

Article

# Evaluation of diagnostic accuracy of saline infusion sonography with hysteroscopy in infertile women

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**Abstract:** Infertility, defined as the inability to achieve pregnancy after one year of regular unprotected sexual intercourse, is a prevalent issue affecting couples worldwide. Among the various causes of infertility, uterine abnormalities have a significant prevalence, ranging from 34% to 62%. This study aimed to assess the effectiveness of saline infusion sonography (SIS) and hysteroscopy in evaluating uterine cavity abnormalities in infertile women. The inclusion criteria included primary and secondary infertility, while exclusion criteria involved active pelvic infection, unexplained genital tract bleeding, suspected pregnancy, and male factor infertility. The study was conducted prospectively in a hospital setting, and the majority of the infertile women were in the age group of 25-29 years. Primary infertility was observed in 75% of the subjects, while secondary infertility was seen in 25% of the patients. The results of SIS revealed the presence of endometrial polyps, submucosal fibroids, septum, and adhesions in various proportions. The overall sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SIS for diagnosing uterine anomalies were determined. However, hysteroscopy remains the gold standard for detecting uterine cavity abnormalities, with a sensitivity of 100% in identifying different structural anomalies and intrauterine adhesions. In conclusion, hysteroscopy is considered the superior technique for detecting uterine abnormalities, while SIS shows moderate sensitivity and specificity in diagnosing uterine anomalies in infertile women.

**Keywords:** Infertility; Uterine Abnormalities; Saline Infusion Sonography; Hysteroscopy; Diagnostic Techniques.

## 1. Introduction

**I**nfertility is the inability of a couple to achieve a clinical pregnancy after one year of regular unprotected sexual intercourse [1]. Infertility in women can result from a variety of conditions that affect the ovaries, uterus, fallopian tubes, and endocrine system among others [2]. It is of two types-primary or secondary infertility. A person has secondary infertility if at least one previous pregnancy has been accomplished, whereas primary infertility is when a pregnancy has never been achieved [3].

Uterine abnormalities have a significant prevalence, estimated to be between 34% and 62% [4], making them one of the most frequent causes of all abnormality cases. Therefore, the first tests that are frequently conducted on infertile women are the evaluation of the uterine cavity, which has the potential to significantly improve the success rate of infertility treatments. A variety of diagnostic techniques, such as hysteroscopy and hysterosalpingography (HSG), have been developed and employed frequently in recent years. Hysteroscopy has been considered to be the primary gold standard in this area, and HSG is a low-cost, simple, and effective procedure with excellent sensitivity in diagnosing uterine deformities and abnormalities. Endoscopic surgery known as hysteroscopy has become a vital method for assessing intrauterine disease. It enables the ability to do a biopsy on suspicious lesions and provides a direct picture of the whole uterine cavity. However, both hysteroscopy and HSG contain invasive procedures that might be painful and inconvenient for patients.

One of the most recently developed methods for the identification of uterine anomalies is hysterosonography, often known as a saline infusion sonogram (SIS). Saline infusion sonography's main objective is to more clearly see the endometrial cavity than is feasible with standard transvaginal

ultrasonography. SIS can show a patent tube in case it is blocked, however, it is challenging to identify the place of the restriction. Improved sonographic identification of endometrial diseases such as polyps, hyperplasia, leiomyomas, and occasionally adhesions is made possible by SIS. In comparison to hysteroscopy, SIS is less painful and uncomfortable since it is less expensive, less invasive, doesn't require anesthesia, takes less time, and poses no danger of radiation exposure [5].

Currently, between 10% and 14% of Indian women are infertile [6]. Developing nations like India are experiencing an increase in infertility. All infertile women must get baseline sonography. The only study that can yield the most information in an average of 10-15 minutes is saline infusion sonography [7]. Only a few studies on the effectiveness of SIS with hysteroscopy in the detection of localized endometrial lesions in infertile women have been carried out in India. In order to evaluate the efficiency of saline infusion sonography and hysteroscopy in the assessment of uterine cavity abnormalities in infertile women was carried out in the present study.

## 2. Material and methods

It was a Prospective non-randomized interventional study in The department of Obstetrics and Gynecology at Teerthanker Mahaveer Medical College & Research Centre.

### 2.1. Inclusion criteria

- Primary infertility,
- Secondary infertility.

### 2.2. Exclusion criteria

- Active pelvic infection,
- Unexplained genital tract bleeding,
- Suspected pregnancy,
- Patient with male factor infertility.

