Original article

Comparing The Pipelle With Dilatation And Curettage (D&C) In Diagnostic Power Of Sampling For Evaluating The Patients With Abnormal Uterine Bleeding

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Abstract:

Introduction: Abnormal uterine bleeding is a common and serious problem in the women of late reproductive age, and an indication for biopsy.

Common diagnostic methods in Iran including the endometrial biopsy with dilatation and curettage (D&C) are the gold standard for diagnosis. The aim of this study is to compare the diagnostic power, complications, and duration of endometrial biopsy caused by two diagnostic methods of endometrial sampling of pipelle with dilatation and curettage (D&C) in patients with AUB.

Methods: This single blinded- parallel randomized clinical trial was performed at the Iranian Center for Clinical Trials (IRCT). The research population is the patients referring to the specialized clinic of Mostafavian and Baghban 1 in Sari with complaints of AUB from October 2016 to September 2018. The patient selection was available for study. The patients were divided in simple random method into two groups of D&C and pipelle alternatively. The samples were sent to pathology after sampling, and when sampling is done, the patient was examined for complications such as uterine bleeding or vasovagal shock symptoms for the cervical stimulation, then, the results were compared with D&C, and also it was compared with the sample histopathologically.

Findings: A number of 70 patients were included, while many of which were excluded, and finally 50 patients were completed the study. First, the biopsy with pipelle and then biopsy with D&C were performed on all the patients. The mean age of subjects was 47.5 years old. The highest number of patients (28%) was in the 40-45 group. The mean thickness of the endometrium in patients was 11.5 mm. In the pipelle group, 34% of the cases of insufficient samples were obtained, while using the biopsy, only 4% of the insufficient samples are obtained. A total of 23 samples from 50 patients undergoing pathologic diagnosis were obtained from two similar sampling methods. In the pipelle group, the insufficient sample with 34% proliferative, and then the secretion and proliferative samples were the second and third (prophylactic and secretion pathology are considered as normal tissues that was calculated 56% in this study) in the diagnosis, and accommodation of the pipelle and D&C samples in proliferative has allocated the highest percentage of 9%, and the lowest accommodation was in the in atrophy and polyps and hyperplasia. The average duration of the procedure in the pipelle group was significantly lower than D&C. The pain was significantly higher in pipelle group than D&C ($P < 0.05$).

Conclusion: Pipelle is a cheap, fast, outpatient method with low side effects without the use of anesthesia and operating room facilities for diagnosis of hyperplasia and cancer with lower susceptibility to D&C. In the D&C with acceptable susceptibility and specificity, the pain was lower, number of insufficient samples was lower, and diagnosis of polyps was higher.

Keywords: Abnormal uterine bleeding, pipelle, D&C.

Introduction:

Abnormal uterus bleeding is a common and serious problem in the women of late reproductive age for the malignancies. The age of 40 and above is a known risk factor for endometrial diseases, and according to many experts, it is an indicator for biopsy in women with abnormal uterine bleeding (1).

For abnormal endometrial sampling among the women at risk of polyps, hyperplasia or endometrial carcinoma, the endometrial sampling is necessary. The endometrial sampling is essential for assessment of bleeding caused by the non-ovulation in the following groups: the women aged above 35-40, obese young women, and women with long history of non-ovulation (2).

Sampling of the endometrium can be useful and definite in many cases.

Before the last decade, the D&C diagnostic curettage was used for endometrial biopsy. In addition to longer duration and anesthetic complications, it is also not free of the surgical risks (3)

Today, the outpatient sampling endometrium techniques are widely replaced D&C as a diagnostic method, which are considerably easier to use with lower risks compared to the D&C (3-5)One of the most recent tools for outpatient sampling of the endometrium is pipelle, the efficiency of which is approved in several studies in the removal of an appropriate sample without causing great discomfort to the patient, since this method has not been widely used for endometrial sampling in various health centers (6)

Common diagnostic methods in Iran including the endometrial biopsy, dilatation and curettage (D&C) are the golden standard for diagnosis (7) With respect to the importance of a review of abnormal uterine bleeding during and after menopause and the need for endometrial sampling in evaluation of cause of bleeding, the outpatient sampling is possible using Kurt pipelle suction with no need for admission, anesthesia and cervical dilatation.

