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ORIGINAL ARTICLE

Transvaginal saline hysterosonography: a comparison with local anaesthetic hysteroscopy for the diagnosis of benign lesions associated with menorrhagia

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Abstract The objective of this paper is to assess the diagnostic accuracy of transvaginal saline hysterosonography (TVHSg) compared to hysteroscopy in the identification of benign lesions affecting the endometrium in women with menorrhagia. A cross-sectional study was reported according to the Standards for Reporting of Diagnostic Accuracy (STARD) guidelines. These standards were introduced by an international steering committee in order to improve the reporting of diagnostic accuracy studies. The study was carried out at a one-stop menorrhagia clinic at a central teaching hospital in Newcastle Upon Tyne, UK. One hundred and forty patients were referred to the menorrhagia clinic. After clarification of their history, TVHSg was performed on each patient and the findings were recorded on a proforma. The patients then underwent hysteroscopy using local anaesthetic and a Pipelle endometrial biopsy was performed. Each operator was blinded to the findings of the preceding investigation until both proformas had been completed. The diagnostic accuracy of TVHSg was compared to hysteroscopy in the diagnosis of benign intrauterine lesions. TVHSg has a sensitivity of 0.88, a specificity of 0.99, a positive predictive value of 0.96, a negative predictive value of 0.97 and a positive likelihood ratio of 99 in the detection of endometrial polyps. For the detection of submucous fibroids, the sensitivity is 0.86, the specificity is 0.98, the positive predictive value is 0.90, the negative predictive value is 0.97 and the positive likelihood ratio is 49. We conclude that TVHSg has high diagnostic accuracy for the detection of intracavitary lesions in patients with menorrhagia when compared to out-patient hysteroscopy.

Keywords Menorrhagia · Transvaginal saline hysterosonography · Out-patient hysteroscopy · Diagnostic accuracy

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Introduction

Menorrhagia, defined as regular heavy menses over several consecutive cycles, is a symptom that affects about 1 in 5 women. Five percent of women consult their GP each year with menorrhagia and as many as 1 in 10 women have a hysterectomy for menorrhagia by the age of 60 [1]. In 75% of women over the age of 35, there is no identifiable cause and the diagnosis of dysfunctional uterine bleeding (DUB) is made. In 25% of women, there are benign lesions, including endometrial polyps and fibroids that cause menorrhagia. Endometrial cancer is rare and is more commonly associated with irregular or post-menopausal bleeding.

In the UK, the first-line management of menorrhagia in the absence of obvious pelvic pathology on examination is medical and is usually undertaken in primary care. Women with uterine enlargement or failed medical therapy should undergo further investigation [2].

Hysteroscopy, performed under local anaesthetic, is widely used to investigate menstrual disorders. It should be combined with endometrial biopsy because, alone, it has poor sensitivity for detecting endometrial hyperplasia. This investigation is generally considered to be the "gold standard" against which others are compared. The 39th RCOG Scientific Study Group state that "hysteroscopy is more sensitive than transvaginal ultrasound in identifying benign lesions" but add that "there is inadequate evidence as to the best method to assess the endometrium but transvaginal ultrasound and endometrial biopsy may be the most appropriate" [3]. Transvaginal ultrasound (TVS) allows the accurate measurement of endometrial thickness, identifies fibroids and detects adnexal pathology, such as ovarian cysts.

In pre-menopausal women, the diagnostic accuracy of TVS in detecting endometrial abnormalities is less certain than in post-menopausal women. This is especially true in attempting to distinguish between endometrial thickening and intracavitary polyps or fibroids. The technique of instilling saline into the uterus during TVS (transvaginal saline hysterosonography, TVHSg) can enhance its diagnostic accuracy. Studies in post-menopausal women have compared TVHSg to hysteroscopy, showing it to be comparable in detecting benign lesions [4–8].

This study set out to assess the diagnostic accuracy of TVHSg in the identification of benign lesions affecting the endometrium in women with menorrhagia and/or menstrual problems who failed to respond to initial medical management. More precisely, TVHSg is compared with hysteroscopy, which is considered to be the "gold standard." The study is reported according to the Standards for Reporting of Diagnostic Accuracy (STARD) guidelines. These standards were introduced by an international steering committee in 2001 in an effort to improve the quality of the reporting of diagnostic studies. They recommend a precise methodology and include a well defined checklist and flow diagram [9].

