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Original Research Article

Role of Three-Dimensional Ultrasonography in the Evaluation of Uterine Cavity in Infertility

Abhisek Basak[1], Jaita Chowdhury[2], Bidyut Kumar Das[3], Kamal Oswal[4], Avijit Hazra[5], Tulika Roy[6], Sukanta Sen[7]

[1]Assistant Professor, Department of Radiodiagnosis, ICARE Institute of Medical Sciences & Research, Haldia 721645, Purba Medinipur, West Bengal, India

[2,3]Associate Professor, Department of Anatomy, ICARE Institute of Medical Sciences & Research, Haldia 721645, Purba Medinipur, West Bengal, India

[4]Professor, Department of Radiodiagnosis, Ramakrishna Mission Seva Pratishthan, Vivekananda Institute of Medical Sciences, 99, Sarat Bose Road, Kolkata 700026, West Bengal, India

[5]Professor, Department of Pharmacology & Dean of Student Affairs, Institute of Postgraduate Medical Education & Research, 244, A. J. C. Bose Road, Kolkata 700020, West Bengal, India

[6]Associate Professor, Department of Obstetrics & Gyanecology, ICARE Institute of Medical Sciences & Research, Haldia 721645, Purba Medinipur, West Bengal, India

[7]Professor and HOD, Department of Pharmacology, ICARE Institute of Medical Sciences & Research, Haldia 721645, Purba Medinipur, West Bengal, India

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Corresponding author: Dr. Bidyut Kumar Das

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Abstract

Introduction: The perspective of gradually increasing availability of higher-end ultrasonography machines having 3D volumetric imaging capacity in our country, it appears necessary to assess the credibility of routine use of 3D sonographic imaging for uterine cavity evaluation in infertility patients and its additional advantages in comparison to cost-effectiveness.

Methodology: This study, done including total 158 patients of different age groups referred to the Department of Radio-diagnosis, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata, West Bengal for radiological evaluation of infertility. All of these patients were imaged by conventional 2D and 3D volumetric ultrasound. Among these, 139 subjects further underwent Hysterosalpingography, 27 underwent Hystero-laparoscopy and 2 subjects were imaged with MRI.

Results: After final possible diagnosis, 12% of the infertile patients were detected to have uterine cavity abnormalities, among which 7.59% were Mullerian Duct Anomalies and 4.43% were other kind of endometrial or sub-endometrial pathology. Again, among the Mullerian Duct anomalies, most common was Arcuate uterus (3.8% of the study population) followed by Septate / Sub-septate uterus (1.9% of the study population). 2D USG, being incapable of imaging of uterus in coronal plane, could only detect 7 abnormal uterine cavities (37% of total 19) with one misdiagnosis, whereas 3D volume Ultrasound detected 18 abnormal cavities (95% of total) with 100% sensitivity and specificity in cases of Mullerian Duct Anomalies unquestionably proving the advantages of 3D USG over 2D USG for detection of uterine cavity pathologies.

Conclusion: Thus, the present work strongly supports the already proposed role of 3D USG in the diagnosis of uterine cavity abnormality, especially for congenital Mullerian duct abnormalities, and its clear benefits over the conventional 2D scan.

Keywords: Infertility, Mullerian Duct Anomalies, Uterine Cavity Abnormalities, 2D Transvaginal Sonography, 3D Transvaginal Sonography, Hysterosalpingography.

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Introduction

Infertility is defined as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse" (WHO-ICMART glossary) [1]. The problem of infertility is gradually increasing in India due to various demographical as well as etiological factors. Among the important causes of infertility, different abnormalities of uterine cavity are some of the most important factors, for which medical

and surgical management is likely to improve the fertility rate [1]. The common uterine cavity abnormalities resulting in infertility are congenital mullerian duct anomalies, endometrial adhesions and Asherman's Syndrome, endometrial polyps or sub-mucosal fibroids distorting the uterine cavity, endometriosis, endometrial hypoplasia, chronic endometritis etc. For imaging and evaluation of these pathologies, various radiological modalities are available starting from transvaginal 2D ultrasound, hysterosalpingography, sonohysterography etc. up to modern evaluation techniques like MRI scan, however ultrasound has proved to be the least expensive, least invasive and most readily available imaging tool for day-to-day clinical practice [2-7].

Traditional views of the uterus and endometrium on 2-dimensional (2D) sonography are usually limited to sagittal and transverse images of the uterus. This is due to inherent limitations of the scan planes that can be obtained with trans-abdominal and trans-vaginal transducers and the limited mobility of the trans-vaginal probe during trans-vaginal sonography. With 3D volume imaging, any desired plane through the uterus can be obtained regardless of the original scan plane of acquisition so that the uterus and endometrium can be imaged in the coronal plane [8-11]. Investigators have shown additional findings on the coronal images that cannot be appreciated by traditional views. This view is essential for evaluating the uterine contour for anomalies [10, 11] and for proper three-dimensional orientation of other abnormalities related to uterine cavity.

Although 3D volume imaging techniques have become routine in computed tomography and magnetic resonance imaging, and their clinical value is well appreciated, it has only been more recently that these techniques have become available in the field of sonography. With 3D sonography, a volume rather than a single image plane is acquired, stored, reformatted, and analyzed, showing any arbitrary plane needed. Using a multi-planar display, 3 perpendicular planes are displayed simultaneously, and correlation among these planes can be obtained [10, 12]. Earlier Jurkovic et al. [11] in 1995 established in their study that there is complete agreement between three-dimensional ultrasound and hysterosalpingography in classifying the uterus as normal or abnormal and three-dimensional ultrasound is superior to that of two-dimensional ultrasound. Similarly, Raga et al. [13] in 1996 in their study concluded that patients with Mullerian anomalies, 3D US examination of the endometrial cavity correlated well with hysterosalpingography as well as the external uterine configuration observed by laparoscopy and the technique may be used reliably in an office setting to diagnose and classify Mullerian anomalies. Ghi et al. [14] after their study in the year 2009 argued that volume transvaginal ultrasound appeared to be extremely accurate for the diagnosis and classification of congenital uterine anomalies and may very well become the only mandatory step in the assessment of the uterine cavity in patients with a history of recurrent miscarriage. And in recent year Bermejo et al. [15] concluded after their study in 2010 that there was high degree of concordance between 3D ultrasound and MRI in the diagnosis of uterine malformations, the relationship between cavity and fundus being visualized equally well with both the techniques. Many other workers from different countries have also done many studies in this regard, but till now, not much studies have been done with 3-dimensional sonographic assessment of uterine cavity in the Indian scenario.

