

# Diagnostic Accuracy of Sonosalpingography for Assessing Tubal Patency in Women with Infertility Taking Laparoscopy as Gold Standard

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## ABSTRACT

**Background:** Infertility is defined as the failure to conceive after 1 year of unprotected sexual intercourse in women less than 35 years of age and 6 months in women older than 35 years [1, 2]. It affects 10 to 15 % of the couples [1]. Abnormalities of fallopian tubes account for 35 to 40 % of the cases of infertility [3]. Sonosalpingography is a non-invasive, safe and cost-effective diagnostic technique which provides reliable diagnosis of tubal patency [4].

**Objective:** To evaluate the diagnostic validity of Sonosalpingography as a tubal patency test in infertile women using laparoscopy as gold standard.

**Methodology:** This study was carried out at the Radiology Departments of Khyber Teaching Hospital and Kuwait Teaching Hospital in Peshawar. We used the WHO method for sample size by taking the prevalence of tuboperitoneal factors as 30%, sensitivity 72.9%, specificity 81.22%, margin of error 12%, and 95% confidence interval. It was a cross-sectional study that lasted for 6 months and assessed a total of 178 patients. Additionally, a non-probability, sequential sampling strategy was utilized to acquire the sample.

**Results:** Our patients aged between 18-45 years, out of which 30% of the participants aged 18 to 25years, 55% were between 26 and 35years, and 15% were between 36 and 45years. Standard deviation was 1.26, with a mean age of 27. The data collected from both the diagnostic tests was analyzed, diagnostic accuracy of Sonosalpingography was calculated as a sensitivity of 81%, specificity of 76%, positive predictive value of 90%, negative predictive value of 60%, and diagnostic accuracy of 79%.

**Conclusion:** According to the results of our study, sonosalpingography is a very helpful supplemental diagnostic tool for evaluating tubal disease in patients with infertility, though direct laparoscopic assessment is the gold standard. Sonosalpingography and laparoscopy can be used to evaluate patients with secondary infertility. This spares the patient from being exposed to radiations and the discomfort of contrast administration in HSG.

**Keywords:** Diagnostic Accuracy, Sonosalpingography, Tubal Patency, Infertility, Laparoscopy

## INTRODUCTION

Infertility is the inability to conceive after one year of unprotected sexual relationship in females less than 35years of age and six months in females more than 35 years of age [1,2]. It affects 10 to 15 % of the couples [1]. There are various causes of infertility in women; including disorders of fallopian tubes, uterus and ovaries. Among these abnormalities of fallopian tubes, account for 35 to 40% of the cases of infertility [3]. In order to treat infertility accurate evaluation of tubal patency is very important [4]. The most common tubal disease responsible for sub fertility in women is PID. Other causes include endometriosis, pelvic tuberculosis, previous pelvic surgery and fibroids [5].The resultant tubal abnormalities include obstruction, stenosis, dilatation and impaired peristalsis. Assessment of the site and extent of tubal disease is important as it will affect the treatment of the patients. Every method of assessment has its own advantages and disadvantages [6].

The methods available for the assessment of endometrial cavity and tubal patency include HSG, TVS, Laparoscopic chromopertubation, Falloposcopy, radionuclide hysterosalpingography [12]. Among the less invasive or non invasive diagnostic modalities are ultrasonography, sonosalpingography and MRI while invasive modalities are HSG, hysteroscopy and laparoscopy [13]. Laparoscopy and dye injection considered as gold standard has various disadvantages associated with it such as time consuming, expensive, use of anesthetic agents and associated morbidity [4]. Another commonly used technique HSG also has a number of associated complications which include pelvic pain, vomiting, fever, contrast allergies, infections, risk of venous and lymphatic intravasation[3, 12]. It can cause transient distortion of the endometrial cavity by blood, mucous, debris and air bubbles which can cause false positive results [12]. Sonohysterography, a modern technique, now widely used for evaluation of female infertility is more sensitive

than TVS, less expensive than hysteroscopy and has a comparable diagnostic accuracy [7].

Sonosalpingography is a non-invasive, safe and cost-effective technique which provides reliable diagnosis of tubal patency [4, 12]. Saline sonosalpingography has fewer side effects, is better tolerated and can be performed during regular transvaginal ultrasound hence a time saving procedure [3, 12]. Saline infusion Sonohysterography is a simple procedure that has a good diagnostic accuracy in detecting intrauterine pathologies, including causes of recurrent implantation failure, hence avoiding the need for more invasive procedures [8, 9]. It is safe as well as less costly, less painful and minimally invasive, reducing the chances of surgical intervention [8, 10]. Saline infused sonography is less invasive and an accurate diagnostic tool for assessment of uterine lesions and tubal pathologies in infertile patients which can be performed as an OPD procedure, not requiring contrast administration, thus eliminating the chances of contrast allergies [8, 11, 12].

