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Correlation between hysterosalpingography diagnosis and final hysterolaparoscopy with dye-test diagnosis in women with utero-tubal infertility: A cross-sectional study of the implication for which test should be the first-line investigation

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Abstract

Objective: To assess the accuracy of hysterosalpingography in diagnosis of uterine and/or tubal factor infertility, using hysterolaparoscopy with dye test as the gold standard with an implication for which test should be the first-line investigation.
Methods: A prospective cross-sectional study of 96 women who underwent hysterosalpingography and hysterolaparoscopy with dye test. All women within reproductive age group with utero-tubal infertility who underwent both hysterosalpingography and hysterolaparoscopy with dye-test procedure were included. The outcome measures were proportions of tubal blockage and intrauterine pathology. Individual and overall mean accuracy were calculated for hysterosalpingography, using hysterolaparoscopy with dye test as the gold standard. Patient had procedure of hysterosalpingography first and both laparoscopic surgeons and patients were blinded to the outcome of hysterolaparoscopy with dye test until analysis. Statistical significance was set at $p < 0.05$.
Results: Overall, 128 women were assessed for eligibility while 96 women finally completed the study. Hysterosalpingography demonstrated diagnostic accuracy of 77.8% ($p < 0.001$), 76.3% ($p < 0.001$) and 78.3% ($p < 0.001$) for right, left and bilateral tubal blockage, respectively. Overall accuracy of hysterosalpingography tubal factor assessment was $77.4 \pm 0.8\%$ (95% confidence interval = 76.5% to 78.4%). Hysterosalpingography showed an accuracy of 85.7%, 86.6% and 76.7% for right, left and bilateral hydrosalpinx, respectively, given overall diagnostic accuracy of $83.0 \pm 5.1\%$ (95% confidence interval = 77.9% to 88.1%). Overall accuracy of hysterosalpingography in diagnosing intrauterine pathology was $68.5 \pm 9.8\%$ (95% confidence interval = 53.9% to 83.1%).
Conclusion: Hysterosalpingography detects tubal blockade and intrauterine pathology poorly compared to hysterolaparoscopy with dye test. Hysterosalpingography may face unpredictable clinical situations biased by technological error, leading to unsuccessful evaluation and uncertain diagnosis. Although the cost-effectiveness, risk of surgery or anaesthesia flaws hysterolaparoscopy with dye test. Hysterosalpingography should not be the first-line utero-tubal assessment tool rather hysterolaparoscopy with dye test.

Keywords

Agreement, patency, predictive values, sensitivity, specificity, tubal blockage, uterine pathology

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Introduction

Tests of tubal patency are crucial in the evaluation of the infertile couples.[1,2] This is because of the rising prevalence of tubal factor infertility,[2] which in turn is the result of the high rates of tubal damage from undiagnosed or poorly treated pelvic inflammatory disease (PID), unsafe abortion and puerperal sepsis.[3] This condition is not only peculiar to sub Saharan Africa but holds true in other parts of the world where similar rates of these conditions exist, and sometimes alongside other factors like genital tuberculosis.[3,4]

Traditionally, hysterosalpingography (HSG) had been deployed worldwide as the standard first-line test of tubal patency.[5] However, with the advent of minimal assess diagnostic procedures such as hysteroscopy, laparoscopy and dye test, assessment of tubal patency while also viewing the pelvic and abdominal cavities for other pathologies have become possible. Moreover, prior to the widespread availability of mid-luteal phase progesterone assay and ultrasound follicular tracking as tests of ovulation, performing hysteroscopy, laparoscopy and dye test in the mid-luteal phase of the menstrual cycle provided the opportunity for inspection of the ovaries for the stigma of ovulation, as well as the collection of an endometrial biopsy for histology – looking for secretory changes which may be suggestive of ovulation in that cycle.[6]

