Novel Application of the Hand-Held Ultra Sound devices in OB-GYN

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***Abstract*—The purpose of the study is to validate a new clinical OB-GYN application for hand-held Ultrasound devices. The system tested was the smallest had-held device in the market with a fixed probe of 1.7-3.8MHz, and color-Doppler facilities that was modified during the study to be use intravaginally.**

The training set were 80 successive patients examined by the same gynecologist: 25 were obstetric and 55 gynecologic. The ultrasound (US) examination was carried out transvaginally with two systems: a) A hand-held US device, the Vscan on which an intravaginal gadget was designed and b) the Voluson 730 Expert both from GE (General Electrics). Diagnostic suitability was carried out with the assessment of the measurements precision and the overall diagnostic detection rate as well as their suitability for teleconsultation. Reproducibility of quantitative measurements made by different systems was carried out with the Pearson correlation coefficient.

Lesion visibility was found to an Optimal Distance between 8-16 cm depending on the examination and a total Detection Rate of 98.7%. The exception was an ovarian endometrioma diagnosed as a follicular cyst with hand-held device. Assessment of the180 measures reproducibility demonstrated a lower calibration in the hand-held device (0.3-0.4 cm) comparing with high resolution devices. Nevertheless, the Pearson correlation was high from 0.72 in Biparietal diameter measures up to a 0.99 in GYN measures, and 0.997 overall correlation. Image transport through USB and SD-flash cards have been proven very convenience in teleconsultations.

A novel TV application of hand-held US devices in OB-GYN has been demonstrated. Detection capability was comparable to high definition US devices, due to the existing heart, abdominal and obstetrics presets together with color-Doppler. Calibration need to be improved since measurements were 0.3-0.4 cm lower.

***Index Terms*— Hand-held Ultrasound. Transvaginal Ultrasound. OB-GYN. Telemedicine. Teleultrasound. Virtual sonography**

***Resumen*-El objetivo del estudio es validar una nueva aplicación de OB-GYN para dispositivos de ultrasonido portátiles. Se testeo el sistema más pequeño que hay en el mercado con una sonda fija de 1.7-3.8MHz y Doppler color al que se le añadió un dispositivo que permite en analisis intravaginal. El sistema se comprobó en 80 pacientes consecutivos examinados por el mismo ginecólogo: 25 de obstetricia y 55 de ginecología. Se compararon: Un dispositivo manual, el Vscan y el Volusion-730E de GE (General Electric). Se analizaron la precisión y la tasa general de detección diagnóstica, así como su idoneidad para la teleconsulta.**

La visibilidad se encontró a una distancia óptima entre 8-16 cm, con tasa de detección total de 98,7%. La reproducibilidad de las medidas mostró un calibrado menor en el dispositivo de mano (0.3-0.4 cm) en comparación con dispositivos de alta resolución. Sin embargo, la correlación de Pearson fue de alta La aplicación es totalmente nueva para dispositivos manuales portátiles.

***Índice de Términos*- ultrasonido de mano . Ultrasonido transvaginal. OB-GYN, Telemedicina. Teleultrasonido. Ecografía virtual**

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I. INTRODUCTION

THE Vscan (GE Healthcare) is a hand-held US device design particularly for GPs (General Practitioners) for abdominal (including obstetrics) and cardiac examinations. Presented officially in 2009, was used in the Vancouver Olympic Games. The device is very versatile, weight 400 g. and display 2D color-Doppler. The device is USB, with 60 minutes of autonomy and voice recording capabilities. It has a fix probe of 1.7-3.8MHz MHz and is capable of transmitting the recorded data to a desktop device for future image analysis or distant telemedicine consultation[1].

At the present moment 12 leading clinical sites throughout the world are working to determine what will be the impact in patients workflow, focusing in primary care, critical care and cardiology examinations. The ultimate goal is to develop a structural protocol for Vscan exams. In the European Union, 3 countries are participating (France-Germany-Spain) and in Spain the Clinic Hospital in Madrid is using 4 units 2 in the hospital and 2 in the primary care units for screening purposes.