Methods

Participants

The study group consisted of 140 patients referred to the Menorrhagia Clinic at the Royal Victoria Infirmary in Newcastle Upon Tyne, UK. The inclusion criteria included women over the age of 35 with menorrhagia or women who had specifically requested investigation and had failed to respond to initial medical management. Initial medical management was carried out in primary care (by the General Practitioner) and consisted mainly of the administration of anti-prostaglandin/anti-fibrinolytic drugs (mefenamic and tranexamic acid) and/or oral progestogens (norethisterone). Exclusion criteria were pregnancy and suspected infection of the genital tract. Uterine bleeding at the time of attendance was not considered as an exclusion criterion, unless the bleeding was heavy.

Recruitment took place over 30 weeks (2000–2001). During this time, 148 patients attended the clinic. Six patients had already undergone investigation, one declined to take part in the study and one was unable to give consent. In total, 140 consecutive patients were sampled, as specified in the inclusion criteria. On attendance, consent was obtained for TVHSg and hysteroscopy and Pipelle biopsy. The local ethics committee had granted approval. The collection of the data was planned before the diagnostic tests were carried out and, therefore, the study was prospective.

Test methods

As mentioned previously, hysteroscopy was our reference standard and transvaginal saline hysterosonography was the test under diagnostic accuracy comparison.

The scan was performed first using an Aloka scanner with 7 MHz transvaginal probe. Patients were put in the dorsal lithotomy position. A bivalve speculum was used to visualise the cervix, which was cleansed with antiseptic solution (Chlorhexidine 0.05%). A 6FG paediatric urinary catheter was inserted into the uterine cavity and the balloon inflated with 1–2 ml of water. The speculum was removed and the catheter connected to a giving set attached to a bag of warmed 0.9% Sodium Chloride solution.

A conventional transvaginal scan of the uterus was initially performed and the adnexa were also examined. In our study, we consider this initial/conventional scan as an important, necessary and integral part of the TVHSg investigation. The saline solution was then slowly infused into the endometrial cavity and the distended cavity was examined in the sagittal and coronal planes (see Fig. 1). Initial uterine distension required between 8 and 45 ml of saline (median 18 ml), with

Fig. 1 Normal transvaginal hysterosonogram (sagittal view)

further fluid as necessary, depending on the duration of the procedure and the loss of fluid via the cervix or fallopian tubes. The findings were recorded on a proforma. This included a measure of endometrial thickness and the diameters of any uterine lesions identified. For the purposes of our study, endometrial polyps were defined as small lesions (<1 cm) that were protruding in the cavity in their entirety, were isoechoic or hyperechoic compared to the endometrium and had a narrow pedicle [10] (see Fig. 2). Submucous fibroids were defined as lesions that were relatively hypoechoic or isoreflective or hyperechoic compared to the myometrium and/or caused acoustic shadowing and had a relatively broad base and/or distorted the regularity of the myometrium [11].

The patients were then transferred to the day theatre, where a diagnostic hysteroscopy was performed using a 4-mm rigid 25° Wolf hysteroscope with a single-channel irrigation sheath and video system. The 4-mm telescope was used since it was the standard instrument for hysteroscopy in our unit at the time of the study. Analgesia included the administration of pre-operative Co-codamol (two tablets) and an intracervical block using 4 ml of Citanest with Octapressin® (Astra Pharmaceuticals Ltd., Hertfordshire, England). The patient was placed in the lithotomy position and the cervix was cleansed with antiseptic solution. After injecting the local anaesthetic, the hysteroscope was introduced. Cervical dilatation was performed where necessary. Warmed normal saline was used as the irrigating fluid, with the infusion pressure set using a pressure cuff at 50 mmHg. The findings were again recorded on a proforma. A Pipelle endometrial biopsy was carried out in all patients. In our study, the Pipelle biopsy was considered to be an important and essential part of the hysteroscopic procedure. A bimanual examination was performed at the end of the procedure. For the purposes of our study, endometrial polyps were defined as lesions that were almost entirely protruding into the uterine cavity and had

Fig. 2 Transvaginal hysterosonogram showing endometrial polyp (transverse view)

Fig. 3 Endometrial polyps (hysteroscopic view)

either a surface which was similar to the surrounding endometrium or were white and covered with branching surface vessels (see Fig. 3).

Submucous fibroids were defined as lesions that were white spherical masses covered with a network of fragile thin-walled vessels [12] (see Fig. 4).

