The role of transvaginal ultrasonography and outpatient diagnostic hysteroscopy in the evaluation of patients with menorrhagia

Paolo Vercellini[1], Ilenia Cortesi, Sabina Oldani, Marta Moschetta, Olga De Giorgi, and Pier Giorgio Crosignani

Clinica Ostetrica e Ginecologica 'Luigi Mangiagalli', University of Milan, Via Commenda, 12, 20122 Milano, Italy

[1]To whom correspondence should be addressed

To verify the reliability of transvaginal ultrasonography in diagnosing intrauterine disease and in evaluating the operability of submucous myomas and to determine the feasibility, acceptability and validity of hysteroscopy for menorrhagia, we performed a prospective 5 year study on 793 women of mean age ± SD of 41.5 ± 7.8 years. All the patients referred for excessive menstrual bleeding with uterine volume <12 week pregnancy who underwent complete physical examination, transvaginal ultrasonography and outpatient hysteroscopy with endometrial biopsy were included in the study. Outpatient hysteroscopy was not completed due to intolerance or was unsatisfactory due to excessive bleeding in 23 cases (2.9%). Only 28 women (3.5%) declared they would have refused the procedure had they imagined the pain involved. One case of pelvic infection was observed. Compared with hysteroscopy, transvaginal ultrasonography had 96% sensitivity, 86% specificity, 91% positive predictive value and 94% negative predictive value in the diagnosis of intrauterine abnormality. The sensitivity, specificity, positive and negative predictive values of ultrasonography in identifying submucous myomas operable hysteroscopically (intramural extension <50%) were respectively 80, 69, 83 and 65% with a *k* index of agreement between ultrasonography and hysteroscopy of 0.48. Thus, considering the good specificity and high negative predictive value, transvaginal ultrasonography may be suggested as the initial investigation in menorrhagic patients, limiting hysteroscopy to cases with positive or doubtful sonographic findings.
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Introduction

Excessive menstrual bleeding is one of the main reasons why premenopausal women consult a gynaecologist. Recently, the results of biochemical and immunohistochemical studies have demonstrated the role of abnormal angiogenesis in determining menorrhagia in patients with and without organic lesions (Abberton *et al.*, 1996; Stewart and Nowak, 1996). However, the main diagnostic methods used in these patients are still transvaginal ultrasonography and outpatient hysteroscopy (Lewis, 1990; Vercellini *et al.*, 1993; Wood *et al.*, 1993; Baskett *et al.*, 1996; Towbin *et al.*, 1996). The former technique has the advantage of limited invasiveness and optimal acceptability and the latter offers the possibility of identifying the type of lesion accurately and of performing targeted biopsies (Mencaglia *et al.*, 1987; Nagele *et al.*, 1996a). Furthermore, operative hysteroscopy is used increasingly frequently for the removal of submucous myomas (Garry, 1990; Wamsteker *et al.*, 1993a). According to some authors, diagnostic hysteroscopy represents an indispensable presurgical investigation (Wamsteker *et al.*, 1993b), although data comparing the value of ultrasonography and hysteroscopy in assessing endoscopic operability of submucous myomas are scanty (Cicinelli *et al.*, 1995). In view of the above considerations and also the elevated incidence of menorrhagia, it is important to attempt to rationalize the diagnostic approach in this group of women. Thus we performed a prospective 5 year study on a large series of premenopausal patients referred for excessive menstrual bleeding. The aims of the study were to verify the reliability of transvaginal ultrasonography in diagnosis of intrauterine disease and in evaluation of the operability of submucous myomas, and to determine the feasibility, acceptability and validity of hysteroscopy in menorrhagic women.

