

Sonopelvimetry: An Innovative Method for Early Prediction of Obstructed Labour

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Abstract

Aim: To evaluate an innovative sonopelvimetry method for early prediction of obstructed labour. **Methods:** A prospective study was conducted in two centers. GPS-based sonopelvimetry, labor-Pro™ (Trig Medical Inc., Yoqneam Ilit, Israel) device, was used prior to labour in nulliparous women at 39 - 42 weeks gestation remote from labor. Maternal pelvic parameters, including inter-iliac transverse diameter, obstetric conjugate and interspinous diameter were evaluated. Fetal parameters included head station, biparietal diameter and occipitofrontal diameter. Data on delivery and outcome were collected from the electronic files. **Results:** The innovative use of sonopelvimetry was applied to 154 consecutive women, none of the participants complained of discomfort or complications observed. The mean time of examination was 15 + 2 minutes. Mean time of examination to delivery interval was 4.8 days (range 0 - 16 days). Small interspinous diameter and high head station were the best predictors for obstructed labour. Analysis indicated 87% sensitivity and 61% specificity for birth weight fetal head station and ISD combined in predicting obstructed labour with an area under the curve of 0.77. **Conclusions:** Our results indicate that GPS-based sonopelvimetry combined with fetal estimated weight is a valuable tool in the risk assessment of obstructed labour. Parameters obtained by sonopelvimetry combined with birth weight may be useful.

Keywords

Foetal Head Station, Interspinous Diameter, Obstructed Labour, Sonopelvimetry

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1. Introduction

Labour is considered obstructed when the presenting part of the fetus cannot progress into the birth canal, despite strong uterine contractions [1] [2]. The most frequent cause of obstructed labour is cephalopelvic disproportion, a mismatch between the fetal head and the mother's pelvic brim [3] [4]. Obstructed labour remains an important cause of maternal death as well as short- and long-term disability [5] and is one of the major causes of maternal mortality and morbidity in developing countries [6] [7]. Although obstructed labour is not a common condition, its prevalence is increased in nulliparous women and it is not surprising that today these women want to know in advance whether they will have a difficult or operative delivery [8]-[12].

Traditionally the diagnosis of obstructed labour has been made only during labour, based on clinical and manual evaluation of the foetal station and the maternal pelvic dimensions. Clinical pelvimetry was introduced over 200 years ago, based on the seminal work of William Smellie (1697-1763) and Jean-Louis Baudelocque (1746-1810), who developed internal and external callipers for measuring maternal pelvic diameter [13]. Later, the introduction of imaging techniques stimulated physicians to seek new methods for predicting obstructed labour before the onset of labour. Although still practiced [14], X-ray pelvimetry has the disadvantage of ionising radiation exposure and has been shown to offer low diagnostic accuracy in predicting dystocia [15] [16]. MRI, which does not involve radiation, has made it possible to assess the relationship between maternal pelvic diameter and head dimensions and estimate pelvic capacity [17]. Some of the parameters measured with MRI are associated with obstructed labour, but the results have not been significantly better than those obtained using earlier pelvimetric techniques [18]. Therefore, new tools are needed to improve risk assessment of obstructed labour. The laborPro™ magnetic position-tracking system is designed for recording and tracking the spatial location of the sensor tip. A low-power magnetic field is generated by a flat transmitter (microBIRD-SA; Ascension Technology, Inc., Burlington, VT) that is placed under the mattress of the patient. One of the capabilities of the system is to determine the spatial position of the pelvic inlet plane, as well as measuring diameters of the pelvis. The system calculates the interspinous diameter (ISD) measured directly in a ruler-like manner, while the transverse pelvic inlet diameter and anterior posterior pelvic diameter (obstetric conjugate) are calculated based on a computerised pelvic model.

The aim of the present study is to evaluate the ability and feasibility—the laborPro™ (Trig Medical Inc., Yoqneam Ilit, Israel), to evaluate maternal pelvic diameters and fetal head station—sonopelvimetry, in women who have reached term prior to labour, and examine prospectively its effectiveness in evaluating the risk assessment of obstructed labour.

2. Materials and Methods

During the period between February 2010 and February 2011, we recruited women scheduled for vaginal delivery according to the following criteria: the criteria for inclusion were: 1) nulliparous women with an uncomplicated singleton pregnancy; 2) gestational age between 39 - 42 weeks; 3) live foetus in cephalic presentation; 4) fetal weight estimated sonographically by Hadlock formula or clinically by a senior obstetrician as less than 4000 gr; 5) intact membranes; 6) no vaginal bleeding; 7) no previous history of uterine surgery.

