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The widely acknowledged European versus the latest American classification of Mullerian duct anomalies- A comparative study.

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Abstract

Mullerian duct anomalies are a clinically important group of pathologies responsible for poor reproductive outcome. Among the Mullerian duct anomalies, some subset of anomalies have more clinical impact than the others, thus necessitating proper characterisation of anomalies to guide appropriate treatment. There are various classification systems proposed to classify the various uterine anomalies, the most common ones being the European Society of Human Reproduction and Embryology–European Society for Gynaecological Endoscopy (ESHRE-ESGE) classification system proposed in 2013 and the latest American society of Reproductive medicine (ASRM)classification system that came in 2021. Since the ASRM classification came very recently, there is very few data available on the comparison of these two classification systems. Therefore, the main objective of our study was to compare both of these classification systems. We conducted an analytical type of observational study in the department of Radiodiagnosis, SMS Medical College and Associated Hospitals, Jaipur from April 2021 to September 2022. The study population included 50 female patients who were diagnosed to have Mullerian duct anomalies either by previous 2D ultrasound or HSG. After taking their written informed consent, relevant clinical history was elicited focusing on the details of the Mullerian abnormality. All recruited participants underwent 3D ultrasound or MRI of the pelvis, whichever was feasible. Anomalies were classified as per ASRM as well as ESHRE-ESGE classification and a statistical comparison between the two classification systems was done using sensitivity, specificity, positive predictive values and negative predictive values.

Keywords: Gynaecological, Endoscopy, 3D Ultrasound,

Introduction

Mullerian duct abnormalities are a diverse category of female reproductive system deformities that may result in recurrent miscarriages and preterm deliveries. The majority of these anomalies are developmental in nature and emerge in the early stages of embryonic development.1The clinical significance stems from a variety of factors. Congenital defects are first and foremost rather common, and more so in a subset of people, especially those who experience repeated pregnancy losses or female infertility. They are thought to affect 4%of infertile women and 0.4% (0.1-3%) of the overall population.2 MDAs are linked to greater odds of preterm delivery, preterm premature membrane rupture, foetal malpresentation during delivery, and perinatal mortality. 3,4 Preterm birth rates rise with the kind of uterine abnormality, with septate (31%), bicornuate (39%), Unicornuate (43%), and didelphys(56%), being the most common.5 In comparison, patients with a septate uterus have the highest relative risk of miscarriage in the first and second trimesters.4Since different subtypes of anomalies have different clinical outcome and management strategy, it is important to accurately classify each uterine anomaly for proper treatment planning. There are several classification systems proposed to categorise the widely diverse Mullerian anomalies, but the most commonly used are the European Society of Human Reproduction and Embryology–European Society for Gynaecological Endoscopy (ESHRE-ESGE) classification system proposed in 2013 and the latest American society of Reproductive medicine (ASRM) classification system that came in 2021. The ESHRE–ESGE classification is used to limit the subjective diagnosis of the American classification. On the contrary, ASRM classification's advantages include its clarity, recognisability and correlation with actual clinical pregnancy outcomes. Since it is based on clear drawings, itis simple and understandable. However, the American classification relies extensively on images without detailed descriptions. As a result, numerous authors have suggested adding more morphometric criteria to this classification.6 Although the basic framework of both classification systems is grossly similar, both the systems use different criteria's to classify the Mullerian duct anomalies. Since both these classification systems are widely accepted and used in day-to-day practice by radiologists and gynaecologists worldwide, our study aimed to statistically compare both these classification systems using sensitivity, specificity, positive predictive values and negative predictive values.

Materials And Methods

Study Design: Analytical type of observational study.

Study Type: Observational cross-sectional study.

Place of Study: Department of Radiodiagnosis, SMS Medical College and Associated Hospitals, Jaipur.

Duration: Data collection for study started after approval from the institutional research and review board, from April 2021 to September 2022 and 2 months were taken for data analysis and compilation.

Study Universe: Cases referred from Obstetrics and Gynaecology Department with suspected uterine anomalies by 2D US or with other investigations like HSG done for infertility workup.

Study Tool: Pre-tested, pre-designed proforma was used to collect data.

Equipments: Philips Affinity 70G Ultrasound machine. 3.0T Philips Ingenia MRI machine.

