Role of transvaginal Ultrasound in assessment of Fallopian Tubes Patency using Hysterosalpingo-Foam Sonography (HyFoSy) in Infertile patients; A randomized controlled study comparing HyFoSy with Hysterosalpingography (HSG) for tubal patency testing

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Abstract

Background: Fallopian tubes patency assessment can be done using a number of methods involving hysterosalpingography, laparoscopy and hysterosalpingo-contrast sonography which can be done as an office setting and also for the uterine cavity assessment.

Objectives: To compare HyFoSy versus HSG in tubal patency assessment in patients without obvious cause of infertility and the incidence of spontaneous pregnancy in the 3-months post procedure.

Patients and methods: This randomized controlled trial was conducted on subfertile women who were referred to the outpatient clinics at Obstetrics and Gynecology department, South Valley University. We included 300 women, randomized into one of 3 groups. Group A had HyFoSy, Group B had HSG and Group C had only follow up without testing. We compared both procedures regarding ease, cost, pain using the visual analogue scale, complications and occurrence of pregnancy within 3 months.

Results: Our groups were comparable regarding age, BMI, type of infertility and previous pelvic surgeries.Cervical cannulation was easier in the HyFoSy group with shorter procedure time, less amount of contrast material and less pain. In both groups complications were self-limiting and managed as outpatients. After 3 months,the incidence of pregnancy among the final cases completed the study was (23.7%) in the HyFoSy group, (16.5%) in the HSG group & (10.5%) in the control group without significant statistical difference between them.

Conclusion: HyFoSy is an effective outpatient method to assess tubal patency with shorter procedure time, less pain, less cost, less amount of injected contrast material, slightly higher pregnancy rates without significant complications compared to HSG.

Keywords: Ultrasound; Fallopian tubes patency; Hysterosalpingo-Foam Sonography; HSG; Infertility.

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Introduction

Assessment of Fallopian tubes patency is an important part of routine infertility work-up **(Collins,1995)**. Hysterosalpingography (HSG) and laparoscopy with chromopertubation (the gold standard) are two of the many tests that can be used for this. Although there are risks associated with the traditional diagnostic methods as invasiveness, allergy, pain, and radiation exposure, laparoscopy is still the gold standard method in assessing tubal patency because it has the additional advantage of evaluation of the abdominal cavity and other pelvic structures and can be used therapeutically at the same time **(Socolov et al.,2009)**.

HyCoSy was developed in the early 1980s as an outpatient procedure which is quick, painless, and risk-free and gained wider acceptance. Echovist was the echogenic material used. It was expensive and galactose sensitivity was a well-known contra-indication. Recently Echovist is no longer available for gynecological use **(Aggarwal ,2019)**. Hystero-salpingofoam sonography (HyFoSy) was developed to evaluate fallopian tubes patency. It has a benefit over saline in that its consistency is fluid enough to pass through the Fallopian tubes while yet being stable enough to show echogenicity for at least five minutes **(Tanaka et al.,2018)**. It is considered to be appropriate and safe outpatient technique for tubal patency testing **(Exalto et al.,2014).**

The aim of this study was to compare transvaginal ultrasound using hysterosalpingo-Foam Sonography (HyFoSy) versus hysterosalpingogram (HSG) in assessment of tubal patency in subfertile patients who had no obvious cause of infertility and the occurrence of spontaneous pregnancy within a limited period of time.

Patients and methods

This randomized controlled study was conducted on subfertile women who were referred to the outpatient clinics at Obstetrics and Gynecology department, South Valley University. Three hundred and sixty patients were recruited for the study and 60 women were excluded as they were not fulfilling the inclusion criteria. The eligible women were randomized into one of three groups; Group A (HyFoSy group): included 100 women who had tubal patency testing using Hysterosalpingo-Foam Sonography (HyFoSy). Group B (HSG group): included 100 women who had tubal patency testing using hysterosalpingogram. Group C (Control group): included 100 women who didn't do tubal patency testing and received ovulation induction for 3 months with follow up. We compared both groups (Group A and Group B) regarding the ease of the procedure, pain using the VAS, the complications and the occurrence of pregnancy in the 3-month period post-test. Intention to treat method was used for analysis. **Ethical approval code:** SVU-MED-OBG024-2-21-4-128.

