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Original Research Article

Hysteroscopic evaluation of menorrhagia and correlation with saline infusion sonography and histopathology of the endometrium

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ABSTRACT

Background: This study aimed to evaluate and compare the diagnostic utility of hysteroscopy and saline infusion sonography in patients presenting with abnormal uterine bleeding, using the International Federation of Gynaecology and obstetrics classification system.
Methods: The study included 97 women with menorrhagia attending the department of obstetrics and gynaecology, R. D. Gardi Medical College, Ujjain, from September 2011 to February 2013. All the participants underwent hysteroscopy, saline infusion sonography (SIS), and endometrial histopathology. The sensitivity, specificity, positive predictive value, and negative predictive value of each diagnostic method was calculated and compared.
Results: Both hysteroscopy and SIS demonstrated high sensitivity and specificity in detecting structural lesions from the PALM group of abnormal uterine bleeding (AUB) aetiologies. For endometrial polyps, hysteroscopy had a sensitivity of 89.47% with a specificity of 87.17%, while SIS had a sensitivity of 100% and specificity of 88.46% ($p<0.01$). For submucous fibroids, hysteroscopy had a sensitivity of 82.35% and specificity of 91.25%, while SIS had a sensitivity of 88.23% and specificity of 88.75% ($p<0.01$). However, neither method was as effective for endometrial hyperplasia and the COEIN group. Hysteroscopy-guided biopsy could improve the sensitivity and specificity of hysteroscopy in detecting endometrial hyperplasia.
Conclusions: Hysteroscopy and SIS are valuable tools in the diagnosis and management of AUB, with both methods demonstrating significant efficacy in detecting structural lesions, such as endometrial polyps and submucous fibroids. Further research is needed to refine these techniques and determine their optimal use in clinical practice, especially for the detection of endometrial hyperplasia and conditions within the COEIN group.

Keywords: Abnormal uterine bleeding, Hysteroscopy, Saline infusion sonography, Menorrhagia

INTRODUCTION

Menorrhagia, characterized by excessive menstrual flow and/or prolonged duration, is a significant gynaecological concern affecting approximately 6% of pubertal girls and women in their reproductive years, with the figure rising to 15% in perimenopausal women. With a growing number of women seeking consultation for menorrhagia, approximately 5% consult their family physician, and 12% of all gynaecological referrals are for menorrhagia. Appropriate management strategies can be implemented provided the aetiology if defined. The International Federation of Gynaecology and Obstetrics (FIGO) etiological classification system identifies nine main categories responsible for abnormal uterine bleeding (AUB), using the acronym PALM-COEIN, which stands for polyp, adenomyosis, leiomyoma, malignancy and hyperplasia, coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, and not yet classified.[1-3]

In recent years, various diagnostic modalities have been employed to evaluate menorrhagia, including non-invasive, invasive, and minimally invasive methods. Non-invasive methods, such as ultrasonography (USG), saline infusion sonography (SIS), and magnetic resonance imaging (MRI), allow assessment of endometrial thickness, filling defects, and vascularity. Minimally invasive methods include hysteroscopy and endometrial sampling, while invasive methods involve endometrial biopsy, dilatation, and curettage (D&C), and fractional curettage. Each modality has its own advantages and disadvantages, with traditional approaches like D&C and USG being the most common investigations.[4,5]

Saline infusion sonography (SIS) is a valuable diagnostic procedure to evaluate intracavitary uterine pathologies. It is easily performed, cost-effective, and widely available. Three-dimensional saline infusion sonography (3D SIS) has emerged as a newer modality, offering an improved evaluation of uterine contour, adhesions, and focal pathologies in comparison to hysteroscopy. It is less invasive, more cost-effective, and does not require general anesthesia, making it an acceptable first-line diagnostic approach for patients with AUB. While D&C has been the primary method for evaluating AUB, it lacks accuracy and reliability for focal lesions. Hysteroscopy, on the other hand, allows direct visualization and diagnosis of intrauterine abnormalities and often provides an opportunity for simultaneous treatment. Combining hysteroscopy with histological examination is now considered the new "gold standard" for evaluating AUB.[6,7]

This study aims to investigate the diagnostic accuracy and effectiveness of three modalities—saline infusion ultrasonography, hysteroscopy, and histopathology of the endometrium—in the evaluation of menorrhagia. The objectives are twofold: to assess the correlation between hysteroscopic evaluation, saline infusion sonography, and histopathology of the endometrium in cases of menorrhagia; and to develop an evaluation plan for primary menorrhagia based on the findings of SIS. A comprehensive understanding of the validity and utility of these diagnostic modalities will enable better management of menorrhagia, potentially reducing the morbidity associated with hysterectomy.