TVHSg, the index test, was carried out by one operator, experienced in the procedure. Hysteroscopy, the reference standard, was carried out by one of three surgeons, all with prior experience and training. Each operator was blinded to the findings of the preceding investigation until both proformas had been completed.

The findings were explained to the patient and a management plan was made.

Statistical methods

The sensitivity, specificity, positive predictive value, negative predictive value and likelihood ratios for the diagnosis of intracavitary lesions (endometrial polyps and submucous

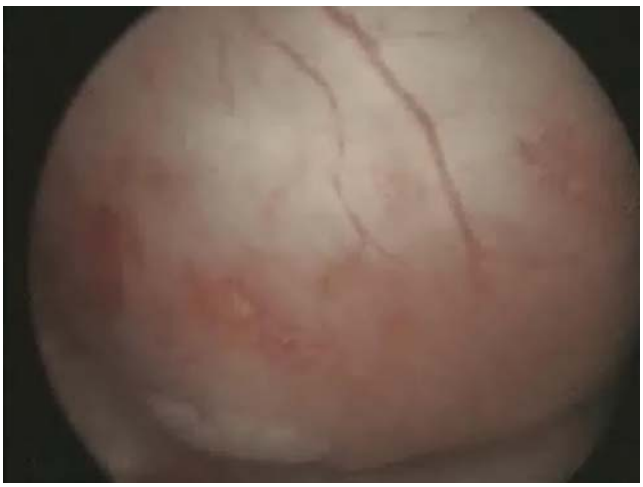


Fig. 4 Submucous fibroid (hysteroscopic view)

fibroids) were calculated. Also, 95% confidence intervals were calculated.

As mentioned previously, this study is reported according to the STARD guidelines and, thus, the recommended checklist and flow diagram are followed. A sample size (power) calculation was not performed beforehand, as this is not a necessary part of the STARD list [13].

Results

Participants

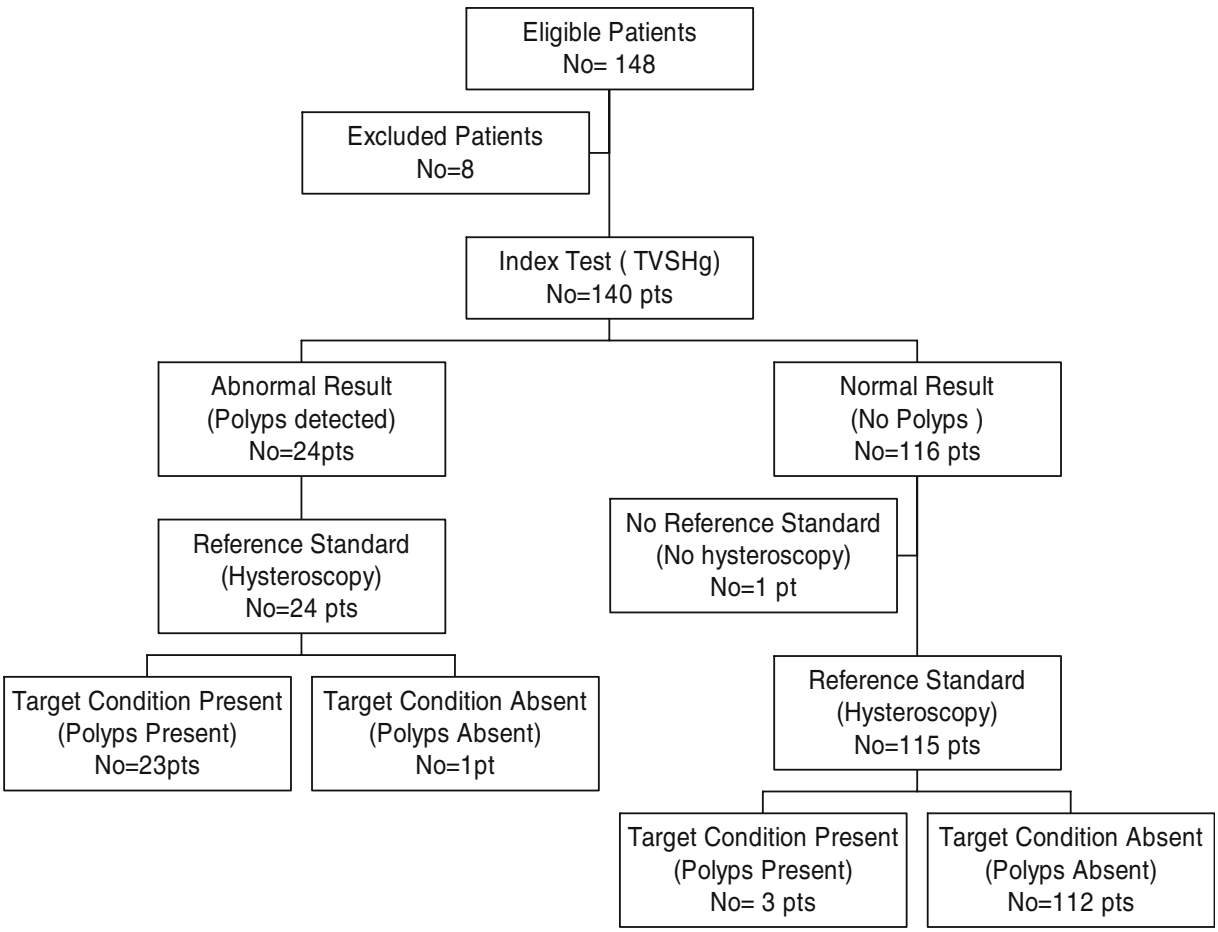
A total of 140 patients were recruited into the study between 2000 and 2001.The median age of the patients was 43 years (range 29–54 years). The majority of patients were over 35 years old. Only five patients younger than 35 were included in our study. These had specifically requested investigation and had failed to respond to initial treatment. All women complained of heavy periods. The primary problem was menorrhagia in 76% of patients, followed by pain in a further 11%. The remainder described irregular bleeding or intermenstrual bleeding as their primary complaint, with menorrhagia being a secondary problem.