In this context with the perspective of gradually increasing availability of higher-end ultrasonography machines having 3D volumetric imaging capacity in our country, it appears necessary to assess the credibility of routine use of 3D sonographic imaging for uterine cavity evaluation in infertility patients and its additional advantages in comparison to cost-effectiveness. So, by evaluating a series of patients undergoing pelvic sonography with routine 2D as well as 3D reconstructed images of the endometrial cavity in the coronal plane, this work tried to assess the additional information shown in this plane and have corroborated the findings with other diagnostic modalities whenever available so that the issue of routine use of this imaging modality can better be answered.

Aims & Objectives: The aim of this study is to establish the role of 3D transvaginal ultrasonography in the evaluation of various uterine cavity abnormalities in infertile patients in local population.

Materials and Methods

Study Design: In the scheduled one year study period, from May, 2014 to April, 2015, total 161 patients referred to the Department of Radio-diagnosis, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata, West Bengal for radiological evaluation of infertility in the age group of 20 to 40 years, both the primary infertility cases and secondary infertility cases with or without previous history of caesarean section or dilatation & curettage were prospectively enrolled in the study and were subsequently subjected to first 2D and then 3D transvaginal sonography done by the researcher. Referred secondary infertility patients having history of any uterine surgical procedures other than caesarean section or dilatation & curettage for previous miscarriage; patients having history of

failed attempt of transvaginal sonography due to any reason and the patients who were not willing to be part of the study or didn't give consent for transvaginal USG were not enrolled for the study.

Among the 161 patients, in 3 patients, optimum 3D volumetric data could not be acquired, in 2 patients due to multiple intramural fibroids with gross distortion of the uterus and uterine cavity and in the other patient due to anteverted retroflexed small uterus having a position unsuitable for acquiring 3D data. So, after exclusion of these 3 patients, the total number of study population became 158.

In these total 158 patients, 139 patients underwent hysterosalpingography, 98 patients before acquiring the USG data and the rest 41 after USG examination. The hysterosalpingograms were reported by different radiologist unaware of USG findings and the HSG images were not available to the researcher while doing the USG. All the patients having abnormal HSG and/or USG findings were subsequently subjected to Hystero/Laparoscopy or MRI as gold standard diagnostic tool, however it was observed that due to high cost and inability to have any therapeutic manoeuvre in case of MRI, clinicians in the said institute preferred hystero-laparoscopy over MRI in infertility patients. In the present study, MRI imaging was done only in two subjects included in the study, one from the same institute for evaluation of lower abdominal pain, and other from outside to evaluate provisionally diagnosed unicornuate uterus. So, though initially it was proposed in the protocol that correlation of 3D USG will be tried with MRI if adequate number of MR images would have been available, practically it was not possible due to unavailability of adequate number of MRI scans. Excluding these 139 patients, rest 19 patients were examined only by USG, which showed no detectable abnormality and no further investigations were advised.

Methodology

All the patients were examined by Voluson E8 Expert ultrasound machine (Make: GE Medical Systems, Serial no: D00203, System ID: 083037600019111), first trans-abdominally through trans-vesical window, and then trans-vaginally both in 2D mode and then in 3D volumetric mode. Trans-abdominal scans were done by 4C-D (2 – 5 MHz) sector probe and the transvaginal scans by RIC 5-9 D (4–9 MHz) endo-cavitory probe (Fig. 2), having automated 3D volume acquisition property, commonly termed as "volume probe". It contains a mechanized drive within its assembly. When these probes are activated, the transducer elements automatically sweep through the operator-selected region of interest (volume "box") while the probe is held stationary, with the help of a mechanical motor system within the terminal part of the probe itself (Fig.1).

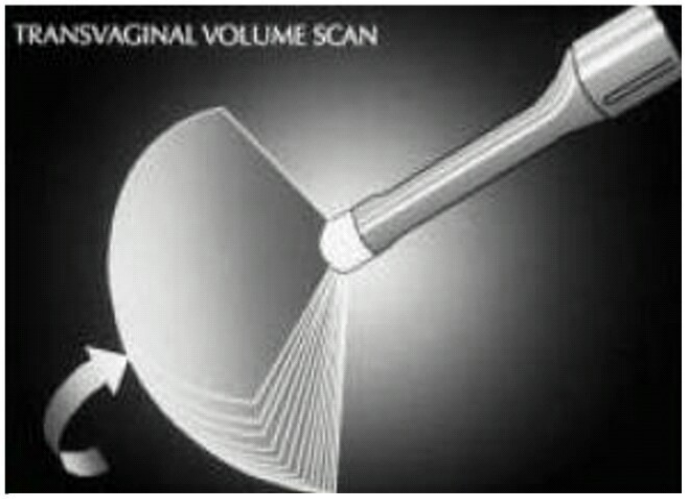

Figure 1: Endo-cavitory probe with 3D volumetric mechanism

The speed of this sweep can be determined by the operator. A slower speed yields the higher resolution because the number of 2D slices within the acquired volume could be maximized. Thus, the larger the volume box, the longer the acquisition time. Longer acquisition time is not a limiting factor in case of gynecological volume imaging in comparison to obstetric imaging due to static property of pelvic organs [16].