Sample size: We used Steven K. Thompson equation to calculate the sample size from this formula: $n = Nxp\ (1-p)\ [[N-1x\ (d2\div z\ 2)]\ +p\ (1-p)]$ **(Hummelshoj et al.,2006).** Where n is the sample size, N is the population size, Z is confidence level at 95% it is 1.96, d (absolute error or precision) =0.05, p is the propability 50%. The result was 300 patients, 100 in each group.

Target population: Subfertile patients attending the outpatient clinics at Obstetrics and Gynecology department, South Valley University.

Inclusion criteria: Patients enrolled in this study were subfertile patients with no obvious cause of infertility. (Primary infertility: defined as one year of unprotected regular intercourse without a previous pregnancy and secondary infertility: two years after a previous pregnancy or delivery)

Exclusion criteria: Age ≥ 40 years or ≤18 years, BMI ≥30, Galactorhea or hyperprolactinemia, Male factor: Abnormal sperm parameters defined as a count ≤ 15 mill/ml, motility ≤ 30%, abnormal forms ≥ 96% (WHO criteria 2010), Irregular marital life and presence of gynecological problem e.g. fibroid, uterine polyp, ovarian tumours mullerian anomalies.

All the patients were subjected to the following after taking informed verbal consent about the steps of the procedure, the possible complications and the expected results:

Initial evaluation (Detailed history and clinical examination, Ovarian reserve testing (serum antimullerian hormone, and basal antral follicular count by US), uterine cavity assessment (by 2D US in addition to Sonohysterography and 3D transvaginal ultrasound if needed), routine investigations (complete blood count, blood grouping, prothrombin time, prothrombin concentration) and semen analysis for the husband.

Eligible women were randomized into 3 groups with 100 patients in each:

Method of randomization: Random allocation of the patients was done using sealed closed envelops into 3 groups.

Group A (HyFoSy group): Patients in this group had tubal patency testing using Hysterosalpingo-Foam Sonography (HyFoSy) which was performed postmenstrual.

The ultrasound machine used was: GE Voluson P8 (software BT 18, serial number VP8802147, production date 3/2019).

All patients were examined as follows: in the lithotomy position, a sterile Cusco speculum was introduced to expose the cervix. The cervix was washed by povidone iodine 10% then cannulated by a pediatric Foley's catheter measuring (8F). The degree of cervical cannulation difficulty was classified as: Low difficulty (centralized cervix, easy cannulated), Moderate difficulty (laterally situated cervix, needed some manipulation with the Cusco), Severe difficulty: the cervix needed grasping with tenaculum. The balloon of the Foley's catheter was inflated with 2-3 cc saline to prevent foam leakage. The foam was prepared by mixing 2 – 3 ml of xylocaine gel 2 % (lidocaine hydrocholoride) (Recipharm Karlskoga, Karlskoga, Sweden for Aspen) with 12 – 13 ml of saline rigoursly for 10-15 times using a 50 cc syringe for the gel and a 20 cc syringe for the saline. The foam was injected slowly into the uterine cavity by the assistant while performing the transvaginal ultrasound examination. The flow of the contrast media through the cavity and the fallopian tubes was evaluated. Tubal patency was classified as:

*Bilateral patency: Both tubes were visualized as seen in **(Fig.1)** and there was periovarian spill as seen in **(Fig. 2).**

*Unilateral patency: Only one tube was visualized with its periovarian spill as seen in **(Fig. 3).**

*Bilateral block: No foam is seen in either tube nor any periovarian spill was seen as seen in **(Fig.4).**