The aim of our study is to determine the diagnostic accuracy of sonosalpingography for the detection of tubal patency in infertile women so that it can be used as an initial diagnostic tool in these patients because it is simple, cheap, safe having no risk of anesthesia/surgical complications and no exposure to radiation or contrast media.

## MATERIALS AND METHODS

This study was carried out in the Radiology Departments of Khyber Teaching Hospital and Kuwait Teaching Hospital in Peshawar. We used WHO method for sample size by taking the prevalence of tuboperitoneal factors as 30%, sensitivity 72.9%, specificity 81.22%, margin of error 12%, and 95% confidence interval. It was a cross-sectional study that lasted for 6 months and assessed a total number of 178 patients. Additionally, samples were collected using a sequential, non-probability sampling technique.

**Inclusion criteria:**

- Age range from 18-45 years
- Normal menstrual cycles
- Unprotected regular intercourse for more than 1 year
- Infertile females coming to gynae departments of Khyber teaching and Kuwait teaching hospitals fulfilling the above criteria and referred for sonosalpingography.

**Exclusion criterion:**

- Females having age below 18 and above 45 years
- History of acute infection, active PID
- Medical or hormonal dysfunction
- Husband having Azoospermia or oligospermia.

After approval from the hospitals, ethical and scientific committees, the study was carried out. All patients who satisfied the inclusion criteria were part of the trial. The patients were informed about the procedure, the purpose and advantages of the research were explained to them, along with the risks involved. Informed consents were acquired. All patients underwent clinical examination and history taking. Sonosalpingography was carried out on day 5<sup>th</sup>-7<sup>th</sup> of the menstrual cycle which entailed uterine catheterization, injection of sterile isotonic saline into the endometrial cavity and concurrent visualization with vaginal sonography for fluid spilling into the peritoneal cavity, which was considered as an indicator of tubal patency. Following sonosalpingography, all patients underwent laparoscopy, and the outcomes of the two procedures were compared.

The study's results were controlled for variables and bias using strict exclusion criteria. Skilled radiologist, fellow of CPSP did sonosalpingography. Data was analyzed with SPSS 16 software using chi square test to determine the sensitivity, specificity and diagnostic accuracy of Sonosalpingography comparing it with the laparoscopic findings.

**RESULTS**

In order to evaluate the diagnostic validity of sonosalpingography for determining tubal patency in infertile women using laparoscopy as the gold standard, a total of 178 patients were evaluated at the Radiology Departments of Khyber Teaching Hospital and Kuwait Teaching Hospital, Peshawar. The findings were evaluated in the following manner:

Analysis of the age distribution of 178 patients revealed that n=53 (or 30%) patients were between the ages of 18 and 25, n=98 (or 55%) patients were between the ages of 26 and 35, and n=27 (or 15%) patients were between the ages of 36 and 45. The standard deviation was 1.26, and the mean age was 27 years (as shown in table No.1). Analysis of the sonosalpingography results among 178 patients revealed that 116 (65%) of the patients had positive results and 62 (35%) had negative results. (As depicted in table No. 2) Analysis of 178 patients' laparoscopic findings revealed that n=160 (90%) had favourable results and n=18 (10%) had negative results. (As indicated in table No.3) Analysis of the sonosalpingography's diagnostic accuracy revealed that it was 79% overall, with sensitivity of 81%, specificity of 76%, positive predictive value of 90%, and negative predictive value of 60%. (As shown by table No. 4, 5)

Table 1: Age Distribution (n=178)

Age Distribution	Frequency	Percentage
18-25 years	53	30%
26-35 years	98	55%
36-45 years	27	15%
Total	178	100%

Mean age was 27 years with standard deviation ± 1.26

Table 2: Sonosalpingography Findings (n=178)

Sonosalpingography	Frequency	Percentage
Positive	116	65%

Negative	62	35%
Total	178	100%

Table 3: Laparoscopy findings (n=178)

Laparoscopy	Frequency	Percentage
Positive	160	90%
Negative	18	10%
Total	178	100%

Table 4: Sonosalpingography Vs Laparoscopy Findings (n=178)

		Laparoscopy Findings		Total
		Yes	No	
Sonosalpingography	Yes	A104(90%) TP	B12(10%) FP	116(65%)
	No	C25(40%) FN	D37(60%) TN	62(35%)
Total		160(90%)	18(10%)	178(100%)

Sensitivity=104/(104+25)\*100 = 104/129\*100=81%

Specificity = 37/(37+12)\*100=37/49\*100 = 76%

Positive predictive value = 104/(104+12)\*100=104/116\*100 = 90%

Negative predictive value = 37/(37+25)\*100=37/62\*100 =60%

Diagnostic Accuracy = 104+37/178 \*100 = 141/178\* 100=79%

Table 5: Diagnostic Accuracy (n=178)

