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THE COMPARATIVE ASSESSMENT OF EFFICACY OF SONOSALPINGOGRAM FOR DETERMINATION OF TUBAL PATENCY WITH HYSTEROSALPINGOGRAM AS GOLD STANDARD

Radiology

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ABSTRACT

Introduction: Infertility is defined as a year of unprotected coitus without contraception. Between thirty and forty percent of infertile cases tubal diseases remains the cause. As part of the preliminary evaluation process to identify the reason of infertility, the fallopian tube's patency is determined. Therefore, while evaluating tubal patency, SSG (sonosalpingogram) and HSG (hysterosalpingogram) are employed. **Aims and Objectives:** The main goals are to analyze the specificity of using Sonosalpinghogram as a minimally invasive screening test for tubal patency and to compare Sonosalpinghogram's accuracy, positive predictive value, and effectiveness with Hysterosalpingogram in this regard. The aim of this study is to evaluate the superiority of SSG over HSG in identifying fallopian tube patency. **Materials and Methods:** Cross-sectional research was carried out at the Radiology department of Chettinad Hospital and Research Institute which spanned over 9 months duration. The study included cases that received HSG within the time frame of the investigation. This research comprised 85 women who presented for HSG at some point throughout the study period. The patient had both fluoroscopy and ultrasound utilizing a Siemens Fluorovision machine and a GE Voluson machine, respectively. **Results and Conclusion:** When compared to HSG as the gold standard test, it was concluded that the SSG was shown to have greater diagnostic effectiveness in predicting instances with tubal blockages.

KEYWORDS

SSG (sonosalpingogram), HSG (hysterosalpingogram), infertility, fallopian tube(FT) patency

INTRODUCTION

Tubal diseases accounts for 25–35% of the underlying cause of infertility in subfertile couples making the examination of the fallopian tubes an essential part of assessing subfertile females. Infertility and tubal disease have been estimated to affect 40% of Indian women. Tubal factors affect 18% to 81% of female infertile patients, depending on the community.[1,2]

Subfertility is known to be caused by tubal factors in at least one-third of infertility cases worldwide.[3] The prevalence of infertility varies widely between countries, genders, and cultures due to various factors.[2,4] Because of the prevalence of persistent infections, (Pelvic Inflammatory Disease) PID, and (Genital Tract) GT tuberculosis, infertile females in our country have a high incidence of tubal factor.[5,6] Tubal factors can be functional or pathologic. Pathological blockage can arise from any pelvic disease, particularly inflammatory causes, or anomalies of the tube.[7,8]. Thus, assessing uterotubal causes are the most crucial components of managing infertility.

There are several invasive and non-invasive diagnostic procedures available to evaluate tubal and uterine pathology.[9] Fallopian tube (FT) patency has been measured using a variety of examinations which includes falloposcopy, salpingoscopy, laparoscopic chromo-pertubation, transvaginal sonosalpingography, radionuclide hysterosalpingography, and hysterosalpingography[5–8]. The invasive methods include laparoscopy, hysteroscopy, and HSG.[8,9] The minimally invasive or non-invasive methods are ultrasonography, sonosalpingography, and magnetic resonance imaging.

It would be beneficial to find an approach that is both reasonably minimally invasive and cost-effective for evaluating both tubal and uterine diseases.

Hysterosalpingography has been the main method used to identify endometrial abnormalities and FT patency in infertile women[10]. The use of HSG has been associated with adverse effects, including pelvic discomfort, vomiting, and fever. Few patients can develop alergic response to the contrast medium used. Treatment for patients may be delayed owing to the length of the HSG wait list at the radiology department.