METHODS

This prospective observational study was conducted at the department of obstetrics and gynaecology, R. D. Medical College and Associated Hospitals, Ujjain, Madhya Pradesh, to investigate the diagnostic accuracy of SIS, hysteroscopy, and endometrial histopathology in the evaluation of menorrhagia. The study population included women attending the obstetrics and gynaecology outpatient department (OPD), which mainly caters to a rural population characterized by socio-economic disadvantage, multiparity, and illiteracy.

A total of 97 women with a history of menorrhagia were enrolled in the study between 01 September 2011, and March 1, 2013. Eligible participants were aged 18-50 years, married, and had menorrhagia (prolonged menses >7 days or 2-3 pads/day for >5 days). Women unwilling to participate, unmarried status, active cervical or uterine infection, carcinoma cervix, and pelvic malignancy were excluded from the study.

After providing informed consent, participants underwent a thorough clinical examination. A predesigned proforma was completed to record relevant clinical data. All subjects underwent SIS, diagnostic hysteroscopy, and D&C for histopathological examination of the endometrium. The findings from hysteroscopy and SIS were compared to those from histopathology to determine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), false-positive rate (FPR), false-negative rate (FNR), concordance (accuracy), and likelihood ratio (LR) of each diagnostic modality. The study protocol was approved by the institutional ethical committee.

Participants underwent a general physical examination, systemic examination, and gynaecological examination. Routine blood investigations were performed, including hemoglobin estimation, platelet count, total leukocyte count (TLC), differential leukocyte count (DLC), blood grouping and Rh typing, blood sugar, HIV, hepatitis B surface antigen (HBsAg), venereal disease research laboratory (VDRL) screening, and urine routine examination. Abdominal and transvaginal sonography was performed for all women with abnormal uterine bleeding (AUB) using an 8-13 MHz probe attached to a LOGIQ P6 ultrasonography machine (general electronics). SIS was performed using a Foley's No. 8 catheter to instill 50 cc of normal saline into the uterine cavity. The uterine cavity was then re-examined using transvaginal sonography (TVS). All participants underwent diagnostic hysteroscopy under general anesthesia using a Karl Storz 0-degree and 30-degree hysteroscope and Karl Storz Camera. The uterine cavity was examined for endometrial lining, submucous fibroid, and endometrial polyp. This was followed by D&C for histopathology of the endometrium. Data were entered into Microsoft excel and analyzed using statistical package for the social sciences (SPSS) 16.0 software. Results were presented as demographic variables and clinical presentations, with comparisons of findings from SIS, hysteroscopy, and histopathology in terms of sensitivity, specificity, PPV, NPV, FPR, FNR, concordance (accuracy), and likelihood ratio (LR). A p value <0.05 was considered statistically significant.

RESULTS

Age distribution

Most of the patients (49.5%) were aged between 30 to 39 years, followed by 32% in the age group of 40 to 49 years.

A smaller percentage of patients were aged between 20 to 29 years (8.2%), 50 to 60 years (7.2%), below 20 years (2.1%), and above 60 years (1%). The age group of 20 to 40 years (reproductive years) constituted 57.7% of the study population, while the perimenopause group (40 to 60 years) accounted for 39.2%.