Hysteroscopy, laparoscopy with dye test was, however, not without problems of its own, not least among which was its invasiveness and need for anaesthesia. It therefore could not completely replace HSG, and both tests began to be considered complimentary.[7,8] Over time, the evolution of video-assisted laparoscopy and laparoscopic surgery, carrying out a laparoscopy and dye test also afforded the opportunity to administer surgical treatments such as laparoscopic tubal adhesiolysis and laparoscopic treatment of endometriosis.[9] Indeed, some management guidelines only recommend laparoscopy and dye test for women after an inconclusive or abnormal HSG, or when there is suspicion of some known risk factors for tubal pathology such as endometriosis or PID, thereby maintaining HSG as the first-line test of tubal patency.[10] The addition of hysteroscopy to the procedure of laparoscopy and dye test does, however, offer the added advantage of endometrial cavity assessment and possible treatment of identified problems such as submucous fibroids, polyps or uterine synechiae.[11,12]

Overall, opinions are divided regarding the optimal first-line test of utero-tubal factor infertility.[13] Some authors have argued for the outright recourse to hysterolaparoscopy with dye test (HLD) as the first-line method of utero-tubal assessment, considering that it is the ultimate diagnostic tool when HSG is inconclusive or abnormal.[13,14] However, the continued use of HSG as the first-line test of tubal patency, considering its less invasiveness and lower cost relative to hysteroscopy, laparoscopy and dye test must also be considered, especially in resource-constrained settings.[7,8,10]

Previous Cochrane review compared HSG and laparoscopy but not hysterolaparoscopy. The authors recommend further studies especially the one comparing HSG versus hysterolaparoscopy.

This study was therefore conceptualised to evaluate whether HSG should continue as the first-line test of utero-tubal factor infertility, by assessing its sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), as well as its diagnostic accuracy among women with utero-tubal factor infertility, comparing it against hysterolaparoscopy and dye test as the gold standard.

Methods

Study design

This cross-sectional study was designed in conformity with the Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines.[15]

Study site

The study was conducted in the Obstetrics and Gynaecology, and the Radiology Departments of the Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Ile-Ife, Nigeria.

Study population

Women of reproductive age presenting with infertility.

Sample size calculation

The sample size for this study was determined using the Bujang and Adnan[16] table for estimation of minimum sample size for sensitivity and specificity studies. Given the 42% prevalence of tubal factor in women with infertility in a previous Nigerian study,[17] a power of 80% and a type 2 error margin of 5%, a minimum total sample size of 96 was obtained for this study.

Methods

Consecutive women of reproductive age with infertility, who presented at the Gynaecology Clinic of OAUTHC and who were to undergo a tubal patency test as part of their infertility evaluation were counselled for participation in this study. The study adhered to the ethical principles for medical research involving human subjects as articulated in the Helsinki declaration.[18] The fact that the study participants would be required to undergo both HSG and HLD was duly explained to them. Their right to withhold consent or withdraw from the study at any time without any repercussions was assured. Written informed consent was obtained from all the willing participants. Women with known allergy to

contrast were excluded from the study. All primary and secondary infertile women within the reproductive age group who presented with utero-tubal infertility and women willing to undergo both HSG and HLD procedure were included. 'WHO defines primary infertility as the failure to conceive after 1 year of sexual intercourse without contraception and secondary infertility as the failure to conceive after the previous pregnancy'.[19,20] Patients with positive pregnancy test (defined at qualitative or quantitative beta human chorionic gonadotropin (hCG) testing during the research period), women with acute pelvic infection (defined as sexually active women who had lower abdominal pain, and vaginal discharge with demonstrable adnexal tenderness ± positive cervical excitation tenderness during her last clinic visit) or participants undergoing active treatment for sexually transmitted infection (STI) or PID (defined as sexually active women who had vaginal discharge ± lower abdominal pain with demonstrable adnexal tenderness and positive cervical excitation tenderness ± visible vulvo-vaginal lesion during her last clinic visit that are undergoing treatment for their disease), and those with known allergy to contrast/dye (women who demonstrated flare, wheal, urticaria rash, itch or other known allergic symptoms following the use of similar dyes or contrast in the past) and women who are unwilling to do both HSG and HLD procedure were excluded (refusal to do both HSG and HLD tests).

