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White Paper

LaborAssist[™]: An automatic measurement tool for labor assessment and management

HS60/50



Figure 1. LaborAssist[™] main display

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Abstract

Objective: The aim of this paper was to evaluate the feasibility and reliability of LaborAssist[™] which automatically provides outlines of the pubic symphysis and the fetal head outline with the angle of progression (AoP) in labor.

Methods: AoP was measured by experts and by LaborAssist[™] on 50 pregnant women, respectively. Both AoP values were subjectively validated and then quantitatively compared with the truths generated by experts.

Results: The automatically provided pubic symphysis outline, fetal head outline and AoP were interpreted as "success" in 98.5% cases by physician. There was an average angle difference less than 8 degrees between the AoP values measured by the experts and LaborAssist[™].

Conclusions: LaborAssist[™] provides automatic measurement of AoP as well as information pertaining to fetal head direction and estimated head station. LaborAssist[™], therefore, is expected to be of great assistance in the assessment of labor progression and decision-making for delivery mode.

Introduction

Background

Traditionally, the assessment and management of a woman in labor is based upon clinical examinations. However, digital examination of head station and position is inaccurate and subjective, especially when caput succedaneum impairs accurate digital examination of fetal head. The use of ultrasound for women in labor is increasing as a result of accumulating evidence of its usefulness for objectively evaluating the progress of labor[1,2]. Compared to vaginal examination, intrapartum transperineal ultrasound scanning does not cause discomfort or pain to the patient, and it also decreases the chances to introduce infection.

Currently used ultrasonographic markers to measure the fetal station during labor include head-perineum distance (HPD), angle of progression (AoP), and fetal head direction. AoP is defined as the angle between a line drawn from the midline of the pubic symphysis and a line drawn from the inferior apex tangentially to the fetal skull. Fetal head station 0 corresponds to an AoP of 116°[3]. Head direction, an indirect marker of head station, is defined as the angle between the longest recognizable axis of the fetal head and the long axis of the pubic symphysis, measured in a midsagittal transperineal view. It is classified categorically as 'head down' (angle < 0°), 'horizontal' (angle 0°–30°) and 'head up' (angle > 30°). As the baby descends toward the pelvic floor, the head direction changes from downward, to horizontal, to upward.

LaborAssist[™] automatically depicts the pubic symphysis outline, fetal head outline and provides AoP which is calculated by the two outlines. AoP is a key measurement parameter for labor progression, for information on fetal head direction and for estimated head station based on the value of AoP. Therefore, LaborAssist[™] provides physicians who are not familiar with intrapartum ultrasound tools to automatically calculate AoP data and easily integrate it into their clinical practice.

Purpose

The purpose of this study was to confirm the feasibility of LaborAssist[™] which automatically provides pubic symphysis outline, fetal head outline and the angle of progression (AoP) during ultrasound examination. LaborAssist[™] has been tested and verified as a usable tool for this purpose in clinical practice.

Materials and Methods

• Materials

LaborAssist[™] is an onboard, commercially available software installed on the HS60 ultrasound system (SAMSUNG MEDISON CO., LTD). Image acquisitions were performed by obstetricians with over one year of intrapartum ultrasound experience, using a convex transducer on Samsung's HS60. Please refer to Table 1 for details.

Items	Contents
Institution name	Korea University Guro Hospital
	(Department of Obstetrics and Gynecology)
Principal Investigator	Oh, Min Jeong, MD, PhD
Study period	Oct 2018 ~ May 2019 (8 months)
Sponsor organization	SAMSUNG MEDSION CO., LTD.
Target sample size	50 patients (203 images)
Primary purpose	To verify the reliability of automatic measurement by comparing
	consistency between manual and automatic measurements

Table 1. Environment for development and evaluation

• Methods

From October 2018 to January 2019, a non-consecutive series of women in active labor with a singleton, uncomplicated term (37-42 weeks) pregnancy were recruited for the aim of the study. A transperineal, two-dimensional ultrasound scan was performed using an ultrasound machine (HS60; SAMSUNG MEDSION CO., LTD) equipped with a convex probe.

For sonographic assessment of fetal station, the operator scanned transperineally to include the pubic symphysis and part of the fetal head skull. It is essential that the maternal bladder is empty. Through the use of the advanced detection algorithm-based LaborAssist[™], the caliper was placed semi-automatically for AoP.