The index test, TVHSg, was performed in all cases (140 patients) but hysteroscopy was not possible in one case because of cervical stenosis. In this case, no difficulty was encountered in performing the TVHSg, which did not show any apparent abnormality. As a result, the reference test, out-patient hysteroscopy, was performed in 139 patients only.

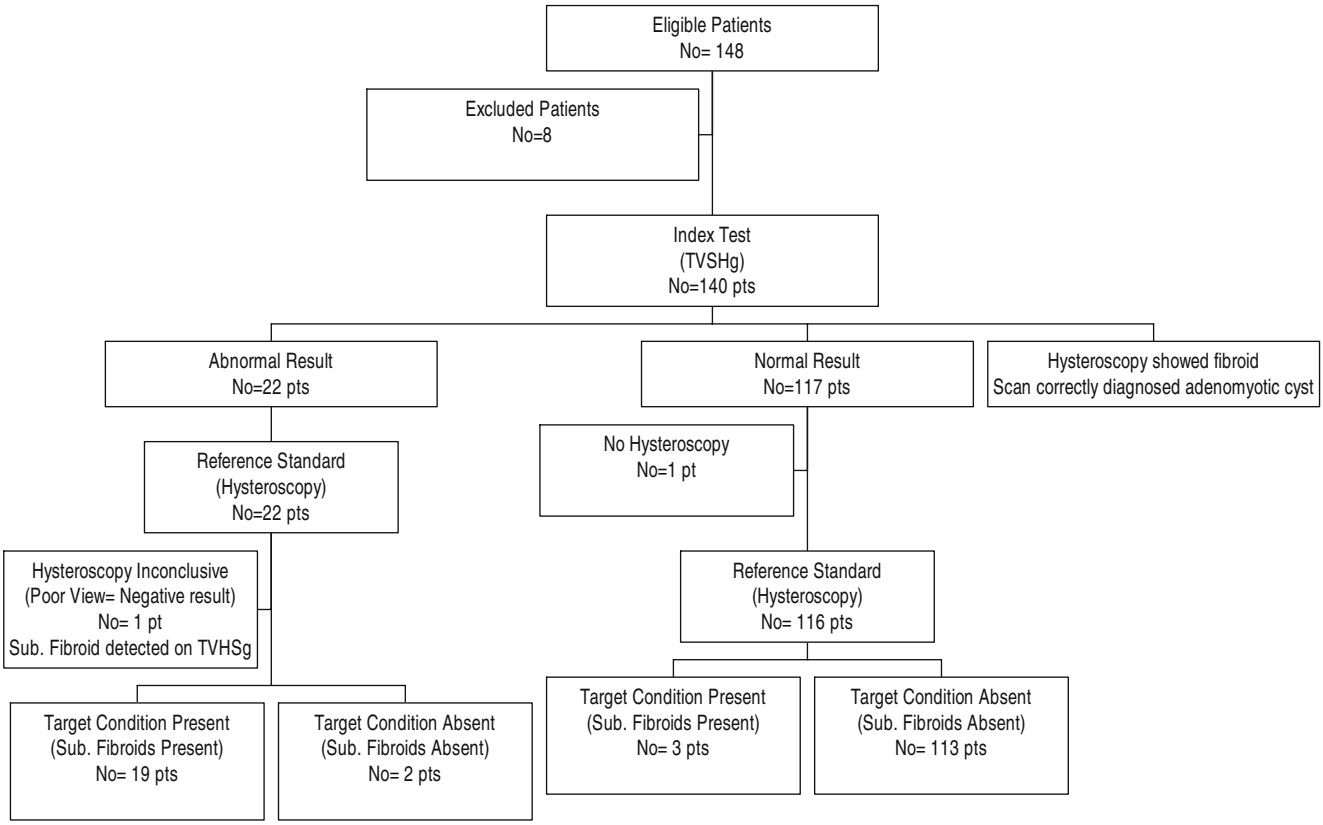
Test results

As seen in the flow charts (Flow Diagrams 1 and 2), one lesion identified by TVHSg as a subendometrial adenomyotic cyst had been reported on hysteroscopic inspection as a fibroid but was correctly diagnosed during the accompanying Pipelle.

Of note also is the fact that the reference standard, namely, out-patient hysteroscopy, gave one false negative diagnosis due to the poor view of the endometrial cavity.



Flow Diagram 1 STARD diagram of diagnostic accuracy of TVHSg compared to hysteroscopy (regarding endometrial polyps)



Flow Diagram 2 STARD diagram of diagnostic accuracy of TVHSg compared to hysteroscopy (regarding submucous fibroids)

Estimates

There were abnormalities affecting the endometrium in 35% of patients (n=49). This encompassed endometrial polyps (26 patients) and submucous fibroids (22 patients) and an adenomyotic cyst. In three of these, submucous fibroids and polyps were identified in the same patient.

TVHSg was feasible in all patients and hysteroscopy was feasible in 139 out of 140 patients. As a result, the estimates of diagnostic accuracy for endometrial polyps were calculated on the final total of 139 patients. The diagnostic accuracy for submucous fibroids was calculated on a total of 137 patients, as the case of the adenomyotic cyst (for which we did not perform a separate diagnostic accuracy calculation since it was a single case only) and the case of the false negative hysteroscopy were excluded.