All the study participants had HSG performed, observing the 10-day rule.[21] About 30 min before the HSG, oral naproxen 500 mg and intramuscular diclofenac 75 mg stat were administered for analgesia, and hyoscine butyl bromide (Buscopan®) 10 mg intramuscularly was administered to prevent tubal spasm.[22] The RAD-12 X-ray tube made for General Electric Company by Varian Medical System, Salt Lake, UT, USA; model number 2226680, serial number 49164HL7 was used. A scout film was first taken, after which a speculum was used to expose the cervix. A Leech-Wilkinson's cannula was then applied to the cervix. Subsequently, 10–15 mL of 45% amidozoate (Urografin®, Schering, Germany) was instilled through Leech-Wilkinson's cannula, and spot radiographs were taken at intervals under fluoroscopy guidance – one during filling of uterus and proximal tubes, one during the filling of tubes and another during peritoneal spillage, respectively. A delayed film was also taken after 30 min. Following the HSG, each woman was scheduled for HLD on the next available operating day. This was within 2–4 weeks in all the women. The HSG results were interpreted by the same Consultant Radiologist, while ensuring that the minimal access gynaecologists were blinded to the result of the HSG until after the study.

The HLD was performed in the operating theatre, under general anaesthesia. First, a routine saline hysteroscopy was performed using a 2.9-mm Karl-Storz™ 30° hysteroscope. Afterwards, the hysteroscope was replaced with a uterine manipulator. The Verres' needle technique was used for primary abdominal entry. Proper placement of the Verres needle was confirmed.

Carbon dioxide pneumoperitoneum was created. The initial stab incision extended to accommodate the 10-mm primary port. Auxiliary ports were inserted under vision, following which the pre-set pressure of the insufflator was reduced from 25 to 15 mm Hg.

The points of entry on the anterior abdominal wall were first inspected for any bleeding, and then a panoramic inspection of the abdominopelvic organs was done. Dye test was performed with methylene blue injected and tubal spillage noted. Spilled dye was subsequently aspirated, and the secondary ports were removed under direct vision. The pneumoperitoneum was then released, and the primary port was removed with the laparoscope lagging. The skin of the secondary port(s) was closed in layers using Vicryl® 2/0 stitches. The port wounds were cleaned, and sterile dressings were applied. The HLD findings were recorded in a purpose-designed proforma. Each woman was discharged in the evening post-operatively after discussing the intraoperative findings with them.

Ethical consideration

Ethical approval (IRB/IEC/0004553 and NHREC/27/02/2009a) was obtained from the institution's ethics committee.

Statistical analysis. The sensitivity, specificity, PPV and NPV, and the diagnostic accuracy of HSG were calculated using MedCalc's Diagnostic test evaluation calculator version 20.009[23] using HLD as the reference standard. The HLD findings were used as a reference standard to calculate sensitivity, specificity, PPV and NPV and accuracies for bilateral tubal no patency and unilateral or bilateral tubal no patency, fimbriae and uterine pathology assessment. A 2×2 table was used for calculating sensitivity, specificity, PPV and NPV and accuracy. The overall accuracy was calculated by finding the average of individual accuracies and dividing by the total number. To compare the findings of HSG with laparoscopy, 2×2 table was constructed and findings were measured at 95% confidence level and Pearson's chi-squared test was used to see the significance levels. The resulting data were analysed using SPSS version 22. The level of significance was set at $p < 0.05$.

Results

A total of 3746 women were seen in the gynaecological outpatient clinic during the period of recruitment for this study (June 2018 to March 2019). Of this number, 723 (19.3%) presented with infertility, out of which 167 (23.1%) had utero-tubal factor infertility and were eligible for study inclusion. As shown in the STARD flow diagram in Figure 1, up to 167 of them met the inclusion criteria, among whom 128 consented and were recruited to participate in the study, while 39 refused consent refusing the procedure of HLD.