### 2.3. Procedure of saline infusion sonography

- SIS was performed on cycle day 5 to day 10 post menses [8].
- The patient was placed in the lithotomy position.
- Preliminary transvaginal ultrasound with measurement of endometrium and evaluation of ovaries, uterus and amount of pelvic free fluid was performed before saline infusion sonography.
- A bimanual examination was performed. Cusco's self-retaining speculum was inserted into the vagina to allow visualization of the cervix.
- Antiseptic cleaning of the cervix and vagina was performed, and a foleys catheter was introduced into the external os.
- 2-3 ml of normal saline was pushed to inflate the bulb [9].
- Around 20 ml of normal saline were kept ready with a 20 ml syringe [9].
- Once the speculum was removed and catheter was in position, the endovaginal transducer was inserted into the vagina [10].
- The normal saline was slowly pushed into catheter with the help of real time ultrasound imaging [10].
- Once adequate view of uterine cavity was achieved, the cavity was evaluated for the presence of any abnormality.

## 3. Results

**Table 1.** Age wise distribution of study subjects (n=60)

Age group	No.	%
20-24 years	11	18.3
25-29 years	32	53.3
30-34 years	11	18.3
35 years	6	10

Most of the women with infertility were in the age group of 25-29 years (53.3%) followed by 20-24 years (18.3%) and 30-34 years (18.3%). Mean age was 28.02±4.18 years.

**Table 2.** Cause of infertility in study subjects (n=60)

Cause of infertility	No.	%
Primary	45	75
Secondary	15	25

Primary infertility was in 75% subjects while secondary infertility was seen in 25% patients.

**Table 3.** Correlation between SIS and hysteroscopy finding (n=60)

SIS finding	Hysteroscopy finding				
	Endometrial polyp	Submucosal fibroid	Septum	Adhesion	Not detected /Normal
Endometrial polyp	3				4
Submucosal fibroid		4			2
Septum			3		3
Adhesion				2	1
Not detected/Normal	2	1		1	34

On SIS, endometrial polyp was seen in 7 (11.7%) women, Submucosal fibroid in 6 (10%) women, septum in 6 (10%) and adhesion in 3 (5%) women. Among these 3 endometrial polyps, 4 Submucosal fibroids, 3 septa and 2 adhesions were confirmed on hysteroscopy. Total 10 cases were detected as abnormal on SIS which were later detected as normal on hysteroscopy while total 4 cases were normal on SIS which were later detected as abnormal on hysteroscopy.

**Table 4.** Diagnostic value of SIS in detecting different uterine pathology

Diagnostic value	Endometrial polyp	Submucosal fibroid	Septum	Adhesion	Overall
Sensitivity	60%	80%	100%	66.67%	75%
Specificity	92.73%	96.36%	94.74%	98.25%	77.27%
LR +ve	8.25	22	19	38	3.3
LR -ve	0.43	0.21	-	0.34	0.32
Positive predictive value	42.86%	66.67%	50%	66.67%	54.55%
Negative predictive value	96.23%	98.15%	100%	98.25%	89.47%
Accuracy	90%	95%	95%	96.67%	76.67%

Overall sensitivity, specificity, PPV and NPV of SIS for diagnosis of all type of uterine anomaly was 75%, 77.27%, 54.55% and 89.47% respectively. The sensitivity, specificity, PPV and NPV for SIS in terms of endometrial polyp was 60%, 92.73%, 42.86% and 96.23% respectively and it was 80%, 96.36%, 66.67% and 98.15% for diagnosis of submucosal fibroid. The sensitivity, specificity, PPV and NPV for SIS in terms of septum was 100%, 94.74%, 50% and 100% respectively and it was 66.67%, 98.25%, 66.67% and 98.25% for diagnosis of adhesion

#### 4. Discussion

It was a hospital based Prospective non-randomized interventional study conducted in department of Obstetrics and Gynecology at Teerthanker Mahaveer Medical College & Research Centre enrolling a total of 60 study subjects. All the patients undergone SIS followed by hysteroscopy irrespective of SIS findings. Most of the women with infertility were in the age group of 25-29 years (53.3%) followed by 20-24 years (18.3%) and 30-34 years (18.3%). Mean age was 28.02±4.18 years. This is similar to another study about saline infusion sonography versus hysteroscopy in the evaluation of uterine cavity in women with unexplained infertility in which the study included 50 women with unexplained infertility in the age range 20–34 years, with a mean age of 26.88±3.42 years [11].

