Saline contrast hysterosonography in infertile patients and in women with abnormal uterine bleeding

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Summary

Objective: We conducted this prospective study to evaluate saline contrast hysterosonography (SCHS) as a diagnostic modality for intrauterine lesions in comparison to hysteroscopy and endometrial biopsy.

Materials and Methods: We included 135 patients, of whom 70 presented with abnormal uterine bleeding and 65 with subfertility problems. All cases were examined with conventional transvaginal sonography and were further investigated with SCHS using saline as contrast medium, and finally hysteroscopy with endometrial biopsy that was used as the reference test.

Results: SCHS revealed the presence of intrauterine pathology in 23 cases and failed in three (4.2%). SCHS had a sensitivity of 94%, a specificity of 71%, a positive predictive value of 76% and a negative predictive value of 95% in the abnormal uterine group. In subfertile patients, SCHS revealed the presence of intrauterine pathology in 34 cases and had a sensitivity of 96%, a specificity of 74%, a positive predictive value of 79% and a negative predictive value of 95%.

Conclusions: We found that SCHS is an extremely accurate modality for the diagnosis of focal endometrial pathology, compared to diagnostic hysteroscopy .

Key words: Saline hysterosonography; Hydrohysterosonography; Hysteroscopy; Transvaginal sonography; Abnormal uterine bleeding.

Introduction

Saline contrast hysterosonography (SCHS) is a diagnostic procedure that enhances endometrial imaging by using saline as contrast medium. It has been used in conjunction with traditional transvaginal sonography (TVS) to aid the diagnosis of uterine and endometrial abnormalities, including abnormal uterine bleeding, infertility, recurrent abortion, suspected Asherman's syndrome and patients receiving tamoxifen therapy [1].

Diagnostic hysteroscopy combined with endometrial biopsy is considered the gold standard in the evaluation of the uterine cavity [2-4]. However, diagnostic hysteroscopy is invasive and expensive [5-7].

Several authors report equal diagnostic accuracy in uterine cavity evaluation of SCHS compared with diagnostic hysteroscopy [8-10]. Most of these studies were performed for the evaluation of abnormal uterine bleeding.

The aim of this prospective study was to evaluate SCHS as a diagnostic procedure in two groups of women. The first group consisted of subfertile young women and the second group consisted of women with abnormal uterine bleeding.

Materials and Methods

This study was performed by means of a prospective investigation between January 1, 2001 and September 30, 2003 and 135 women were included in our protocol. Of these, 70 were referred for the investigation of abnormal uterine bleeding (menorhaggia, menometrorragia, intermenstrual or postmenopausal bleeding), whereas the remaining 65 were investigated for subfertility (at least one year of fruitless efforts for conception). All patients underwent a detailed abdominal and pelvic bimanual examination and a Papanicolaou smear was obtained. During this initial visit premenopausal patients were scheduled to have a transvaginal ultrasound examination if possible between the 7th and 10th day of their next cycle. Obviously, this was not realistic in patients with a history of abnormal uterine bleeding and the examination was performed at any convenient time for both the patient and the department.

Both, conventional TVS and SCHS examinations were performed by the same examiner using the Aloka type 650 equipped with a 5-7.5 MHz transvaginal probe. The ultrosonographer was blinded to the results of previous diagnostic tests, such as hysterosalpingography. Hysteroscopy was performed at a later date by an experienced gynecological endoscopist who was blinded to the results of the previous ultrasonographic assessment. No medical preparation of the endometrium had been prescribed in any of our patients prior to any of these diagnostic procedures.

A diagnostic Hamou type hysteroscope and a Storz resectoscope with an Erbatom 1CC350 generator were used.

For diagnostic hysteroscopy we used sedatives. An endometrial biopsy was obtained from all patients during diagnostic hysteroscopy. From those patients who required subsequent surgical treatment, pathology results were collected on available specimens.

Sensitivity, specificity, positive and negative predictive value of SCHS were calculated with hysteroscopic findings plus the pathology results as the gold standard.

