ORIGINAL ARTICLE

Does the ESHRE/ESGE Classification of Mullerian Anomalies Correlate with the Occurrence Of Pregnancy? A Comparison between Two Definitions of Myometrial Thickness

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Article Information

Received: 20 Jul 2015
Accepted: 06 Sep 2015
Plagiarism software: Turnitin

Keywords:
ESHRE/ESGE classification,
Myometrial thickness,
Mullerian anomalies,
Pregnancy,
3D ultrasound

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ABSTRACT

Introduction: Since the introduction of the European Society of Human Reproduction and Embryology/European Society for Gynaecological Endoscopy (ESHRE/ESGE) classification of Mullerian anomalies, various authors have raised major concern about its clinical implications, as specific diagnostic criteria that clearly correlate to pregnancy have not yet been validated in clinical practice by any prospective or retrospectives studies. In this study, we aimed to correlate the ESHRE/ESGE classification with the occurrence of pregnancy, consideringthetwo different definitions of myometrial thickness. **Methods**: A retrospective study, including an ultra-selected cohort of 79 patients, from January 2010 to March 2014. All women with fertilityproblems, who had an isolated andsuspected uterine malformation, t ultrasound and hysteroscopy, were retrospectively included in this study. Myometrial thickness was defined as the entire myometrial layer, as suggested by the ESHRE/ESGE criteria, or the free myometrial layer, as suggested by Gubbini. **Results**: We failed to evidence an association between the occurrence of pregnancy in the two most representative classes (U0 and U2), considering the free myometrial layer, and the entire myometrial layer. When we considered the effect of hysteroscopic surgery on the occurrence of pregnancy, we also failed to obtain a statistically significant difference. **Discussion**: The ESHRE/ESGE classification may be useful in classifying Mullerian anomalies, but it needs to be applied in larger series. However, we think that new parameters and algorithms are needed for a better prediction of pregnancy. We recommendto associate the fundal uterine vascularization to the ESHRE/ESGE criteria to be analysed in further studies.

INTRODUCTION

A proper classification of uterine anomalies should provide anatomical information in a simple, repeatable and non-invasive way, and suggest the optimal management for each class, in order to improve the pregnancy rate.[1] Three-dimensional (3D) ultrasound (US) seems to be the best diagnostic method for Mullerian anomalies, as it is simple, non-invasive, easily accessible, repeatable and provides objective and measurable representation of the entire uterus (cavity, wall and shape) and the cervix, even its accuracy is operator dependent and variable according to the followed examination methodology.[2–9]

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Website:	Quick Response code
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DOI:	
10.5530ami.2016.1.8	

However, several classification systems are available for Mullerian anomalies at 3D US, but none of these is strongly associated to pregnancy outcome. Indeed, since 1979,[10,11] several classifications have been proposed,[10,12,13]

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but, until now, none of them was able to definitely replace the American Fertility Society's 1988 classification.[10,14,15] Although this one is still the most used, it does not specify which criteria and diagnostic methods should be used to classify uterine anomalies, as it is supportedonly bya subjective evaluation.[16] Recently, in 2013, the European Society of Human Reproduction and Embryology (ESHRE) and the European Society for Gynaecological Endoscopy (ESGE) developed a new accurate and simple classification system at 3D US,that correlate with clinical management of Mullerian anomalies.[17] They are sorted in six main classes according to severity and embryological origin of the anatomical alteration. However, various authors have raised major concern about its clinical implications, due to the lack of a precise definition of the diagnostic criteria of Mullerian anomalies at 3D US, as ESHRE/ESGE criteria are based only on expert consensus and not validated in clinical practice.[18]

The purposes of our study was to apply the ESHRE/ESGE classification system in clinical practice, in anultra-selected cohort of women with provisional diagnosis of isolated uterine malformations, to evaluate its prognostic value in predicting the occurrence of pregnancy, comparing two definitions of myometrial thickness to diagnose a septate uterus.