A total 203 images from 50 patients were used for verification. These images were verified in two ways by experts. The first verification included subjective examination by experts to check if the pubic symphysis and the fetal head outline detected by the LaborAssist[™] algorithm were appropriate. The second verification measured the deviation of the AoP value automatically generated by the LaborAssist[™] algorithm from the value measured by the experts.

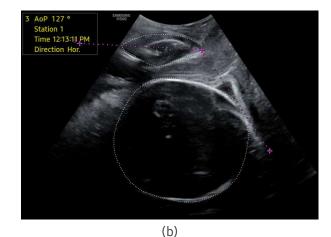
Result

As a result of the first verification, automated measurements by advanced detection algorithm were feasible in a large percentage of cases. Automated assessments correctly depicted the pubic symphysis outline, fetal head outline and AoP in 200 (98.5%) out of 203 on assessments.

Additionally, the second verification showed an average of less than 8 degrees of error for 95 percent of data comparing the AoP values measured by experts and the AoP values measured automatically by the LaborAssist[™] advanced detection algorithm (Figure 2).

In this study, the LaborAssist[™] measurement data were obtained equal to the general AoP workflow in the actual labor environment.





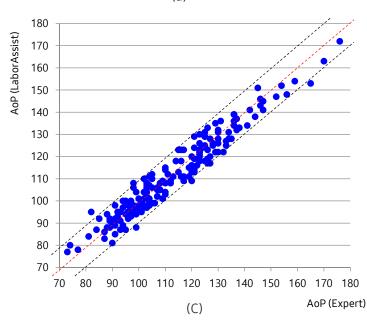


Figure 2. Comparison between expert's AoP and LaborAssistTM AoP:

(a) AoP measurement result from expert
(b) AoP measurement result from LaborAssist[™]
(c) Comparison graph of study results.

- * Red line: Mean line
- * Black lines: ±1.96SD line, indicates the upper and lower 2.5% value

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Discussion

The rapid increase in the rate of cesarean births worldwide has been a significant concern because of the long-term risks associated with subsequent pregnancies such as placenta previa and placenta accreta. The most common indication for primary cesarean delivery is labor dystocia. The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal Fetal Medicine (SMFM) jointly published an Obstetric Care Consensus for safe prevention of the primary cesarean delivery and renewed the definition of labor dystocia[4].

So far, vaginal examination for assessment of cervical dilatation, fetal head station and position is the only method to assess labor progress. However, it is subjective with significant inter- and intraobserver variability. The use of ultrasound for women in labor is increasing as a result of accumulating evidence of its usefulness for objectively evaluating the progress of labor. It is more precise and more reproducible than clinical examination.

According to the 2018 International Society for Ultrasound in Obstetrics and Gynecology (ISOUG) Guideline, ultrasound measurement of either AoP or HPD for fetal station transperineally and assessment of head position transabdominally is recommended in suspected delay or arrest of first or second stage of labor[5]. Also, ultrasound can help to predict the possibility of successful instrumental delivery, consequently improving maternal and fetal outcomes.

LaborAssist[™] provides automatic drawing the pubic symphysis outline, fetal head outline and measurement of AoP. Through the study, these measurements were interpreted as 'success' in 98.5% cases by expert. Additionally, the average angle difference between AoP values measured by experts and LaborAssist[™] was less than 8 degrees. LaborAssist[™] used during the ultrasound examination prior to delivery is expected to aid in the assessment of labor progression and decision-making for delivery mode.

Conclusion

The diagnosis of arrest of labor and decisions regarding the timing or type of intervention rely mostly on digital evaluation of cervical dilatation and the station and position of the fetal head. Digital examination of head station and position is inaccurate and subjective, especially when caput succedaneum impairs accurate digital examination of fetal head.

LaborAssist[™] provides automatic measurement of AoP as well as information pertaining to fetal head direction and estimated head station based on the value of AoP. In this study of 50 pregnant women, this feature was evaluated for accuracy in two different ways. By qualitative analysis, 98.5% accuracy was evaluated by physician, and the average angle difference between AoP values measured by experts and LaborAssist[™] was less than 8 degrees for 95 percent of data as quantitative analysis.

Therefore, LaborAssist[™] can help obstetricians make proper clinical decisions and even help doctors who are not familiar with intrapartum ultrasound be able to use the automatically calculated AoP data easily in their clinical practice. Furthermore, it is useful to explain to the patient and her family how the labor progresses using ultrasound images which show the change of head station during the labor. LaborAssist[™] also provides an animation of labor progress (Figure 3) to help educate the patient.



Figure 3. Example of an image showing the labor progress by LaborAssist™

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Supported System

- HS60

References

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