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## GYNAECOLOGY

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# Transvaginal Saline Sonosalpingography for The Assessment of Tubal Patency

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## ABSTRACT

**Objective** To evaluate the test characteristics of transvaginal saline sonosalpingography (SSG) for the assessment of tubal patency in comparison to laparoscopy with chromoperturbation.

**Design** Diagnostic test (prospective and blind comparative study).

**Setting** Infertile clinic and operative theater, Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital.

**Material and methods** Tubal patency of 44 infertile women with previous unknown tubal function was assessed by transvaginal saline SSG at infertile clinic. Transvaginal saline SSG was performed with a 5 MHz transducer-ATL-HDI 3000 by injection 50 ml isotonic saline solution into the uterine cavity through a pediatric Foley catheter. The collection of free fluid imaged in the cul-de-sac was accepted as the evidence of tubal patency. Diagnostic laparoscopy with chromoperturbation was performed independently at operative theater on the following day. The results of transvaginal saline SSG were compared to the findings from the diagnostic laparoscopy with chromoperturbation.

**Main outcome measures** The prevalence, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, false positive rate and false negative rate.

**Results** 42 of 44 women were finally recruited into the study because the procedure could not be accomplished in two women. The results from transvaginal saline SSG were compared to the findings from the standard diagnostic laparoscopy with chromoperturbation. Transvaginal saline SSG could detect tubal patency (either unilateral or bilateral) with sensitivity, specificity, PPV, NPV and accuracy of 96.97%, 88.89%, 96.97%, 88.89% and 95.24% respectively. Adverse events of transvaginal saline SSG included : mild pelvic pain in 30 (71.43%), severe pelvic pain in two (4.76%) and shoulder pain in one (2.38%) of the women in this study. Infectious complications were not found in this study.

**Conclusion** The results confirm that transvaginal saline SSG is a simple, well tolerated and reliable screening method for the assessment of tubal patency in an outpatient setting with minimal adverse effect. However, other confirmatory tests are required whenever bilateral tubal occlusion is suspected due to possible false negative finding.

**Key words :** tubal patency, laparoscopy, sonosalpingography, infertility

With respect to the various causes of infertility, tubal occlusion is one possibility that needs to be excluded (or confirmed) in infertility investigations. It accounts for 25-50% of the etiologies in infertile couples.<sup>(1)</sup> Traditionally, the assessment of tubal patency has been made by insufflating the fallopian tubes with carbon dioxide gas (Rubin test).<sup>(2)</sup> At present, the more commonly used procedures to evaluate tubal patency are hysterosalpingography (HSG) and/or diagnostic laparoscopy with chromoperturbation. These procedures have several inherent advantages and disadvantages of their own. Rubin test is easy to conduct in an out-patient setting but is highly subjective. HSG, although can directly image the intrauterine findings but certainly exposes the patient to iodinated contrast materials and ionizing radiation which could produce an anaphylactic reaction. For diagnostic laparoscopy which is accepted as the most specific test of all but is an invasive technique that needs to be performed cautiously under general anesthesia and by skillful laparoscopists.

Since early years of 80's, sonosalpingography (SSG) have been introduced as the screening test for tubal patency.<sup>(10,11)</sup> Lately, it has been suggested as the firstline method to evaluate tubal patency due to its benefits of simplicity and reliability compared to laparoscopy with chromoperturbation as the "gold standard"<sup>(3-9)</sup> There are numbers of contrast media used in determination of tubal patency in the process of SSG, for examples a combination of air and saline or 20% galactose microparticles in aqueous solution (Echovist200®, Schering AG).

We have adopted this study for the assessment of tubal patency. The objective is to assess its accuracy in comparison to the diagnostic laparoscopy with chromoperturbation at our institution. Instead of contrast media, we used only isotonic saline solution due to its convenience and availability.

