



Modification of the hand-held Vscan ultrasound and verification of its performance for transvaginal applications

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ABSTRACT

Purpose: The purpose of this work was to validate a new clinical obstetrics and gynecology (OB-GYN) application for a hand-held ultrasound (US) device. We modified the smallest hand-held device on the market and tested the system for transvaginal (TV) use. This device was originally conceived for abdominal scanning only.

Methods: The validation involved 80 successive patients examined by the same operator: 25 obstetric and 55 gynecologic cases. US examination was performed transvaginally with two US systems: the hand-held Vscan (General Electronics; GE Vingmed Ultrasound; Norway) for which an intravaginal gadget TTGP-2010[®] (Troyano transvaginal gadget probe) was designed, and the Voluson 730 Expert (multifrequency transvaginal ultrasound of 3–9 MHz; GE Healthcare, Milwaukee, WI, USA). We performed the same measurements with both US systems in order to confirm whether or not their diagnostic capability was similar. Quantitative difference in measurements between the systems was assessed, as well as the overall diagnostic detection rate and suitability for telemedicine.

Results: Regarding lesion visibility with Vscan, optimal distance was 8–16 cm depending on the examination type, and the total detection rate was 98.7%. The exception was an ovarian endometrioma, diagnosed as a follicular cyst using the hand-held device. Assessment of reproducibility in 180 measurements showed that the measurements obtained with Vscan were 0.3–0.4 cm lower than those obtained with the high resolution US device (Voluson 730 Expert). Nevertheless, Pearson's correlation coefficient was high for biparietal diameter (0.72) and gynecological (GYN) (0.99) measurements, and for overall correlation (0.997). Image transport on USB and SD-flash cards proved convenient for telemedicine.

Conclusions: A novel TV application of a hand-held US device is demonstrated for OB-GYN. Heart, abdominal and obstetrics presets of the Vscan together with color-Doppler enable a detection capability comparable to that of a high-definition US device. The lower values of the measurements obtained by the hand-held device (by 0.3–0.4 cm) must be taken into account, although they have no effect on its diagnostic capability.

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1. Purpose

The Vscan (GE Healthcare, General Electronics; GE Vingmed Ultrasound; Norway) is a battery-operated hand-held ultrasound (US) device designed primarily for abdominal (including obstetric) and cardiac examinations by general practitioners (GPs). It was officially released in 2009, and was used at the 2010 Winter Olympics in

Vancouver for the diagnosis of musculoskeletal injuries, evaluation of cardiac flow, etc. The device is very useful, weighs 400 g, and has a 2D color-Doppler display. It is USB enabled, with 60 min of recording time and voice-recording capability. It has a fixed probe of 1.7–3.8 MHz and is designed to transmit the recorded data to a desktop device for later image analysis or to a remote telemedicine center for additional consultation, if needed [1].

Twelve leading international clinical sites have sought to determine the future impact of this device in terms of patient workflow with regard to primary care, critical care, and cardiology examinations, with the ultimate goal of developing protocols for routine Vscan examinations. Three European Union countries are partici-

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pating in this project (France, Germany, and Spain): in Spain, the Clinic Hospital in Madrid is trialing four units: two in the hospital and two in primary care units for screening purposes.

The Vscan system was made available to us for clinical testing through an initiative of the UNESCO Chair of Telemedicine Group to develop portable, easy to handle and inexpensive devices suitable for everyday healthcare and convenient for use in developing countries. Two systems (the Tele-stroke and the obstetrics-gynecology (OB-GYN) application) were discussed at a general meeting of GE personnel, eHealth-Telefonica SA (an IT company), and two universities in the Canary Islands [2]. Both of the systems that were considered have the major advantage of being hand-held devices, allowing the examination to be performed by healthcare workers with minimal training; the resulting images are sent to an expert for teleconsultation.

As indicated earlier, the Vscan system was not initially designed for trans-vaginal OB-GYN ultrasound examinations (TV-US), which are of paramount importance in the detection of embryo morphology and activity, amniotic volume, placental position, etc., as well as for first trimester pregnancy evaluation, or for uterine cervical length measurement in premature delivery and OB emergencies. In keeping with the simplicity of the system, the device is fitted with a limited range of preset parameters. The Vscan has a 3.5" screen and measurements can be performed during the examination, during image review, and before or after storage. Images are stored locally on a micro-SD card and can be viewed using Vscan Gateway[®], which can be installed on any computer. For teleconsultation purposes, the images along with measurements and voice annotation can be sent via e-mail or any other sharing protocol.

