



## Comparing the Efficacy of Sonosalpingography and Hysterosalpingography in Detecting Tubal and Uterine Pathology in Infertile Women

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#### ABSTRACT

Infertility, defined as the inability to conceive after a year of regular intercourse, poses psychological and societal challenges. In India, tubal factors contribute significantly, linked to conditions like pelvic inflammation and tuberculosis. Traditional methods like Hysterosalpingography (HSG) come with limitations. Sonosalpingography (SSG), a saline-based ultrasound procedure, offers a cost-effective and radiation-free alternative. Dr. Richman championed SSG's reliability. This study highlights SSG's value in tubal assessment, aiming to reduce radiation exposure, lower costs and promote SSG as a primary diagnostic tool for female infertility. SSG simplifies initial assessments and may revolutionize infertility diagnosis and management. This Prospective comparative study, conducted from June 2019 to October 2020 at the Outpatient Department (OPD) of the Department of Obstetrics and Gynaecology, Government Maternity Hospital in Warangal, focused on women with primary or secondary infertility. 50 cases were included. Husbands' seminal parameters were assessed and male factors were excluded as contributors to infertility during subject selection. Among the 50 cases, 84% had primary infertility and 16% had secondary infertility, including those with prior pregnancies. Most patients were aged 21-30, a peak fertility period. In primary infertility, marriage durations ranged from 1-9 years, while secondary infertility primarily lasted 2-3 years for 75% of cases. Diagnostic results showed that 90% had patent fallopian tubes via sonosalpingography, 4% had bilateral blockage and 6% had unilateral blockage. Hysterosalpingography yielded consistent results. Uterine anomalies were identified in 4% of cases. Both procedures demonstrated similar outcomes, with 88% agreement on tubal patency. A strong positive correlation ( $r = 0.804$ ,  $p < 0.001$ ) was observed between the two methods. SSG offers an accessible, time-efficient and cost-effective outpatient option, avoiding anesthesia and radiation risks, with diagnostic accuracy comparable to hysteroscopy and laparoscopy. SSG can serve as an initial patency test, with radiographic salpingography as a follow-up if needed, streamlining infertility evaluations and emphasizing the importance of avoiding unnecessary tests for vulnerable couples.

## INTRODUCTION

Infertility is a complex medical condition, often defined as the inability to conceive despite engaging in regular, unprotected sexual intercourse for a period of one year. It is important to recognize that infertility does not necessarily imply complete sterility; instead, it refers to a reduced ability to achieve pregnancy. Typically, a vast majority (approximately 85-90%) of healthy young couples are able to successfully conceive within the first year of trying, with a significant portion conceiving within the initial six months<sup>[1]</sup>.

The ability to reproduce is a fundamental biological function in females and when this natural process fails, it can lead to considerable psychological distress and societal challenges, including shifts in social status and personal well-being<sup>[2,3]</sup>.

In India, tuboperitoneal factors are a significant contributor to female infertility, accounting for approximately 30-40% of cases. Several factors contribute to this high prevalence. Notably, conditions such as pelvic inflammatory disease, genital tract tuberculosis and chronic infections are relatively common in our region. These conditions often result in tubal damage or obstruction, making tubal factors a prominent cause of infertility in Indian women<sup>[4-6]</sup>.

The history of assessing tubal factors in infertility dates back to 1920 when Rubin introduced the tubal insufflation test, utilizing carbon dioxide (CO<sub>2</sub>). Over time, various methods have been developed to evaluate the condition of the fallopian tubes. Two of the most widely used techniques are Hysterosalpingography (HSG) and laparoscopic chromopertubation. These methods have proven effective in diagnosing tubal issues but come with their own limitations and costs<sup>[6-8]</sup>.

A more recent development in the field of tubal evaluation is sonohysterosalpingography, commonly referred to as sonosalpingography (SSG). This method involves the use of saline as a contrast medium during ultrasound imaging to assess tubal patency. It's important to note that Dr. Richman from the United States was a pioneer in introducing and advocating for SSG as a reliable, straightforward and well-tolerated outpatient procedure for evaluating tubal patency. One notable advantage is that SSG can be performed without the need for prophylactic antibiotics, making it a more accessible and cost-effective option compared to HSG, which often requires the use of expensive catheters<sup>[9,10]</sup>.

