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A Comparative Study of Saline Infusion Sonohysterography Outcomes Between Infertile and Fertile Patients: A Randomized Clinical Prospective

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ABSTRACT

As the prevalence of congenital uterine anomalies in infertile women is high, therefore, detection of them accurately plays an important role in the final therapeutic success. The purpose of this study was comparison of sonohysterography findings in both infertile and fertile patients. Thirty eight infertile and 38 fertile female were enrolled in present study. SIS (saline infusion sonohysterography) was performed in every patient. The results of each group were compared with other group. In all of the fertile women, SIS revealed no polyp, myomas, asherman syndrome, stenosis of cervix, abnormality of the uterine cavity and also the oviduct tubes were opened. In the infertile patients, SIS revealed pathology in the uterine cavity in 10 out of 38 women. However, oviduct tubes were opened in all of the patients. Among 10 patients who had lesions in their uterine cavity, three had abnormalities related to the uterine cavity, five had endometrial polyps and two had submucous myomas. In addition, we observed 2 patients presented more than one polyp lesion and 1 patient had both a submucous myomas and an endometrial polyp lesion. There were not significant correlation between ages of the patients and the lesions (i.e., uterine polyp, myomas and intrauterine malformation) which were seen in them. SIS (saline in fusion sonohysterography) can be a reliable and accurate method for investigation of the endometrium and the uterine cavity. It can be a good alternative technique for the evaluation of uterine intracavitary malformation where office hysteroscopy is not available. SIS allows differentiation of intrauterine cavitary abnormality, without the use of ionizing radiation or contrast agents.

Key words: Saline infusion, sonohysterography, infertility, uterine, malformations

INTRODUCTION

As the incidence of congenital anomalies of the intrauterine is higher in infertile women than in the fertile population, their accurate detection play a decisive role in the final therapeutic success and in restoring the fertility of female (Saravelos *et al*., 2008; Abu Halima and Javaid, 2011).

Valenzano *et al*. (2006) suggested that precise examination of the intrauterine space is often difficult using either the transabdominal or the endovaginal method. The main restriction of the sonographic diagnosis is that the intrauterine cavity is a virtual space (Dudiak, 2001).

In stance, hysteroscopy is established method for diagnosing the origin of intrauterine pathologies. Although this technique is valuable in discovery the origin of uterine abnormality, however, it might have complications and does not offer any data regarding asherman syndrome and myometrium. The non-invasive diagnostic procedures of option in the finding of intrauterine abnormality in patients should be simply applicable and capable determination of which invasive method may, subsequently, be appropriate (Yildizhan *et al*., 2008).

For example, Transvaginal Sonography (TVS) can be used to determine with high sensitivity polyps, submucosal myomas, endometrial hyperplasia and carcinoma (Osser and Valentin, 2011) however, this method may cannot diagnosis focal anomalies (Connor, 2011).

Saline Infusion Sonohysterography (SIS) is a diagnostic procedure consisting of an intrauterine infusion of saline solution through an injector during Transvaginal Ultrsonography (TVS) (Berridge and Winter, 2004). SIS lets demarcation of endometrial, submucosal and intrauterine cavity deformity (De Kroon *et al*., 2004).

In addition, it helps avoid invasive diagnostic procedures as well as optimize the preoperative process for the women requiring therapeutic intervention. It is easily and rapidly carried out at reasonable cost. Also, it is well tolerated and is virtually devoid of complications (Breitkopf *et al*., 2003; American Institute of Ultrasound in Medicine; American College of Obstetricians and Gynecologists; American College of Radiology, 2003).

Some studies have indicated the high diagnostic accuracy of SIS in the potential diagnosis of intrauterine pathologies causes of reduced fertility in women, such as submucosal myomas, endometrial polyps, anomalies and intrauterine adhesions (Mathew *et al*., 2010; Salle *et al*., 1996). The aim of present study was to assess the diagnostic value and usefulness of Saline Infusion Sonohysterography (SIS) in the detection of uterine anomalies in infertile women in comparison to fertile women.

MATERIAL AND METHODS

This is a prospective study that carried out in the obstetrics and gynecology ward of Razi and Imam Khomeini teaching hospitals in Ahvaz. This study was performed between April 2008 to April 2009. Seventy six women that were referred to these wards due to infertility (primary or secondary) or only pelvic pain or ovarian cyst were equally divided into infertile (experiment) group and fertile (control) group. The patients were aged 25-43 years (mean 33.2 years). All patients were studied in the proliferative (follicular) phase.

