



## Bioscientia Medicina: Journal of Biomedicine & Translational Research

Journal Homepage: [www.bioscmed.com](http://www.bioscmed.com)

### The Comparative Efficacy of Endometrial Biopsy using Pipelle and Diagnostic Dilatation & Curettage in Mariano Marcos Memorial Hospital and Medical Center

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#### ARTICLE INFO

##### Keywords:

Curettage  
Diagnostic dilatation  
Endometrial biopsy  
Pipelle

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All authors have reviewed and approved the final version of the manuscript.

<https://doi.org/10.37275/bsm.v7i10.871>

#### ABSTRACT

**Background:** The use of Pipelle sampling for endometrial histology and pathology is of some controversy - and vast importance. Pipelle procedures are performed commonly in medical offices when women show abnormal vaginal bleeding. While the method has several advantages over dilatation and curettage (D&C), clinical questions exist on the precision and accuracy of the procedure. This study aimed to assess the effectiveness of Pipelle biopsy sampling versus Dilatation & Curettage (D&C) in adequacy of sampling specimen in terms of cost effectiveness, diagnosis success rate, sensitivity, specificity, positive predictive value, and negative predictive value. **Methods:** A retrospective study was conducted among all enrolled women with abnormal uterine bleeding counselling outpatient and inpatient in MMMHC Batac from 2016 to 2017. Sample was divided in two groups - those that underwent Pipelle biopsy and those who underwent D&C. Key statistics were computed using SPSS 16. **Results:** Cost effectiveness analysis showed that Pipelle biopsy offers a more cost effective alternative with an estimate of one correct diagnosis every P16 spent versus P61 spent for a correct diagnosis using D&C. Both procedures resulted in a 100% likelihood ratio of having the condition with a positive test result, with D&C resulting in a higher diagnosis success rate of 98% (versus 92% for Pipelle) and higher proportion of those who have the disorder, given the procedure tested positive. **Conclusion:** Pipelle biopsy offers a more cost effective alternative to D&C. Both procedures resulted in equal probability of having the condition with a positive test result, with D&C resulting in a higher success rate of diagnosis and sensitivity rate, albeit not statistically significant.

#### 1. Introduction

Endometrial Cancer is the most common gynecologic cancer among women in the United States. The incidence of this type of cancer increased from approximately 49,560 new cases in 2013 to an estimated 63,230 in 2018, which were new cases. Of these cases, 11,350 women are likely to die from this malignancy.<sup>1</sup> In the Philippines, it is a lot less common, with endometrial cancer only ranking as the 7<sup>th</sup> most common cancer among women. Dilatation and curettage (D&C) has been the method of choice in obtaining endometrial samples as it is reliable. However, D&C requires hospitalization and anesthesia, along with the problem of postoperative

pain. In addition, it costs more due to hospital charges on top of the initial cost of the procedure. In recent years, Pipelle endometrial sampling has become a popular alternative to D&C, addressing many of its limitations. Pipelle is a silastic curette that does not require a tenaculum or the cervical fundus axis straightening due to its flexibility. The procedure does not require anesthesia. Pipelle posts an advantage in being a cheaper and accessible alternative for an outpatient procedure.<sup>2</sup>

However, the use of Pipelle sampling for endometrial histology and pathology is of some controversy - and of vast importance. Pipelle procedures are commonly performed in medical offices

when women show abnormal vaginal bleeding. While the method has several advantages over dilatation and curettage (D&C), clinical questions exist on the precision and accuracy of the procedure. Questions were raised on the representativeness of the small sample obtained with the Pipelle device of the entire endometrial cavity. Concerns were also raised that other procedures, including D&C, are more precise. Questions on the reliability of the specimen were also raised due to potentially aggressive lesions being confined to a polyp or located on a thin, atrophic endometrium.

Although endometrial biopsy is sensitive enough to diagnose hyperplasia or cancer, it is less useful for detecting abnormalities like endometrial polyps or when endometrial atrophy is present. The false-negative rate for endometrial biopsy is 5% to 15%.<sup>3</sup> Endometrial biopsy was the preferred initial procedure for abnormal uterine bleeding evaluation in the past until it was replaced by D&C. In recent years, however, it has been utilized more often in conjunction with other procedures. Hysteroscopy, transvaginal ultrasound for endometrial thickness, and sonohysteroscopy are often combined with or done in lieu of endometrial biopsy. However, because endometrial biopsy is cost-effective, efficient, and readily available in the outpatient setting, it continues to be an important diagnostic tool for several gynecologic conditions. This study aimed to assess the effectiveness of Pipelle biopsy sampling versus dilatation & curettage (D&C) in the adequacy of sampling specimen in terms of cost-effectiveness, diagnosis success rate, sensitivity, specificity, positive predictive value, and negative predictive value.

## **2. Methods**

A retrospective study will be conducted among women with abnormal uterine bleeding. A record review of all histopathological records from the pathology department of patients who experienced abnormal uterine bleeding from 2016 to 2017 will be done. Exclusion and inclusion criteria will be set to clearly identify subjects that will be included in this

study. Records that meet these criteria will also be included in the study. From the results of the record review, subjects will be divided into two groups - patients that underwent endometrial sampling were assigned to group A and patients who underwent D&C were assigned to Group B. All enrolled women with abnormal uterine bleeding who are counseling at outpatient and inpatient in MMMHMC Batac from 2016 – 2017.

