

Comparison of Pipelle and Hysteroscopy with D&C in Postmenopausal Patients

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Abstract

Objective: The aim of the study is to compare the pipelle method and hysteroscopy with D&C in postmenopausal patients

Methods: In this prospective study, only those postmenopausal patients with postmenopausal bleeding and/or with a sonographically highly developed endometrium who were referred for hysteroscopy with D&C were included. A total of 92 patients were included in this study. Before each procedure, patients were explicitly informed about the study and gave consent. On the condition of anonymity of personal data (surname and first name, date of birth) and after signing a special informed consent form, the patients were allowed to be included in the study. The study was performed as a double-blind study. The obtained histologies (from pipelle and D&C) were sent separately to the same pathologist.

Results: The group with malignant and premalignant findings has a central role in our study. After evaluation of the histologically malignant findings from the pipelle and the D&C, the sensitivity of the pipelle in our study was 82%.

Conclusion: Endometrial biopsy is an important step to exclude endometrial carcinoma in postmenopausal bleeding. The aim is to minimize the burden and invasiveness of the procedure while maintaining a high degree of diagnostic certainty to avoid unnecessary invasive surgery. The pipelle sampling can be used as an outpatient method without anaesthesia during routine examination. Our study shows that this method of sampling is a safe, accurate and cost-effective outpatient procedure with high sensitivity for the detection of endometrial carcinoma.

Keywords: pipelle; hysteroscopy; D&C; endometrial carcinoma; postmenopausal bleeding

Introduction

Abnormal uterine bleeding is a common gynecological problem causing 33% of outpatient presentations. In the pre-menopausal and postmenopausal age groups, it accounts for as many as 69% of the presentations [1].

Investigating of postmenopausal bleeding is crucial in order to determine whether the cause is of a benign nature or due to an endometrial carcinoma [2]. Any postmenopausal bleeding should be assumed to be a carcinoma until proven otherwise [3]. Postmenopausal bleeding is most common in the age group of 55–59-year-olds [4]. In contrast, the highest incidence of endometrial cancer is between the ages of 75 and 79 and endometrial carcinoma is the 7th most common malignancy in women

worldwide, with an annual incidence of 142,000 new cases [5, 29]. Postmenopausal bleeding is more common in women who have not taken hormones [6]. Postmenopausal bleeding is special among bleeding cases because this phase of life has the highest incidence of endometrial carcinoma, and postmenopausal bleeding is often the initial symptom for endometrial carcinoma (the most common genital carcinoma in women). Thus, new-onset bleeding at this stage of life requires special clinical attention [7]. Postmenopausal bleeding is associated with an increased risk of endometrial carcinoma even if the endometrium cannot be visualized sonographically [8]. Common causes of bleeding also include endometrial polyps and endometrial hyperplasia; however, submucosal fibroids may also be relevant to bleeding. [7, 9]. The risk of endometrial carcinoma in asymptomatic postmenopausal women with an endometrial

thickness of >11mm is approximately equal to that of postmenopausal women with postmenopausal bleeding and an endometrial thickness of 5mm. The relative risk of endometrial carcinoma is 6.7% in both collectives [10]. Histological examination of the removed tissue is an obligatory requirement for a definitive diagnosis. Hysteroscopy and D&C are the gold standard of endometrial diagnostics [11, 12]. However, in recent decades, thanks to newer simplified diagnostic and therapeutic methods, management has changed [3]. In addition, the surgical risk of general anaesthesia, infection, and perforation still exists [11, 12]. This has led to new and simpler methods for endometrial biopsy, including the pipelle instrument [13, 14]. The pipelle is less expensive compared to hysteroscopy with D&C [15]. Although the pipelle is included in many guidelines, it is rarely used in practice in Germany. However, there are still concerns about the informative value of the obtained sample, especially in the case of focal intrauterine changes [14].

Method and material

In this prospective study, only those postmenopausal patients with postmenopausal bleeding and/or with a sonographically highly developed endometrium who were referred for hysteroscopy with D&C were included.

Post-menopause was defined (according to WHO) as the period beginning 12 months after the last menstrual period. Any bleeding during this period was defined as a postmenopausal bleeding [6, 7].

A total of 92 patients were included in this study. Before each procedure, patients were explicitly informed about the study and gave consent. On the condition of anonymity of personal data (surname and first name, date of birth) and after signing a special informed consent form, the patients were allowed to be included in the study.

Preoperative transvaginal sonography for endometrial assessment and hysteroscopy were mandatory requirements of this study.