## Material and methods

We conducted a comparative study between transvaginal saline SSG and diagnostic laparoscopy with chromoperturbation for the assessment of tubal

patency in infertile women at Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital from September 2000 to December 2001. This study was approved by our institutional review board of ethical committee. All 44 infertile women without signs and symptoms of genital tract infection and bleeding who were going to have infertility investigations were included into the study. Written informed consent was signed after a thorough explanation of the procedure.

All women were in their proliferative phase of the menstrual cycle. Initially, transvaginal sonographic examination of the pelvis was performed in dorsal lithotomy position using an ATL-HDI 3000. This was to assess normal free fluid in cul de sac as a baseline data. Minimal free fluid detected in cul de sac before performing the procedure in some cases would be recorded and imaged with an ultrasonographic picture. Povidine solution was used as antiseptic for vaginal and cervical cleaning after application of bivalve vaginal speculum. The number-8 pediatric Foley catheter with semirigid catheter guide was inserted about 5 cm into the endocervix and passed above the level of the internal os. The balloon was then inflated with 3 ml of isotonic saline solution and pulled down gently so the balloon fitted against the internal os. The semirigid catheter guide in Foley and the speculum were removal together. The transvaginal probe was reinserted followed by intermittent injection of 50 ml of sterile isotonic saline solution through the pediatric Foley catheter into the uterine cavity (Fig. 1). Then, we observed for the collection of fluid in the cul-de-sac for 2 minutes. The collection of fluid in the cul-de-sac (Fig. 2) or an increased volume of the preexisting free fluid in cul-de-sac was considered as the evidence of at least unilateral tubal patency (positive test). Bilateral tubal occlusion was diagnosed by the absence of fluid collection in the cul-de-sac or static level of fluid in the cul de sac after the procedure (negative test).

After this procedure, the patient would be observed at rest for 30 minutes. Analgesic drug (Ibuprofen 400 mg P.O) was given if pelvic or shoulder pain was complained.

Diagnostic laparoscopy with chromoperturbation (gold standard) was performed under general anesthesia on the following day to evaluate pelvic pathology and tubal patency. This was performed by methylene blue dye injection through a cone-shaped adapter which was fixed tightly to the external os of cervix with a tenaculum. If the methylene blue dye could pass through the distal end of fimbria at least one side, it represented tubal patency (positive test). Whereas the dye could not pass through the distal end of both

fimbriae, it represented tubal occlusion (negative test).

Each procedure was performed by different physician in the team of the authors. The findings of each test were blinded to each other. Then, the results of transvaginal saline SSG were evaluated for its test characteristics in comparison to the laparoscopy with chromoperturbation. The prevalence, accuracy, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), false-positive rate and false-negative rate were determined.



**Fig. 1.** A transverse scan of a uterus during instillation of isotonic saline solution.



**Fig. 2.** A longitudinal section of a uterus showing expanded uterine cavity with isotonic saline solution. The collection of fluid was also noted in the cul-de-sac.

## Results

From 44 women who were initially recruited, 33 cases were primary infertile and 11 cases were secondary infertile. There were two women whom transvaginal saline SSG cannot be accomplished due to technical failure. These were resulted from repeated slipping of Foley catheter from the uterine cavity when

hydrotubation were attempted. Both women had bilateral tubal occlusion by laparoscopy with chromoperturbation.

The mean age of women was  $33.61 \pm 3.59$  years (range 27-42 years old). Duration of the transvaginal saline SSG procedure ranged from 5-12 minutes. The mean value was  $7.52 \pm 2.02$  minutes.

**Table 1.** Tubal passage findings from transvaginal saline sonosalpingography and laparoscopy with chromoperturbation

Tubal passage	Transvaginal saline sonosalpingography	Laparoscopy with chromoperturbation
Unilateral or bilateral patency	33	33
Bilateral occlusion	9	11*
Total No. of patients	42	44*

\* There were two cases which bilateral tubal occlusion could not be evaluated by transvaginal saline SSG, due to technical failure.

