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Research Article

SALINE HYSTEROSONOGRAPHY IN DIAGNOSIS OF ENDOMETRIAL HYPERPLASIA

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Abstract:

Cause of Abnormal Uterine bleeding in postmenopausal women from simple atrophic vaginitis to endometrial carcinoma. Saline hystero sonography is a simple and cost effective method with high sensitivity to detect uterine abnormalities causing postmenopausal bleeding as it is a safe, economical and noninvasive alternative to hysteroscopy.

Objective: *To evaluate the diagnostic accuracy of Saline hystero sonography in detecting endometrial hyperplasia in women with Postmenopausal bleeding by taking histopathology as gold standard*

Settings: *Department of obstetrics and gynecology, PMC Allied Hospital, Faisalabad*

Duration Of Study: *6 months after approval From: 01-02-2017 to 31-07-2017*

Study design: *Cross sectional (validation) study*

Method: *After receiving patients in outdoor patient department or after admission in ward ,proper history and relevant examination of patient was done. Then preparartion was made for the procedure. Patient was counseled and technique explained to her. Then folleys catheter no 12 was passed in cervix and sonography was done while instilling normal saline through cervical catheter and scan pictures were frozen and results were given by expert gynecologist of Allied Hospital, Faisalabad. Histopathology specimen was sent to pathology lab.*

Results: *120 cases were enrolled. Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of saline hysterosonography in detecting endometrial hyperplasia was recorded as 96.15%,91.49%,75.76%,98.85% and 92.5% respectively.*

Conclusion: *Saline hysterosonography is a simple and cost effective method with high sensitivity to detect uterine abnormalities causing post-menopausal bleeding as it is a safe, economical and noninvasive alternative to hysteroscopy. Further in many units in Pakistan hysteroscopy is not available, so it can be replaced in local units by saline hysterosonography.*

Keywords: *Saline hysterosonography, Endometrial hyperplasia, postmenopausal bleeding.*

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INTRODUCTION:

Postmenopausal bleeding-PMB occurs in nearly 3% post-menopausal women [1,2] Abnormal bleeding is the cause behind 33% of all admissions to gynecology Center and 69% among postmenopausal Women.[3,4] Excessive Bleeding occurring outside of regular menstruation cycle in which two third of all Hysterectomies are accounted for is characterized as Abnormal Uterine Bleeding.[5] Simple Atrophic Vaginitis to Endometrial Carcinoma in postmenopausal Women are the reasons of Abnormal Bleeding. Surgical treatment may be required for Organic causes for example Endometrial Polyps, Uterine Fibroids, Endometrial Hyperplasia and Endometrial Carcinoma, While Medical treatment is required for dysfunctional causes.[4] The chance of having endometrial carcinoma for patients with PMB is 10–15%.[6,7] For women over the age of 40 with Abnormal Uterine Bleeding the clinician's vital task is to exclude Endometrial Carcinoma.[8]

The excessive proliferation of normal cells can be characterized by the term Endometrial hyperplasia. It can further be ordered into three Types: Simple, Complex and Atypical. The development rate of malignancy is less than 3% for both simple and complex types due to premalignant conditions. In various arrangements the risk of underlying Malignancy has demonstrated to be higher than anticipated. So it is very important to detect it as early as possible to make decisions regarding surgery if the patient is high risk or follow up in low risk cases.⁹ In a previous study, prevalence of endometrial hyperplasia was 26%. [1]

The most common gynecological malignancy is Endometrial cancer.[6] Obesity, unopposed estrogens, polycystic ovary syndrome, and nulliparity are incorporated as the elements of Risk. For the analysis of uterine Abnormality leading to Postmenopausal Bleeding an assortment of tools can be utilized. Among these, For the evaluation of abnormalities of the uterine cavity, hysteroscopy is considered gold standard.[10]

In postmenopausal women TVS is an effective screening test for evaluation of abnormal uterine bleeding caused by endometrial atrophy.[11] But in the figure of thickened and inhomogeneous endometrium, TVS is presented as a low specificity and limited diagnostic test which can be replaced by SCSH.[12] SCSH can distinguish between focal lesions such as polyps and submucous myomas [13,14].

In tamoxifen-treated women endometrial hyperplasia with the occurrence of 1.3-20% is increased.[15] It

seems that SCSH is a noninvasive, cheap and feasible technique with lower pain. The majority of women found that SCSH was not painful, whereas only 25% said the same for hysteroscopy.[16] SCSH is easily accepted by most patients as an outpatient procedure. [17]

The rationale of this study is to introduce a simple and noninvasive investigation tool to detect endometrial abnormalities in patients with postmenopausal bleeding and its effect on clinical administration.