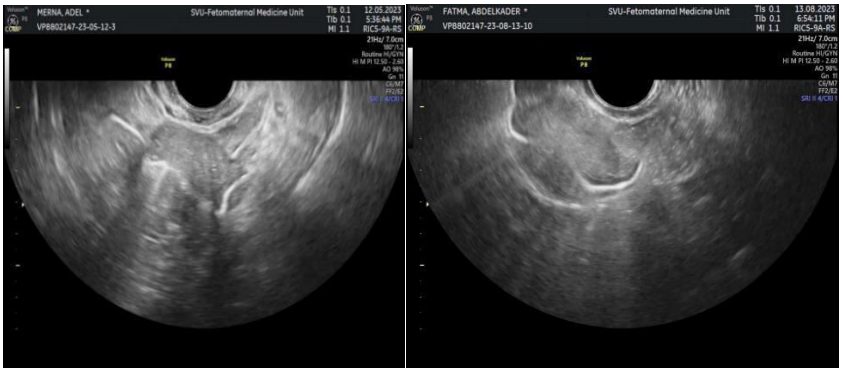

Fig.1. Bilateral patency.

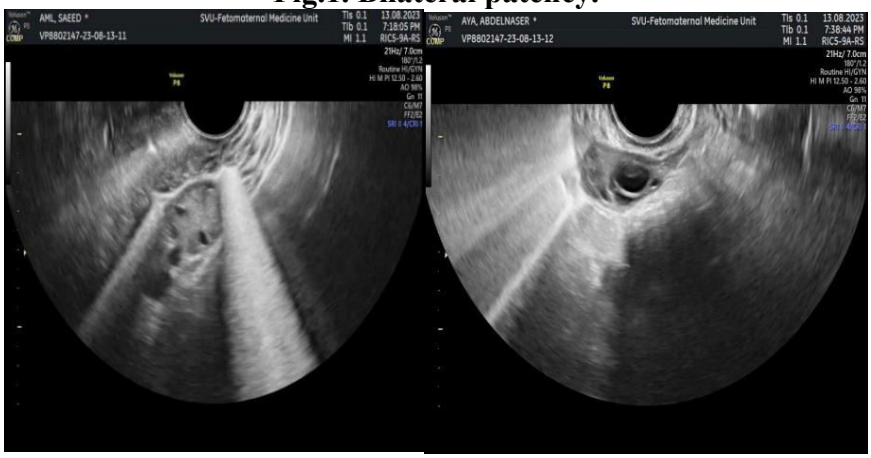

Fig. 2. Periovarian spill.

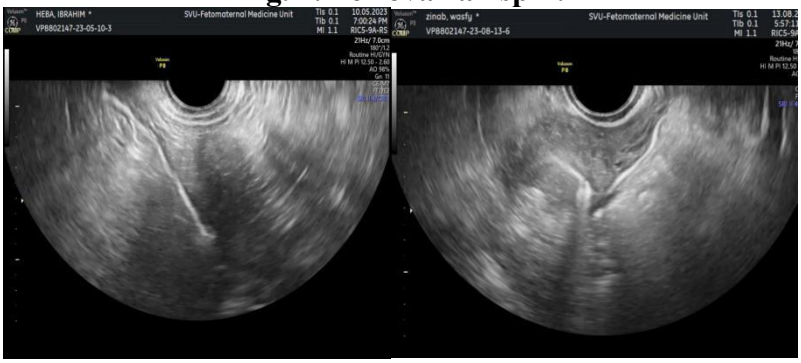

Fig.3. Unilateral patency.

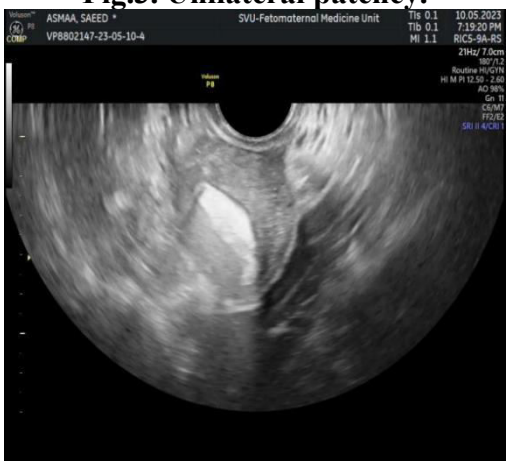

Fig.4.Bilateral block.

