

Vaginal sonosalpingography in the evaluation of tubal patency

PIRJO INKI, PERTTI PALO AND LEENA ANTTILA

From the Department of Obstetrics and Gynecology, Turku University Central Hospital, Turku, Finland

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Background. During the past few years, sonosalpingography has been suggested as the first-line method to study tubal patency. This study was launched in order to study the applicability of this method at our institution.

Methods. Thirty-two patients suffering from primary or secondary infertility were evaluated for tubal patency with sonosalpingography using a pediatric Foley urinary catheter and a combination of air and saline solution as a contrast medium. The uterine tubes were evaluated separately and the results were compared to the findings at laparoscopy and chromotubation performed independently. Four patients conceived before their scheduled laparoscopy and were excluded from the study. In addition, the patency of three Fallopian tubes could not be adequately evaluated, leaving altogether 53 uterine tubes that were evaluated by both methods.

Results. The findings of both methods agreed in 47 out of 53 tubes (concordance, 88.7%). The sensitivity of sonosalpingography in diagnosing tubal patency was 90.2% and the specificity 83.3%. The positive predictive value for tubal patency by sonosalpingography was 94.9% and the negative predictive value 71.4%. Adverse events of sonosalpingography included moderate to severe abdominal pain in three patients, one vasovagal reaction, and one case of shoulder pain. No infectious complications were recorded.

Conclusions. The results confirm that sonosalpingography utilizing air and saline as a contrast medium is a reliable, simple and well-tolerated method to assess tubal patency in an out-patient setting. In addition, the procedure can be performed without prophylactic antibiotics using a regular pediatric Foley urinary catheter instead of an expensive hysterosalpingography catheter.

Key words: infertility; laparoscopy; sonosalpingography; tubal patency

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The assessment of tubal patency belongs to the initial diagnostic tests in the work-up of an infertile woman. To date, X-ray hysterosalpingogram (HSG), which can be used in an out-patient setting, is the most commonly used screening method for evaluation of Fallopian tubes. Recent studies have, however, suggested HSG to exhibit a relatively low sensitivity to detect tubal patency (1–3) and a high inter-observer variation in the interpretation of results (3, 4). Furthermore, the unavoidable

exposure of germ cells to radiation and low patient compliance due to pain, are disadvantages associated with HSG. Since the early 90's, sonosalpingography using either a combination of air and saline or 20% galactose microparticles in aqueous solution (Echovist-200[®], Schering AG) as a contrast medium has been used for determining tubal patency. A few comparative studies using laparoscopy and chromotubation as the 'gold standard' have demonstrated sonosalpingography to be a reliable and simple preliminary test to investigate uterine and tubal patency (5–9). Furthermore, Tekay et al. (10) have recently demonstrated that

Abbreviation:

HSG: hysterosalpingogram.

sonosalpingographic examinations exhibit good reproducibility. However, the need for further comparative studies of sonosalpingography and laparoscopy has also been raised recently by Zaidi and Tan (11). The present study was undertaken in order to study the applicability of this method at our institution.

Material and methods

The study was performed on thirty-two infertile women referred to the outpatient clinic of reproductive endocrinology at Turku University Central Hospital between May 1996 and December 1996. The age of the women ranged from 25 to 38 years (mean \pm s.d.; 31 ± 4 years). Informed consent was obtained from all patients. Patients with a history of pelvic operations, ectopic pregnancy, severe endometriosis, pelvic abscess, or genital tract anomaly were excluded from the study and referred directly to laparoscopy and/or hysteroscopy. No premedications (such as antibiotics or sedatives) were given prior to sonosalpingography. A negative re-

sult of Chlamydia Trachomatis culture from the cervix was considered a prerequisite. Sonosalpingography was performed polyclinically prior to laparoscopy by one author (PI) as follows: The women were examined in the dorsal lithotomy position. After disinfecting of the cervix and vagina with chlorhexidin, a pediatric silicone Foley catheter containing a thin stylet (size CH6, Porges S.A., Cedex, France) was inserted into the uterine cavity (Fig. 1 A), the stylet was removed and the balloon filled with 1.5 ml sterile saline solution. In case of difficulty of insertion, ultrasound was used to measure the length and course of the cervical canal and uterine cavity, or the cervix was grasped with a tenaculum to straighten the cervical canal. If the inflation of the balloon was painful, the balloon was deflated and then slowly inflated again. The placement of the balloon towards the internal os of the cervical canal was secured with gentle traction, which was maintained throughout the procedure. Next, a 6Hz vaginal ultrasound probe (Tosbee SSA-240A, PVF-651 VT, Toshiba Co., Tokyo, Japan) was inserted and the correct position of the

