

## **FIRST PAGE**

**Ultrasound is better tolerated than vaginal examination in and before labour.**

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## ABSTRACT

**Background:** Intrapartum ultrasound has been proposed as a method of assessing labour progress but its acceptability has not been comprehensively assessed.

**Aims:** We evaluated the acceptability of intrapartum ultrasound in women having vaginal examination (VE) and ultrasound (USS) assessment (transabdominal (TA) and transperineal (TP)) prior to delivery, with and without regional analgesia (RA).

**Materials and Methods:** Women 24-42 weeks' gestation were included in a prospective observational cohort study. The acceptability of digital VE and transperineal ultrasound were assessed pre and post examination using the modified validated Wijma-Delivery Experience Questionnaire (W-DEQ). Acceptability scores ranged from 6-36 (6 being most and 36 being least positive) in 6 domains: positive-trust and relax, negative-harmful to baby, worrying, painful, intrusive.

**Results:** Of 119 women recruited, 104 completed both pre and post assessment questionnaires. 89% women were nulliparous with median gestation 40+2 weeks (25-42<sup>+1</sup>). 32% had regional anaesthesia (RA) before assessment, 91% total. Combined acceptability score of both negative and positive experiences (6=most acceptable, 36=least acceptable) for VE and USS pre-assessment were 15 and 7 respectively ( $p < 0.0001^*$ ). VE was associated with less positive more negative domain scoring post-assessment 12 and 6 respectively ( $p < 0.0001$ ). Though RA made no difference to the perceived experience pre-VE ( $p = 0.9$ ), post VE, women with RAs considered VEs more acceptable than those without RA ( $p = 0.0022$ ).

**Conclusion(s):** This is the first study to comprehensively assess the acceptability of VE and intrapartum USS. USS assessment prior to delivery is more acceptable than VE. RA ameliorated the negative experience of the VE post assessment.

## Introduction

Vaginal examinations are universally used to assess labour progress<sup>1</sup> but are deemed painful by pregnant women<sup>2</sup>. They are contraindicated in some circumstances, such as Placenta Praevia or Preterm Prelabour Rupture Of Membranes (PPROM). For some women with a fear of childbirth, previous sexual trauma or vaginismus, digital VEs are especially traumatic and are usually avoided as much as possible. They can also be inaccurate, unreliable and unrecordable<sup>3-5</sup>.

Transperineal ultrasound can be used to assess labour progress: head descent, caput, moulding<sup>6</sup> and cervical dilatation in early labour<sup>7</sup>. Transabdominal ultrasound for labour position is increasingly being used on the labour ward<sup>8,9</sup>. Intrapartum ultrasound allows a more accurate method of assessment, is objective and the results can be recorded. It is also increasingly being used in education and risk prediction<sup>10,11</sup>.

However, whether ultrasound is deemed acceptable to women in labour has been assessed in only few studies<sup>12-14</sup>. Chan et al used simple visual analogue pain scores<sup>15</sup> to assess acceptability in 98 women, Alvarez Colomo et al also used simple visual analogue pain scores on 151 women<sup>14</sup>. Seval et al conducted a single-blinded, parallel, randomised controlled trial also with visual analogue scores of pain and anxiety levels and included 90 parous women<sup>13</sup>.

We have used a modified validated Wijma Delivery Experience questionnaire (W-DEQ)<sup>16</sup> to assess the acceptability of intrapartum ultrasound in nulliparous and multiparous women pre and post assessment and explored the effect of epidural analgesia.

## **Method**

Women were recruited between April 2015-June 2016, in a prospective observational single blind cohort study.. The study received regional ethical approval (Ref 15/L0/0227) prior to recruitment.

Eligibility criteria included all pregnant women between 24-42 weeks gestation booked at an inner city hospital between the ages of 18 and 44 and able to give consent. Those needing immediate medical attention and/or delivery were excluded from the study. Women were consented when first presenting with symptoms requiring a vaginal assessment in the form of speculum and/or digital vaginal examination. The clinician independently choose the assessment method they felt was most appropriate.