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Technique of saline contrast hysterosonography

After disinfection of the vagina and endocervix, a sterile H/S ELIPTOSFHERE catheter (Ackrad Laboratories) is inserted into the cervical canal. This catheter is equipped with two channels: one that ends in a balloon distensible up to 1.5 ml which, after insertion in the uterine cavity, is filled with air to obliterate the cervical canal and another for the injection of saline into the uterine cavity. Depending on the size of the uterus, the amount of saline necessary to adequately distend the uterine cavity ranges from 5-15 ml. We prefer to wait 1-3 minutes for distention of the cavity to occur in order to both improve tolerability of the procedure by the patient and increase image quality. After distention of the cavity, both layers of the endometrium are measured on each side of the saline interface and the contours are inspected for irregularities, polypoid tumors, synechiae and images of projecting structures under the endometrial surface such as myomas.

No pre- or post-examination was needed except for the use of Buscopan suppositories.

Results

Of the 70 patients who presented with abnormal uterine bleeding, 58 were premenopausal and the remaining 12 postmenopausal. Characteristics of these and the other 65 subfertility cases with final diagnoses are presented in Table 1. SCHS was well tolerated by the majority of patients. There was no need for local anesthesia and only the use of a spasmolytic agent was necessary in some cases. Only in three cases was the procedure abandoned and only hysteroscopy was performed.

Table 1. — *Diagnostic potential of SCHS compared with hysteroscopy plus endometrial biopsy.*

		Abnormal uterine bleeding		Subfertility	
		N	%	N	%
1	Normal uterus	35	50	31	47
2	Benign endometrial polyps	12	17.4	5	7.6
3	Myomas	2	28	5	7.6
4	Endometrial hyperplasia	7	10	1	1.5
5	Adenomyosis	2	28	2	3
6	Synechiae	–		19	29
7	Diaphragms	–		2	3
	Sensitivity	0.94		0.96	
	Specificity	0.71		0.74	
	PPV	0.76		0.79	
	NPV	0.95		0.95	

Office hysteroscopy was attempted in all cases and sedation was used. No case of interruption of the procedure was noted.

Overall SCHS was suggestive of a normal uterine cavity in 66 (48%) patients. Of these, 31 were subfertility cases and 35 reported abnormal uterine bleeding. SCHS revealed the presence of polyps in 17 cases, synechiae in 19, a uterine diaphragm in two and submucous myomas in seven cases, respectively. In eight cases endometrial hyperplasia was suspected from the abnormal thickness and sonographic appearance of the endometrium. Additionally, the sonographic characteristics of the uterine wall were suggestive of adenomyosis in a further four cases.

Hysteroscopy performed either subsequently or at a later date to the ultrasonographic examination, confirmed the presence of all focal lesions suggested by SCHS, i.e polyps, synechiae, diaphragms and myomas. On the contrary, in all cases with an adenomyotic appearance of the uterine wall, hysteroscopic appearances of the uterine cavity were normal. At hysteroscopy, endometrial hyperplasia was suspected in all eight cases where such diagnosis was suggested by SCHS. Confirmation after endometrial biopsy and histological examination of the specimen was obtained in all of the cases. Hysteroscopy upgraded their severity identifying more extensive peripheral adhesions when compared to what was suggested by SCHS. We had six cases with false positive results and three cases with false-negative results (Table 2).

Table 2. — *SCHS versus diagnostic hyperoscopy plus endometrial biopsy.*

False-positive case results	Diagnostic with SCHS	Diagnostic hysteroscopy plus endometrial biopsy
1	Polyps and hyperplasia	Polyps
2	Polyps	Blood clot
3	Hyperplasia	Normal
4	Polyps	Normal
5	Hyperplasia and polyps	Hyperplasia
6	Hyperplasia	Normal proliferative
False-negative		
1	Normal	Hyperplasia
1	Myoma	Myoma and polyps

When compared to SCHS, conventional TVS failed to identify polyps in two (16.7%) and synechiae in nine (52.6%) cases, respectively. It had the same accuracy in the diagnosis of myomas, diaphragms, endometrial hyperplasia and adenomyosis (Table 2).

Discussion

Our study is the first, to the best of our knowledge, to address the accuracy of SCHS in evaluation of the endometrial cavity in subfertile patients and in women with abnormal uterine bleeding. There was a statistically significant difference in the mean age between the two groups: 34.6 + 4.8 and 47.5 + 5.1, respectively ($p < 0.001$).

In both groups, about 50% of the final diagnosis from hysteroscopy and biopsy was normal uterus.

In the subfertile group, synechiae was the most common diagnosis (29%) and was statistically significant compared to the abnormal uterine group.