The study was approved by an IRB committee and all participants gave written informed consent for participation in the study.

Measurements were obtained by senior obstetricians in a recumbent position after emptying the urinary bladder. The calculated data was blinded to the women and to the caring physicians.

The laborPro™ system (Trig Medical Inc., Yoqneam Ilit, Israel), which combines ultrasound and a position tracking system, has been found more precise in determining foetal head station, position, and cervical dilatation during labour [19] [20].

First, the maternal pelvis is marked at known points on the pelvis using a position sensor with spinous process L5 marked as a fixed reference point (**Figure 1(a)**). Then, a sensor attached to the index finger under the physician's glove marks the anterior superior iliac spines and pubis, as well as the symphysis pubis by transperineal ultrasound. Finally, the ischial spines are marked during vaginal examination (**Figures 1(a)-(c)**). The system calculates the interspinous diameter (ISD) measured directly in a ruler-like manner, while the transverse pelvic inlet diameter and anterior posterior pelvic diameter (obstetric conjugate) are calculated based on a computerised pelvic model.

Fetal head station is calculated using a calibrated sensor mounted on the ultrasound convex transducer. It is

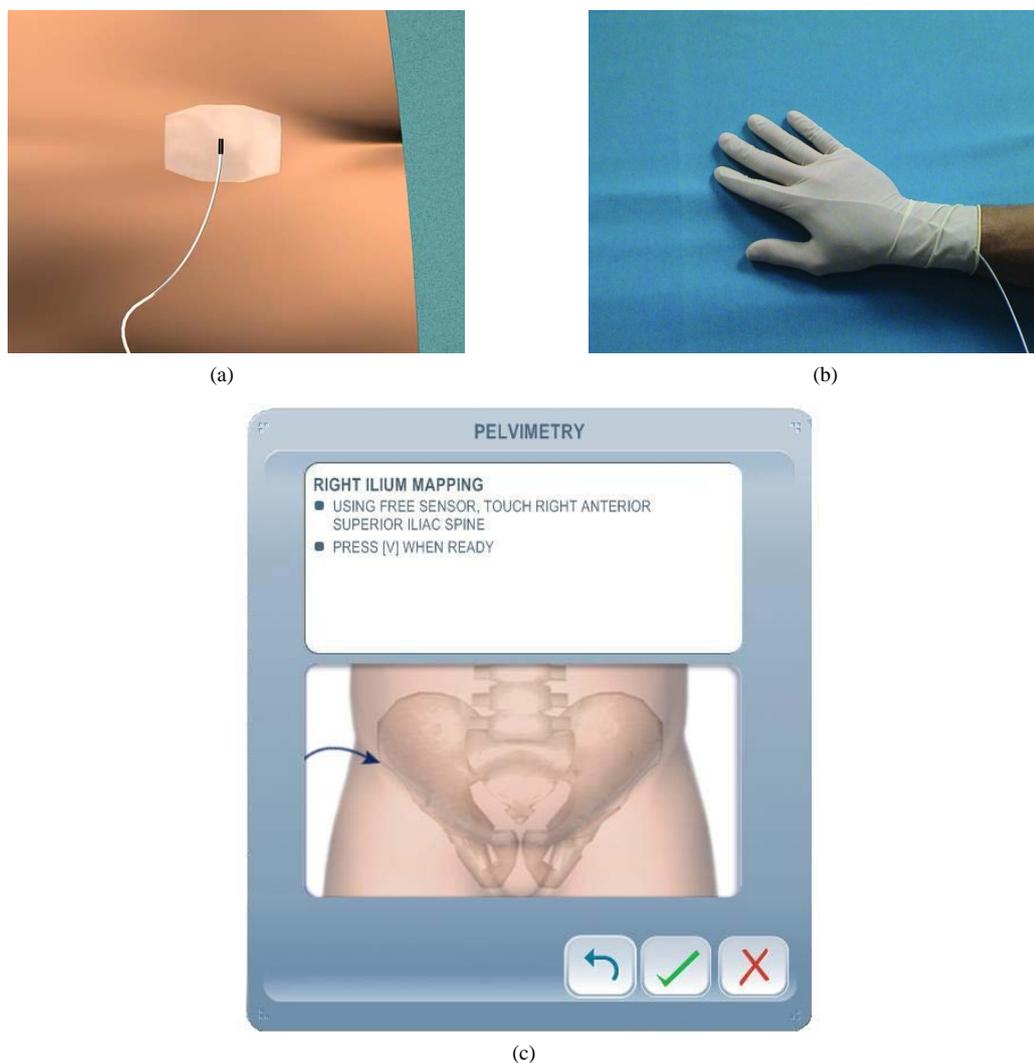


Figure 1. Images demonstrating sensors and markings on the pelvis. (a) Sensor tip located at lumbar vertebra L5; (b) Sensor attached to the physician's index finger; (c) Anterior superior iliac spine marking.

