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Diagnostic Accuracy of Transvaginal Ultrasound (TVS) in Diagnosing Müllerian Duct Anomalies Keeping Magnetic Resonance Imaging (MRI) as Gold Standard

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ABSTRACT

Objective: To determine the diagnostic accuracy of transvaginal ultrasound in diagnosing Müllerian duct anomalies by using magnetic resonance imaging as the gold standard. **Study Design:** Descriptive cross-sectional study. **Duration and Place of Study:** This study was conducted from 2 March 2025 to 2 June 2025 at the Department of Radiology, Liaquat University of Medical and Health Sciences, Jamshoro. **Methodology:** A total of 348 female patients aged 20–45 years presenting with pelvic pain or infertility were included. All patients underwent transvaginal ultrasound followed by magnetic resonance imaging of the pelvis. Findings of both imaging modalities were recorded separately. Magnetic resonance imaging was taken as the reference standard. Data were analyzed using Statistical Package for Social Sciences version 22. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of transvaginal ultrasound were calculated using a 2 × 2 contingency table. **Results:** The mean age of patients was 32.16 ± 7.64 years, and the mean duration of symptoms was 24.46 ± 13.81 months. Transvaginal ultrasound detected Müllerian duct anomalies in 24.7% patients, while magnetic resonance imaging confirmed anomalies in 14.9% patients. Sensitivity of transvaginal ultrasound was 50%, specificity was 79.70%, and overall diagnostic accuracy was 75.30%. **Conclusion:** Transvaginal ultrasound shows moderate diagnostic accuracy in detecting Müllerian duct anomalies.

INTRODUCTION

Müllerian duct anomalies represent a group of congenital abnormalities that occur due to the improper development of the female genital system in the fetal period.[1] Normally, the Müllerian ducts develop into the uterus, cervix, fallopian tubes, and the upper part of the vagina, but abnormalities in the processes of growth, fusion, and canalization of the Müllerian ducts can lead to different anomalies, such as the presence of a septate, bicornuate, unicornuate, or didelphys uterus, and even the agenesis of the uterus.[2] The cervix and vagina can also be affected in some anomalies.[2] Many patients can remain asymptomatic for a long time because the affected system can still function, even with minor abnormalities, but later symptoms can arise due to infertility, recurrent miscarriage, preterm labor, malpresentation, dysmenorrhea, dyspareunia, and pelvic pain.[3] Hematometra can also occur with obstruction of the menses, thereby leading to the high possibility of developing endometriosis.[4]

The diagnosis of Müllerian anomalies needs a complete clinical workup, physical examination, and imaging studies because symptoms only are not sufficient for subclassification.[5] The main goal of the diagnostic workup is to identify the internal uterine cavity and the external uterine contour because this distinction impacts management, for instance, in differentiating septate and bicornuate uterus.[6] The methods used for imaging studies include ultrasonography, transvaginal ultrasonography, three-dimensional ultrasonography, hysterosalpingography (HSG), sonohysterography, hysteroscopy, laparoscopy and Magnetic Resonance Imaging (MRI).[7] HSG shows the uterine cavity and fallopian tubes only and does not outline the contour of the uterus externally, leading sometimes to misclassification of some uterine malformations.[8]

Transvaginal ultrasonography (TVS) is widely used in the field of gynecology and usually is the modality of choice when there is suspicion of Müllerian duct anomaly because it is widely available, inexpensive and does not use ionizing radiation.[9] While TVS offers excellent insights into the uterus and the ovaries because of the proximity of the

probe it can assess the presence of septa within the uterine cavity or double endometrial echos or the presence of abnormally shaped horns.[10] It usually has the ability to strongly infer the type of uterine malformation in many instances, especially when carried out by expert sonologists and good planes are obtained; it may occasionally miss the anterior and posterior contour of the uterus in totality, which is critical to infer the type.[11] Three-dimensional TVS improves the diagnostic capabilities to infer the type of uterine anomaly because it has the ability to reconstruct the coronal plane of the uterus and has the ability to accurately assess the depth of the septa and the depth of the uterine indentations to accurately segregate septate from the bicornuate uterus.[12] A study has shown that transvaginal ultrasound has sensitivity of 42.1% and specificity of 81.2% in diagnosing congenital Müllerian duct anomalies.[13] Another study showed 19% prevalence of uterine anomalies.[14]