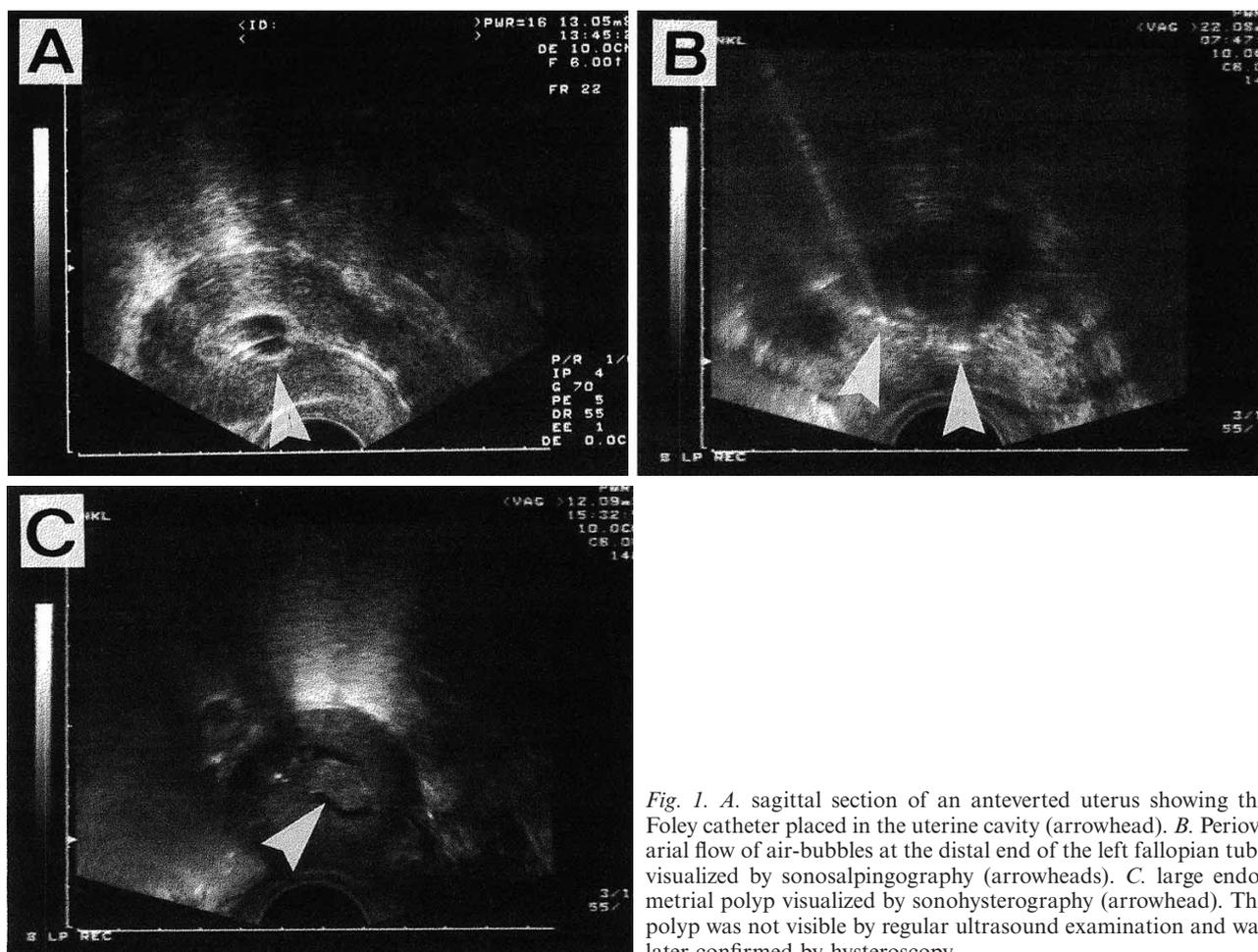


Fig. 1. A. sagittal section of an anteverted uterus showing the Foley catheter placed in the uterine cavity (arrowhead). B. Peri-ovarian flow of air-bubbles at the distal end of the left fallopian tube visualized by sonosalpingography (arrowheads). C. large endometrial polyp visualized by sonohysterography (arrowhead). The polyp was not visible by regular ultrasound examination and was later confirmed by hysteroscopy.

catheter was confirmed. After scanning of the uterine position, endometrium thickness and morphology as well as ovarian morphology, the patency of the uterine tubes was examined by injecting air and saline solution in turn (1–3 ml at time) up to 20 ml of saline and 20 ml of air. Each tube was examined separately. Simultaneously, the periovarian space was scanned for the appearance of air bubbles into the peritoneal cavity and the collection of saline solution into the pouch of Douglas. The tube was considered patent if flow of air bubbles was seen at the distal end of the tube (Fig. 1B). If necessary, the procedure was repeated to exclude tubal spasm. If the repeated injections gave similar results, the tube was considered occluded. After tubal patency evaluation the balloon was deflated and the uterine cavity was examined by injecting 5 ml saline solution. After the removal of the catheter, the patient rested up to 30 min at the polyclinic. Analgesic (ibuprofen 600 mg p.o. or diclofenac 50 mg i.m.) was given if abdominal or shoulder pain was present. The patients were asked to monitor signs of pelvic infection and to contact the authors if such occurred.

