

Endometrial sampling: a comparison between the Pipelle® endometrial sampler and the Endosampler®

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Abstract

Objective: To compare the adequacy of endometrial sampling by the Endosampler® and the Pipelle®.

Methods: A total of 68 women were randomly assigned to submit to pre-hysterectomy endometrial sampling, either by the Endosampler® or the Pipelle®. The amount of endometrial tissue sampled was measured by calculating the percentage endometrium sampled by each of the two devices. Acceptance by the gynaecologist was measured on a linear scale.

Results: The Endosampler® sampled significantly more endometrial tissue than the Pipelle® endometrial sampler (p-value = 0.03). Acceptance of the Endosampler® was better than that of the Pipelle® (p-value = 0.0005). With the use of the Pipelle®, three significant endometrial lesions were missed, including endometrial carcinoma in one instance.

Conclusion: The Endosampler® appears to be an easy-to-use device for endometrial sampling, with reliable diagnostic yield.

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Introduction

Dilatation and curettage (D and C) is used to collect endometrium in patients with abnormal uterine bleeding who are at risk of acquiring endometrial cancer. It has long been considered the gold standard against which other endometrial sampling techniques have been measured. The disadvantages of D and C include the use of a general or regional anaesthetic, and therefore use of an operating theatre. D and C is consequently costly and time consuming, with potential complications from a general anaesthetic. For these reasons, several, mainly outpatient, procedures have replaced the D and C, and are now performed routinely.¹

Many outpatient endometrial sampling methods utilising disposable devices have been studied. Due to time constraints and studies involving small patient numbers, it has proven difficult to prove the superiority of one endometrial sampling device over another. Moreover, not all studies include diagnostic correlation with hysterectomy, which thus precludes

the diagnostic accuracy of endometrial sampling techniques.²⁻³

Over the years, the Pipelle® endometrial suction curette (Unimar, Wilton CONN) has become a very popular device in outpatient endometrial sampling. Reasons for its popularity are that the Pipelle® is easy to use, obtains supposedly enough tissue for diagnosis, and confers acceptable patient comfort. However, there are conflicting reports about its appeal, in particular when comparing the Vabra® aspirator with the Pipelle®. Rodriguez et al found that the Vabra® aspirator obtained more tissue, while Kaunitz et al reported that the Pipelle® obtained more tissue.^{4,5} Manganiello et al found no difference between the Vabra® aspirator and the Pipelle®.⁶

The Endosampler®, a joint venture between MedGyn and Lombard ILL, is a disposable device that is used to sample endometrium. It works in the same way as the Vabra® aspirator, but without the cumbersome set-up. The purpose of the current study was to

compare the yield of the Endosampler® with that of the Pipelle® in patients undergoing hysterectomy.

Method

A total of 68 consecutive patients who had been booked for hysterectomy were recruited for this study. The endometrial samples were obtained just prior to hysterectomy, while the patient was already anaesthetised. After inserting a catheter to empty the bladder prior to the operation, the endometrium was sampled. Patients were randomly assigned to either endometrial sampling using the Pipelle® endometrial sampler or the Endosampler®. All of the patients gave their written consent to undergo the endometrial sampling. Patients who had had an endometrial sample less than one month prior to hysterectomy were excluded from the study.

The Pipelle® endometrial sampler is a flexible plastic device which is 23.5 cm long, with a 3.1 mm external diameter. At the side of the rounded tip of the Pipelle® is a 2 mm circular opening (Figures 1a and 1b). After grasping the cervix with a single tooth vulsellum, the device is inserted into the uterine cavity and negative pressure is created by withdrawing an internal piston. The length of the cavity was carefully recorded. With negative pressure, and with the opening against the endometrium, the Pipelle® was then moved five times back and forth to complete an approximate circle. While maintaining negative pressure, the Pipelle® was removed from the uterine cavity. Its contents were subsequently placed in a container with formalin, after the distal tip of the Pipelle® had been removed.

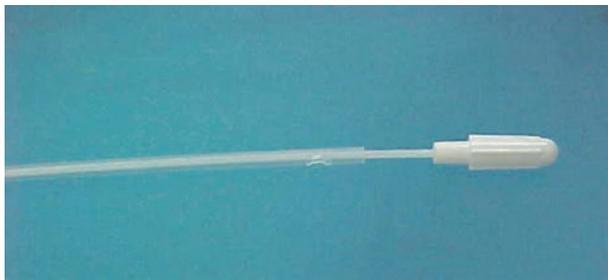


Figure 1a: The Pipelle® sampler



Figure 1b: A detailed view of the Pipelle® sampler

The Endosampler® is a plastic device with length of 23 cm. The external diameter of the tube is 3 mm. At the side of the rounded tip of the device is a 4 mm opening which is not entirely flush with the tube, but has the shape of a small curette (Figures 2a and 2b). Six centimetres from the tip is an angle of 160 degrees to accommodate the angle of the uterus. Negative pressure is created by a 10 ml syringe at the base of the device. The syringe can be detached from the base and has a spring lock to maintain negative pressure. The cervix was grasped with a single-tooth vulsellum, and after insertion of the device, and with the opening against the endometrium, five passes were made to complete an approximate circle. The device was removed from the cavity while maintaining negative pressure. The length of the cavity was carefully recorded and the spring lock was then unfastened. By pushing in the piston of the syringe, the contents were then deposited in a container containing formalin.