Intrauterine(IU) abnormalities, FT patency, and endometrial thickness may all be measured more precisely using sonosalpingography than with other techniques[11]. The basic principle of SSG is to dilate the uterus with saline, which will characterize the pouch of Douglas's volume, estimate the thickness of the endometrium, disclose IU pathology, and describe the contour[9]. Unlike HSG, which carries concerns related to radiation and iodine contrast allergies, SSG is simple, safe and easy to perform[13,16] .It is also non-invasive and does not require anesthesia, in contrast to laparoscopy and hysteroscopy[9,11,12]. Thus, the aim of this research was to evaluate the diagnostic effectiveness of SSG in comparison to HSG in detecting FT patency.

MAETRIALS AND METHOD

This prospective cross-sectional study was carried out at the Radiology department of Chettinad Hospital and Research Institute, Kelambakkam, to evaluate the diagnostic efficiency of SSG compared to that of HSG in identifying the FT patency. Ethical committee approval was obtained from the Institutional Human Ethics Committee. A total number of 85 study cases that received HSG between May 2021 and March 2022 were included in the analysis. Subjects between the ages of 18 and 35 having regular period of menstruation, partners with normal semen analyses and unprotected coitus for more than a year were included in the study. Patients with PID and those with hormonal or medical dysfunction were excluded from the study.

Following the acquisition of written informed consent, the principal investigator used a pre-structured proforma (Table 1) to evaluate each case's clinical presentation and demographics followed by evaluation of each participant's comprehensive medical history. Later, HSG and SSG were performed on each subject. The lead investigator entered the reports on the same proforma containing the clinical presentation. Excel was used to enter the data, and SPSS (Version 16) was used for analysis. For quantitative variables, descriptive statistics including mean, standard deviation(SD), and proportions (%) were computed. Sensitivity(Sn), specificity(Sp), positive predictive value(PPV) and negative predictive value(NPV) were computed to test the hypothesis. Additionally, Z test, chi square, and independent sample t tests were conducted. A p-value of less than 0.05 was deemed statistically significant.

RESULTS

This study consisted a of total of 85 female subjects with (Graph 1) majority (49.4%) in the age group of 25-30 years, followed by 21-24 years (32.9%), 31-35 years (10.6%), 18-20 years (5.9%) and more than 35 years (1.2%). More than half, 56.5% of subjects were affected with primary infertility and 43.5% of subjects with secondary infertility. (Graph 2). Among the subjects affected with secondary infertility, 94.6% of subjects conceived once in their life time and 5.4% of subjects conceived twice during their life time. (Graph 3). According to the assessment of the duration of infertility (Graph 4), 34.1% of the individuals were infertile for a period of 1 to 5 years, 48.2% for a period of 6 to 10 years, and 17.6% for a period of more than 10 years. The right-side fallopian tube was determined to be abnormal in 35.3% of participants and normal in 64.7% of respondents based on HSG findings (Table 2). Of these subjects, 46.7% had cornual block, 10% had hydrosalpinx, 23.3% had fimbrial block, 13.3% had salpingitis ishmica nodosa, and 6.7% had mid salpingeal block. (Table 3). Based on HSG results (Table 4), 60% of individuals had normal left fallopian tubes, whereas 40% had abnormal ones.

Among the 34 participants who had aberrant left side fallopian tubes (Table 5): 38.2% had cornual block, 5.9% had hydrosalpinx, 17.6% had fimbrial block, 8.8% had salpingitis ishmica nodosa, and mid salpingeal block, respectively.

When the two methods (Graph 5) were compared, it was discovered that, according to SSG, the uterus was normal in 83.5% of patients and abnormal in 16.5% of subjects; however according to HSG, the uterus was normal in 87.1% of individuals and abnormal in 12.9% of subjects. SSG showed, there were 28.6% of subjects with endometrial polyps, 21.4% of subjects with submucosal fibroid and arcuate/bicornuate uterus, 7.1% of subjects with small infantile uterus, 14.2% of subjects with unicornuate uterus, and 7.1% of subjects with irregular uterine cavity among the subjects with abnormal uterus (Graph 6). HSG showed, there were 27.3% with endometrial polyps, 9.1% with submucosal fibroid, 27.3% with arcuate/bicornuate uterus, 9.1% with small infantile uterus, 18.2% with unicornuate uterus, and 9.1% with irregular uterine cavity. (Graph 6).