Subjects that meets the following criteria will be included in the study: Women who developed abnormal bleeding due to/or for: Evaluating postmenopausal and premenopausal abnormal uterine bleeding, workup of infertility, especially anovulation or short luteal phase, assessment of the effects of hormone therapy, Investigation of atypical glandular cells of undetermined significance (AGUS) on Papanicolaou (Pap) smear in women 40 years old above, Failure to respond to medical treatment for abnormal uterine bleeding.

Medical and personal data, including age, gravidity, parity, and previous history of Pipelle biopsy or D&C, will be abstracted from the histopathology records of each patient from the pathology department in MMMHMC from 2016- 2017. Collected data will be grouped, analyzed, and concluded in conjunction with the findings from the records. Information collected will include the patient's age, clinical indication for biopsy, menopausal status, date/length of last menstrual period in premenopausal women, and treatment with exogenous hormones.

Data identified as necessary by the research will be collected and recorded in Microsoft Word and Excel, with names of patients masked for privacy. Only the researcher will have access to the data unless a third-party consultant is deemed necessary, in which case, approval will be requested from the researcher. All records will be disposed of once the research paper is submitted and approved. Digital records will be deleted, and printed records will be shredded. Data was organized, cleaned, and refined using Windows Excel, and statistical analyses were performed using SPSS 16 for Windows. Meanwhile, data will be

analyzed using the following statistical tools: Cost-effectiveness analysis (CEA), another form of cost benefit analysis (CBA), was used to assess the net cost of the service relative to outcomes (benefits) generated. Specifically, for the purposes of this study, we used CEA to compare and identify which of the two procedures is considered cost-effective. Sensitivity and specificity are used to measure and validate the test procedures. Specifically, these tests will help define the ability of the test procedures to discern between patients who have a certain condition and those who do not. This will be further explained in the results of this study. Positive predictive values (PPV) and negative predictive values (NPV) will also be measured to identify the prevalence of this disease in the population that is being tested. Specifically, PPV was used to measure the possibility of having the disease or condition, given a positive result. Meanwhile, NPV was used to measure the possibility of not having the disease or condition, given a negative test result.

### 3. Results

Using the aforementioned criteria, a total of 211 patients were included in the study, with 155 that underwent Pipelle biopsy and 56 that underwent D&C

biopsy. On average, 20-30 histopathology results are released monthly from 2016 – 2017.

#### Cost-effectiveness analysis (CEA)

CEA is another form of cost benefit analysis (CBA). It measures the net cost of a project or service relative to the outcomes (benefits) generated.<sup>4,5</sup>

CEA considers another possibility in reference to the ratio among the costs related to each alternative and a single quantified, but not monetary, effectiveness measure. This represents an impediment of CEA as costs are represented by monetary values, while efficacy may be measured in terms of saved lives, time savings, or other similar quantifiable measures. For this reason, a ratio is computed in CEA.

Two forms of ratio can be expressed: 1) Cost-effectiveness ratio: dividing the costs of an alternative by the measure of effectiveness. 2) Effectiveness-cost ratio: dividing effectiveness measured by costs of the alternative.<sup>13</sup> For our analysis, we made use of the cost-effectiveness ratio. Applying the formula to compare the two procedures for the study gives us the values in Table 1.

Table 1. Cost-effectiveness ratio.

Procedure	Cost	Effectiveness ratio	C/E = cost/effectiveness ratio
Pipelle biopsy	1500	92	16.30
Diagnostic curetage	6000	98	61.22

Calculating the ratio of cost to effectiveness (C/E) of the two procedures suggests that Pipelle biopsy is more cost-effective than the alternative, D&C. Pipelle biopsy is estimated to result in one correct diagnosis for every P16 spent versus an estimated P61 spent for a correct diagnosis from D&C.

Results of the cost-effectiveness ratio agree with a similar study done by Rauf et al., with results stating that Pipelle was eight times more cost-effective than

D&C.<sup>3</sup> An earlier study by Antoni also revealed that Pipelle was more cost-effective versus another procedure, cytospat.<sup>9</sup>

#### Success rates, sensitivity, specificity, NPV, and PPV

Other key measures of effectiveness were also computed and compared for both procedures.

Table 2. Diagnosis success rate.

Procedure	Total cases diagnosed	Correct diagnosis	Success rate
Pipelle biopsy	155	142	91.61%
Diagnostic curettage	56	55	98.21%

Diagnosis using the D&C procedure resulted in a higher success rate of 98% versus 92% success rate from of Pipelle biopsy.