Materials and methods

In the period July 1991 to June 1996 all premenopausal women (follicle stimulating hormone <30 mIU/ml) referred for abnormal uterine bleeding to the Centre for the Study and Treatment of Menorrhagia of the First Obstetrics and Gynaecology Department of Milan University were considered for inclusion in the study. Most of the patients had already undergone unsuccessful medical treatments. Excessive menstrual bleeding was diagnosed based on the history, serum haemoglobin and iron concentrations and the pictorial blood loss assessment chart devised by Higham *et al.* (1990). It has been demonstrated that a monthly score ≥100 on this menstrual diary is significantly associated with a uterine blood loss >80 ml as measured by the alkaline haematin method. All the women with uterine volume less than a 12-week pregnancy, iron deficiency anaemia (haemoglobin <12 g/dl, serum iron <40 µg/dl) and menstrual score ≥100 and who underwent a complete physical examination, transvaginal ultrasonography, and outpatient hysteroscopy with endometrial biopsy, were included in the study. Patients with an intrauterine device, who had received hormonal treatment in the previous 3 months [6 months for gonadotrophin releasing hormone (GnRH) agonists], or who had already undergone dilatation and curettage or diagnostic or operative hysteroscopy were excluded from the analysis.

Ultrasonography was performed by gynaecologists independently of the phase of the cycle using Ansaldo AU 440 (Ansaldo, Genoa, Italy) or AU 580 synchronous (Hitachi, Tokyo, Japan) equipment and a

transvaginal transducer of 6.5 MHz. The endometrial cavity outline was studied from the internal os to the uterine fundus in sagittal and coronal sections. The ultrasound finding was considered abnormal when the ultrasonographer visualized a lesion inside the cavity or when the maximum endometrial thickness measured in the sagittal plane according to the technique of Fleischer et al. (1990) was ≥14 mm. Doubtful sonograms with findings neither definitively negative nor positive due to poor visualization and/or difficult interpretation were considered abnormal. Submucous myoma was diagnosed at ultrasonography in the presence of a nodular formation with well defined margins, heterogeneous structure and varying echogenicity, which displaced the endometrial lining. Hysteroscopy was performed in the same or a subsequent menstrual cycle, preferably in the proliferative phase, with a rigid 30° hysteroscope and diagnostic sheath of 5 mm diameter (Storz Endoscopy, Tuttlingen, Germany or Circon-Acmi, Munich, Germany). Thirty minutes before the procedure, 0.5 mg atropine was injected i.m. Hysteroscopy was always carried out in sterile conditions after careful cleansing of external genitalia, vagina, and cervix with a povidone–iodine antiseptic solution. The investigation was postponed if an acute cervico–vaginal infection was present. Only in women with a history of previous pelvic inflammatory disease was a single prophylactic 2 g dose of cefoxitin injected i.m. 30 min before hysteroscopy. Normal saline or a urological solution of 2.7% sorbitol and 0.54% mannitol was used to dilate the uterine cavity, infused by pneumatic cuff under manometric control at a pressure of 100–120 mmHg. For illumination, a cold light source of high intensity and fibre optic cable was used. All the procedures were monitored using an endoscopic single-chip video camera and the images were projected onto a monitor visible to both gynaecologist and patient. Paracervical anaesthesia was administered only for comparative clinical studies or at the specific request of the patient. During hysteroscopy the patients were constantly attended and encouraged by a nurse and the gynaecologist explained each manoeuvre performed and described the progress of the investigation, commenting on the images projected on the monitor. Hysteroscopic diagnosis of myoma was made from the presence of a firm intracavitary formation with thin or no endometrial covering and superficial large blood vessels. The intramural extension of sessile tumours was determined hysteroscopically by observing the angle of the fibroid with the myometrium at the uterine wall attachment. An endometrial polyp was diagnosed when a soft intracavitary formation was observed that was easily mobilized and covered by mucosa with endometrial glands and no distended vascular network. Endometrial hyperplasia was defined as thick, hypervascular, friable mucosa that was mamillated or polypoid. At the end of the procedure an intrauterine biopsy was obtained with a small cutting curette. Expert operators performed all the ultrasonographic and hysteroscopic procedures and reported the findings in detail on preprinted forms. Submucous myomas were subdivided independently at ultrasonography and hysteroscopy into tumours with intramural extension <50% (operable endoscopically) or ≥50% (not operable endoscopically).

The sensitivity, specificity and positive and negative predictive values (PPV, NPV) of transvaginal ultrasonography in detecting the presence of an intrauterine abnormality were calculated considering the hysteroscopic finding as the true diagnosis. We also calculated these variables for the ultrasound assessment of endoscopic operability/non-operability of myomas, as well as the k index of agreement between ultrasonography and hysteroscopy. The sensitivity, specificity, PPV and NPV of hysteroscopy in the diagnosis of myoma, polyp and endometrial hyperplasia were determined based on the histological finding as reference standard.

