The standardization of ultrasound examination of the female pelvic organs

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AUTHORS' CONTRIBUTION: (A) Study Design \cdot (B) Data Collection \cdot (C) Statistical Analysis \cdot (D) Data Interpretation \cdot (E) Manuscript Preparation \cdot (F) Literature Search \cdot (G) Funds Collection

The results of ultrasound examination of the pelvic organs in practically healthy women of the child-bearing age (18-45 years old), conducted with GE Healthcare (Austria) and Philips (Netherlands) high-end ultrasound systems by one doctor, were compared. In each group, there were 30 patients (15 women in the first and second phases of the menstrual cycle) with no statistical differences in their age (p > 0.05). Organ measurements (volume of the uterine body, thickness of the endometrium, volume of the ovaries), Doppler blood flow parameters in the uterine arteries, such as the maximum systolic flow (Vmax) and average flow velocity, (Vmean), the diameter of the uterine arteries, the arterial perfusion index (API), the 3D reconstruction of the uterus, the vascularization index (VI), the flow index (FI), and the vascularization-flow index (VFI) of the uterus and endometrium were obtained in the color flow and power Doppler modes. It was revealed that the VI, FI and VFI indices calculated with the GE device are significantly higher than those obtained with the Philips ultrasound system (p < 0.05). There were no differences in organ measurements, Doppler measurements of the uterine arteries and API (p > 0.05).

Key words: ultrasound; Doppler ultrasound; vascularization index (VI); flow index (FI); vascularization-flow index (VFI)

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INTRODUCTION

A lot of attention has been drawn to the issue of standardization of ultrasound examinations. Protocols are being developed in different directions, which include mandatory items of quantitative parameters [1–3]. To improve the quality of ultrasound in obstetrics, the translation of the recommendations of the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) are posted on the website of the Russian Association of Ultrasound in Medicine (RASUDM) [4].

Ultrasonography is an operator-dependent method, which means that the evaluation of structure, echogenicity and various acoustic effects is associated with experience and psychophysiological features of the examiner, his or her professional training, including clinical. Any violation of the examination methodology may affect organ measurement accuracy, including the measurement of pathological lesions.

Ultrasonography is not only an operatordependent method, but it is also device-dependent. Not only does it result from the fact that devices of different manufacturers and various devices of the same manufacturer can be equipped with different options, but also from the fact that the same modes can have different parameters, indicating both a pathology and a normal situation. For example, shear wave elastography, which is currently being actively developed, has significantly different values in ultrasound systems of different companies, which requires the development of regulatory parameters for each manufacturer. The recommendations on the use of shear wave elastography in liver pathology, published on the RASUDM website [5], are of great help to practitioners [5]. These features justify the need for standardization of ultrasound examinations. When introducing new methods, its informative value is estimated with well-known methods of verification. However, in our country, there have been no studies comparing data obtained with ultrasound scanners of different manufacturers.

AIM

The aim of the study was to compare the results of US scans of the female pelvic organs conducted in healthy women using Philips and GE Healthcare ultrasound systems.

MATERIALS AND METHODS

Ultrasound examination of the pelvic organs was performed in 60 practically healthy patients of child-bearing age (18–45 years). There were no gynecological complaints in this group of patients. The duration of the menstrual cycle was from 26 to 30 (28.1 + 0.8) days, with menstruation lasting 3–6 (4.2 + 0.7) days and being moderately abundant and painless. Thirty-seven patients had a history of delivery (61.7%), 22 had abortions (36.7%), and 9 had miscarriages (15.0%). Bimanual clinical examination did not reveal any pathology of the pelvic organs. Laboratory examination of the cervical canal and vagina was within the normal range. Ultrasound examination of the female pelvic organs was carried out using highend systems: Voluson E8 (GE Healthcare, Austria) and IU22 (Philips, the Netherlands) by the same doctor.

The patients underwent a review transabdominal scan and a subsequent transvaginal examination with appropriate multi-frequency probes. The uterine body volume, endometrial thickness and ovarian volume were measured. The volume of the uterus and ovaries was calculated using the formula: $A \times B \times C \times 0.523$, where A = length, B = thickness, C = width, 0.523 = coefficient. This formula is incorporated into the software of both devices and automatically gets into the report, which is displayed on the monitor to fill in the examination report.

