

Diagnostic Value of Sonohysterography in the Determination of Fallopian Tube Patency as an Initial Step of Routine Infertility Assessment

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Objectives. Infertility is defined as the failure to conceive after 1 year of regular unprotected intercourse. It affects 10% to 15% of couples. Sonohysterography (SHG) is an accurate method for the assessment of fallopian tube patency, reflected in its high positive predictive value compared with hysterosalpingography (HSG) and laparoscopy with chromopertubation. In this study, our goal was to determine the diagnostic value of SHG for the diagnosis of bilateral tubal obstruction by comparison of SHG with HSG and laparoscopic results. **Methods.** This study was based on the evaluation of tubal patency by SHG and by the combination of HSG and laparoscopy in 40 patients. All patients underwent HSG as a routine infertility workup, and all patients with bilateral proximal tubal obstruction diagnosed by HSG subsequently underwent SHG. **Results.** Among 1024 infertile women referred to an infertility clinic, 117 (11.4%) had a diagnosis of a tubal factor as the cause of their infertility. Forty-two patients with HSG findings of bilateral proximal tubal obstruction were enrolled. Forty patients underwent SHG. In 32 patients (80%), at least 1 fallopian tube was patent, and 8 patients (20%) were reported to have bilateral tubal obstruction. Those 8 patients with SHG evidence of bilateral tubal obstruction underwent laparoscopy. Eventually, 6 of those were laparoscopically confirmed to have bilateral tubal obstruction. **Conclusions.** Sonohysterography is an accurate method for the determination of fallopian tube patency. It is a simple, safe, and well-tolerated technique with a low risk of adverse effects and severe complications. **Key words:** hysterosalpingography; infertility; laparoscopy; sonohysterography; tubal obstruction.

Abbreviations

HSG, hysterosalpingography; NPV, negative predictive value; PID, pelvic inflammatory disease; PPV, positive predictive value; SHG, sonohysterography

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Infertility is defined as the failure to conceive after 1 year of regular unprotected intercourse.¹ It affects 10% to 15% of couples.¹ A male factor is the only cause of infertility in 20% of infertile couples, but it may be a contributing factor in as many as 30% to 40% of cases.¹ Main causes of infertility in women include anovulation, a tubal or peritoneal factor, and uterine, cervical, and idiopathic infertility.²

The role of a tubal factor in infertility is increasing, and currently, it determines 30% to 35% of all infertility cases.³ There are multiple etiologic factors responsible for the involvement of the fallopian tube in infertility, which include tubal damage from pelvic inflammatory disease (PID), the use of intrauterine devices, a history of a perforated appendicitis, ectopic pregnancy, and septic abortion.⁴ Tubal adhesions and tubal obstruction can

also be due to endometriosis and previous surgical trauma. Hysterosalpingography (HSG) and laparoscopy with chromopertubation are the most commonly used methods to examine tubal patency.⁴ Bilateral proximal obstruction of the tube at its junction with the uterus can occur because of a tubal spasm during HSG, which is induced by the injection of dye during the procedure. Contractions of the uterus can also lead to transient spasms in the interstitial part of the fallopian tube, which can be mistaken for tubal obstruction during HSG, and this entity needs to be carefully distinguished from pathologic conditions. If the obstruction occurs in the middle or distal part of the fallopian tubes, an underlying pathologic condition is always present.² In comparison with laparoscopy, HSG has shown low sensitivity in the determination of patent fallopian tubes, and the diagnosis of fallopian tube obstruction based on HSG carries as high as 60% probability of actually patent fallopian tubes.² This is the reason why bilateral proximal obstruction of uterine tubes diagnosed by HSG should be subsequently confirmed by laparoscopy.

On the other hand, laparoscopy is an invasive diagnostic method that requires general anesthesia and carries the risk of severe adverse effects, including injury of pelvic blood vessels, intestinal loops, and the urinary bladder. It also does not provide an assessment of the uterine cavity. This implies the need for a diagnostic tool with high sensitivity and specificity to distinguish an actual fallopian tube obstruction from a seeming one and to decrease the need for laparoscopy.

Sonohysterography (SHG) is a simple, safe, and well-tolerated examination technique used for investigation of the uterine cavity and fallopian tubes with very few adverse effects and a low occurrence of complications. It consists of an instillation of sterile saline through a Foley catheter inserted through the cervix with simultaneous transvaginal sonography. This method was shown to be a valuable and safe diagnostic procedure, and it has shown an effect in increasing spontaneous pregnancy rates.^{5,6} The sensitivity and specificity of SHG are comparable with those of hysteroscopy in the diagnosis of uterine cavity anomalies.² The clarity of images obtained during the procedure is comparable with that of magnetic resonance imaging,² and the risks of

adverse effects during the procedure itself are minimal.⁷ It may also be provided as an outpatient procedure.⁸

In this study, our goal was to determine the diagnostic value of SHG for the diagnosis of bilateral tubal obstruction by comparison of SHG with HSG and laparoscopic results.