The primary goal of this study is to emphasize the value of pelvic sonography (ultrasound) as a means to assess tubal patency. This approach is driven by several factors, including the desire to reduce radiation exposure associated with HSG, lower the overall cost of infertility examinations and promote the adoption of SSG as a first-line diagnostic procedure for female

infertility. The study aims to evaluate the feasibility and accessibility of SSG as a reliable alternative to traditional methods for tubal evaluation<sup>[8-11]</sup>.

SSG represents a simple and convenient office-based procedure that can serve as an initial assessment tool for evaluating the uterine cavity and fallopian tubes. By integrating SSG into the diagnostic process, it may be possible to reduce the dependency on HSG, thus minimizing both patient radiation exposure and the financial burden associated with more complex diagnostic procedures<sup>[11,12]</sup>.

In summary, this study underscores the significance of SSG in assessing tubal patency and reducing the drawbacks associated with traditional methods. It seeks to promote SSG as a valuable, cost-effective and accessible tool in the diagnosis of female infertility, potentially revolutionizing the way we approach and manage infertility cases in clinical practice.

## Aim and objectives

### Aim of the study:

- To assess and compare the accuracy, positive predictive value and overall effectiveness of SSG in comparison to hysterosalpingography for the evaluation of tubal and uterine factors in infertile patients
- To investigate the specificity and reliability of SSG as a minimally invasive screening tool for assessing tubal patency and identifying uterine structural anomalies in infertile patients

### Objectives:

- To conduct a comprehensive assessment of the uterine and fallopian tube structures using transvaginal ultrasonography and to appraise the effectiveness of SSG in comparison to HSG for the detection of fallopian tube patency
- To ascertain the viability of employing SSG, a less intrusive diagnostic method, as the primary means for evaluating tubal and uterine factors in cases of both primary and secondary infertility, thus potentially supplanting the use of invasive procedures such as hysterosalpingography, which carries a notable burden of morbidity and, in rare instances, mortality

## MATERIALS AND METHODS

**Study design:** This research was undertaken at the Outpatient Department (OPD) of the Department of Obstetrics and Gynaecology, Government Maternity Hospital in Warangal, spanning from June 2019 to October 2020. From the pool of women seeking care at the gynaecology OPD, individuals experiencing either primary or secondary infertility were meticulously chosen as study subjects. This selection process

involved a thorough assessment of the seminal parameters in the husbands while ensuring the exclusion of male factors contributing to infertility

**Study population:** The study cohort comprised individuals carefully screened to align with the precise inclusion criteria tailored to the research goals. These inclusion and exclusion criteria were meticulously delineated to discern eligible participants. For instance, in cases where the study honed in on a specific medical ailment, individuals afflicted with that condition were incorporated, while those presenting contraindications or concurrent medical conditions that could potentially introduce confounding variables were systematically omitted.

**Inclusion criteria:** To be eligible for participation in this study, patients had to meet the following specific criteria: Individuals experiencing infertility within the age range of 20-35 years. Patients who willingly consented to participate in the study.

**Exclusion criteria:** Patients not meeting the outlined criteria were excluded from the study for the following reasons: Individuals below the age of 20 or above the age of 35, those presenting with an active pelvic inflammatory disease, patients with cervical pathology, such as polyps or cervical stenosis, individuals displaying hypersensitivity to contrast agents, patients with coexisting medical conditions such as hypertension, diabetes mellitus and epilepsy, patients with a documented history of tubal surgery.

In all cases, comprehensive medical histories were meticulously collected, focusing on the nature and duration of infertility. Particular attention was given to identifying potential etiological factors such as pelvic inflammatory disease (PID), tuberculosis (TB) and previous surgical interventions. Menstrual histories, obstetric records (in cases of secondary infertility) and pertinent personal and past medical histories were meticulously documented. Additionally, inquiries were made regarding any male factor contributions to infertility.

Furthermore, each patient underwent a thorough general, abdominal and bimanual pelvic examination to detect any overt pathologies. Vital signs were diligently recorded and basic laboratory investigations were conducted.

Routine tests, including semen analysis for the husband and other relevant diagnostic assessments were administered to all study participants. Subsequently, SSG was performed during the post-menstrual preovulatory phase (Day 8), while hysterosalpingography was conducted on Day 10, in collaboration with the Radiology Department.

**Data management and analysis:** The data gathered was meticulously arranged and securely stored, strictly in compliance with data protection and confidentiality protocols. The process of data management encompassed encoding, input into electronic databases and rigorous scrutiny to identify and rectify any discrepancies or inaccuracies. For the subsequent data analysis, specialized statistical software like Statistical Package for Social Sciences (SPSS) for Windows software IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) or R was employed, with the choice of specific statistical tests or models being contingent upon the research inquiries at hand. This encompassed the use of descriptive statistics, inferential statistics, regression analysis, or any other pertinent analytical techniques as necessitated by the research objectives.

