

## Comparative Study Between Hysterosalpingo-Contrast Sonography and Hysterosalpingography in Evaluating Tubal Patency at Aminu Kano Teaching Hospital, Kano.

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### Abstract

**Background:** Tubal diseases contribute significantly to secondary infertility, affecting 25-35% of couples seeking infertility treatment. Traditional methods for assessing tubal patency, such as laparoscopy and dye tests, are invasive, costly, and require specialized expertise. Hysterosalpingography (HSG) is an alternative, but it involves pain and radiation exposure. This study aimed to compare the effectiveness of Hysterosalpingo-contrast Sonography (HyCoSy) using a saline and air mixture to HSG in assessing tubal patency in infertility patients at Aminu Kano Teaching Hospital.

**Methodology:** A cross-sectional study involved 50 consenting patients seeking fertility evaluation. The researchers used a semi-structured questionnaire to gather demographic information. HyCoSy with the saline and air mixture was performed between the 5th and 10th day of the menstrual cycle, followed by HSG within the next five days. The patency of each fallopian tube was assessed, and pain levels experienced during both procedures were recorded using a numerical rating scale.

**Results:** The results indicated that 68.8% of patients had bilateral patent tubes according to HyCoSy, while 60.4% were found to have patent tubes with HSG. A comparison of findings for individual tubes showed an 89.6% concordance rate between the two tests, with a Kappa index of 0.73, indicating substantial agreement. Importantly, patients reported significantly less pain during the HyCoSy procedure (mean NRS score of 4.1) compared to HSG (mean NRS score of 7.1).

**Conclusion:** This study demonstrated that HyCoSy using a saline and air mixture is highly comparable to HSG in assessing tubal patency. Notably, HyCoSy was preferred by patients due to its reduced pain and better tolerance, with minimal adverse effects. This suggests that HyCoSy may be a more patient-friendly and cost-effective alternative for tubal assessment in cases of infertility.

**Keywords:** HyCoSy; HSG; Tubal patency, Assessment

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## Introduction

Tubal diseases stand as a leading cause of secondary infertility, accounting for infertility in 25-35% of affected couples (1). An array of methodologies has been developed to evaluate tubal patency. An ideal method should be diagnostically accurate, rapid, cost-effective, and minimally invasive. Laparoscopy and dye testing are considered the gold standard for tubal patency assessment(2). However, this invasive procedure demands a high level of expertise, involves significant costs, anesthesia, and might pose operative risks(2).

Hysterosalpingography (HSG) serves as an effective, safe, and widely accepted method for tubal patency evaluation, primarily utilizing radiographic assessment of the uterus and fallopian tubes (2). It exhibits high accuracy in identifying proximal tubal disease and offers optimal visualization of the fallopian tubes(3). Although HSG demonstrates high specificity for confirming tubal patency, its lower sensitivity necessitates confirmation of tubal blockage.

HSG might induce discomfort, particularly in cases of obstructed fallopian tubes. Minor post-procedural bleeding could occur. Additionally, radiation exposure, although generally minimal, poses potential risks. Moreover, the procedure is commonly performed in a radiology department under fluoroscopy, which might be uncomfortable for both the patient and the attending gynecologist.

Sonographic evaluation of the fallopian tubes was introduced by Richman et al. in 1984, utilizing abdominal ultrasonography following saline injection through the cervical canal(4). Subsequently, the procedure has evolved using transvaginal ultrasound scanning, offering enhanced visualization of the pelvic organs. Various modifications have been made using diverse contrast agents, giving rise to hysterosalpingo-contrast sonography (HyCoSy)(3).

HyCoSy employs various contrast media such as Echovist 200, Hyskon, Infuson, SonoVue, and Definity, which, due to their cost and availability limitations, led to the introduction of a mixture of saline and air as a positive contrast medium(5). This cost-effective and safe alternative utilizes the mixture to provide an echo-positive effect and demonstrate scintillations via B mode ultrasound scan, indicating patent fallopian tubes(6,7).

Comparatively, HyCoSy stands as a faster, less painful, and more cost-effective alternative to HSG(8). It combines the advantage of simultaneous evaluation and detection of other pelvic pathologies, along with hysterosalpingographic assessment of the fallopian tubes(9). Furthermore, it mitigates risks associated with radiation exposure and allergic reactions to iodinated contrast used in HSG. The procedure's feasibility in a clinical setting during the initial consultation makes it a more fitting outpatient examination for sub-fertile women.

