

# Diagnostic Accuracy of Hysterosalpingography in the Identification of Intrauterine Adhesions in Infertile Women in a Referral Centre, Southern Nigeria

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## Abstract

**Background:** Examination of the endometrial cavity is crucial in the management of infertile women. This evaluation is done by Hysterosalpingography (HSG) in the University of Port Harcourt Teaching Hospital. The diagnostic value and accuracy of hysterosalpingography varies in various centres and has not been assessed in the University of Port Harcourt Teaching Hospital (UPTH), hence this study. **Methodology:** A prospective cross sectional study done among 101 infertile women at the gynaecology clinic of the UPTH from December 2018 to July 2019. Socio-demographic data of women who met the eligibility criteria were collected. Their hysterosalpingographic and outpatient hysteroscopic findings were statistically analyzed using IBM SPSS for windows version 20.0. The validity and reliability statistics of hysterosalpingography for the identification of endometrial adhesions were determined and significance was reported at p-value < 0.05. The analyzed data was presented in tables and figure. **Result:** The respondents were all married, 66.3% of them were nulliparous, while 54.5% were above 35 years of age. Most, 93.1% of the studied group had at least secondary education and had duration of infertility of more than 2 years. There was a moderate strength of agreement in the diagnostic accuracy of HSG with hysteroscopy in the diagnosis of intrauterine adhesions; showing sensitivity and specificity of 59.6% and 90.9% respectively. The accuracy of HSG in the identification of intrauterine adhesions in this study was 73.3%. The agreement in the diagnostic accuracy of HSG using Hysteroscopy as a gold standard for intrauterine adhesions was therefore moderately significant ( $k = 0.482$ ). **Conclusion:** HSG had an overall fair strength of agreement with office hysteroscopy in the identification of intrauterine adhe-

sions. It is a specific but not a sensitive predictor of intrauterine adhesion.

## Keywords

Intrauterine Adhesion, HSG, Hysteroscopy, Port Harcourt

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## 1. Introduction

The prevalence of infertility is high in sub-Saharan Africa; more worrisome to this is the critical socio-cultural effects of the condition on affected couples and families [1] [2]. Tubo-peritoneal diseases accounts for 45% of cases of inability to conceive, while in about 20% of instances, uterine cavity is implicated [3] [4]. There has been an upwards trend in the prevalence of infertility in the recent times due to uterine and tubal causes secondary to the rising incidence of pelvic inflammatory disease, prior pelvic infection or pelvic surgeries, uterine instrumentation, uterine scarring or synechiae [1] [4] [5].

Endometrial anomaly is common and has been documented in 50% women with implantation failure [5] [6]. Pathologies of the endometrium are usually evaluated using any of the following, transvaginalsonography (TVS), sonohysterography (SHG), hysterosalpingography (HSG), and hysteroscopy (HSC). Of these options, hysterosalpingography is the most commonly used in most centres in developing countries [7] [8]. Carey in 1914 did the first hysterosalpingogram using collergol as contrast medium, while Sicard and Forestier in 1924 had a modified method [9]. Hysterosalpingography is less invasive than hysteroscopy, readily available and most commonly used first line investigation in the evaluation of uterotubal pathologies in infertile women at the UPTH in spite of its low sensitivity.

With a superior sensitivity (100%) and specificity (95%) in the evaluation of the endometrial cavity [10], hysteroscopy remains the gold standard investigation, safe and reliable office procedure for the assessment of the endometrial cavity, with the additional ability to treat endometrial pathology in infertile patients [11] [12] [13] [14].

The world health organization recommends hysterosalpingography alone for the management of infertile women based on the fact that it provides additional information on tubal patency or blockage [15] [16].

Intrauterine adhesions were first described by Fritsch in 1944 but were popularized by Joseph Asherman in 1948 [17]. It is commonly referred to as Asherman's syndrome which is characterized by adherence of uterine walls, partial or complete obliteration of the uterine cavity, variable placement of adhesions and the clinical symptoms of menstrual abnormalities, infertility or recurrent pregnancy loss [18] [19]. In a prospective study by Soares *et al.* [20] in Brazil where the diagnostic accuracies of saline sonohysterography, transvaginalsonography, hysterosalpingography (HSG) were compared with hysteroscopy in 65 infertile women, HSG had a sensitivity of 75% and a specificity of 95% in the diagnosis of intrauterine adhesions and a positive predictive value of 50%. In another study

by Goldberg *et al.* [21], HSG was quite sensitive in the diagnosis of intrauterine adhesions. The quite high sensitivity of HSG in this study and that of Soares *et al.* [20] may probably be due to small sample size in both studies. Aremu *et al.* [22] in Nigeria used transabdominal saline contrast sonohysterography (TASCSH) and HSG. They reported a 100% concordance rate of HSG with TASCSH in diagnosing uterine adhesions with sensitivity, specificity and positive predictive value of HSG of 100%. The high sensitivity of HSG was probably due to the use of TASCSH as the standard for comparison instead of hysteroscopy unlike the studies by Soares *et al.* [20] and Goldberg *et al.* [21]. Ugboaja *et al.* in Nigerian study on infertile women reported a high incidence of intrauterine adhesion; though the study was on hysteroscopy [23] [24].

