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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 Electrics; 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.

1. Purpose

The Vscan (GE Healthcare, General Electrics; 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.

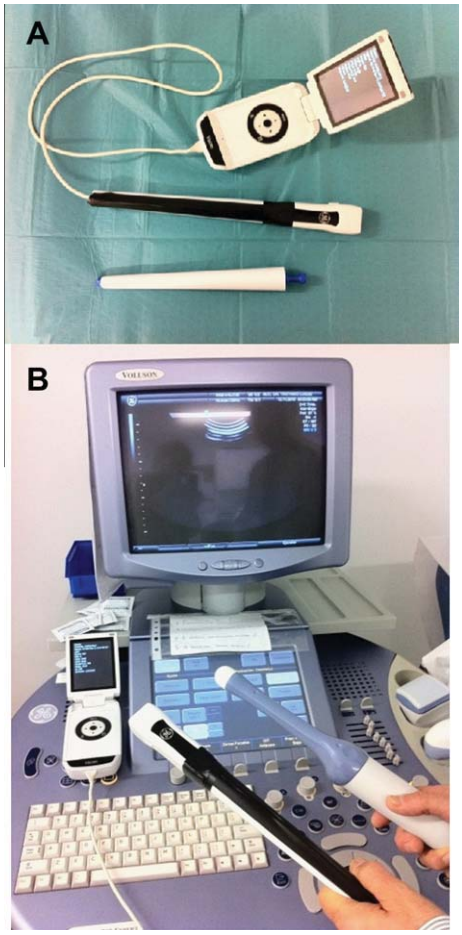

Fig. 1. Transvaginal system TTGP-2010® ultrasound probe mounted and connected to the hand-held US device and comparative views Vscan versus V730-E.

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

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.

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

Table 2
Optimal transvaginal ultrasound viewing distance (cm) and preset with Vscan for obstetrics and for each type of gynecological examination.

Obstetrics			Gynecology		
Fetal organs	Optimal distance	Optimal preset	Structure	Optimal distance	Optimal preset
Brain plexus and ventricles	14	H	Leiomyome	8	AB
Nasal bones (ocular orbits)	14	H	Endometrial	6–14	OB and H
Spine	14	H	Endometrial polyps	14	OB and H
Placenta–amniotic	14	H	Ovary follicles	14	OB and H
Aortic/cardiac Doppler	8	OB	Ovary neoplasia	14	OB and H
Funicular Doppler	8	OB	Ascites	10–12	AB

Table 3
Detection frequencies for Vscan versus V730-E.

Obstetrics ($n = 25$)			Gynecology ($n = 55$)		
Fetal organs	Vscan	V730-E	Structure	Vscan	V730-E
Brain plexus and ventricles	25	25	Leiomyoma	12	12
Nasal bones (ocular orbits)	25	25	Endometrial	16	16
Spine	25	25	Endometrial polyps	11	11
Placenta-amniotic fluid	25	25	Ovary follicles	19	18[a]
Aortic Doppler	15	15	Ovary neoplasia	4	4
Funicular Doppler	19	19	Ascites	4	4
Cardiac Doppler	15	15			

[a] One ovarian follicle detected by Vscan was diagnosed by V730-E as an endometrioma.

Table 4
Quantitative assessment of static images.

Obstetrics			Gynecology		
Anatomy (cases)	Vscan	V730-E	Lesion (cases)	Vscan	V730-E
BPD (25)	2.2 ± 0.2	2.6 ± 0.2	Myomas (12)	5.7 ± 0.9	6.1 ± 0.9
Femur length (7)	6.5 ± 0.3	6.8 ± 0.3	Polyps (11)	1.1 ± 0.3	1.5 ± 0.3
Placenta thick (25)	1.8 ± 0.3	2.1 ± 0.3	Follicles (18)	1.3 ± 0.4	1.7 ± 0.4
Cervical length (4)	3.6 ± 0.3	3.9 ± 0.3	Ovary neoplasia (4)	6.5 ± 0.9	7.4 ± 0.6

preset. The detection rate indicates both (a) the visibility (V) and diagnosis of findings with the Vscan and (b) confirmation and diagnosis with the V730-E.

To evaluate the agreement between the values obtained with the two devices, we compared the measurements (in cm) taken by the Vscan and the V730-E. The initial measurement was taken with the Vscan on a frozen image of the site or lesion (no moving images were measured), and we then used the same technique with the V730-E. In obstetric cases, we measured fetal femoral length (FL) and biparietal diameter (BPD) as well as placental thickness among others. In gynecological cases, all tumoral lesions, including functioning follicles, were measured. In total, 180 measurements were made.