This study aims to assess whether hysterosalpingo-contrast sonography using a saline and air mixture (HyCoSy) is comparable to HSG in determining tubal patency in infertility patients at Aminu Kano Teaching Hospital, Kano State.

## Materials and Method

A cross-sectional study design was employed to compare the outcomes of HyCoSy with air and saline contrast media and Hysterosalpingography (HSG) in the evaluation of tubal patency. The study was conducted at the Obstetrics and Gynecology and Radiology Departments of Aminu Kano Teaching Hospital (AKTH), a tertiary hospital in Kano State, Nigeria. The participants consisted of consenting, currently married, sexually active unmarried women aged 18 to 49 years, presenting with primary or secondary infertility at the infertility clinic in the Obstetrics and Gynecology Department. Exclusion criteria comprised patients exhibiting symptoms and signs of pelvic inflammatory disease, abnormal

bleeding, abnormal cytologic smear tests, or those in whom cervical cannulation was hindered due to cervical stenosis.

All eligible patients attending the infertility clinic and scheduled for HSG to assess tubal patency were included in the study. To mitigate selection bias, consecutive recruitment of eligible patients was adopted, ensuring a more representative sample of the population seeking infertility evaluation.

The sample size was determined using the statistical formula for comparing the diagnostic accuracy of two tests of paired design(10). Using a sensitivity of 85% for HyCoSy from previous study(11), the minimum sample size was determined to be 46 which was increased to 50 to accommodate potential attrition.

The HyCoSy procedure was performed between the 5th and 10th day of the menstrual cycle by two skilled Gynecologists to maintain standardization and minimize inter-observer bias. The process involved preliminary transvaginal scanning to evaluate the uterus, endometrium, ovarian position, and the interstitial part of the tubes and pouch of Douglas. Subsequently, a Cusco's speculum was gently inserted, the cervix cleaned with chlorhexidine solution, and held with a single-toothed tenaculum. A size 8F rigid disposable salpingography catheter was introduced into the lower uterine cavity and the balloon inflated with 1.5mls of saline and gentle traction applied to ensure that the cervical canal was closed to prevent leakage of saline solution and air and to keep the catheter in position.

The HyCoSy procedure utilized a 20-ml syringe loaded with 10 ml of saline solution and 10 ml of air. The saline solution was slowly injected, and the uterine cavity evaluated on transverse and longitudinal images. Subsequently, alternate little boluses of air and saline were injected through the catheter while visualizing the interstitial parts of the tubes. Air bubbles that are highly echogenic would facilitate checking the patency of the fallopian tubes. Criteria for tubal patency included the passage of air and saline bubbles through the interstitial part of the tube, detection of air bubbles around the ovary, and visualization in the pouch of Douglas. Each tube was classified as either patent or blocked. An evaluation was conducted using an Aloka ultrasound system with a 7.5 MHz transvaginal probe. Post-procedure, participants were monitored for 15 minutes to prevent vasovagal reactions. Pain experienced during the procedure was evaluated using an 11-point numerical rating scale. Antibiotic prophylaxis with a single dose of azithromycin 1 g was administered orally immediately after the procedure and non-steroidal analgesics were given when indicated.

HSG was performed within the following 5 days of HyCoSy in the proliferative phase of the menstrual cycle by a radiologist blinded to the HyCoSy findings.

Before the commencement of the procedures, a pretested, semi-structured questionnaire was used to collect sociodemographic data, including age, tribe, religion, educational status, parity, and duration of infertility. Additionally, variables such as pain perception, time to complete the procedure, total volume used, and the preferred diagnostic test were recorded on completion of the procedure.

The pain scale was classified as "absent", "mild", "moderate", and "severe" corresponding to scores of 0, 1-4, 5-7, and 8-10, respectively. Statistical analyses were conducted using SPSS version 21 software.

The study adhered to the ethical standards outlined in The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human subjects. Ethical clearance was obtained from the AKTH Research and Ethics Committee, and written informed consent was secured from all participants. Patients were duly informed of their right to refuse participation or withdraw from the study without any compromise to their clinical care. The cost of the procedure was covered by the researcher.

