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Comparative Analysis of Pain Intensity and Patient Tolerability in Saline Infusion Sonography versus Hysterosalpingography

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ABSTRACT

Background: Infertility evaluation often requires assessment of the uterine cavity and tubal patency. Conventional hysterosalpingography (HSG) remains widely used but is associated with discomfort, radiation exposure, and procedural complications. Saline infusion sonography (SIS) has emerged as a less invasive alternative.

Aim: To perform a comparative analysis of pain intensity and patient tolerability between SIS and HSG in women undergoing infertility evaluation.

Methods: A prospective cohort of women presenting for infertility evaluation underwent both SIS and HSG. Pain intensity was measured using a visual analogue scale (VAS), while acceptability was assessed through patient feedback. Diagnostic accuracy was determined by comparing findings with laparoscopy or clinical follow-up.

Results: The mean age of participants was 27.3 ± 4.9 years, with nearly half (48.7%) falling in the 20–25-year age group. Primary infertility was the predominant presentation, observed in 80.7% of women, while secondary infertility accounted for 19.3%. Pain scores were significantly lower in the SIS group, with 94.7% reporting mild discomfort, compared with 94.7% of HSG patients reporting moderate pain and 4% reporting severe pain ($p<0.001$). SIS was rated as acceptable by 82% of participants, compared to 35% for HSG ($p < 0.001$).

Conclusion: SIS offers a patient-friendly, radiation-free, and diagnostically reliable alternative to HSG. Its higher acceptability and reduced pain intensity make it a practical first-line screening tool in infertility evaluation.

Keywords: Saline infusion sonography; Hysterosalpingography; Tubal patency; Infertility evaluation; Patient acceptability

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INTRODUCTION

Infertility is a global health concern, affecting nearly 10–15% of couples of reproductive age and often associated with profound psychological and social consequences. Among the various etiologies, tubal pathology accounts for 20–40% of female infertility, necessitating accurate evaluation of tubal patency before initiating treatment strategies.[1,2] Traditionally, hysterosalpingography (HSG) has been widely employed as a first-line diagnostic tool. However, despite its diagnostic utility, HSG is associated with significant drawbacks, including radiation exposure, risk of pelvic infection, and considerable patient discomfort due to cervical manipulation and uterine distension.[3,4] These limitations have prompted the exploration of safer, less invasive alternatives.

Saline infusion sonography (SIS) has emerged as a promising modality for evaluating both the uterine cavity and tubal patency. SIS offers multiple advantages over hysterosalpingography HSG, including its simplicity, lower cost, minimal invasiveness, and avoidance of ionising radiation. In addition, SIS provides high diagnostic accuracy and allows more precise characterisation of intrauterine masses.[5] The technique involves instilling sterile saline into the uterine cavity, followed by transvaginal ultrasonography to assess intrauterine abnormalities and tubal patency. Importantly, SIS has been reported to cause significantly less pain and discomfort compared to HSG, making it more acceptable to patients undergoing infertility evaluation.[6,7]

Pain perception during infertility investigations is not merely a procedural inconvenience; it has broader implications for patient compliance, psychological well-being, and willingness to undergo repeated diagnostic interventions. Studies consistently demonstrate that HSG is associated with moderate to severe pain in the majority of patients, whereas SIS is predominantly linked to mild discomfort.[8,9] For instance, Ganai et al. reported that 71.6% of women undergoing SIS experienced only mild pain (VAS 1–3), compared with 8.9% in the HSG group, with most patients reporting moderate pain (VAS 4–6).[10] Similarly, Rezk and Shawky found that SIS was not only better tolerated but also associated with higher patient satisfaction and fewer complications.[11]

The tolerability of SIS is particularly relevant in resource-limited settings, where patient acceptance of procedures directly influences the success of infertility workups. In regions such as North-East India, where healthcare infrastructure and patient awareness may be constrained, a diagnostic modality that combines accuracy, safety, and comfort is invaluable. Furthermore, the psychological burden of infertility is compounded by painful diagnostic experiences, underscoring the need for approaches that minimise distress.[12]

Despite these advantages, SIS is not without limitations. Its diagnostic accuracy for tubal patency may vary, and certain subtle intrauterine abnormalities may require confirmation by hysteroscopy or laparoscopy. Nevertheless, the marked reduction in pain intensity and improved patient tolerability position SIS as a strong candidate for first-line evaluation, reserving HSG for cases requiring further anatomical clarification.[13]

This article focuses specifically on the comparative analysis of pain intensity and patient tolerability between SIS and HSG, highlighting the importance of patient-centred diagnostic strategies in infertility care. The aim of this study was to perform a comparative analysis of pain intensity and patient tolerability between SIS and HSG in women undergoing infertility evaluation.