Up to four months after sonosalpingography the laparoscopy and chromotubation was performed under general anesthesia by other physicians according to the routine method used in our institution with methylene blue injection through a cone-shaped adapter fixed tightly to the external os of cervix with a tenaculum. Both examinations were done irrespectively of the phase of menstrual cycle, excluding the menstrual phase.

The sensitivity, specificity, positive and negative predictive values were calculated as described in Table I. The usefulness of sonosalpingography as a diagnostic test in the infertility work-up was also estimated by calculating the likelihood ratio as well as the pre- and posttest probabilities for tubal patency (Table II).

Table I. Accuracy of sonosalpingography in diagnosing tubal patency*

Sonosalpingography	Laparoscopy and chromopertubation		
	Patent	Not patent	Total
Patent	37	2	39
Not patent	4	10	14
Total	41	12	53

Sensitivity = $37/(37+4) \times 100\% = 90.2\%$ PPV[†] = $37/(37+2) \times 100\% = 94.9\%$
 Specificity = $10/(10+2) \times 100\% = 83.3\%$ NPV[§] = $10/(10+4) \times 100\% = 71.4\%$
 Overall concordance = $47/53 \times 100\% = 88.7\%$

* all numbers refer to number of uterine tubes; [†]PPV=positive predictive value for tubal patency; [§]NPV=negative predictive value for tubal non patency.

Table II. Diagnostic validity of sonosalpingography in assessment of tubal patency studied by using the likelihood ratio and posttest probability

Likelihood ratio =	$\frac{\text{Sensitivity}}{\text{False-positive rate}} = \frac{90.2}{(100-83.3)} = 5.4$
Pretest probability =	41/53 = 0.77
Pretest odds =	$\frac{\text{Pretest probability}}{1 - \text{Pretest probability}} = \frac{0.77}{1-0.77} = 3.35$
Posttest odds =	Pretest odds × Likelihood ratio = 3.35 × 5.4 = 18.08
Posttest probability =	$\frac{\text{Posttest odds}}{1 + \text{Posttest odds}} = \frac{18.08}{1+18.08} = 0.95$

Results

Of the 32 patients initially recruited, four became pregnant before their scheduled laparoscopy (three spontaneously and one after an intrauterine insemination), leaving 28 patients who were studied by both sonosalpingography and laparoscopy. Due to technical difficulties the patency of one tube could not be determined by sonosalpingography and the patency of both tubes of one patient by laparoscopy. Thus, altogether 53 uterine tubes were examined by both methods (Table I). Sonosalpingography showed patency in 39 (73.6%) tubes and laparoscopy in 41 (77.4%) tubes (Table I). The findings of both methods agreed in 47 out of 53 tubes (concordance, 88.7%). The tubal patency found in 39 tubes by sonosalpingography was confirmed by laparoscopy in 37 tubes (positive predictive value, 94.9%). Tubal occlusion found in 14 tubes by sonosalpingography was confirmed by laparoscopy in 10 tubes (negative predictive value, 71.4%). A uni- or bilateral tubal occlusion was observed in nine patients by laparoscopy and chromotubation. In four tubes, occlusion suggested by sonosalpingography was not confirmed by laparoscopy and two tubes patent by sonosalpingography were found to be occluded by laparoscopy. There were four false positive and two false negative findings. The sensitivity of sonosalpingography in diagnosing tubal patency was 90.2% and the specificity 83.3%. The likelihood ratio for open tubes was 5.4, the pretest probability for tubal patency was 77% and posttest probability 95% (Table II).

The insertion of the Foley catheter into the uterine cavity was successful in all cases (Fig. 1A). Frequently, only a few ml of air and saline solution was required to demonstrate the patency of the tube (Fig. 1B). Sonohysterography revealed one endometrial polyp (Fig. 1C) previously missed by a vaginal ultrasound examination. No other pathological intracavitary findings were detected.

Mild pelvic pain during the insertion of the

sonosalpingography catheter or injection of saline-air was experienced by approximately half of the patients. This did not, however, result in stopping the procedure or require any medication. Three patients (9.4%) reported moderate or severe abdominal pain and were treated with analgesics. One of these patients had bilateral and one unilateral tubal occlusion by laparoscopy. The third patient exhibited normal genital status by both methods. One patient experienced vaso-vagal collapse after sonosalpingography, and one patient required medication for shoulder pain. No hospitalization was necessary. No infectious complications occurred during one month follow up.

In laparoscopic examination mild endometriosis was detected in three patients (out of 28, 10.7%) and minor peritubal adhesions in one patient. No other pathological findings relevant to fertility were detected by laparoscopy.

