COMPARISON BETWEEN ULTRASONOGRAPHY AND HYSTEROSCOPY FOR ASSESSMENT OF ENDOMETRIAL PATHOLOGY IN WOMEN WITH ABNORMAL UTERINE BLEEDING

THESIS

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DECLARATION

I hereby declare that the thesis titled "**Comparison between Ultrasonography and hysteroscopy for assessment of endometrial pathology in women with Abnormal Uterine bleeding**" embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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LIST OF ABBREVIATIONS

Abbreviation	
AUB	Abnormal Uterine bleeding
USG	Ultrasonography
EB	Endometrial biopsy
PPV	Positive predictive value
NPV	Negative predictive value
FIGO	International Federation of Gynaecology and Obstetrics
SPSS	Statistical package for social sciences
OPD	Outpatient department
PALM	Polyp, Adenomyosis, Leiomyoma, Malignancy
COEIN	Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic and Not otherwise specified
PCOS	Polycystic ovarian syndrome
HMB	Heavy menstrual bleeding
NICE	National Institute of Clinical Excellence
TVS	Trans Vaginal Ultrasonography
TAS	Trans Abdominal Sonography
MRI	Magnetic Resonance Imaging
COH	Contrast Hysterosonography
SIS	Saline Infusion Sonography
STRAW	Stages of Reproductive Aging Workshop
PMB	Post-menopausal bleeding
AD	Anno Domini
USSR	United Soviet Socialist Republic
D & C	Dilatation and curettage
HPE	Histopathological examination
OR	Odd's ratio
CI	Confidence interval
LR	Likelihood ratio
ET	Endometrial thickness
w.r.t.	With respect to
RCOG	Royal College of Obstetricians and Gynaecologists
OT	Operation theatre
HTN	Hypertension
CKD	Chronic kidney disease
IHD	Ischaemic heart disease

BMI	Body mass Index
WHO	World health organisation
RPOCs	Retained products of conceptions
GTDs	Gestational trophoblastic diseases
PSTTs	Placental site trophoblastic tumour
C-scar	Caesarean scar
IUCD	Intrauterine Contraceptive devices
AVM	Arterio Venous Malformations
Ca	Carcinoma
NAD	No abnormality detected
Hys	Hysteroscopy

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SUMMARY

AUB is a common gynaecological problem in women, occurring in reproductive and post reproductive phase of women's life. They are generally evaluated by Ultrasonography (USG), Endometrial biopsy (EB) /aspiration and hysteroscopy along with blood investigations. Histopathology is considered gold standard for diagnosis of endometrial pathologies.

Objective: To compare the diagnostic accuracy of Ultrasonography and Hysteroscopy as measured in sensitivity, specificity, Positive predictive value and negative predictive value in diagnosing endometrial pathology against histopathology examination as gold standard. Secondary objective was to assess the distribution and pattern of endometrial pathology in all women with abnormal uterine bleedings.

Methods: All patients with abnormal uterine bleeding diagnosed as change in frequency, regularity, duration and flow volume as per FIGO system 1 guidelines underwent ultrasonography, hysteroscopy and endometrial biopsy along with all the necessary investigations directed towards diagnosing abnormal uterine bleeding as per patient clinical profile. Patients fulfilling the inclusion criteria were included in the study after informed consent. Data were collected and analysed by using SPSS version 23.

Results: In total 107 patients were recruited in the study, out of which 18 were post-menopausal females, and 89 were pre-/peri-menopausal females. In the current study Sensitivity, specificity, PPV, NPV and accuracy of hysteroscopy in diagnosing endometrial pathologies was found to be 81.94 %, 81.08 %, 89.87%, 68.67 % and 81.66% respectively and for it was 47.22%, 42.86%, 62.87%, 28.38% and 45.79% respectively. In analysis among post-menopausal females and pre-/peri-menopausal females similar results were reflected. Sensitivity, specificity, PPV, NPV and accuracy of hysteroscopy for diagnosing endometrial polyp was found to be 87.5%, 83.33%, 69.13%, 93.99%, and 84.58% as compared to ultrasonography of 34.38%, 16.67%, 14.96%, 37.32% and 21.96% respectively. In diagnosing endometrial hyperplasia hysteroscopy was found to be having sensitivity, specificity, PPV, NPV and accuracy of 57.15%, 100%, 100%, 93.94% and 94.39% respectively as compared to ultrasonography of 28.57%, 4.12% and 3.74% respectively. In diagnosing endometrial carcinoma hysteroscopy had sensitivity, PPV and accuracy of 66.67%,

100% and 99.07% whereas ultrasonography showed 33.33%, 0.95% and 0.93% respectively. Hysteroscopy was found to have better diagnostic accuracy in comparison to ultrasonography in diagnosing specific endometrial pathologies as endometrial polyps, endocervical polyps, endometrial hyperplasia and endometrial cancer. This difference was statistically significant with p value of <0.00001 in comparing sensitivity, specificity, Positive Predictive Value, Negative predictive value and accuracy of hysteroscopy and ultrasonography. In comparing Hysteroscopy and Ultrasonography, Kappa value was calculated to be 0.30 which is a fair agreement.

Conclusion: Hysteroscopy is found to be having better sensitivity, specificity, Positive Predictive Value, Negative predictive value and accuracy as compared to Ultrasonography for diagnosing endometrial pathologies. Hysteroscopy can be recommended as investigation of choice for assessment and treatment of abnormal uterine bleeding in both reproductive age group and post-menopausal females. USG had lesser diagnostic efficiency and cannot be used for treatment, however being non-invasive it has role in evaluation of AUB.

INTRODUCTION

Abnormal uterine bleeding is a broad term that describes irregularities in the menstrual cycle involving frequency, regularity, duration and volume of flow outside of pregnancy. Abnormal uterine bleeding is experienced by up to one third of women in their life, with irregularities most commonly occurring at menarche and perimenopause. A normal menstrual cycle has a frequency of 24 to 38 days, lasts 7 to 9 days, with 5 to 80 millilitres of blood loss. Variations in any of these 4 parameters constitute abnormal uterine bleeding. (1)

Abnormal uterine bleeding (AUB) is the commonest gynaecological problem seen in outpatient department (OPD) comprising 30-70% of women of pre-menopausal period (1). Main causes are uterine fibroid, endometrial hyperplasia, carcinoma of endometrium and cervix. AUB accounts for two third of hysterectomies. (2) Any vaginal bleeding after menopause is considered abnormal and requires evaluation.

The International Federation of Gynaecology and Obstetrics (FIGO system 1 defines *abnormal uterine bleeding* as changes in frequency, regularity, duration and flow volume, presence of intermenstrual bleeding and unscheduled bleeding on gonadal steroids.

Abnormality in frequency of cycles is defined as amenorrhoea or absent bleeding, infrequent cycles of > 38 days and frequent cycles of <24 days.

Prolonged flow is defined as flow for more than eight days.

Irregularity is defined as variability of shortest to longest cycles of more than eight to ten days. Flow volume being heavy as determined by patient.(3)

FIGO system 2 classifies causes of abnormal uterine bleeding as structural causes being PALM (Polyp, adenomyosis, leiomyoma, and malignancy) and causes unrelated to structural changes being COEIN (Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic and Not otherwise specified)(3). Figure 1 Types and episodes of vaginal bleeding are closely related to age and reproductive state.

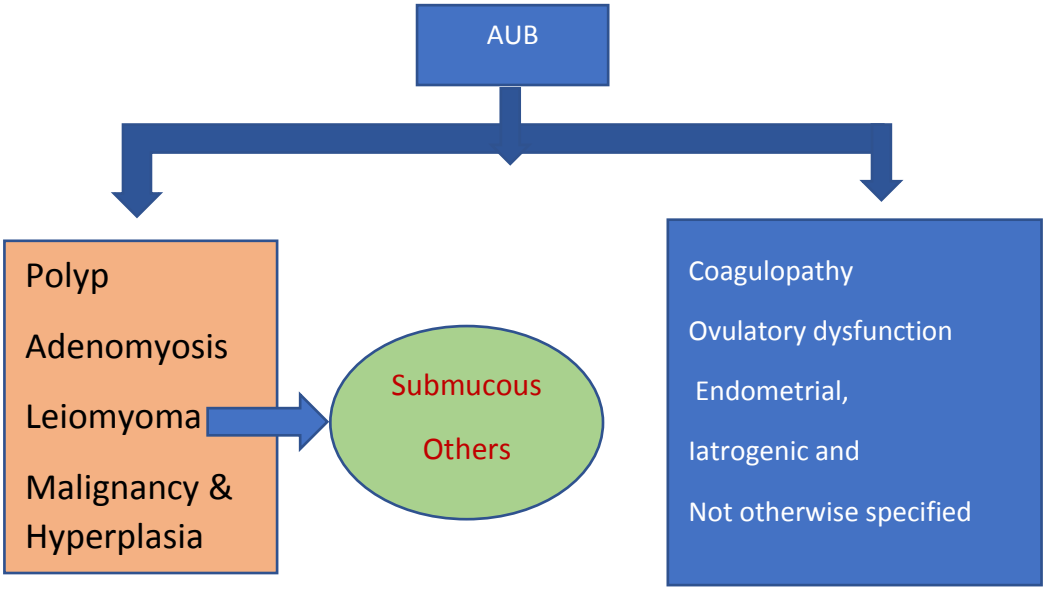

Figure 1: FIGO Classification of AUB

Prepubertal girls

The causes of vaginal bleeding in young premenarchal girls differ substantially from those in post pubertal girls. Most commonly, it is secondary to bleeding from the lower genital tract (vulvovaginitis, foreign body, trauma, urethral prolapse) rather than uterine origin. Bright red spotting should alert regarding the possibility of malignant lesions in the lower genital tract such as sarcoma botryoides or endodermal sinus tumour of the vagina. Other cause of uterine bleeding in this age group is attributed to precocious puberty, which may have hormone-producing ovarian tumour as an underlying cause or other hormonal causes. Relevant investigations should be directed as such.

Postmenarchal/adolescent girls

The most common cause of AUB in adolescents is anovulation. Anovulatory uterine bleeding generally resolves with maturation of the hypothalamic–pituitary–ovarian axis. Approximately 85% of menstrual cycles are anovulatory in the first year after menarche and 56% of menstrual cycles are ovulatory four years after menarche (4). Within the PALM-COEIN classification of AUB, the structural causes (polyps, fibroids, adenomyosis) are rare in adolescents.

Some common causes include bleeding disorders, polycystic ovarian syndrome (PCOS), endocrine dysfunction, stress, hormonal/contraception/pregnancy-related problems and infection. It is estimated that 36%–44% of adolescents with HMB have von Willebrand disease or platelet dysfunction. (5) .

Reproductive age women

Majority of women presenting with AUB belong to this age group. These women are more likely to have the structural abnormalities such as endometrial polyps (AUB-P) or fibroids (AUB-L) and are equally likely to have ovulatory dysfunction (AUB-O) and primary disorder of endometrium (AUB-E) as described within the PALM-COEIN classification system. History taking should take into account the range and natural variability in menstrual cycles and blood loss when diagnosing heavy menstrual bleeding. Physical examination including speculum examination and a bimanual examination is suggested to evaluate the lower genital tract and pelvis to confirm the source of bleeding and to look for structural causes such as fibroids or cervical polyps. Ultrasound assessment may be requested if clinical history or

examination warrants further information such as persistent intermenstrual bleeding, prolonged periods of bleeding and clinical finding of fibroid uterus.

Further investigations such as endometrial biopsy (EB) and hysteroscopic assessment of uterine cavity are not routinely required to investigate AUB, especially in the younger women. These can be associated with significant discomfort and should be used diligently, when necessary, in women who have failed to respond to initial medical therapy or in those with risk factors for endometrial malignancy.

Perimenopausal and postmenopausal women

For women in this age group presenting with new onset AUB, organic pathology, particularly for atypical hyperplasia or endometrial cancer, must be ruled out as anovulatory cycles and organic pathology can coexist, especially in the perimenopausal women. In postmenopausal women, the high incidence of endometrial polyps is well studied. In a Portugal study, 23% of benign endometrial polyps and 100% of malignant ones presented with symptoms of Post-menopausal bleeding.(6)

National Institute of Clinical Excellence (NICE) (2007) recommended ultrasound as the first-line screening tool for identifying structural abnormalities. Hysteroscopy remains the gold standard for accurate and complete assessment of endometrium. Indications for EB for histological assessment include women aged >35 years(4), treatment failure, ineffective treatment, persistent intermenstrual bleeding and presence of risk factors for endometrial cancer; PCOS, obesity, diabetes, late menopause, nulliparity , unopposed oestrogen therapy, functional ovarian tumour, previous pelvic irradiation, family history of cancer of breast, ovary or colon, women on tamoxifen, hypertension and /or history of endometrial hyperplasia .

Initial laboratory evaluation with a simple complete blood count is practical in most cases and should rule out anaemia as a consequence of abnormal bleeding pattern, especially if long-standing or severe symptoms exist. Other blood tests such as thyroid function tests, screening for clotting or bleeding disorders and hormonal profile to determine ovulatory status should be instigated, if necessary, based on the differential diagnoses considered after a thorough clinical history. A pregnancy test to rule out unexpected pregnancy-related bleeding, vaginal swabs to rule out possible pelvic infection and cervical smear should be considered.

Pelvic imaging

Transvaginal ultrasonography (TVS) is an appropriate first-line screening tool for women with AUB as it is inexpensive, non-invasive and easily accessible. It should be performed early in the course of investigations of chronic AUB in women of reproductive age group and even sooner in those women with postmenopausal bleeding. The benefits and diagnostic effectiveness of TVS in assessing the uterus, unlike hysteroscopy, extend to the complete pelvis. TVS is the most convenient way to visualize the endometrial cavity and has an added advantage of assessing uterine myometrium as well as ovarian and adnexal pathology at the same time. Emanuel et al demonstrated TVS to have a sensitivity of 96% and a specificity of 0.89%. (7)

However, even with good quality ultrasound equipment in ideal circumstances, TVS is not 100% sensitive because polyps and other focal lesions may elude detection. It can give false-positive results especially when done in secretory phase of the menstrual cycle. In addition, where vaginal access is difficult, as with adolescents and virginal women, TVS is not appropriate and transabdominal pelvic ultrasound with a full bladder can be used. Alternatively, role of Magnetic Resonance Imaging (MRI) or hysteroscopy under anaesthesia may be considered occasionally to investigate chronic AUB in this group of patients if medical management has failed to improve symptoms. Ultrasonography is generally done by operator of varying experience and with different machines of varying resolution, which may further reduce the efficacy of this modality in diagnosing endometrial pathology in our country.

Other imaging modalities

1. **Contrast Hysterosonography (COH)** with saline infusion sonography (SIS): the accuracy of TVS in diagnosing intracavity pathology such as submucous fibroids and polyps is improved with SIS to levels of accuracy comparable to that of outpatient hysteroscopy. SIS improves efficacy of TVS in evaluating endometrial cavity. However, its benefit is offset by the invasive nature of this scan, and is generally done after a suspicion of these on routine scans.
2. **Magnetic resonance imaging (MRI)** is more accurate than TVS in the presence of multiple fibroids to allow mapping and instigate appropriate treatment in selective cases.

This is an expensive test not available everywhere and hence is not routinely used unless

for cases of endometrial cancer to facilitate staging.

Vaginal bleeding in the early reproductive years is mostly due to pregnancy or pregnancy-related complications, infections and endocrinological disorders. Vaginal bleeding in perimenopausal or postmenopausal women is generally a result of endometrial pathology, and particularly malignancy.

In 2001, the Stages of Reproductive Aging Workshop (STRAW) defined 'perimenopause' as the period beginning with menopausal transition and ending 12 months after the last menstrual period. (4) This may last for 4-8 years. During this period, the endocrinological, biological and clinical features of approaching menopause commence. The perimenopause is often characterised by menstrual cycle irregularities in frequency and volume, due to fluctuating oestrogen levels. (8) These changes are unpredictable and are unique for each woman. Although irregular bleeding patterns are a normal and expected part of perimenopause, the incidence of uterine pathology and associated medical complications also increase in this age group.

Of equal importance is the impact of this abnormal blood loss on the quality of the woman's life. Long anovulatory periods with unopposed oestrogen stimulation may result in endometrial hyperplasia, thus increasing the risk of endometrial cancers.

Causes of postmenopausal bleeding include

- Atrophic vaginitis,
- Cervicitis,
- Endometritis,
- Endometrial atrophy,
- Uterine fibroids,
- Endometrial hyperplasia,
- Endometrial polyps,
- Cervical polyps and
- Endometrial, vulvar, vaginal, and cervical cancers

In total, 80% of cases of endometrial cancer, the most common gynaecological pathology, occur in postmenopausal women. Endometrial cancer usually occurs in

women between 50 and 65 years of age, with a mean age of 60 years. It is diagnosed in between 5 and 12% of women referred for postmenopausal bleeding (2,9)

Common morbid conditions among Endometrial disorders are polyps, myomas, synechiae, septae, hyperplasia, and endometrial cancer both in reproductive and post-menopausal females.

