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The Diagnostic Value of Saline Infusion Sonohysterography Versus Hysteroscopy in Evaluation of Uterine Cavity in Patients with Infertility and Recurrent Pregnancy Loss

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ABSTRACT

Objective: To evaluate the sensitivity, specificity, positive and negative predictive values of saline infusion sonohysterography (SIS) in patients with infertility and recurrent pregnancy loss in comparison with hysteroscopy.

Materials and methods: One-hundred sixty one women with infertility or recurrent pregnancy loss (RPL) were evaluated by SIS and hysteroscopy. The uterine cavity was inspected for irregularities as synechiae, polyps and submucous myomas, as well as uterine malformations.

Results: The mean age of patients was 35.32 ± 6.43 . Endometrial polyps were equally detected by both methods in the two groups. Submucous fibroids were more detected by SIS while intrauterine adhesions and congenital anomalies were more detected by hysteroscopy in both groups. The sensitivity, specificity, positive and negative predictive values of SIS in patients with infertility was higher than those with RPL (84.3 and 75%, 94.1 and 96.7%, 93.1 and 92.5, 74.4 and 67.9% respectively).

Conclusion: Hysteroscopy is superior to SIS in diagnosis of intracavitary abnormalities. However, saline infusion sonohysterography has the advantages of being non-invasive, cheap, affordable, shorter duration and accurate method for uterine cavity evaluation.

Keywords: Infertility, recurrent pregnancy loss, saline infusion sonohysterography.

Introduction

Recurrent pregnancy loss (RPL) is defined by the occurrence of three or more consecutive losses before 12 (early) or before 20 (late) week's gestation, and it causes great stress for patients and doctors⁽¹⁾.

Uterine anomalies, both congenital and acquired, may occur in 15-30% of such patients⁽²⁾.

Saline infusion sonohysterography (SIS) is a real-time imaging technique for visualization of the endometrium and endometrial cavity. Sterile saline

instillation into the endometrial cavity with the aid of the two-dimensional transvaginal ultrasonography (TVS) is an easy, fast, cheap and well-tolerated technique for diagnosis of uterine cavity pathologies. SIS offers a detailed vision of the uterine cavity compared to the TVS and can prevent the patient from more invasive procedures such as diagnostic hysteroscopy.

Additionally, SIS can be used to evaluate the tubal patency in some instances⁽³⁾, and to search for retained products of conception⁽⁴⁾.

This study aims to evaluate the accuracy of SIS in the investigation of uterine cavity in patients with infertility and recurrent pregnancy loss in comparison with hysteroscopy.

Materials and Methods

This is a prospective cross sectional study included 161 women over 20 years old, with infertility or having three or more RPL attending the outpatient gynecology clinic, Qena University Hospital, Egypt between July 2012 and January 2014. All patients were invited to participate in this study after taking an informed consent. The study was approved by the Ethical Review Board of Qena faculty of medicine.

The patients with previous history of cervical surgery, previous difficulties with hysteroscopy, acute or recent pelvic infection and those who are suspected to be pregnant were excluded from the study.

Sample size calculation was done using (Epi-info™, CDC, USA.2008)program using 80% power and level of significance was set at 5% ($P = 0.05$) taking in consideration the population size; adjusted number of patients attended the outpatient gynecology clinic in the preceded year before the study and the prevalence of endometrial lesions as a cause of infertility or RPL established from the previous studies. Sample size was 161 women.

Evaluation of the uterine cavity by SIS and Hysteroscopy was performed for all patients. Both procedures were performed in the first half of the same menstrual cycle sequentially starting with SIS.

SIS was performed using a 5.0-MHz vaginal probe, Logiq B5 ultrasound machine. The same sonographer (A.E.T.); a physician who had been trained

in different ultrasonography techniques, evaluated all patients. A sterile 8-F Foley catheter (length, 30 cm; diameter, 2.7 mm) was inserted through the cervical os until it reached the fundus.

The speculum was removed and the ultrasound probe introduced into the vagina. A 50-mL syringe containing sterile saline used for saline instillation and distention of the uterine cavity with the saline was sonographically observed. The measurements of the endometrium were performed at the thickest part in the longitudinal view of the uterus.