To assess suitability for teleconsultation, 20 frozen images (10 GYN and 10 OB) with and without image annotation were sent by e-mail. The images were 420 by 320 pixels, 4-byte, resulting in a file size of 30–40 Kb.

The SPSS statistical program (PASW 18, IMB, Somer, NY) was used in statistical analysis of the mean and standard deviation of the measured parameters for the hand-held Vscan and V730-E devices. Data distribution was analyzed using Student's t-test.

Variability of measurements in both systems was analyzed using the linear correlation coefficient of Pearson's r, considering only high (correlation coefficient >0.7) and significant two-tailed correlations ($p < 0.01$).

We recognize that, despite the fact that many ultrasonographer physicians are readers of the Ultrasonics Journal, the great majority of its readers are non-physicians and therefore, we include a brief explanation of the terms used in Tables 1–4.

- Brain choroid plexi: double and symmetrical cerebral structures located in each cerebral hemisphere inside the lateral brain ventricles. They are responsible for the production of cerebral fluid, called cerebrospinal fluid (CSF).
- Brain ventricles: although there are four anatomic ventricles, in this paper we refer to the lateral ventricles, which correspond to the symmetrical cerebral cavities in each hemisphere, through which CSF flows. The brain plexi are located inside each brain ventricle and allow early diagnosis of an abnormal volume of such liquid (hydrocephalia).
- Nasal bones: two symmetric bones placed side by side at the middle and upper part of the face; their junction forms the "bridge" of the nose. Their absence can be an indicator for Down Syndrome, among other markers of chromosomapathy.
- Funicular Doppler: this test currently allows us to determine the velocity of the blood flow in umbilical arteries and veins.
- Aortic Doppler: this allows us to assess the arterial flow of blood coming from the left heart ventricle. The aorta carries oxygenated blood to the whole fetus.
- Myoma: benign tumor of muscular origin (the uterus has muscular tissue walls). Its presence can cause symptoms, such as genital bleeding or abdominal pain due to compression of the bowels and bladder.
- Endometrium: intrauterine tissue with cyclical changes which produce menstrual bleeding. Its main function is to serve as natural habitat and nutrition system for the embryo and fetal development.
- Endometrial polyps: usually benign tumors in the endometrium. They may cause severe hemorrhagic menstruations and they can be associated with cancer.
- Ovarian follicles: natural cystic structures, not larger than 2 cm during the woman's fertile period (14 days after menstruation). They contain a single oocyte (mature ovum or egg).
- Ovary neoplasia: ovarian cancer.
- Ascites: pathological excess of liquid in the abdominal (peritoneal) cavity.
- Amniotic fluid: natural liquid surrounding the fetus inside the uterine cavity as a natural environment for its development and protection against external factors.
- Leiomyoma: same concept as myoma (leio refers to smooth muscle tissue).
- BPD: acronym for biparietal diameter, the transverse diameter of the fetal head between the two parietal bones. It is related to gestational development.

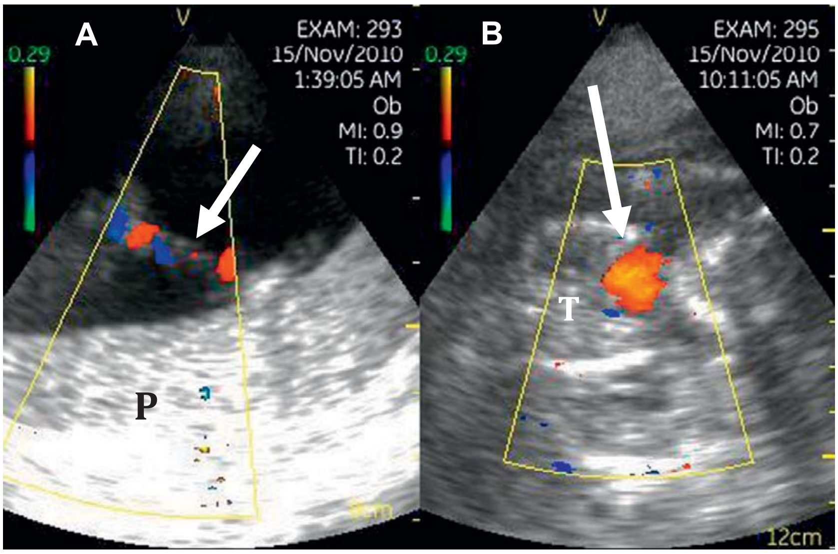

Fig. 2. (A) Transvaginal Vscan Doppler image of the umbilical cord (arrow) with the obstetrics preset. Cross-sectional image of the placenta (P). Distance is shown in centimeters in the bottom right-hand corner. (B) Transvaginal Vscan biventricular Doppler image of the fetal heart (arrow) with the obstetrics preset. Cross-sectional image of the fetal thorax (T).