However, 32 of the consenting women defaulted from the study prior to HSG, while the remaining 96 successfully

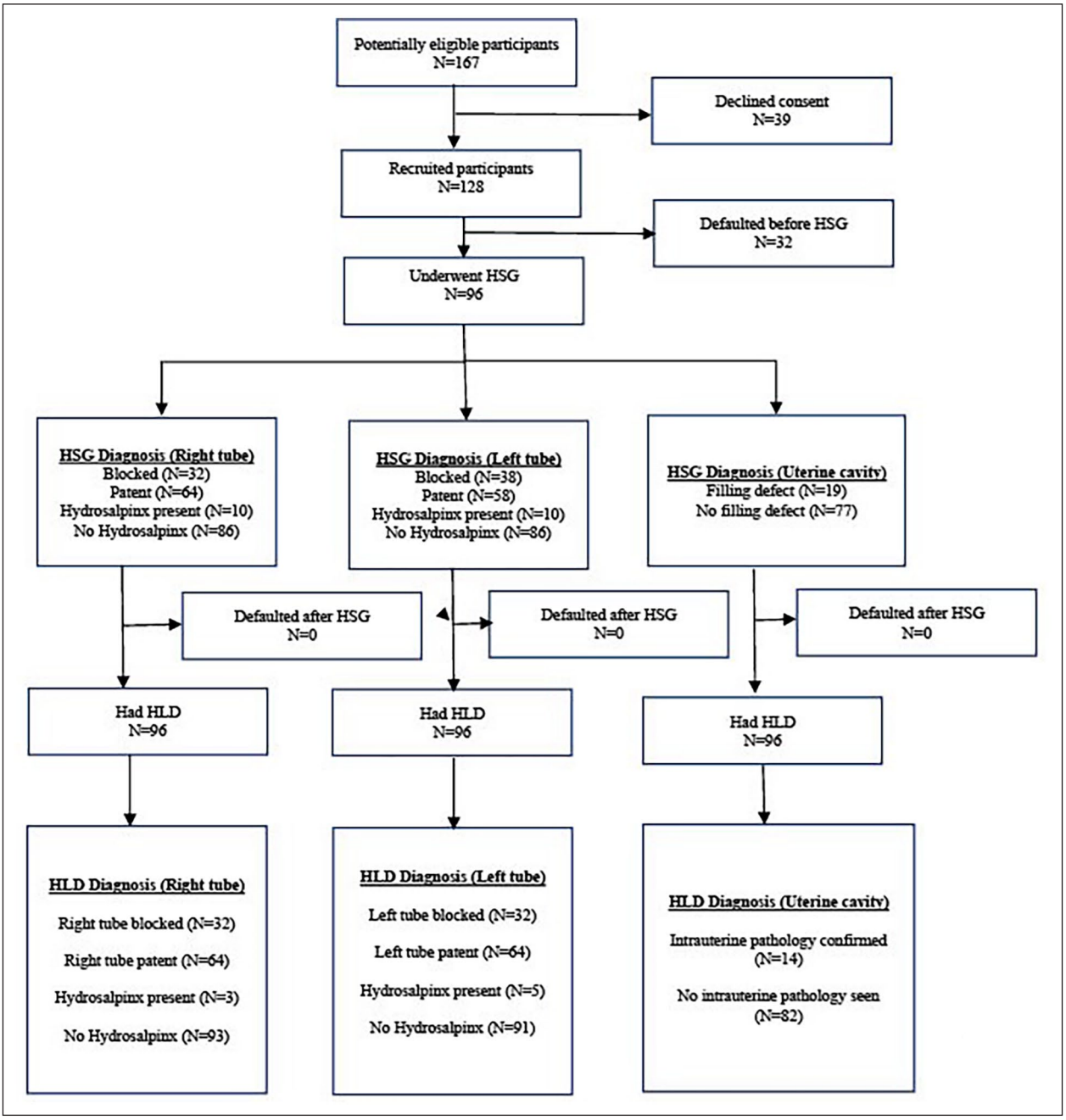

Figure 1. STARD flow diagram of HSG versus HLD study.

completed the study. The mean age of the participants was 33.9 ± 3.8 years. The median duration of their infertility was 48 months. Other details of the sociodemographic characteristics of the participants are as shown in Table 1.