Materials and Methods

This descriptive analytic study was based on evaluation of fallopian tube patency by SHG and by the combination of HSG and laparoscopy in 40 patients. The study was approved by the university Review Board and Research Ethics Committee. All patients were referred to an infertility clinic at a teaching hospital tertiary referral center between January 2007 and March 2009. All patients underwent HSG as a part of a routine infertility workup, and all patients with bilateral proximal tubal obstruction diagnosed by HSG were included in the study. The SHG procedure was fully described and explained to the patients, and afterward, written informed consent was obtained from all participants undergoing the procedure. Sonohysterography was performed and evaluated by a single gynecologic sonographer (T.Z.).

The procedure was performed during the follicular phase, 2 days after the last menstrual period. All patients were initially examined by a gynecologist, and transvaginal sonography was performed to exclude the presence of fluid in the cul-de-sac (retrotrine space) before SHG. None of the patients underwent SHG before this gynecologic and sonographic evaluation. Patients with acute sexually transmitted diseases, PID, abnormal uterine bleeding, fluid in the cul-de-sac before the procedure, and positive pregnancy test results were excluded from the study.

Patients were initially placed on a gynecologic table in a lithotomy position. A speculum was inserted, and the cervix was visualized to ascertain the absence of any cervical disease or infection, and the vagina and the cervix were washed with a 10% povidone-iodine solution. A size 8 or 10 latex Foley catheter was inserted into the lower segment of the uterus, and the balloon of the catheter was inflated by 3 mL of sterile normal saline to prevent retrograde flow of the saline into the vagina.⁹ The position of the balloon was

verified by sonography. The speculum was then removed, and a transvaginal probe was inserted into the posterior vaginal fornix. Instillation of sterile saline through the Foley catheter using a sterile 20-mL syringe was subsequently performed under sonographic guidance. The collection of fluid in the cul-de-sac after the instillation of sterile saline was assessed by observation of the saline flow during the consequent transvaginal sonography and was considered an indicator of patency of at least 1 or both of the fallopian tubes. Conversely, the absence of fluid in the cul-de-sac after the instillation of saline was interpreted as bilateral tubal obstruction. The absence/collection of the fluid was documented in the patient's records. Because no interindividual comparison of the collected fluid amount was intended as a part of the study assessments, no quantification criteria for the collected liquid were established. Patients with SHG evidence of bilateral proximal tubal obstruction underwent laparoscopy for further assessment.

No antibiotic prophylaxis was used during the study. All patients were asked to stay in the hospital for 1 hour after the procedure and to contact us if genital pain, discharge, or any other symptoms developed.

Results

A total of 1024 women unable to conceive were referred to the infertility clinic. All couples involved were evaluated by semen analysis, hor-

monal studies, and HSG to determine the underlying cause of the couple's infertility. If the semen analysis results for the male partner were normal and the female partner's hormonal findings were normal but there was HSG evidence of bilateral tubal obstruction, those patients were enrolled in the study.

Of 1024 infertile patients, 125 (12.2%) were shown to have a tubal factor as a cause of their infertility. Eight of them had a combination of a tubal factor and a male factor underpinning the couple's infertility; hence, those 8 patients were excluded from the study (Table 1). A total of 117 patients met the criteria for inclusion in the study, and those 117 patients underwent HSG. Forty-two patients (35.9%) of a total of 117 patients constituting the final group enrolled in the study were shown to have bilateral proximal obstruction of the fallopian tubes on HSG, and those 42 patients were selected to undergo SHG.

The mean age of the study participants \pm SD was 29.09 ± 4.87 years (range, 20–38 years). The mean duration of infertility was 4.9 years (range, 2–12 years). Thirty-nine patients (92.9%) had primary infertility, and 3 (7.1%) had secondary infertility. One of the patients had a vasovagal reaction from insertion of the catheter, and 1 patient had severe pain, was not able to tolerate the procedure, and quit the study (failure rate, 4.8%).