Patient characteristics and clinical presentation

The study characterized patients according to parity, occupation, geographic location, clinical presentation, duration of complaints, and uterus size. The majority of patients (72.16%) had a parity greater than two, with 2% being nulliparous and 25.77% having a parity less than two (Figure 1). Among the study participants, 38.14% were housewives, 55.67% were farmers, and 6.19% were labourers. Most patients (85.57%) were from rural areas, while 14.43% were from urban areas. The clinical presentation was: 57.74% had menorrhagia, 27.84% had polymenorrhoea, 7.3% had metrorrhagia, and 7.3% had menometrorrhagia (Figure 2). The duration of complaints varied: 38% of patients had complaints for 4–6 months, 32% for 7-9 months, 14.47% for 10-12 months, 8.2% for 1-3 months, and 7.2% for more than 12 months. A correlation was observed between the size of the uterus on clinical examination and the type of complaint.

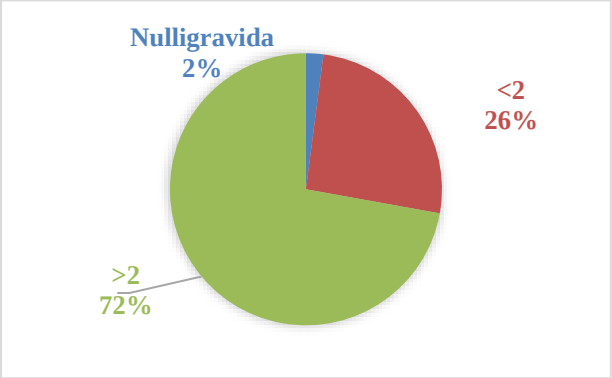

Figure 1: Parity wise distribution of study patients.

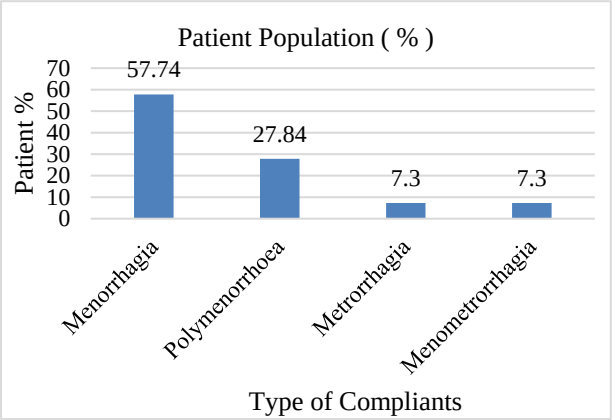

Figure 2: Distribution of patients according to clinical presentation.

Patient complaints and uterus size distribution

The size of the uterus on clinical examination was distributed as follows: normal size uterus (12.5% menorrhagia, 28.57% metrorrhagia, 42.85% menometrorrhagia, 66.66% polymenorrhoea), 6-8 weeks size (80.35% menorrhagia, 71.42% metrorrhagia, 57.14% menometrorrhagia, 22.22% polymenorrhoea), 8-10 weeks size (5.3% menorrhagia, 0% metrorrhagia, 0% menometrorrhagia, 7.4% polymenorrhoea), and more than 10 weeks size (1.7% menorrhagia, 0% metrorrhagia, 0% menometrorrhagia, 3.7% polymenorrhoea).

Findings on SIS, hysteroscopy, and histopathology

SIS revealed normal findings in 41 (42%) patients, and abnormal findings including 28 (28.86%) polyps, 24 (24.74%) submucous fibroids, and 4 (4%) endometrial hyperplasia. Hysteroscopy demonstrated normal findings in 43 (44%) patients, with abnormal findings such as 27 (28%) polyps, 21 (22%) submucous fibroids, 5 (5%) endometrial hyperplasia, and 1 (1%) placental polyp. Histopathology showed normal endometrium in 47 (49%) patients, 13 (13%) endometrial hyperplasia, 19 (20%) polyps, and 17 (18%) submucous fibroids.

Comparison of SIS, hysteroscopy, and histopathology

SIS and histopathology

SIS demonstrated promising results when compared to histopathology for overall morphological lesions, with 96% sensitivity, 82.97% specificity, 85.71% PPV, 95.12% NPV, and 89.69% accuracy. In the context of individual pathologies, SIS showed varying degrees of effectiveness. For normal findings, SIS presented 82.97% sensitivity, 96% specificity, 95.12% PPV, 85.71% NPV, and 89.69% accuracy. For detecting polyps, SIS yielded 100% sensitivity, 88.46% specificity, 67.85% PPV, 100% NPV, and 90.72% accuracy. In the case of submucous fibroids, SIS displayed 88.23% sensitivity, 88.75% specificity, 62.5% PPV, 97.26% NPV, and 88.65% accuracy. Lastly, for endometrial hyperplasia, SIS had 30.76% sensitivity, 100% specificity, 100% PPV, and 90.72% accuracy.

