# Comparison of transvaginal 3D sonohysterography with outpatient hysteroscopy in the evaluation of abnormal uterine bleeding

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**Summary**

*Objective:* To compare transvaginal three-dimensional sonohysterography (3D SHSG) and outpatient hysteroscopy with regards to diagnostic accuracy, procedure time, and patient discomfort with a prospective randomized controlled cohort study in a teaching hospital in London. The study included a population group of 49 women with abnormal uterine bleeding from varied ethnic backgrounds, of which 44 completed the study. Subjects with pregnancies, pelvic infections, large uteruses, suspicious or diagnosed pelvic malignancies, and who did not meet the criteria for day surgery, were excluded. *Materials and Methods:* Patients were randomized into two groups: group 1 had hysteroscopy followed by SHSG while group 2 had SHSG followed by hysteroscopy. Diagnostic accuracy, procedure time, and patient discomfort of SHSG in comparison to hysteroscopy were studied. *Results:* A total of 44 patients completed the study. The average age of the study population was 44.8 years and the mean parity was 1.8. Nulliparas represented 34.03% of the study population and the average duration of symptoms was 14.8 months. *Conclusion:* In the investigation of women with abnormal bleeding in an outpatient setting, both hysteroscopy and SHSG are comparable in the diagnosis of intracavity lesions, pain rating, and procedure time. However patient acceptability of SHSG was significantly more when compared to outpatient hysteroscopy.

*Key words:* Sonohysterography; Hysteroscopy; Evaluation of uterine cavity; Abnormal uterine bleeding; Outpatient approach.

## Introduction

Abnormal uterine bleeding represents 33% [1] of all gynaecological outpatient referrals and this could rise to as much as 69% in the peri- and post-menopausal group [1, 2]. Causes vary from hormonal imbalance, pregnancy-related problems, to focal causes such as fibroids, endometrial and cervical polyps, and endometrial and cervical cancers. Hysteroscopy combined with endometrial biopsy has almost replaced dilatation and curettage for the investigation of this symptom. Though most hysteroscopies are performed under general anaesthetic, there is enough evidence to suggest it is a well-tolerated and acceptable outpatient procedure [3-5].

Transvaginal sonography (TVS), one of the tools in the evaluation of abnormal bleeding, does not always distinguish between certain sonolucent alterations of the endometrium, such as polyps and hyperplasias, or between proliferative phenomena that result from exogenous hormonal therapy. However, when sonographic evaluation follows uterine cavity distension as in sonohysterography (SHSG), the resolution is greatly enhanced, resulting in an impressive increase in diagnostic sensitivity for polyps, myomas, hyperplasias, and foreign bodies [6-10]. SHSG is now more frequently being used in the evaluation of women with gynaecologic conditions since Diechert first reported that TVS detection of uterine lesions could be enhanced by the simultaneous infusion of saline [6]. Three-dimensional (3D) ultrasound is a relatively new investigative technique and offers several advantages over two-dimensional (2D) scanning. Various imaging modes are available and three perpendicular planes displayed simultaneously can be rotated and translated in order to obtain accurate sections and suitable views needed for diagnosis and geometric measurements. SHSG performed with 3D ultrasound could have even more advantages compared to those with conventional 2D ultrasound. It could give more accurate information regarding the location of abnormalities, and using the multiplanar views, polypoid structures can be clearly visualised allowing for the optimal plane to present the pedicle. The surface-rendering mode can also suppress undesirable echoes allowing polypoid structures to be seen in continuity with the endometrial lining. Another advantage is that it allows documentation and storage of volume information of pelvic organs for later review and analysis [11]. This cuts down on the procedure time, enhances patient acceptability, and proves invaluable when planning further treatment for the patient. The aim of this study was to compare transvaginal 3D SHSG and outpatient hysteroscopy with regards to diagnostic accuracy, procedure time, and patient discomfort.

