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Applicability of pocket ultrasound during the first trimester of pregnancy.

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Abstract

Aim: To determine the applicability of pocket ultrasound as a complementary method for clinical evaluation during the first trimester of pregnancy. **Material and methods:** A prospective cross-sectional study was conducted with 86 pregnant women attended in an emergency. The same operator performed the first examination with pocket device Vscan (General Electric, Vingmed Ultrasound, Horten, Norway) and then repeated the exam using a traditional handset high resolution Voluson 730 Expert (General Electric Healthcare Ultrasound, Milwaukee, WI, USA). Data were recorded with individual diagnoses by means of yes/no binary as the visualization of variables: gestational sac, embryo, embryo heartbeat, topical or ectopic pregnancy. Concordance was calculated using the kappa coefficient with its respective 95% confidential intervals (CI). **Results:** There was no disagreement between the methods when compared the pocket and conventional ultrasounds. The best comparative result between the devices was as the visualization of the embryo heartbeat with kappa coefficient of 0.84 (95% CI 0.76 to 0.89). However, the pocket ultrasound had a low correlation for diagnosis of ectopic pregnancy, with kappa coefficient of −0.02 (95% CI −0.23 to 0.19). The smaller structure visualized and studied using the pocket ultrasound was an embryo of 3.4 mm. **Conclusions:** The method of pocket ultrasound has the potential to become a complementary and easy access for diagnostic tool in obstetric patients during the first trimester. However, in ectopic pregnancy cases the diagnosis should be realized by conventional ultrasound.

Keywords: ultrasound, pocket, obstetrics, first trimester, concordance.

Introduction

Ultrasonography as a complementary diagnostic method has become a technological boon to medicine, particularly in obstetrics and gynaecology. Over the years, technological advances have enabled significant improvements in image acquisition and a reduction in equipment size. Recently, a portable, pocket-size ultrasound (US) device was released on the market. This type of device has been tested in applications in the areas of anaesthesiology, cardiology, critical care, dermatology, emergency medicine, neonatology, obstetrics and gynaecology, vascular surgery and rheumatology [1-8].

Because of the close relationship between US and obstetrics and gynaecology, it is possible to speculate that, in the future, more detailed examination of the foetus and the female internal genitalia will be part of routine care. Just as cardiologists use stethoscopes and ophthalmologists use ophthalmoscopes, physicians specialising in gynaecology and obstetrics will use US to assess the uterus and its appendages in a gynaecological consultation or assess the foetus in an obstetric consultation.

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In obstetrics, US is important for assessing early pregnancy [9], defining topography, confirming the gestational age and assessing the vitality of the foetus throughout gestation, during which we can assess foetal presentation, estimated weight [10], amniotic fluid [11], and even monitor the progress of labour [12].

Although pocket US is not a reality in routine health care, in emergency situations it could certainly be an indispensable complement to clinical examination by promptly providing US images. This is especially true in situations where the clinical approach depends on the result of the US examination [13]. Many obstetrics and gynaecology clinics and departments do not have an imaging service capable of performing a complementary US examination in a short period of time.

Therefore, gynaecologists and obstetricians need a US device that is affordable, easy to use, portable, and can be used in emergency situations [14]. In addition, these professionals inquired whether this type of imaging device would have diagnostic benefits similar to those of traditional devices.

The main objective of the study was to determine the diagnostic accuracy of a compact US device using conventional high-definition US devices as the gold standard for emergency situations in an obstetrics clinic.

Material and methods

This cross-sectional and prospective study evaluated 86 pregnant women in their first trimester who were treated at an emergency obstetric US service. This study was conducted over a period of 60 days, was approved by the Health Sciences Research Ethics Committee of the Federal University of Paraná (UFPR), and all patients included in the study signed an informed consent form.

The US examinations were initially performed using a pocket Vscan device (General Electric Vingmed Ultrasound, Horten, Norway) measuring 135 × 73 × 28 mm and weighing 390 g. The images generated had a resolution of 240 × 320 pixels, with a 75 degree field of view and a maximum depth of 25 cm. Data on the examination and diagnosis were recorded on a specific form developed for data collection. Subsequently, the same physician repeated the examination using a traditional high-resolution Voluson 730 Expert US device (General Electric Healthcare Ultrasound, Milwaukee, WI, USA) with a RAB 4–5-MHz abdominal transducer and, when necessary, a transvaginal RIC 5–9-MHz transducer. After completion of the second examination, data from the second test was recorded on the same form, and any changes in the diagnosis using the conventional apparatus were recorded. Discrepancies with regard to the identification of small haematomas, which were visualized only with the transvaginal inducer, were not considered because this information would not change clinical management.

The agreement between methods was calculated by evaluating each diagnosis using a yes/no binary system for the analysed variables and adopting a 95% confidence interval (CI) for each variable. The investigated variables, whether observed or not during the examinations, were the following: gestational sac, embryo, embryonic heartbeat, and the occurrence of uterine or ectopic pregnancy.

The examinations were performed by six different professionals classified as US specialists in obstetrics and gynaecology and/or foetal medicine from the Brazilian Federation of Gynaecology and Obstetrics (FEBRASGO) and the Brazilian Medical Association (AMB). The professionals had an average of 10 years of experience in the field and performed approximately 400 examinations per month.