Primary infertility was in 75% subjects while secondary infertility was seen in 25% patients. Duration of infertility was >5 years in 46.7% patients. In study by Tokgoz VY et al. [12]. Primary infertility was in 86.5% subjects while secondary infertility was seen in 13.5% patients. Mean duration of infertility was 5.35±1.84 years. Out of 60 subjects 36.7% were overweight and 15% were obese. On SIS, endometrial polyp was seen in 7 (11.7%) women, Submucosal fibroid in 6 (10%) women, septum in 6 (10%) and adhesion in 3 (5%) women.

On hysteroscopy, endometrial polyp was seen in 5 (8.3%) women, Submucosal fibroid in 5 (8.3%) women, septum in 3 (5%) and adhesion in 3 (5%) women. On SIS, endometrial polyp was seen in 7 (11.7%) women, Submucosal fibroid in 6 (10%) women, septum in 6 (10%) and adhesion in 3 (5%) women. Tokgoz VY et al. [12] determined the overall intracavitary space-occupying lesions as 18.9% and the data regarding the categorization of the abnormalities were 17.4% and 1.5% for endometrial polyps and submucous fibroid, respectively. Among these 3 endometrial polyps, 4 Submucosal fibroids, 3 septa and 2 adhesions were confirmed on hysteroscopy. Total 10 cases were detected as abnormal on SIS which were later detected as normal on hysteroscopy while total 4 cases were normal on SIS which were later detected as abnormal on hysteroscopy. SIS evaluation of the uterine cavity of the studied cases in the Ezzat L et al. [13] study indicated a normal uterine cavity in 24 (80%) cases and uterine cavity abnormalities in 6 (20%) cases endometrial polyps, 0 (0%) uterine septum, and 0 (0%) myoma). Overall sensitivity, specificity, PPV and NPV of SIS for diagnosis of all type of uterine anomaly was 75%, 77.27%, 54.55% and 89.47% respectively. The sensitivity, specificity, PPV and NPV for SIS in terms of endometrial polyp was 60%, 92.73%, 42.86% and 96.23% respectively and it was 80%, 96.36%, 66.67% and 98.15% for diagnosis of submucosal fibroid. The sensitivity, specificity, PPV and NPV for SIS in terms of septum was 100%, 94.74%, 50% and 100% respectively and it was 66.67%, 98.25%, 66.67% and 98.25% for diagnosis of adhesion. Different studies from different part of India has reported sensitivity of SIS to detected abnormality in uterine cavity between 81-100% and specificity of SIS detected abnormality in uterine cavity between 70%-100% [7,14,15].

## 5. Conclusion

Abnormality in uterine cavity is a major risk factor for infertility in females so to increase the efficacy of treatment of infertility we need to detect abnormality of uterine cavity very early and for that thorough evaluation of uterine cavity is very important role. For detection of abnormality in uterine cavity hysteroscopy has been considered as best technique & gold standard but for doing this procedure good and sound technical knowledge is needed due to its invasive nature also there is risk of development of different complications and adverse effects. SIS is an effective and safe method to assess the uterine cavity and it is also a minimally invasive and less expensive method. SIS can be completed in any phase of the menstrual cycle, but the preferred timing of performing SIS is usually 5-14 days before ovulation which is basically a follicular phase. SIS in detection of fibroids especially submucous is almost near to diagnostic hysteroscopy and it was also observed that SIS can also help to determine the different parts of the myomas. It was also found that SIS was a more accurate method than TVS for evaluating the endometrial polyp ( $p < 0.05$ ). As we know that the sensitivity of diagnostic hysteroscopy is 100% to know different structural anomalies in uterine cavity as well as in detection of intrauterine adhesions it was also observed that in detection of submucous myomas and endometrial polyps the sensitivity and specificity of SIS is equivalent to diagnostic hysteroscopy and can be considered as replacement.

## 6. Limitations

We did not have histopathological finding of each patient which can confirm and verify different endometrial morphological changes and abnormality detected by diagnostic hysteroscopy as well as SIS. Second was lesser sample size as many other findings might be missed due to lesser sample size.

**Author Contributions:** All authors contributed equally to the writing of this paper. All authors read and approved the final manuscript.

**Conflicts of Interest:** The authors declare that they do not have any conflict of interests.

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