Before the vaginal assessment and simultaneous ultrasound could be performed, consented women were given a pre-assessment questionnaire to complete which included questions in 6 domains for each type of assessment; vaginal examination and/or speculum and ultrasound (see appendix 1 for questionnaire). After the assessments were performed, patients completed a questionnaire with questions in the same domain.

### *Questionnaire (see appendix):*

A modified validated Wijma-Delivery Experience Questionnaire, W-DEQ was used<sup>16</sup>. Acceptability scores ranged from 6-36 (6 being most and 36 being least positive) in 6 domains: positive-trust and relaxataion, negative-harmful to baby, worrying, painful and intrusive.

### *Vaginal examinations*

The birth attendant evaluated cervical dilatation and if indicated head descent, position and caput/moulding by digital vaginal examination or speculum as deemed appropriate immediately prior to or immediately after ultrasound examinations.

### *Transabdominal and transperineal ultrasound technique*

One obstetrician (SU) and one midwife (HB) performed the ultrasound examinations. First a transabdominal scan was performed as per Akmal et al<sup>9</sup>. Thereafter, the woman was placed in a semi recumbent position with the legs flexed at the hips and knees at 45° and 90° angles respectively and a transperineal scan performed after ensuring the bladder was empty<sup>17</sup>. Fetal station was assessed from the transperineal scan. HPD was measured in a transverse scan as the shortest distance from the outer bony limit of the fetal skull to perineum. The transducer was placed in the posterior fourchette, and the soft tissue compressed with firm pressure against the pubic bone<sup>6</sup>. A medium sized glove was used to cover the probe after ultrasound gel had been placed on the probe. Additional gel was applied on top of the glove. After use, the probe was cleaned with sterilisation wipes, this cleaning method was repeated before the next use. All ultrasound measurements were done online in 2D in the labour room after the digital vaginal examination. Neither the women nor the birth attendant were informed about the ultrasound results. The ultrasound operator was not involved in clinical decisions or management of labour. Women were not informed of the ultrasound results and measurements were blinded to birth attendants. The ultrasound operator was not involved in the clinical decisions or management of labour. A Samsung PT60A or Samsung HM70 (Samsung Medison, Seoul, Republic of Korea) were used for the ultrasound assessments using standard 2D transabdominal probe.

### *Statistical analyses*

The primary outcome measure was the comparison of acceptability scores of VEs versus USS. We aimed to recruit minimum number in the groups according to the following calculations<sup>18</sup>. In studies thus far, acceptability of transperineal ultrasound (with no or minimal pain) varied from 68%<sup>19</sup> to 95%<sup>20</sup> compared with 20% for vaginal examinations<sup>19</sup>. Using the lowest

percentage of acceptability at 68%, with an alpha of 0.05 and a power of 90%, the minimum sample size required was 42 patients.

Data were analysed with the statistical software package GraphPad PRISM (edition 7). The differences in score were compared using the Mann Whitney U test,  $p < 0.05$  was considered statistically significant. Body mass index (BMI) was calculated from maternal height and booking weight.

## Results

Of the 119 women recruited, 115 women completed the pre-assessment questionnaire and 104 completed both pre and post assessment questionnaires (Figure 1). Median age was 31( $\pm 5$  SD), BMI 25kg/m<sup>2</sup> ( $\pm 4.6$  SD), 86% were nulliparous with median gestation 40+2 weeks (25-42<sup>+1</sup>), 53% Caucasian, 32% Asian and 14% Afro-Caribbean. 32% had regional anaesthesia (RA) at pre assessment and 91% for delivery (Table 1). 99 (95.2%) of the examinations were digital vaginal examinations, 5 (4.8%) of the total examinations were performed by speculum.

Combined acceptability score comprising scores for both negative and positive experiences (6=most acceptable, 36=least acceptable) for VE and USS pre-assessment were 15 and 7 respectively ( $p < 0.0001^*$ ) with VE associated with less positive and more negative domain scoring, post-assessment 12 and 6 respectively ( $p < 0.0001^*$ , Table 2).