## Results

Fifty participants were initially enrolled in the study for HyCoSy, but two patients declined to undergo HSG and were consequently excluded, continuing with routine gynecological evaluation and management. The average age of the participants was  $31.7 \pm 5.9$  years, with the majority (31.3%) falling within the 35–39 years age group. The mean duration of infertility was  $4.8 \pm 2.3$  years. Uterine fibroids were the most prevalent associated findings on ultrasound scans, present in 39.6% of respondents, followed by polycystic ovaries in 31.3%. Other observed pelvic findings included adnexal masses (16.7%) and uterine anomalies (2.1%). Approximately 10% showed no concomitant pelvic pathology upon ultrasound examination. Please refer to Table 1 for a detailed summary of the participants' general characteristics.

The findings from the HyCoSy revealed that among the participants, 33 patients (68.8%) demonstrated bilaterally patent tubes, 7 (14.6%) had one patent tube, and 8 (16.7%) presented with both tubes blocked. Conversely, the HSG results showed bilateral tubal patency in 29 participants (60.4%), with 11 (22.9%) demonstrating patency in one tube and 8 (16.7%) displaying blockage in both tubes. (See Table 2)

In Table 3, a 2x2 contingency table displays the agreement or discordance of findings on individual tubes from the HyCoSy compared with those from the HSG. The two tests exhibited concordance in 86 tubes and discordance in 10 tubes, culminating in a calculated concordance rate of 89.6%. The Kappa index, a measure of agreement between the two tests, was calculated to be 0.73, indicating substantial agreement. Additionally, an exact McNemar's test revealed no statistically significant difference in the results of the two tests (p-value 0.34).

The mean NRS pain score reported by patients during HyCoSy was  $4.1 \pm 1.9$ , whereas during HSG, the mean NRS score was  $7.1 \pm 1.6$ . The disparity in the mean pain scores experienced by the patients during the two procedures was statistically significant (p-value 0.0005). A majority (60.4%) of patients reported mild pain (NRS 1–4) during HyCoSy, while a majority (54.2%) reported moderate pain (NRS 5–7) during the HSG procedure. Only one patient reported severe pain during HyCoSy. The distribution of patient preferences was such that 36 (75%) favored HyCoSy, while 12 patients (25%) preferred HSG, as illustrated in Table 4.

A noteworthy disparity was observed in the prevalence of vasovagal symptoms, with 89.6% of patients reporting no symptoms following HyCoSy, whereas 75% reported symptoms following HSG (p-value 0.0001). Five patients (10.4%) who underwent HyCoSy and 9 patients (18.8%) who had HSG experienced mild vasovagal reactions that were self-limiting. Moreover, only 3 patients who had HSG encountered severe reactions necessitating interventions, while none experienced severe reactions during HyCoSy (Table 5).

## Discussion

Tubal assessment is critical in infertility evaluations, and the methods used to evaluate tubal patency should ideally balance accuracy, patient comfort, and safety. This study compared Hysterosalpingocontrast Sonography (HyCoSy) using saline and air mixture with Hysterosalpingography (HSG) in assessing tubal patency in infertile women. The results indicated a high concordance between HyCoSy and HSG in detecting tubal patency, with an 89.6% concordance rate and a substantial agreement (Kappa index = 0.73).

While our findings support previous studies reporting similar concordance rates between HyCoSy and HSG, it's important to note the limitations of HyCoSy. Although it is a patient-friendly and cost-effective alternative, HyCoSy is highly operator-dependent. The quality of imaging and interpretation might vary,

which emphasizes the need for specialized expertise, preferably by a Gynecologist sonologist, to ensure accurate and consistent results. Additionally, HSG films are easily interpretable and provide a permanent record, offering advantages in terms of clarity and detailed review.

Our findings support previous studies reporting similar concordance rates between HyCoSy and HSG. For instance, studies employing saline and air contrast media in HyCoSy reported comparable concordance rates ranging from 85.1% to 100% in detecting tubal patency, indicating the effectiveness of HyCoSy as a diagnostic tool in line with HSG (5,12,13).

Notably, patients reported significantly lower pain levels during HyCoSy compared to HSG. The mild to moderate pain experienced during HyCoSy, akin to normal menstrual cramping, contrasts with the higher pain reported during HSG. This aligns with prior research, confirming the higher tolerability and lower pain intensity of HyCoSy over HSG (14–17).