Study Population: All women who were diagnosed to have Mullerian duct anomaly either by previous 2D ultrasound or by investigations like HSG and were willing to participate in the study.

Inclusion Criteria

Female patients suspected to have Mullerian anomalies on 2D USG / HSG etc. and gave written consent to participate in the study.

Exclusion Criteria

- Patients who had metallic implants, cardiac pacemakers, hearing aids, dental implants, insulin and medication pumps.
- Patients with an artificial heart valve, metallic stents, neurostimulators, aneurysm clips, cochlear implants, gastric reflux device and other implanted electrical devices.
- Presence of uterine fibroids distorting uterine cavity.
- Patients with claustrophobia.
- Patients who were unwilling to participate or refused to give written consent.

Sampling procedure: All women in reproductive age group being evaluated for infertility /recurrent pregnancy losses who were diagnosed to have a Mullerian duct anomaly either by previous 2D pelvic ultrasound or by other investigations like HSG (willing to participate in the study and would be available for regular follow up) were included on first come first basis after beginning of the study assuming 10% dropouts.

Sample size: Sample size was calculated at 95% confidence level at alpha error of 0.05 assuming the prevalence of 56.7% of septate uterus anomaly, at an AAE of 15%, the required sample size for the study was 42, which was further rounded off to 50 as final sample size.

Methodology

All eligible women fulfilling inclusion criteria were explained about nature and purpose of the study. After taking their written informed consent, history was elicited focusing on details of the Mullerian abnormality, including the age, complaints, parity, past and family history, associated medical conditions and 2D USG /HSG findings were recorded.

All recruited participants underwent 2D USG followed by 3D USG or MRI pelvis, whichever was feasible.

Anomalies were classified as per ASRM as well as ESHRE-ESGE classification, on 3D USG or MRI.

Technique

3D Ultrasound was done using Philips Affiniti 70G machine.

MRI was done using 3.0 T Philips Ingenia machine, with patient in supine position, using a

Body Matrix Coil. Following sequences were taken on MRI (with slice thickness 3mm and interslice gap 0.5mm)-

- T1 axial, sagittal, coronal
- T2 axial, sagittal, coronal
- T2 Oblique coronal
- DWI, GRE and Contrast enhanced sequences whenever needed.

Observation And Results

A total of 50 patients were included in the study who underwent Magnetic resonance imaging of the pelvis in the Department of Radiodiagnosis, SMS medical college, Jaipur, during the study period from April 2021 to September 2022 (total of 18 months).

All the patients were classified into appropriate classes of both ESHRE-ESGE and ASRM classifications.

The comparison of diagnosis as made on imaging was done based on ESHRE-ESGE and ASRM methods. It was observed that there was perfect correlation between ASRM and ESHRE-ESGE methods for the diagnosis of Bicornuate/Didelphys, Septate uterus, Mullerian agenesis and Unicornuate uterus, having a sensitivity and specificity of 100% as well as 100% positive and negative predictive values. For diagnosis of normal/Arcuate uterus, there were ten cases diagnosed as

per ASRM method. Out of the ten normal cases, eight were classified as U2 (septate) on ESHRE-ESGE method. Thus, normal or Arcuate uterus as per ASRM classification had a sensitivity of 20%, specificity of 100%, positive predictive value of 100% and negative predictive value of 83.3% using ESHRE- ESGE classification.

Discussion

We conducted an analytical type of cross-sectional study at a tertiary health care centre on 50 female patients suspected to have Mullerian duct anomalies and compared the diagnostic effectiveness of ESHRE-ESGE and ASRM 2021 classification system.

To differentiate between the Septate and Bicorporeal uteri, the ESHRE-ESGE classification system uses a external fundal midline cleft cutoff of 50% of uterine wall thickness- Septate uterus having convex or flat external contour or serosal indentation of less than 50% of uterine wall thickness and Bicorporeal uterus having serosal indentation of more than 50% of uterine wall thickness. 7 Uterine wall thickness is defined as the distance between the line joining tubal ostia (interostial line) and a parallel line on the top of the fundus.

ASRM classification on the other hand, uses serosal indentation cutoff of 1 cm to differentiate between Septate and Bicornuate uteri- the Septate uteri having serosal indentation of less than 1 cm and Bicornuate uteri having serosal indentation of more than 1 cm. 8 The Bicorporeal class of ESHRE-ESGE classification broadly encompasses both Bicornuate and Didelphys uteri of ASRM classification. In our study, there was no statistical difference between the diagnosis of Septate and Bicorporeal (Bicornuate and Dideplhys) uteri using both ASRM and ESHRE-ESGE classification systems with sensitivity, specificity, positive and negative predictive values of 100% between both groups.