MATERIALS AND METHODS

Study Design and Setting

This was an observational cross-sectional study conducted in the Department of Obstetrics and Gynaecology at Agartala Government Medical College and G.B. Pant Hospital, Tripura, India. The study was carried out over 18 months, from September 2023 to February 2025.

Study Population

Women aged 20–40 years presenting with infertility to the outpatient department were considered eligible. Infertility was defined as the inability to conceive after at least one year of regular, unprotected intercourse.

Inclusion and Exclusion Criteria

- **Inclusion criteria:** Women aged 20–40 years with primary or secondary infertility.
- **Exclusion criteria:** Women younger than 20 or older than 40 years, those with ongoing or recent pelvic inflammatory disease, acute vaginal bleeding, genital tract malignancy, or those unwilling to provide informed consent.

Sample Size and Sampling

Out of 240 infertile women screened during the study period, 150 participants fulfilled the inclusion criteria. A non-probability sampling technique was used. Participants were randomly allocated to two equal groups (n=75 each) using a token-based randomisation method: one group underwent HSG, and the other underwent SIS.

Procedure of Hysterosalpingography (HSG)

HSG was performed between the 8th and 10th day of the menstrual cycle to minimise interference with early pregnancy and optimise visualisation. After aseptic preparation, a size 10 plain rubber catheter was inserted into the uterine cavity. A 2–10 ml volume of Urografin 76% (ionic, monoisomeric, triiodinated contrast medium) was instilled. Radiographs were taken to assess peritoneal spillage and tubal patency. Patients were observed for one hour post-procedure and discharged with antispasmodics and antibiotics.

Procedure of Saline Infusion Sonography (SIS)

SIS was performed after bladder emptying and aseptic preparation. An 8 French Pediatric Foley catheter was introduced into the uterine cavity, and the bulb was inflated with 2–3 ml of distilled water. A baseline transvaginal ultrasound was performed using a Mindray Z5 machine. Approximately 30–40 ml of sterile saline mixed with air was instilled to distend the uterine cavity. Tubal patency was confirmed by observing the "waterfall sign," i.e., saline-air mixture flowing past the ovary into the pouch of Douglas.

Pain Assessment

Pain intensity was assessed immediately after each procedure using the Visual Analogue Scale (VAS), a 10-cm line anchored at "no pain" (0) and "worst imaginable pain" (10). Scores were categorised as:

- 0 = no pain
- 1–3 = mild pain
- 4–6 = moderate pain
- 7–10 = severe pain.

Data Collection and Analysis

Demographic, clinical, and procedural data were collected using a semi-structured proforma. Pain scores were recorded for each participant. Data were entered into Microsoft Excel and analysed using SPSS version 26.0. Descriptive statistics (mean, SD, and percentages) were used to describe baseline characteristics. The chi-square test was used to compare pain intensity between groups, with $p < 0.05$ considered statistically significant.

Ethical Considerations

The study protocol was approved by the Institutional Ethical Committee of Agartala Government Medical College (Ref. No. F.4(6-13)/AGMC/Medical Education/IEC Approval/2022/22309). Written informed consent was obtained from all participants in their preferred language (English, Bengali, or Kokborok). Confidentiality was maintained throughout the study.

RESULTS

Demographic Profile

A total of 150 infertile women were enrolled, equally divided into the HSG group (n=75) and the SIS group (n=75). Table 1 presents the

demographic and clinical characteristics of the study population. The mean age of participants was 27.3 ± 4.9 years, with no significant difference between the HSG and SIS groups. Nearly half of the women (48.7%) were aged 20–25 years, followed by 32% aged 26–30 years, indicating that most participants were in their reproductive age range.

The majority of women in both groups had primary infertility (80.7 %), while secondary infertility accounted for 19.3 %. Menstrual cycle patterns were similar across groups, with regular cycles in 74.7 % of participants. Minor menstrual irregularities such as dysmenorrhea (8.7 %) and oligomenorrhea (4.7 %) were observed in a small proportion of cases (Table 1).