Figure 2a: The Endosampler®



Figure 2b: A detailed view of the Endosampler®

All biopsies were analysed by the same investigator, who was unaware of which device was used. In the laboratory, each uterus was opened in half along the lateral borders. The endometrial surfaces and the endometrial/myometrial interface were photographed in the fresh/unfixed state. A photomicrograph was produced, from which endometrial denudation was quantified. The surface area of the endometrial cavity after hysterectomy was photocopied from the photomicrograph on to gridded graph paper, and areas of denudation caused by endometrial sampling were blocked (Figure 3).

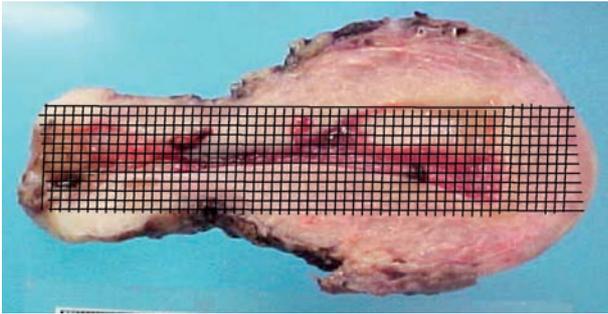


Figure 3: Superimposed grid to assist counting areas of denudation and percentage endometrium sampled

These blocked areas were then proportionally assessed as the percentage of endometrial surface that had been sampled. This method has been described previously.⁴ The endometrial biopsies and the uteruses were subsequently processed in the standard way. At least four sections of the endometrium were submitted (two from the anterior and two from the posterior surface). Additional sections from any macroscopically abnormal areas, or areas of denudation, were also removed. The histological sections were reported in the standard way by one of the authors (JW). A pro forma questionnaire was completed by this author. Demographic data such as age, parity, postmenopausal status and uterine length were recorded. The surgeon was also asked to score the acceptability of the device used, with "1" indicating "well accepted" and "5" for "unacceptable".

Results

A total of 68 patients were entered into the study and randomly assigned to pre-hysterectomy endometrial sampling with either the Pipelle® or the Endosampler®. One patient in the Endosampler® group was excluded from the study, as her pre-hysterectomy endometrial sample specimen has been lost. This left 67 patients for analysis. Thirty-four patients were

assigned to the Pipelle® group and the remaining 33 patients underwent endometrial sampling using the Endosampler®. The mean age for both groups was similar (Table I). Other demographic variables, such as mean parity, number of Caesarean sections, mean uterine size, number of postmenopausal patients and number of previous cervical procedures [large loop excision of the transformation zone (LLETZ)] for the two groups were also similar.

The mean acceptability score by the surgeon for the two devices showed a statistical difference. The spectrum ranged from "1" for "easy to use" to "5" for "very difficult to use". The score for the Endosampler® was 1.2, while that for the Pipelle® was 1.8 (p-value = 0.0005).

Although 8 out of 34 patients (23.5%) in the Pipelle® group rendered inadequate specimens for evaluation, while the corresponding numbers were 5 out of 33 (15.2%) in the Endosampler® group, this proved not to be statistically different (p-value = 0.29). In the Pipelle® group (Table II), in 3 out of 8 patients with an inadequate sample, access to the endometrial cavity could not be obtained. Corresponding figures for the Endosampler® group were 2 out of 5 patients.

An analysis of the sampled endometrium showed that, in the Endosampler® group, statistically significant more endometrium (14.5%, range 1-50%) had been sampled when compared to endometrial sampling with the Pipelle® (9.4%, range 1-20%) (p-value = 0.03). In the Endosampler® group, no significant endometrial abnormalities were found. In the Pipelle® group, three patients with significant endometrial abnormalities were missed using the pre-hysterectomy sampling. Of these three patients, one (44 years old) harboured a grade 1 endometrioid adenocarcinoma in a polyp, surrounded by atypical complex hyperplasia, in the uterine specimen. The second patient (60 years old) was found to have atypical hyperplasia in the uterine specimen, and mild hyperplasia in a polyp was discovered in the remaining patient (77 years old). Significantly, the Pipelle® specimens of these three patients were thought to contain proliferative endometrium. Review of both the endometrial sampling specimens, as well as the hysterectomy specimens in these three patients, revealed no changes from the initial histological assessment. In all three patients it was thought that the Pipelle® specimen was sufficient for a histological assessment, although the percentage of the endometrium sampled was only 5.5% and 2% respectively. None of these patients complained of abnormal bleeding prior to the procedure.