Discussion

In the present study the findings of sonosalpingography and laparoscopic chromopertubation agreed in 47 out of 53 tubes. The concordance (89%) obtained is comparable with previous studies, which have yielded concordance values between 83 and 86% (5–9). The results obtained from different studies are not, however, directly comparable, since some previous studies have reported the occurrence of bilateral or unilateral patency or bilateral occlusion. In our study we scanned and analyzed the tubes separately and screened the tubes only for patency or non-patency. Previously, only Spalding et al. have analyzed the tubes separately using similar equipment (7, 9). Table III summarizes the pooled data obtained from these studies and the present work. The sonosalpingography agrees with laparoscopic chromopertubation in 117 out of 135 tubes (concordance 87%). For the pooled data the positive predictive value for tubal

patency was high (94%), whereas the accuracy in finding out tubal occlusion was somewhat lower (negative predictive value 66%). This indicates that sonosalpingography using air and saline as a contrast medium is a reliable method to find a patent tube. The high sensitivity and specificity of the method in diagnosing tubal patency obtained in the present study also support the role of sonosalpingography as a reliable screening test to assess tubal patency. In order to further validate the usefulness of sonosalpingography in the diagnostic work-up of infertility, the likelihood-ratio for tubal patency was calculated. The ratio obtained (5.4) exceeds the value (5) generally accepted for clinical application. In the present study we used this value to calculate the posttest probability, which indicates by how much sonosalpingography will increase the pretest probability of tubal patency. The pretest probability obtained, 77%, was increased by sonosalpingography – a posttest probability of 95% in case of a normal finding.

Recent studies comparing sonohysterography with hysteroscopy have demonstrated a good correlation between the findings obtained in infertile patients and patients with recurrent pregnancy loss (12–14). In the present study, the uterine cavity was easily visualized at all sonohysterographic examinations. Apart from one endometrial polyp (Fig. 1C) previously missed by a vaginal ultrasound examination, no other intracavitary abnormalities were detected.

According to our experience, the technical performance of sonosalpingography was easy. Only in one case the patency of one tube was impossible to verify due to technical difficulties. In our study, patients exhibiting a high risk for experiencing pain during sonosalpingography or having a condition that could be treated preferably by laparoscopy or hysteroscopy were excluded from the study. Consequently, only four patients reported moderate or severe pain, requiring medication. This closely parallels previously reported incidences of pain during the procedure (5, 6). Mild pelvic discomfort was reported by approximately half of the patients during the insertion of the catheter or injection of saline-air, but this did not result in discontinuation of the procedure. Patient compliance to sonosalpingography has been reported to be better than to HSG (7, 15). Although no prophylactic antibiotic was used in the present study, no infectious complications were recorded during one month follow up.

Ayida and coworkers (16) have recently suggested that laparoscopy and chromotubation have no place as a primary test for tubal patency in a 'non-complicated' patient (i.e. a patient without a history of pelvic inflammatory disease, endome-

Table III. Concordance between sonosalpingography using a combination of air and saline as a contrast medium and laparoscopic chromopertubation, positive predictive value for tubal patency and negative predictive value for tubal occlusion obtained in studies where the tubes have been analyzed separately. The positive and negative predictive values have been measured by using the originally reported results as indicated in Table I

Reference	N*	Concordance	PPV†	NPV‡
Heikkinen et al. 1995 (7)	61	52/61 (86%)	96%	56%
Spalding et al. 1997 (9)	21	18/21 (85%)	88%	80%
The present study	53	47/53 (89%)	95%	71%
Together	135	117/135 (87%)	94%	66%

* N=number of tubes; † PPV=positive predictive value for tubal patency;

‡ NPV=negative predictive value for tubal non patency.

triosis or genital tract anomaly). The odds of finding fertility related pathology by laparoscopy in these patients are relatively low (17). Accordingly, in our material, mild endometriosis was detected in three patients out of 28 and minor peritubal adhesions in one patient. No other pathological findings relevant to fertility were detected by laparoscopy in the present study. Laparoscopy is costly and carries potential risks associated with a general anesthesia and an invasive procedure (18).

Taken together, our results confirm that sonosalpingography is an easy and reliable method to assess tubal patency and uterine cavity without special instrumentation on an outpatient basis. The procedure is relatively painless and does not need any medication, including antibiotics. At present, sonosalpingography has replaced HSG as a primary examination of tubal patency at our institution. Laparoscopy with appropriate therapeutic measures taken during the same operation is still preferred for patients with a history of endometriosis or previous severe pelvic inflammatory disease.

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Address for correspondence:

L. Anttila, M.D.
Department of Obstetrics and Gynecology
Turku University Central Hospital
Kiinamylynkatu 4–8, FIN-20520 Turku
Finland.