Endometrial cancer is the most frequently occurring malignancy of the female reproductive system. Early diagnosis of endometrial cancer is essential for the prompt initiation of oncologic treatment. (2) Older women with endometrial disease may have symptoms such as postmenopausal bleeding, whereas women of reproductive age may experience abnormal uterine bleeding and many a times, they may even remain asymptomatic.

Transvaginal ultrasonography (TVS) has been shown to have good accuracy for the detection of endometrial pathology. It is an inexpensive non-invasive modality permitting the use of higher frequency ultrasound waves at greater proximity to the uterus with no need for anaesthesia. It is considered a natural extension of the bimanual pelvic examination by many gynaecologists. It clearly depicts the uterine contour, echotexture, the status of ovaries and evaluates the endometrium in terms of thickness and its ovulatory and hormonal status.

(10). It is currently used as a method of choice for investigation of the endometrium, either in cases of genital bleeding, or for screening in asymptomatic women, especially in the post menopause.

Uterine fibroids and endometrial polyps are often diagnosed sonographically, while increased endometrial thickness, especially found in menopausal women, suggests the presence of an endometrial pathology.(11) It is convenient for the patients and it allows immediate interpretation of the observed images. (12) Among the postmenopausal women, an endometrial thickness of 4 mm or less on transvaginal ultrasonography can rule out endometrial pathologies with good accuracy. (13)

Nevertheless, despite being an invasive method, ***hysteroscopy*** remains the most accurate technique for the diagnosis of endometrial disease. It allows both direct visualization of the uterine cavity and biopsies of suspicious areas. Although hysteroscopy is a more effective method for diagnosing endometrial disorders, it is more invasive and costlier than ultrasonography and requires specific equipment and

trained staff. In addition, access to hysteroscopy is limited among the Indian population even in big cities. (2)

Uterine curettage has been, for decades, the universal procedure for diagnosis of intrauterine diseases. Although simpler than Hysteroscopy, it is an invasive procedure as well. It has the disadvantage of being blind, therefore, the surgeon is not able to remove or even detect the entire lesion. However, one cannot ignore the fact that it is a procedure available in the vast majority of India's public health services and the gynaecologists, in general, are entitled to perform it. (12)

Endometrial Cancer

It generally occurs in the postmenopausal women with AUB, but in 10% of cases, it could be asymptomatic and therefore, should be discovered as incidental finding during annual ultrasound examination for evaluating the presence of postmenopausal-thickened endometrium. (14) This thickness indicates an increased risk of malignancy or other benign pathology (hyperplasia, myoma, and polyp). Patients with AUB, asymptomatic postmenopausal women with an endometrial thickness >5 mm, found by ultrasound, should undergo a hysteroscopy and an endometrial biopsy, even if there is no consensus among authors about the definition of thickened endometrium for asymptomatic postmenopausal women. In 2014, Giannella *et al*. showed that using an endometrial thickness cut-off value ≥4 mm, only 3% of performed hysteroscopies were useful for the detection of premalignant or malignant lesions. (15)

Endometrial polyps

These are hyperplastic overgrowths of endometrial glands and stroma projecting above the epithelium. Endometrial polyps are one of the most common aetiologies of abnormal uterine bleeding (AUB) in both premenopausal and postmenopausal women.

These can be diagnosed with both non-invasive and invasive techniques. Transvaginal ultrasound (TVS) has been reported to have a sensitivity of 51% and specificity of 95% for diagnosing endometrial polyps.(16) However, it is difficult to differentiate benign and malignant endometrial polyps under ultrasonography.

Hysteroscopy is widely used because of its ability to detect endometrial polyps with a specificity of 93% and sensitivity of 90%. (16)
Use of hysteroscopy in abnormal uterine bleeding is almost replacing blind curettage, as it ‘‘sees’’ and ‘‘decides’’ the cause. This is because the uterine cavity can be observed and the doubtful area can be curetted. In fact, it is an eye in the uterus. (17)

Although several hysteroscopic features of endometrial hyperplasia or cancer have been established in the past, including uneven surface, irregularity of endometrial glands, polypoid pattern, papillomatous pattern, and abnormal endometrial vessels, no study till date to the best of our knowledge has focused on using a specific named pattern to establish a diagnosis. Pattern recognition of various phases of normal endometrium and endometrial pathologies during hysteroscopy has many advantages.

- It would help to triage women with AUB, so as to be selective with biopsies and curettages.
- Recognition of normal variant or benign lesion would reduce burden to the pathologist by decreasing the number of unnecessary samplings.
- It will also decrease anxiety of the patient as the report/prognostication can be instant in many cases.(18)

Cycling of the endometrium occurs based on the erratic production of oestrogen by the perimenopausal ovaries, and as a result, TVS needs to be carefully timed at the end of a bleeding episode so that the endometrial echo will be as thin as it is throughout the month. Therefore, there is a need for further research on the efficacy of TVS in evaluating AUB in perimenopausal women. (19)

Endometrial sampling is a medical procedure that involves taking a biopsy from the tissue lining the uterine cavity. The tissue subsequently undergoes a histopathological evaluation, which aids the physician in making a diagnosis for women who complain of abnormal uterine bleeding. However, the decision for carrying out endometrial sampling is not always guided by ultrasonography findings.
EB is not required for all patients with AUB. Doctors should use their clinical acumen and assessment of risk factors in order to determine which group of patients would benefit from histological evaluation of endometrium.

There are several techniques available to obtain a sample for histology, including simple aspiration (Pipelle biopsy), blind D&C and more recently, directed hysteroscopic biopsies in an outpatient setting. The historical procedure of D&C of endometrium has now become obsolete and is no longer acceptable as the standard of care for endometrial assessment unless it is used concomitantly with hysteroscopy. Bettocchi et al found that 50% of intrauterine lesions were missed when a D&C was performed alone. (20)

Pipelle is a small-diameter, disposable, flexible cannula that can be used to perform a biopsy quickly in a clinic during speculum examination and is reasonably tolerated. Two meta-analyses have clearly emphasized the satisfactory sensitivity and specificity of an EB in the diagnosis of endometrial cancer in women with AUB.(21) However, this is true when there is global endometrial pathology, and blind Pipelle biopsy can be falsely negative in women with focal lesions. A positive test result of EB is more accurate for ruling in disease than a negative test result is for ruling it out. Therefore, in cases of AUB where symptoms persist despite negative biopsy, further evaluation is warranted.

Particularly in premenopausal women, endometrial sampling is not efficient for the diagnosis of endometrial polyps, adenomyosis or fibroids. Focal endometrial abnormalities are frequent causes of AUB in postmenopausal women, and although most of these lesions are benign, it is important to diagnose and treat them to resolve the presenting symptoms and rule out malignancy. This can be achieved by hysteroscopy and removal of the focal lesion under direct vision.

REVIEW OF LITERATURE

History

The problem of abnormal uterine bleeding has been ancient, as long as the history of mankind is dated, though the solutions for this has been quite recent. As civilisations advance, and the common misconceptions prevalent among those are weeded out, the previously thought of taboos such as menstruation are gradually accepted as normal human processes. And soon after quick-witted mankind starts troubleshooting for women suffering from heavy menstrual bleeding.

In parts of eastern world, the trouble has been remedied by use of herbal medicine in parts of India and China, as texts from Indian physician Charaka and Chinese physician Hua Tao says. As years progressed advancement in this field remain stagnant. Likewise, in the relatively long history of man, surgeries such as hysterectomy has been a comparatively recent development.

The first abdominal hysterectomy was performed by Charles Clay in Manchester, England in 1843. (22) Unfortunately the diagnosis was wrong and the patient died in the immediate post-operative period. Vaginal hysterectomy dates back to ancient times. The procedure was performed by Soranus of Ephesus in 120 AD and the many reports of its use in the Middle Ages were nearly always for the extirpation of an inverted uterus and the patients rarely survived. The first successful abdominal hysterectomy for abnormal bleeding of uterus was done in 1930 by Richardson. He demonstrated the safest way with least post operative complications. (22)

With advancement mankind looks for less invasive ways to treat women with abnormal uterine bleeding. Experience with tranexamic acid, an indirect fibrinolytic inhibitor, started as soon as it was released from Shosuke Okamoto's lab in the early 1960s. (23) It was first prescribed to females with heavy menstrual blood loss and to patients with hereditary bleeding disorders.

During the late 1950s and early 1960s, suction curettage attained popularity in the Iron Curtain countries of Eastern Europe and the USSR as a rapid method for first-trimester–induced abortion.(24) Coupled with its rapidity was the advantage of diminished blood loss. By 1963 the technique had been transplanted to the United States and was being used for first-trimester terminations of pregnancy. Soon this same technique was also applied to the evacuation of spontaneous incomplete

abortion, as well as to missed abortion and furthermore extended to management of abnormal uterine bleeding as it was presumed that reproductive women developed irregular heavy bleeding due to overgrowth of endometrium. Soon it gained popularity and was used rampantly all across the world.

Diagnostic methods were developed rapidly following industrial revolution, and after the world wars in the early 20th century, mankind while looking for methods of destruction, also found ways to use those methods for the purpose of cure of its ailments. Ultrasound was first used for clinical purposes in 1956 in Glasgow. Obstetrician Ian Donald and engineer Tom Brown developed the first prototype system based on an instrument used to detect industrial flaws in ships. Transvaginal sonography, which came into widespread use beginning in the late 1980s, provided a new way of seeing gestational sacs earlier in pregnancy and with greater detail. They provide accurate images of uterus, cervix and adnexal structures, as seen just in proximity. It has very high resolution, though lesser penetration effect, hence uterine and adnexal pathologies are visualised in detail. Interventional measures are restricted in Ultrasonographic modality.

Hysteroscopy

History of hysteroscopy is dated back to the work of Pantaleoni in 1869, who conceptualized uterine endoscopy, but work remained in an elementary state, due to poor distension technology and not properly developed intracavitary scope techniques. He evaluated a 60-year-old lady with therapy resistant bleeding and detected a polypoid growth in the uterus on hysteroscopy, which was cauterised with silver nitrate. (25) Distension techniques were developed by Rubin in 1925, and evolved gradually. Rubin used CO2 as the distension media.(25) But as years progressed better distension medias such as dextran by Edstrom and Ternstrom , glycine by Jaques Hamou and Saline by Von Mikulicz, Radecki and Freund were used that was compatible with the scope used for visualisation . It was David who first performed hysteroscopy using cystoscope having an internal light and lens system.(25)

Current day hysteroscopy provides real time images of intra Uterine pathology and also provides interventional measures for specific pathologies.

Myriad of studies has been done worldwide till date to identify the better diagnostic tool available at arms for accurately identifying endometrial pathologies. In the yore, the practice of blind endometrial curettage was rampant, and it was challenged in a landmark study by **Betocchi *et al*** (2001) advocating against blind dilatation and curettage procedures. They found that in 248 of 397 patients (62.5%), D&C failed to detect intrauterine disorders subsequently found at hysterectomy; the sensitivity was 46%, the specificity was 100.0%, the positive predictive value was 100.0%, and the negative predictive value was 7.1%. Dilatation and curettage is an inadequate diagnostic and therapeutic tool for all uterine disorders; this technique missed 62.5% of major intrauterine disorders, and all endometrial disorders were still present in the removed uterus. (20)

As better methods such as Ultrasonography and Hysteroscopy came into being, Studies were conducted to assign which diagnostic modality is better. As both methods had their own advantages and disadvantages. Histopathology was kept as gold standard in all the studies, as inevitably it is the direct visualisation of uterine pathology directly under a microscope.

Studies comparing Hysteroscopy with Histopathology

Sinha *et al* (2018) conducted a study among 56 women and compared hysteroscopy with histological findings. Mean age of the patients recruited was 36.4 ± 7.6 years. The majority (60.7%) presented within 6 months of complaints. Clinically, 66.1% presented with heavy menstrual bleeding, 30.4% with polymenorrhoea and 3.6% intermenstrual bleeding. Hysteroscopically 53.6% presented with abnormal pathology (polyps in 16.1%, calcification in 12.5%, submucous fibroma in 10.7%, necrotic mass in 7.1%, adhesion and forgotten IUCD in 5.4% cases each). However, on histopathology, 33 (58.9%) cases had normal/proliferative/
atrophic endometrium, 12 (21.4%) had hyperplasia, 7 (12.5%) had calcified endometrium, and 12 (21.4%) had polyp. No significant difference between two modalities was observed with respect to number of normal proliferative/atrophic endometrium (P = 0.185).

Histopathology diagnosed hyperplasia in significantly higher proportion of patients as compared to hysteroscopy (P = 0.042). Hysteroscopy diagnosed significantly higher

proportion of patients with submucous myoma (P = 0.012) and necrotic mass (P = 0.042). Statistically, no significant difference between two modalities was observed with respect to other pathologies (P>0.05). Overall agreement between two modalities was 62.5%. For pathological abnormalities in general, hysteroscopy had sensitivity, specificity, PPV, NPV and accuracy values of 78.3, 63.6, 60, 80.8 and 69.6%, respectively. They concluded that Hysteroscopy provided additional information for some of the pathologies, otherwise remaining undiagnosed by HPE. (17)

Pandey *et al* (2017) conducted a combination study of Indian and Taiwanese population for hysteroscopic pattern recognition. They observed that there was good correlation between hysteroscopic patterns and histopathology report as 33% of starry sky appearance correlated with atrophic endometrium, 87% of tongue shaped projections correlated with endometrial polyp, 44.4% of pebble stone appearance correlated with myomatous polyp, 50% of polypoidal pattern correlated with endometrial hyperplasia. 100% correlation was seen in strawberry appearance, pattern for secretory endometrium and cerebroid appearance which was pattern designated to endometrial carcinoma. They concluded that hysteroscopic pattern recognition is a useful concept to triage women who require sampling for histopathological diagnosis. (18)

Another study was done amongst Taiwanese people by **Ngo *et al* (2020)**, to identify hysteroscopic patterns of benign and malignant endometrial polyp. Out of 179 cases with endometrial polyps from 3066 women who underwent hysteroscopy followed by dilatation and curettage or transcervical resection, 154 and 25 cases turned benign and malignant endometrial polyps, respectively. They observed that the hysteroscopic findings of malignant polyps were hyper-vascular (72%, 18/25), ulcerative (64%, 16/25) and polyps with irregular surfaces (24%, 6/25). In contrast, pedunculate small growths with smooth surfaces were usually seen in the benign endometrial polyps (38.3%, 59/154).

Hyper-vascular (OR: 142.6, 95% CI: 25.98-783.4) and polyps with irregular surfaces (OR: 12.02, 95% CI: 1.765-81.83) in hysteroscopic findings were significant strong predictors of endometrial polyps with endometrial cancer. Hysteroscopic findings of ulcerative changes were most strongly associated with a diagnosis of malignant polyps, with sensitivity, specificity, NPV and positive PPV of 64.0%, 100%, 94.5%,

and 100%, respectively. They concluded that women with hysteroscopic findings of endometrial polyps with hyper-vascular, ulcerative, and polyps with irregular surfaces had a high likelihood of endometrial cancer. A target biopsy of the polyps with these specific appearances should be performed to exclude malignant lesions. (16)

Das and Mondal *et al* (2021) conducted a study on 150 women to correlate hysteroscopic and histopathological findings. Mean age of subjects was 39.6 ±6.19 years and the commonest symptom and histopathology findings were menorrhagia (33.3%) and proliferative endometrium (25.3%) respectively. Endometrial thickness of 5-10 mm was the commonest (68.67%) finding by transvaginal sonography. The sensitivity, specificity, PPV and NPV were 96%. 53.8%, 90.9% and 77.8% respectively for detecting overall abnormal pathology by hysteroscopy in comparison to histopathology. Histopathological findings were comparable with hysteroscopy findings. Conclusively for abnormal uterine bleeding, hysteroscopy can be a better tool for collecting proper sample for histopathological test while dilatation and curettage is a blind procedure. (26)

Al-Ani *et al* (2018) did a prospective observational study on 114 patients in Arabian population to assess the role of diagnostic hysteroscopy and histopathology in evaluation of AUB. Hysteroscopy had a sensitivity of 91.9%, specificity of 86.5%, positive predictive value of 93.2%, and negative predictive value of 84.2% and diagnostic accuracy of 90.1% for diagnosing the aetiology of AUB. They documented that Hysteroscopy is a safe and reliable procedure in the diagnosis of AUB with high sensitivity, specificity, positive predictive value and negative predictive value and the results of hysteroscopy are immediately available. Hysteroscopy and histopathology complement each other in evaluating patients with abnormal uterine bleeding for accurate diagnosis and further treatment.(27)

Comparison between Ultrasonography and histopathological examinations: **Ozer *et al*** (2016) did a retrospective review of 350 Turkish women who underwent transvaginal ultrasonography and suction curettage for abnormal uterine bleeding and observed that

sonographic appearance of the endometrium was normal in 244 patients (69.7%), while homogeneous thickening was detected in 47 patients (13.4%) and cystic thickening in 21 patients (6.0%) and endometrial polyp in 38 patients (10.9%).
Histopathological analysis of endometrial samplings revealed proliferative endometrium (36%), secretory endometrium (24.6%), decidualization (10.9%), endometrial polyp (8.3%), endometritis (6.8%), endometrial hyperplasia (4.6%), irregular shedding (3.7%), atrophic endometrium (3.1%), endometrial cancer (1.1%) and placental retention (0.9%). The sonographic and histopathological findings correlated significantly (P = 0.001; r = 0.215). Approximately 51% of the women with homogeneous endometrial thickening had proliferative endometrium.
Only 44.7% of the women with ultrasonographically visualized endometrial polyps had histopathologically diagnosed endometrial polyps. Nearly 57% of the women with cystic endometrial thickening had proliferative endometrium. In conclusion they said if there is no facility for hysteroscopy or hysteroscopy-guided endometrial biopsy for women with abnormal uterine bleeding, transvaginal ultrasonography findings can be efficiently used to make a preliminary diagnosis and, thus, notify the pathologists. (28)

Another Indian study by **Veena B.T. *et al*** (2014) among 60 women observed that transvaginal ultrasound showed an accuracy of 83.3% in detecting the proliferative phase and 66.67% in detecting the secretory phase. TVS has a sensitivity of 0% for a local intra-cavitary lesion. TVS was also preferable in case of post-menopausal patients with endometrial thickness less than 4mm. Both TVS and hysteroscopy can detect endometrial intracavitary abnormalities with varying accuracies. These can supplement and enhance the accuracy of tissue diagnosis. Thus, the first procedure to which patients with AUB are to be subjected should be TVS followed by hysteroscopy and directed biopsy, wherever required.(29)

Comparison of all the three modalities, the ultrasonography, Hysteroscopy and the Histopathological results

A study done by **Yela *et al*** (2018) in Brazilian population, among 754 patients included (256 reproductive age, 498 postmenopausal) cases. In the reproductive-age group, ultrasonography had a sensitivity of 96.0%, specificity of 58.0%, PPV of

94.4%, NPV of 66.6%, and accuracy of 91.5%, whereas hysteroscopy had a sensitivity of 91.8%, specificity of 76.6%, PPV of 96.0%, NPV of 60.5%, and accuracy of 89.7% for the diagnosis of endometrial disease.

