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Comparative study between saline infusions sonohystrography and office hysteroscopy in evaluation of the uterine factor in cases of infertility

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Abstract
Introduction: Infertility is defined as the inability to conceive naturally after one year of regular unprotected intercourse. Most of the time, infertility is some degree of subfertility in which 1 in 7 couples need specialist help to conceive. Subfertility can be either primary or secondary. Primary subfertility is a delay for a couple who have had no previous pregnancies; and, secondary subfertility is a delay for a couple who have conceived previously, although the pregnancy may not have been successful for example, miscarriage, and ectopic pregnancy. Though, Evaluation of the uterine cavity is mandatory when studying infertile patients and it is known that the Hysteroscopy is the gold standard for the investigation of uterine cavity, particularly when pathology is suspected. It is a safe test for the direct and accurate diagnosis of intrauterine abnormalities. It permits direct visualization of the uterine cavity, revealing the nature, location, shape, size and vascular pattern of any uterine cavity abnormalities, such as polyps, submucosal fibroids, differences in endometrial thickness and adhesions.
Aim of Work: The aim of this work is to compare the findings of saline infusion sonohysterography (SIS) & office hysteroscopy (OHS) in patients with suspected uterine causes of infertility by Hystrosalpingography (HSG) or Ultrasonography (US). Cross sectional study
Results: The main pathology finding in HSG and SIS were all cases were normal (80%) except in 6 cases (20%) had intrauterine polyps table the mean pathology finding diagnosed by hysteroscopy were 16 cases (53.33%) polyp. 11cases (36.7%) normal, 2cases (6.7%) with septum and only case with submoucas myoma (3.3%).
Conclusion: (SIS) is a safe and relatively cheap method which allows for ruling out or confirming endometrial polyps or other endometrial defects (septum, myoma). But the accuracy and sensitivity less than the hysteroscopy. Though, Evaluation of the uterine cavity is mandatory when studying infertile patients and it is known that the Hysteroscopy is the gold standard for the investigation of uterine cavity, particularly when pathology is suspected. It is a safe test for the direct and accurate diagnosis of intrauterine abnormalities.

Keywords: infertility, hystrosalpingography saline infusion sonohysterography & office hysteroscopy

Introduction

Infertility is defined as the inability to conceive naturally after one year of regular unprotected intercourse. Most of the time, infertility is some degree of subfertility in which 1 in 7 couples need specialist help to conceive. Subfertility can be either primary or secondary

Primary subfertility is a delay for a couple who have had no previous pregnancies; and, secondary subfertility is a delay for a couple who have conceived previously, although the pregnancy may not have been successful for example, miscarriage, and ectopic pregnancy [1].

Both males and females are equally responsible for the causes. Most of the infertile couples have one of these three major causes including a male factor, ovulatory dysfunction, or tubal-peritoneal disease [2].

In fact, infertility related to uterine cavity abnormalities has been estimated to be the causal factor in as many as 10% to 15% of couples seeking treatment. Moreover, abnormal uterine findings have been found in 34% to 62% of infertile women [3]. Traditionally, Hysterosalpingography (HSG) has been the most commonly used technique in the evaluation of infertility. It gives reliable information about the patency and morphology of the fallopian tubes. It is also helpful in evaluating uterine cavity abnormalities [4]

Though, Evaluation of the uterine cavity is mandatory when studying infertile patients and it is known that the Hysteroscopy is the gold standard for the investigation of uterine cavity, particularly when pathology is suspected. It is a safe test for the direct and accurate diagnosis of intrauterine abnormalities. It permits direct visualization of the uterine cavity, revealing the nature, location, shape, size and vascular pattern of any uterine cavity abnormalities, such as polyps, submucosal fibroids, differences in endometrial thickness and adhesions [4].