Due to the interest of the UNESCO Chair of Telemedicine group to find portable, easy to handled and costless devices for everyday healthcare, capable to be used in developing countries, the Vscan system was available to us for clinical testing. Two main applications were discussed in a general meeting involving GE personnel together with eHealth-Telefónica and the two Universities of Canary Islands[2]. One was the tele-stroke and the second one was the OB-GYN (obstetrics-gynecology) application. In both cases one of the major advantages of the hand-held devices is that examination can be carried out by less expert healthcare workers and sent images for teleconsultation to more expert ones.

Unfortunately the system was not initially designed for trans-vaginal OB-GYN ultrasound examinations (TV-US) of

paramount importance in morphological detection as well as for the first trimester pregnancy evaluation, or for cervical lengh measurement in premature delivery and OB-accidents. Furthermore, the systems in order to be maintained simple do not allow much parameter set, coming with predetermined presets as can be seen in Table I.

The present paper is devoted to build in the Vscan a specific probe suitable for TV-US as well as to validate the initial results with 80 patients, comparing the diagnostic capability in situ and at distance, together with the accuracy of measurements.

TABLE I VSCAN PRESETS		
PRESETS		**Organs to be directed**
1	HEART (H-Pre)	Heart/ Aorta
		Thorax movements
2	ABDOMINAL (AB-Pre)	Liver/ Gall-bladder
		Urology/ Kidney
		Spleen
3	OBSTETRICS (OB-Pre)	Fetal

Table 1. Presets integrated in the Vscan and tested in the paper

II. Material and Methods

The Vscan has a 3.5" screen and allows to measure during the exploration, during the image review, before or after storage. Images stored locally in a micro-SD card can be reviewed with the Vscan Gateway® installed in any computer. For teleconsultation purpose those images together with measurements and voice annotation can be sent via e-mail or any other sharing process.

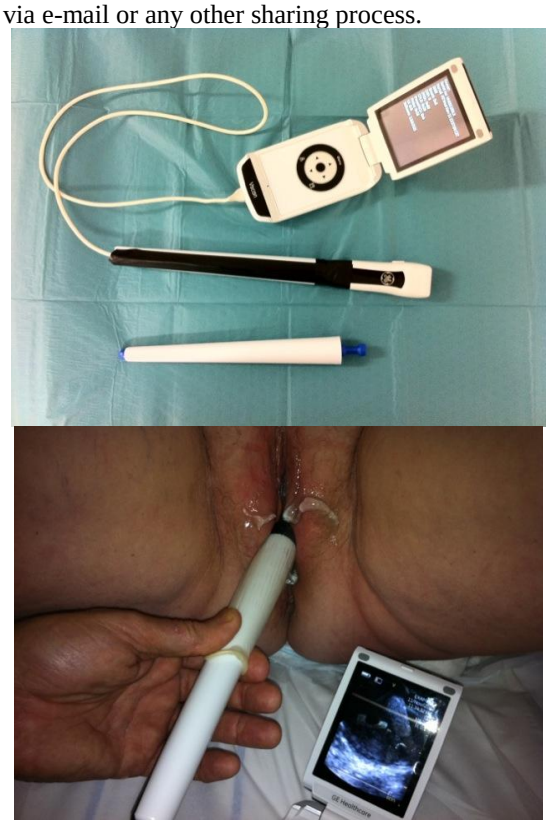

Figure 1. Hand-held-US device with an adapted trans-vaginal probe.

To assess Vscan diagnostic capabilities in situ and at distance in OB-GYN applications:

1. We compared the accuracy of measurements and the overall diagnostic capabilities comparing with a high resolution US device from the GE Healthcare, the VOLUSON 730 Expert (V-730-E).
2. We designed a specific intra-vaginal probe (See Figure 1) by adapting a disposable amnioscope (PRIM S.A Madrid Spain) to the end of the Vscan probe.
3. We tested the Vscan presets: Cardiac, Abdominal, and Obstetrics all of them used trans-vaginally
4. We tested the Vscan Color-Doppler analysis in adnexal pathology, particularly neoplasias and fetal studies (heart, aorta, funicular or other fetal vessels)

In the present study 80 successive patients submitted for diagnosis or follow up to a TV-US, were initially studied with Vscan followed by a Voluson-730-Expert® V-730-E (GE Iberica. Spain). They were integrated by 25 OB and 55 GYN patients (see studied cases in Table II). All examinations were carried out by the same specialist (JMTL) with 25 years of experience.