Statistical analysis was performed using Excel (Microsoft Corp., Redmond, WA, USA) and SPSS for Windows (SPSS Inc., Chicago, IL, USA). Concordance was calculated using the kappa coefficient. The correlation of agreement between the tests was classified using kappa values and agreement scores as follows: <0.19, poor; 0.20–0.39, reasonable; 0.40–0.59, moderate; 0.60–0.79, good; and 0.80–1.00, excellent [15].

The time to perform the examination using portable and conventional US was compared using a paired t test. The level of statistical significance was set at p values of <0.05.

Results

This study involved 86 women in their first trimester, who were treated at an emergency obstetrics and gynaecology service in Clinics Hospital at UFPR. Obstetric complaints that led to US examination were as follows: 9 (10.4%) cases of pelvic pain; 73 (85%) cases of vaginal bleeding; 4 (4.6%) non-obstetric cases.

Among all the tests performed, no divergent results were observed when pocket US was compared with traditional US using a transabdominal probe. In 26% cases (22 patients), the diagnosis was changed after examination with traditional US and a transvaginal transducer.

In a comparative analysis between the portable and traditional US devices for viewing the gestational sac, both methods allowed gestational sac visualization in 86% cases (61 patients). The kappa coefficient for this comparison was 0.60, indicating good agreement (95% CI 0.44–0.77).

The visualization of the embryo and intrauterine gestation using both US devices was possible in 87.2%

Table I. Assessment of the correlation between pocket ultrasound and conventional ultrasound in 86 first-trimester pregnancies.

	Pocket US		**Conventional US**		**Concordance**			
	N	%	N	%	Obs.	Kappa	95% CI	
Gestational sac	63	73.3%	71	82.6%	86.0%	0.60	0.44	0.72
Embryo	48	55.8%	57	66.3%	87.2%	0.73	0.62	0.82
EHB	38	44.2%	45	52.3%	91.9%	0.84	0.76	0.89
Uterine pregnancy	62	72.1%	68	79.1%	87.2%	0.66	0.52	0.77
Ectopic pregnancy	1	1.2%	3	3.5%	95.3%	-0.02	-0.23	0.19
	Pocket US		**Conventional US**		**Difference**			
	Mean ± SD		Mean ± SD		Mean (95% CI)			p*
Time (min)	0.99 ± 0.08		5.95 ± 2.53		–4.96 (–5.5 to–4.43)			< 0.01

EHB = embryonic heartbeat; US = ultrasound; Obs. = percentage of agreement observed between the methods; SD = standard deviation; CI = confidence interval; * = p value determined using the paired t test. The reasons for performing the 86 ultrasound examinations were as follows: pain without bleeding in nine cases, bleeding with or without pain in 73 cases, and non-obstetric reasons in four cases.

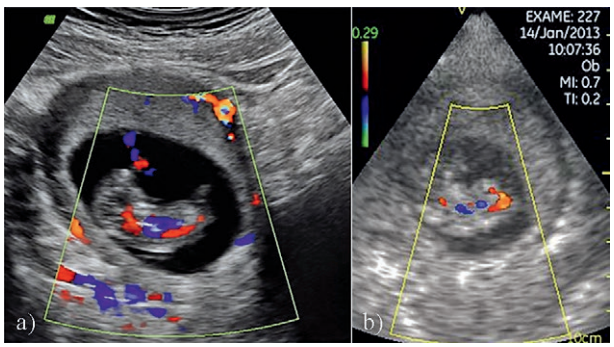

Fig 1. a) B-mode ultrasound image with colour Doppler in the sagittal plane measuring the crown–rump length of an embryo aged 9 weeks and 3 days, acquired using conventional high-resolution ultrasound; b) B-mode ultrasound image with colour Doppler in the sagittal plane measuring the crown–rump length of an embryo aged 9 weeks and 3 days, acquired using pocket ultrasound.

cases, and the agreement between the methods was classified as good (kappa and 95% CI of 0.73 and 0.62–0.82 for comparison of the embryo and 0.66 and 0.52–0.77 for comparison of intrauterine gestation, respectively) (fig 1).

The best result for the agreement between the devices was for the determination of foetal heartbeat, with a kappa index of 0.84 (95% CI 0.76–0.89). However, the US devices had a low correlation for diagnosis of ectopic pregnancy, with kappa coefficient of −0.02 (95% CI −0.23 to 0.19) (Table I).

Another parameter measured was the test duration. The mean duration for diagnosis using the traditional US device was 5.95 ± 2.53 min, which was higher than the mean duration for diagnosis of 0.99 ± 0.08 min for the portable US; the difference was statistically significant.

For cases where the embryo was visible using the pocket device, the mean crown–rump length was 20.3 mm, with a range of 3.4–71.3 mm. In contrast, for the embryos viewed only with the conventional device and an internal probe, the mean crown–rump length was 7.1 mm, with a variation between 1.8 mm and 11.2 mm.

Table II. Comparison of the variables measured using conventional ultrasound and pocket ultrasound.