Diagnostic hysteroscopy offers a reliable evaluation of the uterine cavity and subsequent detection of intrauterine disease. Mean prevalence of uterine malformation in general population 7.6% [5]

Based on the results of the previous studies, it appears that more than 1/3 of the patients interpreted as normal following HSG are found to have a uterine abnormality after diagnostic hysteroscopy, which might be a significant cause of reproductive failure. These women may be wrongly treated, or unnecessarily

investigated, while their intrauterine lesion has been missed [6]. Sonohysterography (SHG) is considered a simple, effective and well tolerated technique for enhanced transvaginal sonographic imaging of the endometrial cavity. The instillation of sterile saline into the uterine cavity via a fine catheter provides both a contrast medium and an expanding agent. So, Saline infusion sonohysterography (SIS) can help to triage patients to: No anatomic pathology; globally thickened anatomic pathology that may be evaluated with blind endometrial sampling; focal abnormalities that must be evaluated under direct vision [7].

Aim of Work

The aim of this work is to compare the findings of saline infusion sonohysterography (SIS) & office hysteroscopy (OHS) in patients with suspected uterine causes of infertility by Hystrosalpingography (HSG) or Ultrasonography (US).

Patients and Methods

Type of the study: Cross sectional study.
Numbers of patients: 30 patients
Sample size: The sample size was calculated using the following formula

$$n = \left[\frac{Z_{\alpha/2}}{E}\right]^2 * P(1-P)$$

Where:
n = sample size
Z α/2 = 1.96 (The critical value that divides the central 95% of the Z distribution from the 5% in the tail)
p = the prevalence of the uterine factor in cases of Infertility=91 % (De Kroon *et al*., 2004)
E = the margin of error **(=width of confidence interval)**
So, by calculation, the sample size is equal to 30 patients.
Duration of study: One year from February 2017 to February 2018
Place of study: Aswan University Hospital and Aswan General Hospital
Patients: *Inclusion criteria*

1. All women in their reproductive age from 18 to 35year
2. Only cases of primary infertility were included with uterine defects
3. Accepting and signing the informed written consent

Exclusion criteria

1. Male factor infertility
2. Patient with vaginal bleeding and gynecological infection

Methodology

All patients with primary infertility with suspected uterine factor were recruited from those visiting the outpatient gynecological clinic; each patient was assessed by history, clinical examination, ultrasound, and laboratory investigations, then they were subjected to SIS followed by office hysteroscopy after completion of SIS.

Office hysteroscopy procedure

Office hysteroscopy was carried out 1 day after SIS using Karl Storz (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) telescope: Rigid 30° Harmou II Hysteroscope model 26157 BT with a 3.5 mm outer diameter of the sheath. The procedure was carried out by the same gynecologist who was kept blind to findings at SIS.

After vaginal disinfection, the tip of the hysteroscope was positioned in the vaginal introitus and the labia being slightly separated with the examiner fingers and the vagina was distended using normal saline. hystroscopy done without using any speculum or tenaculum

The scope was directed to the posterior fornix until portiovaginalis of the uterine cervix was visualized then the scope was withdrawn slowly to visualize the external os, then it was moved through it to the uterine cavity. The uterine cavity was then systematically examined and any pathology found was recorded.

