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● *Original Contribution*

COMPARISON STUDY OF LOW-COST ULTRASOUND DEVICES FOR ESTIMATION OF GESTATIONAL AGE IN RESOURCE-LIMITED COUNTRIES

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Abstract—We investigated how accurately low-cost ultrasound devices can estimate gestational age (GA) using both the standard plane and the obstetric sweep protocol (OSP). The OSP can be taught to health care workers without prior knowledge of ultrasound within one day and thus avoid the need to train dedicated sonographers. Three low-cost ultrasound devices were compared with one high-end ultrasound device. GA was estimated with the head circumference (HC), abdominal circumference (AC) and femur length (FL) using both the standard plane and the OSP. The results revealed that the HC, AC and FL can be used to estimate GA using low-cost ultrasound devices in the standard plane within the inter-observer variability presented in the literature. The OSP can be used to estimate GA by measuring the HC and the AC, but not the FL. This study shows that it is feasible to estimate GA in resource-limited countries with low-cost ultrasound devices using the OSP. This makes it possible to estimate GA and assess fetal growth for pregnant women in rural areas of resource-limited countries. (E-mail: Thomas.vandenHeuvel@radboudumc.nl) © **2018 World Federation for Ultrasound in Medicine & Biology. All rights reserved.**

Key Words: **Ultrasound, Obstetrics, Prenatal, Resource-limited countries, Obstetric sweep protocol.**

INTRODUCTION

Worldwide, 99% of all maternal deaths occur in resource-limited countries (World Health Organization et al. 2014). Ultrasound can be used to manage obstetric care, but too often remains out of reach for pregnant women in resource-limited countries. There are two main reasons for this. Firstly, ultrasound is too expensive for resource-limited countries. Secondly, a trained sonographer is required to acquire and interpret the ultrasound images. However, there is a severe shortage of well-trained sonographers in resource-limited countries (Carrera 2011; Hofmeyr 2009; LaGrone et al. 2012).

The first problem could be solved with the use of low-cost ultrasound devices. Estimation of gestational age (GA) could be helpful in resource-limited countries (Aliyu et al. 2016; Gladstone et al. 2011; Harris and Marks 2009; Kotlyar and Moore 2008; Shah et al. 2008; Sippel et al. 2011; Stanton and Mwanri 2013; Wanyonyi et al. 2017), but it has never been shown how accurate fetal biometrics can be estimated with low-cost ultrasound systems. In this study we therefore compared three low-cost ultrasound devices to measure the head circumference (HC), abdominal circumference (AC) and femur length (FL) by obtaining the standard planes, as described by Verburg et al. (2008b). The biparietal diameter was not evaluated in this study because guidelines state that HC is more reliable when the head shape is flattened or rounded (American Institute of Ultrasound in Medicine [AIUM] 2013).

The second problem could be solved by using the obstetric sweep protocol (OSP). The OSP was introduced by DeStigter et al. (2011) and consists of six pre-defined free-hand sweeps over the abdomen of the pregnant woman with an ultrasound transducer, as visualized in Figure 1. According to DeStigter et al. (2011), the OSP can be taught, within

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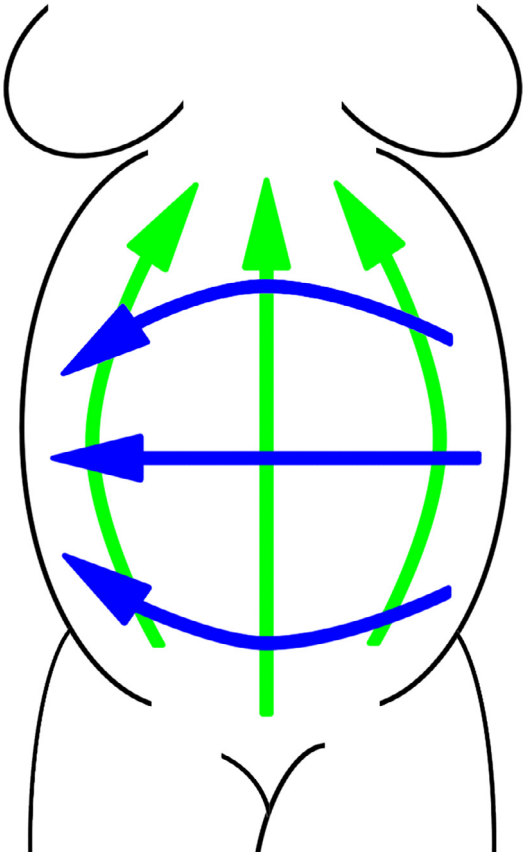