The quantitative assessment of organ vascularization included the vascularization index (VI), which characterizes the percentage of



Fig. 1. The QLab option to obtain VI, FI and Fi of the uterus



Fig. 2. The QLab option to obtain VI, FI and FI of the endometrium

color voxels in the volume of the uterine body and endometrium; the flow index (FI), or the intensity of blood flow, showing the median brightness of color voxels, which depends on the blood flow rate in a given three-dimensional volume; and the vascularization-flow index (VFI), which is a product of the vascularization index and flow index, divided by 100 [6]. These



Fig. 5. The measurement of the diameter of the uterine artery



indices were obtained owing to special software application utilizing 3D-rendering with color flow mapping in the QLab application (Philips) or 3D and power Doppler in the VOCAL application (GE). The image size was adjusted so that the uterus occupied almost the entire area of the display, and for the endometrium, the outer contour of the uterus went beyond the screen. The speed scale was set to 3 cm/s (QLab) or PRF of 0.6 kHz (VOCAL), and the power of color mapping was set at the maximum value, but before the appearance of acoustic noise. The angle of 3D object construction was set at 850 (Lab) or 1200 (VOCAL) so that the entire uterus was included to the region of interest.

Manual tracing of the outline of the uterus was conducted on 10 planes in the QLab application. VI, FI and VFI were calculated automatically by the software, with the values displayed on the monitor (Fig. 1). These indices were obtained in the same way in the endometrium (Fig. 2). In the VOCAL application, manual contouring of the uterus and endometrium was conducted with increments of 300 for the uterus and 150 for the endometrium relative to the axis passing through the center of the organ. Digital values of VI, FI and VFI appear on the monitor after finishing the contouring (Fig. 3, 4).

The next step was to assess the hemodynamics of the uterus considering both uterine arteries. The uterine arteries were found on the lateral surfaces of the uterus, from the isthmus to the tubal angle. Subsequently, their diameters were measured in the most rectilinear area with a large zooming in the area of interest along the color contour perpendicular to the axis of the vessel (Fig. 5). We took into account not only whole millimeters, but also tenths of a millimeter.

In pulsed-wave Doppler examination of the uterine artery, maximum blood flow velocity (Vmax) (cm/s), time-averaged mean blood flow velocity (Vmean) (cm/s), pulsatility index (PI) and resistance index (RI) were studied. These parameters were obtained by Doppler waveform autotracing. The angle-dependent velocity parameters were obtained with adequate Doppler cursor position and Doppler angle correction (Fig. 6). Next, the arterial perfusion index (API) was determined and expressed as a percentage. It reflects blood perfusion at 1 cm3 of the uterine body supplied by both uterine arteries. To do this, the volume of blood flow (in cm3 per cardiac cycle) in each of the uterine arteries was calculated using the following formula:

$$V_{\rm vol} = V_{\rm mean} \times S,$$

where S is the uterine artery area (cm2).

The vessel area was calculated by the standard formula of the circle:

$$S = 1/4\pi d^2$$
,

where d is the diameter of the artery (cm).

Thus, the formula for calculating the volume of blood flow in each of the uterine arteries takes the following form:

 $V_{\rm vol} = 0.785 \times V_{\rm mean} \times d^2$.

API is the total blood flow volume in both uterine arteries per 1 cm3 of the uterine body,



the uterine artery with correction of the angle of insonation, which is 22° (arrow)

expressed as a percentage and calculated using the formula:

EAP (%) = (V_{vol} uterine artery right + V_{vol} uterine artery left) / V uterus × 100,

where V_{vol} uterine artery right is the volume of blood flow in the right uterine artery (in cm3 per cardiac cycle); V_{vol} uterine artery left is the volume of blood flow in the left uterine artery (in cm³ per cardiac cycle); V uterus is the volume of the uterus (cm³).

Due to the fact that the presence or absence of a yellow body or a dominant (preovulatory) follicle is of significant importance in the vasculosis of the ovaries, a comparison of VI, FI and VFI was not performed.

The results were processed by standard statistical methods. Taking into account the fact that some of the data did not follow the normal distribution, all results are presented as medians (50th percentile), 5–95th percentiles and minimum–maximum values. The hypothesis of equality of means was checked using the Mann-Whitney U-test. Differences were assumed to be valid for $p \le 0.05$.

RESULTS

All patients were divided into 2 groups depending on the equipment used. In each group, there were 30 patients, including 15 women in the I and II phases of the cycle, whose age was similar (p > 0.05) (Tab. 1).