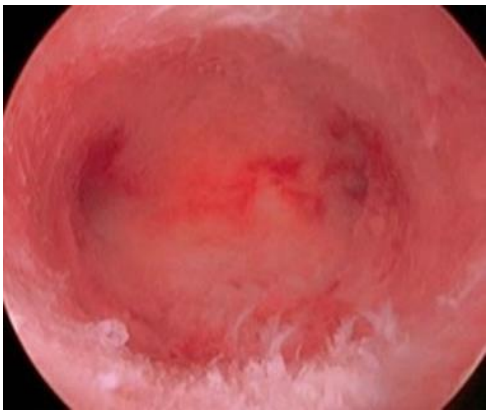

Fig 1: Normal uterine cavity

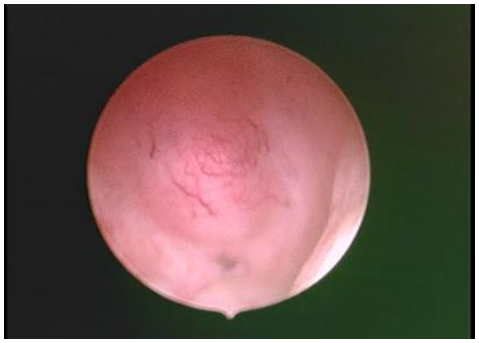

Fig 2: Uterine small myoma

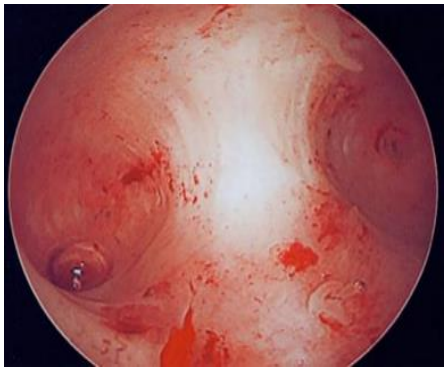

Fig 3: Subseptat uterus hystroscopic view

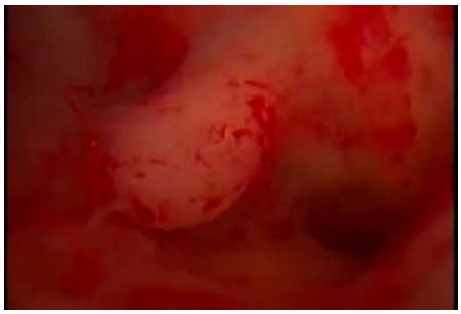

Fig 4: small endometrial polyp

Committee approve

1. Approval from Research Ethics committee (REC) was taken before starting field work
2. All the procedures of the study were approved by the obstetrics department.
3. Agreement of participant without obligation.
4. Confidentiality of data was preserved.
5. Explanation of this project to the participants
6. An informed consent was taken from the patients to participate in the study, after clarifying the aim of the study

Table 1: Statistical methods

Test2 Test 1	Positive	Negative	Total
Positive	True Positive (a)	False Positive (b)	(a +b)
Negative	False Negative (c)	True Negative (d)	(c +d)
Total	a +c	b +d	(a+b+c+d)

Table 2: Statistical methods

Measure	Definition	Formula
sensitivity	True positive/ all diseased	$\frac{a}{a+c}$
specificity	True negative/ all non-diseased	$\frac{d}{b+d}$
Predictive value of positive screen	True positive/ all screened positive	$\frac{a}{a+b}$
Predictive value of negative screeb	True negative/ all negative	$\frac{d}{c+d}$
Accuracy	True negative +true positives results	$\frac{a+d}{a+b+c+d}$

Where a = true positive cases; b = false positive cases; c = false negative cases; d = true negative cases. All these tests will be used as tests of significance at $p< 0.05$.

Results

Among the population that had been admitted in our hospitals (Aswan university and Aswan general hospital) during the period of the study, A total of 30 patients met inclusion criteria for this study

Table 3: Demographic characters of the studied cases.

	Number	Percentage
Age (Mean± SD) Duration of infertility (Mean± SD)	26.1 ± SD 3.36 (1 – 11) year± SD 3.03	
Occupation		
Housewife	11	36.6%
Working	19	63.3%
Educational Level		
Illiterate – 1ry school	13	43.3%
High school	17	56.6%
Residency		
Rural	12	40%
Urban	18	60%

Table 4: HSG finding of the studied cases

Defects	Number	Percentage %
Normal Polyp	24 6	80.0% 20.0%
Myoma Septum	0 0	0. 0.0%
Total	30	100%

The main pathology finding in HSG were summarized in table (4) all cases were normal (80%) except in 6 cases (20%) had intrauterine polyps table (4)