The amount of the injected foam was recorded. The degree of pain perceived by the patient was scored using the Visual analogue scale (VAS) as: No pain (score zero), Mild pain (score 1 -3), Moderate pain (score 4 – 6), Severe pain (score 7 – 10). The duration of the examination was recorded from time of Cusco speculum application to removal of the intrauterine catheter. A dynamic video was recorded for each patient. The cost of the test was calculated including all the supplies used during the examination. All patients received antibiotic coverage; Azithromycin 500 mg once daily for 3 -5 days, starting one day before the procedure. In addition, they also received oral analgesia (non-steroidal anti-inflammatory drug; Diclofenac 50 mg) 1 hour before the examination to minimize the pain.

Group B (HSG): Patients in this group had tubal patency testing by hysterosalpingogram done postmenses. This followed the routine of our hospital for HSG exam.

After exposure of the cervix, cannulation was done using a Spackman cannula **(Fig. 5)**. Radio-opaque dye was injected through the catheter: 20-25 ml of omnipaque, X-ray imaging was taken. The first film showed the outlines of uterine cavity and the shape and patency of Fallopian tubes. The patient was then asked to walk for only 10 - 15 minutes then a second film was taken to evaluate the peritoneal spill. The degree of cervical cannulation difficulty, amount of the injected dye, pain score (VAS), time of the examination, tubal patency status **(Fig. 6 and Fig.7)** and the cost were all recorded. Patients received antibiotics and analgesics similar to the Hyfosy procedure. Few cases chose having the examination under sedation

Fig. 5. Spackman cannula

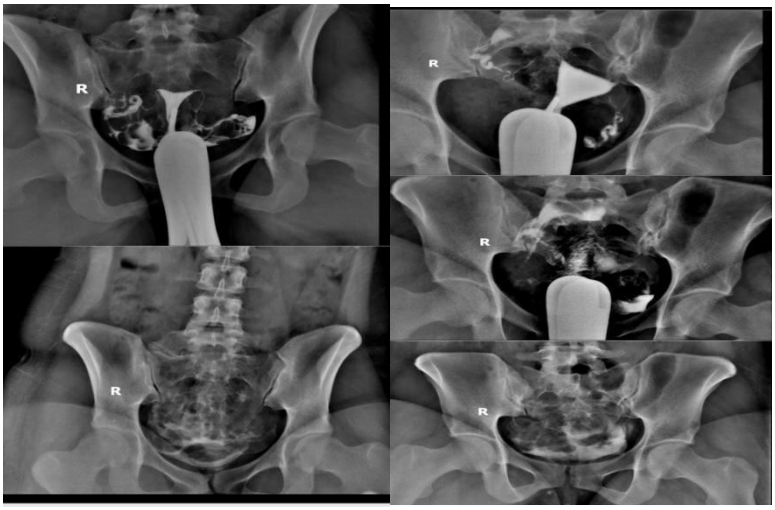

Fig. 6.Bilateral patency with normal peritoneal spill.

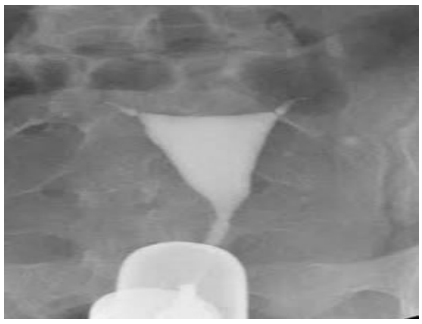

Fig.7. Bilateral block

In both groups (Group A HyFoSy and Group B HSG): If tubal patency was confirmed, patients had ovulation monitoring with or without induction of ovulation by medications; Clomid / letrozole 2.5 mg and trigger using HCG with follow up of spontaneous pregnancy during the 3months post-test. If tubal patency was not confirmed, patients were referred for laparoscopy as the gold standard.

Group C (the control group): Patients didn't have any tubal patency testing and had ovulation monitoring with or without induction of ovulation for 3 months with follow up.