There were no significant differences in the volume of the uterine body, the thickness of the endometrium and the volumes of the ovaries between the two groups (p >0.05) (Tab. 2,3).

Tab. 1. Age of the examined patients in reference to the menstru-	Phase of menstrual cycle	IU22	(Philips)	Voluson E8 (GE)	
al phase		n	Age, years	n	Age, years
	I	15	32.0 23.9-41.0 20-42	15	31.5 23.9-41.0 22-43
		15	31.0 23.0-40.6 20-41	15	29.5 21.0-38.6 20-40

Note: the quantitative parameters are represented as medians (the first line of the cell), the $5-95^{\rm th}$ percentiles (the second line of the cell) and the minimum-maximum values (the third line of the cell).

Tab. 2. The volume of the uterus	Menstrual	IU22 (Philips)	Voluson E8 (GE)				
trium in reference to the menstru- al phase	phase	Volume of uterus, cm ³	Thickness of endometrium, mm	Volume of uterus, cm ³	Thickness of endometrium, mm			
	I	42.3 26.4-72.2 26.1-73.4	5.7 3.8-9.0 3.0-9.6	44.0 27.9-72.1 26.5-74.6	5.2 3.3-8.7 2.8-9.1			
		46.7 27.5-70.5 26.8-72.5	9.0 4.7-12.8 4.5-14.0	49.1 28.3-72.6 26.8-73.9	9.0 6.5-12.9 5.5-14.0			
	Note: the presentation of quantitative parameters as in Tab. 1							

Note: the presentation of quantitative parameters as in Tab. '

Tab. 3. The volume of ovaries in reference to the menstrual phase	Menstrual	IU22 (Philips)	Voluson E8 (GE)		
	phase	Volume of right ovary, cm ³	Volume of left ovary, cm ³	Volume of right ovary, cm ³	Volume of left ovary, cm ³	
	I	6.6 3.2-10.9 2.8-12.5	7.1 2.9-11.5 2.4-12.5	6.4 3.9-14.1 3.6-15.7	6.6 4.0-11.4 3.2-12.0	
	II	6.6 2.7-14.1 2.2-15.9	5.6 3.6-12.4 3.2-14.4	8.0 4.1-12.6 3.2-13.6	6.3 3.8-14.2 3.0-16.1	
	Note: the prese	ntation of quan	titative paramete	rs as in Tab. 1.		

In the study of Doppler blood flow parameters in the uterine arteries, the diameter of these vessels and the API, no significant differences were observed between the sides of the measurements and between the groups (p > 0.05) (Tables 4–6).

Tab. 4. Maximum (V_{max}) and mean (V_{max}) blood flow velocity in the	Menstrual phase	IU22 (F	Philips)	Voluson E8 (GE)		
uterine arteries in reference to the		V _{max} , cm/s	V _{mean} , cm/s	V _{max} , cm/s	V _{mean} , cm/s	
menstrual phase	I	38.5	6.5	37.9	6.0	
		26.7-44.2	4.8-7.9	30.3-42.7	3.8-8.7	
		25.3-48.6	4.3-9.4	27.9-44.0	3.4-9.5	
	11	41.7	7.4	38.8	6.0	
		33.1-46.7	5.0-10.8	26.6-45.9	4.4-12.1	
		30.1-50.0	4.7-12.8	23.6-48.1	3.6-13.0	
	Note: the prese	ntation of quant	itative paramete	rs as in Tab. 1.		

Tab. 5. Pulsatility index (PI) and resistance index (RI) in uterine arteries in reference to the menstrual phase

Menstrual	IU22 (I	Philips)	Voluson E8 (GE)						
phase	PI	RI	PI	RI					
I	2.15	0.84	2.20	0.86					
	1.77-3.58	0.80-0.90	1.58-3.30	0.80-0.90					
	1.53-3.69	0.76-0.94	1.56-3.38	0.76-0.93					
11	2.34	0.85	2.35	0.83					
	1.75-4.21	0.76-0.88	1.50-3.76	0.78-0.88					
	1.64-4.33	0.74-0.90	1.43-3.81	0.76-0.91					
Note: the prese	Note: the presentation of quantitative parameters as in Tab. 1.								