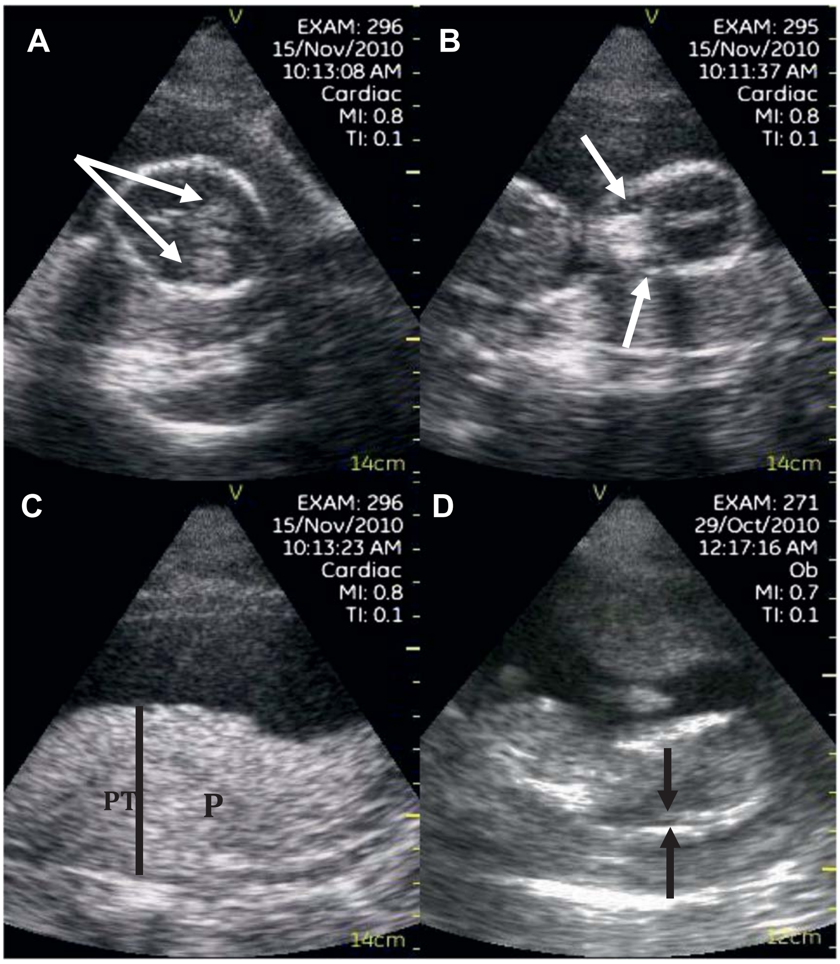

Fig. 3. (A) Transvaginal ultrasound image of fetal choroid plexus inside the fetal head (arrows), using the Heart preset. (B) Transvaginal ultrasound image of fetal facial bones, showing both eyes and nasal bones (arrows) using the Heart preset. (C) Transvaginal ultrasound image of posterior placental insertion (P), using the Heart preset and Placental Thickness (PT). (D) Transvaginal ultrasound image of fetal nuchal translucency (space between arrows), using the obstetrics preset.

- Cervical length: this corresponds to the length of the tubular portion of the uterus (the cervix) through which the fetus emerges during labor. Its normal length should not be less than 3 cm during a normal pregnancy. A shortening of this length can be an indicator of preterm labor or a miscarriage. Transvaginal ultrasound is a fundamental procedure for its early diagnosis.
- Endometrioma: this is a gynecological medical condition in which cells from the lining of the uterus (endometrium) appear and flourish outside the uterine cavity, most commonly in the ovaries, which is the case in this study.

3. Results

3.1. Optimal distance (OD) for diagnostic visibility

The diagnostic capability of the three presets (heart, obstetric, abdominal) was tested in all patients. Visibility rates were similar between the heart (cardiac) and obstetric presets (Figs. 2A and B and 3A–D).

As shown in Table 2, optimal visibility distance was 8–16 cm: 14–16 cm for TV-US in the first trimester of pregnancy, 8–12 cm for umbilical cord and fetal Doppler eco-cardiography, and 12–14 cm for gynecological examinations (both uterine and adnexal images, including color Doppler).

