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Patients' preferences in the evaluation of postmenopausal bleeding

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Abstract

Objective: To assess patients' preferences for diagnostic management of postmenopausal bleeding (PMB).

Methods: A structured interview was taken from 39 women who had had an office hysteroscopy in the diagnostic work-up for PMB. Women were informed about the probability of endometrial carcinoma versus benign disease and about advantages and disadvantages of different diagnostic strategies, i.e. expectant management after ultrasound or complete diagnostic work-up including invasive procedures. Women were asked to make a trade-off between different options.

Results: Most women wanted to be 100% certain that carcinoma could be ruled out. Only 5% of the women were willing to accept more than 5% risk of false reassurance. If the risk of recurrent bleeding due to benign disease exceeded 25% the majority of women would prefer immediate diagnosis and treatment of benign lesions.

Conclusion: Women with PMB are prepared to undergo hysteroscopy to rule out any risk on cancer. This finding implicates that the measurement of endometrial thickness with transvaginal ultrasound as a first line test in the assessment of PMB should be reconsidered.

Introduction

Postmenopausal bleeding (PMB) is generally considered as a first symptom of endometrial cancer. Different authors have suggested starting the diagnostic work-up of women with PMB with transvaginal ultrasound (TVU) for the measurement of endometrial thickness.^{1,3} Guidelines in various countries recommend a cut-off value of 4 or 5 mm double layer of endometrial thickness.^{1,2,4} At this level, measurement of endometrial thickness has a sensitivity of 96% to diagnose endometrial carcinoma for a specificity of 50%. At a prevalence of 10% this implicates that a woman with an endometrial thickness ≤ 4 mm still has almost a 1% chance of having an endometrial carcinoma. Based on this post-test probability, expectant management is at present recommended to these women. In case the endometrial thickness is more than 4 mm, endometrial sampling is recommended. Other diagnostic procedures such as diagnostic hysteroscopy can also be used to further rule out endometrial cancer, but these procedures are substantially more invasive and incur additional health risks, increased discomforts and costs. Diagnostic hysteroscopy is at present not offered to women with endometrial thickness ≤ 4 mm. Although guidelines leave room for individual choices, the preference of the women has never been systematically taken into account when these guidelines were made.^{1,2,4}

The question is to what extent women are willing to accept a higher probability of cancer ($> 1\%$) associated with expectant management in case of thin endometrium, in order to avoid further invasive procedures. Although current guidelines presume that women consider this small risk as acceptable, empirical data on this presumption are lacking.^{1,2,4} The present study therefore addresses trade-offs and preferences for diagnostic management of women presenting with PMB at risk for endometrial carcinoma.

Materials and Methods

Study sample

The study was conducted in the St. Antonius Hospital, Nieuwegein, The Netherlands. The St. Antonius Hospital is a teaching hospital with an outpatient hysteroscopy department, where 500 hysteroscopies are performed annually. In this hospital, all women with PMB and an endometrial thickness > 4 mm undergo an outpatient hysteroscopy. Easily contactable women were selected on a sequential basis from an electronic database in which all women that visit the outpatient gynaecology department for PMB are recorded. Inclusion criteria for the study were: PMB, a completed diagnostic work-up including an outpatient hysteroscopy, benign diagnosis, ability to read and sufficient command of the Dutch language. The interviewer invited women by telephone to participate in a 45-minute interview at the hospital after explaining the study objective and procedure. The interviews were taken from January

2005 until March 2005. Women who had visited the outpatient clinic in 2004 were eligible for this study.

Structured interview

A structured interview was designed for systematic assessment of patient's preferences in the diagnostic work-up of PMB. The interview was reviewed by the department of communication of the St. Antonius Hospital with respect to patients' acceptability to the interview (readability, comprehensibility). All interviews were performed in an identical setting by the first author (A.T.). During the interview women were offered the questions on paper. The interviewer clarified problems, and discussed the questions with the women where necessary. The women provided their answers on paper.

The first part of the interview focused on endometrial carcinoma and consisted of questions regarding a trade-off between expectant management and performing a complete diagnostic work-up including endometrial sampling, providing reassurance with a false negative rate close to 0%. Women were informed about this trade-off and the different diagnostic tests involved (transvaginal ultrasound (TVU), endometrial sampling [Pipelle], saline infusion sonography [SIS], and diagnostic hysteroscopy). Women were presented with two scenarios: (A) TVU as a first step and in case of unsuspecting TVU result, expectant management thereby accepting a small risk of missing an endometrial carcinoma and avoiding further diagnostic invasive measures and (B) immediate invasive diagnostic procedure (office hysteroscopy with endometrial sampling) for all patients with almost complete reassurance. Women were asked whether they were willing to accept expectant management (i.e. no further procedures after ultrasound unless bleeding recurred), and what they considered an acceptable risk for missing a carcinoma (Table 1).