METHODS

Among all women referred to Altamedica of Rome for fertility problems from January 2010 to March 2014, we selected retrospectively only those with provisional diagnosis of isolated uterine malformation at 2D US examination and/or sonohysterography and that executed in our centre both 3D US and hysteroscopy.

Inclusion criteriawere abortion or recurrent abortion (two or more abortions by 12 weeks of gestation), primary infertility, or in vitro fertilization failure. In order to avoid confounding factors, exclusion criteria for the study were: 1) a history of previous uterine reconstructive surgery, 2) intraoperative findings of intracavitary polyps or miomas, 3) male cause of infertility, 4) ovulatory and/or thrombophilic disorders, 5) tubaric diseases, 6) endometriosis, 7) unexplained causes, 8) other minor causes of infertility (cervical disease, infection, etc). We obtained the ethics committee approval from the local institutional board. According to our protocol, a detailed anamnesis was taken for each patient, and a signed informed consent was obtained before each examination.

All patients underwent 3D US for assessment of the uterine anomalies during the luteal phase of their cycles. All examinations were performed by the same expert operator (MG) and were carried out in a systematic and predetermined manner. Ultrasound scan was performed using a Voluson (GE, Milan, Italy), with a multifrequency volume endovaginal probe (set at 7.5-9 MHz). Initially, uterus was visualized on 2D US in a mid-sagittal scan, filling 75% of the screen, adjusting the 3D-box size, and using a sweep angle of 90° at maximum quality. An optimal 3D coronal volume of the uterus was then obtained and stored on the hard drive of the US machine and made available for off-line analysis. We identified uterine anomalies following the American Fertility Society[11] classification system,subsequently modified according to 3D US landmarks (endometrial indentation of the fundus and external contour).[9] (Table 1)

All enrolled patients underwent office hysteroscopy, in order to evaluate the endometrial cavity, in the early follicular phase of the subsequent cycle. Hysteroscopy and ultrasound were performed by two different operators with selective competence for each technique. All surgical procedures were performed by the same surgeon (AL). The ultrasound was performed by MG. The 3D US results were not initially available to the surgeon.

In case of uterine anomaly, women were invited to undergo hysteroscopic surgery to correct their defect, including fundal ablationin arcuate uteri or metroplastyin septate/subseptateuteri.After surgery, 3D US showed the apparent restoring of uterine anatomy. Then,according to their age, women above 35 years were addressed to an assisted reproductive technique after about 6 months of trying to spontaneously conceive.[19] Phone call follow-up was obtained.

All the diagnoses have been revisedjointly by four authors (FP, SC, MG MCT), applying retrospectively the ESHRE/ESGE criteria (Table 2).[17] Myometrial thickness was defined

Table 1: Classification of congenital uterine anomalies according to the American Fertility Society[11] classification system, subsequently modified according to 3D US landmarks[9]

Uterine morphology	Endometrial contour	External contour
Normal	Straight or convex	Uniformly convex or indentation <10 mm
Arcuate	Concave indentation with central angle >90°	Uniformly convex or indentation <10 mm
Subseptate	A uterine septum (not involving the cervix), with central angle <90°	Uniformly convex or indentation <10 mm
Septate	A septum that divides all the cavity (including the cervix)	Uniformly convex or indentation <10 mm
Bicornuate	Two uterine cornua	Fundal indentation >10 mm
Unicornuate with or without rudimentary horn	A single uterine cavity with a single interstitial portion of fallopian tube and concave fundal contour	Fundal indentation >10 mm in case of rudimentary horn

as the entire myometrial layer, as reported in the ESHRE/ESGEcriteria[17] (Figure 1a) or the free myometrial layer, that is the distance between the fundus external contour and the line joining the interstitial portions of the fallopian tubes, suggested by Gubbini et al.[20] (Figure 1b).