HSG showed bilateral blockage, unilateral blockage and no tubal blockage in 28 (29.2%), 13 (13.5%), and 55 (57.3%) women, respectively. The comparison of this to the HLD findings is shown in Table 2. The sensitivity, specificity, PPV, NPV and diagnostic accuracy of HSG were determined for each fallopian tube separately as well as for bilateral tubal blockage, using laparoscopy with dye test as the gold standard. The results are as shown in Table 2.

Also shown in Table 2 is the result of the comparison of the uterine findings of HSG compared to hysteroscopy as the gold standard ($p = 0.001$). The performance of HSG in detecting the presence of hydrosalpinx is also shown in Table 2.

Discussion

This study revealed that when compared to HLD as the gold standard, HSG demonstrated a low sensitivity, specificity, PPV and NPV for detection of tubal blockage affecting each Fallopian tube separately, but even lesser so for bilateral tubal blockage. It also showed that the diagnostic accuracy

Table 1. Baseline sociodemographic characteristics of study participants (n = 96).

Variable	Outcome
Age (mean ± SD), years	33.9 ± 3.8
Duration of infertility (mean ± SD), months	45.0 ± 36.8
Parity (frequency (%))	
0	59 (61.5)
1	24 (25.0)
2	12 (12.5)
3	1 (1.0)
Type of infertility (frequency (%))	
Primary	32 (33.3)
Secondary	64 (66.7)
Highest level of education (frequency (%))	
Primary	1 (1.0)
Secondary	63 (65.6)
Tertiary	32 (33.3)

SD: standard deviation.

Table 2. Assessment of HSG for diagnosis of tubal patency and uterine pathology, using HLD as the gold standard.

	Sensitivity	Specificity	PPV	NPV	Accuracy (95% CI)	p-value
Right tubal blockage	71.9%	85.9%	71.9%	85.9%	77.8% (68.2 to 85.6)	<0.001
Left tubal blockage	78.1%	75.0%	69.4%	82.6%	76.3% (66.5 to 84.4)	<0.001
Bilateral tubal blockage	80.0%	77.1%	71.7%	84.2%	78.3% (68.7 to 86.1)	0.48
Overall mean accuracy of tubal blockage					77.4 ± 0.8% (76.5 to 78.4)	
Right hydrosalpinx	77.8%	96.5%	94.1%	85.7%	88.6% (80.4 to 94.3)	<0.001
Left hydrosalpinx	80.0%	93.4%	89.8%	86.6%	87.8% (79.5 to 93.6)	<0.001
Bilateral hydrosalpinx	66.7%	94.6%	89.9%	79.6%	82.9% (73.7 to 89.8)	<0.001
Overall mean hydrosalpinx accuracy					83.0 ± 5.1% (77.9 to 88.1)	
Intrauterine filling defects						
Smooth	0.0%	96.8%	0.0%	57.2%	56.2% (65.3 to 58.1)	0.85
Irregular	33.3%	95.2%	83.5%	66.4%	69.2% (59.0 to 78.3)	<0.001
Any defect	88.9%	33.3%	87.8%	35.7%	80.2% (70.4 to 90.0)	0.025
Overall mean accuracy of intrauterine lesions					68.5 ± 9.8% (53.9 to 83.1)	

HSG: hysterosalpingography; HLD: hysterosalpingography; PPV: positive predictive value; NPV: negative predictive value; CI: confidence interval.