The uterine cavity contours were inspected for irregularities and suspicious intracavitary lesions were recorded. Deformations of the endometrial lining, absence of central hyperechoic line, and the appearance of any structure with or without well-defined margins or variable echogenicity was considered abnormal.

Hysteroscopy was carried out in an operating theatre using a rigid microhysteroscope with a 3.5-mm diagnostic sheath under general anesthesia. We used saline or glycine as the distention medium. A maximum intrauterine pressure of 100 mm Hg was allowed. The cavity was evaluated visually, with both tubal ostia being noted and the endometrial appearances documented. Another investigator (A.H.A.), who was completely blinded to the results of SIS evaluation, performed the hysteroscopic examination. This was considered the gold standard for the diagnosis of synechiae, polyps and submucous myomas, as well as for the assessment of the presence or absence of uterine malformations. The data were collected and entered on Microsoft access database to be analyzed using the Statistical Package for Social Science (SPSS Inc., Chicago, version 18). Qualitative variables were expressed as percentages and compared by Fisher's exact test. Level of significance "P" value was evaluated, where $P < 0.05$ is considered of significant value. Measures of sensitivity, specificity, positive and negative predictive values for SIS were based on the hysteroscopy results.

Results

The mean age of patients participated in the study was 35.32 ± 6.43 years. One hundred-four patients (64.6%) were suffering from infertility either

primary or secondary, while 57 patients (35.4%) presented with recurrent pregnancy loss.

In both groups, we found that endometrial polyps were the most frequent detected uterine pathology by SIS and Hysteroscopy. Endometrial polyps were diagnosed in 25 patients (15.5%). In all cases, both SIS and hysteroscopy confirmed the presence of an endometrial polyp.

Submucous fibroid was diagnosed in 18 cases. In four cases, the diagnosed fibroid was not confirmed with the hysteroscopic examination of the uterine cavity

(false positive results).

Intrauterine adhesions were significantly more detected by hysteroscopy than SIS only in the infertility group ($P < 0.01$). SIS only diagnosed eight cases out of 15 in the studied population.

In addition, SIS could diagnose only 11 cases out of 24 women with congenital uterine anomalies either septate or bicornuate uterus. The result was statistically significant in both groups of patients (Table 1).

Table 1. Correlation between SIS and Hysteroscopic findings in both infertility and recurrent pregnancy loss groups

	Infertility group (n=104)			Recurrent pregnancy loss group (n=57)		
	SIS, n (%)	Hysteroscopy n (%)	P	SIS, n (%)	Hysteroscopy n (%)	P
Normal	71 (68.3 %)	62 (59.6 %)	0.13	28 (49.1 %)	21 (36.8 %)	0.06
Endometrial polyp	15 (14.4 %)	15 (14.4 %)	0.43	10 (17.5 %)	10 (17.5 %)	0.39
Submucous fibroid	11 (10.6 %)	9 (8.7 %)	0.21	7 (12.3 %)	5 (8.8 %)	0.13
Intrauterine adhesions	3 (2.9 %)	8 (7.7 %)	$< 0.01^*$	5 (8.8 %)	7 (12.3 %)	0.11
Septate uterus	2 (1.9 %)	6 (5.8 %)	$< 0.001^*$	4 (7 %)	9 (15.8 %)	$< 0.01^*$
Bicornuate uterus	2 (1.9 %)	4 (3.8 %)	$< 0.05^*$	3 (5.3 %)	5 (8.8 %)	$< 0.05^*$

SIS: Saline infusion sonohysterography; *statistically significant; Fisher's Exact test was used to compare the difference in proportions.

Sensitivity and specificity of SIS in detecting intracavitary lesions were 84.3% in the infertility group and 75% in RPL group. Sensitivity, Specificity, Positive

and negative predictive values of SIS in patients with infertility were higher than those with RPL (Table 2).