Combined positive experience score pre assessment for VE and USS (2=most positive, 12=least positive) were 5 and 2 and post assessment 4 and 2 respectively ( $p < 0.0001^*$ , Figure 2a). Combined negative experience score pre assessment for VE and USS (4=least negative, 24=most negative) were 10 and 5 and post assessment were 8 and 4 respectively ( $p < 0.0001^*$ , Figure 2b)

Though RA made no difference to the perceived experience pre-VE ( $p = 0.9^*$ ), post VE, women with RAs considered VEs more acceptable than those without RA ( $p = 0.0022^*$ ) (Table 3).

\*Mann Whitney U test

## Conclusions

Though widely used, vaginal examination to assess the progress of labour is a relatively new concept whose rationale is based on the partograms developed by Friedman<sup>21</sup> and adapted by Philpott et al<sup>1</sup>. Alternative methods of assessing labour progress were reported for many years prior to this and include an analysis of behavioural changes in the labouring woman<sup>22</sup>. The views pre and post assessment that we report provide us with a novel understanding of women's experiences. USS assessment prior to delivery is more acceptable than VE assessed as combined scores, or when considered as experience scores for both positive (trust and relaxation) and negative (harmful to baby, worrying, painful, intrusive) feelings. Regional analgesia ameliorates the negative experience of the VE post assessment but had no effect on the USS scores suggesting that without analgesia, USS is preferred.

Over the last 20 years, vaginal examinations have been reported to be subjective<sup>23</sup>, painful<sup>2</sup> and associated with chorioamnionitis<sup>24</sup>. At the same time, ultrasound in labour has developed significantly as image quality has improved and machines have become cheaper and more portable. The acceptability of using ultrasound in labour has previously been assessed using simple visual analogue scores<sup>12-14</sup>. In this study we comprehensively assess the acceptability of VE and intrapartum USS.

The main strength of our study is its design; a prospective, cohort study blinded to the caregivers and participants using a validated questionnaire in a large number of nulliparous and some multiparous women. Although most assessments were by digital vaginal examination (>95%), the minority being by speculum examination, we appreciate that the woman's experience and the information sought by the examiner may be different when the examiner elects to use a speculum compared with digital vaginal examination. The population was



diverse and representative of an inner city tertiary unit; 11 women were lost for the final post assessment questionnaire of the 115 (9.6%). In some cases, women were discharged before the questionnaire could be completed but a future study could utilise email contact or a web based survey to reduce missing data.

The limitation of our study is the inclusion of a high number of nulliparous women; first time labouring women may be more anxious than multiparous women about vaginal examinations thus changing the perception pre-assessment. This may explain why our population had a higher regional analgesia and intervention rate compared to a more mixed parity population. However, the preponderance of nulliparous women participants in this study is not necessarily a weakness. Nulliparous compared with parous women typically have more vaginal examinations during labour so any steps which improve women's experience and increase accuracy, is arguably particularly clinically relevant to this sub-group of Obstetric patients. Importantly, by improving the experience of a first labour this could improve the experience of labour in subsequent childbirths minimizing the impact of vaginal examinations in subsequent labours. These findings suggest a role for ultrasound for women at initial presentation and support a role in conditions such as vaginismus or female genital mutilation where VE is poorly tolerated and ultrasound might be preferred.

Our research group has recently evaluated the feasibility of intrapartum ultrasound<sup>25</sup>. We found that fetal head position is unreliably determined by vaginal examination and agrees poorly with US. Head perineum distance has a moderate correlation with fetal head station in relation to the ischial spines based on vaginal examination. Cervical dilatation is most useful except at dilatations of less than 4 cm. As the use of ultrasound on the delivery suite increases the potential barriers to implementation in other hospitals mainly centres around training, There

should be no additional equipment cost as the delivery suite ultrasound machine with a TA probe can be used..The only study to assess learning curves established that 82 vaginal examinations needed to be performed to assess fetal head position accurately versus only 32 ultrasounds<sup>26</sup>.

More work needs to be carried out in training and evaluating doctors and midwives in ultrasound scan.

**Figure Legends:**

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