was poor for detection of individual tubal blockage, but quite poorer for bilateral tubal blockage since the set point for accuracy testing is less than 90%. Furthermore, while the specificity and NPV of HSG for detecting uterine pathology were poor, its specificity, NPV and overall accuracy were also poor. These results corroborated the findings of some earlier studies and similar with findings by Ikechebelu and Mbamara,[13] Vaid et al.[14] and Gündüz et al.[20] Studies by Gündüz was, however, retrospective, but this study is prospective in design. In a Systematic review by Varlas et al.[24] on the efficiency and safety of hysterolaparoscopy in the management of infertility and other benign uterine pathologies, they suggested that laparoscopy is an option in patients with bilateral tubal hydrosalpinx undergoing assisted reproductive technology (ART) procedures.

The correct interpretation of these findings is that, when there was indeed tubal obstruction as confirmed by HLD, the HSG usually may not have demonstrated tubal blockage. Since the accuracy of HSG is less than 90% for detecting tubal blockade, this is statistically regarded as a poor assessment test compared to HLD. This was true for both the right and left tubes individually but worse for bilateral tubal blockage on HSG. One feasible explanation for this unexpected finding of lower accuracy of HSG for bilateral tubal blockage is the well-known possibility of tubal spasm during HSG, leading to a false impression of bilateral tubal blockage. Although the routine administration of naproxen, diclofenac and hyoscine during HSG was an attempt to mitigate this effect, some existing studies have cast doubt on its efficacy.[25,26] Studies by Gündüz et al.[20] and Varlas et al.[24] did not, however, consider the diagnostic accuracy of HSG and HLD.

The PPV of HSG for detecting tubal blockage implies that in women in whom HSG suggested tubal blockage,

there was a high probability that the tubal blockage may not confirm HLD findings. Similarly, the NPV observed for HSG in predicting tubal blockage in this study means that when HSG may not reveal tubal blockage, it is highly probable that there is also spillage of dye at HLD. The accuracy is, however, poor when compared to HLD. The findings by Gündüz et al.[20] revealed a lower specificity, sensitivity, PPV and NPV for HSG at 64.6%, 81.3%, 56.4% and 86% in the determination of tubal obstruction. When an analysis of the overall accuracy of HSG in detecting tubal blockade was performed, this gave a poor result (<90%); thus, HSG may not be the best of the tools in detecting tubal patency/blockade.

Regarding the presence of hydrosalpinx, HSG demonstrated low specificity and NPVs for both unilateral and bilateral hydrosalpinges. This means that when hydrosalpinx was absent at HLD, the HSG also may show hydrosalpinx (specificity). Correspondingly, whenever the HSG demonstrated no hydrosalpinx, HLD may detect some hydrosalpinx (NPV). The accuracy is, however, poor when compared to HLD which offers a see-and-treat approach. When an analysis of the overall accuracy of HSG in detecting hydrosalpinx was performed, this gave a poor result (<90%); thus, HSG may not be the best of the tools in detecting hydrosalpinx. Varlas et al.[24] in their systematic review has demonstrated the importance of see-and-treat advantage of HLD in the diagnosis of hydrosalpinx.

In addition, the presence of uterine filling defect on HSG demonstrated a low sensitivity and PPV, but poorer specificity and NPV for prediction of intrauterine pathology. Similarly, the demonstration of filling defects on HSG may not necessarily suggest abnormal findings on hysteroscopy (low PPV). The accuracy is, however, poor when compared to HLD. When an analysis of the overall accuracy of HSG in detecting intrauterine lesions was performed, this gave a poor result (<90%); thus, HSG may not be the best of the tools in detecting intrauterine lesions.