In the postmenopausal group, ultrasonography had a sensitivity of 99.0%, specificity of 19.0%, PPV of 96.1%, NPV of 50.0%, and accuracy of 95.3%, whereas hysteroscopy had a sensitivity of 96.7%, specificity of 86.9%, PPV of 99.2%, NPV of 58.8%, and accuracy of 96.2%.

They concluded that Ultrasonography was found to be an effective method for the diagnosis of endometrial disease, especially among postmenopausal women. Ultrasonography and hysteroscopy were found to have a high sensitivity among both reproductive-age and postmenopausal groups; however specificity was higher for hysteroscopy.(11)

Another brazillian study by **Wanderley *et al*** (2016) among 191 patients was conducted. out of total patients, 134 underwent hysteroscopy, and 57, uterine curettage. Hysteroscopy revealed a diagnostic accuracy higher i.e. 90% for all the diseases evaluated, while transvaginal ultrasonography showed an accuracy of 65.9% for polyps, 78.1% for myoma and 63.2% for

endometrial hyperplasia. Within the 57 patients subjected to uterine curettage, there was an accuracy of 56% for polyps and 54.6% for endometrial hyperplasia. They concluded that ideally, after initial investigation with transvaginal ultrasonography, guided biopsy of the lesion should be performed by hysteroscopy, whenever necessary, in order to improve the diagnostic accuracy and subsequent clinical management. (10)

A Greek study by **Tsonis *et al***. (2021) was done among 2675 cases. Of these, 23.2% of were postmenopausal while the majority (76.7%) were of reproductive age. The commonest indication for hysteroscopy was abnormal uterine bleeding (AUB) accounting for 29.7% of the cases. Overall, TVS demonstrated diagnostic accuracy of 84.7% in detecting endometrial pathology, compared to 97.3% of Office hysteroscopy. Sensitivity, specificity, PPV and NPV of TVS detecting endometrial pathology were 84.0, 86.8, 95.3 and 63.0%, respectively. The corresponding values for hysteroscopy were 98.9, 95.1, 98.4 and 93.9%, respectively. They came to the conclusion that Office hysteroscopy is a more reliable tool in detecting endometrial

pathologies compared to TVS regardless of reproductive status or clinical presentation. TVS is likely to orientate and guide specialists on what to expect prior to an hysteroscopic intervention.(12)

Mortakis *et al* (1997) conducted a study in American population to evaluate the diagnostic accuracy of hysteroscopy and TVS w.r.t. histopathology as gold standard among 122 premenopausal and 78 postmenopausal women with abnormal uterine bleeding.

The women underwent TVS combined with aspiration Pipelle biopsy. Hysteroscopy and endometrial sampling by curettage or directed biopsy was done within 4 weeks. In premenopausal patients TVS clearly detected 73% of polyps and myomata, permitting diagnostic and surgical hysteroscopy to be performed at the same time.

In postmenopausal women with endometrial thickness 4 mm or greater, aspiration biopsy failed to detect two cases of atypical hyperplasia and one of focal adenocarcinoma. Pipelle sampling was technically infeasible in a woman with endometrial cancer because of a stenotic cervix. It also missed the majority of benign lesions (polyps and myomas). It was concluded that TVS seems to be an excellent initial diagnostic method, with high sensitivity in diagnosing endometrial abnormalities. Its combination with aspiration biopsy seems to be safe in women with a thin endometrium. Hysteroscopy is necessary in postmenopausal women with an endometrium of 4 mm or more, as well as in premenopausal patients with endometrial thickness more than 5 mm (preovulatory phase of the cycle) and in those with suspected polyps or myomas.(30)

In India a landmark study done by **B.K. Goyal *et al*** (2015) among 100 female patients with AUB. Each patient was subjected to TVS where uterine cavity was studied in detail and hysteroscopy under anaesthesia using saline as distension medium. Sensitivity, specificity and predictive value of TVS as compared to hysteroscopy were calculated. Subgroup analysis within each group was also performed. In result they found that: Menorrhagia was the commonest presenting symptom in the study population (n = 58) followed by metrorrhagia, menometrorrhagia and continuous bleeding >21 days. 74 female patients had normal size uterus. In 57 patients, the uterine cavity was normal on TVS. Thickened endometrium, endometrial polyp and submucous fibroids were seen in 19, 16 and 6 patients respectively. Hysteroscopy showed normal cavity in 59 female patients and

polypoidal endometrium, polyps or submucous fibroids in 41. TVS was found to have high sensitivity and specificity (95.23 and 94.82 respectively) and high positive and negative predictive value. Strength of agreement between TVS and hysteroscopy was high (kappa value 0.898). In conclusion they said, TVS is recommended as first line investigation in AUB. If TVS shows normal cavity, further evaluation can be omitted and patient started directly on medical treatment for her symptoms.(1)

A Retrospective observational cross-sectional study by **Elsersy *et al* (2017)**, among 250 Egyptian women presented with abnormal uterine bleeding. The patients who fulfilled the selection criteria and have been sequentially investigated by transvaginal ultrasound (TVS) and hysteroscopy were included. 90% of patients were from 35 - 49 yrs. Transvaginal ultrasound (TVS) compared well with high sensitivity as regards normal endometrium. (TVS) missed 4 patients of endometrial polyps and one patient of sub mucous fibroid. Three patients of adenomyosis were only diagnosed by (TVS); they were reported as being normal by hysteroscopy. In conclusion Elsersy et al commented (TVS) is considered as an excellent approach to the initial evaluation of uterine pathologies in patients with abnormal uterine bleeding. Analysis of data showed very good agreement of (TVS) findings to hysteroscopy
which is considered the golden standard tool to diagnose intrauterine abnormalities. Focusing on the more commonly diagnosed pathologies as submucous myoma, endometrial polyp, thick endometrium and normal endometrium. (TVS) had sensitivity of 99.57%, specificity of 87.5%, and a positive predictive value of 99.15% and negative predictive value of 93.33% for
the diagnosis of submucous myoma, with Kappa value of 0.897. Also (TVS) had 100% sensitivity, 90.91% specificity, 98.1% a positive predictive value and 100%
of negative predictive value for diagnosis of endometrial polyps. As regards the
diagnosis of thick endometrium as a sole diagnosis (TVS) achieved 97.62% sensitivity,
100% specificity, 100% positive predictive value and 88.89% negative
predictive value with kappa value of 0.929 which is considered as a very good achievement. (31)

There have been studies conducted specifically among post-menopausal women, as women with post-menopausal bleeding has a strong suspicion of having endometrial

cancer. And hysteroscopy has been advocated as we directly visualise uterus via it. There has been a strong user dependent bias for hysteroscopy as well. But in resource deprived areas it is not widely available. Following studies compares between the two modalities to see which one better diagnose the elephant in the room.

A retrospective study done by **Trojano *et al*** (2018) in Italy involving case records of 295 asymptomatic postmenopausal women with a thickened endometrium >5 mm diagnosed at transvaginal ultrasound (TVS), those underwent hysteroscopy with biopsy. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of hysteroscopy were evaluated. When the hysteroscopic findings were normal, a sensitivity of 100%, specificity of 98.6%, PPV of 95.2%, and NPV of 100% were achieved. For polyps and myomas, we found sensitivity, specificity, NPV, and PPV of 100%, 98.7%, 99.5%, and 100%, respectively. In case of endometrial hyperplasia, a sensitivity of 66.7%, a specificity of 100%, a PPV of 100%, and a NPV of 98.1% were achieved. For endometrial cancer hysteroscopy, sensitivity, specificity, PPV, and NPV were 100%, 99.6%, 75%, and 100%, respectively. 4 (1.4%) cases of endometrial cancer by hysteroscopy, three of them were histologically confirmed. The last one was diagnosed histologically as atypical hyperplasia. (14)

Another Prospective study among Italian population by **Gianella *et al*** (2014) among 268 asymptomatic postmenopausal women with endometrial thickness > 4 mm detected by Ultrasonography referred to diagnostic hysteroscopy. The diagnostic accuracy of various endometrial thickness cut-off values was tested. Histological and hysteroscopic results were compared to measure the diagnostic accuracy of outpatient hysteroscopies. No endometrial thickness cut-off values had optimal diagnostic accuracy [positive likelihood ratio (LR+) >10 and negative likelihood ratio (LR-) <0.1]. The best endometrial thickness cut-off value for the detection of all intra-uterine pathologies was >8 mm (LR+ 10.05 and LR- 0.22). An endometrial thickness cut-off value >10 mm did not miss any cases of endometrial cancer. The success rate of diagnostic hysteroscopy was 89%, but 97% of these revealed a benign intra-uterine pathology. The diagnostic accuracy of hysteroscopy was optimal for all intra-uterine pathologies, except endometrial hyperplasia (LR=0.52). In conclusion they said, using an endometrial thickness cut-off value >4 mm, only 3% of performed hysteroscopies

were useful for the detection of pre-malignant or malignant lesions. Despite the finding that endometrial thickness did not show optimal diagnostic accuracy, using the best cut-off value (>8 mm) may be helpful to decrease the number of false-positive results. No cases of endometrial cancer were diagnosed in asymptomatic postmenopausal women with endometrial thickness <10 mm.(15)

Sauvan *et al* (2018) conducted a study among 470 postmenopausal women in French population referred for office hysteroscopy. 350 women (74.5%) out of those experienced
abnormal uterine bleeding. The success rate of office hysteroscopy was 76.4% and was significantly higher in cases of postmenopausal bleeding (80.9%) than in women without postmenopausal bleeding (63.3%) (p=0.01). Three-hundred-sixteen women had both a successful hysteroscopy and TVS. The correlation between hysteroscopy and TVS was 68.5% for the diagnosis of increased endometrial thickness, polyps and submucosal myoma (Kappa=0.28). The rate of endometrial cancer for women with postmenopausal bleeding was 12.6% (n=44) while it was 1.7% (n=2) for asymptomatic women. Two (4.3%) out of these 46 women with endometrial cancer had normal hysteroscopy, while 7 (15.2%) had a normal TVS (including endometrial thickness. Among the 54 women without bleeding and with a thickened 68 endometrium, one (1.8%) had endometrial cancer.
Office hysteroscopy is successful without anaesthesia for 76.4% of postmenopausal women. In conclusion correlation between TVS and hysteroscopy is low, and recommended practice of both sonography and hysteroscopy in women with postmenopausal bleeding. (9)

A retrospective cross-sectional study by **Korkmazer *et al*** (2014) among Turkish population for hysteroscopic assessment of endometrial thickening from case records of 197 women who
have thickened (> 5 mm) endometrium in the postmenopausal period. For the evaluation of postmenopausal thickened endometrium, hysteroscopy revealed sensitivity, specificity, positive predictive value and negative predictive value as 76.4%, 76.9%, 73.1%, 79.8%, respectively. Conclusively they said, Hysteroscopy is a fast and accurate technique in evaluation of the intrauterine space occupying lesions (polyp, fibroid) but only moderate for endometrial hyperplasia. Hysteroscopic view

combined with direct biopsy could be a gold standard for endometrial assessment. (32)

Among Chinese population a study by **Hayatullah *et al*** (2018) among 102 postmenopausal bleeding women were studied retrospectively. ETs of all subjects were measured by transvaginal ultrasonography (TVS), succeeded by hysteroscopy, and eye-directed biopsies were taken during hysteroscopy. Clinical and demographic characteristics of all patients were correlated with Endometrial carcinoma. Sensitivity, specificity, PPV, and NPV of hysteroscopy with 95% confidence interval have been determined against histopathological findings, the latter being considered the reference standard. The mean age of participants was 62.2±7.6 years (range 48 to 80). Of the 102 cases, n=34(33.33%) had ET< 5mm, of those 3(8.82%) women had endometrial cancer. The remaining n=68(66.67%) cases had ET ≥ 5 mm, of those 21(30.88%) cases had Endometrial carcinoma. Histopathology showed normal result in 1(0.98%) case. Histopathology diagnosed hyperplasia in 9(8.82%) cases, polyp in 42(41.18%) cases, myoma in 8(7.84%) cases, Endometrial carcinoma in 24(23.53%) cases, endometritis in 4(3.92%) cases, and cervical lesions in 14[13(12.75%) benign and 1(0.98%) malignant] cases. Hysteroscopy showed an overall sensitivity of 95.05%, specificity of 100%, PPV of 100, NPV 16.67% and accuracy of 95.1%. Hysteroscopy showed high sensitivity, specificity, PPV, NPV and accuracy for polyp and endometrial carcinoma. But substantially lower sensitivity and PPV for diagnosing hyperplasia. Endometrial thickness is unreliable for excluding endometrial carcinoma and/or avoiding further invasive investigations in women with PMB. Despite the fact that hysteroscopy is highly accurate in diagnosing intrauterine lesions but direct biopsy in all patients for the diagnosing of postmenopausal uterine bleeding is warranted. (33)

Another prospective Egyptian study by **Elfaymoy *et al*** (2012) among Eighty-three women presenting with postmenopausal bleeding and endometrial thickness of 5 mm or more measured by transvaginal ultrasound (TVS), and subsequently they underwent diagnostic hysteroscopy and endometrial biopsy. Hysteroscopic data was compared with the final diagnosis established by histological examination. The women's mean age was 61.2 ± 5.2 years (range 44–80). The most frequent endometrial lesion was endometrial polyps (31.1%). Hyperplastic endometrium was confirmed in 23 (27.8%), only 13 cases were suspected

by the hysteroscope. Out of the 14 (16.9%) proven cases of endometrial cancer, only half of the cases were suspected. In benign endometrial lesions, the sensitivity of the hysteroscopic view was 94.7%, specificity was 97.8%, positive (PPV) and negative (NPV) predictive values were 97.3 and 95.7%, respectively. On the other hand, hysteroscopy demonstrated an overall sensitivity, specificity, PPV, and NPV of 56.5, 91.6, 72.2, and 84.6%, respectively, in endometrial hyperplasia, whereas the same parameters for endometrial cancer were 50, 94.2, 63.6, and 90.2%.In conclusion , they said , Hysteroscopy can be used as the first line diagnostic tool for evaluating the benign endometrial lesions, such as endometrial polyp and submucosal myoma, nonetheless hysteroscopy has poor validity for excluding endometrial hyperplasia and cancer in women presenting with the postmenopausal bleeding and thick endometrium. (34)

Another prospective study among Indian Population was carried out by **Acharya *et al* (2009)**, Hysteroscopic examination was done in all patients post-menstrually, whenever possible, except in those cases where menstrual cycles were grossly irregular or patients came with continuous bleeding per vaginum. The patients then underwent dilatation and curettage and endometrium was sent for histopathologic examination. The correlation between findings on hysteroscopy and histopathologic examination was tabulated. The findings of hysteroscopy were as such, proliferative 34%, secretary 16%, hyperplasia 18%, atrophic 8%, endometrial polyp 9%, submucous myoma 11%, carcinoma of endometrium 03%, misplaced Cu-T 1%. In patients with abnormal uterine bleeding, hysteroscopy provides more accurate diagnosis
than dilatation and curettage.(35)

AIMS AND OBJECTIVES

AIM OF STUDY: To compare the diagnostic accuracy of USG and Hysteroscopy in diagnosing endometrial pathology in women with AUB [Abnormal Uterine Bleeding] taking histopathological examination as gold standard test.