Comparison of SIS and hysteroscopy

The comparison between SIS and hysteroscopy revealed the following results for individual pathologies: to detect normal findings, SIS exhibited 95.34% sensitivity, 100% specificity, 100% PPV, 96.42% NPV, and 97.93% accuracy ($p<0.01$). For detecting polyps, SIS showed 96.29% sensitivity, 97.14% specificity, 92.85% PPV, 98.55% NPV, and 96.90% accuracy ($p<0.01$). In the case of submucous fibroids, SIS displayed 95.23% sensitivity, 94.73% specificity, 83.33% PPV, 98.63% NPV, and 94.84% accuracy ($p<0.01$). Finally, for endometrial hyperplasia, SIS had 80% sensitivity, 100% specificity, 100% PPV, 98.92% NPV, and 98.96% accuracy ($p<0.01$).

Table 1: Comparison of SIS and hysteroscopy; SIS and hysteroscopy with respect to histopathologically proved morphological lesion in uterus.

Characteristic tested	SIS and histopathology					SIS and hysteroscopy					Hysteroscopy and histopathology				
	Over-all	Nor-mal	Polyp	S. myoma	E. Hyper-plasia	Over-all	Nor-mal	Polyp	S. myoma	E. Hyper-plasia	Overall	Nor-mal	Polyp	S. myoma	E. Hyper-plasia
Sensitivity	96	82.97	100	88.23	30.76	100	96.29	96.29	95.23	80	96	87.23	89.47	82.35	30.76
Specificity	82.97	96	88.46	88.75	100	95.34	97.14	97.14	94.73	100	87.23	96	87.17	91.25	98.8
Positive predictive value (PPV)	85.71	95.12	67.85	62.5	100	96.42	92.85	92.85	83.33	100	88.88	95.34	62.96	66.66	80
Negative predictive value (NPV)	95.12	85.71	100	97.26	90.32	100	98.55	98.55	98.63	98.92	95.34	88.88	77.14	96.05	90.21
False positive rate (FPR)	17.02	4	11.53	11.25	0	4.65	2.85	2.85	5.26	0	12.76	4	12.82	8.75	1.19
False negative rate (FNR)	4	17.02	0	11.76	69.23	0	3.7	3.7	4.7	20	4	12.76	10.52	17.64	69.23
Concordance (accuracy)	89.69	89.69	90.72	88.65	90.72	97.93	96.9	96.9	94.84	98.96	91.75	91.75	67.62	89.69	89.69
Likelyhood ratio (LR)	140.4	72.46	60.79	39.95	17.29	194.964	89.86	89.86	69.15	28.33	137.2	80.52	42.2	38.03	12.49
Fisher's exact test				0	0					0				0	0.001
P value	<0.001	<0.01	<0.01			<0.001	<0.01	<0.01	<0.01		<0.001	<0.01	<0.01		

Comparison of hysteroscopy and histopathology

The comparison between hysteroscopy and histopathology for individual pathologies yielded the following results: To detect normal findings, hysteroscopy demonstrated 80% sensitivity, 100% specificity, 100% PPV, 98.92% NPV, and 91.75% accuracy ($p<0.01$). For detecting polyps, hysteroscopy showed 89.47% sensitivity, 87.17% specificity, 62.96% PPV, 97.14% NPV, and 87.62% accuracy ($p<0.01$). In the case of submucous fibroids, hysteroscopy displayed 82.35% sensitivity, 91.25% specificity, 66.66% PPV, 96.05% NPV, and 89.69% accuracy ($p<0.01$). Lastly, for endometrial hyperplasia, hysteroscopy had 30.76% sensitivity, 98.80% specificity, 90.21% PPV, 80% NPV, and 89.69% accuracy ($p<0.01$).