Nuchal Translucency (NT) is a prenatal general marker for chromosomopathies, especially Down Syndrome, during the first trimester of pregnancy (11–14 weeks), as well as a non-specific marker for other malformation diseases such as congenital heart malformation. In our study, NT was detected in two pregnancies at OD of 12 cm with the OB preset (Fig. 3D). This shows that the Vscan enables the detection of this important marker when using it transvaginally. In four measurements of uterine cervical length, the OD was 14 cm, also with the OB preset. The shortening of cervical length establishes the risk of premature labor, and its measurement helps us prevent it through medical treatment. In one patient, an intrauterine device (IUD) was seen at OD of 14 cm with the Heart preset (Fig. 4A).

3.2. Detection rate

As shown in Table 3, in all cases, lesions detected with the Vscan were seen with the V730-E and vice versa (Fig. 4A–D), with the exception of one ovarian endometrioma which was misdiagnosed by Vscan as a follicular cyst (ovulatory cyst). The detection rate was 98.75% (79/80), which turns out to be exceptional, given that the ICC (Intraclass Correlation Coefficient) for V730-E is 0.91.

3.3. Quantitative assessment

Measurements (in cm) of the obstetric and gynecological cases are listed in Table 4. In two patients, NT thickness was measured as 0.19 ± 0.01 with Vscan and as 0.22 ± 0.02 with V730-E. All

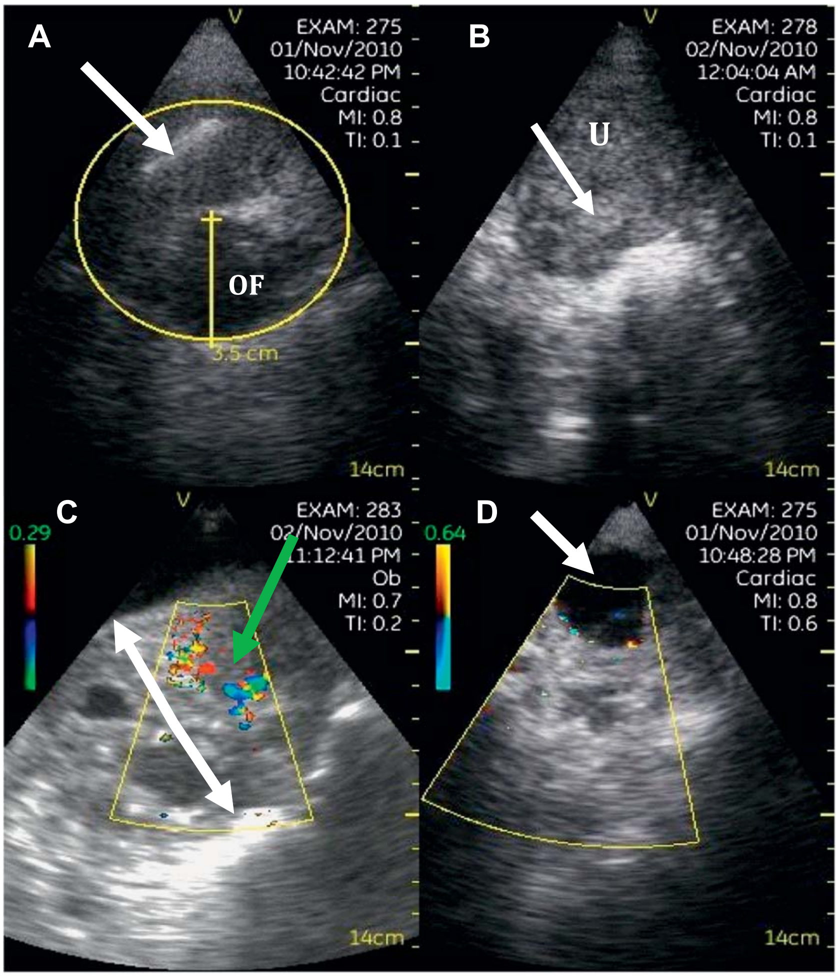

Fig. 4. (A) Transvaginal ultrasound linear image of an intrauterine device (IUD) (arrow) and ovarian follicle (OF), using the Heart preset. (B) Transvaginal ultrasound image of an endometrial polyp (arrow) inside the uterus (U), using the Heart preset. (C) Transvaginal ultrasound image of ovary neoplasia (white arrow) and color Doppler (green arrow) indicating tumoral vascularization, using the obstetrics preset. (D) Transvaginal ultrasound image of a functioning follicle (arrow), using the Heart preset.

measurements by Vscan were on average 0.3–0.4 cm lower than those by V730-E. In all measurements, Student's *t*-test (two-tailed) showed significant difference between the two sets of measurements ($p < 0.001$), except in groups with a low (<3) number of cases ($p < 0.05$). Pearson's correlation coefficient for Vscan versus V-780-E measurements was 0.74 for BPD, 0.92 for placental thickness, 0.97 for follicles, 0.99 for myomas, and 0.99 for polyps ($p < 0.001$). Correlation was not statistically significant in groups with few patients (<3). Considering all measurements as a pool (180 measurements), Pearson's r was 0.997 ($p < 0.0001$).

