

Open-access transvaginal sonography in women of reproductive age with abnormal vaginal bleeding:

a descriptive study in general practice

Abstract

Background

Diagnostic ultrasonography is used by GPs in approximately 10% of patients of reproductive age with abnormal vaginal bleeding. Transvaginal sonography is recommended as a first-line diagnostic instrument for assessing uterine pathology.

Aim

To assess if findings resulting from open-access sonography were in agreement with the GPs' working hypotheses and if these findings contributed to GPs' management.

Design and setting

Prospective observational cohort study of GPs working in the health district of the Academic Medical Center, Amsterdam and their patients consulting with abnormal vaginal bleeding.

Method

Data on patients' history, GPs' primary working hypotheses, and intended management were recorded. After sonography, GPs recorded their actual management.

Results

A total of 122 patients were included by 18 GPs from June 2003 to December 2004. Data from 89 patients were available for analysis. The GPs' working hypotheses implied 'no structural pathology' in 65/89 patients, and 'fibroids' in 24/89 patients. Sonographic findings were confirmed in 50/65 patients where 'no structural pathology', and in 14/24 of those where 'fibroids' were expected. Initially, GPs had intended to refer nine patients to a gynaecologist. Actual management after sonographic assessment was watchful waiting or drug therapy in 57/89 patients. Eighty-nine per cent of these patients had normal sonographic findings. The actual referral rate rose to 27/89 patients. In 17 referred patients, sonographic findings were suggestive of intracavitary abnormalities.

Conclusion

Open-access sonography contributed to more accurate diagnoses and improved GPs' management of women with abnormal vaginal bleeding.

Keywords

primary health care; ultrasonography; uterine hemorrhage.

INTRODUCTION

For women of reproductive age, a change in menstrual bleeding pattern or interference of bleeding with daily life is frequently a reason for consulting their GP.¹⁻⁴ Hormonal disturbances are thought to be the main cause of this abnormal vaginal bleeding. Other causes include uterine fibroids, endometrial polyps, clotting disorders, cervical abnormalities, and chlamydia infection. Bleeding may also be related to complications of early pregnancy. Rarely, abnormal bleeding may be caused by gynaecological cancer in women of reproductive age.⁵⁻⁷

GPs often use descriptive diagnoses such as heavy menstrual bleeding, irregular bleeding, or intermenstrual bleeding.^{4,5} They use diagnostic ultrasonographic procedures in approximately 10% of patients with abnormal bleeding.^{8,9} If abnormal bleeding seems to be caused by a structural uterine abnormality, primary care guidelines for initial management of abnormal uterine bleeding recommend the use of transvaginal sonography as a first-line diagnostic instrument.^{5,10}

Offering GPs open-access sonography may assist them in making a more precise diagnosis and could result in a change in primary care management. However, the clinical value of sonography for abnormal bleeding in general practice has not yet

been evaluated, either in terms of establishing a more precise working hypothesis, or in terms of its impact on further management for individual patients. To provide more insight into the potential role of sonography in the management of women with abnormal vaginal bleeding in primary care, a prospective observational study was conducted.

METHOD

Setting

The study was carried out among 18 GPs providing care for 27 000 patients, including 8025 women of reproductive age (aged 20-55 years), from June 2003 to December 2004. Except for one GP from an adjacent rural area, all participating GPs worked in the urban health district of the Academic Medical Center in Amsterdam. Patients of reproductive age who presented with abnormal vaginal bleeding were eligible for inclusion. The study did not use predefined criteria for abnormal bleeding in terms of the bleeding pattern and its duration, heaviness, or frequency, but followed the subjective perception of the patient.⁵ Women were excluded if they were less than 20 years of age, were pregnant, had started using hormonal contraceptives, or had had an intrauterine contraceptive device (IUCD) inserted within 3 months before consultation. Also, women with

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How this fits in

Open-access transvaginal sonographic assessment revealed disagreement between GPs' working hypotheses and actual sonographic findings. Some of the problems detected by sonography, for example displaced IUCDs, could easily be solved by GPs, while a large proportion of patients with normal scans were able to be reassured with much more confidence than would have been the case if sonography had not been used. Overall, in a relatively high proportion of patients (23/89), anomalies amenable to hysteroscopic treatment were revealed.

postmenopausal bleeding, and those with a previous hysterectomy, were excluded.

