



ORIGINAL ARTICLE

The safety and acceptability of saline infusion sonography versus hysterosalpingography for evaluation of tubal patency in infertile women



Mohamed Rezk ^{a,*}, Mohamed Shawky ^b

^a Department of Obstetrics and Gynecology, Faculty of Medicine, Menoufia University, Egypt

^b Department of Radiology, Faculty of Medicine, Menoufia University, Egypt

Received 6 May 2014; accepted 10 June 2014

Available online 4 August 2014

KEYWORDS

Saline infusion sonography;
Hysterosalpingography;
Tubal patency;
Infertility

Abstract *Objective:* To assess the efficacy, safety and acceptability of saline infusion sonography (SIS) in comparison to hysterosalpingography (HSG) in the evaluation of tubal patency in infertile women.

Materials and methods: In this prospective study, 104 consecutive infertile women underwent SIS and HSG for tubal patency followed by laparoscopy with dye test as the gold standard test. Test parameters, safety and acceptability of both methods were assessed.

Results: SIS showed patency in 90 (86.5%) tubes, HSG in 85 (81.7%) tubes, and laparoscopy in 75 (72.1%) tubes. SIS and laparoscopy agreed in 15 out of 29 occluded tubes (concordance, 51.7%) while HSG and laparoscopy agreed in 11 out of 29 occluded tubes (concordance, 37.9%). The sensitivity, specificity, PPV, NPV were 52%, 95%, 79%, 84% for SIS and 38%, 96%, 79%, 80% for HSG respectively. There were a significant number of women who experienced pain, syncope and cervicovaginal lacerations during HSG examination in comparison to SIS ($P < 0.001$). SIS was more acceptable than HSG as a screening test for tubal patency regarding the overall discomfort and the overall satisfaction rate.

Conclusion: Although HSG is the standard screening test for the diagnosis of tubal infertility, the present study confirmed the higher sensitivity, safety and acceptability of SIS compared to HSG for the evaluation of tubal patency in infertile women.

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1. Introduction

Infertility is defined as the failure to conceive after one year of regular unprotected intercourse (1). Infertility etiology is multifactorial, the role of a tubal factor in infertility is increasing, and currently, it determines 30% to 35% of all infertility cases (2).

* Corresponding author. Tel.: +20 1006237186.

E-mail address: m_rezk9207@yahoo.com (M. Rezk).

Peer review under responsibility of Middle East Fertility Society.



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Screening for tubal occlusion is part of the investigation of subfertile couples and is classically performed using hysterosalpingography (HSG) or laparoscopy with chromotubation (3).

The technique of saline infusion sonohysterography (SIS) which entails the instillation of a fluid into the uterine cavity under ultrasound scan was initially used for assessment of the uterine cavity (4,5).

Recently, SIS was used as the initial step for the assessment of fallopian tube patency because it is a simple, safe, and well-tolerated technique with a low risk of adverse effects and severe complications (6,7).

Initially infertile patients should perform HSG, followed by SIS in all patients with suspected bilateral proximal tubal obstruction based on HSG. If SIS confirms the previously shown obstruction, only then should the patient undergo the more expensive and more invasive diagnostic laparoscopy (6).

The aim of our study was to assess the efficacy, safety and acceptability of saline infusion sonography (SIS) in comparison to hysterosalpingography (HSG) for the evaluation of tubal patency in infertile women with laparoscopy being the gold standard test.

2. Patients and methods

We conducted a prospective observational study of 104 infertile couples from February 2013 to February 2014. Patients were recruited from the Obstetric and Gynecological outpatient Clinic, Menoufia University Hospital, Egypt.

The institutional review board approved the study protocol and an informed consent was obtained from all participants prior to commencing the study.

After revising the test validity parameters of HSG in comparison to SIS from the literature. Accordingly, at $\alpha = 0.05$ and a study power of 80% a total sample size of 90 participants was required after adding a percentage of 10% for possible drop out cases during the study.

All patients initially underwent routine evaluation that included a complete history and physical examination, semen analysis and hormonal assessment. The study group was selected with regard to appropriate inclusion and exclusion criteria. The inclusion criteria were: unexplained infertility, age between 20 and 40 years, infertility by at least 1 year. The exclusion criteria were serious semen abnormalities, $\text{FSH} > 15 \text{ mIU/mL}$ and contraindications for HSG or laparoscopy.