## Materials and Methods

This study was undertaken following approval by the local ethics committee. Both procedures were performed by two

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groups of experienced investigators who were blinded to the results of the other. Patients were recruited from general gynaecology clinics and the one-stop menstrual problem clinic. Consent was obtained following recruitment and to obviate any form of selection bias, patients were randomized to have either hysteroscopy or SHSG first. Sealed opaque envelopes that were numbered were opened on recruitment and patients were assigned to one of two groups: group 1 hysteroscopy followed by sonography; group 2 sonography followed by hysteroscopy. Hysteroscopy was considered the gold standard for uterine cavity evaluation and diagnosis of pathology. All women with abnormal uterine bleeding requiring investigation were included. Those with undiagnosed pregnancies, untreated pelvic infections, suspicious or diagnosed pelvic malignancies, uterine size exceeding 14 weeks, cyeisis, and with medical conditions requiring inpatient hysteroscopy, were excluded. 3D SHSG was performed (GM,CK,DE) in the Early Pregnancy Unit using a Voluson E8 ultrasound (General Electric) equipped with a multifrequency vaginal transducer (5 and 7.5 MHz). SHSG was scheduled for the proliferative phase of the menstrual cycle to exclude any false positive findings. After cleansing of the vulva and vagina, a Cusco's speculum was inserted to visualize the cervix. The cervix was then cleansed and a paediatric Foley's catheter (8-10F) was threaded through it into the uterine cavity. The balloon of the catheter was inflated with 0.5 - 1 ml of sterile saline to prevent it from being dislodged. The speculum was then removed to allow the transvaginal probe to be inserted. Five to 20 ml of sterile saline was then instilled via the catheter into the uterine cavity, while SHSG was performed in both the 2D and 3D modes. Initially the scan was performed in the longitudinal axis and the transducer moved from side to side to ensure a thorough evaluation of the uterus from one ostium to the other. Unlike diagnostic hysteroscopy, total distension of the cavity was not required and even a thin stripe of fluid allowed adequate evaluation of the cavity. The transducer was then rotated through 90° in the coronal plane and moved from above downwards to enable visualization of the uterus from the fundus down to the endocervical canal. Two-dimensional frontal, sagittal, and coronal views of the endometrial cavity and uterus were obtained separately. Simultaneous studies of the three planes were stored after obtaining sections parallel to the transducer. Following analysis of the stored 2D images of the distended endometrium, 3D ultrasound images were generated. This was possible by the ultrasound's computer software integration of the three endometrial planes. The images were then recorded in the computer system for subsequent retrieval and additional processing. Diagnosis was based on the criteria laid down by Parson and Lense [12]. Hysteroscopy was performed (SR,CK,ALM) in the hysteroscopy suite using a 2.7 mm rigid scope with a 30° fore oblique lens (Hamou 1; Karl Storz, Tuttlingen, Germany) and an examination sheath of 3 mm. Normal saline was the distension media. The scope was introduced through the vagina into the cervix without inserting a speculum. As the normal saline distended the vagina and the os came into view, the scope was introduced through the cervical canal into the cavity. All procedures were monitored using a video camera and monitor. However, when cervical stenosis and or pain halted the procedure, dilatation of the cervix with or without local anaesthetic infiltration, was carried out. Cervical dilatation to 5 mm diameter was accomplished with the use of graduated Hegar dilators. Local anaethetic infiltration was carried out using a total of ten mls of Citanest 3% with Octapressin® (3% Prilocaine Hydrochloride 30 mg/ml, Felypressin 0.03 unit/ml, Astra Zeneca) given via a dental syringe. Intracervical injection of this anaesthetic was given at 2, 5, 7, and 11 o'clock positions. A study was judged adequate only when the entire uterine cavity and both tubal ostiae were visualised. An endometrial biopsy using a pipelle endometrial sampler (Laboratoire CCD, Paris) was carried out only when deemed necessary. No premedication was given to the patients before either of the procedures. After each procedure, the patients were asked by an independent examiner to score the pain rating on a visual analogue scale between 0 (none) to 10 (most). Patients were also asked to report any complication or any further discomfort encountered. Time of procedure for the hysteroscopy was defined as starting from initial placement of hysteroscope into the vagina and ending with removal of all equipment; for SHSG, it was time the lapse initiated with speculum placement and ending with simultaneous removal of ultrasound transducer and Foley's catheter. This was a prospective cohort study which aimed to recruit at least 40 patients (20 in each arm) to give the study a statistical power of 80%.