TABLE II PATIENTS & STRUCTURES ANALYZED (80)			
OBSTETRICS*	**Patients (25)**	**GYNECOLOGY**	**Patients (55)**
Brain plexus &ventricles	25	Myomas	17
Facial Bones	25	Endometrial Polyps	11
Placenta	25	Ovarian Follicules**	19
Funicular Doppler	19	Ovarian Neoplasia	4
Heart / Aortic Doppler	15	Ascitis	4

Table 2. Number of patients tested. * In OB-GY two cases had Nuchal Translucency (NT) o Nuchal fold scan, and in 4 cases the cervical length was studied. ** One was an endometrioma.

We tested the diagnostic capability of three presets (heart, obstetric, abdominal). Three main items were studied: Optimal distance (OD) for better visibility, detection rate or lesion visibility (V) and quantitative measure assessment (MA).

- To establish the OD, examinations started at 14 cm recording the point of better visibility together with the type of preset.
- The detection rate implies the visibility (V) and diagnosis of findings with the Vscan and the confirmation and diagnosis with the V-730-E.
- To assess the accuracy of the measurements we measure to the precision of cm. The initial measurement is done with the Vscan after taken a frozen image of the site or of the lesion (no moving images were measured) this was followed by a measurement with the same technique with the V-730-E device. In obstetrics we measured Femoral length and Biparietal diameter (BPD) as well as Placental Thickness. In gynecology, all tumor lesions including functioning follicles were measured. Total number of measurements was 180.

- To assess the suitability for teleconsultation, 20 frozen images (10 GYN-10 OB) with and without marks were sent by e-mail. Images were of 420x320 pixels and were stored with 4 bytes, resulting in 30-40 Kb images.

Statistical analysis was carried out with the SPSS statistic program (now called PASW version 18) with the mean and standard deviation of the measured parameters in the hand-held Vscan and V-730-E devices. Data distribution was analized with the Student t-test.

Assessment of measurement variability in both systems was analyzed with the linear correlation coefficient or Pearson r, considering only high (over 0.7) and significant two tail correlations ($p<0.01$).

III. RESULTS

A. *Optimal distance (OD) for diagnostic visibility*

The diagnostic capability three presets (heart, obstetric, abdominal) were tested with all cases.

Although the visibility rate was comparable, the "solid" cases were better seen with the abdominal-preset and "liquid" cases with the heart-preset (see Figure 2 & 3).

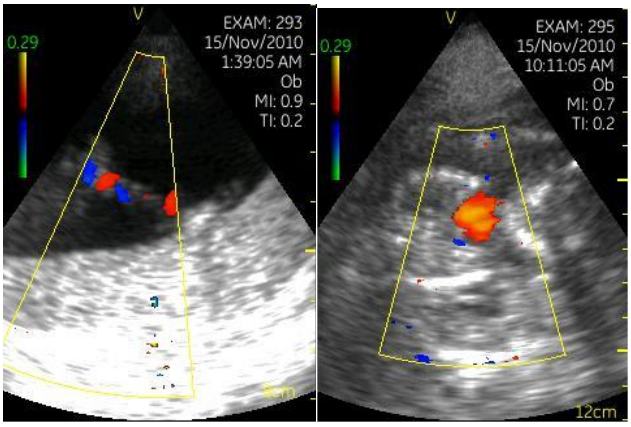

Figure 2. Funicular Doppler and biventricular Doppler. with an OB-Preset. Distance in the corner

B. *Detection rate*

As can be seen in Table IV, all cases lesions detected with Vscan were seen with V-739-E and vice versa, with the exception of one adnexal endometrioma that was misdiagnosed in the Vscan as a follicular cyst. Detection rate 79/80 (98.75%)

TABLE III
Optimal TV-US distance (cm) with the V-scan

OBSTETRICS		
Fetal organs	**Optimal Distance**	**Optimal Preset**
Brain plexus & ventricles	14	H
Face Bones(Ocular)	14	H
Spine	14	H
Placenta-Amniotic.	14	H
Aortic/cardiac Doppler	8	OB
Funicular Doppler	8	OB
GYNECOLOGY		
Structure	**Optimal distance**	**Optimal Preset**
Leiomyome	8	AB
Endometrial	6-14	OB & H
End. Polyps	14	OB & H
Ovary Follicules	14	OB & H
Ovary Neoplasia	14	OB & H
Ascitis	10-12	AB

Table 3. Optimal distance and presets Presets: H-Heart preset, AB-Abdominal, OB-Obstetric.

