

## CME A prospective evaluation of uterine abnormalities by saline infusion sonohysterography in 1,009 women with infertility or abnormal uterine bleeding

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**Objective:** To evaluate the role of saline infusion sonohysterography (SIS) in the investigation of uterine abnormalities and malformations in patients referred for infertility work-up compared with women with abnormal uterine bleeding (AUB).

**Design:** Prospective cohort study.

**Setting:** Academically oriented private practice.

**Patient(s):** One thousand nine consecutive women examined by SIS for infertility work-up (n = 600, infertility group) or AUB investigation (n = 409, AUB group).

**Intervention(s):** SIS.

**Main Outcome Measure(s):** Intracavitary abnormalities and uterine anomalies.

**Result(s):** Among the women in the infertility group, 16.2% (n = 97) were found to have intracavitary abnormalities, including polyps (13.0%), submucous fibroids (2.8%), and adhesions (0.3%). Significantly, more patients in the AUB group (39.6%, n = 162) revealed intracavitary abnormalities, including polyps (29.8%), submucous fibroids (9.0%), and adhesions (0.7%). In contrast, significantly more uterine anomalies were found in the infertility group (20%, n = 120) compared with the AUB group (9.5%, n = 39). Arcuate uterus was the most common finding (15% vs. 6.4% of patients, respectively).

**Conclusion(s):** An SIS procedure for infertility work-up revealed a substantial percentage of infertile patients with intracavitary abnormalities and uterine anomalies. Because the technique is safe, well tolerated, and feasible in an outpatient setting, SIS should be considered routinely in the early stage of infertility and AUB investigation. (Fertil Steril® 2006;86:1731–5. ©2006 by American Society for Reproductive Medicine.)

**Key Words:** Saline infusion sonohysterography, uterine anomalies, infertility, IVF, abnormal uterine bleeding, arcuate uterus, ART, hysterosonography

Evaluation of the uterus should be an integral part of a routine infertility investigation, as recommended by reproductive professional societies in both the U.S. (1) and Europe (2). In an effort to simplify the investigation by using less invasive and inexpensive procedures, new methods that use contrast media to enhance endometrial visualization during transvaginal sonography (TVS) were put into clinical practice.

Saline infusion sonohysterography (SIS) involves transcervical instillation of sterile saline into the endometrial lumen during TVS. The saline distends the uterine cavity,

enabling the anechoic fluid to exquisitely delineate the echogenic endometrium. The technique was first reported two decades ago (3) and was demonstrated to be effective and highly sensitive for diagnosis of endometrial polyps, submucous fibroid, synechiae, and uterine anomalies (4–7). In a recent meta-analysis comparing SIS with gold standard diagnostic methods such as hysterectomy, hysteroscopy, and histologic sampling, the former was found both highly feasible and accurate in evaluating abnormal uterine bleeding (AUB) (8). In addition, compared with hysterosalpingography (HSG) and hysteroscopy, SIS is less invasive and less costly.

In the present study, we evaluated the uterus by SIS as part of the routine infertility work-up. For this purpose, we prospectively studied a large cohort of patients who were screened by SIS as part of early investigation of infertility and compared the results to those of another group of pa-

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tients referred for the investigation of AUB at the same period of time.

## MATERIALS AND METHODS

### Study Design and Subjects

During a period of 8 months (September 2003 to April 2004), 1,009 consecutive women were referred to and underwent SIS at our centers with indications of infertility ( $n = 600$ , mean age  $34 \pm 5.3$  years) or AUB ( $n = 409$ , mean age  $44 \pm 10.2$  years). In the infertility group, primary and secondary infertilities were similarly distributed: 51% and 49%, respectively. Among the AUB patients, 85% had an average of  $2.3 \pm 0.6$  pregnancies and  $1.7 \pm 0.4$  deliveries. Patients consented to the procedure, and upon conclusion of the SIS examination patients were sent back to the referring physician for further evaluation and treatment. Data was collected prospectively. This study was approved by the Institutional Review Board.

### Saline Infusion Sonohysterography

Patients with regular menses were examined during the follicular phase of the cycle. A routine two-dimensional TVS scan was first performed and then SIS. For both procedures, we used a vaginal transducer with a frequency of 5.0 MHz (Logiq 400 Pro; GE, Waukesha, WI). A standard bivalve vaginal speculum was put in place, and the cervix was cleansed with povidone-iodine. A 5-F balloon-tipped catheter (InterV Medical Device Technologies, Gainesville, FL) was inserted into the cervical canal up to the internal os. The balloon was then filled with 0.5 mL physiologic saline, and the appropriate position of the catheter was confirmed by pulling it slightly. Thereafter, the speculum was removed and the TVS probe was reinserted in the posterior vaginal vault. With concomitant TVS examination, 2 to 6 mL physiologic saline solution was slowly injected to distend the endometrial lumen. At the end of the examination, the balloon was emptied and the catheter removed. No analgesics, sedatives, or prophylactic antibiotics were used during or before the procedure.