OBJECTIVES:

PRIMARY OBJECTIVE:

To measure the sensitivity, specificity, negative predictive value and positive predictive value of Ultrasonography and Hysteroscopy in detecting endometrial pathology against histopathology as gold standard.

SECONDARY OBJECTIVE:

To assess the distribution and pattern of endometrial pathologies in women with abnormal uterine bleeding.

METHODOLOGY

METHODOLOGY

This was a prospective observational study conducted in the department of obstetrics and gynaecology, All India Institute of Medical Sciences, Jodhpur from 1st January 2020 to 31st December 2021.

Approval was taken from the Institute's Ethics Committee vide number AIIMS/IEC/2019-20/954.

All women diagnosed with abnormal uterine bleeding (AUB) were approached and those fulfilling the inclusion criteria were included after taking informed consent.

Inclusion criteria:

1. Women aged > 35 years with AUB who are willing to participate in the study and giving consent.
2. Those who were willing to undergo TVS (trans vaginal sonography) and hysteroscopy followed by biopsy.

EXCLUSION CRITERIA:

1. Women < 35 years of age
2. Known Cases of malignancy of genital tract.
3. Women who were diagnosed with endocrinological, tumors of genital tract, coagulation abnormalities as causes of AUB
4. Those not willing for undergoing transvaginal sonography, hysteroscopy and biopsy/aspiration.

SAMPLE SIZE CALCULATION

$$n = \frac{Z^2_{(1-\alpha/2)} \times p(1-P)}{d^2}$$

α=Level of significance i.e. - 5%

Z =Normal standard deviate = 1.96 at 5% level of significance

P= Sensitivity

d= Absolute error i.e. 5 %

Taking sensitivity of 91.8% for hysteroscopy from the study done by Daniela et al (13) sample size was calculated to be – 116

Abnormal uterine bleeding was diagnosed in patients coming with complaints of changes in frequency, regularity, duration and flow volume, presence of intermenstrual bleeding as per FIGO system 1 guidelines. (3) All patients fulfilling the inclusion criteria were enrolled in the study after taking informed consent. Detailed clinical history was taken and general, systemic and pelvic examination was done.

Obstetrical history included parity, mode of delivery, abortions and contraceptive use; detailed menstrual history regarding the cycle length, no of days of flow, type and amount of abnormal bleeding and duration of complaint and any relevant preceding events like IUCD insertion or abortion was taken. Relevant co-morbid conditions were also accounted for. Local and Per speculum examination was done to rule out vulval, cervical and vaginal causes. Per vaginal examination was done to find out any uterine, cervical or adnexal pathology.

The patient was investigated to rule out organic causes of AUB and following tests like complete blood count, thyroid profile, Blood grouping /typing and coagulation studies were done. Urine pregnancy test was done in suspected cases to rule out pregnancy and pregnancy related problems. After taking informed written consent for the procedure, Transvaginal Ultrasonography and Hysteroscopy were performed.

Trans Vaginal Sonography (TVS) -

All transvaginal scans were done on USG machine "Mindray Z6" using TVS probe of frequency 5 MHz (Figure 2).

Figure 2 – Ultrasonography machine

Procedure: Patient was asked to empty the bladder and then lie down in dorsal position, then probe with the condom over it and jelly applied on it was inserted in the vagina. Uterus, endometrial thickness (ET), the endometrial lining echotexture, size and volume of the uterus, and anomalies such as polyps and myomas in the uterine cavity, endo myometrial junction and other notable abnormalities were noted. Bilateral ovaries were also visualised and adnexal mass if present were noted. Endometrial cavity was examined in longitudinal and transverse planes. Normal endometrium was defined by an echo-dense line in the middle, distinct from myometrial margins. Any abnormal structures with diverse lining or variable echo-density were considered pathologic.

The measurement of the endometrial thickness is of the thickest echogenic area from one basal endometrial interface across the endometrial canal to the other basal

surface. Care was taken not to include hypoechoic myometrium or intrauterine fluid in this measurement. ET is measured in the sagittal plane near the level of fundus. Any intrauterine pathology like polyp, adhesions, fibroid and hyperplastic or atrophic endometrium was looked for and endometrial sampling was done from the abnormal sites for Histopathological examination by biopsy forceps. The findings of ultrasonography and Hysteroscopy was then corelated with Histopathology.

Similarly, polyps were seen in the trans vaginal sonogram as iso-echoic substances with endometrium as endometrial polyp, or as iso – echoic with myometrium as fibroid polyp. Usually solitary homogeneous and echogenic lesion, the endometrial polyp focally interrupt the normal mucosal contour of the uterine cavity, it is rarely hypoechoic or heterogeneous, a stalk to the polyp may either be thin (i.e. pedunculated) or broad-based, the appearance of one or two well-defined short echogenic linear echoes at the polyp borders which are perpendicular to the ultrasound beam, may appear isoechoic as a focal non-specific thickened endometrium, without visualization of a discrete mass ,rarely appears as diffuse endometrial thickening as the endometrial polyp fills the endometrial cavity, mimicking endometrial hyperplasia, rarely cystic spaces could be seen within the polyp, maybe surrounded by endometrial fluid. Endometrial hyperplasia is usually seen as cystic lace like structure in ultrasonography.

Other endometrial pathologies such as septum or uterine synechia are also visualised as linear echogenic area within endometrial cavity. Mullerian anomalies such as bicornuate uterus is diagnosed as having external uterine contour being concave or heart shaped.

Uterine pathologies as subserosal and intramural fibroids, a common cause of abnormal uterine bleeding are also visualised by TVS. During ultrasound examination, leiomyomas usually appear as well-defined, solid, concentric, hypoechoic masses that cause a variable amount of acoustic shadowing. Pathologies like adenomyosis features in sonography as a mottled inhomogeneous myometrial texture, globular appearing uterus, small cystic spaces within the myometrium, and a "shaggy" indistinct endometrial stripe, classically known as venetian curtain appearance. Ultrasound features suggestive of endometrial carcinoma are heterogeneous and irregular endometrial thickening, polypoid mass lesion,

intrauterine fluid collection, frank myometrial invasion seen as thinning of myometrium and increased vascularity of mass.

Hysteroscopy

Hysteroscopy was performed in Operation Theatre under anaesthesia [local or general]

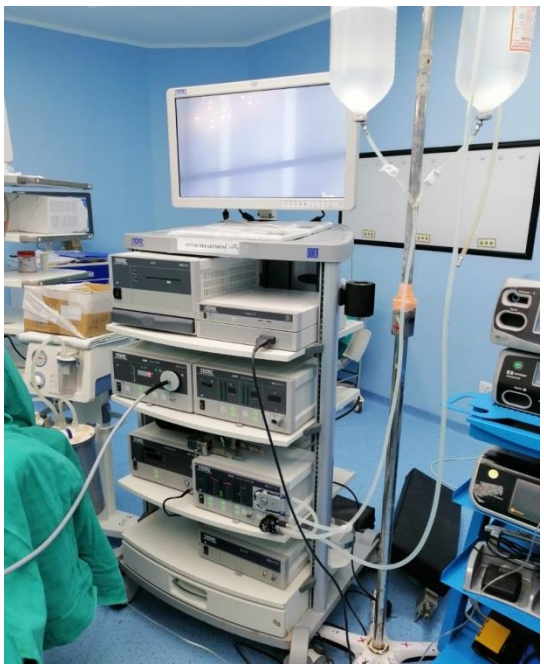

Figure 3 – Hysteroscope assembly with monitor, Xenon light source, and Hysteromat for pressure regulation

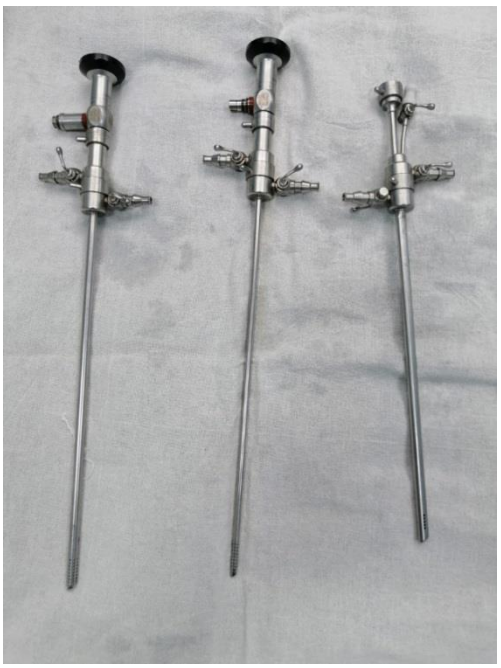

Figure 4- From left to right- 4 mm telescope, 2.9 mm telescope, operative sheath

Procedure:

Under anaesthesia, patient was placed in dorsal lithotomy position, perineum and vagina painted and draped. Posterior vagina was depressed with Sim's speculum. The anterior lip of cervix was grasped with Vulsellum forceps. The light generator is switched on and the fibre-optic cable is attached to the telescope. Telescope is inserted into the diagnostic sheath and the normal saline is flushed through the sheath. The Karl-Storz hysteroscope was inserted into the cervical canal through the external cervical Os and advanced slowly under direct vision. Cervical canal and the endometrial cavity were visualised systematically.

Hysteroscopy was used to visualise the characteristics of the endometrium and the type of lesion, if present (i.e., polyp, myoma, synechiae, septae, mass suggestive of neoplasm).

A 30-degree Karl -Storz hysteroscope (2.9-mm telescope) was used for diagnostic hysteroscopy. Size of diagnostic scope was individualised as per the patient characteristics.

In all hysteroscopies, the distention medium in use was normal saline, with a pressure of 50–70 mmHg and flow rate of 100 ml / min.

Hysteroscopy was done in proliferative phase in premenopausal women as endometrium can be better visualised during this time.

In women with irregular menstrual cycle, it was done after stopping of bleeding.

In post-menopausal women it was done whenever it was convenient to patient and availability of Operation theatre.

Hysteroscopic examination included inspection of the uterine cavity with a panoramic shot, visualization of both tubal ostia and observation of the cervical canal while withdrawing the hysteroscope. Table 1 shows the various hysteroscopic views that can be observed.

Table 1 – Hysteroscopic view and diagnosis

Hysteroscopic view	Hysteroscopic Diagnosis
Smooth surfaced and covered with endometrium	Normal cavity
Pedicle mass covered with endometrium	Endometrial polyp
Pedicle bright mass un-covered with endometrium	Submucosal fibroid
Thickened endometrium with irregular surface	Endometrial hyperplasia
Thickened endometrium with irregularity and endometrial necrosis, and vascularity	Endometrial carcinoma

If a polyp was visualised, evaluation of the number, size, location, consistency, and characteristics of the base of implantation and the vascularity of Endometrial polyps was noted. Hysteroscopic polypectomy was done in the same sitting. Polyps were removed either by resectoscopic approach or via operative hysteroscope by using operative scissors and forceps or polypectomy forceps/snare.

Features of *endometrial hyperplasia* on hysteroscopy were considered as follows- increased endometrial thickness, both localized or diffuse; cystic formations in the endometrial cavity and dilated superficial vessels.

Endometrial cancer was suspected if hysteroscopic findings included: atypical vessels, irregular necrotic tissue, micropapillary or polypoid hypertrophy, with irregular poly lobular, friable excrescences with necrosis or bleeding.

Focal necrosis, friable consistency, papillary projections, irregular surface, mixed colour, diffuse vascular arrangement, loss of branched vascularization, and atypical vessels with discordance between the direction of the vessels and the major axis of the lesion and at times presence of ulceration are specific features of Endometrial cancer. *Synechiae* appears as intrauterine adhesions in hysteroscopic view obliterating the uterine cavity.

Menopause is defined as spontaneous cessation of menses for 1 year or more. Each patient underwent TVS to define endometrial thickness and to see for any pathology in uterus and adnexa. In a sagittal scan, the operator calculated the maximum distance between the two lines of the endometrium/myometrium interface. Endometrial sampling was taken in post-menopausal females with complaints of AUB and ET measured by ultrasonography being >4mm or with history of recurrent bleeding even with ET < 4mm.

All patient underwent pelvic ultrasound, hysteroscopy and endometrial sampling.

The biopsy material was fixed in 10% formalin and sent to pathologist for the histopathological examination; in each case pathologist was informed about ultrasonographic and hysteroscopic findings.

Figure 5 – Endometrial Novak's curette

Statistical Analysis

Data was collected in excel sheet and then statistical analysis was performed using SPSS [statistical package for social studies] version 23.

Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of TVS and hysteroscopy were calculated.

Similarly, diagnostic accuracy of both methods was evaluated in different subgroups as well as, for different pathology. Histopathological reports were considered as gold standard. Statistical analysis i.e. Test of proportion (Z-test) was used to compare the two investigations modality. p-value of <0.05 was considered significant.

The comparison between the two modality was done by finding the agreement by using Cohen's kappa score.

RESULTS

RESULTS:

A total of 107 patients were recruited for the study in the intended time period. The sample size was compromised due to unfortunate COVID-19 pandemic as the OPD and OT were not fully functional and even shut down for a few months.

Demographic Parameters

Age:

- The mean age in the study was 43.49 years, with standard deviation 8.95. Range of the age recruited for the study was 35 to 73.
- Out of 107 patients, 18 were post-menopausal females, and 89 were pre or peri menopausal females.

Table 2 – Age distribution of the study participants

Age groups	**Numbers [n=107]**	**Percentage (%)**
Pre/ Peri menopausal	89	83.1
Post-menopausal	18	16.8

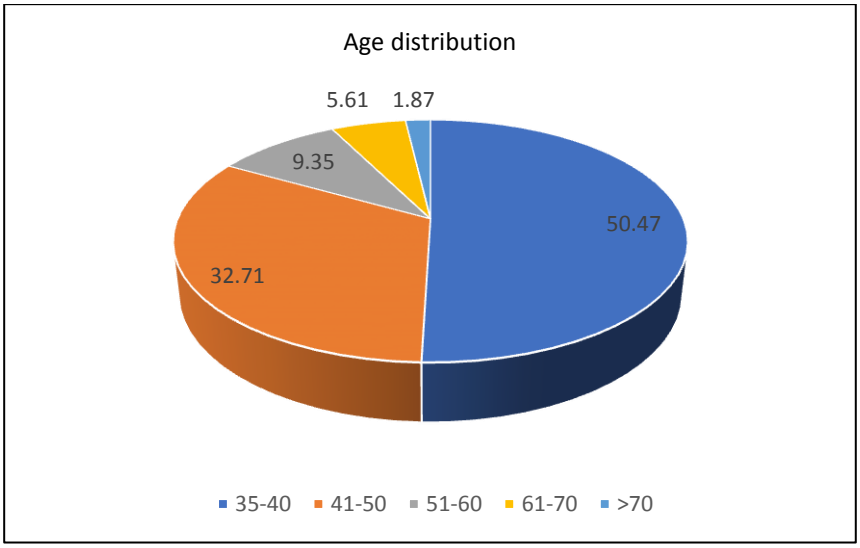

Figure 6 – Distribution of study participants according to age

- Maximum number of patients were in the age group of 35-40, followed by in the age group of 41-50.
- 27 of those are nulliparous females, and 80 were Primi/multiparous females.
- Symptomatology encountered in the recruited females were,

Symptomatology

Table 3 – Distribution of study participants according to complaints

Chief Complaints	**Numbers**	**Percentage (in%)**
Frequent and heavy bleeding	50	46.7
Irregular cycles	30	28
Post-menopausal bleeding	18	16.8
Intermenstrual bleeding	10	9.3
Amenorrhoea f/b bleeding p/v	5	4.6
Secondary amenorrhoea	3	2.3

Majority of the patients (46.7%) had complaints of frequent and heavy bleeding and complaints of irregular cycles. Post-menopausal bleeding was encountered in 18 (16.8%) patients.

Co- Morbidities

Table 4 – Distribution of Co-morbidities among the study participants

Co- Morbidities	**Numbers**	**Percentage (in%)**
Anaemia	63	58.8
Hypertension	21	19.6
Diabetes	28	26.1
Thyroid disorder	10	9.3
Tuberculosis	3	2.8
Ischemic heart disease	1	0.9

Table 4 shows the distribution of co-morbidities among the study participants. Maximum number of patients were having anaemia, followed by hypertension, diabetes and thyroid disorder. Four of the 107 patients were found to be having severe anaemia secondary to heavy menstrual bleeding during evaluation.

36 of those had normal BMI (33.6%), 34 had BMI in the overweight range (31.77%), 34 had grade 1 obesity (31.77%), 3 had grade 2 obesity (0.02%). BMI stratification was done as per the WHO recommendations for BMI calculation for Asians.(37)

Table 5 shows the combined co-morbidities among the cases.

Table 5 – Distribution of combined co-morbidities

Co- Morbidities	**Numbers**
Anaemia with hypertension	9
Anaemia with thyroid disorders	5
Diabetes with hypertension	4
Diabetes with CKD	1
Hypertension with Ischemic heart disease	1

Investigations

A. ULTRASOUND

Following abnormalities were detected in TAS / TVS.

