

Evaluation of Indications of Saline Infusion Sonohysterography in a Private Hospital in Nigeria: A Retrospective Study

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ABSTRACT

Introduction: Despite the obvious advantages of Saline Infusion Sonohysterography (SIS) in the evaluation of infertile couples, its uptake is still poor in developing countries.

Aim: To evaluate the indications and findings of SIS and also to compare the findings in the fallopian tubes of women who had Hysterosalpingography (HSG) before SIS.

Materials and Methods: This was a retrospective study of consecutive SIS done in 27 women with infertility and 1 woman with abnormal uterine bleeding at The Light Specialist Hospital Nnewi, Anambra, Nigeria (November 2012 to May 2017). The ultrasound registers were used to identify women who had SIS. Relevant information was extracted from their folders and ultrasound records. These included sociodemographic characteristics, parity, and indication for the procedure, previous HSG findings and findings from the SIS. Data obtained were entered into SPSS version 24.0 and analysed.

Results: The mean age of the women was 33.6±7 years with 13 (46.4%) out of 28 being greater or equal to 35 years. The mean duration of infertility was 3.4 years. A total of 28 women had SIS during the study period and the procedure could not be completed in one of the patients. Twenty one of the patients had done a HSG before presentation with bilateral tubal blockade demonstrated in 17 of the women while the procedure could not be completed in the four other women. Twenty-two of the women showed spillage of saline during the SIS procedure, of which 12/22 had previously been shown to have bilateral tubal blockade by HSG. Within six months after the procedure, six women had spontaneous intrauterine pregnancy one of whom was diagnosed with tubal blockade by both HSG and SIS.

Conclusion: This study has demonstrated the usefulness of SIS as part of the initial investigations for tubal factors in the management of subfertility. The procedure should be made accessible and available to the women who need it especially in developing countries with high burden of tubal factor infertility.

Keywords: Hysterosalpingography, Pregnancy, Tubal infertility

INTRODUCTION

It is estimated that tubal factor infertility occurs in 68% of females with infertility in developing countries [1]. The first step in the management of tubal factor infertility is the diagnosis. Regrettably, laparoscopy and dye test which is seen as the gold standard is not readily available in resource poor settings. Where it is available, there are concerns about the invasive nature, use of anaesthesia and the cost [2]. Traditionally, HSG has been the most common modality for tubal factor assessment [3,4]. This is because it is cheap, available and non-invasive when compared to laparoscopy and dye test.

Saline infusion sonohysterography has emerged as an important investigative tool in the evaluation of tubal factor infertility and endometrial abnormalities [5,6]. Several studies have shown that it is as sensitive as HSG in determination of tubal patency [7,8]. It can be performed without a contrast medium which increases its safety profile. Though it is less sensitive than laparoscopy, the noninvasive nature, visualisation of endometrium and cost makes it a more attractive option as the first line investigation in the evaluation of tubal and uterine factors infertility. It is also more sensitive than HSG and transvaginal ultrasound in the evaluation of endometrial abnormalities [9].

Despite these advantages, SIS is not routinely done as part of baseline evaluation of tubal infertility and endometrial abnormalities especially in developing countries. The possible reasons for low uptake of SIS include lack of awareness, non-availability of ultrasound machines with transvaginal probes, and lack of skill for the procedure. The

few studies reported from Nigeria were done mainly to delineate uterine pathology prior to assisted conception [10,11]. This study was a review of the indications and findings in patients that did the saline infusion HSG in a private specialist hospital in Nigeria. The study also compared the SIS and HSG findings in women who had previously done the later.

MATERIALS AND METHODS

This was a retrospective study of consecutive SIS done in 28 women at The Light Specialist Hospital Nnewi, Anambra, Nigeria (November 2012 to May 2017).

The Light Specialist Hospital is a private specialist hospital that handles majorly obstetrics and gynaecology patients. There is also a Radiology unit manned by a consultant radiologist who handles specialist ultrasonography and SIS. The ultrasound registers were used to identify women who had SIS. Relevant information was extracted from their folders and ultrasound records. These included sociodemographic characteristics, parity, indication for the procedure, previous HSG findings and findings from the saline infusion HSG. All the patients who had SIS were included in the study. Ethical clearance was obtained from the hospital before the commencement of the study.

The patients were referred for this investigation mostly for re-evaluation of tubal factor infertility following HSG report of bilateral tubal occlusion or for further elucidation of transvaginal ultrasound findings in the endometrium. Others had it post myomectomy to

review tubal patency when preoperative HSG showed bilateral tubal occlusion.

Those patients that had SIS in the study centre were included. Exclusion criteria included women who were allergic to the dyes and those who have not had penetrative vaginal intercourse previously. Women who had pelvic inflammatory disease and those who tested positive to pregnant test were also excluded from the study.