Data collection

After informed consent had been obtained, GPs filled in a standardised questionnaire. The questionnaire addressed the patient's history (bleeding pattern, duration of symptoms, hormonal contraceptive use), findings at physical examination, and the GP's working hypothesis and intended management (predefined as 'watchful waiting', start or stop of medication, additional investigations to be performed, referral to a gynaecologist, or any other management).

GPs were instructed to choose only one of the following predefined working hypotheses in the questionnaire: abnormal bleeding caused by hormonal contraceptive use (oral contraceptive pill or progestogen use), by chlamydia infection, by fibroids, by an IUCD, or without underlying cause; that is, dysfunctional bleeding, or resulting from other causes.

Transvaginal sonography

All included patients underwent standardised transvaginal sonography at the outpatient clinic of the Department of Obstetrics and Gynaecology at the Academic Medical Centre, Amsterdam. Sonography was performed by experienced gynaecologists using a 5–7 MHz transvaginal probe. A cervical chlamydia-polymerase chain reaction (PCR) test was performed immediately before every sonography. The sonographic findings were categorised as (1) normal findings, (2) fibroids, or (3) other findings. Normal findings were defined as a uterus with a regular contour, a homogeneously structured myometrium, or small (<3 cm in

size) fibroids, and a straight regular endometrial line and ovaries without cysts or other abnormalities.¹¹ Small fibroids were assessed as 'normal findings'. Current opinion is that the presence of these small fibroids has no clinical consequences.^{10,12} Predefined cut-off values for endometrial thickness were not used, since proper criteria are lacking.¹³

Fibroids ≥ 3 cm in size, or a uterus with multiple fibroids were categorised as fibroids. Sonographic findings suggestive of intracavitary abnormalities were also assessed as fibroids because of the clinical consequences — namely the necessity to carry out additional investigations.^{10,12} Coincidental abnormal structural findings such as a sonographic lucent ovarian cyst >3 cm in size were clustered as 'other findings'. A displaced IUCD was defined as being in the cervical position or partial cervical position. No validation of sonographic findings was carried out, as the interobserver agreement of experienced gynaecologists is good.¹⁴

Classification of working hypotheses and sonographic findings

To explore the value of sonography, the working hypotheses were related to the sonographic findings. The working hypotheses were therefore clustered into (1) 'no structural pathology', and (2) 'fibroids'. The working hypotheses 'bleeding due to hormonal contraceptive use', 'bleeding as a result of chlamydia infection', 'bleeding caused by an IUCD', or 'bleeding without underlying cause' were assessed as primary working hypotheses implying no structural pathology.

The working hypothesis 'no structural pathology' was considered to be in agreement with normal sonographic findings. The working hypothesis 'fibroids' was classified as being in agreement with sonographic fibroids ≥ 3 cm in size, multiple fibroids, and/or intracavitary abnormalities. Although GPs were not able to detect intracavitary abnormalities without sonography, these abnormalities were arbitrarily categorised as 'fibroids' because of their clinical relevance for carrying out additional investigations.

Contribution of sonography to patient management

To assess the contribution of sonography to the actual management of women with abnormal bleeding, GPs filled in a second questionnaire once sonography had been performed and its findings had been discussed with the patient. The second questionnaire addressed the GP's diagnosis

Table 1. Patient characteristics

Characteristic	
Number of patients	89
Median age [IQR], years	42 [36–46]
Bleeding pattern, <i>n</i>	
Heavy	25
Combination	25
Intermenstrual	22
Irregular	17
Duration of symptoms, <i>n</i>	
<3 months	33
≥3 months	56
Hormonal contraceptive use, <i>n</i>	
None or sterilisation	57
Oral contraceptive pill	14
IUCD	14
Copper	10
Levonorgestrel-releasing	4
Progestogen (continuous)	4
Country of origin, <i>n</i>	
Netherlands	49
Surinam or Netherlands Antilles	27
Other ^a	13

IQR = interquartile range. IUCD = intrauterine contraceptive device. *n* = number of patients.