Although there is an increasing use of transvaginal ultrasound as a first-line imaging tool for diagnosing Müllerian duct anomalies, it is clear that current literature about its sensitivity and specificity remains primarily derived from international research work. There seems to be a gap in local literature detailing comparisons of TVS and magnetic resonance imaging, which serves as a recognized gold-standard diagnostic tool for evaluation. Since there are discrepancies in demographic and technical variables this particular study will play a critical role in assessing its sensitivity and specificity within these local settings.

METHODOLOGY

This cross-sectional study was carried out in the Department of Radiology Liaquat University of Medical and Health Sciences Jamshoro over a period from 2 March 2025 to 2 June 2025. Ethical permission was obtained prior to initiation of study from the ethical review committee of Liaquat University of Medical and Health Sciences, Jamshoro (LUMHS-REC-490. Dated 06-11-2024) along with approval of synopsis from College of Physicians and Surgeons, Pakistan. The sample size was calculated using sensitivity of 42.1%, specificity of 81.2%,[13] margin of error of 12%, prevalence of mullerian duct anomalies of 19%,[14] and confidence level of 95%. Based on these assumptions a total of 348 patients were required. Female patients aged between 20 and 45 years who were referred for transvaginal ultrasound due to pelvic pain or infertility were included. Patients who already had a diagnosed mullerian duct anomaly, known uterine or ovarian malignancy, previously diagnosed pelvic inflammatory disease or those who refused participation were excluded from the study. Pelvic pain was taken as history of lower abdominal or pelvic discomfort of any intensity lasting for at least 2 weeks. Infertility was taken as inability to conceive for more than one year duration. Before data collection, written informed consent was taken from each patient after explaining purpose and procedure of the study. Confidentiality of patient information was maintained throughout the study. Baseline demographic data including age, place of living, family history of mullerian duct anomalies and duration of symptoms were recorded on a predesigned proforma.

All patients were subjected to a detailed history and radiological assessment. Transvaginal ultrasound scanning was done by a high frequency probe and a consultant sonologist with an experience of five years. The results regarding the presence and absence of MDAs were recorded. Subsequently, magnetic resonance imaging (MRI) of the pelvis was done on a 1.5 Tesla unit and without intravenous contrast administration. Surface coils were used, and slices were obtained in axial, sagittal, and coronal planes and were processed for T1W, T2W, and short tau inversion recovery (STIR) sequences. Results were recorded separately. On completing these radiologic investigations, whether MDAs were present or absent was studied by both techniques. MDAs on transvaginal ultrasound were considered to be present if there was an absence and/or hypoplastic uterus, unicornuate and/or bicornuate uterus if a single and/or two uterine horns were noted, didelphys uterus if there were two complete uterine cavities and two cervixes, and septate and/or arcuate uterus if there was a septum and/or an indentation at the fundus of the uterus. MRI detected MDAs as follows: hypoplastic and/or absent uterus, single and double uterine cavities, complete duplication of uterus and cervix and vagina, and septum and/or fundal indentation within the uterine cavity.

Data analysis was performed using SPSS version 22. Quantitative variables like age and duration of symptoms were expressed as mean and standard deviation. Qualitative variables including place of living, family history of mullerian duct anomalies and presence of mullerian duct anomalies were presented by frequencies and percentages. Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of transvaginal ultrasound were calculated using 2 x 2 contingency table. Stratification was done for age, duration of symptoms, family history to observe effect modifiers and post-stratification diagnostic parameters were recalculated.