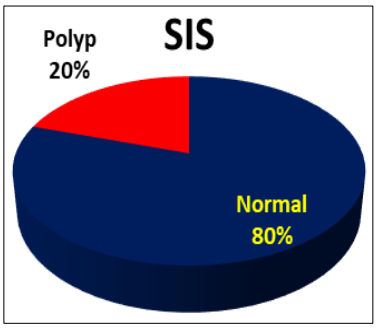

Fig 5: Distribution of findings of SIS among the studied case

Table 5: SIS findings among the studied cases

Defects	Number	Percentage %
Normal	24	80.0%
Polyp	6	20.0%
Myoma Septum Total	0 0 30	0.0% 0.0% 100%

The SIS findings among the studied cases were normal in 80% of cases and had intrauterine polyp in 20%of them table (5)

Table 6: OHS findings among the studied cases

Defects	Number	Percentage %
Normal	11	36.7%
Polyp	16	53.3%
Myoma	1	3.3%
Septum	2	6.7%
Total	30	100.%

The mean pathology finding diagnosed by hysteroscopy were 16 cases (53.33%) polyp. 11cases (36.7%) normal, 2cases (6.7%) with septum and onlycase with submoucas myoma (3.3%) table (6)

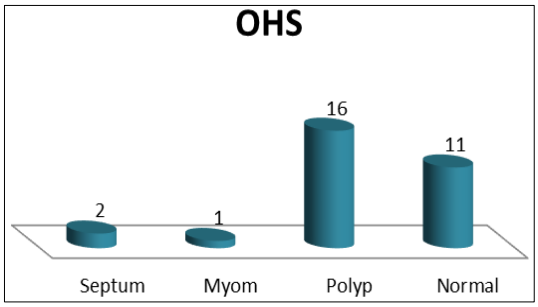

Fig 6: Distribution of findings of OHS among the studied cases

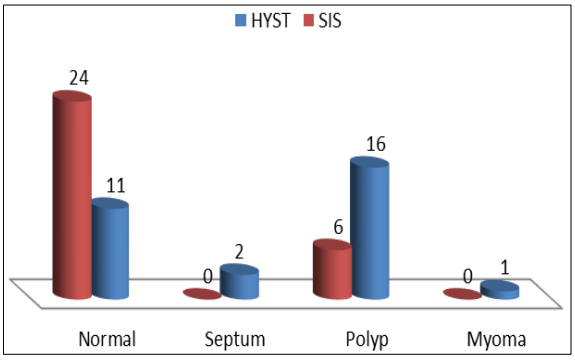

Fig 7: Distribution of findings of SIS and OHS among the studied cases

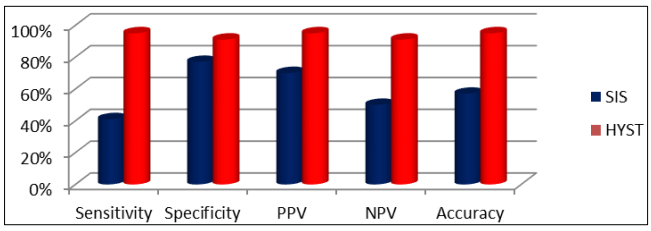

Fig 8: Sensitivity, specificity, PPV, NPV, and accuracy of different used techniques for all the studied cases

Discussion

The acquired and congenital uterine anomalies are important causes of female infertility; hence, investigation of the uterine cavity is obligatory practice in the assessment of infertile women, particularly in patients with unexplained infertility [8].

Many tools are used in the diagnosis of intrauterine pathology, the most frequently used being TVS, SIS, diagnostic OHS, and sampling, individually or in combination. The choice of the best test will depend primarily on its diagnostic accuracy [9]

Although it has been reported that instillation of saline during ultrasound (SIS) enhances and augments the image of the endometrial cavity, diagnostic OHS is still generally accepted as the gold standard for the evaluation of the uterine cavity. It is an invasive procedure, which is associated with discomfort for the patients and sometimes vasovagal attack [10].

In our study, 30 women with unexplained infertility agreed to undergo SIS in addition to the OHS for uterine cavity assessment. Mean age of patients was (26.16 ±3.36 years) (range 21-34 years), the mean of duration of infertility was (3.03 ±2.00 years) (range 1-11 years). This is similar to another study about saline infusion sonography versus hysteroscopy in the evaluation of uterine cavity in women with unexplained infertility in which the study included 50 women with unexplained infertility in the age range 20–34 years, with a mean age of 26.88±3.42 years [11].

