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● *Original Contribution*

DETECTION OF CHANGES IN CERVICAL SOFTNESS USING SHEAR WAVE SPEED IN EARLY VERSUS LATE PREGNANCY: AN *IN VIVO* CROSS-SECTIONAL STUDY

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Abstract—The aim of this study was to assess the ability of shear wave elasticity imaging (SWEI) to detect changes in cervical softness between early and late pregnancy. Using a cross-sectional study design, shear wave speed (SWS) measurements were obtained from women in the first trimester (5–14 wk of gestation) and compared with estimates from a previous study of women at term (37–41 wk). Two sets of five SWS measurements were made using commercial SWEI applications on an ultrasound system equipped with a prototype catheter transducer (128 elements, 3-mm diameter, 14-mm aperture). Average SWS estimates were 4.42 ± 0.32 m/s (n = 12) for the first trimester and 2.13 ± 0.66 m/s (n = 18) for the third trimester (*p* < 0.0001). The area under the curve was 0.95 (95% confidence interval: 0.82–0.99) with a sensitivity and specificity of 83%. SWS estimates indicated that the third-trimester cervix is significantly softer than the first-trimester cervix. SWEI methods may be promising for assessing changes in cervical softness. (E-mail: lcarlson2@wisc.edu)
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Key Words: **Cervix, Shear wave speed, Shear wave elasticity imaging, Cervical softness, Cervical remodeling.**

INTRODUCTION

Soon after conception, the cervix begins to soften ("remodel"), and just before delivery, this softening accelerates as the cervix also shortens and dilates (Aspden 1988; Danforth 1983; Maul et al. 2006; Read et al. 2007; Word et al. 2007). Recent studies suggest that this process is precipitated by complex signaling from the fetus, membranes, placenta and decidua (Menon 2016). Premature activation/signaling in any of these tissues feasibly results in premature cervical remodeling and could lead to spontaneous preterm birth (birth at <37 wk of gestation), the leading global cause of death in children under 5 (Menon et al. 2016; Vink and Feltovich 2016). Cervical softening initiates early (weeks after conception) and accelerates just before delivery. Therefore, one way clinicians try to detect a woman's readiness for labor is to assess the softness of her cervix *via* vaginal examination. This assessment is entirely subjective, which may explain part of why cervical examination is a poor predictor of both delivery timing and success of labor induction (Feltovich 2017).

Our goal is to refine and develop objective, quantitative methods to evaluate the cervix. Ultimately, we hope that combining imaging biomarkers with other factors that inform delivery events (bodily fluid biomarkers, demographic characteristics, race/ethnicity, *etc.*) will improve prediction of delivery timing and induction success. Shear wave elasticity imaging (SWEI) is a non-invasive method to quantify tissue softness. The basic principle is that measuring shear wave speeds in tissue provides objective information about stiffness/softness because shear waves travel faster in stiffer tissue (Sarvazyan et al. 1998). SWEI methods have been successfully used in women (Carlson et al. 2014a, 2014b, 2015; Hernandez-Andrade et al. 2014; Muller et al. 2015) as well as in animal models (Huang et al. 2016; Peralta et al. 2015; Rosado-Mendez et al. 2017). We previously reported that we can quantify cervical softness induced by "ripening" (pharmacologic softening of the cervix with prostaglandins in preparation for labor induction) in both the non-pregnant and late-pregnant (term, 37–41 wk of gestation) cervix (Carlson et al. 2014a, 2014b,

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2015). To further our investigation in preparation for larger trials, we undertook this simple study to determine if SWEI methods can quantify a difference in cervical softness in early versus late pregnancy and to investigate the range and variability of SWS estimates at both time points. To this end, we recruited a group of women in early pregnancy (first trimester, 5–14 wk) and compared their average cervical SWS with those of a group of women in late (term) pregnancy from a previous study.

METHODS

Study design

This was a cross-sectional study of SWS measurements in the cervix in a group of women in early pregnancy (first trimester, 5–14 wk) compared with a group of women at term (37–41 wk) from a previous study (Carlson et al. 2015).