Hysterosalpingography and hysteroscopy are well accepted minimally invasive and safe methods of assessing the endometrial cavity in infertile women. However, HSG remains the main procedure for evaluating the uterine cavity of infertile women in most resource limited countries like Nigeria because hysteroscopy, despite its higher accuracy over HSG, is not readily available, expensive and is associated with lack of expertise in its use. There is therefore the need for this study to determine the diagnostic accuracy of hysterosalpingography in identification of uterine adhesions in infertile women in the University of Port Harcourt Teaching Hospital (UPTH) using office hysteroscopy (the gold standard) as a control.

## 2. Methodology

This is a cross sectional prospective study conducted among infertile women (women who have inability to conceive after one year of adequate/regular unprotected sexual intercourse; or 6 months duration in women 35 years of age or above) attending the gynaecology clinic of the University of Port Harcourt Teaching Hospital, between December 2018 and July 2019. This hospital provides specialized healthcare services for the entire River State, as well as the neighbouring states.

Women being assessed for infertility were enrolled in the study. However, women who withhold consent, previously evaluated patient for infertility in the facility, patients with known allergy to contrast media, women with obvious cervicitis or active pelvic infection and women with genital tract cancer such as cervical or endometrial cancer were excluded.

**SAMPLE SIZE CALCULATION:** The sample size for this study was calculated using a simplified formula for calculating sample size [25].  $n = N / (1 + N(e)^2)$ , where  $n$  = sample size.  $N$  was the average number of new cases of infertility seen at the gynaecologic clinic over a period of six months [26].  $e$  = error margin/margin of error (0.05). The sample size was thus calculated to be 92. Giving an allowance for 10% attrition rate, the sample size for the study was therefore 101 women.

**SAMPLING METHOD:** Women attending the gynaecology clinic of the UPTH for infertility that satisfied the eligibility criteria and consented to the study were recruited until the required sample size was obtained. Socio-demographic data and

data on outcome of hysteroscopy and HSG were collected through a pre-structured questionnaire. The questionnaire was designed by the researchers; and tested for validity and reliability. The data collected included age, level of education, occupation, marital status and parity. Other data that were collected include the type of infertility, duration of infertility, findings of intrauterine adhesion and outcome of HSG and hysteroscopy.

When these patients presents at the gynaecology clinic, the standard work-up for infertility was done. Hysterosalpingography was performed first between the 5<sup>th</sup> and the 10<sup>th</sup> day of the proliferative phase of the menstrual cycle at the radiology department by the radiologist investigator. Excluding this radiologist, the other investigators (blinded to the result of the HSG) performs the hysteroscopy at the gynaecology outpatient procedure room between the 7<sup>th</sup> and the 11<sup>th</sup> day of the same proliferative phase of the menstrual cycle. The hysterosalpingographic images were jointly reviewed by the investigators lead by the radiologist (who is blinded to the result of hysteroscopy). The accuracy of HSG was tested based on its specificity and sensitivity in detecting intrauterine adhesions; as compared with its detection or otherwise by hysteroscopy (the gold standard).

**HYSTEROSALPINGOGRAPHY:** The patient was counseled on procedure the patient and she was told to empty her bladder. Control film which is a plain film of the pelvis was taken. A bivalve speculum was used to expose the cervix. Leech Wilkinson cannula was introduced and stabilized in the cervix. Radio-opaque contrast medium (10 mls) was introduced through the cannula into the uterus. Under fluoroscopic guidance, filling of the uterine cavity and passage of the radio-opaque solution into the fallopian tubes and its spill from the fimbriae end was observed and documented with serial x-ray film.