covered with a glove to which ultrasound gel is applied. The transducer is positioned sagittally on the perineum in infra-pubic position (**Figure 2(a)**). Small lateral movements of the probe are made until an image is obtained showing a sagittal view of maternal pubic symphysis with its upper and lower limits, and the foetal skull below. Using these sonographic landmarks, the system automatically calculates the foetal head station (-5 to $+5$) in the birth canal (**Figure 2(b)**). Foetal head parameters biparietal diameter (BPD) and occipitofrontal diameter (OFD) are calculated by marking their outer borders on the system's touch screen.

Obstructed labour was defined as arrest of dilatation at or beyond 4 cm dilatation in the first stage of labour despite normal uterine contractions (3 or more contractions in 10 minutes with duration of 30 - 60 seconds), or reaching full cervical dilatation in the second stage with the head at a station above $+2$. Our practice is to avoid instrumental delivery when the head station is above $+2$.

The induction rate, course of labour, epidural analgesia rate, maternal characteristics and outcome of delivery were collected from electronic files.

For statistical comparison of the relevant parameters between the obstructed labour and normal vaginal delivery groups we used an independent Wilcoxon Test. Logistic regression was performed to determine which parameters are significantly and independently associated with obstructed labour. Based on the probabilities predicted by the logistic regression, a receiver operating characteristic (ROC) curve was constructed. The area under the curve (AUC), as well as optimal sensitivity and specificity were calculated; optimal values were defined

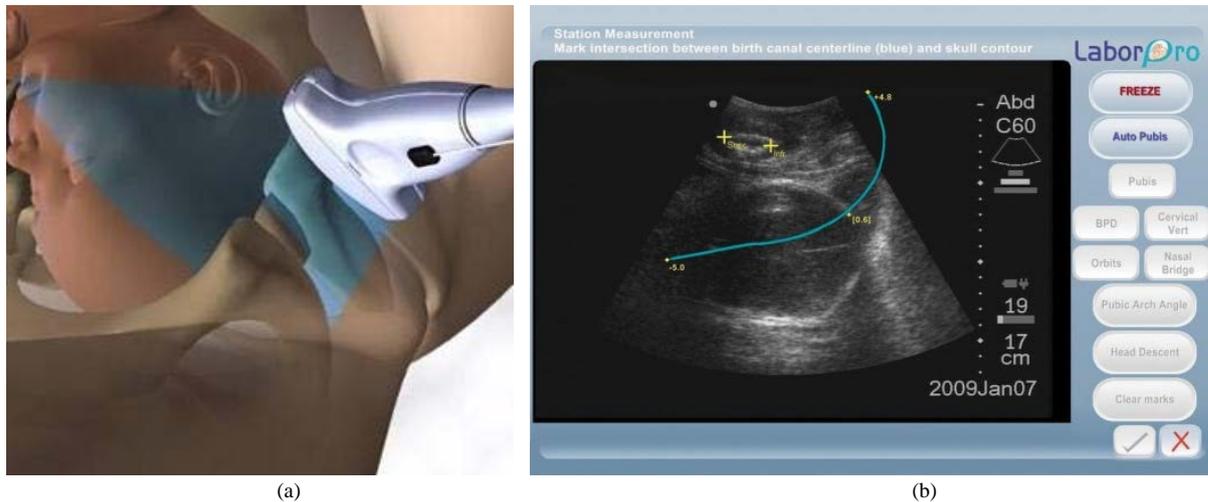


Figure 2. Examination of fetal head parameters using laborPro™. (a) Transperineal sagittal ultrasound using a calibrated sensor mounted on an ultrasound transducer; (b) The image obtained showing the superior and inferior limits of the pubic symphysis and fetal head in center of the birth canal (blue line).

as those providing the maximal sum of sensitivity and specificity. SAS software, version 9.2 was used to perform the analyses.