The inclusion criteria were healthy women and absence of sexually transmitted disease, pelvic inflammatory disease or pregnancy. Patients with active vaginal bleeding were also excluded.

All patients underwent Saline Infusion Sonohysterography (SIS) to rule out pathology of the endometrial cavity. During this procedure the speculum was inserted vaginally and a flexible foley catheter number 8 with inflatable balloon (SUPA, Tehran, Iran) was introduced into the uterine cavity. After fixation of the foley, saline was infused into the uterine cavity. Concomitantly, the distention was observed by transvaginal sonography and continued until the entire cavity was clearly visible. The endometrial cavity was examined for the presence of polyps or submucosal myoma or other pathologic conditions.

Any projection inside the uterine cavity was observed with special attention to its shape and echo whether it was of polypoid like structure or of myomas type. Diffuse uterine enlargement or difference in diameter between the anterior and posterior uterine wall after injection of saline as contrast medium was diagnosed as adenomyosis. During sonohysterography the intrauterine space was evaluated and findings were recorded.

Statistical analysis: All data are expressed as the Means±SEM. All analyses were carried out with the SPSS 16 statistical software. Chi-square test and t-test were used for comparison the data of the infertile group in versus the fertile groups. To process the correlation of age with lesions (i.e., Polyp, uterine myomas and intrauterine malformations) in fertile group, Mann-Whitney test was used. p-value less than 0.05 were considered as significant difference.

RESULT

The two groups (infertile and fertile women) were homogeneous with respect to age (fertile group: 28±4.8 years vs. infertile group: 30.4±7.0 years) (t-test p>0.086), situation of reproduction (fertility or infertility) and has been diagnosed in Table 1.

We did SIS in all patients (fertile and infertile) with no significant problems. We recorded in both fertile and infertile groups no complications or difficulties in the performance of the SIS (none of the women had abdominal pain or nausea and we had no problems in insertion the intrauterine insemination catheter into the cervical canal).

In fertile group, SIS revealed no polyp, myomas, asherman syndrome, stenosis of cervix, abnormality of the uterine cavity and also the oviduct tubes were opened in all of patients (Table 2).

In infertile group, SIS revealed no pathology in the uterine cavity in 30 out of 38 patients. Oviduct tubes also were opened in all of patients. In the remaining 10, SIS evidenced 3 abnormalities related to the uterine cavity, 5 endometrial polyps and 2 submucous myomas. In addition, we observed 2 patients presented more than one polyp lesion and 1 patient had both a submucous myomas and an endometrial polyp lesion (Table 2). These intrauterine abnormalities excluded myomas (Polyp, Uterus abnormality) were higher in the infertile women when compared with fertile population (p>0.05, p>0.05, respectively) (Table 2).

Also the mean age of the women who had abnormalities in their uterine cavity was 34 while the mean age of the patients who had no deformity in their uterine cavity was 39. The mean age of patients who had polyp in their uterine was 31 but the women who revealed no polyp in their uterine was 39 years old. From 3 abnormalities cases related to the submucous myomas, all were observed in the patients that the mean their age was 35 and no submucous myomas case was

Table 1: Age distribution of the 76 cases

	Age				
Groups	<25 year	25-29	30-34	35-39	>39
Fertile	9 (23.7)	10 (26.4)	8 (21)	7 (7)	4 (10.4)
Infertile	10 (26.4)	14 (36.8)	10 (26.3)	3 (7.9)	1 (2.6)

Table 2: Comparison of findings SIS method from uterine evaluation in infertile (38) and fertile (38) women

	Groups		
Findings (mean number) (%)	Fertile women	Infertile women	p value
Polyp	0	5 (13/1)	0.05
Myomas	0	2 (5/3)	0.16
Asherman syndrome	0	0	0
Opened oviduct tubal	38	38	0
Uterus anomaly	0	3 (7/9)	0.05

Table 3: Age distribution of the infertile women who had (or no had) intrauterine lesions

	Age (mean age)		
Group	Yes	No	p value
Polyp	31	39	0.05
Myomas	35	38	0.18
Uterus abnormality	34	39	0.05

shown in woman with 38 years old. It would be noted that we did not detect any intrauterine synechiae in both groups (Table 3). These intrauterine abnormalities excluded myomas (Polyp, Uterus abnormality) were higher in the infertile patients by mean age of 31 years in comparison with fertile population by mean age of 39 years ($p>0.05$, $p>0.05$, respectively) (Table 3).