^aData on two patients missing.

in view of sonographic findings, and the actual management that had been implemented — ‘watchful waiting’, start or stop medication, referral to a gynaecologist, or other type of management.

Analysis

Patient characteristics (age, bleeding pattern, duration of symptoms, contraceptive use, country of origin) were expressed using descriptive statistics. GPs’ working hypotheses were expressed in numbers. In order to explore the value of sonography, analysis was carried out to assess whether sonographic findings had confirmed the primary working hypotheses ‘no structural pathology’ and ‘fibroids’, or if they had resulted in other findings. GPs were instructed to choose only one working hypothesis. If, despite this request, GPs chose multiple working hypotheses without ranking them, these cases were excluded.

The impact of sonographic findings on GPs’ management was expressed in numbers. The initial referral rate and the actual management were described according to sonographic findings. Data were analysed in SPSS for Windows (version 17.0).

RESULTS

General characteristics

The participating GPs enrolled 122 patients (range: 1–20 patients per GP). Ten patients

were lost to follow-up because they did not go back to their GP after sonography. In another seven patients, data on the working hypothesis or management were missing. Data of a further 16 patients were excluded, as the GPs filled in multiple working hypotheses without ranking. This resulted in a total of 89 patients available for analysis (Table 1). The median age of the patients was 42 years (interquartile range 36–46 years). Both heavy bleeding and a combination of bleeding patterns were the most frequently reported symptoms for 25 patients. Almost two-thirds (56/89) had had symptoms for ≥3 months. Additionally, 57/89 did not use hormonal contraceptives or had been sterilised. Fifty-five per cent (49/85) of the patients were of Dutch origin.

Working hypotheses

GPs expected no structural pathology in 65 patients. The working hypothesis ‘no underlying cause’ was most frequently chosen in 37/65 patients, and other hypotheses implying no structural pathology in 28/65 patients. Fibroids were assumed in 24 patients.

With one exception, all included patients were screened for cervical chlamydia by means of a PCR test. In three patients, chlamydia infection was suspected, but PCR tests were negative. In two other patients, the PCR test was unexpectedly positive. Both patients had normal sonographic findings, suggesting that chlamydia infection was the sole cause of abnormal bleeding.

Sonographic findings

Sonography showed normal findings in 60/89 patients (Table 2). Sonographic findings suggestive of intracavitary abnormalities were the most frequently encountered abnormal findings: in 16 patients as a single finding, and in seven in combination with fibroids ≥3 cm in size, or multiple fibroids. Fibroids ≥3 cm in size or multiple fibroids ranked second, in 10 patients. A displaced copper IUCD was seen in five patients, that is, half of the copper IUCD users (5/10) (data not shown). Furthermore, sonography revealed an ovarian cyst in four patients — in two as a single finding, and in the other two in combination with other findings. In one patient, sonography showed a dehiscent cesarean section scar.

Agreement between working hypotheses and sonographic findings

In 50/65 patients with a working hypothesis ‘no structural abnormality’, indeed no

Table 2. Agreement between sonographic findings and GPs' working hypotheses (n = 89)

Sonographic findings	Working hypotheses, n		
	No structural pathology	Fibroids	Total
Normal findings	50	10	60
Fibroids			
Suggestive of intracavitary abnormality	10	6	16
Fibroids ≥ 3 cm ^a	2	8	10
Other findings ^b	3	0	3
Total	65	24	89

^aIn seven patients, sonography also yielded findings suggestive of intracavitary abnormalities. ^bIn two patients, an ovarian cyst was seen, and in one patient a dehiscence caesarean section scar.

abnormalities were detected by sonography (Table 2). Unexpected fibroids were present in 2/65 of these patients. Moreover, sonographic findings suggestive of intracavitary abnormalities were present in 10/65 of patients in whom no structural abnormalities were expected.