Statistical variables are described by frequencies and mean ± standard deviation (SD) of the mean. Differences between groups were analysed by Chi square and Fisher's exact test. We applied a z-test for population proportion to determine whether the hypothesized population proportion differed significantly from the observed sample proportion. To measure the inner-rater agreement between two methods we used the Cohen's kappa index. A p-value < 0.05 was considered statistically significant. As this is a retrospective study, no formal sample-size calculation was necessary and therefore performed.

RESULTS

Among 1,515 women referred to Altamedica of Rome for fertility problems from January 2010 to March 2014, we considered 1,026 (67.7%) women who had not any previous term pregnancy. Then we excluded 231 (22.5%) patients whose partner was cause of infertility, 106 (10.3%) women with ovulatory and/or thrombophilic disorders, 151 (14.7%) with tubaric disease, 183 (17.8%) with unexplained causes, 190 (18.5%) with causes of infertility found in both partners, 50 (4.9%) with endometriosis, 10 (1%) other minor causes of infertility. Therefore, we included retrospectively 105 women with suspected uterine malformation at 2D US examination and/or sonohysterography. From this cohort of patients, we further excluded 7 (6.7%) women with a history of previous uterine reconstructive surgery, 17 (16.2%) with findings of intracavitary polyps or miomas, and 2 (1.9%) women who have already executed 3D US or hysteroscopy in other diagnostic centre. So finally, an ultra-selected cohort of 79 infertile patients withprovisional diagnosis of isolated uterine malformation at 2D US examination and/or sonohysterography and that executed in our centre both 3D US and hysteroscopy, were considered for the analysis (Figure 2). The mean age of the patients was 35.9 years (range 20-50 years). All patients underwent 3D US and consequent hysteroscopy and the respective diagnosis are reported in Table 3. We did not find any difference concerning age, between classes. To measure the inner-rater agreement between the two methods we used the Cohen's kappa index which showed a moderate level of agreement (k=0.6). As expected, most of the differences concerned the identification of the arcuate and sub-septate uteri.

Then, we applied the ESHRE/ESGE criteria for 3D US and reclassified the series according to the two different definitions of myometrial thickness, according to the ESHRE/ESGE criteria[17] as the entire myometrial layer, and to Gubbini et al[20] as the free myometrial layer (Table 4).

Table 2: ESHRE/ESGE 3D US criteria

U0	Normal uterus
U1	Dysmorphic uterus Normal uterine outline butabnormal shape of the uterine cavity Septa are excluded
U2	Septate uterus Normal uterine outline and an internal indentation at the fundal midline >50% of the uterine wall thickness
U3	Bicorporeal uterus Abnormal fundal outline and an external indentation at the fundal midline >50% of the uterine wall thickness
U4	Hemi-uterus Presence of unilateral uterine cavity; the oppositecavity could be incomplete or absent

Table 3: 3D US and hysteroscopic diagnosis

	Hysteroscopy (N=79) (%)	3D US (N=79) (%)	P
Normal	4 (5.1)	4 (5.1)	>0.05
Arcuate	23 (29.1)	32 (40.5)	>0.05
Septate	13 (16.5)	12 (15.2)	>0.05
Sub-septate	31 (39.2)	24 (30.4)	>0.05
Bicornual uterus	5 (6.3)	4 (5.1)	>0.05
Unicorne	3 (3.8)	3 (3.8)	>0.05

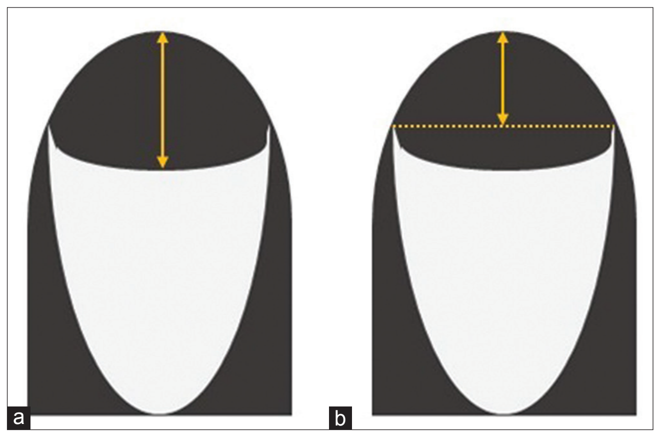

Figure 1: Myometrial thickness defined as the entire myometrial layer (a), orthe free myometrial layer (b)