Summary of overall sensitivity, specificity, PPV, NPV, and concordance (accuracy)

The summary is given in Table 1.

In this study, the diagnostic performance of saline infusion sonohysterography (SIS) compared to hysteroscopy and histopathology in detecting endometrial pathologies was assessed. SIS demonstrated high overall sensitivity (100% versus hysteroscopy; 96% versus histopathology) and specificity (95.34% versus hysteroscopy; 82.97% versus histopathology). It showed particularly strong sensitivity in detecting polyps (100%) and submucous fibroids (95.23%) compared to hysteroscopy. The overall sensitivity of hysteroscopy compared to histopathology was 96%, with the highest value observed for polyps (89.47%).

SIS also exhibited high positive predictive value (PPV; 96.42% versus hysteroscopy; 85.71% versus histopathology) and negative predictive value (NPV; 100% versus hysteroscopy; 95.12% versus histopathology), with notable PPV for normal findings (95.12%) and endometrial hyperplasia (100%) compared to histopathology. The overall PPV and NPV of hysteroscopy compared to histopathology were 88.88% and 95.34%, respectively. The accuracy of SIS and hysteroscopy in detecting normal and abnormal findings was 89.69% (SIS versus histopathology), 97.93% (SIS versus hysteroscopy), and 91.75% (hysteroscopy versus histopathology). The calculated likelihood ratios further supported the diagnostic performance of both SIS and hysteroscopy in detecting various endometrial pathologies. These findings highlight the clinical utility of SIS as a valuable diagnostic tool for endometrial pathologies alongside hysteroscopy and histopathology.

DISCUSSION

The International Federation of Gynecology and Obstetrics (FIGO) has classified AUB into two etiological groups: PALM, which includes structural lesions like polyps, adenomyosis, leiomyoma, malignancy, and hyperplasia; and COEIN, which includes nonstructural lesions like coagulopathy, ovulatory dysfunction, endometrial disorders, iatrogenic causes, and not yet classified conditions. The diagnostic utility of hysteroscopy and SIS was evaluated in this study, in line with the FIGO classification system.[1]

The results show that hysteroscopy has high sensitivity, specificity, and accuracy in detecting the PALM group of etiological causes of AUB, but it is not as effective for endometrial hyperplasia and the COEIN group. SIS also demonstrates similar findings. Hysteroscopy-guided biopsy could potentially improve the sensitivity and specificity of hysteroscopy in detecting endometrial hyperplasia.

When comparing SIS and hysteroscopy, the study found high concordance between the two methods for detecting polyps, submucous fibroids, and endometrial hyperplasia. The sensitivity, specificity, PPV, and NPV of SIS compared to histopathology were also found to be comparable to other studies. Comparisons of this study with previous investigations, such as those by Janssen et al and Steven et al, confirm SIS's value as a diagnostic tool for abnormal uterine bleeding. Various studies have been conducted to examine the factors affecting menorrhagia and abnormal uterine bleeding, as well as the use of SIS for diagnosis.

This study challenges the findings of Janssen et al, which identified age as the sole significant risk marker for menorrhagia. In contrast, this research discovered a wider range of influential factors, including parity and occupation. This study participants, aged between 19 and 60 with a mean age of 39.61 years, showed a statistically significant majority with a parity of more than two (72.16%). Moreover, 61.86% were involved in heavy physical work, suggesting that menorrhagia-related loss of working hours could substantially impact the economy in agricultural countries. These findings indicate the need for further research to better understand the interplay between these factors and their implications for women's health and economic productivity.[8]

In a prospective pilot study by Goldstein, 21 women with abnormal uterine bleeding were evaluated using SIS, revealing that 38.1% had polypoidal lesions, 14.2% had submucous myoma, and 42.85% had no obvious anatomic lesion. A larger study by Goldstein et al involved 431 perimenopausal patients with abnormal uterine bleeding, demonstrating the effectiveness of SIS in diagnosing various types of uterine abnormalities. These findings align with this study, which also utilized SIS and found a similar distribution of uterine lesions and abnormalities.[9]