## Results

A total of 49 patients consented to the study of which only 44 completed it: two dropped out after the hysteroscopy due to pain, two had stenosed cervix, and therefore were put on the day surgery hysteroscopy waiting list, and one had a multifibroid uterus, and thus failed the SHSG. The two main reasons for failure in either procedure were stenosed cervix and pain.

The average age of the subject population was 44.8 years with the age range between 26 - 63 years. The young patient was investigated only because she had persistent irregular bleeding per vaginum despite hormonal modulation. The mean parity was 1.8 with nulliparas comprising 34.03% of the study population. The average duration of the symptoms was 14.8 months. The indications for referral to the unit are set out in Table 1 with menorrhagia being the most common.

### *Hysteroscopy*

Out of the 44 cases, two failed (4.54%) having an outpatient hysteroscopy and were put on the inpatient list. The technique of performing hysteroscopy without the perfunctory insertion of speculum was successful in 30 out of the 44 (68.18%) patients. Fourteen patients required some form of assistance prior to the outpatient hysteroscopy either in the form of some local anesthetic, dilatation, or both. Of these, 12 required dilatation with local anesthetic, one required only dilatation, and one local anesthetic without dilatation. It was also interesting to note that seven out of these 14 (50%) were nulliparas and seven (50%) had previous cervical surgery. Therefore neither of these factors i.e parity or previous surgery, were significant factors in influencing a successful hysteroscopy without the use of a speculum.

### *3D SHSG*

As mentioned earlier, one (2.27%) case failed the SHSG and therefore was excluded from the study. It was observed that 3D scanning provided much better views of the cavity in comparison to 2D in 20 out of 44 (45.45%) cases. These were cases that had fibroids in them and in

Table 1. — *Indications for referral to the unit*.

| Indications | No. of cases (n = 44) |
|---|---|
| Menorrhagia | 23 (52.03%) |
| Post-menopausal bleeding | 6 (13.64%) |
| Metrorrhagia | 6 (13.64%) |
| Menorrhagia and metrorrhagia | 5 (11.31%) |
| Fibroids with acyclical bleeds | 2 (4.55%) |
| Endocervical polyp | 1 (2.27%) |
| Subfertility | 1 (2.27%) |

Table 2. — *Diagnostic potential of sonohysterography as compared to hysteroscopy*.

| | | Hysteroscopy | | | | |
|---|---|---|---|---|---|---|
| | | Polup | Fibroid | Abnormal endometrium | Others | Total |
| Sonohysterography | Polyp | 8 | – | – | – | 8 |
| | Fibroid | – | 14 | 0 | 0 | 14 |
| | Abnormal endometrium | 0 | 0 | 3 | 0 | 3 |
| | Others | 3 | 1 | 0 | 15 | 19 |
| | Total | 11 | 15 | 3 | 15 | 44 |

one where the uterus was studded with multiple fibroids, 2D was unable to produce a satisfactory picture. In one case, unsatisfactory views were obtained with both 3D and 2D scans as the uterus was enlarged with multiple intramural fibroids.

*Comparison of hysteroscopy and 3D SHSG diagnosis*

As mentioned, hysteroscopy was considered the gold standard in investigating abnormal uterine bleeding. Intracavity lesions were noted in 26 out of 44 (59%) women presenting with abnormal uterine bleeding. The diagnostic potential of SHSG as compared to hysteroscopy is set out in Table 2.

3D SHSG missed three uterine polyps that were detected by hysteroscopy. In all these cases, the uterus was enlarged with intramural and subserous fibroids. In one of these, an unsatisfactory view of the cavity was obtained in both 3D and 2D scans. One case of submucous fibroid was missed. Hysteroscopy noted the projection of the fibroid in the cavity by less than 20% with most of it being in the myometrium. None of the cases of abnormal endometrium was missed. The sensitivity of SHSG in diagnosing polyps was 72%, fibroids 93.3%, and abnormal endometrium 100%, in comparison to hysteroscopy. The specificity in all three categories was 100%.

*Pain ratings*

The visual analogue score for pain at hysteroscopy ranged between 0 and 10. The mean score was 2.81 with a standard deviation of 2.65 and 95% CI between 2 and 3.6. The pain score for SHSG ranged between 0 and 9.2 with a standard deviation of 2.63 and 95% CI between 1.8 and 3.4. On using the Wilcoxon signed rank test for matched pairs of data to compare the pain scores between the two procedures, the $p$ value = 0.55.