As can be analyzed in Table III, the visibility distance was established between 8 and 16 cm, being 14-16 cm for the TV-US of the first trimester pregnancy, 8-12 cm for the funicular and fetal Doppler eco-cardio and 12-14 cm for GYN- examinations either uterine, adnexal including color-Doppler.

Two pregnancies were Nuchal Translucency (NT) at an OD of 12 cm with the OB-Preset (see Figure 3), and four cases of cervix-length measurements the OD was 14 cm also with OB-Preset. One case of IUD (Intra uterine dispositive) was seen at an OD of 14 cm with the Heart- preset (see Figure 4A)

TABLE IV
Detection Rate of Vscan versus E-730-E

OBSTETRICS (n=25)		
Fetal organs	**VSCAN**	**V-730-E**
Brain plexus &ventricles	25	25
Facial Bones(Ocular)	25	25
Spine	25	5
Placenta-Amniotic Fluid.	25	25
Aortic Doppler	15	15
Funicular Doppler	19	19
Cardiac Doppler	15	15
GYNECOLOGY(n=55)		
Structure	**VSCAN**	**V-730-E**
Leiomyome	12	12
Endometrial	16	16
Endometrial Polyps	11	11
Ovary Follicles	19	18*
Ovary Neoplasia	4	4
Ascitis	4	4

Table 4. Lesion visibility (V). * One Ovarian Follicle detected by Vscan was diagnosed by V-730-E as an endometrioma

A. *Quantitative assessment*

The measurements in cm of the obstetrics and gynecology cases can be studied in Table V. In two cases the TN thickness was measured obtaining 0.19±0.01 with Vscan and 0.22±0.02 for V-730-E.

In all cases measures carried out with V-730-E showed higher values then those with the Vscan, that had an average of 0.3-0.4 cm less. In all measurements, Student t-Test was significant in two tails with a $p< 0.001$, except in those cases containing few cases where the p was <0.05.

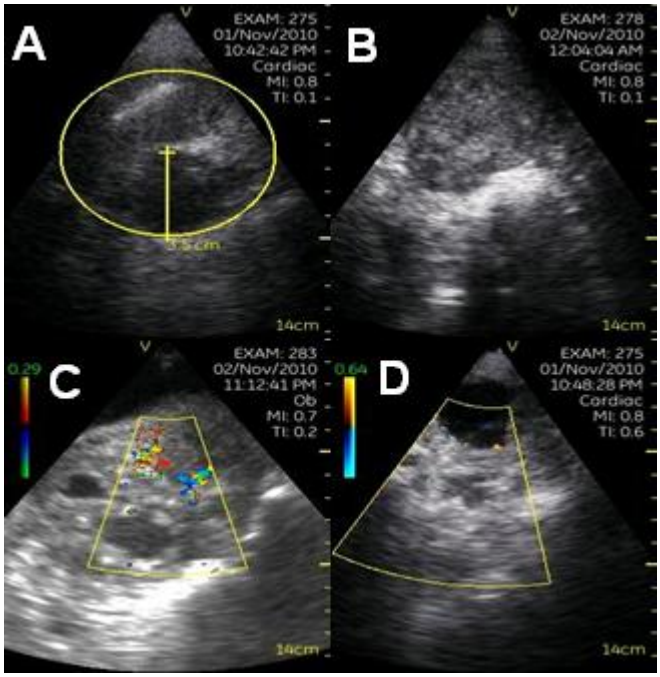

Figure 3. Choroid plexus (A), facial bones (B), posterior placenta insertion (C) and NT (D) in a TV-US. H-Preset. Distance in the corner.