Both procedures were well-tolerated with mild adverse effects reported in a few patients. While vasovagal symptoms, such as nausea and dizziness, were mild and transient in both procedures, severe vasovagal reactions were notably absent during HyCoSy but present in three cases during HSG. These findings corroborate previous studies affirming the safety and tolerability of both procedures (13,15,18,19).

Furthermore, our study echoed patients' preference for HyCoSy over HSG, mainly attributed to the lower pain experienced during HyCoSy. This preference aligns with prior research, indicating patient inclination toward the less painful diagnostic procedure (15,20).

The present study also observed common concomitant pelvic pathologies, such as uterine fibroids and polycystic ovaries, which were accurately identified by HyCoSy due to its additional advantage of pelvic ultrasound. This echoes the utility of HyCoSy in diagnosing pelvic pathologies, which is not feasible with HSG(12,14,21).

## **Conclusion**

This study found HyCoSy to be a reliable and patient-friendly alternative to HSG for tubal patency assessment. The high concordance, lower pain experience, better patient tolerance, and capability to detect concomitant pelvic pathologies position HyCoSy as a promising diagnostic tool for infertility evaluations.

Tables

**Table 1: Characteristics of Patient Population**

Parameter	Value
<b>Mean Age (Years)</b>	31.7 ± 5.9
<b>Age Groups</b>	
20 – 24	7 (14.6)
25 – 29	13 (27.1)
30 – 34	8 (16.7)
35 – 39	15 (31.3)
≥40	5 (10.4)
<b>Tribe</b>	<b>N (%)</b>
Hausa	34 (70.8)
Igbo	5 (10.4)
Yoruba	6 (12.5)
Others	3 (6.3)
<b>Religion</b>	<b>N (%)</b>
Islam	37 (77.1)
Christianity	11 (22.9)
<b>Educational Status</b>	<b>N (%)</b>
No Formal	0
Primary	1 (2.1)
Secondary	23 (47.9)
Tertiary	24 (50)
<b>Type of Infertility</b>	<b>N (%)</b>
Primary	28 (58.3)
Secondary	20 (41.7)
<b>Mean Duration of Infertility</b>	<b>4.8 ± 2.3</b>
<b>Concomitant Pelvic Pathologies</b>	<b>N (%)</b>
None	5 (10.4)
Uterine Fibroid	19 (39.6)
Polycystic Ovaries	15 (31.3)
Uterine Anomalies	1 (2.1)
Adnexal cysts/masses	8 (16.7)

**Table 2: HyCoSy and HSG Findings**

Finding	HyCoSy	HSG
Bilateral Tubal Patency	33 (68.8%)	29 (60.4%)
Unilateral Tubal Patency	7 (14.6)	11 (22.9%)
Bilateral Tubal Blockage	8 (16.7)	8 (16.7%)
<b>Total</b>	<b>48 (100)</b>	<b>48 (100%)</b>

**Table 3: Agreement between HyCoSy and Hysterosalpingography (HSG)**

		HSG FINDINGS		
		Patent tubes	Non Patent tubes	Total
HYCOSY FINDINGS	Patent tubes	66	7	73
	Non Patent tubes	3	20	23
	Total	69	27	96

Concordance rate = 89.6% , Measure of Agreement (Kappa) = 0.73

McNemar test P Value = 0.34

**Table 4: Comparison of Pain Perception**

	HyCoSy N (%)	HSG N (%)
Mean NRS Score	4.1±1.9	7.1±1.6
<b>t – test = 7.134 p – value = 0.0005</b>		
<b>Pain Perception</b>		
Absent (NRS 0)	0	0
Mild (NRS 1-4)	29 (60.4)	1 (2.1)
Moderate (NRS 5-7)	18 (37.5)	26 (54.2)
Severe (NRS 8-10)	1(2.1)	21 (43.7)
<b>Preferred Procedure</b>	<b>36 (75%)</b>	<b>12 (25%)</b>

**Table 5: Adverse Effects (Vaso-Vagal Reactions)**

	HyCoSy N (%)	HSG N (%)	P – Value
None	43 (89.6)	36 (75)	0.014
Mild	5 (10.4)	9(18.8)	
Severe	0	3 (6.3)	
<b>Total</b>	<b>48 (100)</b>	<b>48</b>	

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