**Table 2.** Accuracy of transvaginal saline sonosalpingography in diagnosis of tubal patency

Transvaginal saline sonosalpingography	Laparoscopy with chromoperturbation		Total
	Unilateral or bilateral tubal patency	Bilateral tubal occlusion	
Unilateral or bilateral tubal patency	32	1	33
Bilateral tubal occlusion	1	8	9
Total	33	9	42

**Table 3.** Evaluation of the value of transvaginal saline sonosalpingography in assessment of tubal patency

Results	%
Sensitivity	96.97
Specificity	88.89
Positive predictive value	96.97
Negative predictive value	88.89
False positive rate	11.11
False negative rate	3.03
Likelihood ratio if test positive	8.73
Likelihood ratio if test negative	0.03
Accuracy	95.24
Prevalence	78.57

Positive test = Including either unilateral or bilateral tubal patency

Negative test = Bilateral tubal occlusion

Transvaginal saline SSG show tubal patency (either unilateral or bilateral) in 33 women and bilateral tubal occlusion in 9 women. These were confirmed by laparoscopy with chromoperturbation in

32 and 8 women as tubal patency and tubal occlusion respectively. The findings of both methods agreed in 40 out of 42 women (concordance 95.24%). The PPV was 96.97% (95%CI, 84.70-99.50). The NPV was

88.89% (95%CI, 56.50-98.00). There were one false positive and one false negative findings. The sensitivity of transvaginal saline SSG in diagnosing unilateral or bilateral tubal patency was 96.97% (95%CI, 84.70-99.50) and the specificity was 88.89% (95%CI, 56.50-98.00).

Transvaginal saline SSG revealed one septated uterus. No other pathological intracavitary findings were detected.

Adverse events of transvaginal saline SSG included mild pelvic pain during injection of saline through the uterine cavity in 30 women (71.43%). This did not, however, result in stopping the procedure or required any medication. Two women (4.76%) complained of severe pelvic pain which was relieved with oral analgesics and rest for 30 minutes. Both of them had bilateral tubal occlusion by laparoscopy with chromoperturbation. One women (2.38%), who had positive test, required medication for shoulder pain. No other immediate or remote complication was encountered.

## Discussion

Although HSG and diagnostic laparoscopy with chromoperturbation are useful for the assessment of tubal patency. Nevertheless they have shown some unavoidable disadvantages. With the advent of ultrasound, trends have been towards the application of sonographic hydrotubation for the assessment of tubal patency in a greater manner.<sup>(3-13)</sup>

Transvaginal saline SSG compared with the conventional methods (i.e. HSG, and laparoscopy with chromoperturbation), is easier and safer to perform. It can be used to avoid some disadvantages of HSG, such as exposure to ionizing radiation or allergy to iodinated contrast material in sensitized patient. It also has some advantages in visualization inner contour and pathology of the uterine cavity. Compared to diagnostic laparoscopy which is the gold standard test for tubal study, although SSG is less accurate in evaluation of tubal patency and direct visualization of pelvic pathology is not possible but anesthetic and surgical risk from the former procedure can be avoided,

especially when performed by an inexperienced hand. Moreover transvaginal saline SSG may also be used to assess the tubal status after microsurgery for reanastomosis in an out patient setting.<sup>(3)</sup>