RESULTS

The study included 348 patients with mean age of 32.16 ± 7.64 years and duration of symptoms was 24.46 ± 13.81 months (as shown in Table-I). Regarding residence, majority of patients were from urban areas 224 (64.4%) while 124 (35.6%) were from rural areas. Family history of Müllerian duct anomalies was present in 56 (16.1%) patients and absent in 292 (83.9%) patients (as shown in Table 1).

Table 1

Patient Demographics and Clinical Characteristics

Demographics		Mean ± SD
Age (years)		32.16 ± 7.64
Duration of Symptoms (months)		24.46 ± 13.81
Residence	Urban n (%)	224 (64.4%)
	Rural n (%)	124 (35.6%)
Family History	Yes n (%)	56 (16.1%)
	No n (%)	292 (83.9%)

When overall results of both diagnostic modalities was compared, TVS detected Müllerian duct anomalies in 86 (24.7%) patients and found them absent in 262 (75.3%) patients. On the other hand, MRI which was considered as

gold standard detected anomalies in only 52 (14.9%) patients and found them absent in 296 (85.1%) patients (as shown in Table 2).

Table 2

Overall Results of TVS and MRI in Diagnosis of Müllerian Duct Anomalies

Müllerian Duct Anomalies	TVS	MRI
Present	86 (24.7%)	52 (14.9%)
Absent	262 (75.3%)	296 (85.1%)
Total	348 (100%)	348 (100%)

The comparison between TVS and MRI revealed that out of 86 cases detected positive by TVS, only 26 were true positive when compared with MRI as gold standard, while 60 were false positive. Out of 262 cases where TVS found no anomalies, 26 were false negative and 236 were true negative when MRI was used as reference (as shown in Table 3).

Table 3

Comparison of TVS versus MRI in Diagnosis of Müllerian Duct Anomalies

TVS	MRI		Total
	Present	Absent	
Present	26 (TP)	60 (FP)	86
Absent	26 (FN)	236 (TN)	262
Total	52	296	348

Key: TP = True positive, FP = False positive, FN = False negative, TN = True negative

The diagnostic accuracy parameters of TVS showed that sensitivity was 50%, specificity was 79.70%, and overall diagnostic accuracy was 75.30%. The positive predictive value was 30.20% and negative predictive value was 90.10% (as shown in Table 4).

Table 4

Sensitivity, Specificity, Diagnostic Accuracy, PPV and NPV of TVS in Diagnosis of Müllerian Duct Anomalies

Diagnostic Parameter	Result
Sensitivity	50%
Specificity	79.70%
Diagnostic Accuracy	75.30%
PPV	30.20%
NPV	90.10%

Stratified analysis based on different variables showed varying results. When patients were stratified by age, those aged ≤30 years showed sensitivity of 50%, specificity of 78.50%, diagnostic accuracy of 74%, PPV of 30%, and NPV of 89.50%. For patients aged >30 years, sensitivity remained 50%, specificity was 80.70%, diagnostic accuracy was 76.30%, PPV was 30.40%, and NPV was 90.50%. When stratification was done according to duration of symptoms, patients with symptoms duration ≤12 months had sensitivity of 42.90%, specificity of 84.20%, diagnostic accuracy of 77.80%, PPV of 33.30%, and NPV of 88.90%. While patients with symptoms duration >12 months showed sensitivity of 52.60%, specificity of 78.20%, diagnostic accuracy of 74.40%, PPV of 29.40%, and NPV of 90.50%. Regarding family history stratification, patients with positive family history had sensitivity of 50%, specificity of 83.30%, diagnostic accuracy of 78.60%, PPV of 33.30%, and NPV of 90.90%. Patients with no family history showed sensitivity of 50%, specificity of 79%, diagnostic accuracy of 74.70%, PPV of 29.70%, and NPV of 89.90% (as shown in Table 5).