Table 1. Questions regarding the diagnostic management

Questions					
If I had to choose between expectant management and thereby avoiding further invasive diagnostic procedures (A) or immediate reassurance with a complete diagnostic work-up (B), I would choose	A, surely	A, probably	No preference	B, probably	B, surely
Would you accept a small chance of missing of tumour to avoid unnecessary, invasive diagnostic procedures?	Yes, surely	Yes, probably	Maybe	No, probably	No, surely
How many percent do you need to be sure of absence of a tumour to avoid invasive diagnostic procedures?					

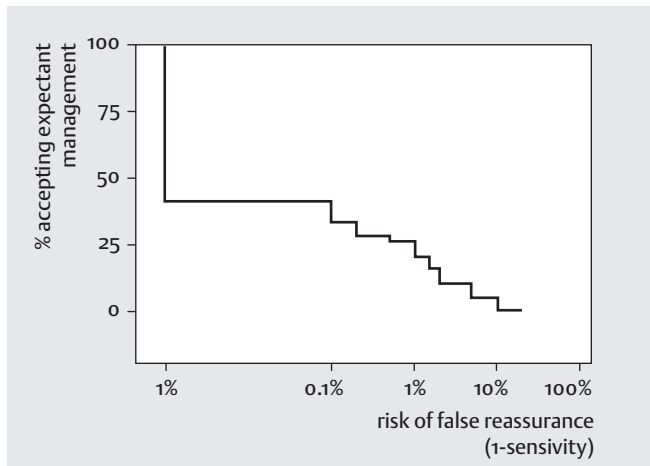
The second part concerned management of polyps. Women were informed that in case malignancy was excluded with endometrial biopsy (Pipelle), there still remained a chance of presence of a benign endometrial polyp. Thereby, they were presented with two scenarios: (A) expectant management and only in case of recurrent bleeding hysteroscopy to evaluate presence or absence of endometrial polyp, and treatment in case of a polyp or (B) immediate hysteroscopy to diagnose endometrial polyp and in case of presence of a polyp, treatment in the same session. In scenario A, the chance of recurrent bleeding was systematically increased from 0 to 100% until women indicated indifference or preference for immediate diagnostic assessment. Costs associated with diagnostic procedures were not considered in the scenarios.

Results

In 2004, 70 women had a hysteroscopy because of PMB, of which 7 women had endometrial carcinoma. Of the remaining 63 women, 49 women were randomly selected from the database. Three women did not meet the inclusion criteria (one woman was deaf, one woman was mentally disabled and one woman could not read or speak Dutch). Three women refused to participate, six women were not mobile enough to come to the hospital and three women did not show up on their interview appointment and for these women three other women were selected in the same manner by which the other women had been selected. Therefore, 40 women were interviewed. At the interview one woman had turned out to have an endometrial carcinoma diagnosed; she was not included in the analysis.

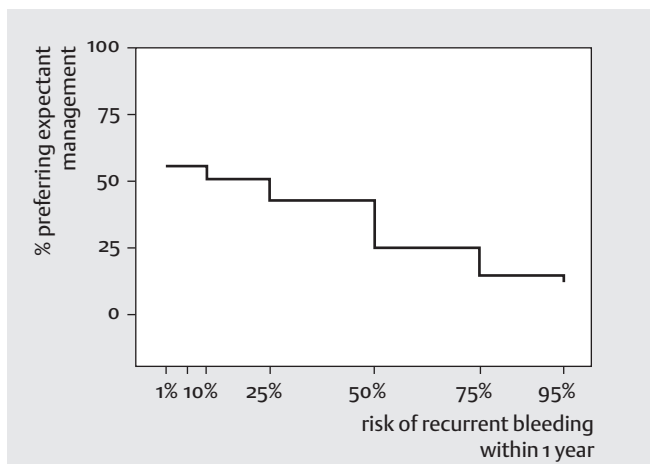
With respect to the diagnostic management to rule out endometrial carcinoma, 35 women (90%; 95% CI: 76 to 96%) indicated that they definitely wanted to rule out presence of carcinoma. Four (10%; 95% CI: 4 to 24%) would opt for expectant management. Subsequently women were asked to give a percentage on the absence of endometrial carcinoma in order to accept expectant management. Twenty-three women (59%; 95% CI: 43 to 73%) wanted to be 100% certain that carcinoma could be ruled out, 14 women (36%; 95% CI: 23 to 52%) wanted to be sure for 95-99.9% that carcinoma could be ruled out, while two women (5%; 95% CI: 1.4 to 17%) were willing to accept a risk > 5% (Figure 1).