Saline infusion sonography (SIS) and hysterosalpingography (HSG) were performed in all cases. Laparoscopy was performed within one week from the screening tests.

2.1. Screening tests

Early in the post-menstrual period (days 4–7), HSG was performed in the radiology department. The Fallopian tubes were considered patent when at least one tube was observed in the HSG (Figs. 1 and 2) and occluded if bilateral (Fig. 3).

The SIS procedure was performed in the Obstetrics and Gynecology department by a different physician blinded to the result of HSG after 48 h. After an initial evaluation of the uterus and adnexa by vaginal ultrasound, a Cusco speculum was inserted and the cervix washed with an antiseptic solution. The anterior lip of the cervix was grasped with a single-toothed tenaculum and a pediatric Foley catheter (8–10 f)

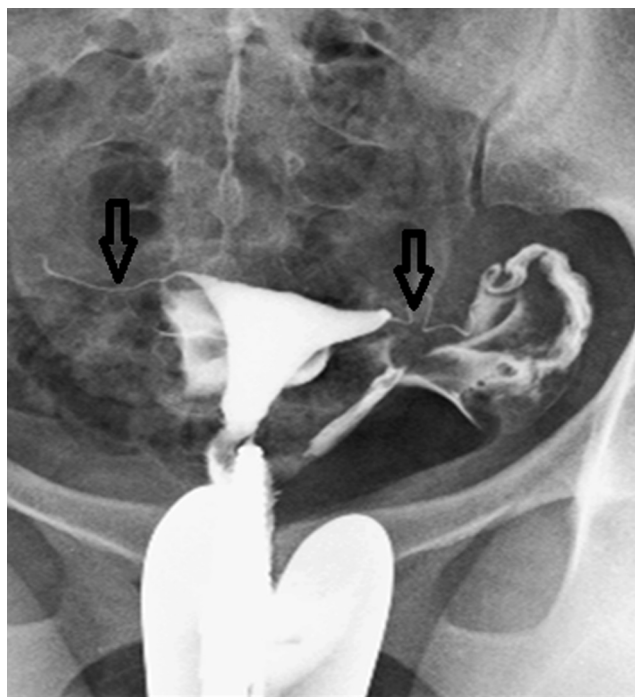


Figure 1 HSG reveals bilateral patent tubes (arrows).

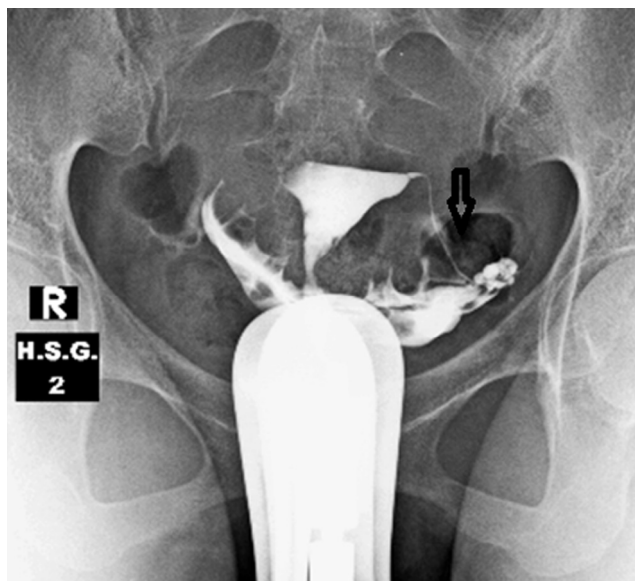


Figure 2 HSG reveals unilateral patent tube (arrow).

was introduced into the lower uterine cavity. A 20-ml syringe loaded with 0.9% saline solution was attached to the external end of the catheter after removal of the speculum and the tenaculum, and ultrasound probe was reintroduced into the vagina. Injecting 20–40 ml of the solution was introduced into the catheter. The patency of Fallopian tubes was determined by the presence of fluid in the Douglas pouch which indicates the patency of at least one tube (Fig. 4). Absence of fluid in the Douglas pouch indicated tubal occlusion (Fig. 5).

Prophylactic antibiotics in the form of Doxycycline 100 mg 1 h before and 200 mg orally after the procedure and analgesics in the form of Diclofenac 50 mg orally half an hour prior to examination were given to all the patients.

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