**OFFICE HYSTEROSCOPY PROCEDURE:** The patient was counseled on the procedure and was told to empty her bladder. She was placed in the lithotomy position and pelvic examination was performed. Vaginoscopic “no-touch” technique using a 2.9 mm continuous flow 30° rigid office hysteroscopy with a 2 mm telescope and a xenon light source was used. About 200 mls of normal saline was used as a distension medium and the hysteroscope with its light source and flowing fluid was gently introduced into the vagina allowing for gradual distension. The hysteroscope was guided into the endometrial cavity under direct vision. A systematic view of the uterine cavity was done involving the uterine cornua, tubal ostia, uterine fundus, lateral, anterior and posterior uterine wall. Two sets of hysteroscopes were used alternatively during the procedure. A high-level disinfection using 0.55% ortho-phthalaldehyde (CIDEX® OPA) Solution which is for heat sensitive medical devices was done.

**DATA ANALYSIS:** Socio-demographic data in addition to findings on hysteroscopy and hysterosalpingography were statistically analyzed using IBM SPSS 20 statistic package. Descriptive statistics were computed for all relevant data and there was cross tabulation between the various findings on hysteroscopy and hysterosalpingography. Statistics for reliability and validity were all calculated.

The study hypothesis was tested using McNemar Chi-square and significance was set at  $p < 0.05$ .

**ETHICAL CONSIDERATION:** Approval for the study was obtained from the ethical committee of the University of Port Harcourt Teaching Hospital (UPTH/ADM/90/S.11/VOL.X1/710). Written informed consent was obtained from the patients.

### 3. Results

Of the 101 women recruited into the study between December 2018 and July 2019, 31.7% were aged between 31 - 35 years. The mean age was  $35.95 \pm 4.65$  years and median age was 36 years (Table 1).

**Table 1.** Socio-demographic characteristics of women with infertility.

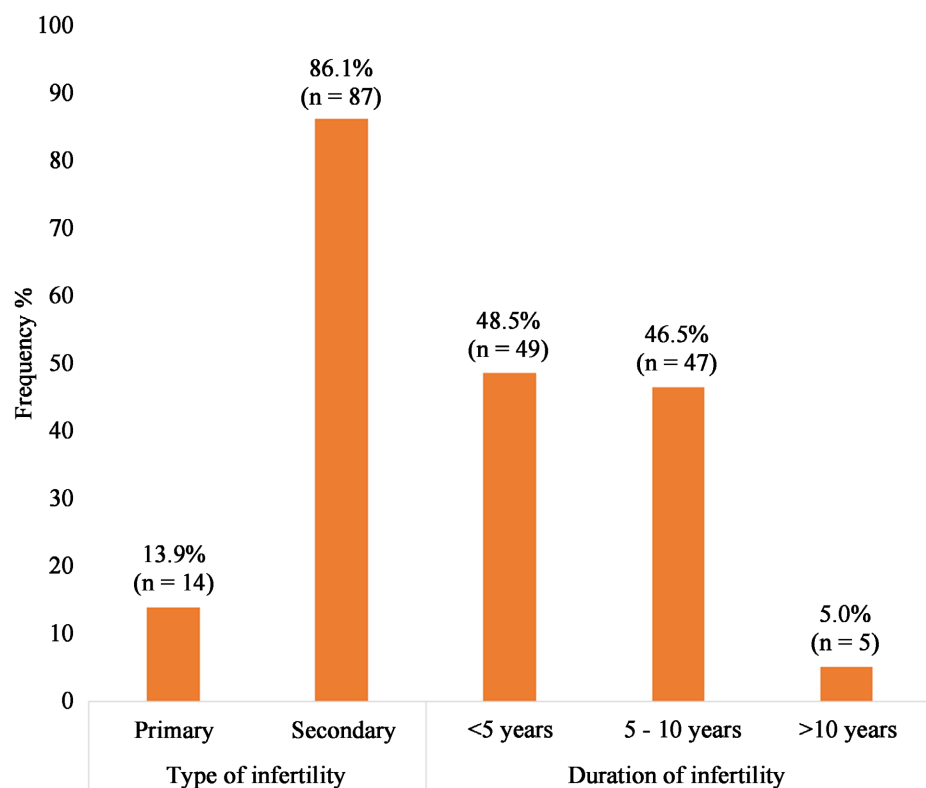
Variables (N = 101)	Frequency	Percentage
<b>Age category</b>		
18 - 25 years	1	1.0
26 - 30 years	13	12.8
31 - 35 years	32	31.7
>35 years	55	54.5
<b>Marital status</b>		
Married	101	100.0
Single	0	0.0
<b>Educational level</b>		
None	1	1.0
Primary	6	5.9
Secondary	33	32.7
Tertiary	61	60.4
<b>Occupational status</b>		
Unemployed	13	12.9
Employee	41	40.6
Self-employed	47	46.5
<b>Parity</b>		
Para 0	67	66.3
Para 1 - 4	34	33.7
Para > 4	0	0.0
<b>Duration of infertility</b>		
<2 years	0	0.0
$\geq 2$ years	101	100.0

Mean age of women  $\pm$  SD =  $35.95 \pm 4.65$  years. Median age = 36 years. Age range = 25 - 46 years.