Diagnostic accuracy	Frequency	Percentage
Yes	141	79%
No	37	21%
Diagnostic accuracy	Frequency	Percentage
Yes	141	79%
No	37	21%
Total	178	100%

**DISCUSSION**

Infertility described as failure to conceive after 1 year of unprotected sexual intercourse in women less than 35 years and 6 months in women older than 35 years , affecting 10 to 15 % of couples worldwide[1,2]. Among the causes of female infertility are disorders of fallopian tubes, uterus and ovaries with fallopian tube abnormalities accounting for 35 to 40 % of cases of infertility [3]. Therefore to treat infertility accurate evaluation of tubal patency is very important [4]. The most common tubal disease responsible for sub fertility in women is PID, other including endometriosis, pelvic tuberculosis, previous pelvic surgery and fibroids resulting in tubal stenosis, obstruction and abnormal dilatation [5, 6, 13]. Sonosalpingography is a non-invasive, safe and cost- effective technique which provides reliable diagnosis of tubal patency having fewer side effects, is better tolerated and can be performed during regular transvaginal ultrasound thus less time consuming[3 ,4]. In our study 30% patients were 18-25 years, 55% patients were in age range 26-35 years, 15% patients were in age range 36-45 years. Mean age was 27 years with standard deviation ± 1.26. Diagnostic accuracy of sonosalpingography was analyzed as the sensitivity was 81%, specificity was 76%, positive predictive value was 90%, negative predictive value was 60% and the diagnostic accuracy was 79%. A study was conducted by E.W.Nnah et al [3] in 2019, he compared the results of Saline Sonohysterosalpingography with HSG for the diagnosis of uterotubal pathology. The total number of patients studied was 101. The mean age was 31.06 yrs. 86 of 101 patients showed agreement in the diagnosis of patent fallopian tubes and disagreement in 1 patient. For blocked fallopian tubes the results of SSHG and HSG were similar in 11 patients and different in 3 of the patients. Concordance between SSHG and HSG for the assessment of tubal patency was 96.04%. In this study SSHG has a sensitivity of 98.69 %, specificity of 78.6%, PPV of 96.6% and NPV of 91.7%. Another study was performed by Zaheer Mustafa et al [1] in 2020 who studied the role of Saline Infused Sono-Hysterosalpingography in infertility due to tubal blockage. The total number of patients studied was 150 with mean age of 32 yrs. The results of SIS and HSG were similar as tubal blockage was seen in 92(61.33%) cases on HSG and 90(60%) on SIS. The sensitivity of

SIS for tubal obstruction was 77.14%, PPV was 78.89% and diagnostic accuracy was 75.33%

A study conducted by Julia Ramos et al. [5] in 2021, which compared the results of Hysterosalpingo-Foam Sonography and Hysterosalpingography in the assessment of tubal patency. A total concordance was seen in 72.6% of the cases while a total discordance in 4.7% of the cases. A study carried out by G.Capobianco et al. [9] in 2018 evaluated the technique, advantages and limits of Saline infusion sonography for the study of uterus and fallopian tubes. SIS is an alternative technique for the evaluation of uterine cavity and intracavitary pathologies like fibroids and endometrial polyps before assisted conception because these may hinder assisted fertilization procedures. The sensitivity and specificity of SIS and HSG are similar for assessment of tubal patency. In our study, 35 individuals had tubal block, either unilaterally or bilaterally, which was accurately identified. Due to tubal spasm and instances of mild to moderate hydrosalpinx, 13 patients were missed. Any approach can be used to observe these aspects. Two cases of tubal dysmotility brought on by pelvic adhesions resulting from pelvic endometriosis were also missed by us. A low-cost, dependable, secure, and pleasant examination technique is transvaginal sonosalpingography with the mixture of air and saline, which may be employed for the study of infertility. Our exams took an average of 10 minutes to complete. One patient's study was stopped due to a severely stenosed cervix.

Based on these evidences we concluded SONOSALPINGOGRAPHY as a sensitive, specific, safe, inexpensive, less time consuming and easily available diagnostic tool for assessment of tubal pathologies in females with infertility.



## CONCLUSION

It is concluded that Sonosalpingography has high sensitivity and specificity for detecting tubal patency in patients with infertility is relatively inexpensive, less invasive, less time-consuming diagnostic tool without much of the complications associated with other diagnostic tests. Easy availability and access of ultrasound in all health care centers is an added advantage, further improvements in this technique can make SSG a first line

diagnostic procedure. At present Sonosalpingography and laparoscopy can be used to evaluate patients with secondary infertility so as to spare the patients from being exposed to radiations and the discomfort of contrast administration.

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