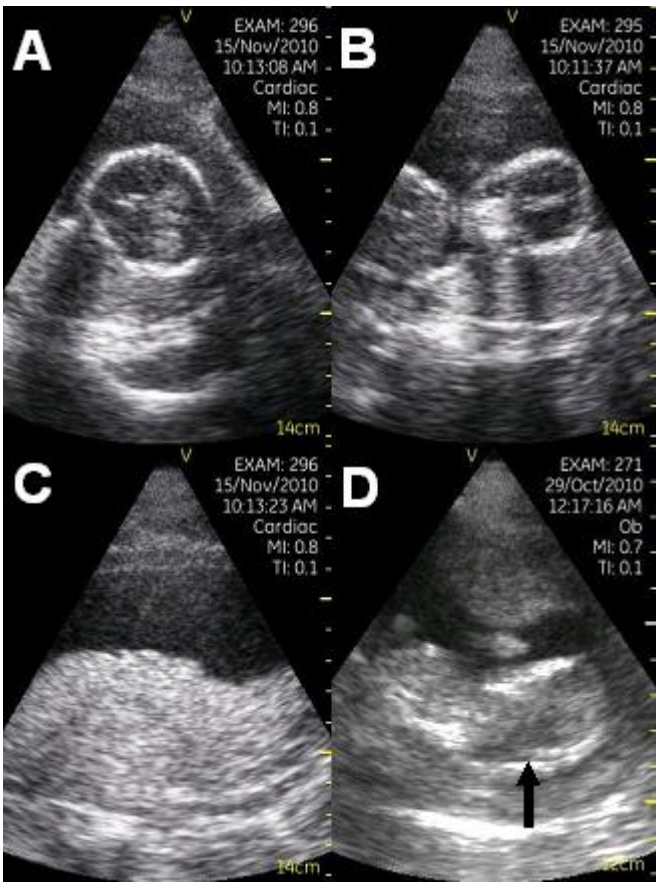

Figure 4. (A) IUD Arrow) and a Follicle, (B) Endometrial Polyp (arrow) (C) Ovarian Neoplasia and (D) functioning follicle. H-Preset

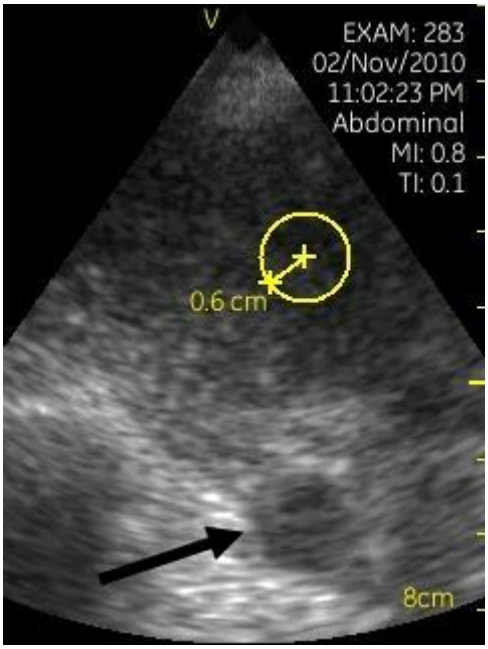

Figure 5. Small subserosal myoma (arrow). The circle is the endometrial section. AB-Preset.

TABLE V Quantitative assessment (cm)		
OBSTETRICS		
Anatomy(cases)	**Vscan**	**V-730-E**
BPD (25)	2.2±0.2	2.6±0.2
Femur Lenght (7)	6.5±0.3	6.8±0.3
Placenta Thick(25)	1.8±0.3	2.1±0.3
Cervical Length (4)	3.6±0.3	3.9±0.3
GYNECOLOGY		
Lesion(cases)	**Vscan**	**V-730-E**
Myomas(12)	5.7±0.9	6.1±0.9
Polyps (11)	1.1±0.3	1.5±0.3
Follicules(18)	1.3±0.4	1.7±0.4
Ov Neoplasia(4)	6.5±0.9	7.4±0.6

Table 5. Quantitative assessment of static image measurements.