Fibroids suspected by the GP were confirmed in 14/24 patients. In 8/24 of these patients, fibroids ≥ 3 cm in size or multiple fibroids were revealed, and in 6/24 patients there were findings suggestive of intracavitary abnormalities. In 10/24 patients, sonography yielded normal findings.

Contribution of sonographic findings to management

The GPs' actual management after sonographic assessment was watchful waiting or drug therapy in 57/89 patients (Table 3). The majority of these patients (51/57) had normal sonographic findings. Watchful waiting or drug therapy was also the GPs' actual management in 5/23 patients with sonographic findings suggestive of intracavitary abnormalities. The initially intended referral rate rose from 9/89 to 27/89 after sonography. The majority of the referred patients (17/27) had sonographic findings suggestive of intracavitary abnormalities.

DISCUSSION

Summary

Open access to transvaginal sonography offered a relevant contribution to the diagnostic and therapeutic management of women with abnormal vaginal bleeding in primary care. Among the GPs' variety of working hypotheses expressed as possible causes of abnormal bleeding, the majority implied 'no structural pathology'. The agreement between normal sonographic findings and GP's working hypotheses 'no structural pathology' was 50/65. The agreement between sonographic fibroids

and the working hypothesis 'fibroids' was 14/24. In 23/89 patients, sonography yielded findings suggestive of intracavitary abnormalities. Sonographic findings allowed GPs to carry out actual management, mainly in terms of well-founded watchful waiting or drug therapy in 57/89 patients, and an increased referral rate for 27/89 patients. In a relatively high proportion of patients (23/89), anomalies amenable to hysteroscopic treatment were revealed. In addition, some problems revealed by ultrasonography could be dealt with in primary care, for example, displaced IUUD.

Strength and limitations

For the first time, this study allows an insight into both the underlying pathology and the contribution of sonography to management of women of reproductive age who consult their GPs for abnormal vaginal bleeding. Some limitations of the study need to be addressed here.

First, the question arises as to whether the patients included are representative of those encountered in primary care. The possibility of selection bias in this study, induced by participating GPs who may have included only those patients in whom underlying pathology was suspected, cannot be excluded entirely. However, the patients included in the study seem to reflect a typical general practice population, as only 9/89 of them were initially considered for referral to a gynaecologist. The included patients showed a variety of bleeding patterns, which were very similar to those found in another study performed in general practice by Shapley *et al.*⁴ This confirms that the study population reflects normal general practice. Further confirmation of this is provided by Emanuel *et al.*, who found a normal uterine cavity in 63% of patients referred for abnormal uterine bleeding.¹⁵ In the present study, a normal uterine cavity was found in 74%

Table 3. Sonographic findings and actual management after sonography (n = 89)

Sonographic findings	Actual management, n				Total
	Watchful waiting	Medication ^a	Referral	Additional investigation	
Normal findings	33	18	5	4	60
Fibroids					
Suggestive of intracavitary abnormality	1	2	13	0	16
Fibroids ≥3 cm ^b	0	3 ^c	6 ^d	1 ^e	10
Other findings ^f	0	0	3	0	3
Total	34	23	27	5	89

^aStart or stop medication, including replacement of an intrauterine contraceptive device. ^bIn seven patients sonography yielded as well findings suggestive of intracavitary abnormalities. ^cIn two patients sonography yielded as well findings suggestive of intracavitary abnormalities. ^dIn four patients sonography yielded as well findings suggestive of intracavitary abnormalities. ^eIn one patient sonography yielded as well findings suggestive of intracavitary abnormalities. ^fIn two patients ovarian cysts were seen, and in one patient a dehiscent caesarean section scar.

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Ethics committee

The study was approved by the medical ethics committee of the Academic Medical Center, University of Amsterdam, Amsterdam (reference number: 03/099).