MATERIAL AND METHODS:

Objective of this Cross sectional (validation) study was to assess the diagnostic accuracy of saline hystero sonography in detecting endometrial hyperplasia in women with Postmenopausal bleeding by taking histopathology as gold standard. Post-Menopausal Bleeding was diagnosed when a woman after menopause presented with complain of per-vaginal bleeding that may range from spotting to massive pool of blood. Menopause is defined as last menstrual period after a minimum of 1 years amenorrhea and her age >50.

With saline hysterosonography endometrial hyperplasia, typically appear as diffuse thickening of the endometrium with endometrial thickness 5mm to 8mm. On histopathology of biopsy specimen, endometrial hyperplasia is characterized by mild to marked increase in number of glands of different sizes and unpredictable shapes with cystic dilatation, with mild to marked escalation in gland to stroma ratio and glandular epithelial cells may or may not have cytologic atypia as defined by loss of polarity, vesicular nuclei and prominent nucleoli.

Sensitivity is the proportion of true positives out of all those who truly have the endometrial hyperplasia. Specificity is the proportion of true negatives out of all those who truly don't have the endometrial hyperplasia. Positive predictive value is the proportion of true positives out of all those who are positive on saline hysterosonography. Negative predictive value is the proportion of true negatives out of all those who are negative on saline hysterosonography. True positives (TP) are those individuals who are positive on saline hysterosonography as well as on histopathology. True negatives (TN) are those individuals who are negative on saline hysterosonography as well as on histopathology. False positives (FP) are those individuals who are positive on saline hysterosonography but negative on histopathology. False negatives (FN) are those individuals who are

negative on saline hysterosonography but positive on histopathology.

It was conducted in the Department of obstetrics and gynecology, PMC Allied Hospital, Faisalabad after 6 months synopsis approval. Sample size 120 was calculated using sample size calculator for sensitivity and specificity, taking Sensitivity=92%1 Specificity=78%[1]

Expected prevalence of endometrial hyperplasia of 26%1 and confidence level=95%, arecision for sensitivity=8%, for specificity=10%. Sampling was done using non probability consecutive sampling. All postmenopausal women with age >50 years having postmenopausal bleeding was included in the study. Following were excluded: already diagnosed cases of cervical carcinoma, pyometra and hematometra; patients with acute pelvic infection, acute uterine hemorrhage, and diagnosed cases of endometrial cancer.

After taking approval from hospital ethical committee, patients presenting in gynecological outdoor patient department and ward, Those who fulfilled the inclusion criteria for the study were enrolled. The Identity of patients was recorded and informed, assent was gotten from patients or their

Histopathology:	+ve	-ve
	a(TP)	b(FP)
	c(FN)	d(TN)
Salinehystero	+ve	Sonography -ve

Sensitivity= $a/a+c*100$

Specificity= $d/b+d*100$

Positive predictive value= $a/a+b*100$

Negative predictive value= $d/c+d*100$

Diagnostic accuracy= $a+d/a+b+c+d*100$

RESULTS:

In all out 120 cases satisfying the inclusion/exclusion criteria were selected to assess the diagnostic accuracy of saline hysterosonography in detecting endometrial hyperplasia in patients with post-menopausal bleeding. Age distribution of the patients was done showing that 76.7% (n=92) were in Group-A i.e between 50-60years of age and 23.3%(n=28) were in Group-B i.e between 61-70 years of age. (Table No. 1)

Mean age and endometrial thickness of the patients was calculated which shows that 76.7%(n=92) in Group-A and 23.3%(n=28) in Group-B so mean+sd was calculated as 57.18+4.922. In the same way mean +sd for endometrial thickness was 3.9958+1.54008 . (Table No. 2) Sensitivity, specificity, positive

guardians to incorporate the information in research work. Prohibition criteria were meticulously looked for after.

After receiving patients in outdoor patient department or after admission in ward, proper history and relevant examination of patient was done. Then preparation was made for the procedure. Patient was counseled and technique explained to her. Then folleys catheter no 12 was passed in cervix and sonography was done while instilling normal saline through cervical catheter and scan pictures were frozen and results were given by expert gynecologist of Allied Hospital, Faisalabad. Regarding histopathology specimen, it was sent to pathology lab in Punjab Medical College where results were given by Expert pathologist.