Based on SSG, the tubal diseases were evaluated in 36.5% of the individuals, and in 63.5% of the cases, the tubes looked normal. However, according to HSG, 40% of individuals had tubal diseases, whereas 60% of subjects' tubes seemed normal. (Graph 7). SSG showed, 45.2% had cornual block, 16.1% had hydrosalpinx and fimbrial block, 12.9% had salpingitis ishmica nodosa, and 9.7% had mid salpingeal block (Image 2). HSG showed , 44.1% of individuals had cornual block, 14.7% had hydrosalpinx, 20.6% had fimbrial block, 11.8% had salpingitis isthmica nodosa, and 8.8% had mid-salpingeal block. (Graph 8)(Image 1).

Fallopian tubes were patent in 64.7% of individuals and blocked in 35.3% of subjects according to SSG (Graph 9); however, according to HSG, 60% of subjects had patent fallopian tubes and 40% had obstructed fallopian tubes. SSG revealed that 35.3% of the tubal block subjects (Graph 10) (Image 6) had bilateral tubal block and 64.7% of the participants had unilateral tubal block. Similarly, HSG revealed that 30% of individuals had unilateral tubal block and 70% had bilateral tubal block. (Image 5)

After evaluating the uterine pathologies, 11.8% of participants with uterine pathologies and 82.3% of subjects without any uterine disease were detected by both SSG and HSG (Table 6) (Image3, 4, 7 and 8). But although HSG found 1.2% of participants with uterine disease that SSG had not discovered, SSG selected 4.7% of subjects with uterine pathology that HSG had not reported. A strong correlation ($p<0.001$) was observed in their study when evaluating the relationship between the uterine results of SSG and HSG.

According to Graph 11, which compares the diagnostic efficacy of SSG to HSG (Gold Standard) in predicting uterine diseases, 12.9% of study participants had uterine pathology, with Sn (Sensitivity) of 90.9%, Sp (Specificity) of 94.6%, PPV (Positive predictive value) of 71.4%, NPV (Negative Predictive Value) of 98.6%, and diagnostic efficacy of 94.1%.

Both SSG and HSG (Table 7) identified 35.3% of participants with uterine diseases and 58.9% of subjects without any tubal block based on their assessment of the tubal block. On the other hand, SSG identified 1.2% of tubal block patients that were not reported in HSG, while HSG identified 4.7% of tubal block participants that SSG had not recognized. The correlation between the tubal block results of SSG and HSG was found to be substantial. When tubal blocks were compared to HSG (Gold Standard) to determine the diagnostic efficacy of SSG (Graph 12), the results showed that 40% of study participants had tubal blocks, with Sn of 88.2%, Sp of 98%, PPV of 96.8%, NPV of 92.6%, and diagnostic efficacy of 94.1%.

DISCUSSION

According to Volpi E et al.[13], 218 patients had FT patency, 15.1% of patients had unilateral patency, and 4.4% of patients had bilateral tubal blockage. Of the 43 individuals who had HSG, 11.6% had discrepancies between the two tests. However, just 6.9 percent had different results. There was just one incidence of complete disagreement. The reason for the disparity was that three of the four patients had obstruction at HSG and patency detected at SSG. Of the 55 patients who had laparoscopies, 21.8% had unsatisfactory results. While there was a full disparity in two cases, eleven additional patients had a varied patency report. According to Radic V et al.[14], the HSG's Sn and Sp values for evaluating the uterine cavity were 100% and 88.8%, respectively. The PPV was 97% and the NPV was 100%. The approach's Sn and Sp values for tubal status were 100 and 66 percent, respectively, while the NPV and PPV values were 100 and 61 percent, respectively. They concluded that when choosing on further procedures for the diagnosis and treatment of infertility, HSG is useful.