In our study, we found in the abnormal uterine group a sensitivity of 94%, a specificity of 71%, a positive predective value (PPV) of 76% and a negative predictive value (NPV) of 95%, while in the subfertile group a sensitivity of 96%, a specificity of 74%, a PPV of 79% and a NPV of 95%.

The reason for lower sensitivity and specificity in the group with abnormal uterine bleeding is unclear, but may be explained in part by the difficulty in differentiating anatomic abnormalities from intrauterine irregularities.

Several studies in the literature have shown equal diagnostic accuracy for diagnostic hysteroscopy and SCHS [11-15].

SCHS was very effective for evaluating uterine myomas.

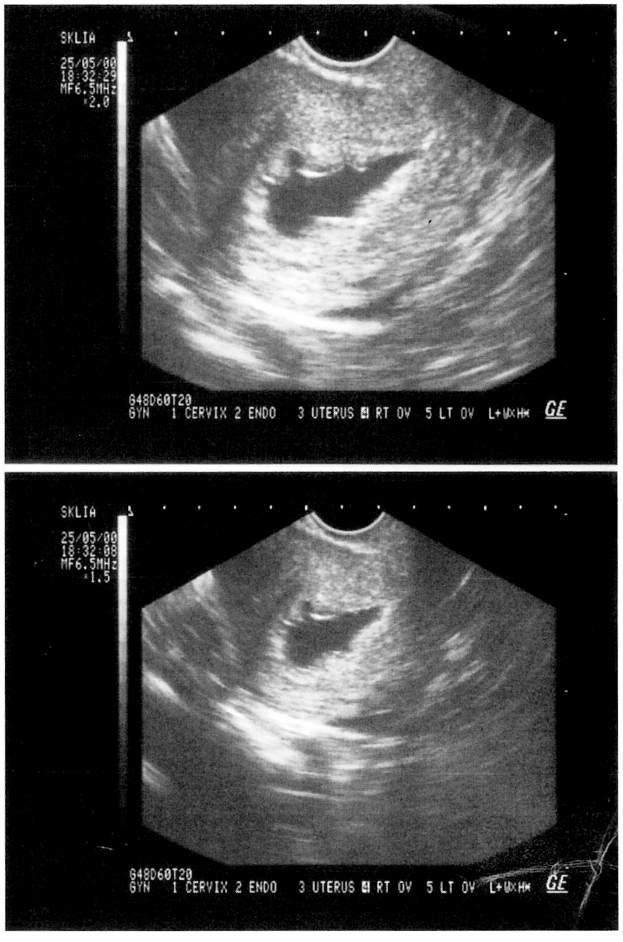

Figure 1. — Endometrial polyp in anterior wall.

SCHS has the capacity to "to look into" the uterine wall and determine the intramural component of submucous myomas and locate other intramural myomas. SCHS was also very effective in describing the adenomyotic appearance.

In our study, hyperplasia and synechiae were diagnosed successfully from SCHS in 99 % and 100%, respectively.

Moreover, SCHS was satisfactory for detecting polyps (Figure 1). In this pathology we had some false-positive findings. Clots that have formed in the endometrial cavity of a woman with recent bleeding can have the appearance of a polyp. Also distinguishing between large polyps and pedunculated myomas was difficult with both SCHS and hysteroscopy.

In a recent study, Cornelis *et al.* have demonstrated that SCHS was able to replace 84% of outpatient diagnostic hysteroscopies for uterine cavity evaluation in women suspected of having intrauterine abnormalities. Our results are in agreement with their study.

The number of failed SCHS in our study (2.2%) is less than the failure rate reported in 4.6-7%. The failure rate was 0% for the infertile group and 4.2% in the abnormal uterine bleeding group.

SCHS is a very good tool in the preoperative management of intrauterine and intramural pathology and gives us the opportunity for a better hysteroscopic intervention that can be performed in an examination room without sedation.

In order to make the goal of every surgical intervention real, that is "the pathology must be accurate before treatment", we considered that if there was a non-invasive diagnostic method with excellent sensitivity and specificity, it could be possible to perform only operative hysteroscopies and to restrict diagnostic hysteroscopy only for questionable cases.

Conclusions

We conclude that SCHS is a non-invasive method without complications and can be proposed as an alternative to diagnostic hysteroscopy.

It can provide information about the uterus and intrauterine lesions, allowing the surgeon to choose the most appropriate surgical option.

This prospective study demonstrates a very good correlation with hysteroscopy and a better visualization of the underlying endometrium and myometrium.

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