

Original Article

Air Contrast Sono-HysteroSalpingography Versus Hysterosalpingography for Tubal Evaluation in Subfertility

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Abstract

Objective: To compare the diagnostic accuracy of sono-hysterosalpingography (HyCoSy) using gaseous spring water for tubal patency with hysterosalpingography (HSG) in sub fertile women.

Methodology: A cross-sectional study was conducted from June to December 2022 at the Maternal and Child Health Center and Radiology Department of PIMS, Islamabad This study included subfertile women of reproductive age presenting in infertility clinic. Pregnant women, those with male factor subfertility, per vaginal bleeding at time of procedure, active pelvic infection or history of unprotected intercourse in current cycle were excluded. Tubal evaluation done in late follicular phase of menstrual cycle, immediately after menstruation cessation in the outpatients of MCHC by HyCoSy using gaseous spring water at transvaginal ultrasound (TVS). Hysterosalpingography was done in all these women in radiology department using oil based iodinated contrast.

Results: Among 65 studied women with subfertility, 23 (35.4%) had primary subfertility while 42 (64.6%) had secondary subfertility. Mean age was 32.25 years. The average duration of subfertility was 5.09 years. HSG showed 40 (58.4%) had Patent tubes while with HyCoSy patent tubes were reported in 43 (66.1%). HSG and HyCoSy had unilateral non visualization of fallopian tubes in 4 (5.3%) and 3 (4.6%) cases respectively. No hydrosalpinx was noted in the two tests. The positive predictive value for diagnosis of tubal patency for HyCoSy versus HSG was 86.41%. The negative predictive value for diagnostic accuracy of HyCoSy was 90.41%.

Conclusion: HSG and HyCoSy were complementary to each other for tubal evaluation in subfertility. HyCoSy showed high positive and negative predictive value compared to HSG.

Keywords: Infertility, Hysterosalpingography, Sonosalpingography, Laparoscopy.

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Introduction

Subfertility is the term used for a clinical condition in which the partners fail to achieve a clinical pregnancy after the passage of 12 months of regular unprotected sexual activity.^{1,2} Across the globe, 8 to 12 percent individuals are affected by subfertility.³ Survey conducted by WHO between 1990 till 2021 determined the worldwide estimated lifetime risk of infertility in one's life as 17.5%.⁴ The lifetime prevalence of subfertility is similar among the countries with different income levels, being 17.8% in higher-income countries like America, U.K, France while in low- and middle-income countries it is 16.5%.⁵ According to the report given by WHO in 2023, worldwide approximately 48.5

million (15%) couples face difficulty in conceiving.⁵

Studies have also revealed that around one third of the subfertility related problems in couples are due to male partners, one third due to female issues, and another one third due to unknown factors.⁶ Women have highest fertility in their twenties and thirties, while men maintain it till their forties.⁶ Subfertility affects a person's life adversely. There is a strong association between subfertility and psychological stress, as well as social and emotional health of women and their families.^{7,8}

Female subfertility can be primary or secondary. The

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term primary subfertility is used for a female who has never had a clinical pregnancy. Secondary female infertility is applicable to women unsuccessful in establishing a clinical pregnancy after previously been diagnosed with a clinical pregnancy. Globally, secondary subfertility is most commonly due to pelvic inflammatory disease and prevalence varies around the world.⁹ In Pakistan, studies have reported subfertility rates up to 22%, wherein 4% have primary and 18% have secondary subfertility.¹⁰ Study conducted in Gujrat, Pakistan showed that primary subfertility is higher between 20-to-25-year ages women and secondary is more among 36-40 years old women.¹¹

This study also showed common causes of subfertility were PCOS, Hormonal imbalance and uterine fibroids. According to the socio-economic status, 10.6% couples belonged to low-income, 53.3% from middle-income and 36% were from higher income status.¹¹

In some parts of the world like Africa prevalence of primary and secondary is equal. However, many studies suggest that secondary subfertility is more common.¹² In different parts of the world, secondary infertility results from elevated unsafe abortion rates and substandard maternity care, leading to infections in the postpartum and post-abortion period. Fallopian tube disease is one of the most common factors contributing to the secondary subfertility in females and accounts for 30-40% of overall female causes. It has variable pathogenesis including ascending reproductive tract infections (PID), tuberculosis and past pelvis surgeries leading to damage or adhesions.¹³

Patent fallopian tubes plays an important role in conception. In cases of suspected blocked tubes and / or for fertility work up, tubal patency is evaluated by different imaging techniques, like HSG, HyCoSy, hysteroscopy and laproscopy.¹⁴ In cases where tubal patency remains in doubt after doing HSG, laparoscopy is recommended and it should be done after three months of HSG.