Pipelle sampling was performed as part of the usual planned procedure under general anaesthesia. After disinfection of the external and internal genital organs and speculum insertion without fixation and dilatation of the cervix as well as probing the uterus (exceptions only in individual cases), the pipelle was inserted through the cervical canal into the fundus of the uterus. It was then possible to determine the probe length using the printed scale. Then the plunger of the pipelle was pulled out as far as possible to achieve an optimal vacuum. The suction curette was pushed back and forth in the uterus several times with simultaneous rotations in order to obtain examination material from all around the cavity. The pipelle was then completely withdrawn from the uterus. This was followed by planned hysteroscopy and D&C.

The study was performed as a double-blind study. The obtained histologies (from pipelle and D&C) were sent separately to the same pathologist. The pipelle material was labelled with a specific number without patient data. Unblinding of the materials was performed if carcinomas, atypical hyperplasia, or other suspicious findings (of unclear cause) were found in the biopsies. In these cases, the findings were assigned to the patients and compared with the histology of the D&C.

Since complex hyperplasia has a higher risk of coexisting with atypical hyperplasia and/or endometrial carcinoma than simple hyperplasia without atypia, it was evaluated separately.

Pipelle sensitivity was calculated:

Sensitivity = (true positive/ true positive + false negative) X 100.

Results

The age of the patients was between 44 and 97, with the largest group being age group between 50 and 55 years (Figure 1).

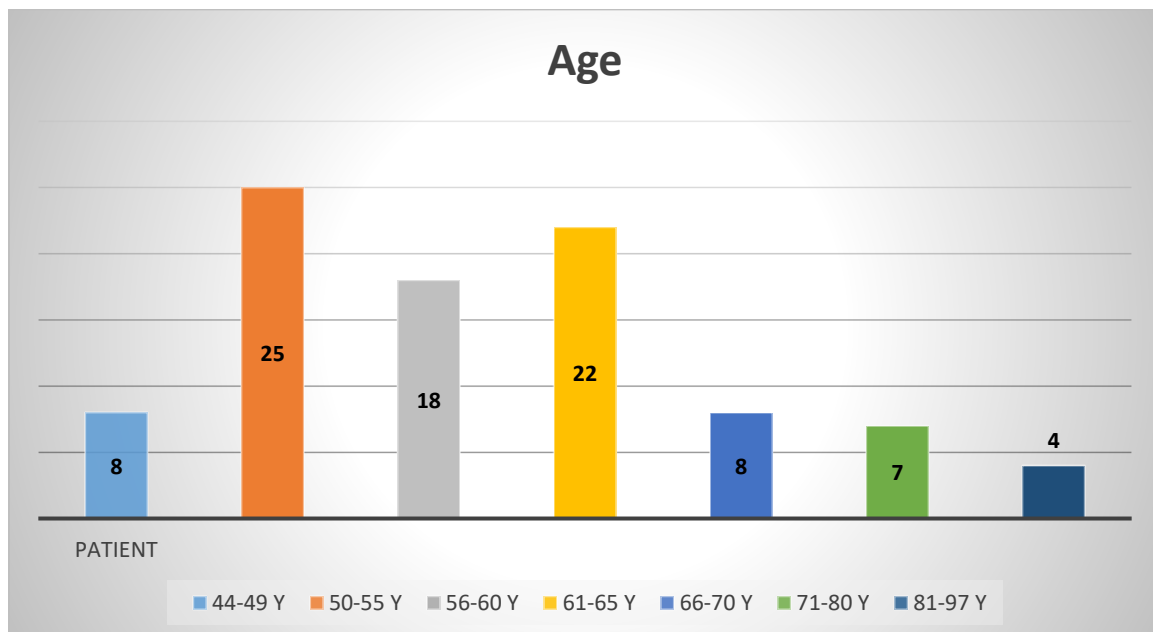


Fig. 1 Age groups of female patients

11 patients (12%) had a double endometrial thickness of <5 mm, 46 patients (50%) of 5-10 mm, and 35 patients (38%) of >10 mm.

The indication for hysteroscopy with D&C was postmenopausal bleeding in 74 cases (80.4%) and a sonographically high endometrium in 18 cases (19.6%), with an average double endometrial thickness of 12 mm in asymptomatic patients.

Figure 2 shows the histologic findings obtained by hysteroscopy with D&C.