DISCUSSION

The detecting of a congenital uterine abnormality is usually performed by Ionizing radiation ultrasonohysterography (ISG) (Mol *et al.*, 1996). ISG exhibits a number of potential problems in assessing the internal genital tract. Exposure to ionizing radiation elevates anxieties of possible oncogenesis or teratogenesis. Iodinated contrast substances could make an anaphylactic reaction in a sensitized patient (Valenzano *et al.*, 2006).

In other hand the data gained is restricted to genital tract, requiring laparoscopy or hysteroscopy to define uterus malformations (Al-Beiti and Lu, 2008). However, the aforementioned methods are invasive and may be associated with some problems. Therefore, there is a need for new method that allow obtaining on the one hand, significant diagnostic results and on the other, a reduction in technical complications, side effects and costs (Hassan *et al.*, 2010).

In the present study, an endometrial polyps and submucous myomas also were shown as projections into the intrauterine cavity through infusion of saline under sonohysterographic (SIS) imaging. An endometrial polyp was detected as a polypoid like structure, homogeneous echogenicity with no deformation of the endometrial-myometrial connection. As a submucous myomas initiate from the myometrium, the integrity of the uterine wall and the relationship of the lesion to the endometrial floor were easily detected. We did not determine any asherman syndrome. All together these intrauterine abnormalities were more incidences in the infertile women than fertile population.

The occurrence of intrauterine abnormality such as myoma and polyp in the infertile women has not been studied in detail (Osman, 2011, 2010). In a study of more than 5700 women undergoing IVF cycles, Transvaginal Ultrasound (TVS) uncovered suspected polyps in 1.4% of women and in the patients with suspected polypoid endometrium who selected for assessing by means of the hysteroscopy, nearly nineteen percent were proved to have polyps or polypoid endometrium (Lass *et al.*, 1999).

This means that SIS is a high-performance device in characterizing uterine anatomy and in diagnosing congenital uterine anomalies as well as in providing details that were very helpful during hysteroscopic surgical management of the lesions.

Randolph *et al.* (1986) were the first to carry out TVS during saline infusion into the uterine cavity. Gaucherand *et al.* (1995) recommended that Saline Infusion Ultrasonography (SIS) exhibited an improvement over TVS and was fully capable of replacing SIS for evaluating the uterine cavity.

Recently, Kelekci *et al.* (2005) showed that SIS has higher sensitivity in the identification of uterine deformity in comparison to the other two imaging methods (TVS and ISG). Jansen *et al.* (2006) demonstrated that SIS has high diagnostic accuracy for differentiating a polyp from submucous myomas.

Cullinen *et al.* (1995) also reported the importance of sonohysterography for the demarcation of intrauterine cavity, endometrial and submucosal malformations.

In addition Cicinelli *et al.* (1995) recommended that sonohysterography represented an improvement over hysteroscopy for investigating the endouterine polyps.

On the other hand, in a further study which four different diagnostic means were compared with one another there was no notable difference between them. However, sonohysterography appeared to be more sensitive when compared with TVS and HSG.

The SIS which was used in this study was painless and examiner well tolerated in every case. Alatas *et al.* (1997) suggested that there is a potential risk of transporting malignant cells into the peritoneum through intrauterine saline infusion in sonohysterography. However, Alatas *et al.* (1997) claimed that the SIS has a lower risk of cell transportation in comparison to hysteroscopy. Despite of this finding, in the present study the patients with malignancy or with infection problems were excluded from the study group.

As oviductal obstruction is the most common cause of infertility in the women, recently numerous methods such as HSG, SHG and laparoscopy were carried out in the evaluating of oviduct tube patency. The results were shown an elevated correlation between SHG outcome and findings at HSG and laparoscopy (Korell *et al.*, 1997; Strandell *et al.*, 1999). In agreement with this finding, the present study also showed that SIS is useful to evaluate of fallopian tube obstruction. However, some authors have questioned the diagnostic accuracy of SHG in the evaluation of proximal fallopian tube obstruction and pathological conditions related to the fallopian tubes (Hassan *et al.*, 2010).

Despite the increased use of SIS in the study of female infertility, it is therefore generally accepted that SIS cannot completely substitute HSG. However, it should be kept in mind that SIS can minimize diagnostic investigation time. Pain to the patient is also reduced noticeably, as the injector is fed into the cervix only once.

In addition, Sonohysterography is an easy, sensitive and well tolerated diagnostic method. It is not time consuming and does not require anesthesia. Under sterile conditions, it does not lead to infectious morbidity. It can be performed as an outpatient procedure.

CONCLUSION

In conclusion, we recommend the use of sonohysterography in conjunction with transvaginal ultrasonography for the diagnosis of intrauterine pathologies in infertile patients.

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