The median parity group was the nulliparous group (para 0) with 66.3% of the sampled population in this group. The parity range was para 0 - 4. Majority (60.4%) of the women recruited into this study had tertiary education. Most (86.1%) of these women had secondary infertility, and 13.9% had primary infertility. The duration of infertility was less than five years in 48.5% (**Figure 1**).

Hysterosalpingograph concordance with hysteroscopy was observed in 36 of the study participants in diagnosing the presence of intrauterine adhesions; it agreed with hysteroscopy in diagnosing the absence of intrauterine adhesions in 29 of the study participants and disagreed in 6 of the study participants as shown in **Table 2**. HSG had a sensitivity of 59.6% and a specificity of 90.9%. The positive predictive value of HSG was 89.5% and the negative predictive value was 63.5%, as shown in **Table 3**. The accuracy of HSG in the identification of intrauterine adhesions in this study was 73.3% as shown in **Table 3**. There was a moderate agreement in the diagnostic accuracy of HSG using Hysteroscopy as a gold standard for intrauterine adhesions ( $k = 0.482$ ).

The overall sensitivity and specificity of HSG in the identification of endometrial adhesions in this study were 54.5% and 82.9% respectively. The positive predictive value was 85.7% and the negative predictive value was 49.2% as shown in **Table 3**. The overall diagnostic accuracy of HSG in the identification of uterine adhesion in this study was 64.4%. There was fair overall strength of agreement ( $k = 0.322$ ) in the diagnostic accuracy of HSG in the identification of uterine



Mean duration of infertility  $\pm$  SD = 5.03  $\pm$  2.56 years; Range = 2 - 13 years.

**Figure 1.** Type of infertility and duration among the women.

**Table 2.** Overall diagnostic accuracy of hysterosalpingography (HSG) in the identification of uterine adhesions using hysteroscopy as gold standard among women with infertility.

	Hysteroscopy		Total
	Uterine adhesion	No Uterine adhesion	
<b>HSG</b>	Uterine adhesions <i>True positive</i>	6 <i>False positive</i>	42
	No uterine adhesions <i>False negative</i>	29 <i>True negative</i>	59
<b>Total</b>	<b>66</b>	<b>35</b>	<b>101</b>

**Table 3.** Validity statistics of hysterosalpingography (HSG) in the identification of uterine adhesion using hysteroscopy as a gold standard among women with infertility.

Findings	Sensitivity	Specificity	PPV	NPV	Accuracy	Kappa agreement	p-value
Uterine adhesions	59.6%	90.9%	89.5%	63.5%	73.3%	0.482	0.0001
Overall findings	54.5%	82.9%	85.7%	49.2%	64.4%	0.322	0.0001

adhesions using hysteroscopy as a reference standard.

#### 4. Discussion

In this study, there was a fair strength of agreement ( $k = 0.322$ ) in the overall diagnostic accuracy of HSG in the identification of endometrial pathologies in infertile women in the University of Port Harcourt Teaching Hospital using hysteroscopy as a reference. The overall sensitivity and specificity of HSG in the identification of endometrial pathologies in this study were 54.5% and 82.9% respectively. The positive predictive value was 85.7% and the negative predictive value was 49.2%. The overall diagnostic accuracy of HSG in the identification of endometrial pathologies in this study was 64.4%.

There was a statistically significant moderate strength of agreement between HSG and hysteroscopy ( $k$ -value = 0.482) in the diagnostic accuracy of HSG in the identification of intrauterine adhesions in infertile women. The sensitivity and specificity of HSG in this study in the identification of intrauterine adhesions were 59.6% and 90.9% respectively, and the positive and negative predictive values were 89.5% and 63.5% respectively. The accuracy of HSG in this study was 73.3%. The sensitivity in this study was low at 59.6% when compared to a sensitivity of 75% by Soares *et al.* [20] and the specificity was similar to the specificity of 95% reported by Soares *et al.* [20]. HSG was quite sensitive in the diagnosis of intrauterine adhesions in a study by Goldberg *et al.* [21] in which of the 9 women diagnosed with intrauterine adhesions using HSG, 6 of them had the same diagnosis with hysteroscopy. The high sensitivity of HSG in these stu-

dies by Soares *et al.* [20] and Goldberg *et al.* [21] may probably be due to small sample size in both studies. A low sensitivity of HSG in the diagnosis of intra-uterine adhesion in this study implies that there is an increase possibility of HSG not detecting those women with intrauterine adhesion. The high specificity of HSG in this study and in the study by Soares *et al.* [20] implies that HSG has an increase possibility of ruling out the presence of intrauterine adhesions in women who have no intrauterine adhesion.