Statistical analysis

The data was entered into the computer system and subsequently subjected to analysis via IBM SPSS software, specifically version 25.0, which was developed by IBM Corporation and introduced in 2017. The software used for data analysis in this research was IBM SPSS Statistics for Windows, Version 25.0, created by IBM Corp, headquartered in Armonk, New York. To represent the qualitative data, numerical values and percentages were employed. The distribution's normality was evaluated using the Kolmogorov-Smirnov test. The quantitative data were described through various statistical measures, including the range (comprising the minimum and maximum values), the mean, standard deviation, and the interquartile range (IQR). Statistical significance of the obtained results was determined using a significance threshold of 5%. The statistical tests utilized in this study included the Chi-square test and the Mann Whitney test.

Results

Regarding age, BMI, parity, type of infertility and previous pelvic surgeries; our groups were comparable without statistical difference ($p>0.05$). The duration of infertility had a mean (range) of 3.69± 2.75 (1-19) years in the HyFoSy group, 4.24± 2.21 (1- 11) years in the HSG group and 5.56± 3.18 (1- 14) years in the control groups. There was statistical significant difference between the three groups as infertility duration was longer in the control group compared to the HyFoSy group. Cervical cannulation was significantly easier to be performed in the Hyfosy procedure ($p<0.001$) as shown in **(Table.1).** The Hyfosy procedure was significantly less painful using the VAS compared to the HSG as shown in **(Fig.9).**