HSG can also reveal the shape of the fallopian tube as S or C shaped. HSG requires X Rays and fluoroscopy while injecting contrast material via cervical catheter. Pre procedure antibiotic and effective NSAID painkillers are recommended.¹⁵ The preparation for HSG and HyCoSy is similar and they are done in preovulatory phase, injecting a dye/contrast through cervical catheter and directly visualizing uterine cavity and fallopian tubes. Significant increase in rate of up to 5%

and live birth rate of 7.5% has been reported among women who underwent oil based HSG tubal testing.¹⁶

In current practice, HyCoSy with TVS is increasingly becoming the first line test for fallopian tube evaluation, whereby radiation exposure to female gonads is avoided.¹⁷ Commonly, saline infusion is used for HyCoSy. For the current study another novel contrast medium, gaseous spring water also called sparkling water was used. It is low cost, readily available and makes visualization of uterus and fallopian tubes more obvious and prominent¹⁸ than normal saline due to added presence of gaseous bubbles as contrast on TVS. The results were then compared with Xray HSG in the same patient.

Methodology

A Cross sectional was undertaken in Gynecology and Obstetrics Outpatients Department and Radiology department, MCH Centre, PIMS, Islamabad from 4th June 2022 to 5th December 2022 after approval by the institutional review board. The Sample size of 65 women was calculated by using sensitivity and specificity calculator with Confidence level of 95%, Sensitivity 3.3%, Specificity 89.7%, Prevalence 40%, absolute precision 10%. Consecutive non-probability sampling method was used. For Sample Selection the inclusion criteria were women of reproductive age (18-45 years) with primary or secondary subfertility in Immediate post-menstrual phase, Day 6-10 of cycle. All cases enrolled in study had either their previous HSG done more than three years back or never had any tubal patency evaluation for subfertility workup. The exclusion criteria were pregnancy, male factor subfertility, any per vaginal bleeding at the time of procedure, active pelvic infection or history of unprotected intercourse in current cycle.

All patients presenting at infertility clinic, in the OPD of MCHC unit I, PIMS and fulfilling the inclusion criteria were recruited after informed consent. All enrolled women had detailed medical and menstrual history followed by general, systemic and gynecological examination along with all routine investigations. All patients had recent transabdominal ultrasonography report. All information was entered on specially designed Performa. After evaluation in Subfertility clinic, date for sono-hysterosalpingography and hysterosalpingography was given in immediate post menstrual phase.

Both procedures were performed on outpatient basis under supervision of specialist. The patient was asked to empty bladder. After placing the patient in dorsal position, intrauterine catheter inserted using aseptic precautions. For Sono-Hysterosalpingography, contrast media of gaseous spring water was instilled and simultaneously tubes were visualized by transvaginal ultrasound. Position of the probe was actively changed relative to uterus and tubes to depict the flow of contrast along the entire length of each tube. In our study we used sterile gaseous spring water as a contrast media for evaluation of tubal patency using real time transvaginal ultrasonography, which showed like a sparkling bead spreading from endocervical canal into the uterine cavity, followed by bilateral spread of sparkles of beads in fallopian tubes and peritoneal spill in patent tubes. Time taken for the outpatient HycoSy and the volume of sterile gaseous spring water used as a contrast media for evaluation of tubal patency with real time transvaginal ultrasonography was noted. For hysterosalpingography, iodinated contrast media was infused via transcervical catheter, X-ray and fluoroscopic examination done while instilling contrast. Patients were advised to stay in hospital daycare for 60-90 minutes after completing the procedure. Post procedure pain relief in the form of oral paracetamol on as required basis was prescribed. Routine antibiotic was not given.

Data entered in SPSS version 21.0 for analysis. Frequencies and percentages calculated for qualitative variables like primary or secondary subfertility, single or bilateral blocked tubes. Quantitative variables like age, marriage duration were calculated as mean \pm SD. Table of 2x2 was constructed to calculate the sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and accuracy Effect modifiers including previous pelvic surgeries, past history of abortion, history of pelvic inflammatory disease and type of subfertility were analyzed and correlated.

Results

A total of 65 women with subfertility were studied. The mean age of the women was 32.25 with a range of 22-43 years. The average duration of subfertility was 5.09 years with a range of 1-13 years. 23 (35.4%) women had primary and 42 (64.6%) had secondary subfertility. History of abortion was present in 24 (36.9%) of the women and 20 (30.8%) had delivered in the past.