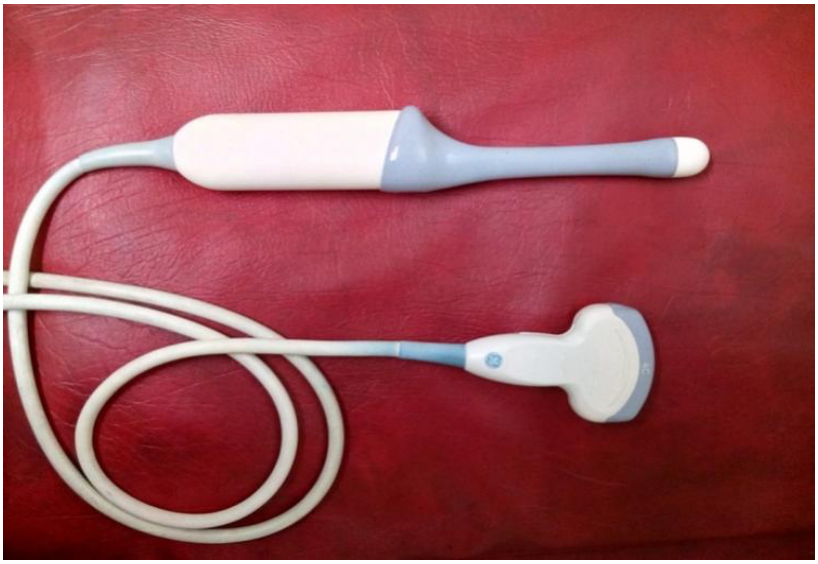

Figure 2: Trans-abdominal and Endo-cavitory volume probes used in this study

The researcher obtained trans-vaginally between three to five static volumes of the uterus, with a quality ranging from medium to high. The volume data when stored digitally took around 30 to 50 MB of hard drive space. Initially the uterus was visualized on 2D ultrasound in a strict mid-sagittal view, adjusting the capture window to obtain the optimal 3D volume.

The volume was then obtained using a sweep angle of 100^0 to 120^0 from one side of the uterus to the other, bisecting the capture plane (Figure 3).

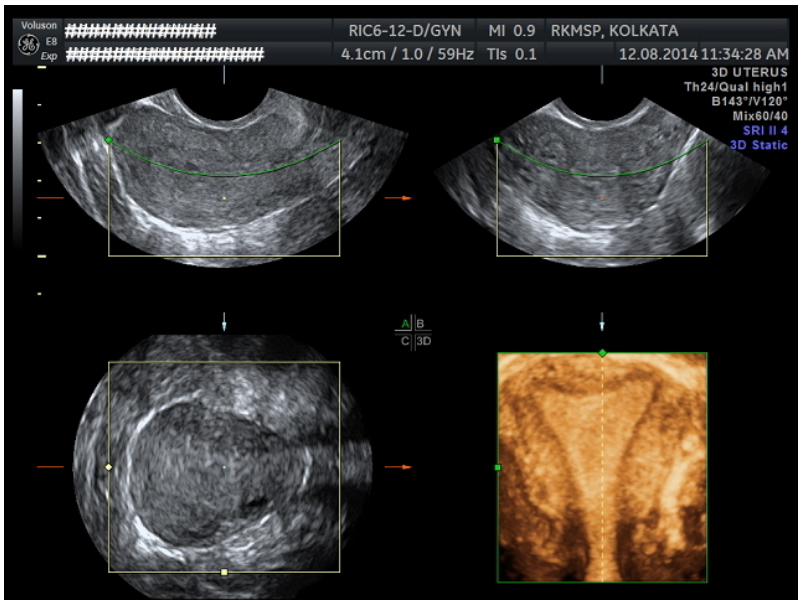

Figure 3: Obtaining 3D volume data in multi-planar image taking mid-sagittal plane as reference and getting 3D image of uterus in coronal plane

In cases with anomalies resulting in a large transverse uterine diameter or normally widened fundus of the uterus, the volume was obtained from a transverse plane so that both uterine cornua could be visualized in the 3D coronal image, so that to allow better estimation of the cavity/fundus relationship in the 3D reconstruction. In these cases, for evaluation of lower uterine body and cervix, a separate volume was taken [15].

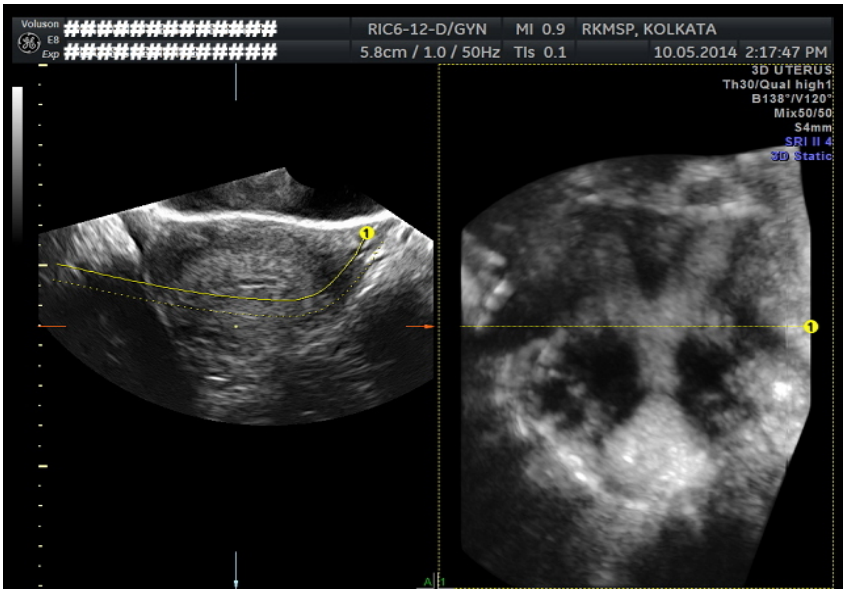

Figure 4: Widened fundus in a sub-septate uterus needed fundal volume to be obtained from taking transverse section of uterus as reference plane.

The volumes were manipulated so that a satisfactory surface rendered image was obtained of the fundus and uterine cavity as well as the cervical canal.