Structure	**Pocket ultrasound**	**Conventional transvaginal ultrasound**
Gestational sac	10 mm	3.4 mm
Embryo	3.4 mm	1.8 mm

The mean diameter of the gestational sacs observed with the pocket US device was 24.8 mm, with a range of 10–47.7 mm. In contrast, the mean diameter of the gestational sacs observed with the transvaginal probe was 16 mm, with range of 3.4–36.8 mm (Table II).

Discussions

Most studies on the applicability of pocket US devices are limited to cardiology. These studies clearly show the value of pocket US as a method of assessing cardiac abnormalities with good agreement compared with traditional echocardiographic devices [16,17].

In a study on the use of pocket US in obstetrics and gynaecology published by a research group from the University of London, the comparison of pocket US with traditional US was stratified into three groups: bleeding and/or pain in the first trimester of pregnancy; routine obstetric examination at gestational age of >14 weeks; and gynaecological pathologies. These researchers found very good agreement in the measurement of the gestational sac diameter, crown–rump length and diameter of ovarian mass [intraclass correlation coefficient (ICC) > 0.90]. In contrast, the correlation was only moderate in the evaluation of endometrial thickness (ICC = 0.71) [18].

Pocket US may not replace conventional devices for measuring structures, but we believe it will be best applied to assist in the diagnosis, especially in emergency situations where conventional US may not be available. Above all, our goal is not to underestimate the importance that the larger US devices have on decision making when compared with portable devices. Portable devices provide real-time analysis, assisting the physician in diagnosis, procedures and patient screening, without the risk of complications or delays and without the need for a specific storage area [19].

A portable imaging device can be an essential tool in the management of patients in wards, clinics and, in particular, in emergency and delivery rooms. To this end, through this project, we aimed to compare the applicability of a portable US device and a traditional device, as a method that complements the immediate diagnosis in gynaecological and obstetric emergency units [20].

In the study conducted at the University of London, the examiner's experience had no significant impact on the degree of agreement between the results obtained with the pocket and conventional devices [18]. This result is important, considering that it can be argued that a pocket US device in inexperienced hands can cause more harm than good. Nevertheless, only a few studies are available on the learning curve of pocket devices, but several studies have shown that the learning curve for diverse situations ranges between 50 and 100 examinations [21,22]. Therefore, it is expected that user's training period will be relatively short.

The results of the study from the University of London helped elucidate the diagnosis during the comparative analysis of the pocket and conventional devices using a transabdominal transducer, considering that no disagreement was observed in any of the cases analysed. Furthermore, the final diagnosis was also consistent between the portable and conventional devices using a transvaginal transducer in 86% of the first-trimester obstetric patients [18].

In a recent study, pocket US was used in routine third-trimester obstetric US examinations on a sample of 51 women with a mean gestation age of 31 weeks and 1 day. A perfect correlation was observed between the pocket and conventional US devices for assessing foetal position, foetal bladder size and bladder visualization (kappa coefficient = 1.0), and a very good agreement was observed in the assessment of the position of the placenta (kappa coefficient = 0.86) [23].

Some factors should be considered when diagnoses were made using only the transvaginal transducer. The non-visualization of structures such as the gestational sac and ectopic pregnancy may have been affected by the presence of an empty bladder, which occurred in all of the cases when the transabdominal transducer was used, regardless of the device; this is a result of the greater proximity of the transvaginal transducer to the area being evaluated, allowing better accuracy and better image resolution. In addition, it was technically difficult to distinguish intrauterine structures in six cases where the uterus was retroverse/retroflex, and the final diagnosis was made using the transvaginal transducer and a conventional US device.

Transvaginal transducers have the benefit of being in close proximity to the structures compared with transabdominal transducers. This advantage was evident in 22 cases (26%) that could not be diagnosed using the transabdominal transducer, regardless of the US device used. The intrauterine images visualized only with the internal transducer were as follows: embryo in 12 cases (54%), evidence of embryonic cardiac activity in two cases (9%), ectopic pregnancies in two cases (9%), molar pregnancy in one case (4.5%) and gestational sac in 5 cases (22.7%). In addition, the possibility of visualizing small intrauterine structures using the pocket US device was also significant, and the smallest structure visualized and studied using this device was a 3.4-mm embryo.

The period of examination using the portable US device was shorter in all study patients when compared with the traditional device, and this is because image storage and measurements need only be made with the traditional device. However, despite the significant difference, this result may not be translated to clinical practice.

One of the limitations of this study involved the low concordance in the diagnosis of ectopic pregnancy using pocket and conventional US. An ectopic pregnancy was suspected using pocket US but was not confirmed on conventional US; in contrast, three cases of ectopic pregnancy were diagnosed on conventional US but were not visualized using pocket US. However, the few number cases of ectopic pregnancy preclude definitive conclusions. Further studies with larger number cases are necessary to prove our results.

In summary, the images acquired using the pocket US device provide enough information for making important decisions in emergency situations in obstetrics during the first trimester of pregnancy. However, in ectopic pregnancy cases the diagnosis should be realized by conventional US.

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Conflict of interest: none

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