According to the findings of the HSG, it was observed that the right fallopian tube was open in 38 (58.5%) of

women, while it was blocked in 25 (38.5%) and absent in 2 (3%) of the cases. Similarly, the left fallopian tube was found to be open in 38 (58.5%) of women and blocked in 22 (33.8%) and absent in 5 (7.7%). As for the right ovary, it was determined to be normal in 81.5% of women, bulky in 15.4% of cases, and not visible in 3.1% of women. On the other hand, the left ovary appeared normal in 78.5% of women, bulky in 16.9% of women, and not visible in 4.6% of cases. Table I

Based on the HyCoSy findings, it was observed that the right fallopian tube was open in 64.6% of cases, while it was blocked in 32.3% of cases. In addition, the left fallopian tube was found to be open in 67.7% of the women and blocked in 26.2% of women. The right ovary appeared normal in 81.5% and was bulky in 18.5% of women. On the other hand, the left ovary was normal in 76.9% of women, bulky in 18.5% of women, and not visible in 4.6% of cases. Furthermore, fibroid uterus was seen in 06.2% and polyp was observed in 3.1%. Table (I)

Table I: HSG and HycoSy findings regarding fallopian tubes and ovaries. (n=65)

Site	Finding	HSG.	HycoSy
Right ovary	Patent	38 (58.5%)	42 (64.6%)
	Blocked	25 (38.5%)	21 (32.3%)
	Absent	2 (03.1%)	2 (3.1%)
Left tube	Patent	38 (58.5%)	44 (67.7%)
	Blocked	22 (33.8%)	17 (26%)
	Absent	5 (7.7%)	4 (6.2%)
Right ovary	Normal	53 (81.5%)	53 (81.5%)
	Bulky	10 (15.4%)	12 (18.5%)
	Absent	2 (3.1%)	-
Left ovary	Normal	51 (78.5%)	50 (76.9%)
	Bulky	11 (16.9%)	12 (18.5%)
	Absent	3 (4.6%)	3 (4.6%)
Uterus	Visualized	16 (24.6%)	59 (90.8%)
	Not visualized	49 (75.4%)	-
	Fibroid	-	4 (6.2%)
	Polyp	-	2 (3.1%)

Seven patients gave the history of absent tube after surgical management of ectopic pregnancy and the tube was not appreciated on HSG as well as HyCoSy. Out of seven women, two had absent right tube and one also had absent right ovary on HyCoSy, Five patients had absent left tube on both HSG and HyCoSy and three of them had non visualized left ovary on scan. More details of intrauterine cavity were seen on transvaginal ultrasound during HyCoSy procedure.

In this study, we compared the findings in the uterine cavity with HSG and HyCoSy, with the transvaginal scan. Eight patients had uterine pathology on HyCoSy,

Table II: Diagnostic accuracy of HyCoSy versus HSG for right & left tube evaluation. (n=65)

(HyCoSy)	Right tube (HSG)		Left tube (HSG)	
	Patent	Blocked	Patent	Blocked
Patent	38	6	40	8
Blocked	2	19	3	14
Total	40	25	43	22
Sensitivity = TP / (TP+FN) x 100 = 95%		Sensitivity = TP / (TP+FN) x 100 = 93%		
Specificity = TN / (TN + FP) x 100 = 76%		Specificity = TN / (TN + FP) x 100 = 63%		
PPV = TP / (TP+FP) x 100 = 86%		PPV = TP / (TP+FP) x 100 = 83%		
NPP= TN / (TN+FN) x 100 = 90%		NPP= TN / (TN+FN) x 100 = 82%		

four (6.2%) with fibroid uterus and two (3.1%) with endometrial polyp, which were not picked up on HSG. HyCoSy showed ovarian pathology which is not seen with HSG.

Average time for performing the HyCoSy in OPD was 20 to 30 minutes duration. The volume of sterile gaseous spring water used as a contrast media for evaluation of tubal patency with real time transvaginal ultrasonography was 15 ml on average and maximum need was 20ml. None of the patients reported any severe pain during or after the procedure, or any allergic reaction to the contrast material. Twenty-three patients out of 65 women (35.38%) complained mild abdominal discomfort, they were advised to take oral NSAIDs in daycare and sent home when satisfied.