**Ethical considerations:** Prior to the commencement of this study, rigorous adherence to ethical protocols was upheld. Ethical clearance was meticulously sought and duly granted by the Institutional Review Board (IRB) or Ethics Committee of Kakatiya Medical College, Warangal strictly in compliance with the highest standards and guidelines governing research involving human subjects. To further uphold the ethical integrity of the study, the process of informed consent was conscientiously administered to all prospective participants. This entailed providing comprehensive information about the study's objectives, potential risks and benefits. Importantly, each participant was accorded the opportunity to ask questions and seek clarifications. Their voluntary commitment to participate, devoid of any coercion, was explicitly and unequivocally affirmed through the signed informed consent documentation. This process ensured that participants engaged in the study of their own volition, fully aware of the study's implications and in a manner entirely consonant with ethical principles.

## RESULTS

### Infertility

**Primary and secondary infertility:** Among the 50 cases encompassed within this study, a significant majority, constituting 84% (42/50), presented with primary infertility, while a smaller fraction, accounting for 16% (8/50), experienced secondary infertility. Notably, within the group of patients grappling with secondary infertility, two individuals endured three spontaneous abortions, one patient faced one abortion and a prior full-term delivery, while the remaining five patients had previously undergone full-term deliveries. Delineating the demographics, it is discerned that 4.76% (2/42) of women grappling with primary infertility in the study cohort were of the age of 20. Furthermore, 33.33% (14/42) fell within the age

bracket of 21-25 years, 47.62% (20/42) resided within the age group ranging from 26-30 years and 14.29% (6/42) were between the ages of 31-35 years. Among women grappling with secondary infertility within the study group, 25% (2/8) were within the age group of 21-25 years, 50% (4/8) fell within the age bracket of 26-30 years, 25% (2/8) belonged to the age group of 31-35 years, with no patients in the 20-year age range. The preponderance of individuals in the study cohort was concentrated within the age group of 21-30 years, a period characterized by peak fertility rates.

Delving deeper into the realm of primary infertility, it is worth noting that 9.5% (4/42) of the study group had a marital duration of one year. Of these, 38% (16/42) had been married for 2-3 years, 40.5% (17/42) for 4-5 years, 7.1% (3/42) for 6-7 years and 4.7% (2/42) for 8-9 years. Concerning secondary infertility, 75% (6/8) of the study group experienced infertility for a duration of 2-3 years, while 25% (2/8) had grappled with infertility for a duration of 8-9 years (Table 1-4).

Turning to the results obtained through the diagnostic procedures, in a substantial 90% (45/50) of the study group, the SSG displayed tubes that appeared echogenic while the contrast agent traversed through them. Furthermore, the contrast spillage from the fimbrial end manifested as a "shower" within the intraperitoneal cavity, accompanied by the presence of periovarian fluid on both sides, collectively indicating the patent status of both fallopian tubes. In contrast, 4% (2/50) of cases exhibited a lack of echogenic tubes and spillage on both sides, signifying bilateral tubal blockage. Additionally, 6% (3/50) of cases unveiled

unilateral tubal blockage, with one-third displaying blockage on the right side and two-thirds on the left side. Employing hysterosalpingography, an impressive 92% (46/50) of the study group exhibited peritoneal spillage on both sides, once again confirming the patency of both fallopian tubes. Conversely, 4% (2/50) of cases showcased an absence of peritoneal spillage on both sides, indicative of bilateral tubal blockage. Lastly, in 4% (2/50) of cases, unilateral tubal blockage was identified, solely on the right side.

Furthermore, the diagnostic procedures succeeded in identifying certain uterine anomalies, a phenomenon that was consistently demonstrable with both SSG and HSG. Specifically, septate uterus with bilateral tubal block was discerned in 2% (1/50) of patients using both methods, while unicornuate uterus was observed in 2% (1/50) of patients through both diagnostic approaches (Table 1-4).

**Comparative study between the two procedures:** The comparative analysis between these two procedures revealed striking similarities in the outcomes.