The ASRM classification defines Arcuate uterus as having convex fundal contour and an internal indentation of less than 1 cm and an angle of divergence more than 90 degrees.

The latest ASRM classification classifies Arcuate uterus as normal uterus because it has no significant impact on clinical outcome.8 The ESHRE-ESGE classification classifies Arcuate uterus under Class U1c which includes all mild uterine cavity deformities, including those with an interior indentation at the fundal midline level of 50% of uterine wall thickness.7 Internal midline indentation is defined as the distance between the interostial line and a parallel line on the top of midline indentation.

An Arcuate uterus may be classified as a partial Septate uterus in the ESHRE–ESGE classification. Somayya et al. stated that the diagnosis of Septate uterus is made frequently by following the ESHRE–ESGE classification, resulting in increased hysteroscopic metroplasty.[9]

In study done by Ludwin et al., among 36.4% of cases of Septate uterus, internal fundal indentation was <1 cm by ESHRE–ESGE criteria and is usually considered as a normal uterus by ASRM. Their study further stated that the Septate uterus was over diagnosed and needed to be redefined for determining the treatment option of hysteroscopic metroplasty.10 According to Ludwin et al.11, patients who obtained a diagnosis from the same set of observers had a 5% prevalence of Septate uteri when the ASRM criteria were employed, a 12% prevalence when the CUME criteria were used and a 31% prevalence when the ESHRE/ESGE criteria were used. n our study also, it was observed that there was perfect correlation between ASRM and ESHRE- ESGE methods on MRI for the diagnosis of Bicornuate/Didelphys, Septate uterus, Mullerian agenesis and Unicornuate uterus. However, there were ten cases of

normal/Arcuate uterus diagnosed as per ASRM method. Out of the ten normal cases, eight were classified as U2 (septate) on ESHRE ESGE method. Hence, normal or Arcuate uterus as per ASRM classification had a sensitivity of 20%, specificity of 100%, positive predictive value of 100% and negative predictive value of 83.3% utilising ESHRE-ESGE classification.

Ludwin et al.12 states that according to ESHRE-ESGE criteria, 30% of women will have a septate uterus, which could lead to a billion-dollar industry for often needless hysteroscopic metroplasty in women who would otherwise have a normal or arcuate uterus by other classifications.

This difference was due to the different diagnostic criteria of ESHRE-ESGE and ASRM classification systems- the ASRM system classifying uteri with internal indentation of less than 1 cm as Arcuate uteri whereas the ESHRE-ESGE system classifying uteri with internal indentation of less than 50% uterine wall thickness as Arcuate uteri.

Summary And Conclusion

As compared to ASRM, ESHRE-ESGE system overdiagnoses the normal or Arcuate uteri as Septate uteri, unnecessarily complicating the management and subjecting normal patients having Arcuate uteri with non-significant reproductive outcome to hysteroscopic metroplasty and other irrelevant diagnostic tests which are time consuming and have an intolerable impact on the out-of-pocket expenses of a poor patient.

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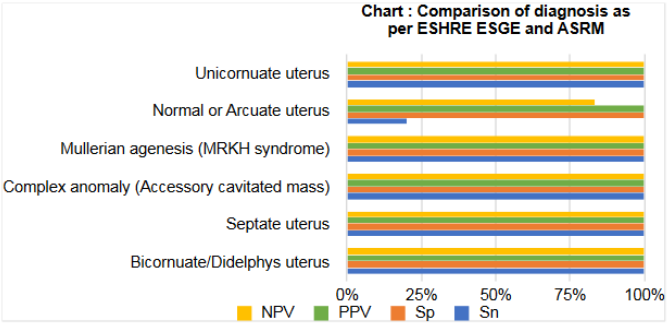
Legend Table and Figure

