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ORIGINAL ARTICLE

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A longitudinal study investigating cervical changes during labor using a wireless ultrasound device

Juyoung Kim, Sukyoung Kim, Seungjoo Jeon and Sunyoung Jung

Department of Obstetrics and Gynecology, Gachon University Gil Hospital, Incheon, South Korea

ABSTRACT

Purpose: Cervical assessment during digital vaginal examination (DVE) includes assessing cervical dilatation, effacement, position and consistency. Only cervical dilatation during labor has been previously researched. We investigated cervical changes, including cervical dilatation and effacement, using a wireless ultrasound (US) device.

Materials and methods: This was a longitudinal study investigating cervical changes during labor using a wireless US device. Twenty-five women in labor participated in a serial comparison of cervical dilatation, length and thickness measured during intrapartum transperineal sonography using a wireless mobile US device (SONON) with measurements of cervical dilatation and effacement obtained during serial DVEs.

Results: Intrapartum sonography showed strong correlation with DVE in assessing cervical changes during labor including the measurement of cervical dilatation and thickness ($p < .001$). The failure rate of cervical length image collection was high; therefore, we could not determine the correlation between cervical length and effacement.

Conclusions: We developed a new technique for evaluating effacement with cervical thickness. Cervical dilation and thickness using a transperineal intrapartum US demonstrated significant correlation with DVE findings. The use of a wireless US device is convenient and may be advantageous in the labor ward; however, further research is needed to define the role of this wireless device.

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Introduction

Digital vaginal examination (DVE) has been the gold standard for the evaluation of labor progress [1]. However, it can be inaccurate, subjective and uncomfortable for the mother [2,3]. Also, it does not provide objective documentation; thus, the labor progress record depends solely on the subjective assessment of the examiners [4]. There is also a risk of introducing infection with frequent DVE [5]. For these reasons, the development of an alternative to DVE has been encouraged [6,7].

Intrapartum sonography is a promising ultrasound (US)-based substitute alternative to DVE that allows the assessment of labor progress in a non-intrusive recordable manner; which is sonopartography [6–9]. The major components of partography are maternal, fetal and labor assessment [10]. In sonopartography, DVE information is substituted with sonographic information [9].

Cervical assessment is the most recently introduced aspect of US-based labor progress monitoring [6,9]. Cervical assessment in DVE includes cervical dilatation, effacement, position and consistency [10,11]. However, only cervical dilatation during labor has been previously researched ultrasonographically [6,9]. In this prospective observational study of 25 patients in labor, we further investigated the cervical changes, including cervical dilatation and effacement, using a wireless US device.

Materials and methods

This prospective observational study was conducted from August 2015 to February 2016. This study was approved by the institutional ethical review board of Gachon University Gil Hospital and conformed to the tenets of the Declaration of Helsinki, and written informed consent was obtained from all participants. Recently, a venture company, Healcerion, developed a

CONTACT Sukyoung Kim ksyob@gilhospital.com, ksyobgy@gmail.com Department of Obstetrics and Gynecology, Gachon University Gil Hospital, 21, Namdong-daero 774 beon-gil, Namdong-Gu, Incheon 21565, South Korea

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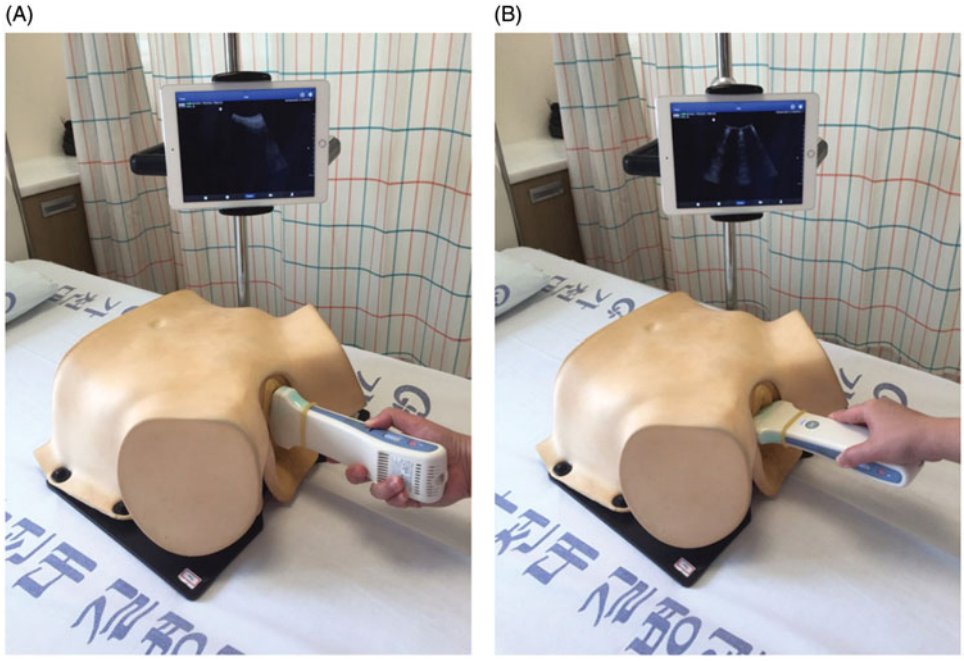