Table 1: Type of Infertility

Type	No.	Percentage	Mean age
Primary	42	84	26.5
Secondary	8	16	27.6
Total	50	100	-

Table 2: Age group-type of infertility

Age (years)	No. of cases		Percentage (%)	
	Primary	Secondary	Primary	Secondary
20	2	0	4.76	0
21-25	14	2	33.33	25
26-30	20	4	47.62	50
31-35	6	2	14.29	25
Total	42	08	100.00	100

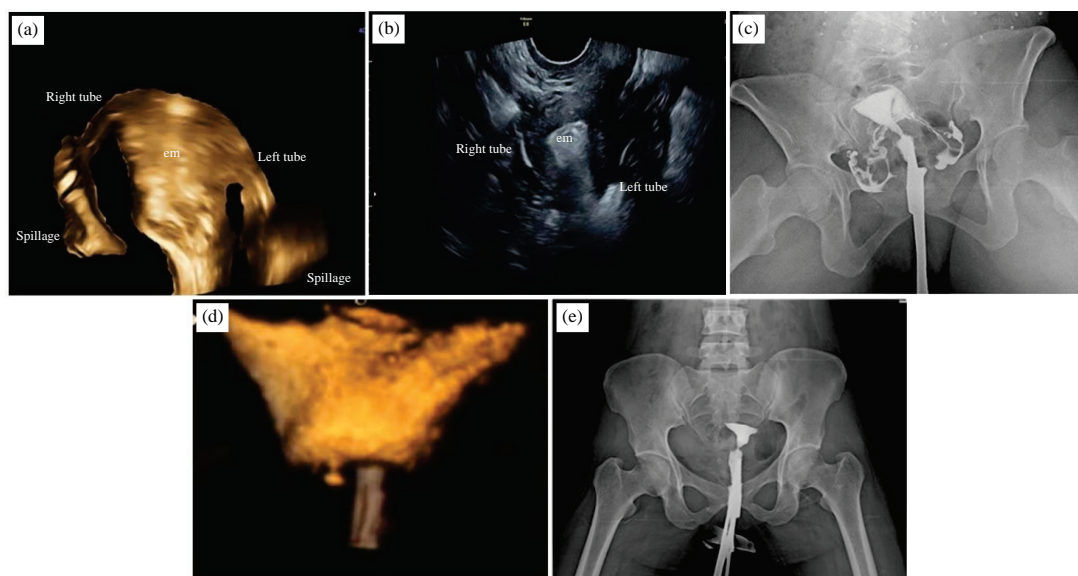


Fig. 1 (a-e): SSG and HSG images: Normal vs tubal block condition (a) Normal study in SSG (3-D), (b) Normal tubes in SSG (2-D), (c) Normal HSG (bilateral patent tubes), (d) Bilateral tubal block in SSG and (e) Bilateral tubal block in HSG

Table 3: Duration of infertility

Duration in years	No. of cases		Percentage (%)	
	Primary	Secondary	Primary	Secondary
1	4	Nil	9.52	-
2-3	16	6	38.10	75
4-5	17	2	40.48	25
6-7	3	Nil	7.14	-
8-9	2	nil	4.76	-
10-11	nil	nil	-	-
Total	42	08	100.00	100
Mean duration (year)	3.6	3.2	3.60	3.2

Table 4: Tubal patency-diagnosis by SSG and HSG

Results	SSG		HSG	
	No.	Patients (%)	No.	Patients (%)
Presence of peritoneal spill (periovarian fluid)	45	90	46	92
No peritoneal spill (no periovarian fluid)	5	10	4	8
Total	50	100	50	100

Table 5: Comparing the results of SSG and HSG

Procedure	Patent		Not patent	
	No.	Percentage	No.	Percentage
SSG	45	90	5	10
HSG	46	92	4	8

Table 6: SSG Vs HSG: True positives (TP), True negatives (TNs), False positives (FP), false negatives (FNs)

	HSG		
	Normal	Abnormal	Total
SSG			
Normal	44 (TP)	1 (FP)	45
Abnormal	2 (FN)	3 (TN)	5
Total	46	4	50

Table 6: HSG and SSG: mean, SD, t-value and p-value

Test variables	HSG		SSG		t-value	p-value
	Mean	SD	Mean	SD		
Spillage	1.1600	0.61809	1.2200	0.70826	-1	0.32 (NS)

Table 7: HSG and SSG: Comparisons of p-value

Comparison groups	Pearson's correlation coefficient (r)	p-value
HSG- SSG	0.804	<0.001*