Final diagnosis (ASRM)	Final diagnosis (ESHRE ESGE)						Sn	Sp	PPV	NPV
	U1c	U2	U3	U4	U5	U6				
Bicornuate/ Didelphys uterus	0	0	10 (100%)	0	0	0	100%	100%	100%	100%
Septate uterus	0	19 (100%)	0	0	0	0	100%	100%	100%	100%
Complex anomaly (Accessory cavitated mass)	0	0	0	0	0	1 (100%)	100%	100%	100%	100%
Mullerian agenesis (MRKH syndrome)	0	0	0	0	5 (100%)	0	100%	100%	100%	100%
Normal or Arcuate uterus	2 (20%)	8 (80%)	0	0	0	0	20%	100%	100%	83.3%
Unicornuate uterus	0	0	0	5 (100%)	0	0	100%	100%	100%	100%

Table 1: Comparison of diagnosis as per ESHRE ESGE and ASRM classification (N = 50)



Graph 1: Chart comparing the diagnosis as per ESHRE-ESGE and ASRM classification.

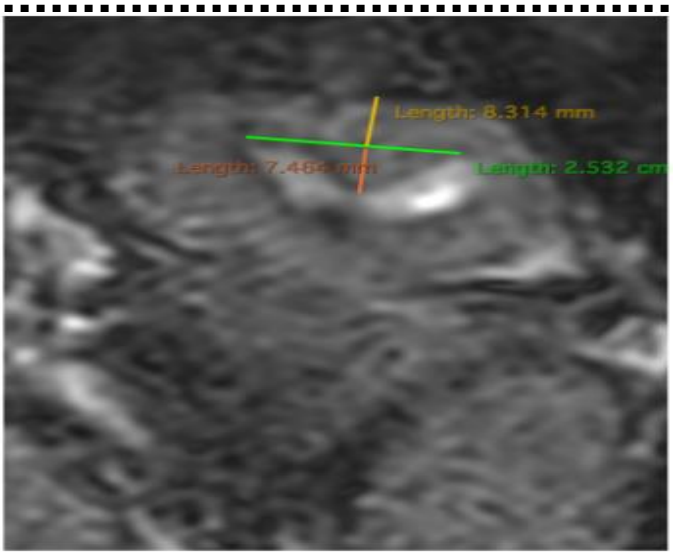


Figure 1: Coronal T2FS MR image showing the uterine wall thickness in yellow- measuring approximately 8.3 mm and internal indentation in orange measuring approximately 7.4 mm. Thus, according to ASRM criteria, the internal indentation is less than 1 cm and therefore this is a normal/Arcuate uterus. However, according to ESHRE-ESGE classification, the internal indentation is more than 50% uterine wall thickness and therefore, this falls under the category of partial Septate uterus.

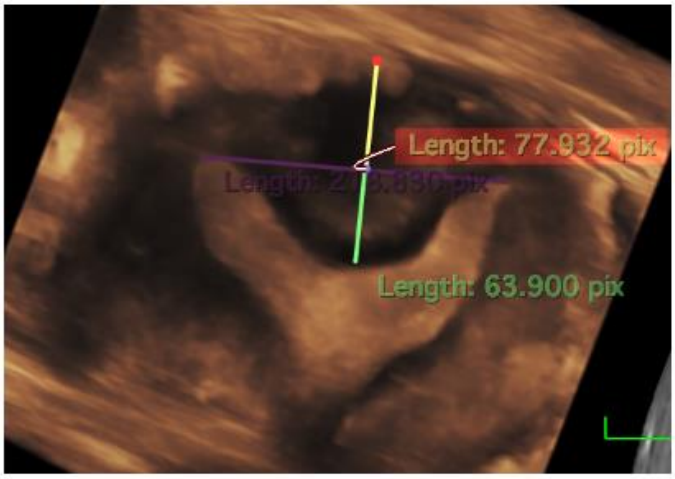


Figure 2: Three-dimensional ultrasound showing uterine wall thickness in yellow measuring approximately 7.8 mm and internal indentation in green measuring approximately 6.4 mm. Thus, according to ESHRE-ESGE classification, the internal indentation is more than 50% uterine wall thickness and therefore this fall under the category of partial Septate uterus. However, according to ASRM criteria, the internal indentation is less than 1 cm and therefore this is a normal/Arcuate uterus.