Figure 1. Transperineal sonography with SONON. (A) Transperineal sagittal approach. (B) Transperineal transverse approach.

wireless mobile US device (SONON, Healcerion Inc., Seoul, South Korea) that uses a mobile display system including an iPhone, iPad or Android smartphone [12]. This wireless US device uses wireless signals to transfer images to a display system that displays the images with B-mode in real time.

During labor, we performed intrapartum sonography using a transperineal approach (Figure 1). We enrolled both nulliparous and multiparous women in labor with a cephalic singleton fetus to participate in a serial comparison of cervical dilatation, length and thickness. Inclusion criteria included a gestational age of >32 weeks and an estimated fetal weight >2000 g. One examiner used SONON for intrapartum transperineal sonography, while serial DVEs evaluating cervical dilatation and effacement were conducted by the other four examiners, who were senior residents at our hospital. The first sonography evaluation was performed after urination and was followed by DVE. All examiners were blinded to the other examiner's results. The images were stored on an iPad, and the examiner reviewed and measured cervical dilatation, thickness and length.

At our hospital, we have begun using the US-based scan, regardless of cervical dilatation, in patients with regular uterine contractions over 200 Montevideo units (MVUs). The SONON (SONON 300c), which was linked to a fourth generation iPad (iOS version 8.3, application version m1.1.13), was placed transperineally to obtain transperineal, sagittal and transverse views of the cervix (Figure 1). The collected cervical dilatation images were scored using the scoring scale suggested by Hassan et al. [6].

The sonographic definition of cervical dilatation in this study was the anterior-to-posterior inner-to-inner length of the dilated area. When the dilated area was too small to measure, we categorized it as a non-circular space (Figure 2(A,C)). Other cervical dilatation images obtained as labor progressed are shown in Figure 2(BD,EG,FH; thick arrow). During statistical analysis, the non-circular space was defined as 1 cm. We also considered effacement during the sonographic evaluation. Although there has been no definitive US study of cervical effacement, we decided to measure both cervical length and cervical thickness to determine their correlation with cervical effacement as measured in the digital examination. We measured cervical length in the sagittal view of the internal-to-external cervical length at the margin of the fetal head in the upper part of the cervical opening. Cervical thickness assessment, which was introduced in this study for the first time, was measured in the same view as that used for cervical dilatation, using the inner and outer distances of the cervix in the 12-o'clock direction and 6-o'clock directions, using the more clearly visible location (Figure 2(AC,BD,EG,FH); thin arrows).

For cervical dilatation, the association was examined using linear regression analysis and Pearson's correlation coefficient. Agreement was examined using the Bland–Altman method. For cervical effacement, we used a scatter plot, linear regression analysis and Pearson's correlation coefficient. Statistical testing was