When a mid-sagittal plane was used to capture the volume, the rendering box in Window A (capture image) was adjusted to include the uterine fundus and the green rendering line was adjusted tracing the sagittal curved plane of the uterine cavity so that the line was located on the endometrium, and simultaneously checking in Window B that the plane is in the midline (Figure 4). Unlike older machines, newer Ultrasound machines are equipped with capability of changing the curvature of the green rendering line according to the sonographer's choice, so that it becomes a lot easier to align the rendering line with the curved endometrial cavity. In cases of studying the cervix separately the rendering box and the green lines were adjusted accordingly. When the volume was obtained from a transverse plane, both uterine horns were included in the rendering box and the green line was adjusted so that a good quality image showing both cavity and fundus was obtained in the rendered view. Luminosity and contrast curves were adjusted for both multi-planar and rendered images, as well as for threshold and transparency.

The uterus was then imaged in 4D VCI Omni view mode (Fig. 5), where the plane of 3D volume rendering could be manipulated completely as per user's choice as line, curve, polyline or trace (Fig. 3) – so that the rendering line could be matched and aligned exactly like that of endometrial lining.

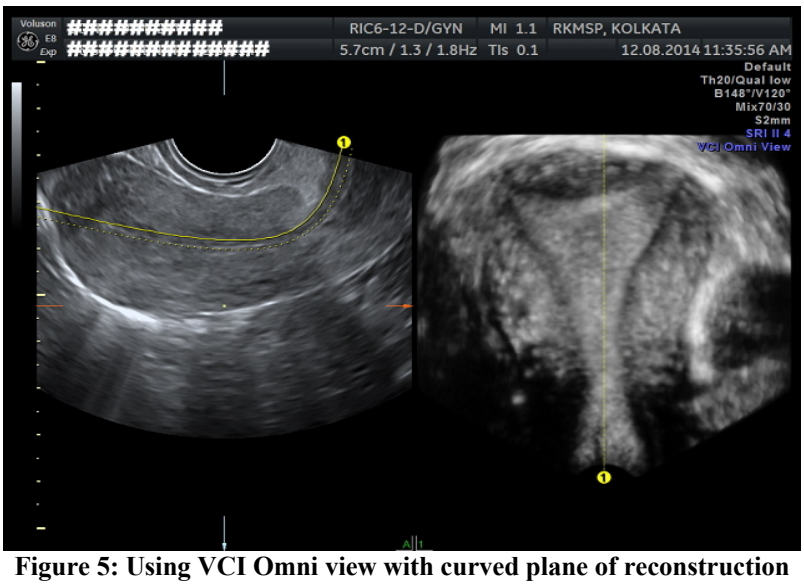

Figure 5: Using VCI Omni view with curved plane of reconstruction

In the present study, the endometrial rendering was mostly done by "curve" plane reconstruction and the slice thickness was kept in either 2mm or 4mm range. With use of this newer VCI Omni View mode, it was possible to image most of the uterus within a single volume completely from fundus to cervix and having almost perfect reconstruction plane aligned to the endometrial cavity. The 3D volume rendered image was seen in real time and necessary manipulations regarding appropriate positioning and volume angles could be achieved. The post-acquisition processing was also done whenever appropriate after the patient was released [17-19]. The post-processing in a sagittal uterine volume data with the Omni View "Trace" method also gave images like virtual hysteroscopy.