Table 2. Sensitivity, Specificity, Positive and negative predictive values of SIS in detecting intracavitary abnormalities compared with hysteroscopy

	Saline Infusion Sonohysterography (SIS)			
	Sensitivity	Specificity	PPV	NPV
Infertility	84.3%	94.1%	96.7%	74.4%
RPL	75%	90.5%	93.1%	67.9%

PPV: positive predictive value; NPV: negative predictive value; RPL: recurrent pregnancy loss

Post-procedure bleeding is the most common complication of SIS represented in 12% of cases; moreover, there was no clinical significance in the occurrence of complications with both SIS and hysteroscopy.

Discussion

There are many tools used in diagnosis of intrauterine pathology, the most frequently used being transvaginal ultrasound, saline infusion sonohysterography, diagnostic hysteroscopy and sampling, used individually or in combination. The choice of one test over another will be depend primarily on its diagnostic accuracy⁽⁵⁾.

The introduction of intrauterine fluid during TVS constitutes one of the most significant advances in ultrasonography during this past decade. Instillation of saline during ultrasound (SIS) enhances and augments the image of the endometrial cavity⁽⁶⁾.

Diagnostic hysteroscopy has generally been accepted as the gold standard for evaluation of the uterine cavity. It is an invasive procedure, which is associated with discomfort for the patients and sometimes-vasovagal attack. It can be performed in the office setting or as a day-case procedure. Diagnostic hysteroscopy can be performed by a flexible and rigid hysteroscope. The flexible hysteroscope is not only safer, better tolerated, less painful but also gives an excellent view⁽⁷⁾.

Unfortunately, hysteroscopy is a more expensive and more invasive method than ultrasonography. An alternative to diagnostic hysteroscopy could be SIS, which is used to evaluate the uterine cavity after application of fluid medium.

The patients with infertility in our study constituted the majority of patients but the unacceptance of hysteroscopy and exposure to the anesthesia make this investigation delayed. Therefore, the mean age of patients included in the study was 35.32 ± 6.43 . In both groups of patients, the main symptom forcing the patient and the physician to proceed toward the hysteroscopic and SIS examination was the abnormal uterine bleeding. This is supported by findings of Khan⁽⁸⁾.

In our study, we found the endometrial polyp was

the most frequent detected uterine pathology by SIS and Hysteroscopy. Submucous fibroids came next then intrauterine adhesions. As regard to the congenital anomalies the septate uterus was common than bicornuate uterus in both groups.

The impact of endometrial polyps on fertility is uncertain but some studies have shown improved pregnancy rates following their removal⁽⁹⁾.

In our study the Sensitivity, Specificity, Positive and negative predictive values of SIS in patients with infertility was higher than those with RPL (84.3 and 75%, 94.1 and 96.7%, 93.1 and 92.5, 74.4 and 67.9% respectively). These results were analyzed using the hysteroscopy as a gold standard method for diagnosis of intracavitary lesions.

These findings were nearly comparable with the findings of Dueholm et al⁽¹⁰⁾, who reported in their study that the overall sensitivity of SIS was 83%, specificity 90%, positive predictive value 85% and negative predictive value 89%.

On the other hand, our result were contrary with the findings of Khan et al⁽⁸⁾ who reported in their study 100% sensitivity, 67% specificity, 98% positive predictive value and 100% negative predictive value for SIS in detection of endometrial cavity abnormalities. This may be attributed to the use of 3D ultrasound in their evaluation of the cavity by SIS that makes the examination rapid, enhances visualization and illustrates a more detailed pathology of the endometrial cavity.

One of the limitations of our study that concurrent laparoscopy was not performed with hysteroscopy for most of patients, although evaluation of the uterus by combination of both methods is known to be the gold standard in diagnosis of congenital uterine anomalies. No major complications were reported in our study; the main finding was slight bleeding after SIS and improved within few hours.

Conclusion

Hysteroscopy is superior to SIS in diagnosis of intracavitary abnormalities. However, saline infusion sonohysterography has the advantages of being non-invasive, cheap, affordable, shorter duration and

accurate method for uterine cavity evaluation.

Conflict of Interest

The authors declare that they have no conflict of interest.

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