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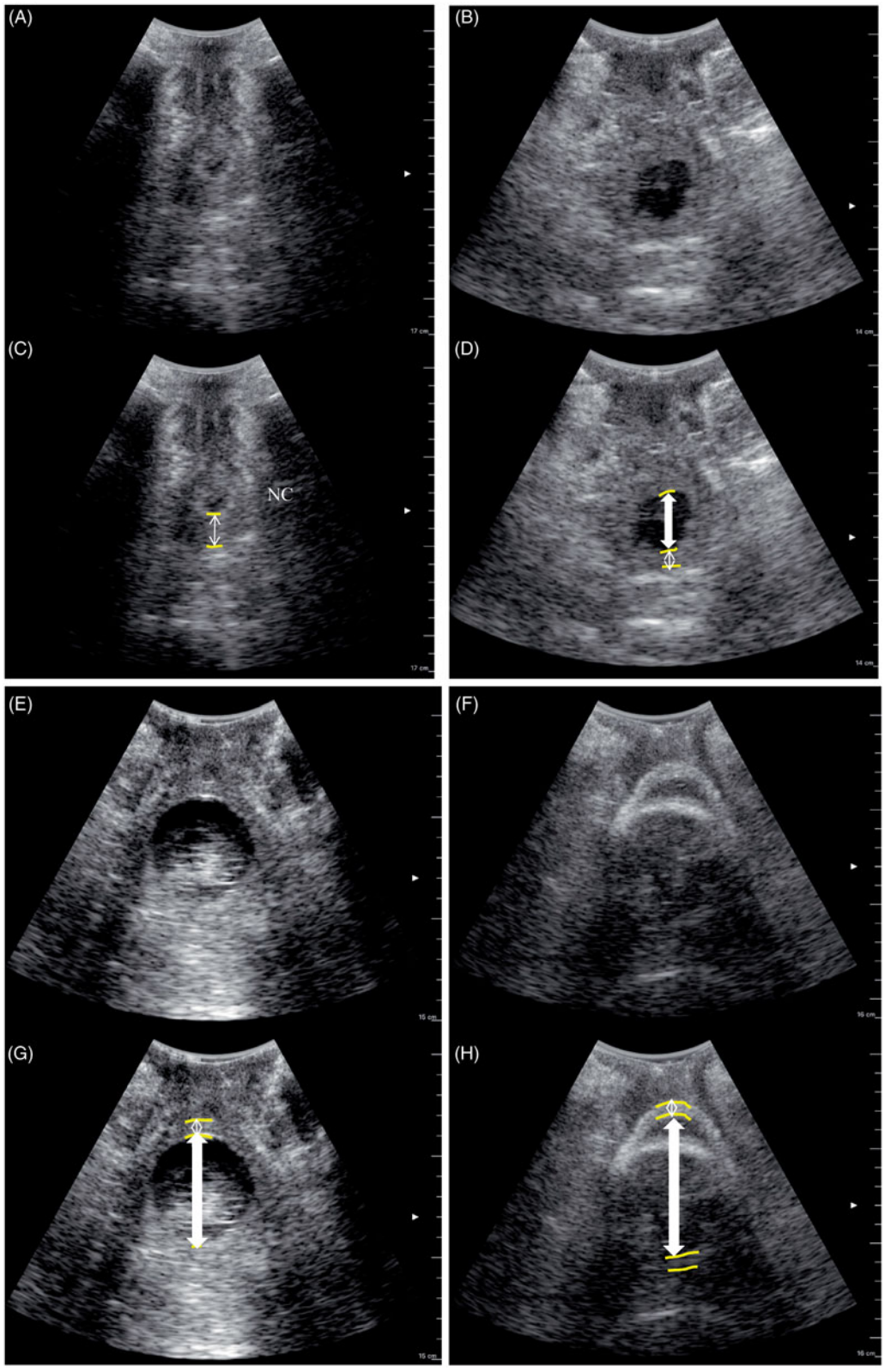

Figure 2. The transperineal transverse approach provides a cervical dilatation view. Inner to inner length represents cervical dilatation (thick arrow). In the same image, cervical thickness was measured via the inner and outer distance (thin arrow). All images were collected with the wireless mobile ultrasound SONON 300c linked to a fourth generation iPad (iOS version 8.3, application version m1.1.13). (A, C) When the dilated area was too small to measure, we categorized it as a non-circular space. Cervical thickness of 1.7 cm. Cervical dilatation and cervical thickness of (B, D) 2.7 cm and 0.8 cm, respectively; (E, G) 5.2 cm and 0.6 cm, respectively; and (F, H) 7.2 cm and 0.55 cm, respectively.

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performed using SPSS version 18 (SPSS Inc., Chicago, IL). A p value of $<.05$ implied statistical significance.

Results

Transperineal US was performed in 25 women; the characteristics of the study population are presented in Supplementary Table 1.