The Pearson correlation between measurements of Vscan versus V-780-E were 0.74 in BPD, 0.92 in Placental thickness, 0.97 in Follicles, 0.99 in the Myomas, 0.99 in the Polyps, with a $p< 0.001$. Correlation did not achieved the statistical significances in the groups containing a low number of cases. Considering all measurements as a pool (108 cases) Pearson r was 0.997 with a $p<0.0001$.

The 20 cases sent for evaluation at distance showed no image deterioration, and identical visibility than locally. The average sending time was 40 seconds.

IV. Discussion

The purpose of the paper is to validate the suitability of US-hand held devices in the majority of clinical examinations. This paper is focused in the OB-GYN transvaginal indications in a training set with 80 patients demonstrating its suitability for detection provided that an add-on system to elongate the size of the probe is built in. Nevertheless obtained measurements were lower than high resolution US, indicating that re-calibration is essential.

We have primarily chosen Vscan from the hand held devices existing in the market for several reasons: It is the smallest one, has 60 minutes autonomy enough for OB-GYN examinations, it allows color Doppler at 30 degrees and its cardiac probe is from 1.7 to 3.8 MHz and has a head 2.6 cm wide. Furthermore, allows connecting USB or its micro-SD flash card to a desktop to send acquired images for distance teleconsultation. The later of paramount importance considering that most exploratory procedures with hand-held devices will be done at home, in primary care or in emergency rooms by GPs that require distance advice of a trained specialist, much less in number. In many of those circumstances big devices even on-wheel devices cannot be used, for that reason hand-held devices will be progressively taken its place, provided that diagnostic capabilities are similar.

Comparison was carried out with a high resolution ecography, a very versatile technique with a high diagnostic sensitivity for which accuracy of measurements has been established with an Error Mean (EM) of 0.126+/-0.08 cm [3.]. Our results demonstrated that for transvaginal explorations the VSCAN hand held device has similar detection rate but less accuracy of measurement than high resolution ecography [4.]. Detectability have been excellent in OB-GYN particularly for its color-Doppler facilities, that allow to be used with tumour pathology as well as in funicular and embriocardic activity as any high resolution US-device.

Provided it robustness (measurement accuracy have to be improved) the price of the device make hand-held US affordable to developing countries and easy to use in battle areas. An initial disadvantage in OB-GYN was the size of the probe, not suitable for intravaginal explorations due to its short length (12 cm) and wide head (0.5 cm bigger than usual intravaginal probes) [4.]. To overcome the problem, we added a tubular hand-holder-device integrated by a aseptic, spare, plastic part of an amnioscope. Tip was fixed by pressing and the cable of the probe was taken at the opposite site as seen in the figure 1. With that system the length of the transvaginal probes was achieved.

In contrast with a high resolution US-devices capable to dynamically change parameters, hand held US devices are very limited. Nevertheless, the Vscan have built-on presets for different applications (abdominal, cardiac and OB-GYN). According to our opinion, the high diagnostic capability is linked to the versatility of the various presets and particularly to the color-doppler that provide an aid of paramount importance to detect physical conditions of the lesion under study [5.]. In all the studied lesions at least one preset is provided useful for diagnosis.

The versatility of the device to bring recorded images to a computer to be seen with image-processing systems or to be sent for teleconsultation reinforce its suitability, since visibility will be increased consulting an expert.

A great improvement in the hand-held devices for telemedicine applications will be the introduction of 3D-probes [5.], to allow building virtual sonographies [6.][7.][8.][9.] that assure that any non-expert sonographer could record images that can be of diagnostic capability in the hands of an expert located closely or at distance[7.].

V. Summary

The present paper is devoted to show the adequacy of a novel application of TV-US OB-GYN using the smallest hand-held US device, the Vscan, after building a specific adaptive gadget for TV use. Diagnostic capability and measurements accuracy were validated in an initial training set of 80 patients, 20 of which were also tested at distance.

Diagnostic visibility was found at an Optimal Distance-OD from 8 to 16 cm reaching a total Detection Rate-DR of 98.7%. Compared with high resolution US devices calibration was lower (0.3-0.4 cm).

Images were transported to a computer either through USB or SD-flash cards providing a very comfortable system for e-mail teleconsultation.

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