Procedure: The 10 day rule observed in HSG was observed in this procedure. Patients were extensively counseled and oral consent was obtained. The patient was placed in dorsal position. Routine cleansing and draping of the perineum was then carried out. A preliminary transvaginal ultrasound scan was done to evaluate the pelvic structures and assess the presence and amount of fluid in the pouch of Douglas. When there was significant fluid, the procedure was postponed and patient was evaluated for possible Pelvic Inflammatory Disease (PID) using clinical features and laboratory investigations. Those who were found to have PID were treated as appropriate. When there was no fluid, a bivalve Cusco's speculum was used to expose the external cervical os. A size 8 Foley's catheter with guard wire was introduced into the uterine cavity using sponge holding forceps. A transabdominal ultrasound was used to confirm that the catheter was in the uterine cavity.

Subsequently, 3 mL of water for injection was used to inflate the balloon of the catheter. The speculum was removed to allow the introduction of transvaginal probe (which was covered with condom and coupling gel) into the vagina. Before injection of saline, 10 mg of intramuscular buscopan was injected to reduce abdominal pain. A syringe was used to introduce 20 mL of warm normal saline through the Foley's catheter. More fluid was infused as necessary up to 80 mL. The distension of the endometrial cavity and any irregularity in the outline were observed. The spillage of fluid in the adnexa and pouch of Douglas were noted. Patients were placed on prophylactic oral antibiotics (co-amoxiclav and metronidazole) after the procedure. The patients were then counseled on the findings from the procedure and report written to the referring physician.

STATISTICAL ANALYSIS

Data obtained were entered into SPSS version 24.0 and analysed. There was cross tabulation to determine correlation between the SIS and HSG findings at a p-value of less than 0.05.

RESULTS

During the study period, a total of 5315 ultrasound scans were done, 2052 were gynaecological scan. A total of 28 SIS was done within the study period comprising 1.4% of all the gynaecological scan referral and 0.5% of all the total scan referral. The mean age of the women was 33.6±7 years. The mean parity was 0.5±1.0 with 22 (78.6%) out of 28 being nulliparous. The biosocial characteristics are shown in [Table/Fig-1]. The most common indication for the procedure was primary infertility 17 (60.7%) out of 28 while the mean duration of infertility was 3.2±1 years. The indications and duration of infertility is shown in [Table/Fig-2].

The SIS showed spillage in 22 (78.6%) and no spillage in 5 (17.9) of the cases. The procedure could not be completed in one patient 1 (3.5%). Twenty-one of the women had done a previous HSG which showed blocked tubes in 17 of the cases while the procedure was not completed in four cases. Twelve out of the 17 cases that were shown to have blocked tubes by HSG demonstrated spillage by SIS. The concordance rate between HSG and SIS in this study was 25.0%. There was a negative correlation between the findings from previous HSG and SIS procedures but this was not statistically significant (spearman correlation coefficient=0.153, p-value=0.439). The correlation and concordance between HSG and SIS is as shown in [Table/Fig-3].

Six of the 27 women conceived spontaneously within six months of undergoing the procedure. Four of them that conceived had positive

Parameter	Frequency (%)
Age (years)	
20-24	1 (3.6)
25-29	2 (7.1)
30-34	12 (42.9)
≥35	13 (46.4)
Total	28 (100)
Parity	
0.00	22 (78.6)
1.00	2 (7.1)
2.00	1 (3.6)
3.00	1 (3.6)
4.00	2 (7.1)
Total	28 (100)
Marital status	
Currently married	28 (100)
Past history of pelvic surgery	12 (42.9)

[Table/Fig-1]: Biosocial characteristics.

Indication	Frequency (n=28)	Percentage (%)
primary infertility	17	60.7
secondary infertility	10	35.7
dysfunctional uterine bleeding	1	3.6
Total	28	100.0
Duration of Infertility/years		
	Frequency (n=27)	Percentage (%)
<1	3	11.1
1.00	3	11.1
2.00	6	22.2
3.00	6	22.2
4.00	3	11.1
5.00	1	3.7
6.00	2	7.4
7.00	2	7.4
8.00	1	3.7
Total	27	100

[Table/Fig-2]: Indications for the procedure.

	Findings from SIS				Pearson's correlation	p-value
	Free spillage	No spillage	Unsuccessful	Total		
Findings from HSG					-0.152	0.439
Both tubes blocked	12	4	1	17		
Not done	7	0	0	7		
Unsuccessful	3	1	0	4		
Total	22	5	1	28		
Concordance between SIS and HSG	4/16 (25.0%)					

[Table/Fig-3]: Concordance between HSG findings and SIS findings.

bilateral tubal blockade from HSG result and 1 had nil spillage from SIS procedure [Table/Fig-4]. One of the two women with past history of PID demonstrated spillage while 10/11 women with past pelvic surgery demonstrated spillage. There was negative correlation between risk factors for tubal blockade and spillage during SIS (spearman correlation coefficient -0.526, p-value=0.004) [Table/Fig-5].