All the data was analyzed by SPSS V-10 Quantitative variables like age endometrial thickness will be measured by mean standard deviation. Frequency and percentage will be determined for all qualitative variables like true positives. Sensitivity, Specificity, positive predictive value, negative predictive value and diagnostic preciseness was determined by building two into two tables by taking histopathology as highest level Standard.

predictive value, negative predictive value and diagnostic accuracy of saline hysterosonography in detecting endometrial hyperplasia was recorded as 96.15%,91.49%,75.76%,98.85% and 92.5% respectively. (Table No. 3)

Regarding age distribution, Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of saline hysterosonography in detecting endometrial hyperplasia in group A i.e between 50-60 years of age were recorded as 100%,97.6%,80%,100% and 97.8% respectively, while these values for Group B i.e between 61-70 years of age were recorded as 94.4%,40%,73.9%,80% and 75% respectively.(Table no.4)

TABLE No. 1 AGE DISTRIBUTION (n=120)

	Frequency	Percent
50-60 year	92	76.7
61-70 year	28	23.3
Total	120	100.0

TABLE No. 2 MEAN AGE & ENDOMETRIAL THICKNESS (n=120)

	N	Minimum	Maximum	Mean	Std. Deviation
Age	120	51	70	57.18	4.922
endometrial thickness	120	2.00	9.00	3.9958	1.54008

TABLE NO. 3 DIAGNOSTIC ACCURACY OF SIS

	Endometrial hyperplasia on histopathology		Total
	Yes	no	
Endometrial hyperplasia on saline Hysterosonography Yes	25	8	33
No	1	86	87
Total	26	94	120

Sensitivity = 96.15%

Specificity = 91.49%

PPV = 75.76%

NPV = 98.85%

Diagnostic accuracy = 92.5%

TABLE NO. 4: DIAGNOSTIC ACCURACY OF SIS IN DIFFERENT AGE GROUPS

Age distribution	Endometrial hyperplasia on saline hysterosonography	Endometrial hyperplasia on histopathology		Total	
		Yes	No		
50-60 year	Yes	8	2	10	Sensitivity = 100% Specificity = 97.6% PPV=80% NPV = 100% DA=97.8%
	No	0	82	82	
	Total	8	84	92	
61-70 year	Yes	17	6	23	Sensitivity = 94.4% Specificity = 40% PPV=73.9% NPV = 80% DA=75%
	No	1	4	5	
	Total	18	10	28	

DISCUSSION:

A common patient complaint is Postmenopausal bleeding that is experienced by all doctors and different clinicians of gynecologic consideration. Endometrial Carcinoma is excluded in the likelihood that there exists an underlying malignancy that the clinician might face. In the past, institution-based dilation and curettage (D&C) were considered best quality level of clinical examination, be that as it may, there now exists various office-based techniques for the assessment of women with this Complaint.

With the methodology of additional cutting-edge imaging modalities the evaluation and management of postmenopausal bleeding is evolving rapidly. In postmenopausal patients due to diffuse endomyometrial border endometrium is more difficult to measure.

Transvaginal sonography is a first line insightful methodology in the assessment of postmenopausal Bleeding, however it has restricted an incentive in assessment and differential determination of intracavitary unusual pathologies. For women with postmenopausal bleeding hysteroscopy and saline hysterosonography are alternative diagnostic procedures and are more effective in detection of intracavitary abnormal pathologies than TVS. While SIS is cost-effective and noninvasive, Hysteroscopy is uncomfortable and Invasive Expansive. In recent times such methods have come to be popular in diagnosis of postmenopausal bleeding.

This study was conducted with the purpose to establish the indicative accuracy of SIS in postmenopausal patients. As patients with immeasurable endometrium often harbour a cancer so these patients were included in the study. In this study 5 mm cut-off was used. All the ladies with abnormal SIS had diagnostic or therapeutic procedures.

de Kroon *et al.* did a meta-analysis of diagnostic accuracy of SIS among women reporting with abnormal uterine bleeding. 18 24 studies evaluated three studies reported on efficacy exclusively in postmenopausal women with hysteroscopy and or hysterectomy as a reference test. [13,19,20] Two studies used > 5 mm cutoff and one used > 6 mm cut-off, all at variance with this study with a cut-off of 3 5 mm. The sensitivity and specificity in these studies were 96/92%, 100/95% and 89/50% respectively. The present results of 96.15% sensitivity and 91.49% specificity are close to the pooled result of de Kroon's meta-analysis -95% for sensitivity 88% for

specificity [12]. In another study, same results of 95% sensitivity and 88% specificity were found. [8]

For the screening of intracavitary pathologies a useful procedure is Hydrosonography it allows differentiation of intracavitary, endometrial, and sub-mucosal abnormalities. SIS was abnormal in all cases of endometrial carcinoma in the current study. There was a good comparison between hysteroscopy and SIS where the former was the gold standard. The accuracy of hysteroscopy and SIS was almost equal though SIS is less expensive and better tolerated. [21] These results have been further refined by 3-D SIS. [22] Also in our unit only indoor hysteroscopy is available. Many studies have confirmed that SIS is as good as hysteroscopy under general anaesthesia at detecting/excluding focal lesions. Hydrosonography is less painful and cost effective than hysteroscopy. [23] In many units in Pakistan hysteroscopy is not available. Hence the latter can be replaced in the local setting by SIS. SIS greatly reduces the number of unnecessary hysteroscopy as it is only indicated where focal lesions need further evaluation/removal. Because D and C fails to diagnose about 10% of endometrial cancers and 50% of polyps and hyperplasias, the presence of a focal lesion dictates an operative hysteroscopy. [24]