Table 6 – Distributions of abnormalities diagnosed in TAS/TVS

USG reporting	**Numbers**	**Percentage (in%)**
Endometrial polyp	16	14.8
Congenital Uterine Anomaly	14	13
Adenomyosis	9	8.4
Intramural fibroid	9	8.4
Pregnancy related bleeding disorders (RPOCs, GTDs, C– scar ectopic)	8	7.4
Endometrial hyperplasia	8	7.4
Subserosal fibroids	7	6.5
Endocervical polyp	6	5.6
Submucosal fibroids	6	5.6
IUCD [broken]	4	3.7
Sub endometriotic cyst	4	3.7
Ca endometrium	4	3.7
AVM	2	1.85
Cervical fibroid	2	1.85
NAD	21	19.6

RPOC- retained products of conception, GTD- gestational trophoblastic disease, C-scar- caesarean scar, IUCD- intrauterine contraceptive device, AVM- arterio venous malformation, NAD- no abnormality detected

Maximum numbers of abnormalities found on Ultrasound were Endometrial polyps, Congenital Uterine anomalies such as septate uterus, bicornuate uterus etc. followed by adenomyosis. Endometrial hyperplasia was diagnosed to be in 8 cases (7.4%). Carcinoma endometrium was diagnosed in 3 cases. (3.7%) Normal findings were seen in 21 cases. (19.6%)

B. Hysteroscopy,

Following abnormalities were detected on Hysteroscopy

Table 7- Distribution of abnormalities visualized on hysteroscopy

Hysteroscopy reporting	**Numbers**	**Percentage(in%)**
Endometrial Polyp	29	27.1
Endocervical Polyp	13	12.1
Congenital Uterine anomaly	11	10.2
Endometrial hyperplasia	8	7.4
Submucous Fibroid	7	6.5
IUCD [broken pieces]	4	3.7
C scar ectopic	3	2.7
RPOCs	2	1.8
Ca endometrium	2	1.8
AVM	1	0.9
Cervical fibroid	1	0.9
Bony spicule	1	0.9
Pyometra	1	0.9
Asherman's Syndrome	1	0.9
Normal Endometrial Cavity	29	27.1

Maximum number of reporting was done for endometrial polyp, endocervical polyps followed by congenital uterine anomalies. Endometrial hyperplasia was suspected in eight cases. (7.4%) Ca Endometrium was suspected in two cases. (1.8%)

Histopathology

Table 8 – Distribution of Histopathological diagnosis among the study participants

Pathology	**Numbers**	**Percentage (in%)**
Benign Endometrial Histopathology	57	53.2
Endometrial polyp	34	31.7
Hyperplasia without atypia	13	12.1
Pregnancy related Diagnosis (RPOCs, GTDs, PSTT)	12	11.2
Endocervical Polyp	8	7.4
Submucosal fibroid	4	3.7
Ca Endometrium	3	2.8
Senile Cystic atrophy	1	0.9
Hyperplasia with atypia	1	0.9
Osseous Metaplasia	1	0.9

Benign endometrial histopathology was reported in 57 cases. (53.2%) This was followed by endometrial polyp in 34 cases (31.7%). Hyperplasia without atypia was seen in 13 cases (12.1%). Carcinoma endometrium was diagnosed in 3 cases (2.8%).

Performance of Hysteroscopy versus Histopathology report

Table 9 -Performance of Hysteroscopy versus Histopathology report

HYSTEROSCOPY	**HISTOPATHOLOGY**	
	POSITIVE	**NEGATIVE**
POSITIVE	59	7
NEGATIVE	13	30
Accounting to following results-		
	Value (In %)	**95 % CI (In %)**
Sensitivity	81.94	71.11-90.02
Specificity	81.08	64.84-92.04
PPV	89.87	81.87-94.58
NPV	68.67	56.69-78.60
Positive Likelihood ratio	4.33	2.2- 8.51
Negative likelihood ratio	0.22	0.13-0.37
Accuracy	81.66	73.11- 88.43

PPV- positive predictive value, NPV- negative predictive value, CI- confidence interval. Sensitivity, specificity, PPV, NPV and accuracy was found to be 81.94 %, 81.08 %, 89.87%, 68.67 % and 81.66% respectively for hysteroscopy.

Performance of Ultrasonography versus histopathology

Table 10 - Performance of Ultrasonography versus histopathological report

ULTRASONOGRAPHY	HISTOPATHOLOGY	
	POSITIVE	**NEGATIVE**
POSITIVE	34	20
NEGATIVE	38	15
Accounting to following results -		
	Value (In %)	**95 % CI (In %)**
Sensitivity	47.22	35.33-59.35
Specificity	42.86	26.32-60.65
PPV	62.87	53.74-71.16
NPV	28.38	20.33-38.11
Positive Likelihood ratio	0.83	0.57-1.20
Negative likelihood ratio	1.23	0.79-1.91
Accuracy	45.79	36.62- 55.70

USG had Sensitivity, specificity, PPV, NPV and accuracy of 47.22 %, 42.86%, 62.87%, 28.38%, 45.79%. respectively in evaluating uterine pathologies responsible for abnormal uterine bleeding.

Sub group Analysis in Post-Menopausal Females

Further on Sub – Dividing the study Population into Post-Menopausal Women group and women in Pre/Peri-menopausal Age group, following observations were noted.

Among the Post-Menopausal females-

Performance of Hysteroscopy

Table 11- Performance of Hysteroscopy versus Histopathology report among post-menopausal females

HYSTEROSCOPY	HISTOPATHOLOGY	
	POSITIVE	**NEGATIVE**
POSITIVE	11	1
NEGATIVE	2	4
Accounting to following results.		
	Value (In %)	**95 % CI (In %)**
Sensitivity	84.62	54.55-98.08
Specificity	80	28.36-99.49
PPV	44.62	12.09-82.53
NPV	96.47	87.64-99.06
Positive Likelihood ratio	4.23	0.72-24.80
Negative likelihood ratio	0.19	0.05-0.74
Accuracy	80.74	55.62-95.16

sensitivity, specificity, PPV, NPV and accuracy of 84.48%, 87.10 %, 88.57%, 82.59%, 85.68% respectively were found for hysteroscopy done amongst post-menopausal females.

Performance of Ultrasonography

Table 12- Performance of Ultrasonography versus Histopathology report among post-menopausal females

ULTRASONOGRAPHY	**HISTOPATHOLOGY**	
	POSITIVE	**NEGATIVE**
POSITIVE	4	3
NEGATIVE	9	2
Accounting to following results-		
	Value (In %)	**95 % CI (In %)**
Sensitivity	30.77	9.09- 61.43
Specificity	40	5.27-85.34
PPV	8.9	3.2-22.42
NPV	75.21	49.42- 90.40
Positive Likelihood ratio	0.51	0.17-1.52
Negative likelihood ratio	1.73	0.56-5.37
Accuracy	38.52	17.03- 63.92

Ultrasonography had Sensitivity, specificity, PPV, NPV and accuracy of 51.72%, 45.16%, 52.75%, 44.15%, 48.72%.

Hysteroscopy had better Sensitivity, specificity, PPV, NPV and accuracy w.r.t. Ultrasonography in diagnosing endometrial pathologies among post-menopausal females.

- **<u>Pre - /Peri Menopausal Age group of females</u>** –

  Performance of Hysteroscopy

Table 13- Performance of Hysteroscopy versus Histopathology report among pre-/peri-menopausal females

HYSTEROSCOPY	HISTOPATHOLOGY	
	POSITIVE	**NEGATIVE**
POSITIVE	49	4
NEGATIVE	9	27
Accounting to following results-		
	Value (In %)	**95 % CI (In %)**
Sensitivity	84.48	72.58-92.65
Specificity	87.10	70.17-96.37
PPV	88.57	75.51-95.11
NPV	82.59	71.93-89.77
Positive Likelihood ratio	6.55	2.61-16.45
Negative likelihood ratio	0.18	0.10-0.33
Accuracy	85.68	76.65-92.20

Sensitivity, specificity, PPV, NPV and accuracy was 84.48 %, 87.10%, 88.57%, 82.59%, 85.68% respectively among the Pre /Perimenopausal age group for hysteroscopy.

Performance of Ultrasonography among pre-/peri-menopausal females –

Table 14-Performance of Ultrasonography versus Histopathology report among pre-/peri-menopausal females

ULTRASONOGRAPHY	HISTOPATHOLOGY	
	POSITIVE	**NEGATIVE**
POSITIVE	30	17
NEGATIVE	28	14
Accounting to following results-		
	Value (In %)	**95 % CI (In %)**
Sensitivity	51.72	38.22-65.05
Specificity	45.16	27.32-63.97
PPV	52.75	42.68-62.59
NPV	44.15	33.06-55.86
Positive Likelihood ratio	0.94	0.63-1.41
Negative likelihood ratio	1.07	0.67-1.71
Accuracy	48.72	37.97-59.55

- Sensitivity, specificity, PPV, NPV and accuracy of 51.72%, 45.16% 52.75%, 44.15%, 48.72% respectively were observed for Ultrasonography among Pre-/Peri-menopausal females.
- Hysteroscopy had better Sensitivity, specificity, PPV, NPV and accuracy w.r.t. Ultrasonography in diagnosing endometrial pathologies among pre-/peri-menopausal females.

- **SUB GROUP ANALYSIS:**
    - **DISEASE SPECIFIC CALCULATION –**

1. Endometrial Polyp

- **Performance of hysteroscopy**

	HPR (positive result)	**HPR (negative result)**
Hysteroscopy (Positive result)	28	1
Hysteroscopy (Negative result)	4	5
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	87.50	71.10-96.49
Specificity	83.33	35.88-99.58
PPV	69.13	27.13-93.09
NPV	93.99	85.38-97.66
Positive Likelihood ratio	5.25	0.87-31.57
Negative likelihood ratio	0.15	0.06-0.40
Accuracy	84.58	69.18-94.21

Table 15- Performance of Hysteroscopy for endometrial polyp

- Sensitivity, specificity, PPV, NPV, Accuracy of hysteroscopy for endometrial polyps were found to be 87.5%, 83.33%, 69.13%, 93.99%, 84.58%.

- **Performance of Ultrasonography for endometrial polyp**

	HPR (positive result)	**HPR (negative result)**
Ultrasonography (Positive result)	11	5
Ultrasonography (Negative result)	21	1
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	34.38	18.57-53.19
Specificity	16.67	0.42-64.12
PPV	14.96	8.82-24.23
NPV	37.32	8.91-78.38
Positive Likelihood ratio	0.41	0.23-0.75
Negative likelihood ratio	3.94	0.65-23.98
Accuracy	21.96	10.2-38.34

Table 16- Performance of Ultrasonography for endometrial polyp

- Ultrasonography had sensitivity, specificity, PPV, NPV and accuracy of 34.38%, 16.67%, 14.96%, 37.32%, 21.96% respectively for diagnosing endometrial polyps.
- Hysteroscopy had better Sensitivity, specificity, PPV, NPV and accuracy w.r.t. Ultrasonography in diagnosing endometrial polyps.

2. **Endocervical Polyp**

- **Hysteroscopy**

	HPR (positive result)	**HPR (negative result)**
Hysteroscopy (Positive result)	13	0
Hysteroscopy (Negative result)	2	0
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	86.67	59.54-98.34
PPV	12.36	

Table 17 - Performance of Hysteroscopy for endocervical polyp

- **Ultrasonography**

	HPR (positive result)	**HPR (negative result)**
Ultrasonography (Positive result)	6	0
Ultrasonography (Negative result)	9	0
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	40	16.34-67.71
PPV	14	

Table 18- Performance of Ultrasonography for endocervical polyp

- Hysteroscopy had better sensitivity and PPV in diagnosing endocervical polyps w.r.t. ultrasonography.

3. Endometrial Hyperplasia

- **Hysteroscopy**

	HPR (positive result)	**HPR (negative result)**
Hysteroscopy (Positive result)	8	0
Hysteroscopy (Negative result)	6	4
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	57.15	28.16-82.34
Specificity	100	39.76-100
PPV	100	
NPV	93.94	89.44-96.60
Negative likelihood ratio	0.43	0.23-0.78
Accuracy	94.39	72.63- 99.85

Table 19 - Performance of Hysteroscopy for endometrial hyperplasia

- **Ultrasonography**

	HPR (positive result)	**HPR (negative result)**
Ultrasonography (Positive result)	4	4
Ultrasonography (Negative result)	10	0
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	28.57	8.39-58.10
PPV	4.12	1.84-8.96
Positive Likelihood ratio	0.29	0.12- 0.65
Accuracy	3.74	0.02-24.63

Table 20- Performance of Ultrasonography for endometrial hyperplasia

Hysteroscopy had better diagnostic accuracy in diagnosing endometrial hyperplasia with having 100% specificity.

4.Endometrial Carcinoma

- **Hysteroscopy**

	HPR (positive result)	**HPR (negative result)**
Hysteroscopy (Positive result)	2	0
Hysteroscopy (Negative result)	1	0
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	66.67	9.43-99.16
Specificity	100	29.42-100
PPV	100	
Accuracy	99.07	

Table 21- Performance of Hysteroscopy for endometrial carcinoma

- **Ultrasonography**

	HPR (positive result)	**HPR (negative result)**
Ultrasonography (Positive result)	1	3
Ultrasonography (Negative result)	2	0
Accounting to following results		
	Value (In %)	**95 % CI (In %)**
Sensitivity	33.33	0.84-90.57
PPV	0.95	0.19-4.54
Positive Likelihood ratio	0.33	0.07-1.65
Accuracy	0.93	

Table 22- Performance of Ultrasonography for endometrial carcinoma

Hysteroscopy had better diagnostic accuracy in diagnosing endometrial cancer.

Age group	Sensitivity (in %)		Specificity (in %)		PPV (in %)		NPV (in %)		Accuracy (in %)	
	Hys	USG	Hys	USG	Hys	USG	Hys	USG	Hys	USG
Overall	81.94	47.22	81.08	42.86	89.87	62.87	68.67	28.38	81.66	45.79
Post Menopausal	84.62	30.77	80	40	44.62	8.9	96.47	75.21	80.74	38.52
Pre-/Peri – Menopausal	84.48	51.72	87.10	45.16	88.57	52.75	82.59	44.15	85.68	48.72
Endometrial Polyp	87.50	34.38	83.33	16.67	69.13	14.96	93.99	37.32	84.58	21.96
Endocervical Polyp	86.67	40	-	-	12.36	14	-	-	-	-
Endometrial Hyperplasia	57.15	28.75	100	0	100	4.12	93.94	0	94.39	3.74
Endometrial Cancer	66.67	33.33	100	0	100	0.95	99.05	0	99.07	0.93

Table 23- Overall conglomerated results

- Pre and Peri menopausal women constituted maximum number of cases for whom both hysteroscopy and Ultrasonography were performed. Common chief complaints reported among the study group were frequent and heavy bleeding, intermenstrual bleeding and irregular cycles associated with infertility. Diabetes was the common associated co- morbid condition found. And most of the cases were found to be lying the normal, overweight and grade 1 obesity BMI group.
- Endometrial Polyp was the commonest anomaly detected in both TVS, and hysteroscopy.
- One peculiar finding of Bony spicule was detected by hysteroscopy and confirmed by HPR as being osseous metaplasia.

- One patient having Asherman's syndrome was detected while performing hysteroscopy. While USG couldn't detect the same.
- Findings like Adenomyosis, intramural fibroids and subserosal fibroids were almost exclusively detected by USG. Both hysteroscopy and USG performed equally in detecting IUCD.
- Uterine anomaly was suspected in 14 cases by USG, while confirmed in 11 cases.
- AVM malformation was suspected in 2 cases by USG, and in one by Hysteroscopy while confirmed to be having in none by advanced imaging. One case of AVM reported in Hysteroscopy was later found to be having PSTT by HPR. As both Placental site trophoblastic tumours and AV malformations are hyper vascular and appear morphologically similar.
- Normal findings were reported in 21 of the cases while hysteroscopy reported 29 cases to be having normal uterine cavity. And on HPR 57 cases were found to be having benign results.
- Hysteroscopy performed better in overall study group, and both in post-menopausal and pre - / peri menopausal age group as showed better sensitivity, specificity, NPV, PPV and accuracy.
- Same was reflected in disease specific pathologies like, Endometrial polyp, endocervical polyp, Endometrial Hyperplasia and endometrial Cancer.
- Hysteroscopy was found to be having 100 % specificity in both endometrial hyperplasia and endometrial cancer. Making it the best diagnostic study available for the same.