Fig. 1. Visualization of the obstetric sweep protocol, consisting of six pre-defined free-hand sweeps with the ultrasound transducer over the abdomen of the pregnant woman.

a day, to any health care worker without prior knowledge of ultrasound, which makes it a suitable approach for resource-limited countries.

We investigated if it is possible to estimate GA using the OSP. "Correct assessment of GA and fetal growth is essential for optimal obstetric management" (Verburg et al. 2008b). The GA can, for example, be used to estimate due date, to schedule prenatal care and to estimate fetal viability. However, the OSP will most likely not contain the correct standard plane to obtain fetal biometrics. Therefore, we investigated whether it is possible to accurately estimate the HC, AC and FL by manually selecting the frame within the OSP that best resembles the standard plane. If this is possible, computer-aided detection systems could potentially be used to automatically measure these biometrics. Such a system could make ultrasound more widely available in resource-limited countries, because there would be no need for a trained sonographer to acquire and interpret the image to estimate GA and monitor growth of the fetus.

METHODS

Data acquisition

Four different ultrasound devices were used to acquire the data for this comparison study: (i) the high-end Voluson E10 in combination with the RM6C transducer (General Electric, Zipf, Austria), which can be purchased around $100,000; (ii) the low-cost MicrUs EXT-1H in combination with the C5-2R60S-3 transducer (Telemed Ultrasound Medical Systems, Milan, Italy); (iii) the low-cost SeeMore USB Probe GP 3.5 MHz (Interson Medical Instruments, Pleasanton, CA, USA) (both the MicrUs and SeeMore are approved by the U.S. Food and Drug Administration (FDA) and are commercially available for between $2000 and $3000); (iv) the custom-developed very low-cost SESAS (Newcastle University, Newcastle upon Tyne, UK), which production costs are around $100 and provides conformance to the FDA Track 1 standards—fetal imaging application—and is described in detail elsewhere (van den Heuvel et al. 2017). All three low-cost ultrasound devices were connected to a laptop using a USB, thus providing a portable solution for rural areas in resource-limited countries.

All 60 participants in this study received a routine ultrasound examination (Salomon et al. 2011) performed by one of three sonographers (D.d.B., D.M. and A.B.), with 27, 14 and 30 years of experience as a sonographer, respectively. The routine ultrasound examinations were performed between December 2016 and March 2017 at the Department of Obstetrics and Gynecology, Radboud University Medical Center, Nijmegen, the Netherlands. During this examination, the standard planes for obtaining the HC, AC and FL measurements were acquired using the Voluson E10 according to the standards of Verburg et al. (2008b). After completion of the examination, the OSP was performed using the Voluson E10. In addition, the three standard planes and the OSP were acquired using one of the three low-cost ultrasound devices. This resulted in three 20-participant groups matched on body mass index of the participant and GA of the fetus. Data were acquired at either 20 or 33 weeks GA, because these are standard time points of routine ultrasound screening for pregnant women in the Netherlands. Only participants with a fetus that did not show any growth abnormalities were included in this study. All ultrasound devices were tested for electrical safety, and the SESAS was also tested on acoustic output power to ensure patient safety. All participants signed an informed consent form approved by the local ethics committee. All data was anonymized according to the tenets of the Declaration of Helsinki.