The 20 cases sent for remote evaluation showed no image deterioration, and visibility was identical to that observed locally. The average time taken to send images was 40 s.

4. Discussion

The purpose of the present study was to validate the suitability of a hand-held US device, originally conceived for transabdominal use, and widening its possibilities through transvaginal application, for a range of clinical examinations. We focused on OB–GYN transvaginal indications in a training set of 80 patients to demonstrate the suitability of the device for lesion detection, after customizing the system using an add-on vaginal insertion device to hold the probe. The values obtained with the Vscan were slightly lower than those obtained with a high-resolution US device (V730-E), although this fact is diagnostically irrelevant.

We chose Vscan from among the existing hand-held devices on the market for several reasons: it has the smallest size, a recording time of 60 min (which is enough for OB–GYN examinations), it enables color Doppler at 30°, and has a 1.7–3.8 MHz cardiac probe and a head 2.6 cm wide. It also enables connection by USB or micro-SD flash card to a desktop PC, to send the acquired images for teleconsultation, which is of paramount importance considering that most exploratory procedures with hand-held devices will be done by GPs at home, in primary care, or in emergency rooms, and that image interpretation will require the expertise of a geographically distant trained specialist. In many of the circumstances listed above, large US devices cannot be used. For this reason, hand-held devices will progressively take the place of larger devices, provided that their diagnostic capabilities are similar.

We compared the Vscan with a versatile high-resolution US scanner (V730-E) that has high diagnostic sensitivity, with measurements yielding a mean error (ME) of 0.126 ± 0.08 cm [3]. The present results show that the Vscan hand-held device has a similar detection rate but gives slightly lower values than high-resolution ultrasound scans [4], without affecting diagnostic capability. Detection rate of the Vscan was excellent for OB-GYN; specifically, its color Doppler facility can be used to evaluate ovarian tumour vascularization as well as umbilical cord, and it performs as well as any high-resolution US device in detecting embryocardiac activity. Considering the results obtained, the device is affordable for developing countries, and it is suitable for use in military zones. An initial disadvantage for OB–GYN was the size of the probe, which was not suitable for intravaginal explorations due to its short length (12 cm) and wide head (0.5 cm wider than most intravaginal probes) [4]. This problem was overcome with the TTGP-2010® add-onto lengthen the probe.

Compared with the ability of high-resolution US devices that change parameters dynamically, hand-held US devices are much more restricted. Nevertheless, the Vscan has built-in presets for various applications (abdominal, cardiac, and OB-GYN). The high diagnostic capability of the Vscan (98.75%) is linked to the versatility of the various presets, and particularly to the provision of color Doppler, which is of paramount importance for evaluating the hemodynamic status of the lesion under study [5]. In all lesions observed in the present study, at least one of the presets was useful for diagnosis. The usefulness of the Vscan is reinforced by its versatility in enabling recorded images to be studied using image-processing programs on a computer, and enabling images to be sent for teleconsultation, because the diagnostic capability will be increased by interpretation by an expert.

The introduction of 3D-probes will greatly improve hand-held devices used for telemedicine applications [5] because they will enable the creation of virtual sonography [6–9] in which any non-expert sonographer could record images that would have diagnostic validity in the hands of an expert, whether local or distant [6,10,11].

5. Conclusions

The present paper reports on the usefulness of a novel application of TV–US OB–GYN using the Vscan, the smallest currently available hand-held US device, after our specific adaption of the device for TV use.

The diagnostic capability and accuracy of measurements were validated in an initial training set of 80 patients, with images for 20 of the patients being assessed at a distance by telemedicine.

The optimal focal distance for diagnostic visibility ranged from 8 to 16 cm, and attained a total detection rate of 98.7%. Compared with high-resolution US devices, the values obtained were lower (0.3–0.4 cm).

Images were transferred to a computer via USB or SD-flash cards and the system easily enabled remote teleconsultation.

The use of such device enhances the diagnostic possibilities in isolated areas and developing countries. It also implies new possibilities for transvaginal application, for which it was not originally conceived, as well as its usual use in emergency medicine.

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