Impressively, in 88% (44/50) of cases, both SSG and HSG concurred in demonstrating tubal patency. In 4% (2/50) of cases, a bilateral tubal blockage was unequivocally identified by both diagnostic methods. Furthermore, in 2% (1/50) of cases, unilateral tubal blockage was consistently observed, presenting as blockage on the right side in both SSG and HSG. Interestingly, in 4% (2/50) of cases, a nuanced discrepancy emerged, wherein SSG detected a blockage on the left side of the fallopian tube, whereas hysterosalpingography portrayed patent tubes on both sides (Table 4, 6 and Fig. 1). Similarly, in 2% (1/50) of cases, SSG indicated tubal patency on both sides, while hysterosalpingography specifically identified right tubal blockage. High positive correlation was found when two groups (HSG and SSG) were compared, as the person's correlation coefficient  $r = 0.804$  and the  $*p < 0.001$  which is significant (Table 7).

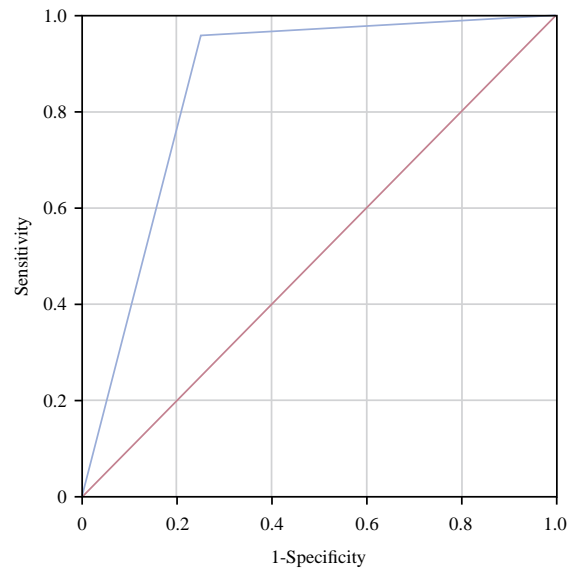


Fig. 2: ROC curve for calculating specificity, sensitivity and diagnostic accuracy for SSG and HSG

The diagnostic precision of Sonosalpingography was meticulously evaluated, with HSG serving as the gold standard for comparison. The results yielded an impressive Area Under the Curve (AUC) of 0.83, accompanied by a significant  $*p$ -value of 0.020. These findings unequivocally indicate that Sonosalpingography boasts an exceptional level of diagnostic accuracy, falling within the category of "excellent" or "good" (Fig. 2).

## DISCUSSIONS

Infertility represents a significant global health concern, impacting approximately 8-10% of couples worldwide. Among the staggering 60-80 million couples grappling with infertility each year on a global scale, it's estimated that a substantial 25%, which equates to roughly 15-20 million cases, originate in India alone. This alarming trend, as highlighted in a report by the World Health Organization (WHO), indicates that one out of every four couples in developing countries contends with infertility. Such pervasive infertility issues underscore the need for immediate intervention, especially when considering that many infertility cases are preventable [6,11,13-19,20-22]. Within the realm of tubal infertility management, assessing tubal patency plays a pivotal role. Tubal disease encompasses a broad spectrum of pathologies, including obstruction, stenosis, dilatation and impaired peristaltic function, resulting from anatomical alterations in the fallopian tubes due to conditions such as salpingitis, adenomyosis, or previous surgical procedures [23-27].

In our study, we utilized two distinct procedures for testing tubal patency: SSG and HSG. We meticulously examined the outcomes obtained from



Table 8: Findings From other research groups vs our study

Study groups	Year	Sensitivity	Specificity	PPV	NPV
Kore <i>et al.</i> <sup>[31]</sup> Journal of obst. and Gyn, India	2000	100	83	97	100
Oguntoyinbo <i>et al.</i> <sup>[30]</sup> African Journal of Rep. Health	2001	85.5	96.8	98.3	75
Radic <i>et al.</i> <sup>[30]</sup> Eur. J. Radiol.	2005	100	88	100	97
Kulkarni <i>et al.</i> <sup>[32]</sup> Int. J. Reprod. Contracept Obstet Gynecol.	2016	100	84.6	94.8	100
Kumari <i>et al.</i> <sup>[32]</sup> Int. J. Reprod Contracept Obstet Gynecol.	2018	84.7	92.8	97.5	65
Our hospital study	2023	97.6	75	97.7	60