Diagnoses by SIS were defined and recorded as follows: normal uterine cavity (smooth endometrium with normal regular contour); endometrial polyp (hyperechogenic pedunculated lesion); submucous fibroid (lesion of mixed echogenicity disrupting the endometrial continuity); intrauterine adhesions (asymmetric dense echogenic lesions and hypoechoic cystic areas within the cavity); and intramural fibroid (intramural lesion with clear margins) (4). Adenomyosis was diagnosed by TVS during SIS examination according to the criteria reviewed by Reinhold et al. (9). Decreased echogenicity or heterogeneity of the myometrium, which was shown to be the most common sign of adenomyosis, and other TVS signs (such as myometrial cysts, echogenic myometrial nodules or striations, and poor definition of endometrial junction) were found to diagnose adenomyosis with a sensitivity of 80%–86%, specificity of 50%–96%, and

overall accuracy of 68%–86% (9). Uterine anomalies were defined according to the criteria of the American Society for Reproductive Medicine with a slight modification for arcuate uterus that included the ratio of the height of the fundal indentation of the cavity to the distance between the horns  $>0.1$  cm (10).

### Statistical Analysis

Data are expressed as number of patients and percentage and are compared between the infertility group and the AUB group with the  $\chi^2$  test.  $P < .05$  is considered statistically significant.

## RESULTS

A total of 1,009 consecutive women in both groups successfully underwent SIS. No complications or difficulties were encountered during or after the procedure. Significantly, a higher percentage of patients with one or more uterine abnormalities were found in the AUB group compared with the infertility one (85.3% vs. 48.2%, respectively,  $P < .0001$ ).

Distribution of the intracavitary abnormalities is summarized in Table 1. Out of the 600 women that were referred for SIS as part of their infertility work-up, 16.2% ( $n = 97$ ) revealed intracavitary abnormal findings. In comparison, of the 409 women that were referred for AUB investigation, significantly more patients displayed intracavitary abnormalities (39.6%,  $n = 162$ ). Patients with polyps were the most common in both groups, followed by submucous fibroids, and significantly more prevalent in the AUB group than among the infertile women (Table 1).

Patients with intramural pathologies were significantly more prevalent in the AUB group in comparison with the infertility one (71.4%,  $n = 292$  vs. 40.2%,  $n = 241$ , respectively,  $P < .0001$ ). Adenomyosis was significantly more com-

**TABLE 1**  
Prevalence of intracavitary abnormalities diagnosed by saline infusion sonohysterography.

Uterine cavity diagnoses	Infertility group ( $n = 600$ )	AUB group ( $n = 409$ )
Endometrial polyp	78 (13.0) <sup>a</sup>	122 (29.8)
Submucous myoma	17 (2.8) <sup>a</sup>	37 (9.0)
Adhesions	2 (0.3)	3 (0.7)
Total intracavitary abnormalities	97 (16.2) <sup>a</sup>	162 (39.6)

Note: Data are expressed as  $n$  (%). AUB = abnormal uterine bleeding.

<sup>a</sup>  $P < .0001$ , infertility group vs. AUB group,  $\chi^2$  test.

Tur-Kaspa. SIS for infertility investigation. Fertil Steril 2006.

**TABLE 2****Prevalence of uterine anomalies diagnosed by saline infusion sonohysterography.**

Uterine anomaly	Infertility group (n = 600)	AUB group (n = 409)
Arcuate	90 (15.0) <sup>a</sup>	26 (6.4)
Partial septate	15 (2.5)	5 (1.2)
Complete septate	13 (2.2)	6 (1.5)
Bicornuate	0 (0.0)	1 (0.2)
Didelphus	0 (0.0)	1 (0.2)
Unicornuate	1 (0.2)	0 (0.0)
Hypoplastic	1 (0.2)	0 (0.0)
Total uterine anomalies	120 (20.0) <sup>a</sup>	39 (9.5)

Note: Data are expressed as n (%). AUB = abnormal uterine bleeding.

<sup>a</sup>  $P < .0001$ , infertility group vs. AUB group,  $\chi^2$  test.

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mon in the AUB group than in the infertility group (52.3%, n = 214 vs. 24.0%, n = 144, respectively,  $P < .0001$ ), followed by intramural fibroid (37.2%, n = 152 vs. 20.50%, n = 123, respectively,  $P < .0001$ ).

In contrast with the intracavitary and intramural abnormalities that predominated in the AUB group, uterine anomalies significantly prevailed in the infertility group (Table 2). The most common anomaly diagnosed by SIS was an arcuate uterus, which was significantly more prevalent among the infertile women compared with the patients with AUB (Table 2). The second most frequent anomaly found in both groups was a septate uterus (partial septate and complete septate), and although it was not found to be statistically significant it was more prevalent in the infertility group.