3. Results

154 nulliparous patients were evaluated using the laborPro™ device. The mean examination to delivery interval was 4.8 days (range 0 - 16 days). The induction rate was 33%. Ninety six patients (64%) delivered spontaneously. Twenty patients (11%) delivered by successful vacuum extraction, 15 of them during prolonged second stage. Thirty-eight (25%) underwent caesarean delivery (CD); of these 30 were due to obstructed labour. Eight were operated due to non-reassuring foetal heart rate monitoring and therefore were excluded from the study. In the obstructed labour group, CD was performed on 16 patients in the first stage and 14 in the second stage of labour.

Descriptive statistics for maternal data and labour characteristics are presented by mode of delivery in **Table 1**. Fetal weight was the only parameter that differed significantly between CD, spontaneous vaginal deliveries and instrumental deliveries ($p < 0.01$) and was found to be larger among the obstructed labour group. No significance was found when comparing the rate of labour induction, epidural analgesia, oxytocin augmentation and head position between the three groups ($p = 1.0$, $p = 0.42$, $p = 0.32$, $p = 0.08$).

Descriptive statistics for maternal pelvic diameters and fetal head measurements by modes of delivery are presented in **Table 2**. The women who delivered by caesarean delivery due to obstructed labour had significantly smaller ISD compared to the normal vaginal delivery group ($p = 0.03$). No other maternal pelvic diameters differed significantly by mode of delivery. Comparison of head parameters between the obstructed labour and spontaneous delivery groups indicated a significant difference in head station, which was significantly higher in the obstructed labour group (-2.5) compared with the normal vaginal delivery group (-2.0) ($p = 0.02$). None of the other foetal head parameters (BPD or OFD) had statistical significance.

When comparing the maternal and labour characteristics of obstructed labour in the first stage of labour to obstructed labour in the second stage of labour, foetal weight was significantly larger in the second stage obstruction of labour compared to first stage of labour: 3815 ± 562 gr vs 3367 ± 236 gr mean ($p = 0.03$). There were no significant differences in the maternal age, maternal BMI, median gestational age at delivery, rate of induction of labour and laborPro™ parameters between these two groups.

To identify factors that predict obstructed labour, we used logistic regression analysis models. In all models, predictors were selected for inclusion in stepwise regression.

The initial set of potential predictors included all the variables listed in **Table 2** and all two-way interactions. The automatic stepwise regression indicated three predictors of delivery mode (spontaneous delivery versus caesarean section due to obstructed labour) for inclusion in this model: birth weight, head station and interspinous diameter in combinations. The output of this logistic model is presented in **Table 3**.

Table 1. Maternal characteristics by delivery type.

Parameters	Spontaneous delivery (N = 96)	Vacuum delivery (N = 20)	Cesarean due to obstructed labor (N = 30)	p-Value for spontaneous vs cesarean
Maternal age	30.1 ± 5.3	30.9 ± 3.4	30.4 ± 5.6	0.80
Maternal body mass index (kg/sq·m)	42.9 ± 6.3	40.3 ± 7.9	45.2 ± 8	0.21
Maternal height (cm)	164.5 ± 7.1	163.8 ± 4.2	161.9 ±	0.10
Maternal weight (kg)	70 ± 11.5	66.1 ± 13	73.5 ± 14.1	0.28
Birth weight (gr)	3291.8 ± 490.4	3221.5 ± 344.7	3576.7 ± 471.8	0.01
Gestational age (weeks)	40.2 ± 1	40.2 ± 1.1	40.3 ± 1.2	0.38

Wilcoxon Test; Means ± standard deviations.

Table 2. Maternal pelvic diameters and fetal head measurements by mode of delivery.

Parameters	Spontaneous delivery	Operative delivery	Cesarean due to obstructed labor	p-Value
Station	-2 ± 0.9	-2.1 ± 0.8	-2.5 ± 0.8	0.02
Transverse diameter (cm)	13.1 ± 1	13 ± 1.1	13.1 ± 1.3	0.78
Obstetric conjugate (cm)	12.8 ± 1.6	12.1 ± 1.3	13.1 ± 1.4	0.30
Interspinous diameter (cm)	9.4 ± 1.1	9.2 ± 1	8.9 ± 1.2	0.03
Biparietal diameter (cm)	9.5 ± 0.6	9.4 ± 0.5	9.5 ± 0.7	0.90
Occipitofrontal diameter (cm)	11.5 ± 0.8	11.5 ± 1.4	11.4 ± 1	0.36
Inter ilium diameter (cm)	17.6 ± 8.9	17.1 ± 10.3	18 ± 9.4	0.68

Wilcoxon Test; Means ± standard deviations.