Due to the high diagnostic value of pipelle, the insufficient sample is lower, and the patient's comfort with no need for hospitalization and anesthesia is recommended, the pipelle method can be used instead of D&C (6)

Multiple internal studies have examined each of these two methods individually. In the study of Khademi et al., the D&C method of the histopathologic results of biopsy was investigated.

Studies on the comparison of two methods and superiority in duration of process, patient’s satisfaction and pain, and complications of the two methods have not been performed yet at the Middle East. Ganbari et al. investigated the results of histopathology from D&C with radiographic indexes of transvaginal ultrasonography (5). Mousavifar performed a study in Iran for the first time on pipelle of the results of biopsy, and according to Behnamfar et al., the two D&C methods were compared in terms of results of susceptibility and precision. From the review of internal literature, it is found that the studies were few and performed a long time ago, and both methods have shortcomings in terms of many indices that

are important to make decisions for the method.

The aim of this study is to compare the diagnostic power, complications, and duration of endometrial biopsy caused by two diagnostic endometrial sampling methods of pipelle with dilatation and curettage (D&C) in patients with AUB.

Methods:

The single blinded- parallel randomized clinical trial is performed and registered at IRCT. The research population was the patients referring to the specialized clinic of Mostafavian and Baghban 1, Sari, with complaints of AUB from October 2016 to September 2018.

In the study population, diagnosis of AUB was performed by the gynecologist of Mazandaran University of Medical Sciences, and a senior resident of obstetrics and maternity based on the WHO criteria.

Inclusion criteria includes Endometrial thickness over 6 mm in the transvaginal sonography on the 6th day of menstrual cycle and Above 36 years old

Exclusion criteria was Pregnancy, History of OCP consumption, Endometrial thickness below 4 mm ,Personal dissatisfaction ,Failure to accompany the patient in the further study.

The sample size was calculated by considering P=0.9 and Q=0.99, and α=5%, and loss of 15% in 50 subjects per group.

Patient selection was available for study. The patients were divided in simple random method into two groups of D&C and pipelle alternatively. Prior to diagnostic procedure, the patients were asked for CBC, coagulation, thyroid, and prolactin tests.

In Pipelle method The sampling was performed with a 3.1 mm pipelle manufactured by Cooper Surgical. For pipelle sampling, patient should be placed in the lithotomy condition. After the speculum and vaginal washing, the sample was taken without cervical lobes measurement using tenaculum, and anesthesia or analgesia by the pipelle, while in this method, the pipelle did not pass through the cervix, and the cervical lobe was measured using tenaculum. After placement of pipelle into the piston uterus, the pod was pulled down so the sample is taken using the negative gradient. When the sample that was drawn into the uterus was seen from the opening of the cervix, the pipelle was removed slowly from the womb. In case the enough sample was not obtained, all if all the contents inside the uterus were liquid, the operation was repeated once again. The sample obtained from the pipelle was poured into the formol solution, and quality and quantity of the sample was supposed based on sample size and amount of flotation, but the pathologist was responsible for exact determination of quantity and quality.

Sample with specific code of the patient was sent for pathology to the certain researcher and uncertain pathologist, and after the sampling, the patient was examined in terms of complications such as bleeding from the uterus, vasovagal shock signs, due to cervical stimulation.

In D&C methodAfter receiving anesthesia or local anesthesia, the patients were undergoing D&C gradually with dilatation of the cervix, and the sample was poured into the formol. In case of hysterectomy of the patient, the uterus was sent for pathology.

Both samples obtained with pipelle and D&C was investigated by a pathologist. The pathologist reviewed the sample in terms of quantity and quality and histopathology, and the samples with sufficient quantity and quality were called satisfactory, while the samples with insufficient quantity and quality were called unsatisfactory.

Then, it was compared with results of D&C, it was also histopathologically compared with the sample.