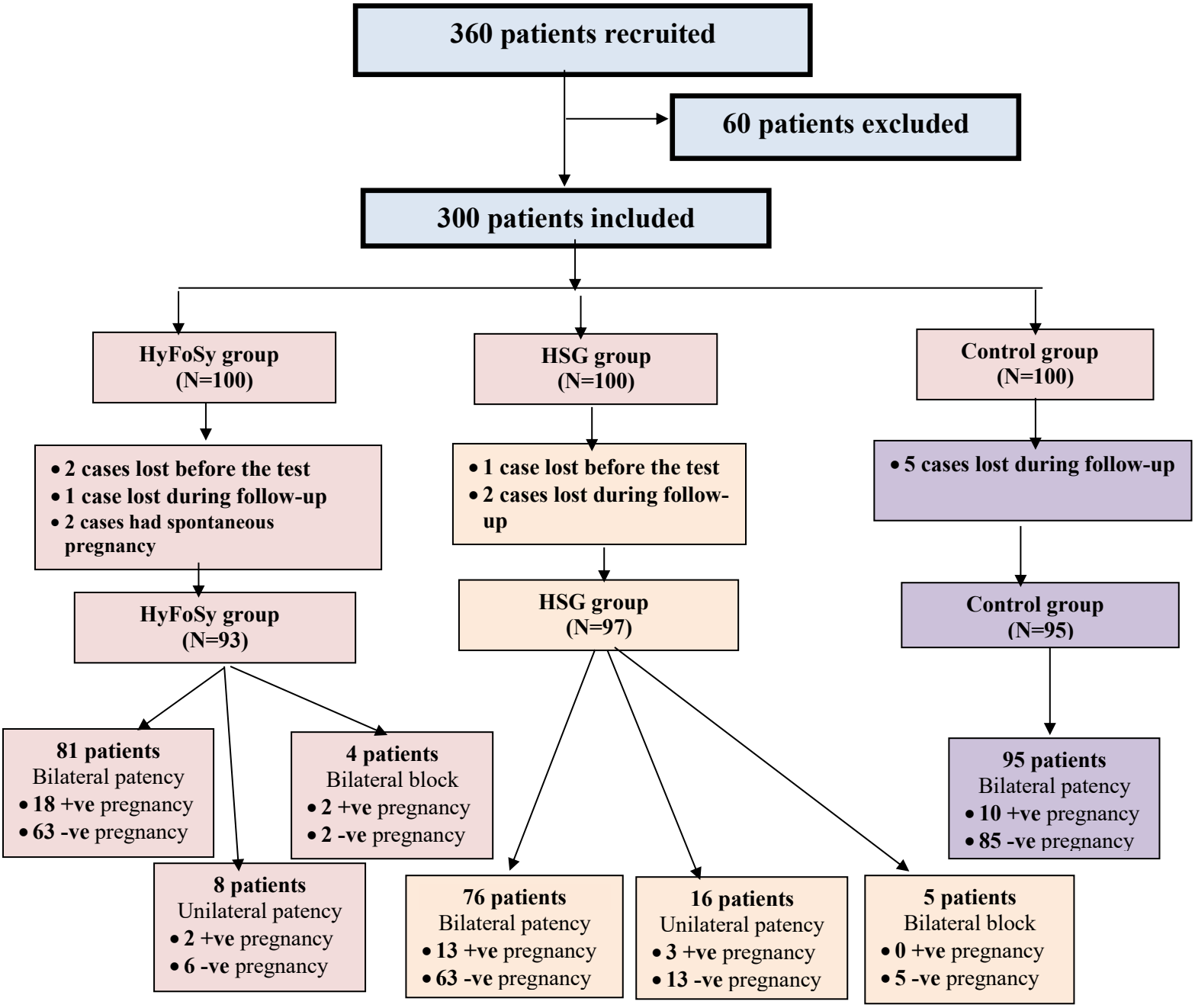

Fig.8. Flow chart of the study.

Table 1. Comparison between the studied groups regarding cervical cannulation difficulty

Variables		HyFoSy group (No.= 96)		HSG group (No.= 99)		Chi-Square test	
		No.	%	No.	%	Test value (X^2)	P-value
Cervical cannulation difficulty	Low	84	87.5%	63	63.64%	21.943	<0.001 (HS)
	Moderate	8	8.3%	24	24.24%		
	Severe	2	2.1%	12	12.12%		
	Failed	2	2.1%	0	0.0%		

p≤0.05 is significant; p≤0.01 is highly significant (HS), X^2: Chi-Square test. After exclusion of the 2 patients that had been lost before the test and the 2 patients that got spontaneous pregnancy in the HyFoSy group and the 1 patient that had been lost before the test in the HSG group.

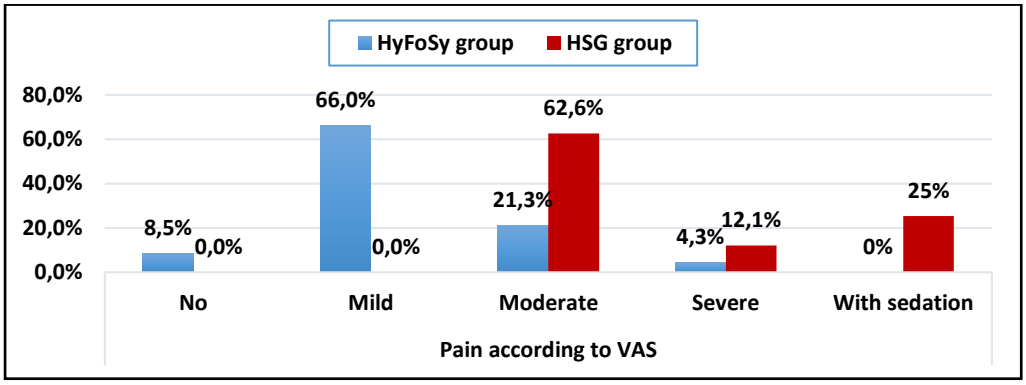

Fig.9. Comparison between the studied groups regarding pain according to VAS.

The time of the procedure, the cost and the amount of the contrast media were significantly less in the Hyfosy group compared to the HSG group (p<0.001) as shown in **(Table 2).**

Table2. Comparison between the studied groups regarding the technical parameters (cost, amount and time of test).