A total of 40 patients eventually underwent SHG (Table 2). In 32 patients (80%), at least 1 tube was shown to be patent by SHG, and 8 patients (20%) were shown to have bilateral tubal

Table 1. Distribution of All Patients Referred to the Infertility Clinic

| Patient Type | n | % |
|---|------|--------|
| All patients referred to in vitro fertilization center | 1024 | 100.00 |
| Infertile patients with tubal factor infertility and other findings within the normal range | 117 | 11.43 |
| Patients with bilateral proximal obstruction diagnosed by HSG selected for participation in the study | 42 | 4.10 |
| Patients to undergo SHG among total enrolled | 40 | 95.23 |
| Patients unable to undergo SHG | 2 | 4.76 |
| Patients to undergo laparoscopy among those who underwent SHG | 8 | 20.00 |

Table 2. Distribution of Patients Enrolled in the Study

| Patient Type | n | % |
|---|----|--------|
| Patients with bilateral proximal obstruction diagnosed by HSG selected for participation in the study | 42 | 100.00 |
| Patients to undergo SHG | 40 | 95.23 |
| Patients unable to undergo SHG | 2 | 4.76 |
| Patients to undergo laparoscopy among those who underwent SHG | 8 | 20.00 |
| Patients with primary infertility | 39 | 92.85 |
| Patients with secondary Infertility | 3 | 7.14 |

obstruction, which confirmed the initial HSG finding of this condition. Because laparoscopy is considered the reference standard in the assessment of tubal patency, those 8 patients with both HSG and SHG evidence of bilateral obstruction underwent laparoscopy. Six of them were laparoscopically confirmed to have bilateral tubal obstruction. Two of the 8 patients undergoing laparoscopy were shown to have a patent fallopian tube despite a negative finding on SHG. Both of the patients were shown to have tubal adhesions. In 1 of the patients, this condition was due to previous surgery, and in the other patient, no relevant cause of the tubal adhesions was found.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SHG in comparison with laparoscopy were 94%, 100%, 100%, and 75%, respectively (Table 3). Nine of the 42 patients (21.5%) conceived after intrauterine insemination during the study period. None of the patients enrolled in this study had an infection in association with the procedure.

Discussion

Precise evaluation of the uterine anatomy and fallopian tubes is an important step in a routine infertility assessment. Accurate diagnosis of anatomic abnormalities that may hinder fertilization plays an important role in both infertility screening and the consideration of available therapeutic options.

Tubal factor infertility is caused by occlusions in the fallopian tube, preventing fertilization of the ovum by the sperm. Dysfunction of the sperm and failure of trophoblastic transport are attributable to tubal inflammation. Tubal pathologic conditions are the underlying causes in 30% to 40% of infertility cases,^{1,2} but according to the data from our infertility center, a tubal factor is the cause of infertility in only 11.4% of our patients (M.H., T.Z., V.R.Z., M.G.-R., Z.Y., and

N.M., unpublished data, 2009), which may be due to the low prevalence of sexually transmitted diseases and PID in this population. This may be implied by the low rate of high-risk sexual behavior and multiple sexual partners in Iranian society.

Hysterosalpingography and laparoscopy are the 2 classic examination methods in the assessment of tubal patency in infertile women, but in addition to the identified benefits, each method also carries the risk of severe adverse effects. Hysterosalpingography as an outpatient procedure is relatively inexpensive, does not require general anesthesia, and is associated with a therapeutic effect.² Unlike laparoscopy, HSG enables a view within the uterine cavity and fallopian tubes. Nevertheless, this procedure is rather painful and is associated with exposure to ionizing radiation and its related risks. Hysterosalpingography has a 5% rate of false positivity and a 60% rate of false negativity; hence, it is of intermediate sensitivity and of high specificity for fallopian tube obstruction.^{2,7} A substantial number (60%–85%) of obstructions detected on HSG are not based on actual tubal conditions but are due to a transient spasm. This was also confirmed in this study, in which actual tubal obstruction was found in only 15% of the enrolled patients, whereas initially, HSG showed bilateral tubal obstruction in 40 patients (85%).

Laparoscopy is a more invasive procedure that requires general anesthesia. It is associated with the risk of accidental injury of the intestine, urinary bladder, and pelvic vessels, but at the same time, this method provides valuable information about the pelvic anatomy that cannot be obtained during HSG.

Sonohysterography can be provided in an outpatient setting, and it is associated with minimal patient discomfort and a low risk of infection. This procedure is noninvasive and rather easy to perform in almost any medical setting because it does not require sedation or anesthesia, nor does it have any adverse effects or severe related complications.¹⁰ It can be used as both a diagnostic tool and a therapeutic method in an infertile patient with tubal infertility. According to the currently available literature, the diagnostic accuracy of SHG is comparable with that of hysteroscopy. Although hysteroscopy enables visu-