## DISCUSSION

Saline infusion sonohysterography is an easy, safe, and well tolerated alternative to diagnostic hysteroscopy. Because it is adjunctive to TVS, it offers the exclusive advantage of a comprehensive imaging of the uterus and the adnexa in one setting. In addition, it was shown to enhance endometrial visualization and to improve detection of intrauterine pathologies and uterine anomalies (5–7). In a recent meta-analysis including 2,278 procedures, the diagnostic accuracy of SIS was found to equal that of diagnostic hysteroscopy in the evaluation of AUB, reporting sensitivity and specificity of 95% and 88%, respectively (8). Similar results on the diagnostic accuracy of SIS were reproduced in studies with small numbers of infertile patients (5, 11, 12). Therefore, we aimed in the present study to evaluate the yield of uterine screening by SIS as part of the routine work-up of infertility in a large cohort of patients.

Our study reports the largest group of patients with infertility examined by SIS. Out of 600 infertile women, 16.2% revealed intracavitary abnormalities, including polyps, submucous fibroids, and adhesions. These results are in agreement with other small series where SIS was part of the infertility investigation. In a series of 72 infertile women that underwent SIS for uterine screening before proceeding to IVF, Kim et al. (12) found 11.1% of patients with intracavitary findings, including mainly polyps. Lindheim and Sauer (13) performed SIS in 50 women awaiting donated oocytes and found 38% of patients with uterine pathologies, including polyps, submucous fibroids, adhesions, and bicornuate uterus. Another study, involving high-risk patients for uterine abnormalities, performing SIS in 54 women with infertility, repeated abortions, or suspected uterine findings, found 18.5% of patients with uterine polyps and fibroids and 48.1% with uterine malformations (11). A recent study found that 32.6% of 98 infertile women screened by SIS demonstrated endometrial polyps and submucous myoma (7).

For comparison reasons we included in the study a cohort of 409 consecutive women that were referred to SIS for the investigation of AUB at the same period of time. As expected in this group, significantly more patients (39.6%) revealed abnormal intracavitary findings including polyps and fibroids. Our results are in accordance with other studies (6, 14) where polyps and myomata were the most prevalent findings among patients with AUB. Moreover, as in our symptomatic patients, others reported high prevalence of SIS-detected intracavitary abnormalities among AUB patients. In a meta-analysis, de Kroon et al. (8) reported 56% with abnormal intracavitary findings among a pooled of 877 patients; Bernard et al. (6) found 74.6% with intracavitary abnormalities among 233 patients; and, of 452 symptomatic women Dueholm et al. (14) reported 37% with intracavitary abnormalities.

Endometrial polyps were the main intracavitary lesions among the infertile patients. There are increasing data to support polypectomy before infertility treatment. In an effort to study whether polypectomy affects pregnancy rates, Demiroglu and Gurgan (15) prospectively randomized 421 IVF patients and concluded that polypectomy was effective and the pregnancy rate increased to the levels comparable with the control group. In another study of 215 infertile patients, polypectomy before intrauterine insemination increased by 2.1-fold the chance of becoming pregnant (16). In a recent small study, 3 out of the 6 IVF patients that underwent polypectomy just before oocyte retrieval conceived (17). Polypectomy was shown to restore reproduction independently of the size of the removed polyps (smaller or larger than 2.5 cm) (18).

Submucous fibroids were the second most frequent intracavitary lesion found in the infertility group. Several studies have suggested that submucous myomata may reduce the efficacy of assisted reproductive treatments (19). Large my-

omata that distort the cavity have a negative impact on fertility. Indeed, higher pregnancy rates were rendered following myomectomy compared with the untreated controls. In this context, the effect of cavity distortion from submucous myomata and polyps on implantation is readily imagined. However, the effect on infertility when intramural myomata do not involve the uterine cavity is controversial. A recent review of Benecke et al. (20) evaluated this issue and concluded that intramural myomata with no cavity distortion had a negative impact on implantation rate (odds ratio 0.62) versus the control group without myomata. However, a larger meta-analysis found a relative risk for pregnancy of only 0.94 in IVF patients with intramural myomata compared with patients without fibroids, thus attenuating the indication for removal of intramural myomata in case of infertility (21). When there is doubt regarding involvement of the uterine lumen by an intramural myoma, SIS, which is a TVS-based technique, can visualize with high specificity both the myometrium and the endometrium and assist in the decision regarding optimal management.