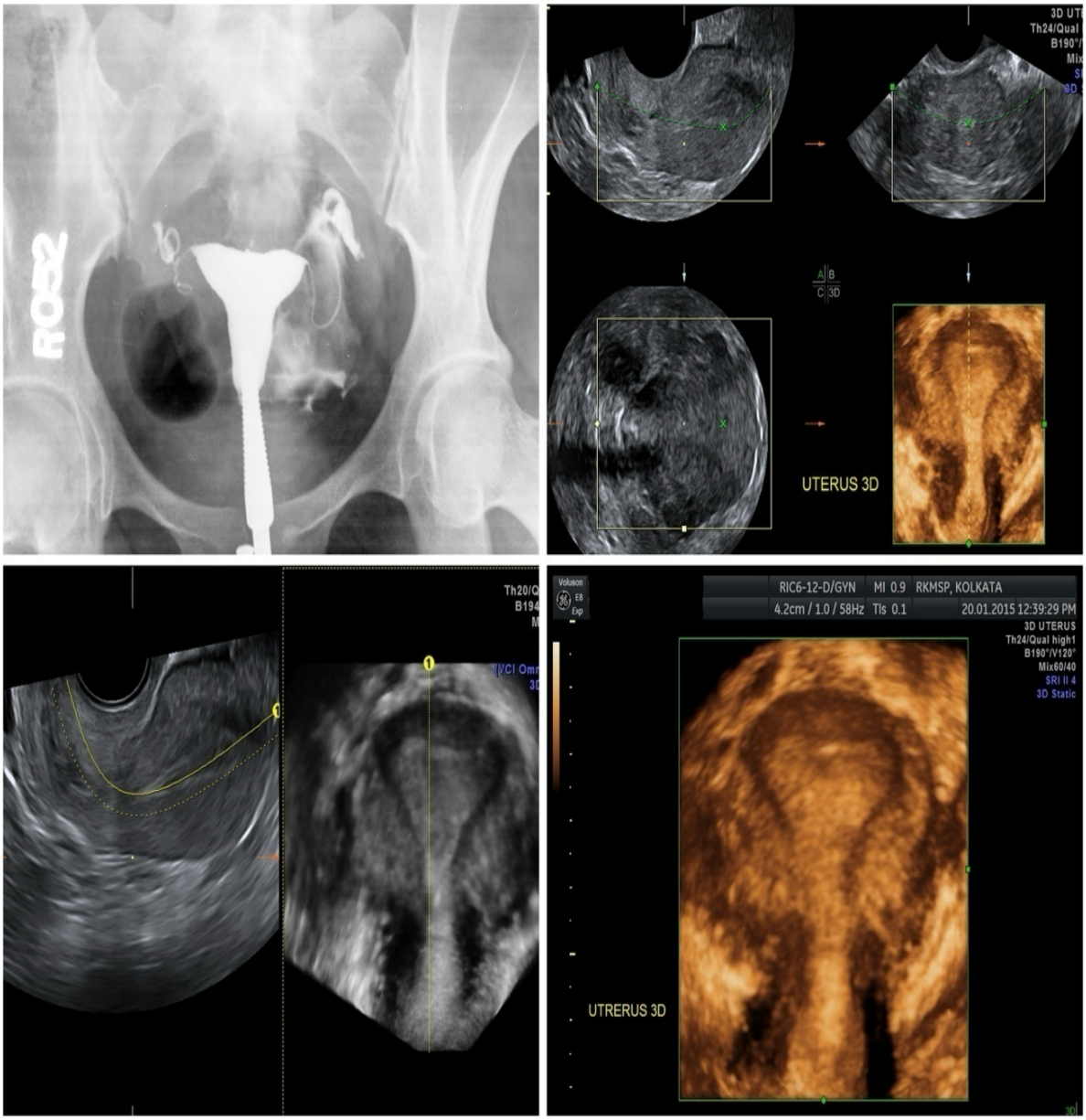

Figure 6: Normal uterine cavity demonstrated on Hysterosalpingography and 3D Ultrasonography. In 3D USG taken in static 3D Protocol or by VCI Omni View (Left lower image), post processing is possible to obtain coronal view of uterus with beautiful demonstration of uterine cavity and fundal contour.

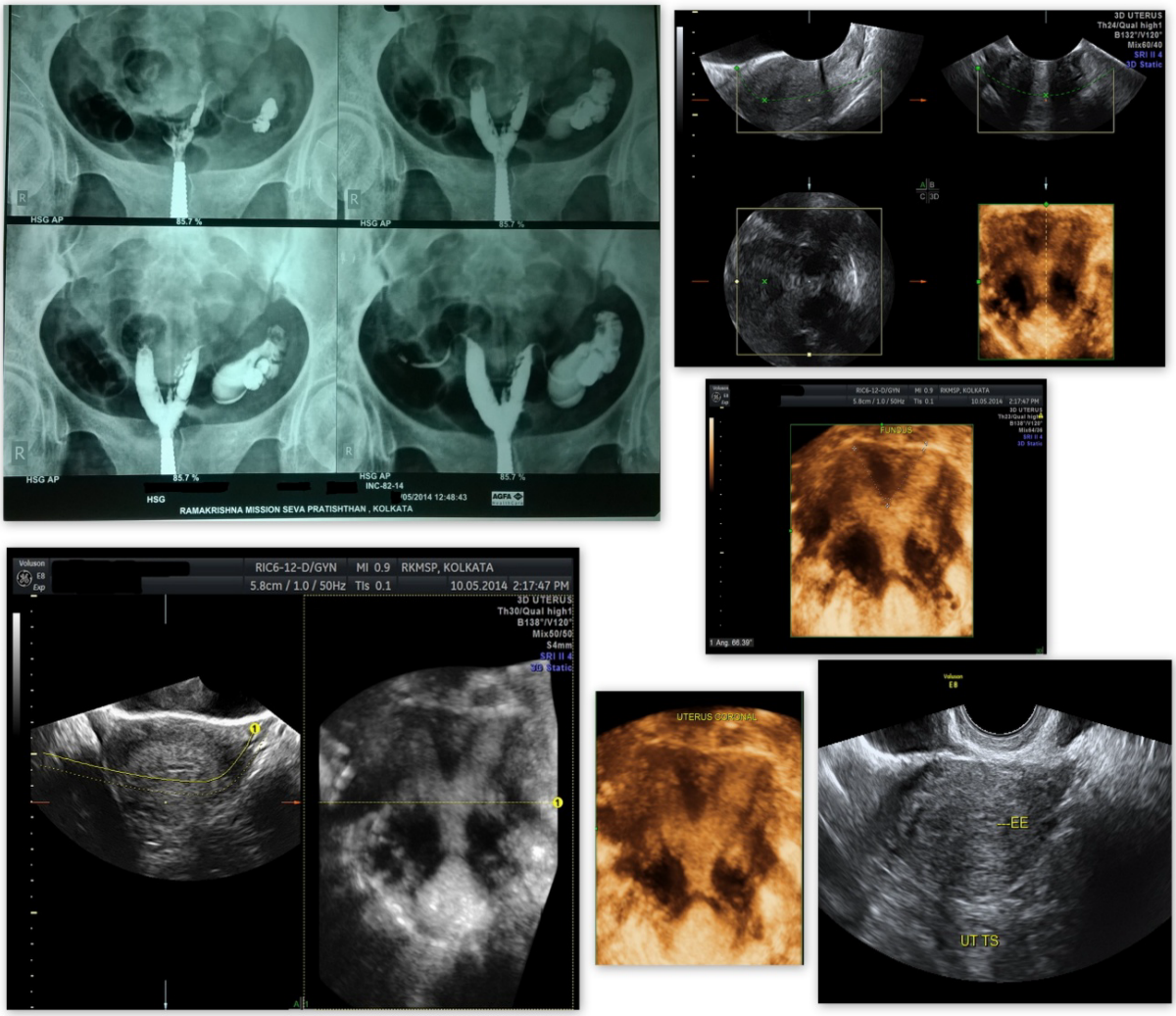

Figure 7: Sub-septate uterus. 2D USG showing two separate endometrial echoline in transverse section separated by myometrium like tissue initially diagnosed it as Bicornuate uterus, however HSG and 3D USG made the correct diagnosis of Sub-septate uterus.