Figure 1. Acceptance of expectant management



In the trade-off between immediate diagnosis and subsequent treatment of polyps on one hand or expectant management on the other hand, women were more likely to accept an expectant approach. The lower the risk of recurrent bleeding was made, the more women would opt for expectant management. Only if the risk of recurrent bleeding within one year exceeded 25%, the majority of women would prefer immediate hysteroscopy for polyp detection (Figure 2).

Figure 2. Acceptance of expectant management depending on risk of recurrent bleeding after malignancy has been excluded



Discussion

To our knowledge, this study is the first to elicit preferences from women with PMB with respect to the diagnostic management. Most women with PMB expressed a strong preference for being informed about the diagnostic management of their complaints and the different options available to them, and they preferred to participate in this decision. The vast majority of women wanted cancer to be ruled out with almost 100% certainty. In this study women were given a choice between an invasive test with almost 100% certainty and expectant management with less but still high certainty. The women in this study were aware of the fact that in the context of diagnostic testing 100% certainty is not available. With respect to the diagnostic work-up of benign pathology (endometrial polyps) women were more likely to accept expectant management, but only if the risk of recurrent bleeding did not exceed 25%.

A potential limitation of our study is that women were interviewed after establishment of a diagnosis and that all but one woman had benign disease. However, we speculate that women with a diagnosis of endometrial carcinoma are more willing to rule out uncertainty. As women were almost unanimous in their choice to rule out cancer with almost 100% certainty, it is not likely that including women with endometrial carcinoma in the sample would alter our main findings. Moreover, our sample was relatively small and of 49 women meeting the inclusion criteria, 40 women participated. As nonparticipation (17%) was merely due to logistic problems, it is not likely that these women would have deviating preferences, although this cannot be completely ruled out. However, the results were homogenous and show strong pointing into an almost 100% certainty.

Another source of bias could result from the fact that all women had undergone a hysteroscopy at the time of the interview. Due to a phenomenon called cognitive dissonance reduction, people change their perceptions in order to make their situation seem better. This might have influenced the results in a more positive attitude towards hysteroscopy. However, the actual experience of the hysteroscopy has provided women with realistic information of this procedure. Most women deemed office hysteroscopy a rather easy and minimal invasive procedure.

What are the implications of our findings for clinical practice? The definition of evidence-based medicine is to integrate the best available research evidence with clinical expertise and patients' values.⁵ At present, guidelines for the diagnostic work-up of women with PMB recommend to start with TVU and advise expectant management in case endometrial thickness < 5 mm.¹⁻⁴ Our study shows that this is not in line with patients' preferences as thin endometrium does not rule out cancer and the probability of false reassurance is 1%. One should keep in mind that the prevalence of endometrial carcinoma can vary among different populations.

In the Netherlands the prevalence of endometrial carcinoma lies around 10%.⁴ In the UK, the prevalence has been reported to be 5%, this changes the probability of false reassurance after TVU to 0.4%.⁶ With respect to endometrial carcinoma, 60% wanted to be sure for 100%. The majority of the patients would not even accept a risk of 0.4% of missing endometrial carcinoma, as is the case in a population with a prevalence of 5%. This implicates that the position of TVU as a first test in women with PMB should be reconsidered.

Women expressed a preference for immediate diagnosis and treatment of endometrial polyps in case the probability of recurrence of bleeding was estimated to be 25% or more. This contradicts with current practice where expectant management usually is advised once cancer has been ruled out by endometrial sampling and evaluation of the uterine cavity for the presence of polyps is only undertaken in case the bleeding recurs. However, the risk of recurrent bleeding in case an endometrial polyp left in situ is not known, therefore it is difficult to formulate an evidence-based policy for benign lesions.⁷

In summary we found that women with PMB show a strong risk aversion. As a consequence, they are prepared to undergo invasive procedures to rule out endometrial cancer. In our opinion the choice of TVU as a first step in the work up for PMB should be reconsidered.

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