In the diagnosis of the right fallopian tube, HyCoSy compared to HSG, demonstrated a sensitivity of 95%, specificity of 76%, positive predictive value (PPV) of 86%, and negative predictive value (NPV) of 90%. (Table II) HyCoSy compared to HSG as the gold standard, exhibited a sensitivity of 93%, specificity of 63%, PPV of 86%, and NPV of 90% in diagnosing the left fallopian tube status. (Table II)

In sub group analysis, the diagnosis of the right fallopian tube according to positive abortion history, HyCoSy showed a sensitivity of 92%, specificity of 72%, positive predictive value (PPV) of 80%, and negative predictive value (NPV) of 88% compared to HSG. Whereas on assessing the left fallopian tube status in women with positive abortion history. HyCoSy exhibited a sensitivity of 100%, specificity of 70%, PPV of 93%, and NPV of 100% compared to the gold standard HSG.

In women with primary subfertility, for the diagnosis of right fallopian tube status HyCoSy showed a sensitivity of 96%, specificity of 68%, positive predictive value (PPV) of 83%, and negative predictive value (NPV) of 91%. While for the left fallopian tube, HyCoSy showed a sensitivity of 96%, specificity of 50%, PPV of 86%, and NPV of 83%.

In women with secondary subfertility, for the diagnosis of the right fallopian tube, HyCoSy showed a sensitivity of 96%, specificity of 68%, positive predictive value (PPV) of 83%, and negative predictive value (NPV) of 91%, while HyCoSy showed a sensitivity of 81%, specificity of 75%, PPV of 75%, and NPV of 81% in diagnosing the left fallopian tube status.

Discussion

Among the women presenting with subfertility, common anatomical causes include uterine or tubal pathology with tubal factor being the most frequent. Different methods are available for assessment of pelvic pathology related to uterine, fallopian tubes, ovaries, and lower genital tract, but no definitive consensus is available on any single best approach for a specific pathology.¹⁹ Main indication for performing HSG and HyCoSy remains subfertility in the female partner to rule out the tubal factor.

In our study, the frequency of secondary subfertility was 64.6% compared to 35.4% with primary subfertility among the 65 women studied. Patient with the secondary subfertility had previous history of abortion in 36.9% cases and history of last child birth was noted in 30.8%. A study conducted by *Kumari R et al* comparing HSG and HyCoSy also showed the incidence of secondary was more than primary subfertility i.e. 82.6% and 18.4% respectively.²⁰ Similar study done in Henan province of China showed that the prevalence of infertility in their population was 24.58%, and of which prevalence of secondary infertility was more compared to primary infertility.²¹ The WHO reports globally STIs have a major impact on the sexual and reproductive health. Gonorrhoea and chlamydia remain the major contributors to infertility and pelvic inflammatory disease among women.²²

Our study showed that HyCoSy in comparison to HSG had a similar sensitivity and specificity for tubal patency. This was without the inconvenience of visiting the radiology department and potential hazards of HSG, such as possible iodine-based sensitivity to the

radiopaque dye and exposure to radiation. No patient enrolled in study reported any significant side effects or inconvenience compared to HSG, and procedure was easy to be performed in gynecology outpatient department using transvaginal ultrasound. With fluoroscopy at HSG, the uterine cavity is also visualized. The advantage of using HyCoSy is that in addition to the visualization of uterine cavity, ovarian pathology can also be ascertained. Intrauterine assessment via TVS includes fibroids, polyps and adhesions with filling defect noted on HyCoSy. Use of HSG requires the radiology equipment and staff involvement namely, Xray machine, technician and does not assess myometrium and ovaries.²⁰ Using HyCoSy, avoids Xray radiation exposure to gonads, and other endocrine organs like pancreas. Khanum N et al concluded in 2022 that transvaginal SHSG was useful as a first-line method for evaluation of endometrial cavity and tubal patency before recourse to more invasive gold standard methods like Hysteroscopy and Laparoscopy.²³

The present study showed high diagnostic accuracy for HyCoSy in comparison to HSG, with a sensitivity of 95%, specificity of 76% in right fallopian tube, whereas in left tube it is 93% sensitivity and specificity of 63%. Diagnostic accuracy of HyCoSy in comparison of HSG was equal. Luciano et al. report a satisfactory analysis between the HSG and HyCoSy, where 102 fallopian tubes were examined, and all findings were in concordant.²³ Using HyCoSy as first line investigation in evaluation of tubal patency was suggested as it was less painful and time-efficient.^{23,24,25} Overall, many studies showed similar results in terms of sensitivity and specificity for HyCoSy and HSG, and some studies showed better results for HyCoSy.^{20,25,26}

Seven patients gave the history of absent tube after surgical management of ectopic pregnancy and the tube was not appreciated on HSG as well as HyCoSy. Limited studies are available that showed the results with absent tubes on HSG and HyCoSy due to congenitally absent or removed via surgery.

