a small minority of women (2%) declined the IPUS monitoring. Further research is merited on the characteristics and views of this subgroup, in a larger population.

About one fifth of laboring women without regional anesthesia experienced some mild / distressing pain during the procedure and a very small minority (one woman) found the IPUS scan distressing. We did not encounter high levels of pain, or clinically significant levels of psychological trauma. Even the laboring women without regional epidural analgesia found the IPUS monitoring less difficult than other common procedures such as cervical smears, transvaginal scan or digital clinical examination. This was an expected outcome, as the transabdominal / transperineal scan is less invasive as the vaginal exploration and this argument was used in favor to a sonographic monitoring of labor (sonopartogram) [32]. Given the discomfort related to the clinical exploration, a non-invasive monitoring technique that prevents or minimizes the negative psychological outcomes, would be of benefit to both women and labor ward personnel.

It is important to note the limitations of our study. Our study involved only one center, with Caucasian Christian population. The findings cannot necessarily be generalized to different population mixes, although the scanning procedures are less intrusive as the clinical monitoring of birth.

Women who declined IPUS monitoring were poorly represented in the sample and the small number of decliners did not allow the characterization of this group.

The eligible patients were invited to participate in the study depending on the availability of an ultrasound operator. Therefore, the laboring women in the sample were unselected, but not truly consecutive in our center. The fact that the scans were undertaken in an observational research context is unlikely to have had a major effect on the generalizability...
of the findings since the consenting rate was very high and the decliners expressed their future willingness for the protocol if a certain benefit of the procedure will be proven. Most likely, if the protocol is presented as an effective and superior imagistic tool in labor management, the acceptability rate would be even higher in parturient women.

It should also be noted that our findings cannot necessarily be generalized to women having transperineal ultrasound with other indication (e.g. urogynecology).

This study has a number of implications for labor ward practice and research. Its findings encourage those considering introducing an intrapartum sonographic monitoring protocol in terms of likely levels of acceptability and psychosocial outcomes.

Also, the findings may be used to elaborate informational material for women undergoing ultrasound labor monitoring, giving them a realistic picture of how they might feel. However, the findings that most women find it easy to make the decision whether to have or not to have IPUS, suggests that the provision of supplementary information is unlikely to influence uptake.

Further multicenter research is needed to confirm the high acceptance shown in our study. A significant difference between the acceptance rates should trigger research regarding the reasons behind the high uptake rates in certain social groups.

Finally, larger studies should investigate the small minority of parturient women who find having the IPUS scan protocol a difficult experience, and an awareness of the existence of this minority is likely to enhance the care that scan operators give before, during and after labor scans.

Conclusions

IPUS protocol for labor monitoring was overwhelmingly acceptable in our population of women, despite the fact that they were learning about the procedure for the first time. More than two thirds of the patients expressed increased confidence while being able to follow along the medical personnel the progression of the labor on the ultrasound screen and almost all the participants were willing to have the procedure again in future, further reinforcing their favorable attitude to the procedure.

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