However, cases also abounded in which hysteroscopy confirmed intrauterine abnormalities such as small polyps and fibroids, while the HSG had revealed no abnormality. This is a testament to the superiority of direct visualisation of the uterine cavity as afforded by hysteroscopy, compared to the indirect assessment by HSG. Also, filling defects were quite often found on HSG, which were not due to the actual presence of any intrauterine pathology confirmed on hysteroscopy. This was especially so for round filling defects. This could sometimes be due to an air bubble in the uterus from injection of contrast, rather than an endometrial polyp or submucous fibroids. Irregular filling defects on HSG performed slightly better for prediction of synechiae at hysteroscopy, but the sensitivity is still too poor.

The accuracy of HSG was all below 90% suggests that HSG is not an ideal first test for the assessment of utero-tubal factor infertility. It is poor in detecting tubal patency and presence of hydrosalpinx. Its reliability in the diagnosis of bilateral tubal blockage was quite low possibly due to tubal spasm. HSG is even less ideal for the assessment of intrauterine pathology, due to its low sensitivity, PPV and diagnostic accuracy. These observations are also in keeping with earlier studies.[8,11,14,27] Varlas in his systematic review believed that one-step hysterolaparoscopy or various combinations are effective methods for identifying and treating anatomical structural abnormalities related to infertility, but they, however, did not relate their conclusions with HSG. Furthermore, Varlas et al.[24] did not discuss which of the procedures should come first, whether HLD or HSG justifying the gaps filled by this study. They, however, recognised the combined procedures of laparoscopy and hysteroscopy as the gold standard for utero-tubal assessment.[24]

Strengths and limitations

The strengths of this study lie in its prospective nature, reporting of the HSG by the same Consultant Radiologist, and the blinding of both the participants and the Minimal Access Gynaecologists to the findings of the HSG until after the HLD – thus reducing bias. Its limitations include the fact that both the HSG and HLD could not be performed on the same day due to logistical challenges. However, the effect of this was probably limited, as each subject's HLD was performed within 2–4 weeks of the HSG. Another limitation was that this study did not assess the economic evaluations between the two tests.

Conclusion

HSG is poor in detecting both tubal blockade and intrauterine pathology compared to HLD.

We are aware that pure HSG may face many unpredictable clinical situations biased by technology and/or patients, for example, severe pain, cramping pain and technology error may result in the unsuccessful evaluation and subsequently contribute to uncertain diagnosis. Therefore, hysterolaparoscopy under the general anaesthesia may minimise the risks. However, cost-effectiveness and the potential risk of surgery or anaesthesia should be considered in patients who had HLD. Therefore, suffices to say that the 'first-line' tool may not necessarily depend only on the 'accuracy', 'sensitivity' or 'specificity' of the rater.

We recommend that HSG should not be the first-line utero-tubal assessment tool, unless HLD is unavailable especially when information on intraperitoneal health is needed. Multicentre studies with a larger sample size that will consider cost-effectiveness analysis of the two tests is further recommended.

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Author contributions

E.P.I. contributed to the conception and design of study; data collection; data analysis and interpretation; responsible surgeon or imager; statistical analysis; article preparation; patient recruitment. O.O.B. contributed to the conception and design of study; data analysis and interpretation; responsible surgeon or imager; statistical analysis; article preparation. O.B.F. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. B.O.I. contributed to the conception and design of study; data analysis and interpretation; responsible surgeon or imager; statistical analysis; article preparation. O.M.L. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. J.I.I. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. G.U.E. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. A.A.O. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. B.C.O. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. O.S.U. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation. O.M.O. contributed to the conception and design of study; data analysis and interpretation; statistical analysis; article preparation.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Ethical approval

Ethical approval for this study was obtained from Obafemi Awolowo University Teaching Hospitals Complex institution's ethics committee between 4 June 2018 and 3 March 2019; after which an ethical clearance extension was obtained between 12 March 2019 and 11 September 2019, during which the work was concluded (Board (approval number/ID): IRB/IEC/0004553 and NHREC/27/02/2009a).

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Informed consent

Written informed consent was obtained from all subjects before the study.

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Data availability statement

Data will be made available to the public upon request.

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