Variables		HyFoSy group (No.= 93)	HSG group (No.= 97)	P-value
Amount of the injected foam/dye (ml)	Mean± SD	8.10± 1.16	21.26± 2.97	<0.001 (HS)
	Range	6.0- 12.0	20.0- 30.0	
Time of test (min.)	Mean± SD	4.95± 0.81	21.41± 2.95	<0.001 (HS)
	Range	4.0- 8.0	20.0- 30.0	
Cost		100 L.E	800 L.E	<0.001 (HS)

p≤0.05 is significant; p≤0.01 is highly significant(HS), X^2: Chi-Square test

PID was reported in 2 patients in the Hyfosy group and 5 patients in the HSG group in the form of bilateral lower abdominal pain, abnormal vaginal discharge and fever. It was managed as outpatients with oral antibiotics without need for hospital admission. Hypersensitivity was

reported in only 2 patients in the Hyfosy group (fever, abdominal pain and vomiting) and 4 patients in the HSG group (itching and mild dyspnea) and in both groups it was self-limiting and managed as outpatients without need for hospital admission. Two patients in the Hyfosy group and 5 patients in the HSG group experienced vaginal spotting, for the Hyfosy patients it was few days after the procedure and resolved spontaneously, while the HSG patients it was at the site of tenaculum grasping and also stopped spontaneously. There was no hospital admission nor surgical intervention in both groups. There was no statistically significant difference between the HyFoSy & HSG groups regarding complications (p>0.05) as shown in **(Table.3)**.

Table 3. Comparison between the studied groups regarding complications

Variables		HyFoSy group (No.= 93)		HSG group (No.= 97)		P-value
		No.	%	No.	%	
Complications	PID	2	2.2%	5	5.15%	0.475 (NS)
	Hypersensitivity	2	2.2%	4	4.12%	0.683 (NS)
	Fever	2	2.2%	1	1.03%	0.615 (NS)
	Vaginal spotting	2	2.2%	5	5.15%	0.475 (NS)
	Hospital admission	0	0.0%	0	0.0%	NA

P value >0.05: Not significant (NS), P value <0.05 is significant (S), p<0.01 is highly significant (HS).Analysis done by Chi-Square test, FET: Fischer Exact Test

After 3 months, the final cases analyzed and completed the study was 93 women in HyFoSy group, 97 women in HSG group & 95 women in control group. Twenty-two (23.7%) women got pregnant in the HyFoSy group; 20 of them were clinical pregnancies; seven patients had a full term pregnancy, nine had clinical pregnancy confirmed by US "gestational sac with fetal pole inside and positive pulsations", three had clinical pregnancy ended by missed abortion, one case reported ectopic pregnancy and only two cases had chemical pregnancy. In the HSG group, sixteen (16.5%) of them got pregnant; all were clinical pregnancies, four cases had a full term pregnancy, ten cases had clinical pregnancy that confirmed by US and two cases had a clinical pregnancy ended by missed abortion. While in the control group, only ten (10.5%) women got pregnant; all were clinical pregnancies, five had full term pregnancies and three had clinical pregnancy confirmed by US and two women had missed abortions. The pregnancy rate was higher in group A, however was not statistically significant.

Discussion

Because tubal factor of infertility is thought to play a role in 12-33% of subfertile couples, assessing Fallopian tube patency is an essential step of a typical infertility work-up as reported by **Shinde et al. (2019)**.

Our groups were comparable as regards; age, BMI, parity, duration and type of infertility, previous pelvic surgeries.

Our results showed a significantly easier cervical cannulation, shorter procedure duration for the Hyfosy with less amount of pain, less cost and less amount of injected contrast material with few

self-limiting complications in both groups without need for hospital admission. The results as regards assessment of tubal patency were similar and waiting for spontaneous pregnancy resulted in non-significant higher spontaneous pregnancy rate in the Hyfosy group compared to the HSG group.

Our results were aligned with previous research by **Welie et al. (2022)** in which VAS pain scores for HyFoSy were reported by 98% (1003/1026 women) and VAS scores for HSG were reported by 93% (953/1026 women). The study showed that HyFoSy was significantly less painful than HSG**. Situmorang et al. (2020)** conducted a study involving twenty subfertile Indonesian females who were examined by HSG and subsequent HyFoSy to demonstrate tubal patency with a minimum interval of 48 hours. It was found that the mean VAS score for HyFoSy was significantly lower at 1.8 ± 1.4 compared to HSG, which had a mean VAS score of 5.4 ± 2.4**.**