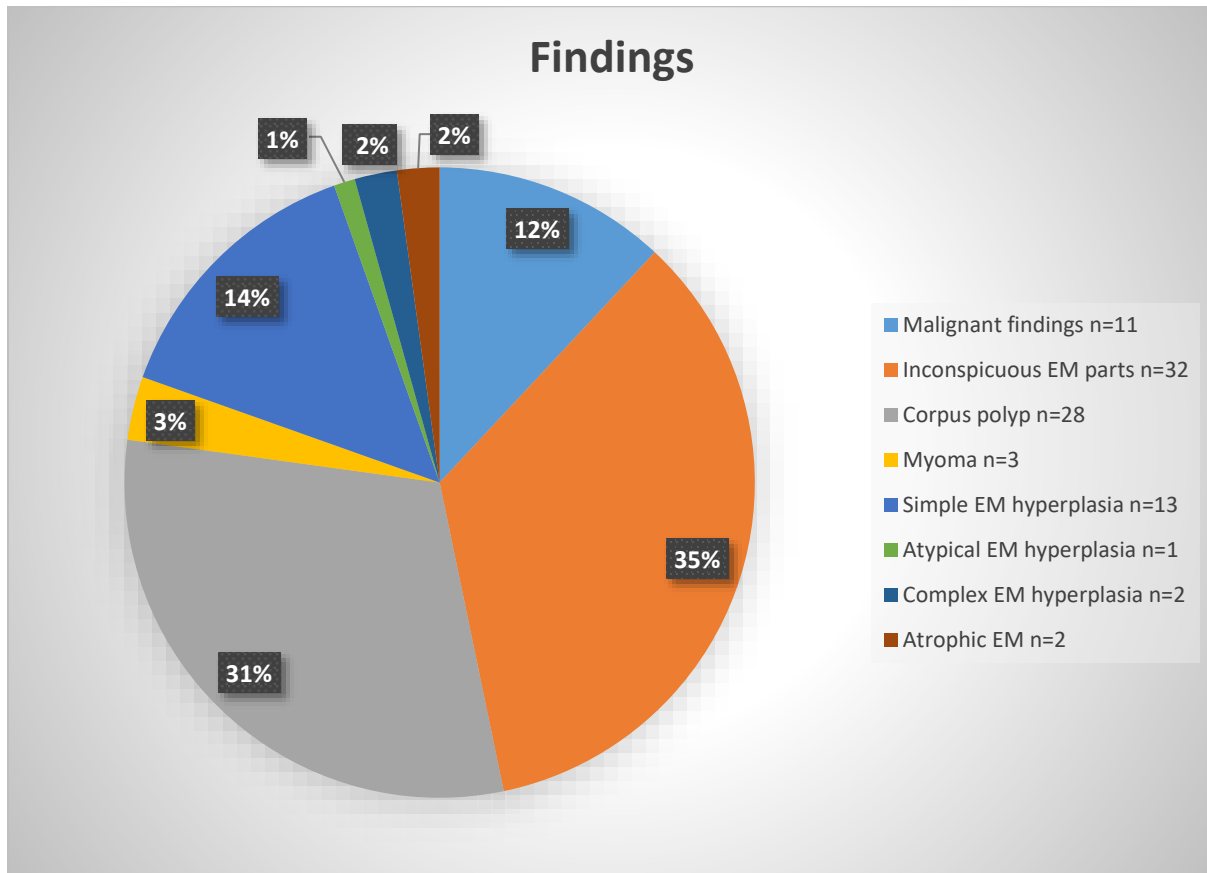


Fig.2 Histological findings obtained by hysteroscopy with D&C

13 patients had malignant findings. Of these hysteroscopy with D&C was able to detect the findings in 11 cases and using the pipelle method 9 cases were detected (Table 1).

Case	Double EM Thick-ness	Pipelle	Curettag	Uterus
1	6 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
2	6 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
3	8 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
4	10 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
5	11 mm	No atypia	Focal atypical endometrial hyperplasia	Focal endometrial hyperplasia without atypia (complex hyperplasia)
6	13 mm	Complex hyperplasia (without atypia)	Complex hyperplasia (without atypia)	Endometrial carcinoma
7	13 mm	No atypia	Endometrial carcinoma	Endometrial carcinoma
8	14 mm	No atypia	Focal complex hyperplasia (without atypia)	Focal endometrial carcinoma
9	16 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
10	16 mm	Endometrial hyperplasia without atypia (complex EM hyperplasia)	Endometrial carcinoma	Endometrial carcinoma
11	19 mm	Suspicious finding. Cause cannot be clearly assessed.	Endometrial carcinoma	Endometrial carcinoma
12	23 mm	Endometrial carcinoma	Endometrial carcinoma	The patient has refused further therapy
13	23 mm	Endometrial carcinoma	Endometrial carcinoma	Endometrial carcinoma
14	28 mm	Sparse EM-portions with focal strong decidual stromal reaction. Suspicious findings	Cx: necrotic tissue parts. Suspicious findings	Intramurally developed endometrial stromal sarcoma.