In this study, a questionnaire was developed containing patient's demographic information (age, sex, duration of menstrual bleeding, menarche age, marriage age, parity ...), as well as information on radiological indexes (transvaginal sonography), and medical history of the patient. Also, the duration of the biopsy, patient's pain score, and possible complications of patients were registered. In order to collected the data on the pain intensity, the VAS was used, therefore, 30 minutes after the procedure, patients were asked to express the pain intensity using VAS. The zero represents the absence of pain, and 100 represents the maximum pain. Also, the results of pathology including polyps, endometrial hyperplasia, adenocarcinoma, inadequate samples, were compared in two methods, and placed in the data sheet.

After data collection, the data was analyzed by SPSS 18. To describe the qualitative statistics, including sufficient and insufficient sampling and gender, the frequency distribution and percentage was used. To describe quantitative variables, such as age and duration of biopsy using pipelle and D&C and normal data distribution, the mean and standard deviation were used for data with normal distribution and the mean and IQR were used for abnormal distribution. To evaluate qualitative data, the chi-square test was used.

For normal data distribution, using histogram and normal distribution curve, the Kolmogorov-Smironov test (K-S) was used. In order to evaluate the comparison of duration of biopsy, using pipelle and D&C, with respect to the abnormal distribution of variables, the Mann–Whitney test was used. In order to assess the susceptibility and specificity, the pipelle and D&C, and diagnostic power comparison between these two methods, the roc curve test and roc curve area calculation were used. P value <0.05 was considered statistically significant.

Findings:

This study was performed with a purpose to compare the diagnostic power, complications, and duration of endometrial biopsy resulting from two endometrial sampling methods of pipelle and conventional dilatation and curettage (D&C), in the patients with AUB from September 2016 to April 2018. A number of 70 patients were studied, and many of these patients were excluded due to issues in the

exclusion criteria, 6 patients for OCP consumption, and 8 patients for lack of tendency of patient to participate in study, and 6 patients for endometrial thickness below 4 mm. Finally, a number of 50 patients completed the study, the biopsy was first performed for all patients with pipelle and D&C.

The mean age of the patients in the study was 47.5 years with a standard deviation of 5.17 years. The patients were divided into 6 age groups as seen in the table, and 28% of patients in this study were in the 40-45 group. The second group of patients was in the age group of 60-65% with 20%. The second group of patients was in the age group of 35-40 with 14%. The mean endometrial thickness of the patients was 11.5 mm, with a standard deviation of 5.17. The patients were divided into 5 groups based on the thickness of the endometrium as seen in the table. The most cases of patients was 30% with a endometrial thickness of 8-10 mm, and 28% of cases had endometrial thickness of 10-15 mm.

The results of this study, in accordance to Table 3-4, showed that in the pipelle group, 34% of the samples were insufficient, while only 4% of the insufficient sample was obtained using the biopsy. In the pipelle group, the insufficient sample with 34%, and then the secretion and proliferative samples were the second and third (prophylactic and secretion pathology are considered as normal tissues that was calculated 56% in this study) in the diagnosis, while the pipelle only detected 2% of the polyps, so the polyps didn't have sufficient adequacy for diagnose of polyps. The most important diagnosis was in the D&C groups, where in 38% of the cases, the causes of AUB were estimated, while in the pipelle only 2% of polyps were diagnosed. The second and third ranks were assigned into the proliferative and secretion.

The results obtained from this study, in accordance to Table 4-4, showed that the accommodation of pipelle and D&C samples in the proliferative has assigned the highest percentage (10%), with the minimum similarity in atrophy, polyps and hyperplasia. A total of 23 samples from 50 patients of pathologic diagnosis were resulted from similar samplings.

Results of this study, in accordance to Table 4-6, indicated that the average biopsy duration was 8.65 in the pipelle group, and 14.63 in D&C, with a statistical significant difference ($P<0.05$), and duration of operation was lower in the pipelle method.