Twenty percent of our infertile patients revealed uterine anomalies. This was significantly more prevalent than in the AUB group (9.5%). These results can be compared with the prevalence of uterine malformations (1%–26%) reported in various studies on infertile patients (22). This wide range of prevalence is attributed to limiting factors as differences between studied populations, methods of diagnosis, classification systems, and omission of asymptomatic cases.

Arcuate uterus was the most prevalent anomaly in our infertility group (15.0% of patients, 75% of anomalies), followed by septate uterus (4.3% of patients, 23.3% of anomalies for partial septate and complete septate). Although the prevalence for septate uterus reported in two reviews of the literature, 22% (23) and 34.9% (22), corroborate our findings, those reported for the arcuate uterus, 15% (23) and 18.3% (22), are lower than ours. It is possible that in those series the diagnostic criteria delineated mild forms of arcuate uterus as a variant of the normal findings.

The relevance of arcuate uterus to infertility is undetermined. While it is usually interpreted not to affect women's fertility, in a recent comprehensive review Grimbizis et al. (22) concluded that the reproductive performances of patients with arcuate uterus is impaired although it is better than that of patients with other types of uterine malformations. They reviewed three studies with 102 patients with untreated arcuate uterus and 241 pregnancies. The mean rates of abortion, ectopic pregnancy, term delivery, and live birth were 25.8%, 2.9%, 62.7%, and 66.0%, respectively (22). Our finding of 15% of infertile patients with arcuate uterus justifies further investigation in the role of such uterine anomaly in infertility and pregnancy outcome. Closer monitoring of these patients throughout infertility treatment and pregnancy follow-up should be implemented. The recent use of 3D sonography for diagnosis of uterine anomalies may shed new light on the prevalence of arcuate uterus

among a nonselected group of infertile patients (24, 25), and a comparison between three-dimensional ultrasound and SIS is needed.

The uterine cavity is virtual for 2D TVS. However, with the adjunct of SIS, both the uterine cavity and the myometrium are visualized by a single technique. Whereas patients evaluated by SIS are not exposed to irradiation as with HSG, several studies have shown additional advantages of SIS over TVS and HSG, the two commonly used techniques for uterine assessment. In a study of 65 infertile women, Soares et al. (5) compared diagnostic accuracies of SIS, HSG, and TVS for uterine cavity diseases with that of hysteroscopy as the gold standard. Saline infusion sonohysterography had the same diagnostic accuracy as the hysteroscopy for polypoid lesions and endometrial hyperplasia, whereas TVS's sensitivities were 75% for both lesions and those of HSG were only 50% and 0%, respectively. Only for intrauterine adhesions, SIS and HSG had similar sensitivities of 75% whereas that of TVS was 0%. The authors concluded that SIS was better than HSG and TVS.

In another comparative study of SIS versus TVS with hysteroscopy in 98 infertile patients by Ragni et al. (7), SIS yielded higher diagnostic accuracies than TVS for intrauterine pathology. Compared with hysteroscopy, the sensitivity and specificity of SIS were 98% and 94%, respectively, whereas those of TVS were 91% and 83%, respectively. In a prospective randomized trial, Brown et al. (26) compared the diagnostic accuracy, pain scores, and procedure length of outpatient hysteroscopy, HSG, and SIS for the evaluation of the uterine cavity. They concluded that hysteroscopy, SIS, and HSG were statistically equivalent regarding evaluation of uterine cavity pathology in infertile women. However, the average pain score (scale of 0–10) was significantly lower for SIS (2.7 for SIS vs. 5.8 for HSG and 5.3 for hysteroscopy).

Saline infusion sonohysterography has been demonstrated to be superior to TVS and/or HSG also for the diagnosis of uterine malformations. Soares et al. (5) found that SIS had a higher sensitivity (77.8%) compared with TVS and HSG (44.4%). Alborzi et al. (27) showed in a study of 20 patients with history of recurrent pregnancy loss and an HSG diagnosis of septate/bicornuate uterus that SIS was better than HSG for differentiating a septate from bicornuate uterus. The authors suggested that SIS might eliminate the need for laparoscopy to diagnose these uterine anomalies. In a recent study of 54 patients with infertility/repeated abortions, Valenzano et al. (11) assessed the diagnostic value of SIS, TVS, and HSG for the detection of uterine anomalies that were confirmed later by hysteroscopy/laparoscopy. Saline infusion sonohysterography was found to be more sensitive than TVS and HSG (100% vs. 77.8% and 55.6%, respectively, for bicornuate uteri, 100% vs. 66.7% and 33.3% for septate uteri). Their conclusion was that SIS, compared with TVS and HSG, provides an accurate and complete assessment of uterine anatomy (11).

In conclusion, SIS diagnosed uterine abnormalities in a substantial percentage of patients with infertility and AUB. Because this technique is safe, low-cost, well tolerated, and feasible in most of outpatient infertility clinics, SIS should be routinely performed in the early stage of infertility investigation.

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