This is also in agreement with Reda *et al*., [12] study in which the mean ± standard deviation (SD) of age of the studied patients was 30.55 ± 3.62 years (range from 22 to 35), and the mean ± SD of the duration of infertility was 6.32 ± 3.24 years with a range between 2 and 17 years.

SIS evaluation of the uterine cavity of the studied cases in the present study indicated a normal uterine cavity in 24 (80%) cases and uterine cavity abnormalities in 6 (20%) cases endometrial polyps, 0 (0%) uterine septum, and 0 (0%) myoma). This is in agreement with Reda *et al*., [12] study in which initial transvaginal ultrasonography showed abnormalities in 4 patients (6.7%); 2 cases (3.3%) with endometrial polyp and the other 2 cases (3.3%) had a submucosal myoma. SIS was carried out in the same setting with abnormalities were detected in 7 cases (11.7%); endometrial polyp was detected in 5 patients (8.3%) and the remaining 2 cases (3.3%) had submucosl myoma.

Radwan *et al*., [13] found that endometrial polyps were diagnosed in 74 patients (30.7%). In 72 cases both SIS examination and hysteroscopy confirmed the occurrence of an endometrial polyp. In seven examinations the diagnosed polyp was not confirmed with an endoscopic examination of the uterine cavity (false-positive results). Two SIS procedures did not confirm the occurrence of the polyp (false-negative results).

Bingol *et al*., [14] in their study demonstrated that SIS detected endometrial polyp and submucosal myoma in 121 cases (35%) and 101 cases (29.2%) respectively which was confirmed with hysteroscopy in 109 cases (31.5%) and 102 cases (29.5%) respectively. The accuracy in detecting submucosal myoma is nearly 100% and small false positive rate in detecting endometrial polyp. The same study disagrees with our finding in that SIS detected IUA in all cases identified with hysteroscopy. The nature of these adhesions was not specified.

In this study, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SIS to detect intrauterine pathology was 41%, 77%, 70%, and 50%

respectively. This is different from Reda *et al*., [12] results who found that. the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SIS to detect intrauterine pathology is 41.2%, 100%, 100%, and 81.1%, respectively, some studies reported SIS to be more sensitive. Ragni *et al*., [15] reported sensitivity, specificity, PPV and NPV of 98%, 94%, 95%, and 98%, respectively. Furthermore, Alborzi *et al*., (16) reported that SIS had sensitivity of 94.1%, specificity of 95%, PPV of 96%, and NPV of 90%. Bocca *et al*., [17] tried to detect endometrial polyps and hyperplasia. In order to do it they compared 65 sonohysterographic with hysteroscopic examinations and confirmed complete agreement (100% sensitivity, specificity, positive predictive value – PPV, negative predictive value – NPV).

Conclusion

Hydrosonography (SIS) is a safe and relatively cheap method which allows for ruling out or confirming endometrial polyps or other endometrial defects (septum, myoma). But the accuracy and sensitivity less than the hysteroscopy

Though, Evaluation of the uterine cavity is mandatory when studying infertile patients and it is known that the Hysteroscopy is the gold standard for the investigation of uterine cavity, particularly when pathology is suspected. It is a safe test for the direct and accurate diagnosis of intrauterine abnormalities.

It permits direct visualization of the uterine cavity, revealing the nature, location, shape, size and vascular pattern of any uterine cavity abnormalities, such as polyps, submucosal fibroids, differences in endometrial thickness and adhesions

Recommendations

1. The Hysteroscopy is the gold standard for the investigation of uterine cavity, particularly when pathology is suspected. It is a safe test for the direct and accurate diagnosis of intrauterine abnormalities.
2. It permits direct visualization of the uterine cavity, revealing the nature, location, shape, size and vascular pattern of any uterine cavity abnormalities, such as polyps, submucosal fibroids, differences in endometrial thickness and adhesions

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