The purpose of the present study is to describe the customization of the Vscan with a specific transabdominal probe to enable its use for TV-US, (although this was not its original purpose, hence widening the probés diagnostic possibilities), to validate the initial results in 80 patients, to demonstrate its diagnostic capability *in situ* and remotely, and to confirm the agreement of measurements with those obtained using the Voluson 730-E.

2. Materials and methods

To assess the diagnostic capabilities of the Vscan *in situ* and remotely in OB-GYN applications, we first compared the accuracy of measurements and the overall diagnostic capabilities of the Vscan with those of the Voluson 730 Expert (V-730-E), a high-resolution, multi-frequency (3–9 MHz) transvaginal ultrasound device (GE Healthcare, Milwaukee, WI). Second, we designed a specific intra-vaginal gadget, the TTGP-2010[®] (Troyano transvaginal gadget probe) to attach to the Vscan. This new gadget is a 20 cm long tubular truncated cone, with a diameter comparable to that of a conventional disposable amnioscope. We opened the cone longitudinally to insert the probe's cable inside the tube and pressed the back of the probe tightly into the wider end of the cone (Fig. 1A and B).

We tested all the Vscan presets (cardiac, abdominal, and obstetrics) in combination with the modified trans-vaginal probe. We also tested Vscan color-Doppler analysis of ovarian pathologies, particularly cancer, and fetal studies (heart, aorta, umbilical cord, and other fetal vessels).

We studied 80 consecutive patients referred for TV-US for diagnosis or follow-up: 25 obstetric (11–13 weeks gestational age) and 55 gynecological patients (Table 1). The patients were initially examined with Vscan, followed by the Voluson730-E (V730-E). All examinations were carried out by the same specialist (JT) with 25 years of experience, and oral informed consent was obtained

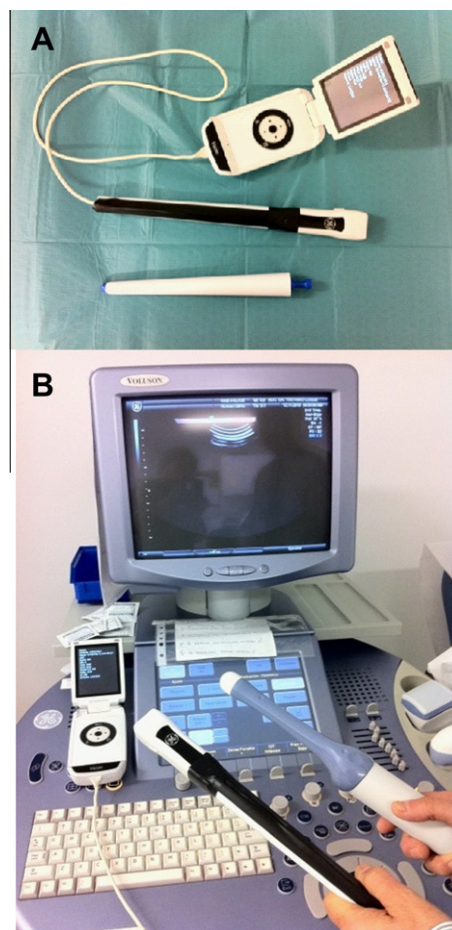


Fig. 1. Transvaginal system TTGP-2010[®] ultrasound probe mounted and connected to the hand-held US device and comparative views Vscan versus V730-E.

Table 1

Structures analyzed and number of patients tested.

Patients and structures analyzed (80)			
Obstetrics ^a	Patients (25)	Gynecology	Patients (55)
Brain plexus and ventricles	25	Myomas	17
Nasal bones	25	Endometrial polyps	11
Placenta	25	Ovarian follicles ^b	19
Funicular Doppler	19	Ovary neoplasia	4
Heart/aortic Doppler	15	Ascites	4

^a In OB-GY two cases had Nuchal Translucency (NT) o Nuchal fold scan, and in four cases the cervical length was studied.

^b One was an endometrioma.

from all patients. Approval for this study was granted by the Ethics Review Board of our institution.

We tested the diagnostic capability of Vscan's three presets (heart, obstetric, abdominal) and studied three main parameters: optimal distance (OD) for best visibility, since the probe allows us to work at different focal distances and we needed to know the best focal distance when using the new TV gadget, detection rate or lesion visibility (V) compared to the V730-E, and quantitative measurement assessment (MA). The diagnostic quality of this new examination tool in OB-GYN depends on these three basic parameters. To establish the OD, examinations started at 14 cm and the distance of best visibility was recorded, together with the type of

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