	Sensitivity		**Specificity**		**PPV**		**NPV**		**Accuracy**	
	Hys	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**
Overall	81.94	47.22	81.08	42.86	89.87	62.87	68.67	28.38	81.66	45.79
	z = 5.3099 p < .00001		Z =5.7586 p< .00001		Z =4.6489 p< .00001		Z =5.8965 p< .00001		Z =5.4569 p< .00001	

Table 24- Comparison of Sensitivity, specificity, PPV, NPV and accuracy of Hysteroscopy and Ultrasonography among overall population

	Sensitivity		Specificity		PPV		NPV		Accuracy	
	Hys	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**
Post Menopausal	84.62	30.77	80	40	44.62	8.9	96.47	75.21	80.74	38.52
	$z = 7.2711$ $p < .00001$		$z = 5.4467$ $p < .00001$		$z = 5.3824$ $p < .00001$		$z = 4.0679$ $p < .00001$		$z = 5.7403$ $p < .00001$	

Table 25- Comparison of Sensitivity, specificity, PPV, NPV and accuracy of Hysteroscopy and Ultrasonography among Post-menopausal females

	Sensitivity		Specificity		PPV		NPV		Accuracy	
	Hys	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**
Pre/ Peri Menopausal	84.48	51.72	87.10	45.16	88.57	52.75	82.59	44.15	85.68	48.72
	$z = 4.6887$ $p < .00001$		$z = 6.7209$ $p < .00001$		$z = 4.6875$ $p < .00001$		$z = 5.2891$ $p < .00001$		$z = 6.2873$ $p < .00001$	

Table 26- Comparison of Sensitivity, specificity, PPV, NPV and accuracy of Hysteroscopy and Ultrasonography among Pre-/peri-menopausal females

- Hysteroscopy was found to be having better sensitivity, specificity, PPV, NPV and accuracy w.r.t. ultrasonography when compared with each other, with p Value of <0.00001.
- Kappa value was calculated to be 0.30, implying fair agreement among hysteroscopy and ultrasonography.

	Observation by Hysteroscopy	
Observation by Ultrasonography	**Positive result**	**Negative Result**
Positive Result	29 (a)	24(b)
Negative Result	36(c)	17(d)

Table 27- Measurement of Kappa Value

ROC curve between ET (in mm) and HPR report

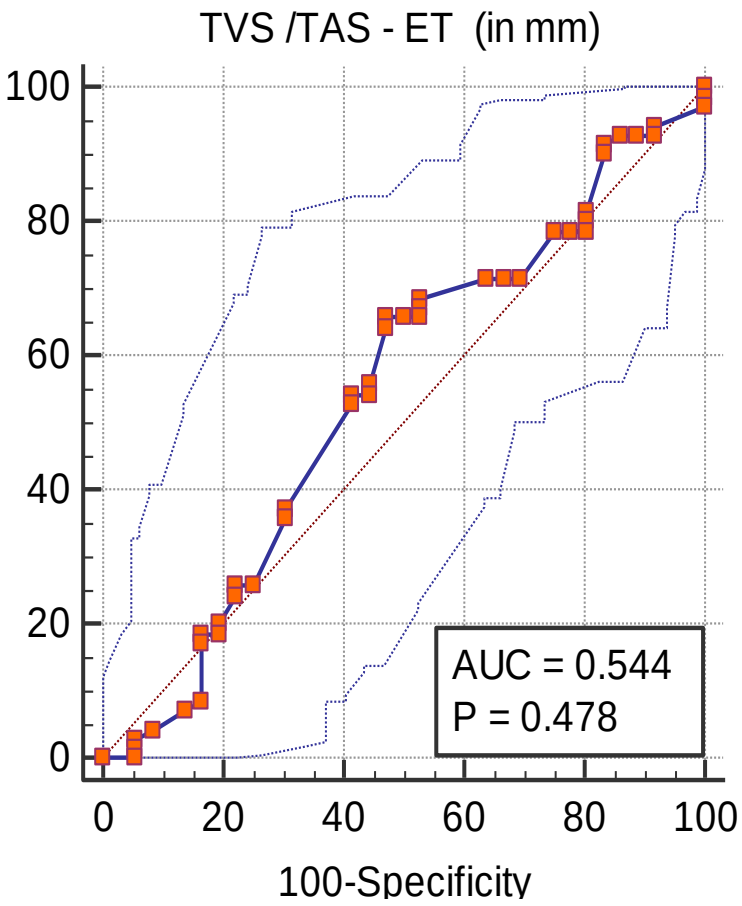

Figure 7 – ROC curve between ET and HPR among overall population

- ROC curve was plotted for Endometrial thickness value against histopathological result and was found to be having no association.
- Cutoff was found at 7.8 mm for high sensitive and specific results.

- **<u>ROC curve between ET and HPR (Post Menopausal Females)</u>**

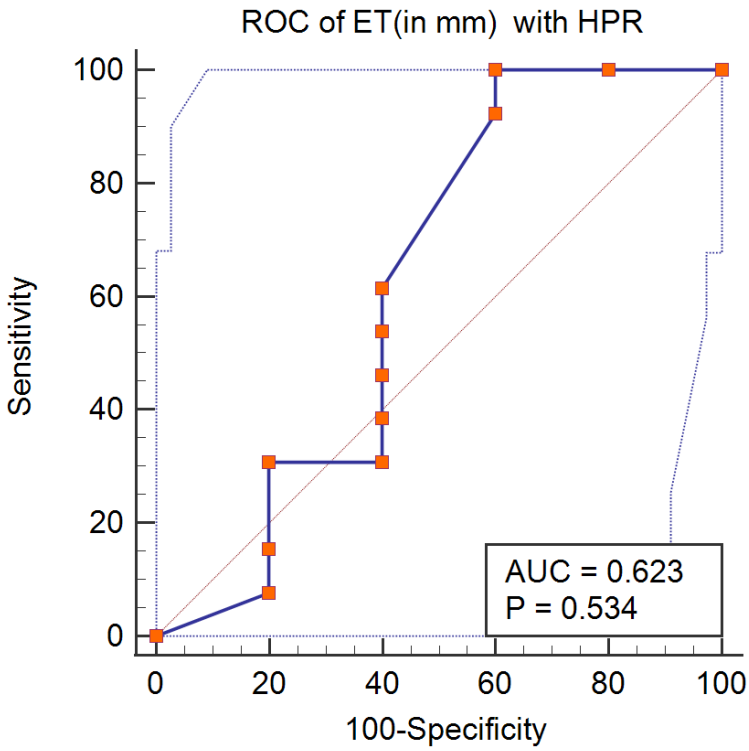

Figure 8- ROC curve between ET and HPR among post-menopausal females

- ROC curve was plotted for Endometrial thickness value against histopathological result and was found to be having no association among post-menopausal females.
- Cutoff was found at 4.6 mm for highly sensitive and specific results.

ROC curve between ET and HPR (Pre and Peri Menopausal Women)

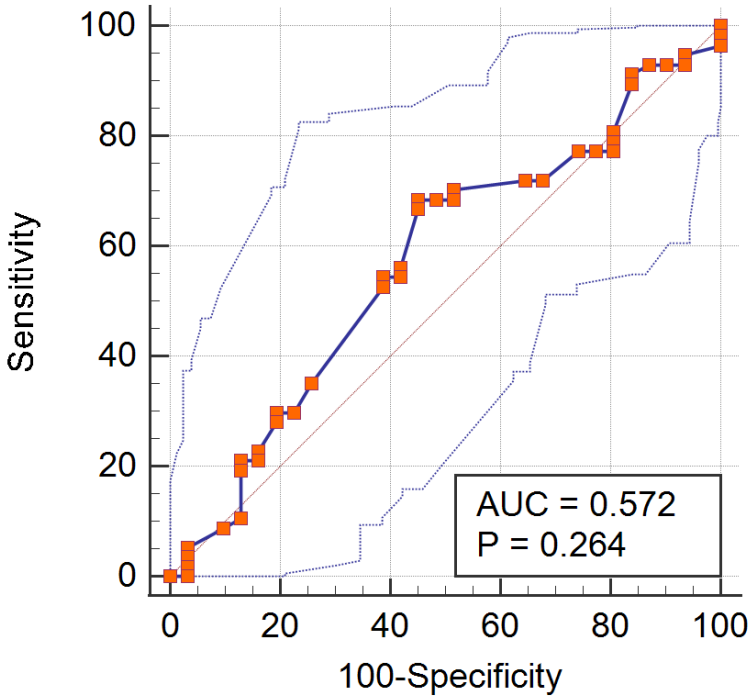

Figure 9 - ROC curve between ET and HPR among pre-/peri-menopausal females.

- ROC curve was plotted for Endometrial thickness value against histopathological result and was found to be having no association among post-menopausal females.

DISCUSSION

This was a prospective observational study during the COVID pandemics to study the diagnosing accuracy of Ultrasonography and Hysteroscopy in diagnosing endometrial pathology in women with abnormal uterine bleeding.

Overall study result of the study while being compared with similar studies done by **Wanderley *et al*** in Brazilian population among 191 women, **Tsonis *et al*** in Greek population among 2675 women and by **B K Goyal *et al*** in Indian Population among 100 women.

	Hys	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**	**Hys**	**USG**
Study	**Sensitivity**		**Specificity**		**PPV**		**NPV**		**Accuracy**	
Wanderley *et al*	84.4	71.4	100	60.3	100	62.5	87.5	69.5	92.2	65.9
BK Goyal *et al*	96.7	95.23	96.5	94.28	92.9	77.8	88.6	79.4	78.2	76.9
Tsonis *et al*	98.9	84	95.1	86.8	98.4	95.3	93.9	63	97.3	84.7
Current Study	81.94	47.22	81.08	42.86	89.87	62.87	68.67	28.38	81.66	45.79

Table 28 - Comparison between current study and other studies for performance of USG and HYS

- **Wanderley *et al*** found Sensitivity, specificity, PPV NPV and accuracy of 84.4 %, 100 %, 100 %, 87.5 % and 92.2% respectively **Tsonis *et al*** found Sensitivity specificity, PPV, NPV and accuracy of 98.9 %, 95.1 %, 98.4 %, 93.9 %, 97.3 %, and study done by **BK Goyal *et al*** among Indian population found Sensitivity, specificity, PPV, NPV and accuracy of 96.7 %, 96.5%, 92.9 %, 88.6 %, 78.2 % where as in the current study Sensitivity, specificity, PPV, NPV and accuracy was found to be 81.94 %, 81.08 %, 89.87%, 68.67 % and 81.66% respectively. USG had Sensitivity, specificity, PPV, NPV and accuracy reported in study by Wanderley to be 71.4 %, 60.3 %, 62.5%, 69.5%, 65.9 %. **BK Goyal *et al*** demonstrated USG had very high Sensitivity, specificity, PPV, NPV and accuracy w.r.t. hysteroscopy and was 95.23% 94.28%, 77.8%, 79.4%, 76.9%. **Tsonis *et al*** had Sensitivity specificity, PPV NPV and accuracy for USG as 84 %, 86.8%, 95.3%, 63%, 84.7%. Whereas in the current study USG had considerably low Sensitivity, specificity, PPV, NPV and accuracy as 47.22 %, 42.86%, 62.87%, 28.38%, 45.79%. Reason for hysteroscopy having lesser sensitivity as compared to other studies

can be attributed to the fact that, hysteroscopy being done by multiple observers and the sample size of the study being less as compared to other studies. Study done by **BK Goyal *et al*** was a single observer study with better ultrasonography machine with transducer probe frequency of 10 MHz, hence better anatomic clarifications of uterus whereas in the current study, ultrasonography machine with 5 MHz transducer probe frequency was used. **Yela *et al*** studied among total 754 patients in the brazillian population.

Studies	**Sensitivity (in %)**		**Specificity (in %)**		**PPV (in %)**		**NPV (in %)**		**Accuracy (in %)**	
AUB (Pre-Peri Menopausal)	Hys	USG	Hys	USG	Hys	USG	Hys	USG	Hys	USG
Yela *et al*	91.8	96	76.6	58	96	94	60.5	66	89.7	91.5
Current Study	84.48	51.72	87.10	45.16	88.57	52.75	82.59	44.15	85.68	48.72

Table 29- Comparison between current study and the study done by **Yela *et al*** among pre-/perimenopausal age group

Studies	**Sensitivity (in %)**		**Specificity (in %)**		**PPV (in %)**		**NPV (in %)**		**Accuracy (in %)**	
Post-Menopausal	Hys	USG	Hys	USG	Hys	USG	Hys	USG	Hys	USG
Yela *et al*	91.8	96	76.6	58	96	94	60.5	66	89.7	91.5
Current Study	84.48	51.72	87.10	45.16	88.57	52.75	82.59	44.15	85.68	48.72

Table 30-Comparison between current study and the study done by **Yela *et al*** among post-menopausal age group

Among Sub group analysis, **Yela *et al*** found Sensitivity, specificity, PPV, NPV and accuracy among pre-/Peri Menopausal females to be 91.8%, 76.6%, 96 %, 60.5%, 89.7% for hysteroscopy. Whereas the current study found Sensitivity, specificity, PPV, NPV and accuracy to be 84.48 %, 87.10%, 88.57%, 82.59%, 85.68% among Pre /Perimenopausal age group. Similarly, USG had a Sensitivity, specificity, PPV, NPV

and accuracy of 96%, 58 %, 94%, 66%, 91.5% among pre / Peri menopausal females in the study by **Yela *et al*.** In the current study USG had a Sensitivity, specificity, PPV, NPV and accuracy of 51.72%, 45.16%, 52.75%, 44.15%, 48.72 % which is found to be considerably lower with respect to hysteroscopy. Among post-menopausal age group **Yela *et al*** found sensitivity, specificity, PPV, NPV and accuracy to be 91.8%, 76.6%, 96%, 60.5%, 89.7% respectively for hysteroscopy. Whereas current study had sensitivity, specificity, PPV, NPV and accuracy of 84.48%, 87.10 %, 88.57%, 82.59%, 85.68% for hysteroscopy. For USG among post-menopausal age females, Yela et. al found Sensitivity, specificity, PPV, NPV and accuracy to be 96%, 58 %, 94%, 66% and 91.5% whereas current study found Sensitivity, specificity, PPV, NPV and accuracy of 51.72%, 45.16%, 52.75%, 44.15%, 48.72%. Hysteroscopy was found to be having comparable results with the study done by **Yela *et al*** whereas ultrasonography was found to be having significantly low performance in diagnosing endometrial pathology in both pre-/peri-menopausal females and post-menopausal females. Sample size in the study done by **Yela *et al*** was significantly higher than the current study.

Korkmazer *et al* studied among 197 post-menopausal women among Turkish population whereas **Hyatullah *et al*** studied among 102 post-menopausal females among Arabian population.

Post-Menopausal females, Hysteroscopy				
Study	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Korkmazer *et al*	76.4	76.9	73.1	79.8
Hyatullah *et al*	95.05	100	100	16.67
Current Study	84.48	87.10	88.57	82.59

Table 31- Comparison between current study and the other studies among post-menopausal females for performance of USG and HYS

Other specific studies for comparing Hysteroscopy with HPR such as by **Korkmazer *et al*** found Sensitivity, specificity, PPV, NPV and accuracy to be 76.4 %, 76.9%, 73.1 %, 79.8%. **Hyatullah *et al*** found Sensitivity, specificity, PPV, NPV and accuracy to be 95.05 %, 100 %, 100%, 16.67% respectively. Post-Menopausal females recruited in the study was considerably lower, yet the diagnostic power of hysteroscopy was

found to be similar as compared to other studies in diagnosing endometrial pathology in post-menopausal females.

Elfaymoy *et al* studied among 83 females in Egyptian population whereas **Trojano *et al*** studied among 295 females among Italian population.

Endometrial Hyperplasia Hysteroscopy	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Elfaymoy *et al*	56.05	91.6	72.2	84.6
Trojano *et al*	66.07	100	100	98.1
Current Study	57.15	100	100	93.94

Table 32- Comparison between current study and other study for diagnostic accuracy of hysteroscopy for endometrial hyperplasia

For endometrial hyperplasia, Study done by **Elfaymoy *et al*** found Sensitivity specificity PPV, NPV to be 56.05 %, 91.6 %, 72.2 %, 84.6% and by **Trojano *et al*** found Sensitivity, specificity, PPV, NPV to be 66.07%, 100%, 100%, 98.1% for hysteroscopy. Whereas the current study found Sensitivity, specificity, PPV, NPV to be 57.15%, 100 %, 100%, 93.94% for hysteroscopy for diagnosing endometrial hyperplasia. Hysteroscopy in the current study appear to have comparable diagnostic accuracy with the study done by **Elfaymoy *et al*** and **Trojano *et al***.

Elsersy *et al* conducted the study among 250 Egyptian females and **Trojano *et al*** studied among 295 females among Italian population.

USG Polyp	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Elsersy et. Al	99.57	87.5	99.15	99.15
Trojano et. Al	100	98.7	99.5	100
Current Study	34.38	16.67	14.96	37.32

Table 33- Comparison between current study and other studies for diagnostic accuracy of Ultrasonography for endometrial polyp

For endometrial polyp study done by **Elsersy *et al*** found Sensitivity, specificity, PPV, NPV to be 99.57%, 87.5 %, 99.15%, 99.15%, whereas current study found sensitivity, specificity, PPV, NPV and accuracy of 34.38%, 16.67%, 14.96%, 37.32%, 21.96%. Whereas **Trojano *et al*** found Sensitivity, specificity, PPV, NPV to be 100%, 98.7%, 99.5 %, 100 %. In the current study Ultrasonography was found to be having considerably low sensitivity, specificity, PPV, NPV and accuracy as compared to other studies. This can be attributed to a smaller number of sample size studied in the population and observer dependent interpretation. Such as some cases of endocervical polyps were erroneously diagnosed as endometrial polyp and vice versa as they can be very much confusing as their morphological appearance appear similar.