Table 1: Baseline demographic and infertility profile of participants

Variable	HSG Group (n=75)	SIS Group (n=75)	Total (n=150)
Mean Age (years)	27.4 ± 4.8	27.2 ± 5.1	27.3 ± 4.9
Age 20–25 years	36 (48.0%)	37 (49.3%)	73 (48.7%)
Age 26–30 years	24 (32.0%)	24 (32.0%)	48 (32.0%)
Age 31–35 years	12 (16.0%)	11 (14.7%)	23 (15.3%)
Age 36–40 years	3 (4.0%)	3 (4.0%)	6 (4.0%)
Primary Infertility	61 (81.3%)	60 (80.0%)	121 (80.7%)
Secondary Infertility	14 (18.7%)	15 (20.0%)	29 (19.3%)
Regular Menstrual Cycles	56 (74.7%)	56 (74.7%)	112 (74.7%)
Irregular/Delayed Cycles	9 (12.0%)	9 (12.0%)	18 (12.0%)
Dysmenorrhea	7 (9.3%)	6 (8.0%)	13 (8.7%)
Oligomenorrhea	3 (4.0%)	4 (5.3%)	7 (4.7%)

Pain Intensity Distribution

- **HSG group:**

Mild pain (VAS 1–3): 1.3% (n=1)
Moderate pain (VAS 4–6): 94.7% (n=71)
Severe pain (VAS 7–10): 4% (n=3)

- **SIS group:**

Mild pain (VAS 1–3): 94.7% (n=71)
Moderate pain (VAS 4–6): 5.3% (n=4)
Severe pain (VAS 7–10): 0%

This demonstrates that SIS was overwhelmingly associated with mild pain, whereas HSG was predominantly associated with moderate pain, with a small proportion experiencing severe discomfort (Table 2). Chi-square testing confirmed a highly significant difference in pain intensity between the two groups ($p < 0.001$).

Table 2: Comparison of pain intensity between HSG and SIS

Pain Intensity (VAS)	HSG Group (n=75)	SIS Group (n =75)	p-value
Mild (VAS 1–3)	1 (1.3%)	71(94.7%)	<0.001
Moderate (VAS 4–6)	71 (94.7%)	4 (5.3%)	
Severe (VAS 7–10)	3 (4.0%)	0 (0%)	

Patient Tolerability and Feedback

Qualitative feedback collected during post-procedure monitoring revealed distinct differences in patient experience:

- Women undergoing HSG frequently reported discomfort (65%) due to cervical manipulation, uterine distension by contrast medium, and radiation exposure anxiety.
- In contrast, women undergoing SIS described the procedure as less invasive, quicker, and more acceptable (82%), with discomfort limited to transient uterine distension from saline infusion (Figure 1).

No severe adverse events were reported in either group. However, minor complications such as transient cramping and spotting were more common in HSG.

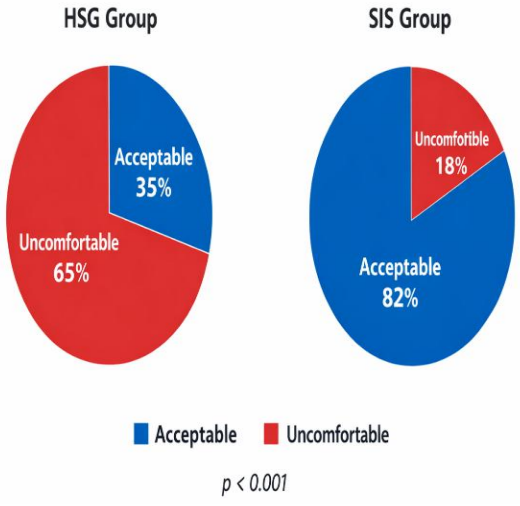

Figure 1: Pie chart showing patient-reported tolerability (acceptable vs uncomfortable) for HSG and SIS

DISCUSSION

The evaluation of tubal patency remains a cornerstone in infertility workups, as tuboperitoneal factors account for nearly 30–40% of female infertility worldwide.[14] Traditionally, HSG has been the first-line diagnostic tool, but its limitations—pain, radiation exposure, and risk of pelvic infection—have prompted the search for safer alternatives. SIS has emerged as a promising option, offering comparable diagnostic accuracy with significantly better patient tolerability.[15] Our study contributes to this growing body of evidence by demonstrating that SIS is overwhelmingly associated with mild pain and greater patient acceptability than HSG.

Pain Intensity and Patient Experience

In the present study, pain intensity differed markedly between the two diagnostic modalities. Among women undergoing SIS, 94.7% reported only mild pain, while 5.3% experienced moderate pain, and none reported severe pain. In contrast, in the HSG group, 94.7% experienced moderate pain, 4% severe, and only 1.3% mild. This highly significant difference ($p < 0.001$) underscores the superior tolerability of SIS.