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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(66/89) of patients, a sufficiently higher prevalence than was found in referred patients. In the Netherlands, the proportion of women aged 18–45 years taking oral contraception is much higher [41%]¹⁶ than the 16% (14/89) seen in the present study population. This may be explained by the fact that the use of oral contraceptives reduces and probably even prevents the occurrence of heavy and irregular bleeding, thus reducing the probability of its users being entered into the study.¹⁷ Compared with the general Dutch population, the present study population contained more patients of non-Western ethnicity. These were mainly black women from Surinam and the Netherlands Antilles, a population well known for its high prevalence of fibroids.¹⁸

Secondly, in the Netherlands, gynaecological ultrasound scans are usually done by gynaecologists, as in the present study, rather than by ultrasonographers. Therefore, some effect of inflating the actual referral number cannot be completely ruled out. The participating gynaecologists filled in a standardised sonography form and were instructed to refer the patient back to their GP for further management. In practice, gynaecologists advocate additional diagnostic work-up and removal of intracavitary abnormalities such as submucous fibroids and endometrial polyps.^{10,19} It might have been difficult for the GP not to refer. On the other hand, all patients contacted their GP for management after the ultrasound scan, and 5/23 patients with intracavitary abnormalities were not referred. The researchers did not ask the GPs to explain the motivation behind their management. Reasons for first-line treatment instead of referral might be mild symptoms, the patient's preference, or GP-related factors

and preferences.²⁰ Since the study was performed, the actual advocated management on abnormal bleeding has not been changed in more recent guidelines in the Netherlands.²¹

Third, despite vaginal sonography being generally accepted as a useful first-line diagnostic procedure, its accuracy varies depending on the type of uterine abnormality. In diagnosing intracavitary abnormalities in particular, transvaginal sonography is not considered as being the gold standard, but is generally accepted as being the first diagnostic step.^{10,12,13} Obviously, the diagnostic accuracy of vaginal sonography was beyond the scope of the present study.

Apart from the impact of sonographic findings on GPs' management of patients, some other important observations were made. A remarkably high number of displaced copper IUCDs was found — in 5/10 patients who had one. Displaced IUCDs are quite common, and apart from causing abnormal bleeding, are thought to be less effective in preventing pregnancies. A recent study reported that displaced copper IUCDs occurred in 29% of patients during an observation period up to 60 months.²² GPs should be aware of partial IUCD expulsion as a cause of abnormal vaginal bleeding, a complication that is easily detected by ultrasonography.

Comparison with existing literature

Some guidelines on abnormal vaginal bleeding recommend initial symptom-based medical treatment without further investigations.^{5,10} However, more information about normal sonographic findings may confirm the GP's diagnosis and may imply a solid argument for prescribing medical therapy to well-informed patients in general practice.^{20,23–25} Sonography is a safe procedure that is well-

tolerated by patients.²⁶ Nonetheless, vaginal sonography is an intimate procedure that might cause distress and discomfort for some women. Therefore, adequate information about the procedure is required.^{27,28}

To date, little is known about the cost-effectiveness of diagnostic procedures in patients with abnormal uterine bleeding.²⁹ Julian *et al* carried out a prospective non-randomised comparative study of a GP-led integrated care pathway and a consultant-led one-stop menstrual clinic for referred patients with menorrhagia.³⁰ After 8 months, there was no difference in treatment between the two groups, except for fewer outpatient appointments in the GP-led care pathway. In the present study, open-access sonography resulted in an increased number of referred patients who, outside this study, would have stayed under primary care. Obviously, some of these women would probably have been referred anyway, albeit at a later stage. The consequences of this change in management in terms of cost-effectiveness deserve further evaluation.

Giving GPs open access to transvaginal

sonography revealed the disagreement between their working hypotheses and sonographic findings. The contribution of this study to the management of women with normal scans is that GPs were able to reassure their patients with more confidence. It was also beneficial to those women with findings amenable to gynaecological treatment, who, because of the additional information from sonography, were referred more efficiently and without undue delay. This is especially important for those women with intracavitary abnormalities, amenable for hysteroscopic resection, which cannot be suspected and detected by any other means. In addition, some problems revealed by sonography could be solved in primary care, for example displaced IUCDs.

Implications for research and practice

Future research should focus on the yield of transvaginal sonography in primary care patients with abnormal vaginal bleeding in relation to symptom reduction and GP management, the patients' perspectives, and cost-effectiveness.

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