Dreyer et al. (2014) conducted a randomized controlled trial involving 40 subfertile women, comparing VAS pain scores during tubal patency testing using HyFoSy and serial HSG. This study reported a lower VAS score for the HyFoSy group (1.7 cm) compared to the HSG group (3.7 cm) ($P<0.01$). Additionally, their study found that the HyFoSy procedure had a significantly shorter duration, with a median duration of 5.0 minutes, in contrast to HSG which had a median duration of 12.5 minutes**.** Furthermore, **Serrano et al. (2022)** conducted a study that agreed with our findings regarding pain scores, cervical cannulation difficulty and the amount of injected contrast material. Their study which included 99 patients in the HSG group and 111 patients in the HyFoSy group, reported that the median pain intensity was lower in the HyFoSy group compared to the HSG group. Cervical cannulation difficulty was also significantly easier in the HyFoSy group, with high difficulty was observed in only 1.9% of HyFoSy patients compared to 6.9% of HSG patients. Additionally, the contrast media volume instilled was significantly lower in the HyFoSy group (4.5 ± 2 ml/patient) compared to the HSG group (8.8 ± 4.1 ml/patient)**.**
In terms of tubal patency status, our study found no statistically significant difference between the two groups, which is consistent with the findings of **Serrano et al. (2022)**. On the other hand, a study by **Schoubroeck et al. (2013)** aimed to determine the accuracy of HyFoSy in assessment of tubal patency compared to laparoscopy. Their study, which involved 20 subfertile women scheduled for laparoscopic chromopertubation, revealed 100% agreement between tubal patency data obtained through HyFoSy testing and laparoscopic chromopertubation testing, so they concluded that HyFoSy was both feasible and accurate for diagnosing tubal patency**.**

In our study, we found minimal complications in both groups, which were self-limiting and didn't require hospital admission. **Schoubroeck et al. (2015)** conducted a study involving 216 patients who had HyFoSy and reported that 92.1% of participants experienced only tolerable pain as the worst side effect.

In contrast to our findings, **Situmorang et al. (2020)** observed no hypersensitivity reactions or severe adverse effects in the 20 Indonesian women who had HyFoSy or HSG procedures**. Emanuel et al. (2012)** examined 73 patients with subfertility and low risk of tubal pathology using

HyFoSy and HSG and reported that five patients (7%) experienced vasovagal discomfort during or after the procedure, which resolved spontaneously with time**.**

Our results, after a 3-month follow-up, showed that 93 women in the HyFoSy group, 97 in the HSG group, and 95 in the control group completed the study. In the HyFoSy group, 23.7% of women achieved spontaneous pregnancy, while in the HSG group, 16.5% achieved pregnancy. The control group had only 10.5% of women got pregnant as shown in the study flow chart in **(Fig. 8)**. Although the pregnancy rate was higher in the HyFoSy group, it didn't reach the statistical significance. A study by **Welie et al. (2022)** reported that in cases of discordant results between HyFoSy and HSG, the choice of management based on either procedure yielded similar pregnancy outcomes.

Finally, we have to mention the limitations that we faced in our study. The short period of follow up as it was 3 months only after the procedure and some cases got pregnant beyond this, and this was in a line with **Engles et al. (2023**) who reported in their study that patients spent a median of 4 months after tubal patency testing to achieve spontaneous pregnancy. Also**,** HSG is a well-established screening test for tubal patency, but has many disadvantages as high cost and radiation exposure, so we designed this research to compare Hyfosy with HSG in all aspects, however data regarding both tests performance for evaluation of tubal patency status must be taken cautiously because we didn't compare each test with the standard diagnostic test (laparoscopy with chromotubation). On the other side, the points of strength in our study depended mainly on the study design as a randomized controlled study, also the large sample size included in the research. So we recommend further future studies with longer period of follow up and comparison with the gold standard laparoscopy.

Conclusion

Transvaginal ultrasound using Hysterosalpingo-Foam Sonography (HyFoSy) in assessment of tubal patency in subfertile patients can be used as one step fertility scan as we can assess the uterine cavity, tubal patency and the ovarian reserve by AFC at the same time. It is safe, cost effective, less painful, shorter procedure duration, no radiation exposure outpatient method compared to the HSG.

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