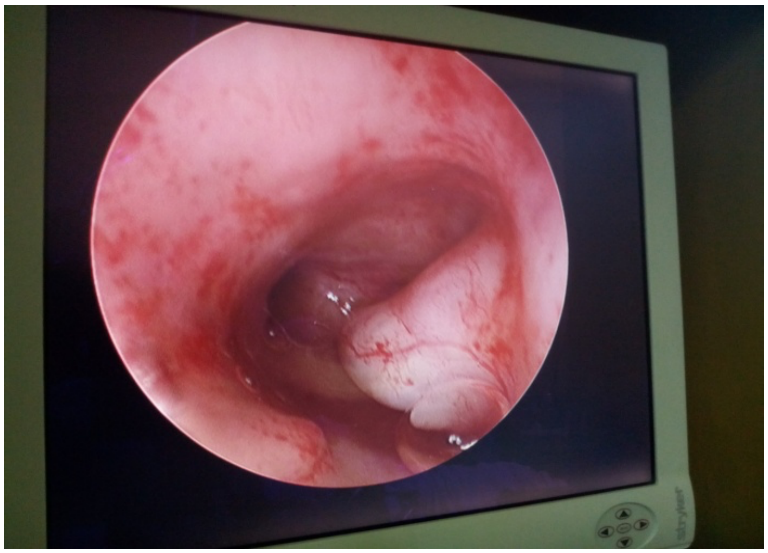

Figure 8: Sub-mucosal fibroids. 2D USG only detected endometrial thickening, but 3D USG in HSG, both showed the sub-mucosal fibroids in left lateral and superior wall of uterine cavity. Hysteroscopic removal was done.

Results

Among the total 158 infertility patients [Fig. 9] within this study, the age distribution was: 4 patients in the age group of 18 to 20 year, 45 in the age group of 21 to 25 years, 53 patients between 26 to 30 years, 43 patients between 31 to 35 years and 13 patients were above 35 years of age. Again, among the 158 patients, the number of primary infertility patients was relatively more than the secondary infertility group. Total 121 patients presented with primary infertility, whereas only 37 patients presented with the history of secondary infertility. After the final possible imaging, among the 158 patients, 139 patients were diagnosed to have normal uterine cavity, rest 19 were diagnosed to have either any Mullerian duct abnormality or any endometrial or sub-endometrial pathology.

The subjects were classified into six main groups:

1. No detectable uterine cavity abnormality: n = 139
2. Arcuate Uterus: n = 6
3. Septate or Sub-septate uterus: n = 3
4. Other Mullerian Duct abnormality: n = 3
5. Mucosal / Sub-mucosal pathology: n = 4
6. Endometrial adhesion: n = 3

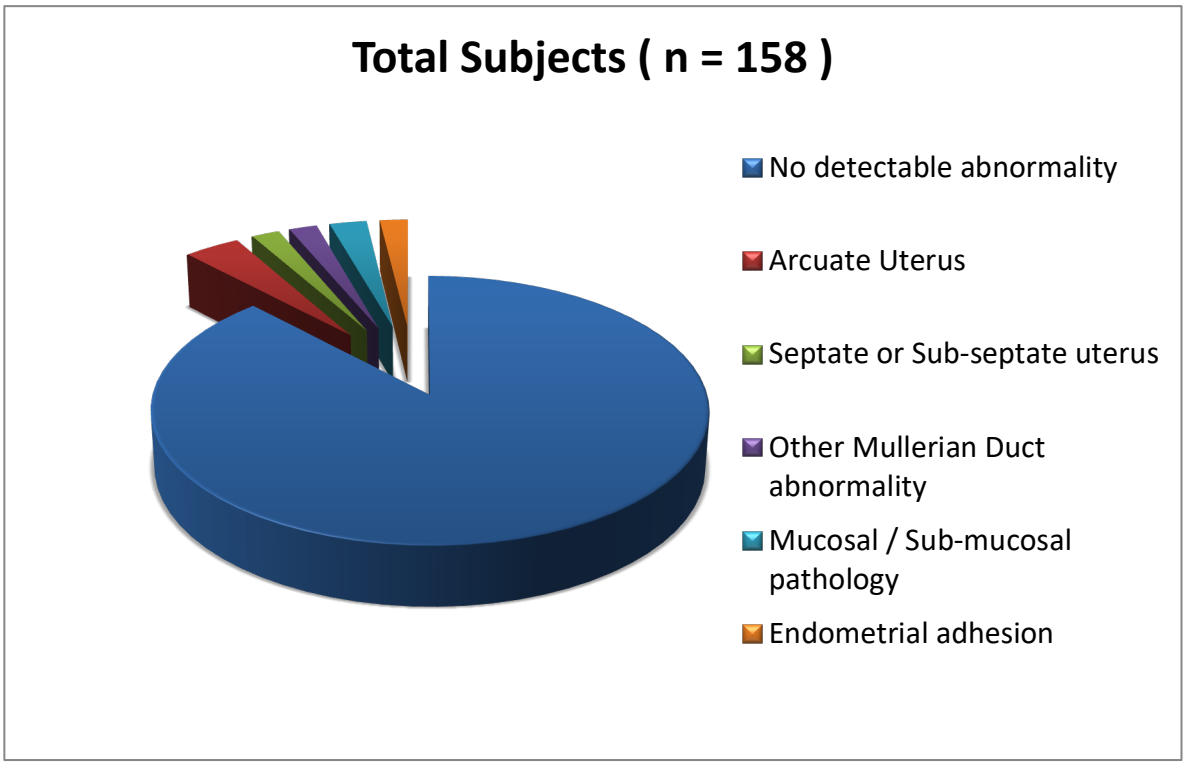

Figure 9: Distribution of the study participants

Among the imaging modality used; 2D USG, 3D USG and hysterosalpingography were compared on their own as well as with each other in terms of abnormality detection, relative sensitivity, specificity, predictive values and inter-modality agreement taking hystero-laparoscopy or MRI as the gold standard for confirmation of the abnormalities in available cases.

2D USG detected total 7 abnormal uterine cavities among 158 total scans (prevalence 4.43% with 0.95 confidence interval 1.22%to 7.64%), among which it misdiagnosed one Septate uterus as Bicornuate uterus. Hysterosalpingography itself detected 21 abnormalities in uterine cavity among the 139 subjects in whom it was done (detection prevalence being 15.11% with 0.95 confidence interval 9.2% to 21.1%), having misinterpreted one normal uterine cavity for an arcuate uterus and falsely detecting one intrauterine filling defect and 3D Ultrasonography was done in all 158 subjects, detected 18 abnormal uterine cavities with detection rate of 11.39% and 0.95 confidence interval from 6.44% to 16.35%.