Table I: Comparison of demographic characteristics of patients

Demographic variables	Pipelle® (n = 34)	Endosampler® (n = 33)	p-value
Age (years, mean ± SD)	48.4 ± 11	48.2 ± 11	0.94
Parity (mean ± SD)	2 ± 1.04	1.97 ± 0.88	0.9
Number Caesarean sections (%)	13 (38.3)	11 (33.3)	0.75
Uterine size (cm, mean ± SD)	7.4 ± 1.8	8.1 ± 1.4	0.42
Number postmenopausal patients (%)	11 (32.4)	6 (18.2)	0.18
Number previous cervical surgery (%)	1 (2.9)	2 (6.1)	0.54

Table II: Average percentage endometrium sampled.

	Pipelle® (n = 34)	Endosampler® (n = 33)	p-value
Average % endometrium sampled	9.4	14.5	0.03*
No access (%)	3 (8.8)	2 (6.1)	0.32
Inadequate samples (%)	5 (14.7)	3 (9.4)	0.21
Total inadequate (%)	8 (23.5)	5 (15.6)	0.29

* Statistically different

Discussion

Office endometrial sampling has been widely accepted as a procedure that can be used to diagnose endometrial pathology. The yield of endometrial devices for endometrial carcinoma has been reported to compare favourably to that of the classical D and C.¹ There are several reasons why office endometrial sampling is preferable to D and C. Office endometrial sampling should reduce costs accrued by hospital admission and theatre time. As office endometrial sampling is done with a local anaesthetic, or without it, the general anaesthetic required for D and C is avoided. Lastly, it is convenient for the patient to have the procedure performed during the first visit to the clinic, decreasing the delay in diagnosis.

Choosing the best device for office endometrial sampling has been the topic of many publications. The ideal device should be simple to use, causing minimal, if any patient discomfort, should be inexpensive and should not be associated with major complications. Lastly, the tissue yield should be sufficient for histopathological evaluation.

In this small prospective study, the Pipelle® was compared with the Endosampler® in a randomised fashion. Patient discomfort could not be investigated as the specimens were obtained while the patients were under general anaesthetic. However, compared to the Pipelle®, the Endosampler® appeared to be easier to use (p-value = 0.0005). Neither devices were associated with major complications.

It can be assumed that the percentage of endometrium that is removed is a reasonable reflection of the efficacy of any endometrial sampling device. The Endosampler® performed significantly better than the Pipelle® (14% versus 9%; p-value = 0.03). Similar findings were reported when the Pipelle® was compared with other devices. In a publication by Rodriguez et al, the Pipelle® was compared with the Vabra® aspirator. The authors found that, with the Pipelle®, the percentage of sampled endometrium obtained was significantly lower than

with that of the Vabra® aspirator (p-value < 0.001).⁴

A worrying finding was, that with the Pipelle®, significant endometrial abnormalities were not sampled on three occasions (8.8%). One patient had endometrial cancer and another two had hyperplasia. This seems to be higher than findings reported earlier (4.8%).⁵ The failure to detect a malignant change of the endometrium is by no means limited to patients undergoing outpatient sampling, and may also occur in patients

having a formal D and C.⁶ Two of the three patients in the current study had polyps. Similar failures to detect polyps were reported earlier. "Blind" endometrial sampling is an unreliable method to detect polyps.⁵⁻⁸ No significant abnormalities were found in patients from whom endometrial samples were obtained with the Endosampler®.

The current study, due to its design, could not be used to evaluate patient acceptance, but ease of use of the Endosampler®, when compared with the Pipelle®, was perceived by the gynaecological surgeon to be significantly better.

There may be some criticism concerning this study. The number of patients entered into the study is relatively small. Sixty-seven patients were eligible for analysis. However, the intention of the study was to test whether the Endosampler® was acceptable for surgeons, and secondly, whether or not it would render acceptable results. Although this is a prospective comparative study, the fact that the device could be identified by the surgeon made it impossible for the study to be "blind." Even so, the pathologist was unaware of which device was used. Lastly, no significant histological abnormalities were found in the patients where the endometrium was sampled with the Endosampler®, while in the Pipelle® group, three cases of significant histological abnormalities were recorded. In this respect, a comparison between the Endosampler® and the Pipelle® is not possible.

The Endosampler® collected more endometrium than the Pipelle®. This may well translate into a higher adequacy of specimen obtained by the Endosampler®. The finding that three significant lesions were missed by Pipelle® sampling shows that, wherever possible, the clinical picture should correlate with the endometrial sampling findings.

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