Results

In the 5 year period considered, 793 premenopausal women underwent clinical, ultrasound and endoscopic evaluation for

Table I. Hysteroscopic diagnosis in a series of 770 consecutive women with menorrhagia according to strata of age[a]

Condition[b]	Strata of age in decades				
	<20 (n = 12)	20–29 (n = 114)	30–39 (n =292)	40–49 (n = 264)	>50 (n = 88)
Normal cavity	–	32 (28.1)	107 (36.7)	142 (53.8)	44 (50.0)
Submucous myoma	12 (100)	77 (67.5)	104 (35.6)	37 (14.0)	4 (4.5)
Endometrial polyp	–	7 (6.1)	61 (20.9)	62 (23.5)	25 (28.4)
Endometrial hyperplasia	–	3 (2.6)	29 (9.9)	28 (10.6)	16 (18.2)
Endometrial carcinoma	–	–	–	–	2 (2.3)

[a]Some women had more than one condition. Fifteen had both myomas and polyps; seven had other combinations (i.e. myomas and hyperplasia or polyps and hyperplasia).
[b]Data are presented as number (%). Percentage distribution is within specific strata of age.

excessive menstrual bleeding. Their mean age ± standard deviation (SD) was 41.5 ± 7.8 years. The series included 148 (18.7%) nulliparas. In 13 cases (1.6%) hysteroscopy was not completed due to intolerance of the procedure and in 10 (1.3%) complete visualization of the cavity was prevented by intrauterine bleeding; these subjects were excluded from all further analyses. In 15 other instances (1.9%) the patient refused endometrial biopsy after completion of the hysteroscopy and in 17 (2.1%) the quantity of mucosa sent to the pathologist was insufficient for a correct histological diagnosis; these subjects were excluded from the evaluation of hysteroscopy in the diagnosis of various types of intrauterine disorders. Local paracervical anaesthesia was used on 139 (17.5%) occasions. At the end of the procedure, 28 (3.5%) women declared that they would not have undergone the examination had they imagined the pain involved. No immediate complications related to hysteroscopy or injection of the local anaesthetic were observed. Forty-eight hours after the endoscopic investigation one patient, with no known risk factor for, or history of, pelvic inflammatory disease, was hospitalized for 2 days for tubal infection which resolved with antibiotics.

Ultrasonography was normal in 300 (39.0%) cases, abnormal in 417 (54.2%) and doubtful in 53 (6.8%). Hysteroscopy was negative in 325 (42.2%) cases and pathological in 445 (57.8%). Table I reports the hysteroscopic findings in relation to age. The prevalence of submucous myomas was inversely correlated with age, being 46.2% (193/418) under 40 and 11.6% (41/352) over 40 years [χ^2 =106.1; P = 0.0001, odds ratio 6.5; 95% confidence interval (CI) 4.5–9.5]. Conversely, endometrial polyps were observed more frequently with advancing age, with a prevalence of 16.3% (68/418) under and 24.7% (87/352) over 40 years (χ^2 = 8.0; P = 0.005, odds ratio 0.6; 95% CI 0.4–0.8). Fifteen subjects had both myomas and polyps. We also observed a uterus with arcuate fundus or partial septum in 28 women, four unicornuate uteri and four cases of mild synechiae. As these abnormalities are not recognized causes of menorrhagia, their diagnosis at ultrasonography or hysteroscopy was considered as normal.

Comparing the ultrasound with the hysteroscopic findings, transvaginal ultrasonography had a sensitivity of 96%, specifi-

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Table II. Comparison of ultrasonographic with hysteroscopic findings in a series of 770 consecutive women with menorrhagia

Transvaginal sonographic finding	Hysteroscopic finding		
	Abnormal	Normal	Total
Abnormal	426	44[a]	470
Normal	19[b]	281	300
Total	445	325	770

[a]Thirty-one leiomyomas, 12 polyps, one endometrial hyperplasia (including 18 cases with doubtful ultrasonography and negative hysteroscopy).
[b]Six leiomyomas, nine polyps, four endometrial hyperplasias.