Table 3. Output of logistic regression predicting obstructive labor.

Variable in the model	Coefficient	p-Value	Odds ratio	Lower 95% confidence limit for odds ratio	Upper 95% confidence limit for odds ratio
Intercept	5.48	0.09	-	-	-
Station	0.73	0.02	2.07	1.09	3.92
ISD	0.35	0.22	1.43	0.80	2.55
Birth weight	-0.00	<0.01	0.99	0.99	0.99

Variables were selected to the model by stepwise method + SDn; Logit (probability of normal delivery) = station + birth weight + interspinous diameter.

Based on the probabilities predicted by the logistic models, we constructed receiver operating characteristic (ROC) curves and calculated the area under the curve. The optimal sensitivity and specificity rates are presented in **Table 4**. The ROC curve for birth weight ISD and head station combined, indicated 87% sensitivity and 61% specificity in predicting obstructed labour, with an area under the curve of 0.77 at a 95% confidence interval of 0.67 - 0.907 (**Figure 3**).

4. Discussion

To the best of our knowledge, this is the first study to describe the use of the innovative laborPro™ device in characterizing maternal and foetal parameters for the purpose of predicting obstructed labour in nullipara women at term and remote from labour.

The maternal pelvimetric dimensions obtained in our study are consistent with those in previous MRI studies that compared the pelvic dimensions of patients who delivered by normal vaginal delivery to those with obstructed labour (**Table 5**). However, the mean ISD measurements obtained with the laborPro™ were shorter

Table 4. Sensitivity and specificity (which give the maximal sum) for each model.

Comparison	Predictors	Sensitivity	Specificity
OL vs. NVD	Station	57%	78%
OL vs. NVD	Station + ISD	59%	83%
OL vs. NVD	Station + birth weight	74%	78%
OL vs. NVD	Station + ISD + birth weight	87%	61%

OL—obstructed labor; NVD—normal vaginal delivery; ISD—interspinous diameter.

Table 5. Comparison of mean pelvic diameters calculated by previous MRI studies and by laborPro™ for normal vaginal delivery and obstructed labor groups.

	Normal vaginal delivery			Obstructed labor		
	TD (cm)	OC (cm)	ISD (cm)	TD (cm)	OC (cm)	ISD (cm)
MRI—Zaretsky (2005) [18]	13.0	11.9	11.9	12.8	11.5	11.3
MRI—Keller (2003) [37]	13.0	12.2	11.2	12.4	11.4	10.5
MRI—Sporri (2002) [38]	12.5	11.8	10.7	12.1	10.8	9.6
laborPro™	13.2	12.8	9.4	13.1	13.1	8.9

TD—transverse diameter; OC—obstetric conjugate; ISD—interspinous diameter.