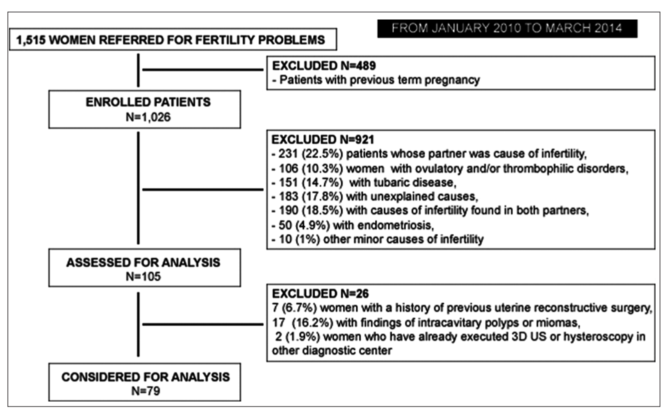

Figure 2: Cosort flow diagram for patients who were accrued into the study

With the new classification, according to the entire myometrial thickness, most of arcuate uteri were reclassified into class U0, with a higher percentage of U0 (62%) than U2 (29.1%). When we considered the free myometrial thickness, we found a balance between U0 (43%) and U2 (48.1%) uteri. However, after excluding 12 women who no longer desired to become pregnant, we failed to obtain a statistically significance difference in the occurrence of pregnancy within each class, according to the two classifications (Table 5).

When we considered the effect of hysteroscopic surgery on the occurrence of pregnancy, we also failed to obtain a statistically significant difference (Table 6).

DISCUSSION

The combined useof 2D US, sonohysterography and hysteroscopy is the accepted usualassessment protocol for screening Mullerian anomalies, whilst the combined application of hysteroscopy andlaparoscopy is believed to be the gold standard in the diagnosis of genital malformations.[21] Transvaginal 2D US has high sensitivity (90%–92%) in screening uterine anomalies.[22] However,

Table 4: ESHRE/ESGE criteria for 3D US, considering the two definitions of myometrial thickness

	The entire myometrial layer (%)	The free myometrial layer (%)	P
U0	49 (62)	34 (43)	>0.05
U1	1 (1.3)	1 (1.3)	>0.05
U2	23 (29.1)	38 (48.1)	>0.05
U3	3 (3.8)	3 (3.8)	>0.05
U4	3 (3.8)	3 (3.8)	>0.05

Table 5: Occurrence of pregnancy in the two main classes of Mullerian anomalies, considering the two definitions of myometrial thickness

	Occurrence of pregnancy (%)		P
	The entire myometrial layer	The free myometrial layer	
U0	33/48 (68.75)	24/34 (70.58)	>0.05
U2	13/19 (68.4)	22/33 (66.67)	>0.05
U3	1/3 (33.3)	1/3 (33.3)	>0.05
U4	1/3 (33.3)	1/3 (33.3)	>0.05

Table 6: Occurrence of pregnancy in relation to hysteroscopic surgery, according to hysteroscopic and 3D US diagnosis

	Hysteroscopic surgery	Occurrence of pregnancy (%)		P
		The entire myometrial layer	The free myometrial layer	
U0	Yes	21/29 (72.4)	14/18 (77.7)	>0.05
	Not	11/15 (73.3)	9/12 (75)	>0.05
U2	Yes	10/14 (71.4)	17/25 (68)	>0.05
	Not	2/2 (100)	4/5 (80)	>0.05

the ability of 2D US to differentiate between subtypes of uterine abnormalities is limited and operator dependent. Three-dimensional US overcomes these limits, as it is a simple method that alone, can provide measurable information on the myometrial layer, both the external contours and internal morphology of the uterus, with the exception of tubes, with high accuracy in detecting major genitalmalformations.[2–9,23,24] However, there is a strong limit to a precise definition of the anomaly,since the diagnosis is operator dependent.[2]

Furthermore, several classification systems are available for Mullerian anomalies at 3D US, even if they are not well standardized and do not correlate with clinical outcome, such as pregnancy.