Table III. Predictive characteristics of hysteroscopy in the diagnosis of various conditions in a series of 770 consecutive women with menorrhagia

Condition	Sensitivity	Specificity	Positive predictive value	Negative predictive value
	(%)	(%)	(%)	(%)
Submucous myomas	95	81	85	93
Endometrial polyps	86	94	91	90
Endometrial hyperplasia	45	99	38	94

city of 86%, PPV of 91% and NPV of 94% in the diagnosis of intrauterine abnormality (Table II). Ultrasonography did not detect a small submucous myoma in six cases, a small polyp in nine, and endometrial hyperplasia in four. It yielded a false positive diagnosis of submucous myoma in 31 cases (which were intramural myomas not distorting the cavity), of polyp in 12, and of endometrial hyperplasia in one. In all these patients hysteroscopy demonstrated a regular cavity and eutrophic mucosa. Hysteroscopy was negative in 18 of the women with doubtful ultrasound finding and revealed a small polyp in 35.

In 228 subjects the ultrasound diagnosis of submucous myoma was confirmed at hysteroscopy. Compared with the hysteroscopic findings, ultrasonography correctly indicated as operable endoscopically 118/148 myomas with intramural extension <50% and as not endoscopically operable 55/80 with intramural extension ⩾50%. The sensitivity, specificity, PPV and NPV of ultrasonography in the identification of submucous myomas operable at hysteroscopy were 80, 69, 83 and 65% respectively. The agreement between ultrasonography and hysteroscopy in the diagnosis of intramural extension of submucous myomas was fair (*k* index, 0.48).

Of the 234 patients with hysteroscopic diagnosis of submucous myoma, 103 underwent endoscopic resection and 131 hysterectomy. The polyps observed at hysteroscopy in 155 subjects were removed during the diagnostic session in 16 cases and at operative hysteroscopy in the other 139. At hysteroscopy myoma was misdiagnosed in 22 cases of polyp, all 11 cases of adenomyoma and one case of myxoid tumour, polyp in 11 cases of myoma, and in three of adenomyosis. The pathologist observed histologically 66 cases of endometrial hyperplasia. Hysteroscopy yielded 48 false positives and 36 false negatives. Table III indicates the value of hysteroscopy as diagnostic test for submucous myoma, polyp and endometrial hyperplasia compared with the histological diagnosis. Ultra-

sonography gave a false negative result in one case of simple endometrial hyperplasia detected at histology and three false positives. The two cases of endometrial carcinoma were identified at both ultrasonography and hysteroscopy. Overall, the histological prevalence of intracavitary abnormalities in the study population was 57.0% (421/738 cases).

Discussion

Recently transvaginal ultrasonography has been proposed as an alternative to, or in combination with, hysteroscopy in the work-up of menorrhagic patients (Fedele *et al.*, 1991; Wood *et al.*, 1993; Towbin *et al.*, 1996). The reliability of ultrasonography in excluding the presence of intracavitary disorders in pre- and postmenopausal women has been demonstrated repeatedly and some authors have therefore questioned the appropriateness of a hysteroscopy after negative transvaginal ultrasonography (Emmanuel *et al.*, 1995; Indman, 1995). The present series included only premenopausal women, which obviously limits generalization of the results. The high predictive value of a normal ultrasound examination observed also in our study (94%) supports the notion that hysteroscopic investigation should be reserved for women with a positive or doubtful sonogram or who are not responsive to medical treatments. An endometrial biopsy, particularly in older subjects, may be easily performed by suction curettage. However, especially in the routine investigation of young, non-anaemic patients presenting with menorrhagia, transvaginal sonography should be performed only after an unsuccessful trial of medical therapy. We subdivided the ultrasound diagnosis into the presence/absence of intrauterine disorders or doubtful finding because of the suboptimal reliability of ultrasonography in distinguishing between the various lesions (Fedele *et al.*, 1991). This should be of scant clinical importance as further investigations are always performed in case of a generic ultrasound diagnosis of intrauterine anomaly. Also, the predictive value of an abnormal sonogram was satisfactory (89%), although undoubtedly influenced by the high prevalence of intracavitary abnormalities in the study population. The case of simple hyperplasia not recognized by ultrasonography raises doubts about the cut-off of 14 mm endometrial thickness adopted by us. Emmanuel *et al.* (1995) did not report any false negatives with a cut-off of 12 mm. Only scanty data are available on ultrasound diagnosis of endometrial hyperplasia in premenopausal women.