There were three cases in which both polyps and submucous fibroids were present. These were detected by both TVHSg and hysteroscopy (Tables 1 and 2).

In our study, we describe the TVHSg as saline instillation and scanning of the uterine cavity preceded by a conventional transvaginal ultrasound scan, as we believed that this would allow us to have a complete picture of the pelvic organs and/or their pathology. We regard the two practices as one inseparable diagnostic procedure and we believe this to be essential for good medical practice (and in the UK, it is common to perform the complete procedure). TVHSg in this context, compared to hysteroscopy alone, had the additional advantage of the detection of intramural fibroids and the detection of adnexal lesions.

We have not calculated separately how many fibroids were identified by the initial conventional ultrasound scan and how many were identified by the subsequent saline hydrosonography, as we consider the two practices to be

Table 1 Diagnostic accuracy of TVHSg in identifying endometrial polyps

	Disease present	Disease absent
Test result positive	23	1
Test result negative	3	112

Sensitivity=23/26=0.88 (0.69–097, 95% CI)
Specificity=112/113=0.99 (0.94–0.99, 95% CI)
For any particular positive result, the probability that it is positive (positive predictive value) is:23/24=0.96 (0.77–0.99, 95% CI)
For any particular negative result, the probability that it is negative (negative predictive value)is: 112/115=0.97 (0.91–0.99, 95% CI)
Positive likelihood ratio=sensitivity/(1−specificity)=0.88/(1−0.99)=0.88/0.01=99.96 (14.13–706.96, 95% CI)
Negative likelihood ratio=(1−sensitivity)/specificity=(1−0.88)/0.99=0.116 (0.0401–0.337, 95% CI)