Acholonu UC et al[15] found that the Sn content in the HSG and Sonohysterography (SHG) is 81.8 percent and 58.1 percent, respectively. Sp for HSG and SHG were 74.4 percent and 93.8 percent, in that order. The differences between Sn and Sp were both statistically significant. The overall accuracy for SHG was 83.9 percent, much higher than the accuracy for HSG, which was 62.4 percent. According to Bingol B et al.[16], hysteroscopy had Sn, Sp, PPV, and NPV of 98%, 83%, 96%, and 91%, respectively, for all uterine disorders. When hysteroscopy is employed as the gold standard, Saline Infusion Sonogram (SIS) seems to be more effective than Transvaginal ultrasound (TVS) in terms of uterine disorders.

According to Kulkarni NN et al[17], there was no appreciable difference between the SSG and HSG outcomes when they compared the Sn and Sp of SSG and HSG findings for FT patency tests in cases of infertile patients. Acceptance in SSG was 100%, however it was just 96% in HSG. SSG and HSG had a 92.3 percent agreement rate, according to Madhok R et al[18]. This suggests that SSG is as effective as HSG in diagnosing FT patency and may eventually replace HSG as the industry standard as primary outpatient infertility evaluation. According to Dasan TA et al.[19], the percentages of Sn, Sp, PPV, and NPV of SIS that were able to identify FT patency were 94.3 percent, 75%, 97.1 percent, and 50%, respectively. Furthermore, it was shown that SIS was more cost- and time-effective than conventional HSG.

According to the study's findings, Lakshmi CS et al.[20] reported that, in contrast to HSG, there is no statistically significant difference between the outcomes of SSG and HSG. Since SSG contains a high Sn and Sp content and is less invasive, they concluded that in instances of infertility, it should be used initially to verify the FT patency. In terms of a non-invasive, indirect, external technique for assessing FT patency, Agrawal R et al.[21] found that HSG was superior than SSG. According to Shanmugham D et al[1], SSG's Sn for FT patency determination in their study is 95.34 percent, Sp is 75%, PPV is 97.65 percent, and NPV is 60%. They concluded that SIS is a realistic, safe, and straightforward method for figuring out a woman's FT patency. It might be included in the first evaluation for infertility. Izhar R et al[22], on the other hand, concluded that SIS was a more accurate method than HSG for detecting tubal or uterine anomalies in infertile patients. According to Mustafa Z et al [23], SIS had significant levels of Sn, Sp, PPV, NPV, and DA, which were on par with standard HSG. Nnah EW et al[24] reported through their investigation that SSG had a 98.9% and 78.6% Sn and Sp for identifying patent fallopian tubes, respectively.

According to Dey D et al.[25], TVS had 95.12 percent Sn, 88.89 percent Sp, 97.5 percent PPV, and 80 percent NPV in the evaluation of FT patency, which is consistent with the results of this study. According to Parijatha T et al.[26], bilateral FT patency was found in 75% of patients by HSG and 83.93 percent of cases by SSG. Equal DA was shown by SSG and HSG, which both demonstrated strong correlations (95.3%). In this trial, the NPV was 94.6 percent and the PPV was 95.2 percent. The accuracy rate of this study was 95.8%, Sn was 98.3%, and Sp was

85.6%. The results of the study show that there is no statistically significant difference between the levels of SSG and HSG.

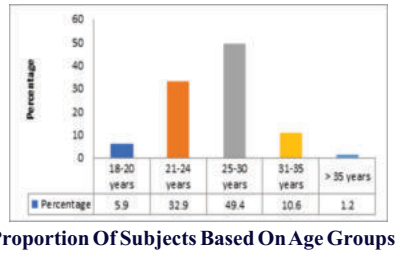
CONCLUSION

There were 56.5% of primary infertility patients and 43.5% of secondary infertility cases in the current research. Based on SSG assessment of the tubal abnormalities, 36.5% of individuals had tubal diseases identified, while 63.5% of cases had tubes that seemed normal. Similarly, according to HSG, 40% of patients had tubal diseases, while 60% of cases had tubes that were normal. While fallopian tubes were obstructed in 35.3% of instances and patent in 64.7% of cases according to SSG, they were patent in 60% of cases and blocked in 40% of cases according to HSG.