Mihm and colleagues investigated the accuracy of endometrial biopsy and saline sonohysterography in determining the cause of abnormal uterine bleeding. They concluded that the high sensitivity (97%) and high negative predictive value (94.3%) of saline sonography combined with endometrial biopsy make this technique

useful for evaluating abnormal uterine bleeding. This is comparable to our study, which reported a sensitivity of 96% and an NPV of 95.12%. The primary conclusion of this study is that hysteroscopy and SIS are similarly effective in detecting structural lesions. If a structural lesion is not detected by SIS, hysteroscopy is recommended, as hysteroscopic guided biopsy increases diagnostic accuracy and can aid in definitive management. If a structural lesion is detected, appropriate management can be planned based on various factors such as age, parity, and the desire to preserve the uterus.[10]

Garuti et al conducted a study to estimate the accuracy of hysteroscopy in predicting endometrial histopathology in 1500 women with abnormal uterine bleeding. Hysteroscopy demonstrated sensitivity, specificity, NPV, and PPV of 94.2%, 88.8%, 96.3%, and 83.1%, respectively. The highest accuracy was achieved in diagnosing endometrial polyps, with a sensitivity of 95.3%, specificity of 95.4%, PPV of 98.9%, and NPV of 81.7%. In our study, we observed a sensitivity of 96%, specificity of 87.23%, PPV of 88.88%, and NPV of 95.34%.[11]

In comparison to other studies, the findings demonstrate high sensitivity, specificity, PPV, and NPV values for SIS and hysteroscopy in detecting lesions. For instance, Widrich et al reported a total of 61 lesions identified by SIS and 56 by hysteroscopy, with a sensitivity of 96%, specificity of 88%, PPV of 89%, and NPV of 96%.[12] Similarly, Kamel et al found a total of 56 lesions on SIS and 53 on hysteroscopy, with a sensitivity of 93.1%, specificity of 93.9%, PPV of 94.6%, and NPV of 92%. In the present study, 56 lesions were detected using SIS and 53 using hysteroscopy, achieving a sensitivity of 100%, specificity of 95.34%, PPV of 96.42%, and NPV of 100% (significant p value). These results underscore the diagnostic accuracy of both SIS and hysteroscopy in evaluating abnormal uterine bleeding.[13]

In summary, the main outcome of the study reveals that hysteroscopy and SIS are comparable in detecting structural lesions associated with abnormal uterine bleeding. If a structural lesion is not identified by SIS, hysteroscopy is recommended, as hysteroscopic-guided biopsy enhances diagnostic accuracy and aids in determining the definitive management. When a structural lesion is detected, appropriate management strategies can be planned, taking into account factors such as age, parity, and the patient's desire to preserve the uterus.

Limitations

Despite the significant findings, this study has a few noteworthy limitations that must be addressed. The study was conducted with a relatively modest sample size of 97 women, which may limit the applicability of the results to a larger, more diverse population. Furthermore, the research took place within a single medical institution, raising concerns about potential biases specific to local medical practices. The study also fell short in assessing the diagnostic performance of hysteroscopy and SIS for the COEIN group of AUB etiologies, leaving a gap in the comprehensive understanding of these diagnostic modalities.

Lastly, the study did not include an analysis of the cost-effectiveness of hysteroscopy and SIS, which is an essential factor in real-world clinical decision-making. Future research should consider these limitations, employing larger sample sizes across multiple centers and incorporating a broader range of AUB etiologies, as well as an evaluation of cost-effectiveness, to provide more robust and comprehensive findings.

CONCLUSION

The present study demonstrated that menorrhagia predominantly affects women in the reproductive age group of 20-40 years and is more common in those with a parity of 2 or higher. The majority of patients seek treatment within one year of symptom onset, and the uterine size tends to differ depending on the specific type of abnormal uterine bleeding experienced. Both hysteroscopy and SIS have proven to be valuable diagnostic tools in evaluating and managing abnormal uterine bleeding. Each method demonstrates significant sensitivity and specificity in detecting structural lesions, such as endometrial polyps and submucous fibroids. This study highlights the comparable diagnostic capabilities of hysteroscopy and SIS, emphasizing their utility in determining appropriate management strategies based on factors like age, parity, and the patient's desire to preserve the uterus.

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