Tab. 6. The diameter of the uterine arteries (d) and the index of arterial perfusion (API) in reference to the menstrual phase

Menstrual	IU22 (I	Philips)	Voluson E8 (GE)			
phase	d, mm	API, %	d, mm	API, %		
I	2.2	1.2	2.3	1.2		
	2.0-2.6	1.0-1.7	2.0-2.6	0.9-1.9		
	1.9-2.7	0.9-1.9	1.9-2.7	0.8-2.0		
11	2.3	1.3	2.6	1.5		
	2.0-2.9	1.1-2.1	2.2-2.8	1.0-2.2		
	1.8-3.0	0.9-2.3	2.1-2.9	0.9-2.4		
 	2.3 2.0-2.9 1.8-3.0	1.3 1.1-2.1 0.9-2.3	2.6 2.2-2.8 2.1-2.9	1 1.0 0.9		

Note: the presentation of quantitative parameters as in Tab. 1.

Tab.7. VI, FI and VFI of the uterus in reference to the menstrual pha-	Menstrual	IU22 (Philips)			Voluson E8 (GE)		
se	phase	VI, %	FI	VFI	VI, %	FI	VFI
	I	4.9	16.8	0.8	12.0*	32.8*	3.9*
		2.4-7.8	12.8-23.0	0.5-1.8	6.9-24.7	22.3-38.5	2.7-8.1
		2.2-8.7	12.6-23.2	0.3-2.2	6.3-26.0	21.1-40.1	2.1-9.6
	11	6.0	17.2	1.1	13.5*	33.7*	4.5*
		2.5-9.8	12.4-24.0	0.7-1.8	7.7-20.8	29.3-38.7	2.6-8.6
		2.4-10.2	12.1-24.5	0.4-2.0	6.1-22.3	28.4-40.0	2.0-8.9
	Note: the p	resentation	of quantita	ative param	neters as in	Tab. 1. * -	significant

difference between compared groups at p <0.05.

Tab.8.	VI,	FI	and	VFI	in	the	endo-
metriu	m iı	n r	efere	ence	to	the	men-
strual	pha	se					

Menstrual	п	IU22 (Philips)			Voluson E8 (GE)		
phase	VI, %	FI	FI VFI		FI	VFI	
I	0.8	3.6	0	3.6*	14.2*	0.3*	
	0.2-3.1	0.7-8.2	0-0.2	0.8-7.2	6.6-20.3	0.1-1.5	
	0-3.9	0-9.4	0-0.3	0.5-8.0	5.4-22.1	0.1-1.8	
II	1.0	4.4	0.1	3.6*	24.6*	0.8*	
	0.3-4.0	0.6-9.7	0-0.3	1.0-11.6	6.5-23.5	0.1-3.1	
	0.2-4.4	0.4-10.7	0-0.3	0.5-13.5	4.8-34.2	0.1-4.0	

Note: the presentation of quantitative parameters as in Tab. 1.* - significant difference between compared groups at $p\ <\!0.05$

The comparison of the parameters of vascularization of the uterus and endometrium obtained using ultrasound systems of different manufacturers revealed a significant (p < 0.05) difference in VI, FI and VFI (Tab. 7,8).

DISCUSSION

The comparison of the results obtained using ultrasound systems of different manufacturers revealed the absence of a reliable difference in the accuracy of measurements of linear dimensions and the volumes, velocity indices of blood flow, observing adequate Doppler angles, and angle-independent indices. This implies that the results of studies performed in different medical institutions and on different ultrasound scanners will be comparable, which is especially important for assessing dynamic changes. The data concerning the arterial perfusion index also turned out to be similar due to the fact that the calculation formula included the diameter of the uterine arteries, the average flow velocity in the uterine arteries and the volume of the uterine body, and each criterion, as well as the API, did not present significant differences (p > 0.05).

There was a significant difference (p < 0.05) when comparing the 3D ultrasound image obtained in combination with color Doppler mode. In part, this difference is probably due to the different Doppler modes: the IU22 (Philips) uses the standard color flow mapping, and the Voluson E8 (GE) uses power Doppler, enabling the identification of low-speed blood flows. The main reason for the differences probably lies in the different software algorithms developed by different manufacturers.



This conclusion is based on the fact that not only the value of the VI in the VOCAL application was significantly higher than in the QLab application, but also the value of FI, depending on the speed of blood flow in three-dimensional volume, was significantly higher. The difference in VI, FI and VFI in practical work significantly complicates the interpretation of results, which can lead to diagnostic errors, delayed interventions or unreasonable treatment.