This study suggests that the diagnostic accuracy of HSG in the identification of endometrial pathologies among infertile women varies amongst centres [20] [21] [22] and the type of endometrial pathology to be identified. It was more likely to detect intrauterine adhesions when present and a higher probability to detect the absence of intrauterine adhesions when there was none.

Study on the hysteroscopy which is referred to as the gold standard in making diagnosis of endometrial pathology abounds [27] [28] [29]. However, this study has shown that HSG is comparable to hysteroscopy especially in low resource country like ours. This is buttressed by a multicentre study by Ugboaja *et al.*, where intrauterine adhesion was the commonest endometrial finding, using hysteroscopy as a gold standard [30].

Funding of the project was done by the researchers.

## 5. Limitation

In this study, the interpretation of images was operator dependent hence subjective. Grade 1 uterine adhesions which may have been diagnosed by HSG may have been lysed during hysteroscopy.

## 6. Conclusion

This study showed that HSG is a specific but not a sensitive predictor of intra-uterine adhesion. In this center, HSG had an overall fair strength of agreement with office hysteroscopy as a reference standard in the identification of intra-uterine adhesions.

## 7. Recommendation

Based on the findings above, both hysteroscopy and HSG should be considered first-line investigation and complementary to each other in the complete work-up of infertile women rather than being mutually exclusive. This is more important in selected group of women embarking on the usual expensive assisted reproductive conception to reduce to barest minimum the chance of pregnancy losses after such huge financial spending.

## What Is Known about This Study

- 1) Hysterosalpingography is routinely used in the evaluation of pathologies of the endometrial cavity in most poor resource settings/centres.
- 2) The gold standard for this evaluation, where it is possible (considering



availability of human and material resources), is hysteroscopy.

### What This Study Adds to Knowledge

1) This is the first study at the University of Port Harcourt that compared our routine method (HSG) of evaluating the endometrial cavity for pathologies (intra-uterine adhesions) and the gold standard (Hysteroscopy) for this evaluation.

2) This study showed that HSG is a specific predictor of intrauterine adhesion. This is very important and reassuring to us for now until such a time we can afford hysteroscopy, routinely.

3) There was a moderate strength of agreement in diagnostic accuracy between HSG and hysteroscopy in the identification of intrauterine adhesion.

### Authors' Contributions

Dr. Amike Inusa and Dr. Oranu Emmanuel conceptualized the research and Dr. Amike did the literature search. All authors participated in data acquisition and drafting—Drs. Nyengidiki, Oriji, Amike and Oranu alternatively carried out the hysteroscopy while Drs. Ugboma and Amike did the Hysterosalpingography. Drs. Oranu, Amike and Nyengidiki did the data analysis and interpretation. All authors read and approved the manuscript.

### Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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## Appendix

### Questionnaire

This questionnaire is designed to collect bio-data and record results of investigations of the study population for statistical analysis.

#### Section A: Socio-Demographic Characteristics

##### Serial number .....

1. Age in years (a) 18 - 25 (b) 26 - 30 (c) 31 - 35 (d) >35
2. Marital Status (a) Single (b) Married (c) Divorced (d) Separated
3. Level of Education (a) Primary (b) Secondary (c) Tertiary (d) Informal
4. Parity (a) 0 (b) 1 - 4 (c) >5
5. Type of infertility (a) primary (b) secondary
6. Duration of infertility (a) <2 years (b) >2 years

#### Section B: Hysteroscopy

1. Detection of submucous fibroid (a) yes (b) no
2. Detection of intrauterine adhesion (a) yes (b) no
3. Detection of endometrial polyp (a) yes (b) no
4. Detection of congenital uterine anomalies (a) yes (b) no
5. Detection of endometrial hyperplasia (a) yes (b) no
6. Detection of foreign bodies (a) yes (b) no
7. Pain perception during procedure (a) none (b) mild (c) moderate (d) severe

#### Hysterosalpingography

1. Detection of submucous fibroid (a) yes (b) no
2. Detection of intrauterine adhesion (a) yes (b) no
3. Detection of endometrial polyp (a) yes (b) no
4. Detection of congenital uterine anomalies (a) yes (b) no
5. Detection of endometrial hyperplasia (a) yes (b) no
6. Detection of foreign bodies (a) yes (b) no
7. Pain perception during procedure (a) none (b) mild (c) moderate (d) severe