The increasingly frequent recourse to operative hysteroscopy for the removal of submucous myomas (Wamsteker *et al.*, 1993a; Vercellini *et al.*, 1996) makes a precise preoperative diagnosis particularly important for correct counselling and adequate intervention (Wamsteker *et al.*, 1993b). It is commonly believed that myomas with half or more of their volume extending into the uterine wall cannot be removed at hysteroscopy, or not in a single surgical session (Wamsteker *et al.*, 1993a,b). In our study the predictive value of ultrasonography in the diagnosis of submucous myomas operable endoscopically was suboptimal. In particular, without a preoperative hysteroscopy, some patients would have been sent for endoscopic intervention even in the presence of prevalently

intramural myomas. The introduction of normal saline solution into the uterine cavity probably increases the diagnostic reliability of ultrasound investigations (Cicinelli *et al.*, 1995; Widrich *et al.*, 1996). However, transvaginal ultrasonography and hysteroscopy should be considered complementary investigations and not alternatives in planning an operative hysteroscopy. Ultrasonography provides information on the minimal distance between myoma and perimetrium, the presence of other nodes or areas of adenomyosis in the uterus, and the conditions of the adnexa; these data may influence treatment choices.

Hysteroscopy was not found sufficiently reliable in the identification of endometrial hyperplasia. This has already been reported recently (Widrich *et al.*, 1996) and confirms the need for a routine biopsy even in the presence of endoscopically normal mucosa. False positives are less worrying as in these cases a biopsy sample is always obtained. Furthermore, hysteroscopy did not always correctly differentiate myomas from polyps and did not identify polypoid adenomyomas. Also in this case the clinical consequences are of scant importance as the intracavitary lesions were removed in all cases.

In general, outpatient hysteroscopy was highly feasible; only in 23 of our 793 patients (2.9%) was the procedure not completed due to intolerance or was unsatisfactory due to excessive bleeding. Also acceptability was good, as only 28 (3.5%) women declared that they would have refused the examination had they been aware of the pain involved; 19 of these patients were nulliparous (odds ratio 10.4, 95% CI 4.6–23.5). Other authors have already reported that nulliparity is associated with increased frequency of cervical dilatation, local anaesthesia and reduced tolerance of hysteroscopy (Nagele *et al.*, 1996a). We do not perform paracervical block routinely, as it has not been demonstrated that local anaesthesia reduces pain during outpatient hysteroscopy (Broadbent *et al.*, 1992; Vercellini *et al.*, 1994). In our opinion, a detailed explanation of the stages of the investigation and adequate, constant support from paramedical personnel may be more effective than analgesics, local anaesthetics and general sedatives in improving tolerance of the examination. The use of a liquid medium to distend the uterus is supported by the reduced time needed for the investigation and reduced abdominal pain in women undergoing hysteroscopy with saline solution instead of carbon dioxide (Nagele *et al.*, 1996b). Intramuscular atropine did not cause adverse events and avoided the vasovagal attacks sometimes observed by other authors (Nagele *et al.*, 1996a). The high prevalence of intrauterine anomalies observed by us (~50%) was probably related to the selective referral of patients with severe menorrhagia and to the multiple criteria used to diagnose excessive uterine bleeding (history, haematological values and menstrual diary). Young women are particularly at risk for an intracavitary disorder; in the present series almost two in every three women aged <30 years had a submucous myoma.

In conclusion, considering the good specificity and NPV, transvaginal ultrasonography may be suggested as the initial investigation in premenopausal women with menorrhagia. When appropriate, an endometrial biopsy may be performed by suction curettage. Hysteroscopy may be limited to cases with a positive or doubtful ultrasound finding, with the aim of defining the lesion, obtaining targeted biopsies, and evaluating endoscopic operability correctly.

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