The evaluation of blood flow in a structurally unchanged uterus is used in the examination and treatment of infertile women [7,8]. If there is a gynecological pathology, various methods of hemodynamic assessment are also used, including not only angle-independent Doppler indices, but also VI, FI and VFI, which are currently the most significant [9,10].

In recent years, the results of painstaking work of international teams on the standardization of ultrasound examinations of myometrial pathology (MUSA), the endometrium (IETA) and the appendages (IOTA) have been published [11–13]. The proposed ultrasound examination standards take into account the degree of vascularization, evaluated both subjectively and in scores: from 1 to 4, where 0 =absence of vascularization and 4 = abundant vascularization. In connection with the possibility of objective evaluation by using the definition of VI, FI and VFI, it would be a logical continuation of the started work to introduce these indicators in the US examination protocol. However, there is still a question of the threshold values that are different when working on devices of leading manufacturers, which requires the development of separate regulatory parameters.

Prior verification of ultrasound equipment influences the accuracy of measurements. The tests include B-mode, Doppler modes and correct 3D rendering (Fig. 7–9).

When introducing new methods, it is therefore necessary to study information about a given modality, to rely on the reference values obtained on the devices of the same manufacturers as well as to conduct a clinical and ultrasonographic comparison of own results to avoid incorrect data interpretation.

1. Vetsheva NN. Standardization of methods for conducting ultrasound examinations //http://event.medradiology.moscow/d/1387577/d/standartizatsiya_metodik_provedeniya_uz_issledovaniy_vetshevann.pdf ISMIENN

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- 2. Zubarev AR. Standards of ultrasound phlebology //https:/ /mks.ru/library/conf/angiodop/2000/angiol/zub2.html
- Gabliya MYu. Unification of ultrasound diagnostic protocols of the prostate // https://www.youtube.com/watch? v=Zw6k-Kuer3M
- 4. http://www.rasudm.org/recomendation/
- Recommendations for the shear wave elastography, Philips ultrasound systems // http://www.rasudm.org/recomendation/details.htm?id=15
- Raine-Fenning NJ, Nordin NM, Ramnarine KV et al. Evaluation of the effect of machine settings on quantitative three-dimensional power Doppler angiography: an in-vitro flow phantom experiment. *Ultrasound Obstet & Gynecol* 2008;32(4):551–559. DOI: 10.1002/uog.6138.
- Omran E, El-Sharkawy M, El-Mazny A et al. Effect of clomiphene citrate on uterine hemodynamics in women with unexplained infertility. *Int J Womens Health* 2018;10:147-152. DOI: 10.2147/IJWH.S155335.
- Dong Y, Cai Y, Zhang Y et al. The effect of fertility stress on endometrial and subendometrial blood flow among infertile women. *Reprod Biol Endocrinol* 2017;15:15-26. DOI: 10.1186/s12958-017-0236-7.



Fig. 9. Testing the US scanner for accuracy of 3D building

- El-Mazny A, Kamel A, Ramadan W et al. Effect of ovarian endometrioma on uterine and ovarian blood flow in infertile women. *Int J Womens Health* 2016;8:677–682. DOI: 10.2147/JJWH.S124229.
- El-Mazny A, Ramadan W, Kamel A, Gad-Allah S. Effect of hydrosalpinx on uterine and ovarian hemodynamics in women with tubal factor infertility. *Eur J Obstet Gynecol Reprod Biol.* 2016;199:55-59. DOI: 10.1016/j.ejogrb. 2016.01.046.
- Van den Bosch T, Dueholm M, Valentin L et al. Terms, definitions and measurements to describe sonographic features of myometrium and uterine masses: a consensus opinion from the Morphological Uterus Sonographic Assessment (MUSA) group. Ultrasound Obstet & Gynecol. 2015;46(3):284-298. DOI: 10.1002/uog.14806.
- Leone FPG, Timmerman D, Bourne T et al. Terms, definitions and measurements to describe the sonographic features of the endometrium and intrauterine lesions: a consensus opinion from the International Endometrial Tumor Analysis (IETA) group. Ultrasound Obstet & Gynecol. 2010;35(1):103-112. DOI: 10.1002/ uog.7487.
- Timmerman D, Valentin L, Bourne T et al. Terms, definitions and measurements to describe sonographic features of adnexal tumor: a consensus opinion from the International Ovarian Tumor Analysis (IOTA) group. Ultrasound Obstet & Gynecol. 2000;16(c):500-505. DOI: 10.1046/j.1469-0705.2000.00287.x.