These findings are consistent with those of Ganai et al., who observed that 71.6% of women undergoing SIS experienced mild pain, compared with only 8.9% in the HSG group, and that most patients reported moderate pain.[10] In another prospective study, Rezk and Shawky highlighted that SIS was associated with fewer complications and higher patient satisfaction, whereas HSG was linked to adverse events such as syncope and cervicovaginal lacerations.[11]

In another randomised controlled trial, mean pain scores were significantly lower with SIS compared to HSG when assessed on a 0–10 scale (mean scores of 2.7 versus 5.8; p <

0.0001), where higher scores reflected greater pain intensity, further confirming that SIS is consistently associated with reduced discomfort across infertility evaluations.[16]

Pain perception during infertility investigations is not a trivial matter. It directly influences patient compliance, psychological wellbeing, and willingness to undergo repeated procedures. In resource-limited settings, where awareness and acceptance of infertility care may already be low, a painful diagnostic experience can deter women from completing evaluations. By minimising pain, SIS improves patient adherence to infertility workups and reduces psychological distress, thereby enhancing the overall success of infertility management.

Diagnostic Accuracy and Clinical Utility

Diagnostic accuracy remains critical in the evaluation of infertility. In our cohort, 94.7% of women undergoing SIS reported mild pain, 94.7% of HSG patients reported moderate pain, and 4% reported severe pain. Despite this striking difference in pain intensity, SIS maintained diagnostic reliability comparable to HSG.

Agrawal et al., in a North-East Indian cohort, demonstrated that SIS not only significantly reduced pain intensity ($p < 0.001$) but also achieved diagnostic accuracy comparable to HSG, making it a practical first-line screening tool.[17] SIS additionally avoids ionising radiation and hypersensitivity reactions to contrast agents, inherent risks of HSG. This makes SIS particularly suitable for women who require repeated evaluations or have contraindications to iodinated contrast.[18] Furthermore, SIS can be performed as an outpatient procedure, reducing costs and logistical burdens — a major advantage in low-resource regions such as North-East India.

Patient Tolerability and Acceptability

In our cohort, 82% of women undergoing SIS rated the procedure as acceptable, whereas only 35% of HSG patients did so; conversely, 65% of HSG patients described the procedure as uncomfortable, compared with just 18% in the SIS group ($p < 0.001$). Qualitative feedback reinforced these findings, with women perceiving SIS as less invasive, quicker, and more acceptable, whereas HSG was consistently associated with discomfort due to cervical manipulation and anxiety about radiation exposure. Both our data and prior studies demonstrate that SIS is consistently more acceptable to patients, and this improved tolerability not only enhances comfort but also increases compliance with infertility workups.[1,19]

Limitations and Future Directions

Despite its advantages, SIS is not without limitations. Its sensitivity for subtle intrauterine abnormalities may be lower than that of hysteroscopy, and false positives can occur with small polyps or unilateral tubal blockages. Therefore, SIS should be considered a first-line screening tool, with HSG or laparoscopy reserved for cases requiring further anatomical clarification. Future research should focus on multicentric trials with larger sample sizes to validate these findings across diverse populations. Integration of advanced ultrasound techniques, such as contrast-enhanced sonohysterography and 3D ultrasound, may further enhance the diagnostic yield of SIS while maintaining its tolerability advantage.

Clinical Implications

The implications of our findings are significant. In regions like North-East India, where healthcare infrastructure is limited, a diagnostic modality that combines accuracy, safety, and patient comfort is invaluable. By prioritising SIS as the first-line tool, clinicians can improve patient compliance, reduce psychological distress, and streamline infertility evaluations. HSG may be reserved for cases where SIS findings are inconclusive or when detailed anatomical assessment is required.

CONCLUSION

SIS significantly improves patient tolerability and acceptability compared with HSG, while maintaining comparable diagnostic accuracy in assessing tubal patency. By eliminating radiation exposure and reducing procedural discomfort, SIS enhances compliance with infertility investigations and provides additional value in detecting intrauterine pathology. These findings, supported by both our cohort and published evidence, suggest that SIS should be considered a preferred first-line modality in infertility workups.

Declaration by Authors

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- **Data Availability Statement:** The datasets supporting the conclusions of this study are accessible from the corresponding author upon reasonable request.

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