each procedure. Our study enrolled 50 infertile women who were registered at the Department of Obstetrics and Gynaecology, Government Maternity Hospital in Hanumkonda, spanning from June 2019 to October 2020. Each patient underwent SSG on Day 8 and hysterosalpingography on Day 10 in the Radiology Department. Analysis of the age distribution of women with infertility revealed intriguing insights. Four percent (2/50) of women in the study group were 20 years old, while 32% (16/50) fell within the 21-25 age bracket. Additionally, 48% (24/50) were in the age group ranging from 26-30 years and the remaining 16% (8/50) were between 31 and 35 years old. Notably, the majority of the study group (80%) was within the prime fertility window of 21-30 years. Among the various factors contributing to infertility, the tubal factor played a significant role, accounting for 45% of infertility cases. Within the cohort of 50 cases studied, 84% (42/50) presented with primary infertility, whereas only 16% (8/50) experienced secondary infertility. It is worth noting that primary infertility is the predominant concern among infertile couples globally.

The duration of infertility varied within the study group, ranging from 2-9 years. In our study, SSG effectively identified tubal patency in 90% (45/50) of patients, as evidenced by the visualization of echogenic tubes during the passage of the contrast agent, along with the spill of contrast into the intraperitoneal cavity, resembling a "shower." Conversely, in 10% (5/10) of patients, echogenic tubes and spill were not observed, indicating tubal blockage. In 4% (2/50) of cases, bilateral tubal blockage was evident, with no echogenic tubes or spill observed on both sides. Additionally, 6% (3/50) exhibited unilateral tubal blockage, with one-third of these cases showing blockage on the right side and two-thirds on the left side. In the occluded tubes, there was an increased resistance felt during the contrast injection due to backflow. These findings align closely with a study by Rao *et al.*<sup>[23]</sup> which utilized 3D Hycosy with lignocaine as a contrast agent for tubal patency assessment. In that study, 89.03% of cases demonstrated bilateral tubal patency, 9.42% displayed unilateral tubal occlusion and 1.53% exhibited bilateral tubal occlusion. Conversely, when the same patients underwent HSG, 92% (46/50) exhibited peritoneal spill on both sides, indicating the patency of both fallopian tubes. In 4% (2/50) of cases, peritoneal spill was absent

on both sides, signaling bilateral tubal blockage. Furthermore, 4% (2/50) of patients experienced unilateral blockage on the right side.

Additionally, SSG and HSG were instrumental in identifying certain uterine anomalies. For instance, septate uterus with bilateral tubal block was identified in 2% of patients using both procedures and unicornuate uterus was identified in another 2% of patients through both methods. Uterine anomalies contributing to infertility may be congenital or a result of exposure to diethylstilbestrol (DES). Mullerian duct fusion anomalies could also come into play. Comparing the efficacy of both procedures in identifying tubal blockage, our study revealed consistent results. It is noteworthy that our study employed a low concentration (0.2%) of lignocaine for sonographic examination of tubal patency. Lignocaine, a sterile aqueous product, has been deemed safe for various applications, including vaginal, intrauterine and intraperitoneal use<sup>[25-29]</sup>. The safety margin is notably ample, considering that the peak lidocaine concentration observed after a 10% local lidocaine application for vaginal use is considerably lower than concentrations required for antiarrhythmic purposes. Hence, the chances of systemic toxicity are exceedingly low<sup>[30-32]</sup>.

Some patients reported mild discomfort, which was effectively alleviated with simple analgesics. Importantly, no major complications or infections were recorded and there were no instances of syncopal attacks.

## CONCLUSION

Transvaginal sonography is essential for assessing female infertility, offering superior resolution to examine crucial factors like follicular development, ovulation and peritoneal fluid with added Doppler capabilities. In contrast, SSG is a straightforward office procedure that eliminates the need for iodinated contrast and radiation concerns, excelling in exploring intramural and adnexal pathologies. However, SSG has limitations, occasionally yielding misleading impressions of tubal patency in tubal flow evaluation, necessitating careful interpretation. Hysterosalpingogram remains the premier method for assessing fallopian tube patency, despite drawbacks such as pain, dye intravasation and granuloma formation.

In conclusion, SSG offers an easily accessible, time-efficient and cost-effective outpatient option, avoiding anesthesia, radiation and allergic risks, with diagnostic accuracy comparable to hysteroscopy and laparoscopy, making it a superior screening procedure for infertility investigations. SSG can also serve as an initial patency test for infertile women, with radiographic salpingography as a complementary procedure in inconclusive cases. This streamlined approach significantly reduces the time and financial burden of infertility evaluations, emphasizing the importance of avoiding unnecessary, costly tests for vulnerable couples.

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