Table 1 Overview of malignant and premalignant findings

The accordance of the pipelle method with the D&C was calculated for individual findings in the total group as well as in the subgroups, depending on the endometrial double thickness (Table 2).

Findings	Total			<5mm			5-10 mm			>10mm		
	Curettagage	Pipelle	Accordance	C	P	A	C	P	A	C	P	A
Inconspicuous endometrium parts	32	31	97%	7	7	100%	21	20	95%	4	4	100%
Corpus polyp	28	2	7%	2	0	0%	13	1	7,7%	13	1	7,7%
Myoma	3	0	0%	-	-	-	2	0	0%	1	0	0%
Atrophic endometrium	2	1	50%	1	0	0%	1	1	100%	-	-	-
Simple endometrial hyperplasia	13	5	38,5%	1	0	0%	5	3	60%	7	2	28,6%
Complex endometrial hyperplasia without atypia	2	1	50%	-	-	-	-	-	-	2	1	50%
Atypical endometrial hyperplasia	1	0	0%	-	-	-	-	-	-	1	0	0%
Malignant	11	9	82%	-	-	-	4	4	100%	7	5	71,4%

Table. 2 Accordance of the pipelle with the D&C

Discussion

The aim of this study is to investigate the sensitivity of the pipelle in the group with postmenopausal patients. A correlation between endometrial thickness and pipelle sensitivity could not be investigated due to the small number of patients with endometrial thickness <5mm (Table 2). With an endometrial thickness above 5mm, the pipelle showed almost equal results in both groups, with endometrial thickness 5-10mm and >10mm (Table 2). Our previous study showed that although the probability of obtaining an adequate sample is largely independent of endometrial thickness in the overall population regardless of menopausal status, it increases for individual findings at an endometrial thickness greater than 5mm [16]. The study by Elsandabesee and Greenwood [17], who examined 97 patients with postmenopausal bleeding, showed that in a group of women with an endometrial thickness of <5mm, there was only a 27% chance of obtaining an adequate endometrial sample.

The sensitivity of the pipelle depends on the type of findings (Tab. 2). In the case of an unremarkable endometrium, the pipelle showed a 97% accuracy (Tab. 2). Unremarkable endometrium was defined as regular, proliferated, and secretory endometrium. In one case, the pipelle method showed simple hyperplasia. Histological examination of the sample from the D&C revealed an unremarkable endometrium.

The situation is different for polyps (7%) and myomas (0%). When diagnosing polyps and fibroids, it should be noted that these are local findings which are difficult to detect even with a curettage without prior hysteroscopy. Especially if a fibroid or polyp is already suspected on sonography, it is particularly useful to perform a hysteroscopy in order to be able to perform a targeted sampling and, if necessary, a surgical hysteroscopy. Kuruvilla et al [18] also found that the most common missed diagnosis on endometrial sampling using the pipelle was an endometrial polyp. They included 102 patients over 35 years old in their study. In 32 cases with insufficient or no endometrial tissue, endometrial polyps were found in 22 cases (68.7%) [18].

The sensitivity for simple hyperplasia in our study is 38.5%, with the best results at an endometrial thickness of 5-10mm (60%) (Table 2). As

described above, in one case simple hyperplasia was detected by pipelle but could not be detected by D&C.

Due to the small number of patients, the sensitivity of the pipelle in complex and atypical hyperplasia could not be sufficiently investigated in this study. However, false positive findings did not occur. In one case, the pipelle showed an unremarkable finding, although focal atypical hyperplasia was detected in the histology from the D&C (Table 1, case 5). However, only focal complex hyperplasia without atypia was noted in the hysterectomy preparation. It can be assumed that the focal atypical hyperplasia was completely removed during the D&C.

Clark et al [19] concluded that ambulatory endometrial biopsy has moderate accuracy in diagnosing endometrial hyperplasia. Therefore, additional endometrial examination (vaginal sonography, hysteroscopy, D&C) should be performed, especially if symptoms persist or intrauterine structural abnormalities are suspected [19]. In contrast, Sarwar et al [20] proved that the Pipelle showed 100% sensitivity in endometrial hyperplasia (in women with postmenopausal bleeding).

The group with malignant and premalignant findings has a central role in our study. As shown in Table 1, 13 patients had malignant findings and one patient had a premalignant finding.