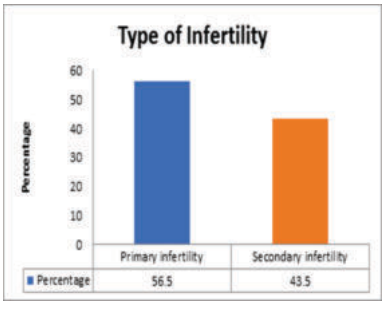
When evaluating tubal block, SSG identified 35.3% of cases with uterine diseases and 58.9% of cases in which there was no tubal block. In contrast, HSG identified 4.7% of patients with tubal block that SSG failed to identify, whereas SSG identified 1.2% patients with tubal block that were not recorded in HSG. Regarding the evaluation of SSG's diagnostic efficacy in predicting tubal blocks in contrast to HSG (Gold Standard), it was found that 40% of study participants had tubal block, with Sn of 88.2%, Sp of 98%, PPV of 96.8%, NPV of 92.6%, and diagnostic efficacy of 94.1%. When compared to HSG as the gold standard test, we conclude that SSG helps in better visualization of uterine abnormalities and confidently ruling out tubal pathology better than HSG.

Table 1: Patients Demographic Details, History And Clinical Presentation

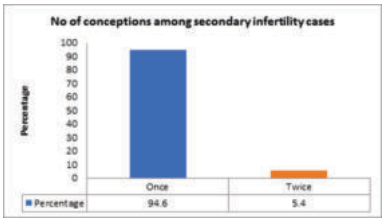
PATIENTS DEMOGRAPHIC DETAILS, HISTORY AND CLINICAL PRESENTATION	
Age	
Type of infertility	
No. of Conceptions	
Duration of infertility	
HSG Rt FT	
Findings of Rt FT	
HSG Lt FT	
Findings of Lt FT	
Uterine findings- SSG	
Abnormalities- SSG	
Uterine findings- HSG	
Abnormalities- HSG	
T path- SSG	
T path- HSG	
T abnormalities- SSG	
T abnormalities- HSG	
T patency -SSG	
T patency- SSG side	
T patency- HSG	
T patency- HSG side	



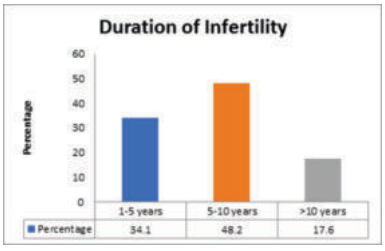
Graph 1: Proportion Of Subjects Based On Age Groups



Graph 2: Proportion Of Subjects Based On Types Of Infertility



Graph 3: Number Of Conceptions Among Secondary Infertility Subject



Graph 4: Duration Of Infertility Among Study Participants

Table 2: HSG Findings Of Right FT

Findings in right fallopian tube	Frequency	Percentage
Normal	55	64.7
Abnormal	30	35.3
Total	85	100.0

Table 3: Proportion Of Abnormal Findings In Right FT

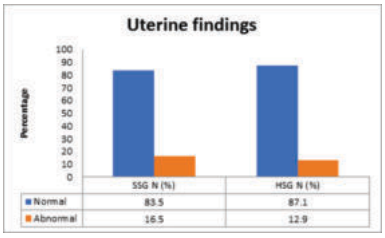
Abnormal findings in right FT	Frequency	Percentage
Cornual block	14	46.7
Hydrosalpinx	03	10.0
Fimbrial block	07	23.3
Salpingitis ishmica nodosa	04	13.3
Mid salpingeal block	02	6.7
Total	30	100.0