Table 2 Diagnostic accuracy of TVHSg in identifying submucous fibroids

	Disease present	Disease absent
Test result positive	19	2
Test result negative	3	113

Sensitivity=19/22=0.86 (0.64–0.96, 95% CI)
Specificity=113/115=0.98 (0.93–0.99, 95% CI)
Positive predictive value=19/21=0.90 (0.68–0.98, 95% CI)
Negative predictive value=113/116=0.97 (0.92–0.99, 95% CI)
Positive likelihood ratio=sensitivity/(1−specificity)=0.86/(1–0.98)=0.86/0.2=49.65 (12.44–198.14, 95% CI)
Negative likelihood ratio=(1−sensitivity)/specificity=0.138 (0.048–0.397, 95% CI)

complementary and necessary for a full investigation of the pelvic organs.

Intramural fibroids were identified in a total of 41 patients, 40 of whom were identified by ultrasound. Twenty-six of these were identified by both TVHSg and hysteroscopy. However, 14 cases of intramural fibroids were missed by hysteroscopy but were identified by TVHSg, and only one case was detected by hysteroscopy but missed by TVHSg. In total, 27 cases of fibroids were detected by hysteroscopy alone.

TVHSg identified 14 ovarian cysts of more than 2 cm and two of these measured more than 5 cm. One of these only was identified with bimanual examination.

There were no cases of endometrial carcinoma in this group of patients, which is not unexpected given its low incidence in this population of pre-menopausal women. There were three cases of hyperplasia but none with cytological atypia.

There were no adverse events or complications from either TVHSg or hysteroscopy.

Discussion

This study is the largest to date comparing TVHSg and local anaesthetic hysteroscopy, confining its population to pre-menopausal women with menorrhagia or menstrual problems after failed initial medical management, which is reported according to the Standards of Reporting of Diagnostic Accuracy (STARD) guidelines. The percentage of patients with intrauterine abnormalities detected is higher than one might expect but these patients were selected because they had not responded to initial treatment.

In our study, TVHSg performed well in the detection of intracavitary lesions. We found that TVHSg has a sensitivity of 0.88 (0.68–0.96, 95% CI) and a specificity of 0.99 (0.94–0.99, 95% CI) in the detection of endometrial polyps and a sensitivity of 0.86 (0.64–0.96, 95% CI) and a specificity of 0.98 (0.93–0.99, 95% CI) in the detection of submucous fibroids. The positive likelihood ratios were 99.9 (14–706, 95% CI) and 49 (12–198, 95% CI). The feasibility for TVHSg was 100%, as it was possible to carry out the investigation in all of our patients.

TVHSg missed three cases of endometrial polyps and three cases of submucous fibroids. In two of the three cases of polyps that went undetected by TVHSg, hysteroscopy showed that the polyps were no more than 2–3 mm in diameter. Such small lesions are unlikely to be of relevance to the clinical complaint. In the third case, the visualisation at hysteroscopy was poor because of bleeding and only suspicion of a polyp was noted. Bernard et al. [5] missed one polyp on TVHSg in their study.

In one of the three cases of submucous fibroids that were missed by TVHSg, a small submucous fibroid was seen near the internal cervical os at hysteroscopy and was most likely obscured by the catheter balloon at the time of saline instillation.

In general, in this study, TVHSg missed minor abnormalities that were unlikely to have influenced treatment options.

Regarding the detection of endometrial polyps, there was one case of false positive. In this case, TVHSg showed several small polyps. However, these were found, on hysteroscopy, to be folds of the endometrium. Other authors have reported this but whether the two can clearly be distinguished on examination with the naked eye is open to question. Histological examination showed no abnormality.

There were two cases of false positives in which submucous fibroids were detected on scanning but these were absent on hysteroscopy. In a separate case, TVHSg showed the presence of an adenomyotic subendometrial cyst, while hysteroscopic inspection suggested an intramural fibroid impinging on the cavity. On taking a biopsy, the Pipelle sampling device entered and decompressed the cyst and “chocolate” material was obtained, making the initial diagnosis on TVHSg correct. Although the adenomyotic cyst was missed at the hysteroscopic inspection, it was revealed by the accompanying Pipelle biopsy, so both methods (TVHSg and hysteroscopy with Pipelle biopsy) reached the same, correct, diagnosis. We did not make a separate calculation/flow diagram regarding the diagnostic accuracy of adenomyotic cysts, as this was only one case and, thus, it would be impossible to reach significant or reliable conclusions.