In another study, sensitivity and specificity of saline hysterosonography was 92.9% and 89.7% [25] respectively which is also in agreement with my results. But in another study [10], these results were different i.e 82% sensitivity and 95% specificity. Still two other studies, [3,26] showed sensitivity of 71.4% and 89.3 and specificity of 82.3% and 77.3%. In these studies overall sensitivities and specificities are less than that found in our study, in fact specificity is more than sensitivity in first two studies whereas sensitivity is more in last study which is in agreement with our study. Initial two examinations are directed in women with unusual uterine bleeding of all ages but last study was conducted in women with postmenopausal bleeding. This may be the reason of this difference found in these studies.

The learning curve of SIS is considered to be very short for those familiar with gynaecological ultrasound. Failure is almost always due to cervical stenosis. In present series poor cavity distension was found in cases of endometrial cancer and same was observed earlier. Distension difficulties in SIS raise the suspicion of carcinoma. In these cases even the clinical value of, spectral Doppler ultrasound, examination of the uterine, sub-endometrial and endometrial vessels using Doppler ultrasound is uncertain. [27,28] Endometrial vascularity may be

useful in predicting focal lesions in women with postmenopausal bleeding, but not for making a specific diagnosis. State-of-the-art Doppler ultrasound for endometrial vascularity is not widely available. False positive cases are very high (52%), while determining the value of endometrial vascularity in the prediction of focal lesions.[28]The detection rate of Doppler ultrasound is slightly lower than that for saline infusion, whereas the false-positive rate of Doppler is around five times higher. The clinical value of 3D ultrasound is a matter of current debate.[18]

Another study claimed that hysteroscopy can be replaced by Saline-infusion sonography in more than half of AUB cases [29] and also there is very good agreement between sonohysterography and hysteroscopy for diagnosis of endometrial abnormalities in postmenopausal women [30]. Mathew *et al* [31] concluded that saline infusion sonohysterography is a simple evaluating method with minimal invasiveness and cost which is more accurate than TVS and can be done as a screening tool before hysteroscopy. Saline infusion sono-hysterography also is a satisfactory method of identifying endometrial lesions which is less invasive alternative to hysteroscopy and result in less morbidity in the evaluation of AUB in women. [32]

The examination of hysterectomy specimen is the ultimate gold standard. Two studies compared SIS and hysteroscopy to hysterectomy showed comparable diagnostic value of the two. [24] However, SIS could not differentiate benign from malignant lesions. But SIS helps in choosing the patient where operative hysteroscopy is required. For women suspected of having Intrauterine Abnormalities with Abnormal Uterine Bleeding, Study was led by Cornelis D. de Kroon *et al* to assess the clinical relevance of 3-dimensional saline Infusion Sonography (3D-SIS) in addition to conventional SIS. Saline infusion sonography and 3D-SIS were correspondingly precise in assessing the histological nature, intrauterine degree, and area of intrauterine abnormalities. The dependability of 3D-SIS was good: intraobserver and interobserver agreement were 0.78 and 0.72. They concluded that Three-dimensional saline infusion sonography is legitimate and dependable for women suspected of having intrauterine variations from the norm (Abnormalities). It may have relevant clinical value in addition to conventional SIS as the endometrial cavity is three dimensional. [18]

Two recent studies have shown the promising feasibility of ultrasound guided biopsy of endometrial

pathology. Wei *et al.* used a curette during SIS and removed lesions < 20 mm. [34]

Lee *et al.* [35] removed polyps under SIS guidance. A question of concern is –does SIS facilitate dissemination of malignant cells? Most studies have found no association with hysteroscopy. In a retrospective study of endometrial carcinoma with similar stage I disease, there was no difference in survival at 5 years between patients who had undergone hysteroscopy before definitive surgery. [36] SIS is assumed to be equally safe.

CONCLUSION:

The best standard for diagnosing intra uterine diseases was viewed to be Hysteroscopy however the present survey of writing recommend sonohysterography to be a practicable and precise option to office hysteroscopy specially in distinguishing focal and diffuse endometrial pathologies and diagnosing reasons of abnormal uterine bleeding. The fact that it very well can be performed in outpatient clinics with negligible burden to the patient, in couple of minutes with instruments that are basic and cheap makes it a reasonable alternative over office hysteroscopy. The utilization of Sonobiopsy catheter to consolidate sonohysterography and endometrial biopsy at a similar sitting will decrease the quantity of patients requiring diagnostic hysteroscopy and curettage. However hysteroscopy is a therapeutic procedure and it is preferable for its therapeutic role.

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