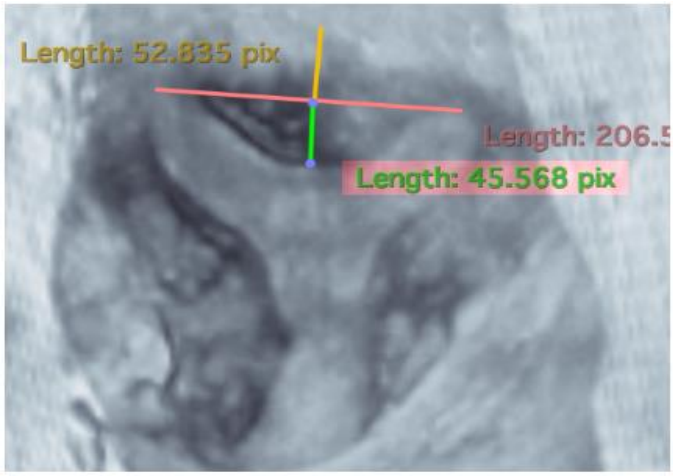


Figure 3: Three-dimensional ultrasound showing uterine wall thickness in yellow measuring approximately 5.3 mm and internal indentation in green measuring approximately 4.5 mm. Thus, according to ESHRE-ESGE classification, the internal indentation is more than 50% uterine wall thickness and therefore this fall under the category of partial Septate uterus. However, according to ASRM criteria, the internal indentation is less than 1 cm and therefore this is a normal/Arcuate uterus.

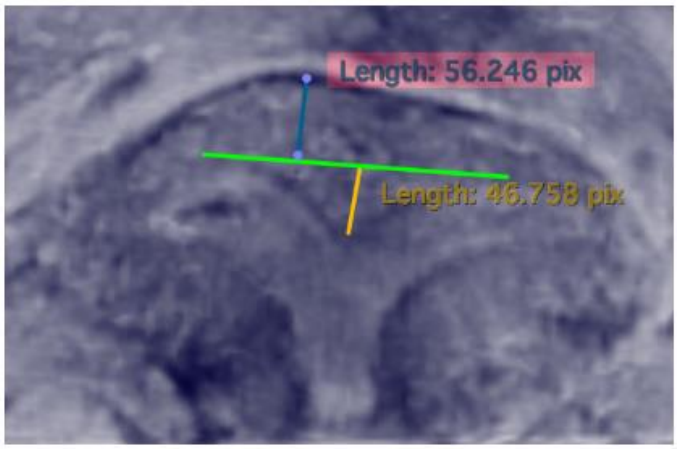


Figure 4: Three dimensional ultrasound showing uterine wall thickness in blue measuring approximately 5.6 mm

and internal indentation in yellow measuring approximately 4.6 mm. Thus, according to ESHRE-ESGE classification, the internal indentation is more than 50% uterine wall thickness and therefore this falls under the category of partial Septate uterus. However, according to ASRM criteria, the internal indentation is less than 1 cm and therefore this is a normal/Arcuate uterus.

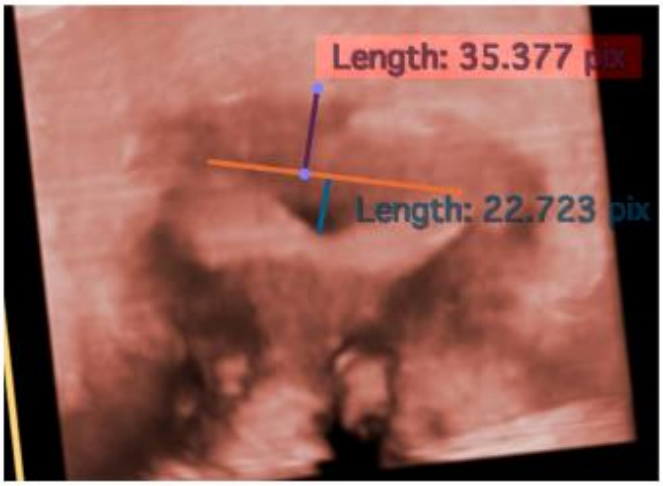


Figure 5: Three dimensional ultrasound showing uterine wall thickness in magenta measuring approximately 3.5 mm and internal indentation in blue measuring approximately 2.2 mm. Thus, according to ESHRE-ESGE classification, the internal indentation is more than 50% uterine wall thickness and therefore this falls under the category of partial Septate uterus. However, according to ASRM criteria, the internal indentation is less than 1 cm and therefore this is a normal/Arcuate uterus.