As mentioned before, TVHSg was performed by one practitioner and the hysteroscopy was performed by three different surgeons. One may argue that this might have led to the poorer outcome for hysteroscopy. However, all three surgeons had undergone approved theoretical training and already had adequate practical experience in the procedure before being allowed to take part in the study.

In the study by Williams and Marshburn [6], hydrosonography detected all patients with intrauterine pathology.

They did find, however, that if multiple lesions existed together, the number was often underestimated. They also reported more false positive results than our study, related to mistaking endometrial folds for intracavitary lesions. They had difficulty distinguishing between polyps and submucosal fibroids in a small number of cases in their study, as with one case in this study.

A further advantage of TVHSg over hysteroscopy is in the distinction between fibroids and polyps, as the core of the lesion can be viewed. In one case, two distinct polyps on TVHSg were reported, although hysteroscopy identified one as a submucous fibroid. In practice, the distinction is of minor importance, as treatment options are likely to be the same.

Our results are similar have reported by Kelecki et al. [14], who recorded a sensitivity of 81% and a specificity of 100%. However, our study is larger and includes exclusively symptomatic women with menorrhagia who failed to respond to initial medical management.

In their systematic review and meta-analysis in assessing the diagnostic accuracy of TVHSg in the evaluation of the uterine cavity in both pre-menopausal and post-menopausal women with abnormal uterine bleeding, de Kroon et al. [15] report a pooled sensitivity and specificity of 95% and 88%, respectively, and a pooled likelihood ratio of 91. They also report that the feasibility of TVHSg in pre-menopausal women carries a success rate of 95%. Our data suggest lower sensitivities and higher specificities, a higher positive likelihood ratio for polyps and a lower positive likelihood ratio for submucous fibroids. As mentioned before, in our study, the feasibility for TVHSg is 100%.

Several studies have calculated sensitivities and specificities for TVHSg compared with hysteroscopy [16, 17]. There are, however, some limitations to doing this. In our study, in one case, the view at hysteroscopy was poor and imaging by TVHSg correctly detected the submucous fibroid. Hysteroscopy, on occasion, may not provide satisfactory views of the endometrial cavity and lesions may be incorrectly classified. Van Dongen et al. [18], in their recent systematic review and meta-analysis, reported that the pooled sensitivities of hysteroscopy were 0.94 for endometrial polyps and 0.87 for submucous fibroids. The specificities were found to be 0.92 and 0.95, respectively.

In our study, there were two cases of large (>5 cm) ovarian cysts identified. The one that was not detected with bimanual examination underwent surgery for a mature teratoma. The majority of identified cysts were subsequently resolved. Clearly, the latter group are of importance, as the presence of adnexal pathology is a factor to consider in planning management. These may have gone unnoticed if hysteroscopy and bimanual examination were the sole investigations used.

There were no cases of endometrial carcinoma or atypia on Pipelle biopsy. This is not surprising, as the incidence of these conditions before the menopause is low. In Bernard et al.'s study [5], in which post-menopausal women were included, TVHSg was poor at correctly identifying cancers, but in all cases of cancer, an endometrial abnormality was recognised that prompted surgical exploration.

TVHSg is a relatively simple technique to learn by those already accustomed to transvaginal sonography [19]. Hysteroscopic surgery, endometrial ablation techniques, embolisation of fibroids and progestogen-releasing intrauterine systems are now more commonplace but require accurate identification of the cause of the menorrhagia in order to be used to their full effect. TVHSg has a role in identifying those patients who will benefit from these treatment modalities.

The other advantage of TVHSg is that it can be performed outside the hospital setting. There is an increasing movement to manage more patients in the community and community gynaecologists are being appointed with this in mind. So long as access to sonographic equipment is available, this technique is easy to learn. It can be used to select a group of patients who will benefit from referral for surgery, with implications for cost savings in so doing.

Conclusion

Transvaginal saline hysterosonography (TVHSg) has high sensitivity, specificity, positive predictive value and negative predictive value in detecting endometrial lesions in pre-menopausal women with menorrhagia in whom initial management has failed. It has the additional advantage of detecting myometrial and ovarian pathology. Because of its high diagnostic accuracy, we highly recommend its use as a primary investigative method in patients with menorrhagia.

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