Earlier studies had applied transabdominal sonography to evaluate tubal patency.<sup>(10,11)</sup> Richman et al, by a 3.5 MHz sector scanner ultrasound, assessed the tubal patency by injecting Hyskon solution transcervically and observed free fluid in the cul-de-sac as the positive evidence.<sup>(10)</sup> The patency of at least one uterine tube was detected by demonstrating free fluid in the cul-de-sac. They concluded that this technique had several advantages over the traditional HSG. Randolph et al also used transabdominal scanner sonography, a 3.5 RT 3,000 real-time sector to assess the tubal patency by injecting saline solution transcervically and observed the turbulent flow of fluid in the uterine cavity and cul-de-sac.<sup>(11)</sup> They suggested that ultrasonography was as accurate as HSG in demonstrating the tubal patency.<sup>(10,11)</sup> Anyhow, their studies did not specify that which tube was the patent one. So, later studies tried to answer this question. Inki et al 8 used the combination of air and saline solution as a contrast medium to evaluate the uterine tubes separately by a 5 MHz vaginal ultrasound probe. The tube was considered patent if flow of air bubbles was seen at the distal end of the tube. The results were compared to the findings at laparoscopy with chromoperturbation performed independently. In their report, the sensitivity and the specificity were 90.20% and 83.30% respectively. Other studies compared transvaginal SSG to laparoscopy with chromoperturbation and found its accuracy in detection of tubal patency ranged from 76%-87%.<sup>(3-5)</sup> Sensitivity in detection of tubal occlusion was also high above 90%.<sup>(13)</sup>

In our study we used a 5 MHz vaginal transducer to assess tubal patency transcervically by injecting isotonic saline solution. Patency of at least one fallopian tube was detected by demonstrating the collection of free fluid in cul de sac. The accuracy in establishing which tube was patent in this study was not in our scope because it would be time consuming

and need extra skill for interpretation. In this work, we expect for simple and available method in clinical practice to exclude bilateral tubal occlusion from infertility investigations.

There was broad agreement between the tubal findings from transvaginal saline SSG and laparoscopy with chromoperturbation. Transvaginal saline SSG could detect almost all cases of the tubal patency with high percentage of accuracy, 95.24%. It yielded sensitivity of 96.97% and specificity of 88.89%. When it predicted good tubal patency, only one case of tubal occlusion was diagnosed by laparoscopy with chromoperturbation (false positive rate = 11.11, PPV = 96.97%, likelihood ratio if test positive = 8.73). However, when the test showed nine cases of tubal occlusion, one case had tubal patency by laparoscopy with chromoperturbation (false negative rate = 3.03, NPV = 88.89%, likelihood ratio if test negative = 0.03).

Our study revealed one false positive case. She had free fluid detected in cul de sac before performing the test and seemed to have increased fluid level after the test. Since the indicator of an unobstructed tubal passage used in this study was collection of free fluid in the cul de sac. This was probably due to interpretation error of ultrasonographic picture. False negative was detected in one case. This might be explained by the tubal spasm caused by injection of the media into the uterine cavity. Hence if suspected of tubal spasm, it was better to wait for a while until the patient feels relaxed and then the test was reattempted. With this step we could easily demonstrate the collection of fluid in some cases. Nine cases of tubal occlusion could be injected totally 50 ml of isotonic saline without serious complications.

From this information, it appears that transvaginal saline SSG is a good screening test of tubal patency. Nevertheless when it shows tubal occlusion, the test should be confirmed by other tests due to possible false negative finding.

Regarding to the adverse effects, other studies did not report any serious side effects including infectious complication.<sup>(3-13)</sup> In our study, we found only 2 out of 42 patients experienced severe pelvic pain.

They were relieved with oral analgesics and rest for 30 minutes. Their tubal pathology might be the factor of this symptom because both women had bilateral tubal occlusion by laparoscopy with chromoperturbation. No other complications were encountered in this study.

The adjunctive use of hydrotubation during ultrasonography provided more information of the female genital tract in infertile women than the use of ultrasonography alone. Hydrotubation enhanced the ability of ultrasonography to detect uterine anomalies such as intrauterine septum, endometrial polyps or submucous myoma etc, which may not have been detectable by only ultrasonography.<sup>(13)</sup> We also incidentally found intrauterine septum in one case study.

We concluded from our study that transvaginal saline SSG is a simple and convenient technique that possesses some beneficial aspects over HSG and laparoscopy with chromoperturbation. It can be used as an alternative method to assess tubal patency in order to avoid many potential disadvantages of the conventional methods. However repeated procedures or other confirmatory tests is still suggested if tubal occlusion is suspected due to possibility of false negative.

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