None of the patients in our study reported any severe pain during or after the procedure, or any allergic reaction to the contrast material. About 35% complained mild abdominal discomfort. Another study showed mild to moderate pain in comparison to HSG in 65 patients (74%) with similar sensitivity, specificity and diagnostic accuracy for both procedures.²⁰ Bisogni et al reported that 50% women had no pain during the

HyCoSy exam and 36% experienced only mild pain.²⁷ A study among 121 women comparing pain between the HSG and HyCoSy, using Stacey score showed that women experienced more pain after HyCoSy ($p < 0.001$) procedure as compared to HSG, as the median was 2 in HyCoSy and 1 in HSG. However, they noted no significant difference in time for both procedures²⁵, as in our study. No patient showed significant dilated tubes to be labelled as hydrosalpinx in both procedures, and no difficulty related to their BMI was experienced. Study conducted in India in 2019, among the 92 cases of infertility for evaluating fallopian tubes patency, showed hydrosalpinx in 18 (19.56%) patients with HyCoSy and 17 (18.45%) patients with HSG. They demonstrated uterine pathology in 9(9.79%) cases, ovarian mass in 3 cases (3.26%), PCOS in 1 case, patent tubes in 67 cases (72.83%) and bilateral blocked tubes in 25 (27.17%) patients. In our present study 14 patients showed bilateral blocked tubes on HSG and only 9 patients showed bilateral blocked tubes on HyCoSy. The difference in bilateral blocked tubes can be due to flushing of the tubes in the first setting and variation in expertise at interpretation of procedure.²⁴

Extensive, single center study was conducted in London with 500 patients by HyCoSy done using Echovist-200 contrast medium. The pain reported was mild in 51%, moderate for 33.5% and severe pain reported in 15.6% cases.²⁸ The median time for procedure was 12 minutes and average amount of contrast used was 15ml. The London study also commented upon the difficulty in visualization of tubes among the obese cases, such as learning the curve of TVS probe 50-100 has significantly improved the visualization. In our study we used sterile gaseous spring water as a contrast media for evaluation of tubal patency using real time transvaginal ultrasonography, which showed like a sparkling beads spreading from endocervical canal into the uterine cavity, followed by bilateral spread of sparkles of beads in fallopian tubes and peritoneal spill in patent tubes. A recent review in 2022 on status of saline infusion, Sonohysterosalpingography for evaluation of various uterine pathologies adds to the argument that in addition to its role in evaluating tubal patency other contributors to subfertility are detectable.²⁹

Study conducted in Spain using a gel foam as a contrast media for evaluating a tubal patency, showed it as less time consuming as compared to HSG, with average duration of 5 minutes and 12 minutes respectively. Gel foam contrast is less painful and only

5ml is required followed by Saline infusion sonography for distending the uterine cavity as compared to other contrast agents used for Sono-Hysterosalpingography and HSG and additionally noted antral follicular count.³⁰ Follow up is required to observe the pregnancy rate after performing HSG and HyCoSy both. Investigators found that rate of conception increases after oil based contrast while performing HSG as a therapeutic effect in cases of unexplained infertility.¹⁶

Several studies showed similar results in evaluating tubal patency by HSG in comparison to HyCoSy using different contrast medium, oil or water based, and taking laparoscopy as a gold standard. However, our study had a limitation of being performed in a single center, but the advantage was that all transvaginal scans for HyCoSy were done by same team members so, operator based variability was reduced. Procedure using 2D or 3D ultrasound can be used as a first choice among females for tubal patency investigation, using contrast of gaseous spring water and simultaneously complete evaluation of pelvic cavity, uterus and ovaries were done. This contrast is low cost, easily available, no therapeutic hazards known and fallopian tubes visualized during the real time sonography. HyCoSy can be used primarily as a diagnostic procedure with an advantage of being therapeutic in tubal flushing. Our study suggests Air contrast sono-hysterosalpingo graphy as a first-choice investigation to rule out the tubal factor of subfertility in women with primary or secondary subfertility.

Conclusion

We conclude, that HyCoSy is complementary to HSG in evaluating tubal patency in sub fertile women. It's safe, minimally invasive, with no radiation exposure, and can be a routine office procedure, simultaneously examining the patient and performing transvaginal ultrasound for uterus, ovaries, and other pathology in pelvis. HyCoSy can be used in early stages of subfertility testing followed by HSG if deemed necessary.

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