It also failed to detect a case of tubercular endometritis subsequently confirmed by hystero-laparoscopy.

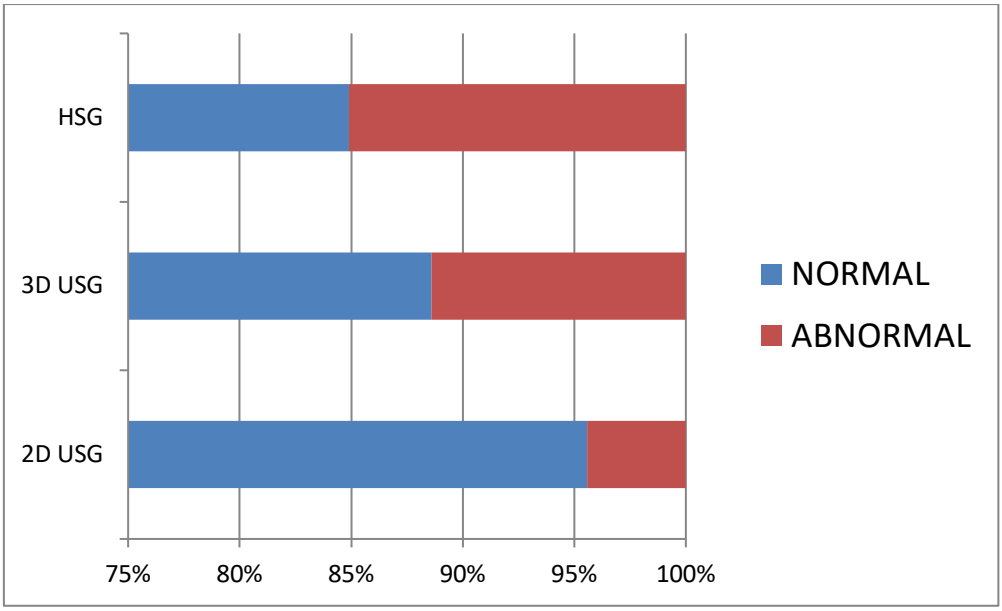

Figure 10: Abnormality detection rate in Hysterosalpingography, 3D Ultrasonography and 2D Ultrasonography

Thus, it was observed that abnormality detection rate were comparable in Hysterosalpingography and 3D Ultrasonography, but 2D Ultrasonography lagged a way behind for detection of uterine cavity abnormalities [Table 10].

Then inter-modality agreement for different abnormality detection was calculated between 3D USG and other two modalities, i.e. Hysterosalpingography and 2D USG and between 3D USG and gold-standard as Hystero-laparoscopy by "Kappa statistics". The subjects were again classified into six groups as before (1.No detectable uterine cavity abnormality, 2.Arcuate Uterus, 3.Septate or Sub-septate uterus, 4.Other Mullerian Duct abnormality, 5.Mucosal/Sub-mucosal pathology and 6.Endometrial adhesion) and kappa values calculated as un-weighted method in 6 by 6 table. The agreement was categorized into strong (Kappa value 0.7 or more), good (0.5 to 0.7), fair (0.3 to 0.5) and poor (less than 0.3). Then sensitivity, specificity and predictive values of each diagnostic modality were calculated separately for detection of Mullerian Duct anomalies and other endometrial or uterine cavity pathologies by 2 by 2 table analysis. Finally, sensitivity, specificity and predictive values of each diagnostic modality were calculated. The values were calculated for 2D USG, 3D USG and HSG separately for Mullerian duct abnormalities and for endometrial and sub-mucosal pathologies.

The cases were taken to be true positive when they were confirmed by either Hystero-laparoscopy or by MRI, which are taken to be gold-standard for the diagnosis. So only 28 subjects were taken into account for these calculations where either of these two modalities was available.

Table 1: 2D USG in Detection of Mullerian Duct Abnormality

	Abnormality present	Abnormality absent
Detected	4	0
Not detected	3	21

The calculated sensitivity is57.14% (0.95 CI 18.41% - 90.10%), Specificity is 100% (0.95 CI 83.89% - 100.00%), positive predictive value 100% (0.95 CI 39.76% – 100.00%) and Negative predictive value 87.50% (0.95 CI 67.64% - 97.34%).

Table 2: 2D USG in Detection of Endometrial / Sub-Mucosal Pathology

	Abnormality present	Abnormality absent
Detected	3	0
Not detected	4	21

The calculated sensitivity is 42.86% (0.95 CI 9.90% - 81.59%), Specificity is 100% (0.95 CI 83.89% - 100.00%), and positive predictive value 100% (0.95 CI 29.24% – 100.00%) and Negative predictive value 84.00% (0.95 CI 63.92% - 95.46%).

Table 3: 3D USG in Detection of Mullerian Duct Abnormality:

	Abnormality present	Abnormality absent
Detected	7	0
Not detected	0	21

The calculated sensitivity is 100.00% (0.95 CI 59.04% - 100.00%), Specificity is 100.00% (0.95 CI 83.89% - 100.00%), and positive predictive value 100.00% (0.95 CI 59.04% – 100.00%) and Negative predictive value 100.00% (0.95 CI 83.89% - 95.46%).

Table 4: 3D USG in Detection of Endometrial / Sub-Mucosal Pathology:

	Abnormality present	Abnormality absent
Detected	6	0
Not detected	1	21

The calculated sensitivity is 85.71% (0.95 CI 42.13% - 99.64%), Specificity is 100.00% (0.95 CI 83.89% - 100.00%), and positive predictive value 100.00% (0.95 CI 54.07% – 100.00%) and Negative predictive value 95.45% (0.95 CI 77.16% - 99.88%).