	Findings from HSG			
	Both tubes blocked	No previous HSG	Abandoned	Total
Pregnant within six months after the procedure				
No	14	4	4	22
Yes	3	3	0	6
Total	17	7	4	28
Findings at SIS		Unsuccessful because of cervical stenosis		Total
Spillage		No spillage		
Pregnant within six months after the procedure				
No	17	4	1	22
Yes	5	1	0	6
Total	22	5	1	28

[Table/Fig-4]: Spontaneous pregnancy rate within six months of the procedure.

Risk factors for tubal blockade	Finds from saline infusion				Pearson's correlation	p-value
	Free spillage	Nil spillage	Unsuccessful because of cervical stenosis	Total		
PID	1	1	0	2	-0.536	0.004
Pelvic surgery	11	0	1	12		
Termination of pregnancy	3	0	0	3		
None	7	4	0	11		
Total	22	5	1	28		

[Table/Fig-5]: Risk factors and spillage during SIS.

DISCUSSION

The mean age of the subjects was 33 years while the mean parity was 0.6 with primary infertility accounting for the majority of the cases of infertility. The mean duration of infertility was 3.4 years. A total of 28 women had SIS during the study period and the procedure could not be completed in one of the patients. Twenty one of the patients had done a HSG before presentation with bilateral tubal blockade demonstrated in 17 of the women while the procedure could not be completed in the four other women. Twenty-eight women underwent the SIS procedure with 22 showing spillage of saline. A total of 12/22 that demonstrated spillage on SIS had previously been shown to have bilateral tubal blockade by HSG. The concordance rate between HSG and SIS in this study was 25.0%. Within six months after the procedure, six women had spontaneous intrauterine pregnancy one of whom was diagnosed with tubal blockade by both HSG and SIS.

The concordance rate of 29.4% between HSG and SIS in this study was poor but this was not significant enough to dispute observation of many studies that SIS has a similar accuracy in evaluating tubal patency [12, 13]. Despite the comparable result reported in literature, SIS has an added advantage of being less invasive. A meta-analysis by Maheux-Lacroix S et al., observed that the sensitivity and specificity of SIS and HSG were comparable in the diagnosis of tubal blockade but concluded that SIS should be used as a first line investigation given the other advantages over HSG [14].

The possible reason for the poor correlation is not clearly related to intra observer variability, quality of the films and machines used in the HSG procedure. This may also be connected with proximal tubal spasm in HSG [15]. Hajishafiha M et al., evaluated women who had proximal tubal occlusion with SIS and observed that 80% had at least a patent tube [16]. The poor sensitivity and specificity of HSG in diagnosis of tubal factor infertility was also demonstrated in the pregnancy outcome where 33.3% women with bilateral tubal blockade has spontaneous conception. This is far higher than 4.5%

spontaneous pregnancy rate in women who had spillage after SIS procedure. It is difficult to state the reason for this observation of the nature of present study. A prospective study comparing the two procedures simultaneous will be better in drawing this inference.

The overall rate of spontaneous pregnancy of 22.2% recorded in present study was higher than 8.4% observed by Hamilton J et al., [17] but comparable to 22.5% reported by Hajishafiha M et al., after artificial insemination [16]. The pregnancy rate may also be explained by the cumulative effects of HSG and SIS procedures in the opening of the tubes which improves pregnancy outcome.

The failure to complete the procedure in present study was 3.6% which is comparable to observation by previous studies [18]. The failure was as a result of cervical stenosis. Cervical stenosis is the commonest cause of failure to complete the procedure as reported in literature [19,20]. Other causes include vasovagal reaction and severe pain which were not recorded in present study.

There was poor correlation between the risk factors for tubal blockade and findings at both HSG and SIS. This shows that relying heavily on the presence and absence of the risk factors in making diagnosis of tubal blockade may be misleading. This is expected since majority of pelvic inflammatory diseases caused by chlamydia are asymptomatic and hence cannot be easily detected by clinical features [21].

LIMITATION

One of the limitations of this study was the retrospective nature which did not allow us to evaluate and compare patients satisfaction between HSG and SIS in this study. This is a key factor which contributes to their choices of treatment. In addition, we could not evaluate and compare degree of pain perception in both procedures because of the nature of the study design. However, various studies had shown that pain score is lower in SIS which increases study patients satisfaction and preferences [22]. The major indication for the SIS procedure was evaluation of the tubes in infertile women; this made it difficult to assess the other uses of SIS.

CONCLUSION

This study showed usefulness of SIS as a cheap, non-invasive evaluation method for tubal factor infertility. It is also helpful for re-evaluating HSG findings. The high pregnancy rate suggests that it may have a therapeutic value. SIS should be made available especially in developing countries where laparoscopy is not readily available.

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