A Chi-square test of proportion was then used to check if there was indeed a significant difference between the success rates of the two procedures. Running the test resulted in a Chi-square value=2.458 and a significant level of  $p=0.1169$ . This means that at 95% level of significance, we cannot conclude that there is a significant difference in the success rate of

the two procedures. The same results were evident in a similar study done by Rezk on the effectiveness of Pipelle sampling versus D&C. Concordance rate, which was considered to indicate the similarity of histopathological diagnosis between the two procedures and hysterectomy, was measured, and compared. The results of that study revealed no significant difference between the two methods on the concordance rate with hysterectomy, considered to be the golden standard.<sup>10</sup>

	Disorder	No Disorder
Positive Test Result	True Positive (TP)	False Positive (FP)
Negative Test Result	False Negative (FN)	True Negative (TN)

Sensitivity =  $TP/(TP+FN)$   
 Specificity =  $TN/(TN+FP)$   
 PPV =  $TP/(TP+FP)$   
 NPV =  $TN/(FN+TN)$

Figure 1. Computation guide for sensitivity, specificity, PPV, and NPV.

Sensitivity and specificity are specific elements of the concept of validity. The validity of a test is defined as its ability to discern between patients who have a certain condition and those who do not.

Sensitivity is a measure to report how effective a test is in recognizing individuals with a disease or condition. That is, the sensitivity of a diagnostic procedure refers to the proportion of patients with the disorder in which the results tested positive. The higher the sensitivity, the better. This is computed by dividing the total number of patients who tested positive by the total number of patients who have the

actual disease. The formula is provided in Figure 1.

Specificity, on the other hand, is the ability of a test to identify correctly patients who do not have a disease or condition. It is the proportion of patients who do not have a disease in which the test result is negative. The formula is again provided in Figure 1. It is computed by dividing the number of patients who have negative test results by the number of patients who do not have the disease or condition.

Sensitivity and specificity are characteristics of the test. The population does not affect the results.

Meanwhile, PPV and NPV are influenced by the prevalence of disease in the population that is being tested. If we test in a setting of high prevalence, it is more likely that persons who test positive truly have the disease than if the test is performed in a low prevalence setting population.

PPV is used to measure the likelihood of having the disease or condition, given a positive test result. It is

computed by dividing the true positive (TP) by the total number of patients who have positive test results (TP + FP). NPV, on the other hand, is used to measure the likelihood of not having the disease or condition, given a negative test result. It is computed by dividing the true negative (TN) by the total number of patients with negative test results (FN + TN).

Table 3. Pipelle biopsy procedure results.

		Actual status	
		Has disease	Non-disease
Test result	Positive	142	0
	Negative	13	0

Diagnosis as a result of Pipelle biopsy gave us a high sensitivity rate of 92%. This means then that using Pipelle biopsy procedure gives us confidence that we can safely conclude that 92% of patients with the disease will have a positive screening test result. This procedure also resulted in a 100% PPV. That is, individuals with a positive test result from using this

procedure for diagnosis have a 100% chance of having the disease. This is twice as high as the results shared by Seto et al., with results showing a 56% PPV of Pipelle endometrial samples in confirming endometrial polyps.<sup>11</sup> Specificity and NPV were not computed for this procedure as we have 0 subjects that did not have the disease.

Table 4. Dilatation & curettage procedure results.

		Actual status	
		Has disease	Non-disease
Test result	Positive	55	0
	Negative	1	0

Diagnosis from dilatation and curettage procedure resulted in a 98% sensitivity rate, higher than the 92% sensitivity rate of Pipelle biopsy. Using the D&C procedure to diagnose the condition gives us confirmation that 98% of patients with the disease will have a positive screening test result. Similar to Pipelle biopsy, D&C also gives us a PPV value of 100% so that individuals with a positive test result have a 100% chance of having the disease. Again, specificity and NPV cannot be computed for this procedure as our samples have zero subjects that did not have the disease.

#### 4. Discussion

Endometrial tissue sampling is a medical procedure performed to take a small sample of the

inner lining of the uterus (endometrium) for diagnostic purposes. This process can be carried out using two main methods, namely Pipelle, and the dilation and curettage (D&C) procedure. Pipelle is a device consisting of a flexible tube that is inserted through the cervix (cervix) into the uterine cavity. Pipelle is used to take samples of endometrial tissue that will be analyzed in the laboratory to detect abnormalities such as polyps, endometrial hyperplasia, endometrial cancer, or other conditions.<sup>8,9</sup>

D&C is a more invasive procedure that involves dilating the cervix (dilating it) and sampling endometrial tissue with a curette shaped like a spoon or spatula. D&C is often used to take larger samples of endometrial tissue or in situations where Pipelle may be insufficient. It can also be used as a cleansing

measure of the uterine cavity after miscarriage or incomplete labor. D&C can provide a larger and possibly more accurate tissue sample in some situations where Pipelle is insufficient. However, it is a more invasive procedure and requires a longer recovery compared to Pipelle.<sup>10,11</sup>

## 5. Conclusion

In conclusion, Pipelle biopsy offers a more cost-effective alternative to D&C. Both procedures resulted in an equal probability of having the condition with a positive test result, with D&C resulting in a higher success rate of diagnosis and sensitivity rate, albeit not statistically significant. Caution should also be taken into account when reading the results of this study, as specificity and NPV measures were not available. This study also presents limitations in that only a small number of patients participated. A much larger retrospective and possibly prospective study is required to confirm the findings from this study.

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