Discussion

In the study population of 158, total 12 patients (n = 12, 7.59% of total study population) were diagnosed to have Mullerian duct abnormality, and 7 patients (n = 7, 4.43% of total study population) were diagnosed to have different kind of endometrial or sub-mucosal pathology. Thus around 12% patients (n = 19) were detected to have uterine cavity abnormality.

Among the Mullerian duct abnormalities, the most common was arcuate uterus (n = 6, 3.8% of study population), the second most common abnormality being Septate / Sub-septate uterus (n = 3, 1.9% of study population). Other detected Mullerian abnormalities comprised of rest 3 cases of congenital uterine abnormality.

Sotirios et al. [20] in their large-scale analysis of different studies published at different times published in 2008 found that the prevalence of congenital uterine anomalies is 6.7% [95% confidence interval (CI), 6.0–7.4] in the general population, 7.3% (95% CI, 6.7–7.9) in the infertile population and 16.7% (95% CI, 14.8–18.6) in the population having history of recurrent miscarriage.

The present study also showed the prevalence of congenital uterine abnormality in the southern region of West Bengal to be very much similar. In their study they found that arcuate uterus is the commonest anomaly in the general and recurrent miscarriage population whereas the septate uterus is the commonest anomaly in the infertile population. Though the present study does not divide the infertile population into infertility and recurrent miscarriage group, the most common two types of abnormality were the same i.e. Arcuate and Septate / Sub-septate uterus respectively [21, 22]. Fatemi et al. [7] in 2010 in their study done in a total population of 678 infertile patients found that the prevalence of uterine cavity abnormality including endometrial polyp, submucosal fibroids, adhesion, septae etc. in infertility patients was around 11%. The present study also matched the data showing a total prevalence of uterine cavity abnormality around 12% in the study group. In regard of comparison of efficacy between 2D and 3D ultrasonography, the researcher found undoubted superiority of 3D USG in detection of abnormalities of uterine cavity.

2D USG detected total 7 abnormal uterine cavities among the total 19 abnormal cavities (near about 37% of total), among which it misdiagnosed one Septate uterus as Bicornuate uterus. Though 3D USG also failed to detect a case of tubercular endometritis subsequently confirmed by hystero-laparoscopy, it was able to diagnose correctly 18 cases of uterine cavity abnormality among the total 19 abnormal uterine cavities (approximately 95% of total).

There were no false positive cases for 2D USG showing a specificity and positive predictive value of 100% in diagnosis of both congenital uterine abnormality as well as the endometrial/Sub-mucosal pathology emphasizing the negligible chance of falsely diagnosing abnormality in a normal cavity, and the necessity of further definitive work up when the cavity is abnormal by 2D sonography. However the sensitivity of 2D USG was very much less (for congenital abnormality 57.14% and for mucosal/sub-mucosal pathology 42.86%).

In comparison, 3D USG showed very good sensitivity and specificity for diagnosis of both congenital anomalies as well as endometrial / Sub-mucosal pathologies. It showed complete agreement with the definitive diagnostic tests for diagnosis of congenital Mullerian duct abnormalities with 100% sensitivity and specificity. For mucosal abnormality detection also, it achieved 85.71% sensitivity and 100% specificity proving its diagnostic capabilities in this regard. Finally, the calculated kappa of 3D USG with the definitive diagnostic modality Hystero-laparoscopy showed strong agreement between these two modalities

(kappa value 0.947). According to our data, 2D Ultrasonography showed a very high positive predictive value proposing high chance of having definite uterine cavity abnormality in cases of an abnormal 2D USG finding, and necessity for further evaluation. However it missed significant number of uterine cavity abnormality showing a high number of false negative cases. So it seems very necessary to include 3D USG scanning as a routine imaging modality for evaluation of uterine cavity to detect that set of abnormalities. When compared to the definite diagnostic modality like Hystero-laparoscopy, 3D USG showed excellent concordance of finding with approximately near total agreement [23].

The most widely used imaging for diagnosis of uterine cavity pathology in the study area, Hyterosalpingography, gave two false positive results, for which the patient had to undergo additional imaging, the correct diagnoses being already proposed by 3D USG. However, 3D USG also failed to detect a case of tubercular endometritis, which was detected by HSG, possibly due to the better appreciation of subtle endometrial irregularities in a contrast distended uterine cavity. Both of these two techniques have their unique added advantages, i.e. assessment of fallopian tube luminal morphology and their patency in HSG and evaluation of myometrium and extra-uterine other pelvic soft tissue pathologies in 3D USG, proposing the importance of individualized choice of these modalities according to the clinical scenario. This study showed comparable efficacy of these two modalities in detection of endometrial and sub-mucosal pathology, but in the question of detection of congenital Mullerian duct abnormality, 3D USG undoubtedly scores ahead of HSG, supposedly due to its unique ability to visualize uterine fundal contour.

The limitation of this study was the smaller size of population. Definite recommendations about the efficacy of different imaging modalities needs a larger scale study in a larger population area. Another limitation of this study was limited number of Hystero-laparoscopic or histo-pathological correlation. Definitive evaluation were only done in cases of detectable abnormality in either 3D USG and/or Hysterosalpingography, thus the distant possibility of missing an abnormality by both 3D USG and HSG could not be totally ruled out.

Conclusion

Infertility, being a growing concern in modern day Gynaecology, needs proper and precise evaluation of the uterine cavity as uterine cavity abnormalities has been proved to be among the major and correctable cause of the same. There was near complete agreement of 3D USG findings with other commonly used imaging modality like Hysterosalpingography or more definitive diagnostic modality like Hystero-laparoscopy. Though correlation with MRI was not statistically possible due to inadequate number of MRI performed, in the 2 cases, where MRI was done, the findings of uterine cavity perfectly matched with 3D USG finding. Thus, the present work strongly supports the already proposed role of 3D USG in the diagnosis of uterine cavity abnormality, especially for congenital Mullerian duct abnormalities, and its clear benefits over the conventional 2D scan.

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