Patients

Pregnant women scheduled for first-trimester termination of pregnancy were recruited (n = 15) from Planned Parenthood Metro Health Center in Salt Lake City, Utah, from August 2015 to August 2016. This study was approved by the institutional review boards at the University of Utah and the University of Wisconsin, and each subject provided written informed consent. Data were compared with de-identified data from our previous study of cervical softening in pregnant women (n = 18) presenting for induction of labor at term. (Carlson et al. 2015) In that study, pregnant women scheduled for cervical ripening before induction were recruited from the Labor and Delivery Unit at Intermountain Medical Center in Salt Lake City, Utah, from March to August 2013. Figure 1 is a summary flow diagram of recruitment. Exclusion criteria for both groups included history of preterm birth, cervical surgery or collagen vascular disease. The age, pregnancy history and gestational age were recorded for each patient.

Data acquisition and processing

All examinations were done by the same clinician (H.F.), and acquisitions were supervised by the same engineer (L.C.C.) to reduce inter-observer variability. The same transducer, scanning technique and data processing methods applied in our previous study of women at term (37–41 wk) (Carlson et al. 2015) were utilized to facilitate direct comparison between findings in early versus late pregnancy. Specifically, scanning was performed using a Siemens ACUSON S3000 ultrasound system (Siemens Medical Solutions USA, Malvern, PA, USA). A prototype catheter transducer (128 elements, 14-mm aperture, 3-mm diameter), operated in linear array mode, was used to acquire shear wave data. (We use a linear transducer to align ultrasound echo signals with underlying cervical structure and because we have found that a typical curvilinear array creates wave behavior that is too complex for meaningful evaluation.) The transducer was secured to the clinician's finger and inserted into a glove filled with gel for acoustic coupling, as described by Carlson et al (2015, fig. 1). The clinician's finger was placed on the posterior surface of the cervix, as illustrated in Figure 2(a), roughly parallel to the endocervical canal, in the mid-position along the length of the canal. Location was verified by comparing B-mode images from sector imaging mode, as illustrated by Figure 2(b), which has a larger field of view, with the rectilinear mode image in Figure 2(c). The *dotted lines* in Figure 2(a) indicate the location of the sector image in Figure 2(b), and similarly, the *dotted lines* in Figure 2(b) indicate the location of the rectilinear image in Figure 2(c). This location was chosen based on our *ex vivo* studies of the human cervix (Carlson et al. 2014b). Because undue pressure may cause a tissue to stiffen and

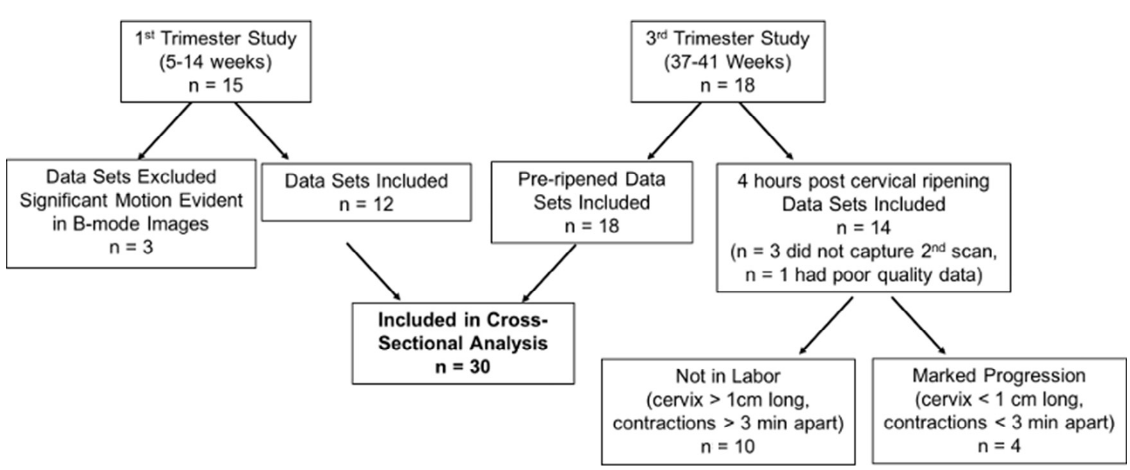

Fig. 1. Summary flow diagram of recruitment for the first- and third-trimester studies.

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