D&C detected malignant findings in 11 cases and pipelle in 9 cases:

- Pipelle histology and D&C histology matched in nine cases

- In one case, the pipelle biopsy did not show a definite malignant finding, but the finding was described as suspicious (Table 1, case 11). A carcinoma was detected in the D&C. This statement can be considered a suspicious finding that could indicate a malignant finding. In another case, a suspicious finding was detected by pipelle biopsy. D&C revealed necrotic tissue (suspicious finding). Following the workup of the endometrium after hysterectomy, an endometrial stromal sarcoma was found (Table 1, case 14). Since a malignant finding was detected in both cases, the pipelle result can be considered a true positive in these cases.

After evaluation of the histologically malignant findings from the pipelle and the D&C, the sensitivity of the pipelle in our study was 82% (Table 2).

In two cases, neither the pipelle, nor the D&C could detect an endometrial carcinoma. In one case, both pipelle biopsy and D&C showed the same findings but no malignancy: complex hyperplasia without atypia. The result after a hysterectomy was an endometrial carcinoma of the endometrioid type (Table 1, case 6).

And in one case, the pipelle biopsy showed unremarkable findings and the D&C showed complex hyperplasia without atypia. However, a focal adenocarcinoma was found in the post-hysterectomy preparation (Table 2, case 10).

The results of the present study show that pipelle is as safe as D&C for malignant findings in all but 82% of the total group, although the number of cases of malignant findings is small (Table 2).

According to the literature review, the sensitivity of the pipelle for malignant findings ranges from 83% to 100% [15, 16, 21-28].

Behnamfar et al [21] compared pipelle and D&C in 87 patients with postmenopausal bleeding. A total of 17 malignant findings were found. The sensitivity of the pipelle was 94%. Machado et al [22] demonstrated a sensitivity of 84.2% for endometrial carcinoma and atypical hyperplasia in their study and concluded that endometrial biopsy by pipelle is an accurate method for the diagnosis of endometrial carcinoma and atypical hyperplasia. Huang G. et al [23] studied 360 patients with endometrial carcinoma and concluded that the pipelle has a sensitivity of 93.8% in low-differentiated and 99.2% in highly differentiated endometrial carcinoma.

They concluded that endometrial biopsy with the pipelle is an accurate method [23]. In the study by Del Priore et al [24], 101 patients (mean age 58 years, range 35-86) received the pipelle sampling. 21 carcinomas were detected, with a sensitivity of 86%. Sany et al [25] also showed a 86% sensitivity of pipelle for carcinomas. In the study by Fakhar et al [15], 100 patients were examined with the pipelle followed by normal curettage. Two endometrial carcinomas were found and for these, the pipelle examination showed a sensitivity of 100% in diagnosing an endometrial carcinoma [15]. The study by Stovall et al [26] also showed a high sensitivity of the pipelle in endometrial carcinomas. 40 patients with a known endometrial carcinoma were included in this study. In 39 cases, pipelle was able to confirm this diagnosis. Therefore, this study showed a sensitivity of the pipelle in endometrial carcinoma of 97.5% [26]. In their study, Guido et al [27] examined 65 patients with known endometrial carcinoma. Malignancy was detected in 54 of 65 patients with a sensitivity of 83% by pipelle biopsy [27]. However, it should be critically noted that in both studies the diagnosis was already known prior to pipelle biopsy.

A 100% sensitivity was shown by Ibrahim et al [28] in his work, in which they had 10 carcinoma cases.

In our study, no endometrium was obtained by pipelle in only three cases (33 %) which can be considered a good result. It should be noted that the pipelle biopsy was performed under anaesthesia, but without prior dilatation. When used without anaesthesia in practice, the error rate could be slightly higher.

It must be mentioned separately that there were no false positive malignant findings in the study.

Limitation of the study:

The pipelle biopsy was carried out under anaesthesia.

Conclusion

Endometrial biopsy is an important step to exclude endometrial carcinoma in postmenopausal bleeding. The aim is to minimize the burden and invasiveness of the procedure while maintaining a high degree of diagnostic certainty to avoid unnecessary invasive surgery. In practice,

various methods of endometrial sampling and endometrial assessment are used. Hysteroscopy combined with a D&C is a minimally invasive procedure usually performed under general anaesthesia. By contrast, the pipelle sampling can be used as an outpatient method without anaesthesia during routine examination. Our study shows that this method of sampling is a safe, accurate and cost-effective outpatient procedure with high sensitivity for the detection of endometrial carcinoma.

Informed consent

Each patient was informed about the study. Written consent from the patient was a prerequisite for this study.

Ethical approval

All patients have been explicitly informed and the intervention took place after the patient's written consent, as part of the planned hysteroscopy with curettage. This study was carried out in consensus with our university's ethics guidelines.

Conflict of interest

The authors have no conflict of interest.

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