Cervical dilatation was measured in 42 paired examination cases. One case did not have sufficient images to qualify for examination because the cervix was located too posteriorly. The image scores decreased as the cervix dilated. The frequency of each image score is shown in Supplementary Table 2.

Cervical dilatation on transperineal intrapartum sonography showed a strong correlation with cervical dilatation on DVE ($p < .0001$; Supplementary Table 3). Using the Bland–Altman method in this subset, the average difference between the DVE and SONON cervical dilatation measurement was −0.0417 (95% limits of agreement: −1.57, 1.48) cm. Cervical length was measured in 28 cases; however, we did not evaluate cervical length because of a high failure rate in image collection (39%). Cervical thickness was measured in the same view as that of cervical dilatation, and in 34 cases, a strong correlation with effacement was observed ($p < .0001$) (Figure 3).

Discussion

Our data report a correlation between DVE measured cervical dilatation and transperineal US measured dilatation, similar to the findings reported by Hassan et al. in a previous study [6]. Since there have been no prior studies regarding the US assessment of cervical effacement, we evaluated both cervical length and thickness [13]. We believe that one of the most interesting findings of this study was the significant correlation between US measured cervical effacement and cervical thickness. To the best of our knowledge, this is the first study to report this correlation.

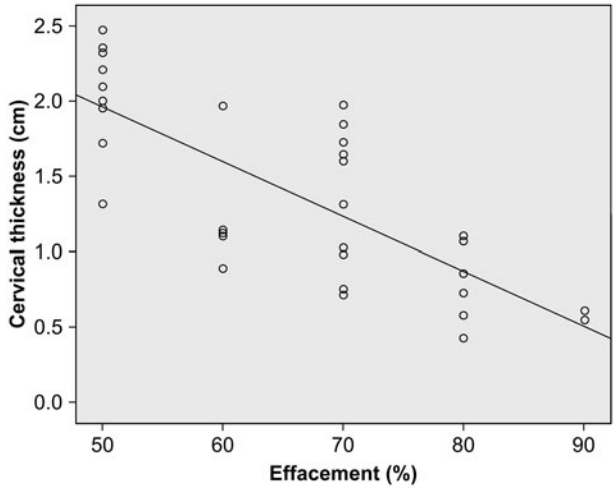

Figure 3. Scatterplot of cervical thickness for cervical effacement expressed as a percentage ($r^2 = 0.562$, $p < .001$).

Another important aspect of our study is that we used a wireless US device to assess cervical parameters in the delivery ward. We believe that the portability of this US device is an important aspect regarding its use for the performance of US studies in the delivery ward. Typically, with conventional US devices, device setup requires significant time, and the equipment is difficult to place at the patient's bedside. However, in the delivery unit, prompt monitoring of ongoing changes occurring during the delivery process is required. In addition, most conventional high-end sonography machines are very expensive, and they may not be available for use in all delivery wards. Ours is the first study to use a wireless sonography device for sonopartography. This wireless US device is light, inexpensive and portable, and because of this, it may be particularly suitable for use in the delivery ward.

This study has several limitations. We compared US-based cervical changes with those of DVE examination, which are imprecise and observer dependent [14]. To evaluate cervical effacement, we measured cervical thickness and length, but we could not collect images reflecting cervical length. However, ongoing development in sonography techniques will enable improved imaging. Transvaginal US produces more accurate images for the measurement of cervical length. More studies regarding cervical changes during labor as measured with the transvaginal approach are needed, including transvaginally measured cervical length changes during labor and their correlation with cervical thickness measured transperineally. In addition, although this study included data regarding changes in cervical thickness for both multiparous and primiparous subjects, further research is needed to clarify the differences in these two groups of women. It is evident that the present study is also limited by the small number of cases. Therefore, further investigation is necessary to clarify the potential role of intrapartum cervical assessment, particularly when using a mobile US device, in a larger number of patients.

In conclusion, we performed a longitudinal study investigating cervical changes during labor using a wireless US device. We developed a new technique for evaluating effacement with cervical thickness. Cervical dilation and thickness using a transperineal intrapartum US demonstrated a significant correlation with DVE findings. A wireless US device might be

advantageous in the labor ward as it is convenient to use; further studies to define the role of this new technology are needed.

Disclosure statement

The authors report no conflicts of interest.

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