Table 4: HSG Findings Of Left FT

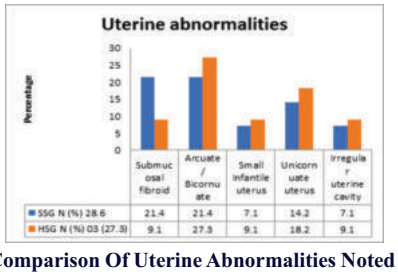
Findings in left fallopian	Frequency	Percentage
Normal	51	60.0
Abnormal	34	40.0
Total	85	100.0

Table 5: Proportion Of Abnormal Findings In Left FT

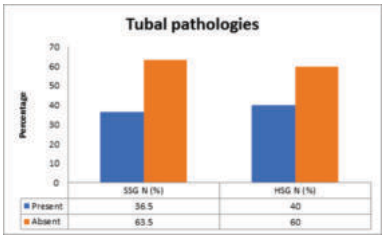
Abnormal findings in left FT	Frequency	Percentage
Cornual block	13	38.2
Hydrosalpinx	02	5.9
Fimbrial block	06	17.6
Salpingitis ishmica nodosa	03	8.8
Mid salpingeal block	03	8.8
Total	34	100.0



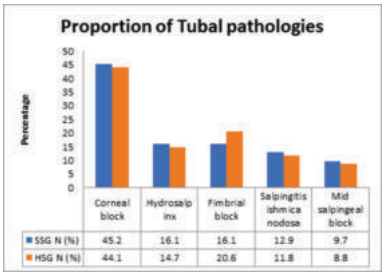
Graph 5: Comparison Of Uterine Findings In SSG & HSG



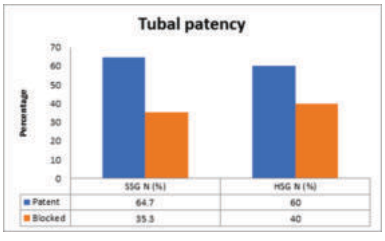
Graph 6: Comparison Of Uterine Abnormalities Noted In SSG & HSG



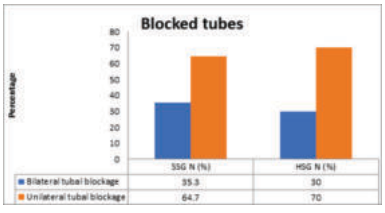
Graph 7: Comparison Of Tubal Pathologies In SSG & HSG



Graph 8: Comparison Of Tubal Pathologies Noted In SSG & HSG



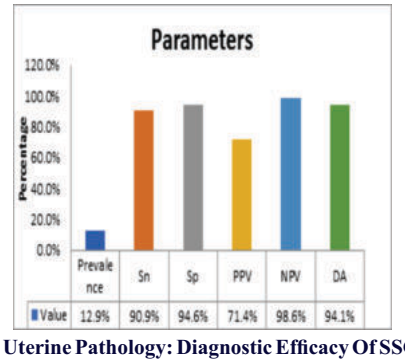
Graph 9: Proportion Of Subjects With Ft Patency Based On SSG & HSG



Graph 10: Proportion Of Subjects With Tubal Block Based On SSG & HSG

Table 6: Comparison Of Uterine Pathology: SSG Vs HSG

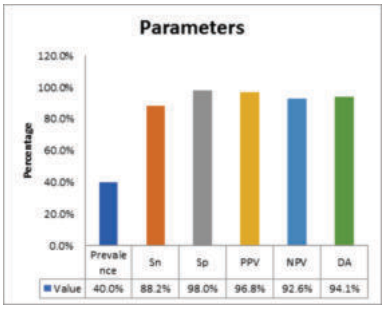
Uterine pathology (SSG)	HSG		Total	P value
	Present	Absent		
Present	10 (11.8)	04 (4.7)	14 (16.5)	<0.0001*
Absent	01 (1.2)	70 (82.3)	71 (83.5)	
Total	11 (13)	74 (87.1)	85 (100)	