Table 5

Stratified Analysis of Sensitivity, Specificity, Diagnostic Accuracy, PPV and NPV of TVS in Diagnosis of Müllerian Duct Anomalies with Age, Duration of Symptoms and Family History

Variables	Groups	Diagnostic Parameter	Result
Age (years)	≤30	Sen	50%
		Spec	78.50%
		DA	74%
		PPV	30%
		NPV	89.50%
	>30	Sen	50%
		Spec	80.70%
		DA	76.30%
		PPV	30.40%
		NPV	90.50%
Duration of Symptoms (months)	≤12	Sen	42.90%
		Spec	84.20%
		DA	77.80%
		PPV	33.30%
		NPV	88.90%
	>12	Sen	52.60%
		Spec	78.20%
		DA	74.40%
		PPV	29.40%
		NPV	90.50%
Family History	Yes	Sen	50%
		Spec	83.30%
		DA	78.60%
		PPV	33.30%
		NPV	90.90%
	No	Sen	50%
		Spec	79%
		DA	74.70%
		PPV	29.70%
		NPV	89.90%

DISCUSSION

The findings of this study show that the transvaginal sonography (TVS) technique has moderate diagnostic ability with a diagnostic accuracy of 75.30% in identifying Müllerian duct anomalies with a sensitivity of 50% and a specificity of 79.70%. The observed 50% sensitivity rate signifies that only half of the positives actually possessing the condition of Müllerian duct anomalies are correctly diagnosed through ultrasonographic evaluation. The observed lower sensitivity may be attributed to the limitation in visualization of the entire uterus fundal margin and outer uterine contour through TVS. These are paramount in precise classification of the uterine malformation. The TVS window is limited and depends on the individual performing the evaluation. The value of specificity (79.70%) is higher than the sensitivity, which means TVS specifically predicts the non-existence of anomalies. However, the high rate of false positives, at 60 among the 86 TVS positives, could indicate a possible over-detection of Müllerian duct anomalies by TVS. This could occur when the TVS falsely diagnoses some variants or the arcuate uterus to be pathological variants, due to its limited field of vision, as well as difficulties encountered while analyzing the myometrial architecture. The positive predictive value, which stands at 30.20%, is very low, which means that TVS prediction of an anomaly actually has only a 30.20% probability of being true. This could be

due to the high rate of false positives and the overall disease prevalence rate among the population studied. However, the negative predictive value of 90.10% means that the TVS result of no anomaly actually has a high probability of being true. The diagnostic accuracy of 75.30% indicates that TVS is able to correctly diagnose about three-fourths of all cases, while about one-fourth escape diagnosis. While this accuracy rate may seem low, it is adequate enough to suggest that TVS can serve as the preliminary tool of choice, but definitely not the final diagnostic approach required for the correct evaluation of Müllerian duct anomalies. Magnetic Resonance Imaging (MRI) provides more clear visualization of the uterus as well as the endometrial cavity.

The present study found sensitivity of 50% and specificity of 79.70% for 2-D TVS in diagnosing Müllerian duct anomalies which is considerably lower compared to most of published literature. Bermejo C *et al.* [15] reported much higher diagnostic accuracy for 3-D TVS with sensitivity of 100%, specificity of 98%, PPV of 97% and NPV of 100% when compared with MRI. Similarly, Chapidze I *et al.* [16] demonstrated that 3-D TVUS achieved sensitivity of 95.83% and specificity of 100% for septate uterus when compared with MRI. The substantial difference in sensitivity between present study findings and these studies can be attributed to the fact that current study used conventional 2-D TVS while Bermejo C *et al.* [15] and Chapidze I *et al.* [16] utilized 3-D ultrasound technology which provide better visualization of uterine fundal contour and allow coronal plane assessment which is not possible with 2-D imaging. However, findings of present study show some similarity with Senger KPS *et al.* [17] who reported sensitivity of 81.8% and specificity of 100% for 2-D trans-abdominal ultrasound compared with MRI, though their sensitivity was still higher than current study. The lower sensitivity in present study might be due to operator dependency and technical limitations of 2-D TVS in detecting subtle anomalies. Alcázar JL *et al.* [18] in their meta-analysis reported pooled sensitivity of 83% and specificity of 99% for 2-D TVS which is also higher than present findings of 50% sensitivity, this discrepancy can be explained by fact that meta-analysis included multiple studies with varying expertise levels and patient populations.