Table 3. Comparison of SHG and Laparoscopic Findings in the Diagnosis of Tubal Patency

| Laparoscopy | SHG | | Total |
|-----------------|-------------|-----------------|-------|
| | Patent Tube | Obstructed Tube | |
| Patent tube | 32 | 2 | 34 |
| Obstructed tube | 0 | 6 | 6 |
| Total | 32 | 8 | 40 |

alization and evaluation of the uterine cavity only, SHG allows evaluation of both the uterus and adnexa.⁶

Concerning the use of SHG as a diagnostic tool in other gynecologic conditions, SHG also provides more precise information regarding the size and location of a myoma within the uterine cavity, and it is able to correctly differentiate a septate uterus from a bicornuate uterus.^{11,12} As mentioned previously, several comparative studies have shown that the diagnostic accuracy of hysteroscopy is equal to that of SHG.^{8,13–17} The diagnostic value of SHG is comparable with that of magnetic resonance imaging in the diagnosis of adenomyosis.¹⁰ On the other hand, SHG is a rather simple method. Its main advantage is the ability to distinguish between pathologic tubal obstruction and obstruction due to a spasm. It has been previously shown to have high sensitivity and specificity in tubal patency examinations.^{13,14,18–22} Sonohysterography has also been used to evaluate women with a history of breast cancer receiving tamoxifen,^{23,24} to evaluate women entering menopause who have not started hormonal replacement therapy yet,^{23,24} and to detect retention of trophoblastic tissue in the uterine cavity. It is also used in many hospitals as a first-line diagnostic procedure in cases of abnormal uterine bleeding and müllerian abnormalities.^{12,17,25–28}

It has also been shown that SHG provides more precise and detailed information in evaluation of the uterus compared with HSG.²⁹ In our study, 40 patients undergoing SHG had no uterine conditions previously reported by HSG. In 3 of those patients, a uterine polyp or submucosal myoma was reported. This shows that SHG is a more accurate tool in examination of the uterine cavity compared with HSG.

Our study had sensitivity, specificity, PPV, and NPV of 94%, 100%, 100%, and 75%, respectively. These values are comparable with the results of another study, which showed sensitivity, specificity, PPV, and NPV for SHG in detection of fallopian tube patency of 100%, 67%, 89%, and 100%, respectively.³⁰ The rates of spontaneous conception after intrauterine insemination following SHG were reported to be 8.4% and 48.6% in 2 different studies.^{5,6} In our study, the rate was 22.5%, showing that SHG can be used as both a

diagnostic and a therapeutic tool in infertility management. Nevertheless, because due to the study design the patients initially underwent HSG, which has also been shown to increase spontaneous conception rates, it is impossible to distinguish the individual contribution of each diagnostic method to the overall increase of spontaneous conception rates in the study participants.

The adverse effects of SHG experienced during the study consisted of pain and vasovagal reactions. Stenosis of the cervix is the most common cause of the SHG failure.³¹ The failure rate in our study was 4.8%, which is equal to failure rates reported in the literature: 4.6% to 7%.^{11,13} In 1 case, the failure was due to a vasovagal reaction, and in another case, it was due to severe pain experienced by the patient. Use of a Foley catheter without a balloon is generally recommended in less tolerant patients to prevent pain and vasovagal symptoms.⁹ The discomfort associated with this procedure seems to be due to the small amount of fluid that is necessary for visualization of the uterine cavity.¹³ Although no antibiotic prophylaxis was administered during the study, none of the patients had an infection after the procedure.

In conclusion, the results of this study show that SHG can be used as a standard tool in routine infertility assessment of patients before the use of less accessible, more expensive, and more invasive diagnostic methods. In cases of negative SHG results indicating bilateral tubal obstruction, the procedure may be followed by in vitro fertilization. On the basis of availability, accessibility, associated risks, and costs, we consider SHG with saline instillation the most efficient first-line diagnostic tool for evaluation of fallopian tube obstruction. It would be advisable to incorporate SHG in routine workups of all couples with female factor infertility, thus reducing the risk of exposure to ionizing radiation and potential development of allergic reactions to iodinated contrast media used during HSG. Also, unlike costly and invasive hysteroscopy, which is associated with a high level of discomfort for the patient, SHG is a simple, cost-effective procedure that is easy to perform, is associated with a low risk of side effects, does not require anesthesia, and causes less discomfort to the patient in comparison with other diagnostic methods.

Our recommendation for clinical practice is to initially perform HSG in infertile patients when required, followed by SHG in all patients with suspected bilateral proximal tubal obstruction based on HSG. If SHG confirms the previously shown obstruction, only then should the patient undergo laparoscopy. This policy may reduce the number of unnecessary laparoscopies performed in infertile patients due to the current standard diagnostic approach combining HSG and laparoscopy. Avoiding complications related to laparoscopy may thus be achieved, and such a policy would also lead to reduction of health care costs in the management of infertility.

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