Graph 11: Uterine Pathology: Diagnostic Efficacy Of SSG Vs HSG

Table 7: Comparison Of Tubal Blockage: SSG Vs HSG

Tubal blockage on SSG	Tubal blockage on HSG		Total	P value
	Present	Absent		
Present	30 (35.3)	01 (1.2)	31 (36.5)	<0.0001*
Absent	04 (4.7)	50 (58.9)	54 (63.5)	
Total	34 (40)	51 (60)	85 (100)	



Graph 12: Tubal Blockage: Diagnostic Efficacy Of SSG Vs HSG

Case 1:

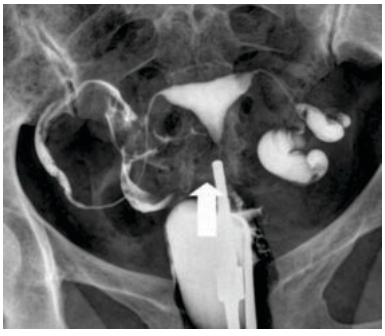


Image 1: HSG shows dilatation of left fallopian tube with no contrast spilling into the peritoneal cavity indicating left hydrosalpinx with tubal block.

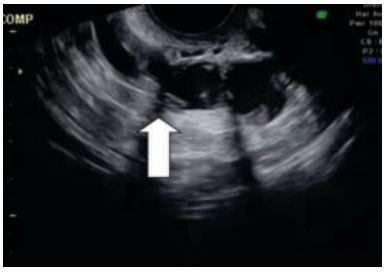


Image 2: SSG shows an elongated fluid filled dilated tubular structure with incomplete septations and lack of vascularity in the left adnexa indicating left hydrosalpinx with tubal block.

Case 2

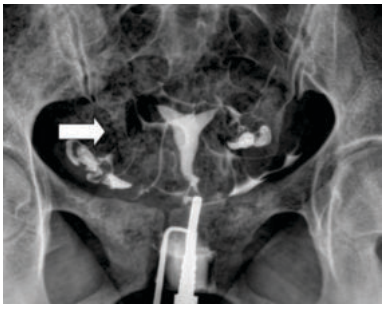


Image 3: HSG shows an oval shaped filling defect with a smooth margin in the endometrial cavity indicating endometrial polyp.

Image 4: SSG shows saline outlining the endometrial polyp.

Case 3

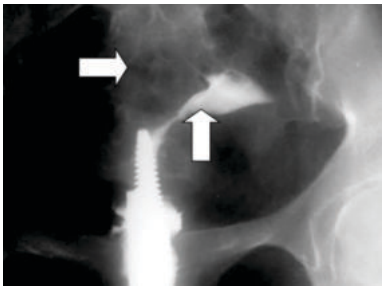


Image 5: In HSG, contrast fails to outline the fallopian tube on both side. No free peritoneal spill seen on either side indicating bilateral tubal block.

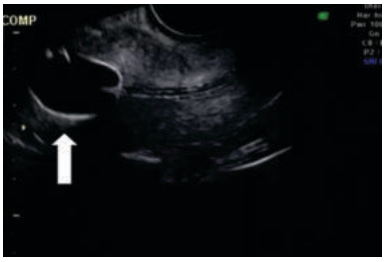


Image 6: SSG shows saline outlining the endometrial cavity with focal pooling of saline near fundal endometrial cavity and absence of filling in bilateral fallopian tube indicating bilateral tubal block.

Case 4

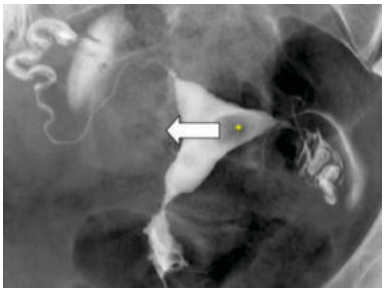


Image 7: HSG shows persistent, smooth, ovoid filling defect is seen near the left fundal portion of the cavity corresponding to the submucosal fibroid.

Image 8: SSG shows saline outlining the posterior submucosal fibroid.

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