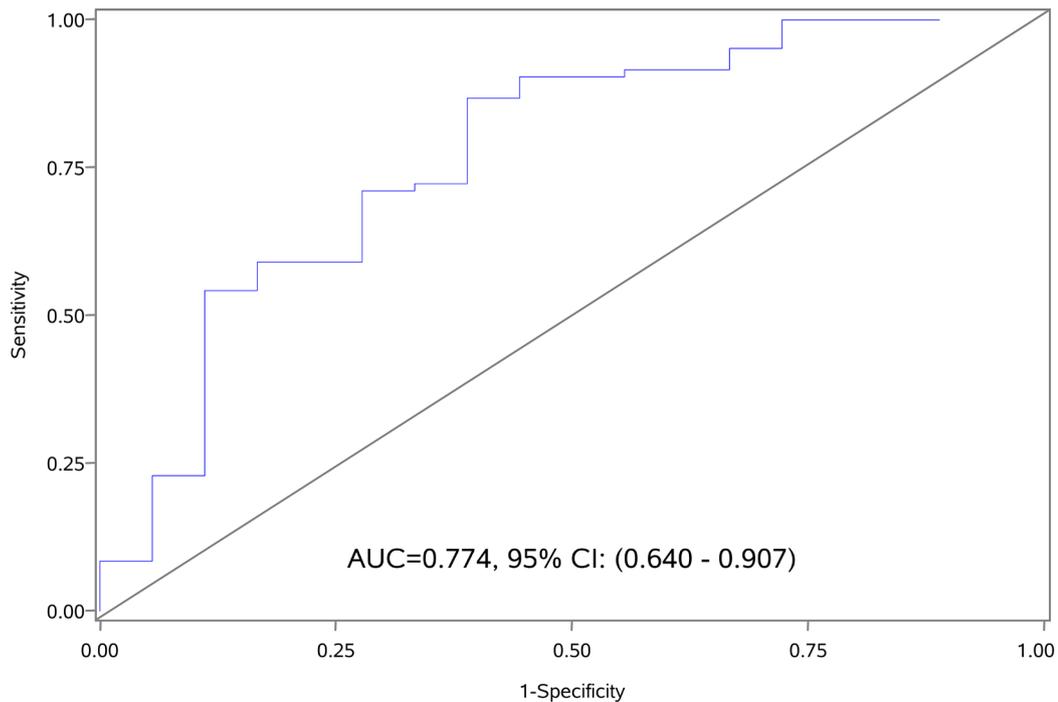


Figure 3. ROC analysis showing the diagnostic accuracy of combining fetal weight interspinous diameter and head station for the prediction of obstructed labor.

compared with the MRI measurements and also shorter than previously reported measurements produced by conventional X-ray [21] [22]. This might be explained by the fact that the MRI and CT do not include the soft tissues adjacent to the bony ischial spines, and thus measure a larger ISD, while the direct measurements with laborPro™ include the soft tissues and thus produce a more precise measurement of the transverse mid-pelvic

distance in the birth canal.

Regarding foetal head diameters evaluated and their association with successful vaginal delivery, none of them differed between the vaginal delivery and obstructed labour groups. This finding is consistent with the previous research of Zaretsky *et al.* [18] on nulliparous women, based on MRI pelvimetry prior to induction of labour. They did not demonstrate any difference in the foetal head biometric measurements between the groups.

Our study was specifically designed to evaluate the association between pelvic parameters and labour outcome in low-risk pregnancies. Therefore we excluded women with an estimated foetal weight above 4000 grams. Importantly, a previous study by Zaretsky *et al.* [18] eliminated cases of macrosomia and large foetal head circumference, which are well-known to effect normal progress of labour [23]. Surprisingly, Ferguson *et al.* assessed a high-risk group for obstructed labour based on previous delivery and risk factors in the current pregnancy and did not find an association between foetal head parameters and obstructed labour [24]. Therefore, the statement by Adolphe Pinard (1844-1934) that “the foetal head is the best pelvimeter” does not pertain to our research population.

Although we excluded macrosomic fetuses by clinical assessment and foetal weight estimation by ultrasound, birth weight was significantly associated with obstructed labour. Our results are in concordance with previous studies that demonstrated the correlation between foetal weight and obstructed labour [25] [26].

Previous studies demonstrated an association between the clinical estimation of fetal head station during labour and the risk of CD in nulliparous women [27]-[31]. In recent years, transperineal ultrasound has been used to quantify head engagement before labour and during active labour. It has been suggested that the ultrasound image produced by this approach is an objective and reproducible technique for the prediction of vaginal delivery [32]-[35]. By using this ultrasound approach a narrow angle of progression (<95) corresponding to a high station was associated with a high rate of caesarean section in non-labouring nulliparous at term [36]-[38]. In the present study we report an association between high foetal head station before labour and obstructed labour.

So far two studies were published using the laborPro™ device in labouring women. Haberman demonstrated an association between laborPro™ determinations of foetal head station and cervical dilatation assessed clinically during active labour [20].

Nizard *et al.* found transperineal ultrasound with the laborPro™ device to be a reliable and objective tool for determination of foetal head station during labour [19]. The ability of the device to objectively and automatically calculate the head station using transperineal sonography may be particularly useful in identifying patients who are prone to obstructed labour and alerting the medical staff. The sensitivity and specificity of predicting obstructed labour are increased when the head station is combined with ISD. Our data demonstrate for the first time the feasibility of this non-invasive, innovative technology for evaluating low-risk patients for unexpected obstructed labour. Although it has the potential to improve the capability to assess prospectively abnormal labour, the clinical benefits of such a system should be evaluated by future larger studies including studies addressing inter- and intra-observer variability of the system at term pregnancy.

Disclosure

None of the authors have a conflict of interest. There has been no financial support. The results of this manuscript have not been distorted by research funding or conflicts of interest.

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