Trojano et.al studied among 295 females among Italian population.

Endometrial Cancer Hys	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Trojano *et al*	100	99.6	100	100
Current Study	66.67	100	100	99.05

Table 34 - Comparison between current study and other study for diagnostic accuracy of hysteroscopy for endometrial cancer

For Endometrial cancer Sensitivity, specificity PPV, NPV in study done by **Trojano *et al*** found 100%, 99.6%, 100%, 100% whereas current study found Sensitivity, specificity, PPV, NPV to be 66.67% , 100 %, 100% , 99.05%. Sensitivity was significantly less. This can be attributed to the significantly lesser number of sample size in the current study and among them only 3 cases of endometrial cancer were diagnosed.

We observed wide range of confidence interval in the parameters observed in the study i.e., sensitivity, specificity, PPV, NPV, and accuracy due to lesser number of sample size in the study.

- **STRENGTHS OF THE STUDY**

  This was the first of its kind of study to be conducted among populations of western Rajasthan as no such previous study was available to the best of our knowledge.

  This study was done during COVID pandemic and we made an effort to complete all the management in one or two visits to reduce the hospital visits and risk of acquiring COVID infection. This study added importance of use of hysteroscopy in diagnosing and managing endometrial pathology in abnormal uterine bleeding during COVID pandemic.

  We took into account wide range of age group; and a wide range of endometrial pathology was diagnosed among Ultrasonography, hysteroscopy and histopathology in our study.

- **DRAWBACKS**

  Sample size was less than expected due to ongoing COVID 19 Pandemic. Most patients who reported to OPD had severe symptoms or had not responded to medical management prescribed to them by telephonic/telemedicine consultation. So, patients having mild symptoms were missed in our study

  Sample size was compromised due to the above-mentioned reasons.

CONCLUSION

- This was a prospective observational study was conducted at AIIMS, Jodhpur in the department of Obstetrics and Gynecology aimed to compare the sensitivity, specificity, Positive predictive value and negative predictive value of hysteroscopy and ultrasonography in diagnosing abnormal uterine bleeding while taking histopathology as gold standard.
- To assess the distribution and pattern of endometrial pathologies in women with abnormal uterine bleeding.
- All patients underwent Ultrasonography, hysteroscopy and endometrial biopsy as a part of management for Abnormal uterine bleeding.
- In total 107 patients were recruited in the study, out of which 18 were post-menopausal females, and 18 were pre-/peri-menopausal females.
- In the current study Sensitivity, specificity, PPV, NPV and accuracy of hysteroscopy in diagnosing endometrial pathologies was found to be 81.94 %, 81.08 %, 89.87%, 68.67 % and 81.66% respectively and Ultrasonography had Sensitivity, specificity, PPV, NPV and accuracy 47.22%, 42.86%, 62.87%, 28.38% and 45.79% respectively. In analysis among post-menopausal females, pre-/peri-menopausal females similar results were reflected.
- Sensitivity, specificity, PPV, NPV and accuracy of hysteroscopy for diagnosing endometrial polyp was found to be 87.5%, 83.33%, 69.13%, 93.99%, and 84.58% as compared to ultrasonography having sensitivity, specificity, PPV, NPV and accuracy of 34.38%, 16.67%, 14.96%, 37.32% and 21.96%.
- In diagnosing endometrial hyperplasia hysteroscopy was found to be having sensitivity, specificity, PPV, NPV and accuracy of 57.15%, 100%, 100%, 93.94% and 94.39% respectively as compared to ultrasonography having sensitivity, PPV, and accuracy of 28.57%, 4.12% and 3.74% respectively.
- In diagnosing endometrial carcinoma hysteroscopy was found to be having sensitivity, PPV and accuracy of 66.67%, 100% and 99.07% whereas ultrasonography was found to be having sensitivity, PPV and accuracy of 33.33%, 0.95% and 0.93%.
- Hence, Hysteroscopy was found to have better diagnostic accuracy in comparison to ultrasonography in diagnosing specific endometrial pathologies as endometrial polyps, endocervical polyps, endometrial hyperplasia and

endometrial cancer. The difference was statistically significant with p value of <0.00001 in comparing sensitivity, specificity, Positive Predictive Value, Negative predictive value and accuracy of hysteroscopy and ultrasonography.

- Ultrasonography had maximum number of cases reported as endometrial polyp 16 (14.8%), followed by Congenital uterine anomaly in cases (13%). Endometrial hyperplasia was reported in 8 cases (7.4%), Endometrial carcinoma was suspected in 4 cases and normal cavity was reported in 21 cases (19.6%).
- Similarly, hysteroscopy reported endometrial polyps in 13 cases (12.1%), Endometrial hyperplasia was reported in 8 cases (7.4%), Endometrial carcinoma was suspected in 2 cases (1.8%).
- Benign endometrial histopathology was reported in 57 cases (53.2%), Endometrial polyp was diagnosed in 34 cases (31.7%). Endometrial hyperplasia was diagnosed in total of 14 cases. Ca Endometrium was diagnosed in 3 cases out of 107 patients studied.
- The study adds to the body of evidence available in literature regarding usefulness of hysteroscopy in management of abnormal uterine bleeding. It is recommended that hysteroscopy be used as first line investigation in management of abnormal uterine bleeding. Ultrasonography can be used as an adjunctive investigation to hysteroscopy for diagnosis uterine pathologies that cannot possibly be picked by hysteroscopy such as subserosal and intramural fibroids and adenomyosis and adnexal pathologies.
- This adds benefits to patient management in properly diagnosing the endometrial pathology and planning intervention that are possibly missed by ultrasonography alone.

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ANNEXURE

List of Annexures

Annexure no	Title
1	IEC certificate
2	Patient Information sheet in English
3	Patient Information sheet in Hindi
4	Consent form in English
5	Consent from in Hindi
6	Case record form
7	Master chart

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2066

Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/954**

Project title: **"Comparison between ultrasonography and hysteroscopy for assessment of endometrial pathology in women with abnormal uterine bleeding"**

Nature of Project:	**Research Project**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Bikash Choudhary**
Guide:	**Dr.Pratibha Singh**
Co-Guide:	**Dr.Garima Yadav, Dr.Charu Sharma, Dr.Meenakshi Gothwal, Dr.Meenakshi Rao & Dr.Priyanka Kathuria**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Enclose:
1. Annexure 1

Basni Phase-2, Jodhpur, Rajasthan-342005, **Website:** www.aiimsjodhpur.edu.in, **Phone:** 0291-2740741 Extn. 3109
Email: ethicscommittee@aiimsjodhpur.edu.in

Patient Information Sheets (PIS)

Part 1

You are invited to take part in this study entitled "**Comparison between Ultrasonography and hysteroscopy for assessment of endometrial pathology in women with Abnormal Uterine bleeding**

It is informed that it is entirely voluntary and you may refuse to take part or discontinue at any time without losing your right to adequate gynaecological care.

This research is aimed at comparing the diagnostic accuracy of both the procedures and corelating them with the gold standard i.e. Histopathology. The endometrial biopsy will be done in standard manner

All the records will be kept confidential.

You have the right to ask for any further information that you require.

In case of any doubt regarding the study you are welcome to contact the undersigned personally or telephonically.

Part-2

Investigator's statement

I have explained the purpose, procedures, benefits and harms of the study in detail to the patient/ patient's relative.

All information regarding the study has been disclosed.

Enough Time and Opportunity for asking questions regarding the study was given to the patient/ patient's relative.

Investigator signature: -

Witness signature: -

Phone no. 7894235574

रोगी सूचना पत्र

आपको इस अध्ययन में भाग लेने के लिए आमंत्रित किया गयाहै "असामान्य गर्भाशय रक्तस्राव के साथ महिलाओं में एंडोमेट्रियल पैथोलॉजी के आकलन के लिए अल्ट्रासोनोग्राफी और हिस्टेरोस्कोपी के बीच तुलना" यह सूचित किया जाता है कि यह पूरी तरह से ऐच्छिक है और आप देखभाल के अपने अधिकार को खोए बिना किसी भी समय हिस्सा ले सकते हैं या बाहर निकल सकते हैं।

अगर आप इस अध्ययन में भाग लेने से इनकार करते हैं तो जांच और उचित उपचार नियमित प्रोटोकॉल के रूप में किया जाएगा। इस शोध का उद्देश्य दोनों प्रक्रियाओं की नैदानिक सटीकता की तुलना करना और उन्हें हिस्टैथोलोजी से जोड़ना है। एंडोमेट्रियल बायोप्सी मानक तरीके से की जाएगी

अध्ययन के कारण कोई विशिष्ट नुकसान नहीं है।

सभी रिकॉर्ड गोपनीय रखें जायेंगे।

आपके पास किसी भी प्रकार की अधिक जानकारी लेने का अधिकार है।

अध्ययन के बारे में किसी भी संदेह की स्थिति में आपका व्यक्तिगत रूप से या टेलीफ़ोनिक रूप से संपर्क करने के लिए स्वागत है।

जांचकर्ता का बयान

मैंने अध्ययन के उद्देश्य, प्रक्रियाओं, लाभ और हानि को रोगी / रोगी के रिश्तेदार को विस्तार से समझाया है।

अध्ययन के बारे में सभी जानकारी का खुलासा किया गया है।

अध्ययन के संबंध में प्रश्न पूछने के लिए पर्याप्त समय और अवसर रोगी / रोगी के रिश्तेदार को दिया गया था।

जांचकर्ता हस्ताक्षर: - **साक्षी हस्ताक्षर**:

फोननंबर- 7894235574

All India Institute of Medical Sciences

Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation : **Comparison between Ultrasonography and hysteroscopy for assessment of endometrial pathology in women with Abnormal Uterine bleeding**

Name of PG Student : Dr. Bikash Choudhury

Tel. No. : +91-7894235574

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of the study "**Comparison between Ultrasonography and hysteroscopy for assessment of endometrial pathology in women with Abnormal Uterine bleeding "** the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.
I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS, Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.
Date: _____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of PG Student

Witness 1 2. Witness

_____ _____

Signature Signature

Name: _____ Name: _____

Address: _____ Address: _____

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस

जोधपुर, राजस्थान

सूचित सहमति प्रपत्र

थीसिस / निबंधकाशीर्षक: 'असामान्य गर्भाशय रक्तस्राव के साथ महिलाओं में एंडोमेट्रियल पैथोलॉजी के आकलन के लिए अल्ट्रासोनोग्राफी और हिस्टेरोस्कोपी के बीच तुलना"

पीजी छात्र का नाम: डॉक्टर बिकाश चौधरी

रोगी / स्वयं सेवक पहचान संख्या: _____

मैं, _____ पुत्री/पत्नी _____

निवासी_____

अध्ययन" असामान्य गर्भाशय रक्तस्राव के साथ महिलाओं में एंडोमेट्रियल पैथोलॉजी के आकलन के लिए अल्ट्रासोनोग्राफी और हिस्टेरोस्कोपी के बीच तुलना' में भाग लेने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति देती हूं, जिसकी प्रक्रिया और प्रकृति मुझे मेरी भाषा में समझाई गई है। मैं पुष्टि करती हूं कि मुझे प्रश्न पूछने का अवसर मिला है। मैं समझती हूं कि मेरी भागीदारी स्वैच्छिक है और मुझे किसी भी समय अध्ययन से बाहर निकलने का अधिकार है| । मैं समझती हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस के जिम्मेदार व्यक्ति द्वारा देखा जा सकता है |मैं इन लोगों को मेरे रिकॉर्ड देखने की अनुमति देती हूं|

तारीख : _____

जगह: _____ हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है

तारीख : _____ _____

जगह: _____ पीजी छात्र के हस्ताक्षर

1. **गवाह** 2.**गवाह**

_____ _____

हस्ताक्षर हस्ताक्षर

नाम _____ नाम:_____

पता _____ पता : _____

Case Record Proforma

Case No: **Hospital- Id. No:**

Name: **Date:**

Age:

Occupation: Patient:

Husband:

Address: **Date of Admission:**

Date of USG **Date of Surgery (Hysteroscopy)**
Date of Discharge:

Complaints of Patient

HISTORY:

Menstrual History:

Attained menarche at the age of _____

Cycles: Regular /Irregular

Pain / Clots

LMP:

Marital History: Married since _____years/months

Consanguineous marriage- Yes/No

Contraceptive history -

Obstetric History : G P

Mode of delivery-

Last Child birth

Tubectomy- Yes/No

Co-morbidities:

Hypertension / diabetes / chronic renal failure / chronic obstructive pulmonary disease / ischemic heart disease / tuberculosis / epilepsy /cirrhosis of liver

H/O Drug / hormonal intake :

PAST HISTORY –

Personal History-

Family History-

GPE-General Physical Examination:

General Appearance:

Height: Weight: BMI:

Temperature:

Pallor: Y/N

Pulse: BP: Respiratory rate: Oedema: Y/N

Breast: Thyroid: Spine:

Systemic Examination:

CVS:

RS:

P/A:

Local Examination:

P/S:

P/V:

Investigations:

CBC: Hb- TLC- DLC- Platelets- PT- APTT-

RBS- Urea- Creatinine-

Blood grouping and Rh typing-

Thyroid Function Test- Prolactin- other hormonal tests:

Others-

HIV- HbsAg- VDRL- UPT:

Ultrasonogram (TVS)

Uterus size, myometrium echotexture

ET (mm) echotexture uniform / focal

Any other pathology

Ovary size any pathology[describe]

Hysteroscopy:

Anaesthesia: yes / no Type

Cervix cervical canal

Endometrial cavity Normal abnormal [describe]

Endometrium smooth irregular[describe]

Atrophic thin thick focal/ diffuse

Colour: pale pink

Blood vessels

Any lesion seen [describe]

Intra operative Findings:

Post operatively:

Histopathological Report:

case number	hospital Id	Age	SES	chief complaints	severe anemia	Parity	Co-Morbidities	height (in centimetres)	weight (on Kgs)	TAS / TVS	TVS /TAS - ET (in mm)	Hysteroscopy	HPR	code_USG	code_hyst	code_HPR
1	2019/12/008282	39	lower middle	continuous bleeding PV x 3months and generalized weakness x 1	yes	2002	Hypertension	155	68	intramural fibroid	12.6	fibroid with intramural and su	benign endometrial fibroid , secretory	1	1	1
2	2015/01/015030	36	lower middle	amenorrhoea along with cyclic abdominal pain x 3 months		0	tuberculosis	158	62	hematometra/ echogenic conten	5	hematometra	benign, hemosiderin laden macropha	1	1	0
4	2020/01/028137	44	lower middle	pain abdomen x 2-3 months		1001	NAD	168	85	RPOCs ? Molar pregnancy	9.7	AV malformation	GTD	1	0	1
5	2020/02/004737	42	lower middle	Heavy menstrual bleeding x 2 months		5005	NAD	168	74	endometrial polyp	9.6	NAD , thickened endometriu	benign , secretory endometrium	1	0	0
6	2019/09/020929	41	lower middle	infertility and irregular cycles x 1.5 years		0000	NAD	170	82	polyp (endo cervical)	5	endocervical polyp	myomatous polyp	1	1	1
6	2019/10/004015	41	lower middle	bleeding p/v x 2 months		0010	thyroid disorder	162	58	NAD	5.8	NAD, thickened endometriun	benign , no malignancy	0	0	0
7	2020/02/012269	51	lower middle	Heavy bleeding with irregular cycles x 6 months		3003	NAD	168	82	adenomyosis+ endocervical poly	8	endometrial polyp	benign endometrial polyp , secretory	0	1	1
8	2019/03/011350	52	lower middle	Post menopausal bleeding x 5 months , something coming out of vagina		4004	NAD	155	54	NAD	2	endocervical polyp	borderline squamous metaplasia in p	0	1	1
9	2020/02/000883	37	lower middle	Primary infertility with irregular cycles		0000	Diabetes Mellitus	170	84.5	submucosal + intramuralfibroid	1	submucosal fibroid + posteri	benign cervical fibroid , proliferative e	0	1	1
10	2020/02/014038	40	lower middle	discharge p/v x 1 year		5005	tobacco chewing +, Mucosal	168	84	endometrial polyp	20.5	endocervical polyp	benign , myomatous polyp endometr	1	0	1
11	2020/01/032748	50	lower middle	Continuous bleeding p/v x 17 days		4004	NAD	165	84	endometrial polyp	10	endometrial polyp	benign endometrial polyp , proliferati	1	1	1
12	2020/03/006653	43	lower middle	Continuous bleeding p/v x 1 month		4004	Diabetes Mellitus	163.5	58	endometrial polyp	8.6	endometrial polyp	endocervical polyp , basal endometri	0	0	1
13	2019/12/005692	37	lower middle	Infertility with irregular cycles since menarche		0000	NAD	154	72	intramural fibrosis in posterior my	6	NAD	benign , secretory endometrium	0	0	0
14	2018/04/007045	41	lower middle	Amenorrhoea x 9 months with Missing Cu T thread		2022	Diabetes Mellitus	155	62	IUCD	5.4	IUCD + spiculated bone like	osseous metaplasia with proliferative	0	1	1
15	2020/07/006566	44	lower middle	HMB with irregular cycles x 10 years , Continuous bleeding p/v x 10 day		2002	NAD	153	48	adenomyosis	8	endometrial polyp	benign endometrial polyp , secretory	0	1	1
16	2020/02/009561	36	lower middle	secondary amenorrhoea		0000	Diabetes Mellitus	150	52	PID + IUCD + bicornuate uterus	7.2	NAD +IUCD	benign , fibrin +hemosiderin	1	1	1
18	2021/02/004690	59	lower middle	something coming out of vagina with whitish discharge		4102	Diabetes Mellitus , CKD	160	65.4	thickened endometrium	11	cervical polyp	benign cervical polyp	0	1	1
18	2015/07/004558	40	lower middle	heavy mestrual bleeding x 3-4 years	yes	2002	NAD	165	74.5	endometrial polyp	5	endometrial polyp	endometrial polyp , secretory phase v	1	1	1
19	2021/01/015692	65	lower middle	something coming out of vagina with post menopausal bleeding		4002	Hypertension	155	68	cystic spaces in endometrial cav	7.3	endometrial polyp	benign polyp , EB - inadequate	0	1	1
20	2021/01/011615	40	lower middle	post menopausal bleeding		3003	Hypertension	148	46	NAD	10.8	thickened endometrium	hyperplasia	0	1	1
21	2018/05/020336	48	lower middle	secondary infertility with hypothyroidism with irregular cycles		0010	thyroid disorder	166	65	NAD	8	NAD	disordered proliferative endometrium	0	0	0
22	2020/12/006726	36	lower middle	AUB under evaluation with moderate anemia		2002	NAD	155	72	adenomyosis	7	NAD	Proliferative endometrium	0	0	0
23	2021/01/014167	35	lower middle	heavy menstrual bleeding x 3 months		3003	NAD	148	46.5	endometrial polyp	4	endocervical polyp	endocervical polyp , proliferative end	0	1	1
24	2020/11/008218	39	lower middle	continuous bleeding p/v x 20 days		0000	NAD	170	74	AV malformation , neoplasia	2.7	clots	benign , hemorrhage +fibrin	1	0	0
25	2107/11/004852	36	lower middle	Primary infertillity with grade 1 obesity with right ovarian cyst with irregul		0000	Hypertension	145	88	NAD	7	NAD	disordered proliferative endometrium	0	0	0
26	2018/03/000025	52	lower middle	pain in lower abdomen with irregular cycles		2002	ischemic heart disease	155	72	multiple intramural and subseros	11	NAD	Proliferative endometrium	1	0	0
27	2020/12/008881	71	lower middle	AUB under evaluation		6006	Hypertension , IHD	154.5	68	endometrium nodular	6	endometrium nodular +Pus	benign hyperplasia	1	1	1
28	2019/11/006158	36	lower middle	primary infertility with irregular cycles		0000	NAD	172	68	NAD	7.8	NAD	Proliferative endometrium	0	0	0
29	2019/04/010229	52	lower middle	post menopausal female with spotting per vaginum		3003	Hypertension	153	79	NAD	2	NAD	benign , scanty endometrial glands	0	0	0
30	2020/08/003192	38	lower middle	primary infertility with irregular cycles		0000	NAD	155	48	bicornuate , bicollis uterus	15	bicornuate , bicollis uterus	proliferative endometrium	1	1	1
31	2020/11/003781	38	lower middle	Spotting per vaginum with USG s/o scar ectopic		2012	thyroid disorder	144	70	C scar ectopic	10	c scar ectopic	Product of conception	1	1	1
32	2019/01/030763	37	lower middle	heavy menstrual bleeding x 1.5 years		2002	Diabetes Mellitus	165	66	IUCD	10	IUCD	benign , secretory endometrium	1	1	1
33	2020/08/009669	35	lower middle	heavy menstrual bleeding x 2 years		5005	Hypertension	157	58	hypertrophied and thickened end	17	NAD	benign , out of phase endometrium	1	0	0
34	2020/09/008701	48	lower middle	HMB x 1 year		3003	Diabetes Mellitus	155	46.5	adenomyosis	2	NAD	disordered proliferative endometrium	0	0	0
35	2020/07/004343	35	lower middle	incidental findings of HWW syndrome		0000	Diabetes Mellitus	155	46	hematocolpos	5	hematocolpos	not done	1	1	1
36	2019/08/015309	36	upper middle	irregular spotting p/v . with intermenstruyal bleeding		0000	Diabetes Mellitus	146	48	RPOCs + septae	10	septa , no RPOCs	secretory endometrium , no RPOCs	1	0	0
37	2018/01/017549	40	upper middle	FUC of transverse vaginal septum , dyspareunia with foul smelling disch		0000	Diabetes Mellitus	160	65	hematocolpos	15	hematometra +hematocolpo	EB - benign , no growth in specimen	1	1	1
38	2021/12/005268	38	lower middle	frequent and heavy bleeding		2002	Hypertension	165	55	endocervical polyp +Submucosa	20	endometrial polyp + submuc	benign endometrial polyp + submuco	0	1	1
39	2020/02/007116	36	lower middle	irregular cycles		2002	Hypertension	161	74	IUCD	8	IUCD	benign , no e/o malignancy	1	1	1
40	2021/08/014886	37	lower middle	irregular cycles		3003	Diabetes Mellitus	160	65	subendometriotic cyst	6	NAD	bening , late secretory endometrium	1	0	0
41	2021/11/012038	44	upper middle	frequent and heavy bleeding		0000	Diabetes Mellitus	157	72	subendometriotic cyst	15	NAD	benign hyperplasia	0	0	1
42	2021/10/003904	42	upper middle	imb			Diabetes Mellitus	145	71	endocervical polyp	12	endocervical polyp	benign fibroid polyp , late secretory p	1	1	1
43	2021/11/003480	43	lower middle	imb		2002	thyroid disorder	158	63	hematometra	2.6	pyometra	benign	0	1	0
44	2021/10/008379	35	lower middle	IMB		2002	NAD	158	67	subendometriotic cyst	10	endometrial polyp	benign endometrial polyp	0	1	1
45	2021/10/012492	45	upper middle	frequent and heavy bleeding	yes	3003	Hypertension + DM	167	72	endometrial polyp	15	endometrial polyp	benign polyp , proliferative phase en	1	1	1
46	2021/10/017167	37	upper middle	amenorrhoea f/b spotting p/v		0000	NAD	162	47	scar ectopic		scar ectopic	rpocs	1	1	1
47	2021/09/012765	38	upper middle	imb		3003	Diabetes Mellitus	161	77	ACUM	7	NAD		1	0	0
48	2021/09/009825	39	upper middle	IMB		2002	tuberculosis	166	71	septate uterus	8	septate uterus	late secretory endometrium	1	1	1
49	2021/08/007132	36	upper middle	frequent and heavy bleeding p/v		3003	Hypertension	158	75	adenomyosis	2	NAD	proliferative endometrium	1	0	0
50	2021/06/004571	70	lower	PMB		0000	Hypertension	165	72	submucosal fibroid	6	endometrial polyp	endometrial polyp	0	1	1
51	2021/08/015528	38	upper middle	irregular cycles		2002	Hypertension	166	78	septate uterus	8	septate uterus	proliferative endometrium	1	1	1
52	2021/08/017572	46	lower middle	irregular cycles		4004	Diabetes Mellitus	158	77	multiple fibroid SS + Intramural	10	NAD	Proliferative endometrium	1	0	0
53	2021/04/002689	46	lower middle	frequent and heavy bleeding		3003	Hypertension	147	67	NAD	7.9	Fluffy hyperplastic endometr	Benign hyperplasia	0	1	1
54	2021/08/015811	44	lower	frequent and heavy bleeding		3003	NAD	144	65	multiple polyps	7	fluffy endometrium	Proliferative endometrium with chron	0	1	1
55	2021/08/008286	44	upper middle	irregular cycles		2002	Diabetes Mellitus	143	64	cystic hyperplasia	12	fluffy endometrium	secretory endometrium	1	0	0
56	2019/04/008740	39	lower middle	frequent and heavy bleeding		3003	Diabetes Mellitus	146	43	NAD	10	NAD	late secretory endometrium	0	0	0
57	2021/08/014626	42	upper middle	imb		0000	Diabetes Mellitus	145	67	endocervical polyp	10	endometrial polyp	benign endometrial polyp + secretory	0	1	1
58	2021/06/005301	37	lower middle	frequent and heavy bleeding		0000	Hypertension	158	69	intramural + subserosal fibroid	6.7	NAD	PROLIFERATIVE ENDOMETRIUM	1	0	0
59	2021/07/005002	42	upper middle	imb		2002	NAD	155	97	septum	11	septum	late secretory endometrium	1	1	1
60	2021/07/001389	39	upper middle	imb		3003	Diabetes Mellitus	156	98	endocervical polyp	17	endometrial polyp	benign endometrial polyp , No e/o hy	0	1	1
61	2021/04/010552	49	upper middle	pmb		4004	Hypertension	159	81	nad	6.9	fluffy endometrium	benign	0	1	0
62	2018/08/017766	39	upper middle	frequent and heavy bleeding		0000	Diabetes Mellitus , HTN	158	73	intramural fibroid	10	NAD	benign , proliferative endometrium	1	0	0
63	2021/07/011029	48	upper middle	pmb		2002	Hypertension	156	71	cervical fibroid	15	fluffy endometrium + cervica	cervical polyp , benign	1	1	1
64	2021/07/013530	53	lower middle	pmb		4004	NAD	158	77	NAD	7	fluffy endometrium , cystic p	ca endometrium	0	1	1
65	2021/06/000136	40	lower	irregular cycles		2002	NAD	154	66	adenomyosis +endometrial polyp	5.2	endocervical polyp	cervical polyp , benign secretory end	0	1	1
66	2021/07/002591	46	lower middle	continuous bleeding p/v	yes	2002	Diabetes Mellitus	153	65	? Malignancy	22	fluffy endometrium with endo	benign , no polyp	1	0	0

67	2021/03/007212	46	lower middle	frequent and heavy bleeding		4004	Hypertension	152	55	NAD	17	endometrial polyp	disordered proliferative endometrium	0	1	0
68	2021/07/006383	67	lower middle	pmb		2002	Diabetes Mellitus	158	91	focal thickening ? Malignancy	22	endometrial polyp	benign polyp + atrophic endometrium	1	0	0
69	2021/06/008482	51	lower upper	irregular cycles		4004	Hypertension	154	45	adenomyosis +endometrial polyp	8	endometrial polyp	benign polyp	1	1	1
70	2021/07/005424	39	lower	irregular cycles		0000	NAD	155	56	c- scar ectopic	12	c -scar ectopic	rpocs	1	1	1
71	2021/06/012158	35	lower	continuous bleeding p/v		4004	Hypertension , DM	154	57	gtd	10	rpocs	rpocs	1	1	1
72	2021/05/009722	38	lower	continuous bleeding p/v		4004	NAD	156	52	? AVM	2	rpocs	GTD	0	1	1
73	2021/06/006404	60	lower	pmb		2002	Diabetes Mellitus	158	53	endometrial polyp	18	NAD	benign senile cystic atrophy	1	0	0
74	2021/06/003849	40	lower	frequent and heavy bleeding		0000	NAD	157	45	cervical fibroid	0.8	fluffy endometrium	benign hyperplasia	0	1	1
75	2021/06/004196	38	lower upper	irregular cycles		2002	NAD	158	76	NAD	5.7	NAD	late secretory endometrium	0	0	0
76	2021/03/010578	38	lower middle	frequent and heavy bleeding		2002	tuberculosis	159	87	intramural fibroid	11.8	endometrial polyp	benign fibroid polyp , late secretory p	0	1	1
77	2020/04/000397	64	lower middle	pmb		2002	NAD	160	67	NAD	5	endometrial polyp	benign endometrial polyp	0	1	1
78	2020/07/011267	36	lower middle	frequent and heavy bleeding		0000	NAD	167	79	endometrial polyp	2.2	submucosal fibroid	submucosal fibroid	0	1	1
79	2021/03/010936	44	lower	irregular cycles		2002	NAD	152	98	endometrial polyp	15	submucosal fibroid	submucosal fibroid	0	1	1
80	2018/03/002074	37	lower middle	frequent and heavy bleeding		2002	Diabetes Mellitus	154	78	endometrial polyp	11	endometrial polyp	benign polyp , non secretory endome	1	1	1
81	2021/02/004047	56	lower	pmb		2002	NAD	157	65	? Cervical echogenicity	10	focal endometrial hyperplasi	differentiated carcinoma	0	1	1
82	2021/03/007596	36	lower middle	irregular cycles		2002	Diabetes Mellitus	150	56	septum	12	septum	disordered proliferative endometrium	1	1	1
83	2021/03/003797	42	lower middle	irregular cycles		2002	NAD	152	46	endometrial polyp	10	endometrial polyp	endometrial polyp	1	1	1
84	2021/02/009292	35	lower upper	irregular cycles		2002	Hypertension	154	74	submucosal fibroid	11	septa	endometrial polyp	0	0	1
85	2021/08/007879	45	lower middle	frequent and heavy bleeding		0000	NAD	150	47	NAD	4	NAD	disordered proliferative endometrium	0	0	0
86	2018/12/007539	50	lower	continuous bleeding p/v		3003	NAD	151	67	NAD	16	fluffy endometrium	benign pill endometrium	0	1	0
87	2020/12/009798	52	lower middle	continuous bleeding p/v		0000	Diabetes Mellitus	153	87	endometrial polyp	10	fibroid polyp	fibroid polyp , proliferative endometri	1	1	1
88	2021/02/010709	64	lower middle	pmb		0000	NAD	155	78	hypertrophied and thickened enc	11	NAD	serous endometrial cancer	1	0	1
89	2021/01/019888	73	lower	pmb		3003	NAD	153	92	cystic endometrial hyperplasia	11	submucosal fibroid	cystic endometrial hyperplasia	1	0	1
90	2021/02/009333	46	lower middle	frequent and heavy bleeding		2002	NAD	152	96	NAD	4.5	endometrial polyp	benign endometrial polyp , proliferati	0	1	1
91	2021/02/008345	41	lower middle	frequent and heavy bleeding		2002	Diabetes Mellitus	156	97	endometrial polyp	18	NAD	benign hyperplasia	0	0	1
92	2020/01/030921	35	lower middle	irregular cycles		1001	NAD	136	98	submucosal fibroid	11.1	NAD	PROLIFERATIVE endometrium	1	0	0
93	2021/02/004690	70	lower middle	pmb		2002	NAD	143	99	NAD	11	cervical polyp	benign cervical polyp	0	1	1
94	2017/06/007254	35	lower upper	imb		1103	NAD	144	111	endometrial polyp	5	endometrial polyp	benign endometrial polyp	1	1	1
95	2015/01/015030	36	lower middle	amenorrhoea		1103	Diabetes Mellitus	159	76	distended cavity with septa	13	asherman	secretory endometrium	0	1	0
96	2019/12/007845	41	lower middle	irregular cycles		0000	NAD	150	58	scar ectopic	10	NAD	RPOCs	1	0	1
97	2019/04/019101	39	lower middle	irregular cycles		2022	NAD	157	55	endometrial polyp	11	fluffy endometrium	secretory endometrium	1	0	0
98	2020/08/003192	38	lower middle	irregular cycles		2002	NAD	154	65	bicornuate , bicollis uterus	6	bicornuate , bicollis uterus	benign	1	1	1
99	2020/09/002604	41	lower middle	frequent and heavy bleeding		1001	Hypertension	157	67	endometrial polyp	6	NAD	benign hyperplasia	0	1	1
100	2020/01/024114	46	lower middle	frequent and heavy bleeding		2012	Diabetes Mellitus	154	66	NAD	16	submucosal polyp	benign polyp	0	1	1
101	2020/07/004254	45	lower middle	irregular cycles		2002	NAD	155	65	submucosal fibroid	10	endometrial polyp	benign endometrial polyp , secretory	0	1	1
102	2020/07/004144	37	lower middle	frequent and heavy bleeding		2002	NAD	153	89	subseptate uterus + polyp	7	NAD	disordered proliferative endometrium	1	0	0
103	2020/06/004739	35	lower middle	spotting p/v , following amenorrhoea		2002	Diabetes Mellitus	158	78	RPOCs	5	NAD	PSTT	1	0	1
104	2020/07/006566	44	lower middle	frequent and heavy bleeding		2002	NAD	145	76	adenomyosis	6	endometrial polyp	benign endometrial polyp	0	1	1
105	2020/06/007302	40	lower middle	frequent and heavy bleeding		1103	NAD	155	63	NAD	7.5	NAD	late secretory endometrium	0	0	0
106	2021/11/006470	38	lower middle	imb		2002	NAD	156	74	intramural fibroids	14	NAD	hyperplasia without atypia	0	0	1
107	2021/08/008011	39	lower upper	frequent and heavy bleeding		2002	NAD	167	63	NAD	17	NAD	hyperplasia without atypia	0	0	1