The PPV of 30.20% in current study was notably low compared to Bermejo C *et al.* [15] who reported PPV of 97% for 3-D TVS. Canzone G *et al.* [19] also demonstrated PPV of 100% for 3-D ultrasound versus only 50% for 2-D ultrasound which is more comparable to present study results. This low PPV indicate high false positive rate of 60 cases out of 86 TVS positive cases in present study which suggest that 2-D TVS tend to over-diagnose anomalies due to inability to accurately assess external uterine contour. The NPV of 90.10% in current study was relatively good and comparable to Senger KPS *et al.* [17] who reported NPV of 93.4%, indicating that negative results on 2-D ultrasound are more reliable than positive results. Shiva M *et al.* [20] reported similar limitations of 2-D TVS with sensitivity of only 61.5% for septate uterus and 29.9% for arcuate uterus, which support present study findings of low sensitivity. They concluded that 2-D TVS lack sensitivity despite having high specificity which is consistent with current study results. The overall diagnostic accuracy of 75.30% in present study fall between the extremes reported in literature, with some studies showing accuracy above 94% for 3-D techniques while 2-D modalities demonstrate more modest performance.

The stratified analysis in present study showed minimal variation in diagnostic parameters across different age groups, duration of symptoms and family history, with sensitivity remaining constant at 50% across all subgroups. This consistent performance across stratification suggest that patient demographic factors do not significantly impact diagnostic accuracy of 2-D TVS, rather the technical limitations of modality itself are more important factor. None of referenced studies performed similar stratified analysis to compare with present findings. The evidence from multiple studies including Bermejo C *et al.* [15], Chapidze I *et al.* [16], and Negm SM *et al.* [21] consistently demonstrate superiority of 3-D ultrasound over 2-D TVS, with some studies reporting sensitivity and specificity approaching 100%. This highlight the technological advancement in ultrasound imaging and suggest that 3-D modality should be preferred when available for diagnosis of Müllerian duct anomalies. Shaikh Fayazoddin LA *et al.* [22] emphasized that while ultrasound serve as first investigation, MRI remain gold standard for complete anatomical delineation which is consistent with present study approach of using MRI as reference standard.

There are some limitations to the current study which need to be considered. Firstly, the study being single-centered at a single institution might limit the generalizability of the data. In other words, this study might not be representative of either similar institutions or similar populations. Moreover, the study being cross-sectional cannot assess the relationship or the long-term outcome. Third, the current study did not evaluate the ultrasound examination operator dependence because the variability among the observers was not assessed, which can be important factors to assess the examination accuracy. Fourth, the current study did not include some categories of Müllerian duct anomalies separately.

CONCLUSION

Based on the present study, it can be concluded that the transvaginal ultrasonography has moderate accuracy in diagnosing the Müllerian duct anomalies as compared to magnetic resonance imaging, the gold standard. There was less sensitivity and comparatively higher specificity, revealing its reliability for the exclusion of the anomaly rather than its confirmation. The number of false-positive results was high, clearly establishing the fact that the transvaginal ultrasonography over-diagnoses the Müllerian duct anomalies because of the limitation in the view of the uterine structure. There was a remarkably low positive predictive value, but the negative predictive value was high, establishing the fact that the negative results are more trustworthy than the positive results.

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Ethical Approval: Ethical clearance for study was obtained from Ethical Committee. All procedures and research activities were conducted in compliance with committee guidelines and principles outlined in Helsinki Declaration.

Patients' Consent: Consent from each participant was sought before they could be approached to participate in this study. They were made aware of the confidentiality of their information and could opt out of this study at any time.

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