Among all the concern about the ESHRE/ESGE criteria, the reclassification of the arcuate uterus into normal (U0) or septate uterus (U2), modifies the number of diagnosed uterine septa. However, it is not known how much it is relevant in clinical practice or which rate is really associated with an unfavourable prognosis and it cannot identify the uterus that may benefit from the different endoscopic surgeries.

A septate uterus generally leads to the highest incidence of reproductive complications, but surgical correction substantially improves the reproductive outcome.[25] On the other hand, the correlation between arcuate uterus and reproductive outcome has still been debated,[26–28] such as the need for surgical correction.[29,30] A recent review of the literature highlights that the efficacy of hysteroscopic surgery, in women with unexplained infertility or before in vitro fertilization techniques, has not yet been demonstrated and requires more randomized trials.[31]

Different options have been proposed to differentiate between arcuate and septate uterus at 3D US, but unanimous criteria have not yet been validated. We believe that subjective evaluations or measurements in centimetres rather than in percentages should be abandoned, even it is a simple way to distinguishes between normal and abnormal fundi and may be useful during septum resection and postoperative evaluation.[32]

According to the ESHRE/ESGE classification, a septate uterus hasamidline internal indentation at the fundal site>50% of myometrial thickness.

However,since myometrial thickness may vary at different areas of the uterus, Grimbizis et al.[33] have suggested to consider the mean thickness of both anterior and posterior walls.

Furthermore, in coronal sections, myometrial thickness can be considered as the entire myometrial layer, as reported by the ESHRE/ESGE criteria[17] or the free myometrial layer, that is the distance between the fundus external contour and the line joining the interstitial portions of the fallopian tubes, as suggested by Gubbini et al.[20]

Lastly, in a recent paper, Ludwin A. and Ludwin I.[34] concluded that the ESHRE/ESGE classification should not be used for the diagnosis of aseptate uterus, until new criteria will be defined.

In this setting, we aimed to introduce the promising ESHRE/ESGE 3D US criteria in clinical practice, considering two alternative definitions of myometrial thickness.

In our ultra-selected cohort of patients, we could not find any statistically difference in classifying according to the two different definitions of myometrial thickness. This is may be limited by the low number of patients, even an ultra-selected cohort, and need to be considered as preliminary.

The ESHRE/ESGE 3D US classification may be useful in classifying of Mullerian anomalies, but, in our series, according to the two definitions of myometrial thickness, it seems to be equally useful in predicting the occurrence of pregnancy. From a clinical point of view, it is of little use a classification that includes the same pregnancy rate for different classes. It might depend on the reduced number of our sample, or on factors that the ESHRE/ESGE classification has not yet been considered. In clinical practice, new parameters and algorithms are needed for a better prediction of pregnancy, in particular,we recommendto associate the fundal uterine vascularization to the ESHRE/ESGE criteria to be analysed in further studies.

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How to cite this article: Padula F, Giorlandino M, Capriglione S, Teodoro MC, Lippa A, Minutolo SE, Lena A, Lanteri A, Brutti P, D'Emidio L, Mangiafico L, Cignini P, Giorlandino C. Does the ESHRE/ESGE classification of mullerian anomalies correlate with the occurrence of pregnancy? A comparison between two definitions of myometrial thickness. Acta Medica International. 2016;3(1):24-29.

Source of Support: Nil, **Conflict of Interest:** None declared.