*Duration of procedure*

Time taken to perform hysteroscopy varied between one and 13 minutes with a mean of six minutes (standard deviation ± 2.86 with a 95% CI between 5.119 and 6.881). Time taken to perform SHSG varied between 10 and 30 minutes. The mean was 17.29 with a standard deviation of 4.43 and 95% CI between 15.76 and 18.81. On using the Wilcoxon signed rank test to compare the duration between the two procedures, the $p$ value was ≤ 0.001.

*Patient satisfaction*

This was an important outcome measure in this study. Thirty out of 44 (68.18%) cases felt they would prefer SHSG if given the choice again. In contrast, only seven out of the 44 (15.91%) cases would choose hysteroscopy again. Three of the cases (6.82%) had no specific preference and three cases (6.82%) did not respond to the question. These results show that despite pain being comparable in both the procedures, there was a marked preference for SHSG.

## Discussion

Abnormal uterine bleeding generates a diagnostic challenge for the gynaecologist and the ideal diagnostic tool would be an accurate, safe, and easily performed procedure in an office setting. The authors detected a prevalence rate for intracavity lesion of 59% in women with abnormal uterine bleeding. This is similar to the findings of other investigators [6, 10-15]. The present study though small and involving only 44 patients, shows that SHSG is comparable to office hysteroscopy in terms of diagnosis and ease of performance. These findings are similar to those of Gumus II. *et al*. [9], Widrich T. *et al*. [13] and other researchers, who compared SHSG and office hysteroscopy in premenopausal women and found nearly identical sensitivity and specificity. Saidi *et al*. [14] however found SHSG to have higher sensitivity and specificity than hysteroscopy. The authors scheduled the SHSG in the proliferative phase of the cycle in menstruating women to avoid false positive results. However it has been reported that SHSG findings are independent of cyclic endometrial changes [12]. The authors noted that the use of 3D-SHSG allowed a better definition and characterization of focal endometrial thickenings and myometrial extensions of submucous fibroids. This property proved useful in mapping fibroids prior to resection and needs to be addressed in a proper randomized trial. A similar study comparing 2D and 3D SHSG in the evaluation of uterine lesions found the latter to be more effective with 100% specificity [16]. The above results show that the SHSG took a much longer time than hysteroscopy with the average time being roughly 17.29 ± 4.43 min. However it is important to point out that this is actually the total duration of procedure time which commences with insertion of the speculum, insertion of the catheter, and transvaginal scanning along with 2D and 3D SHSG.

If 3D SHSG were to be looked at in isolation, the average time from insertion of catheter to completion of procedure was < 5 min which was comparable to that recorded by others [13]. It was surprising to note that pain ratings were comparable for both procedures. This was contrary to that found by other investigators [13] and the present authors believe that the technique used i.e. not inserting a speculum prior to performing the hysteroscopy, is probably responsible for the low pain scores. Unfortunately the comparable pain ratings were not reflected in patient acceptability. Hysteroscopy was considered more invasive and to some extent more of an "operative procedure" than SHSG. This is an issue that needs to be addressed in a larger study. The authors also noted that parity, previous cervical surgery, and post-menopausal status did not significantly influence success at outpatient hysteroscopy.

In summary, this study compares two procedures that are useful in investigating women with abnormal bleeding in an outpatient setting. Both are comparable in the diagnosis of intracavitary lesions, pain rating, and procedure time. This brings to light an important point i.e. in units which lack an outpatient hysteroscopy set up, performing a SHSG in cases where a conventional scan is unable to offer a diagnosis or where an abnormality is suspected, could prove to be just as useful. Besides, to set up a SHSG service, there is no need of a theatre setting with additional theatre staff and therefore could prove to be cost-effective. While the present study, because of its size, could not conclusively prove the advantages of choosing a 3D ultrasound machine over a 2D one, it was clear that in the presence of abnormalities, such as fibroids, the cavity was much easily visualized with the 3D machine. The development of SHSG is a significant advance in gynaecologic investigation and there is a case for incorporating it in gynaecologic scanning services. Therefore in terms of patient acceptability, post-operative complications, visualizing the adnexae, and determining myometrial extension, SHSG scores over hysteroscopy.

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