Results of this study, in accordance to Table 4-7, indicated that the mean pain in pipelle group was 3.41 ± 1.292, and 1.65 ± 1.370 in the D & C group, which was statistically significant different ($P<0.05$), and pain was less in D&C. In the pipelle group, 50% of patients had mild pain with pain score of 1, while in the D&C group, 90% of patients had the score of 1. In the pipelle group, the maximum score of patients was 5, but in the D&C group, 2 was the highest pain score.

Discussion:

Abnormal uterus bleeding (AUB) is the estimated cause that 2 million women are referring to the doctor, and about 150,000 people are also undergoing hysterectomy for

AUB per year. Since the hysterectomy is a major surgery, following the risks of anesthetic and surgery, such as many major surgical operations, its psychological and psychological effects should also be considered.

Mean age of patients under study was 47.5, the results were consistent with contents of reference as well as many literature reviews (8)

Before the prevalence of hysterectomy in the advanced countries, the dilatation and curettage was the standard method for diagnosis of endometrial cancer, giving more texture than endometrial biopsy to the pathologist for studying the histopathology. In many cases, the accurate diagnosis is required to make decision for diagnosis of hysterectomy, since it should be done with proper indication. In most of the perimenopausal patients (patients who are around the age of menopause), so it is also recommended to consider the endometrium after menopausal. On the other hand, by increasing the age, the pathological causes leading to AUB are increased. Thus, it should be mentioned that although the perimenopausal and postmenopausal patients with AUB might have uterine lesions such as lymum, adenomyosis, and endometrial polyps in transvaginal or abdominal ultrasonography, it is better to be investigated in terms of histopathological endometrial before the medical or surgical treatment. In each patient with perimenopausal abnormal hemorrhage, the pregnancy should be considered and rejected. The side effects of pregnancy leading to the abnormal uterine bleeding require the special treatment, and in cases of post-abortion continued bleeding, the review should be done in terms of choriocarcinoma by ßhcG serum measurement (8-10)

Histopathologic examination of endometrium is emphasized in most of the reference books and articles in patients over 35 years old, especially those over 40 years, and in younger women with the risk factor such as diabetes, chronic non-ovulation, obesity, hypertension, and noli paritati.

This study shows that D&C has high susceptibility for equipment and costs, however, it has shortcomings comparing with situation under the hysteroscopic view. Since 1869, when the first hysteroscopy was performed for endometrial polyp cauterization with silver nitrate, the diagnostic and therapeutic indications were increasingly added. In various studies, the diagnostic errors of D&C are noted 50% for cases of endometrial polyps and 60% for complex atypical hyperplasia. In 11% of the cases, the endometrial concave was not diagnosed by D&C.

In 100% of the dilatation and curettage patients, the pain level was low, in 70% of pipelle the pain was low, and only in 20% of the pipelle the pain was at medium level, which is similar to other studies, and in 80% of the cases, the mild discomfort is caused for uterine cramps (11).

In this study, 85% of patients were at premenopausal or menopausal periods, indicating that the perimenopausal and postmenopausal abnormal bleeding should always be taken seriously, although small and unstable. The cause of these bleeding

might be non-genital, genital or uterine. The possible uterine causes include the endometrial atrophy, endometrial polyps, estrogen replacement therapy, hyperplasia, carcinoma, or sarcoma. The physical examination barely reveals any evidence of any of these cases. The D&C are widely used to obtain the tissue for pathological examination, requiring the anesthesia and cervical dilatation. At present, the aspiration biopsy is accepted in the clinic using the relatively cheap plastic cannulas of the first step, which is widely accepted by the patients for the low complications. This method is successful in over 95% of cases in obtaining a sufficient tissue sample. In case of cervical tension, the paracervical block can be used, and dilated the cervix, and administration of antiprostaglandin drugs reduces the contractions of the uterus, however, in the situations such as cervical tension and patient intolerance, the bleeding recurrence is essential after a negative biopsy, insufficient sample. The further studies are performed using other diagnostic methods such as hysterectomy and biopsy, vaginal sonography with or without fluid injection into the endometrium (sonography) and biopsy.

In the present study, in all the cases, the pipelle was passed through the cervix without the dilatation and no need for anesthesia or paracervical block. In 33 cases (66%), the sufficient tissue was obtained by the pipelle. In other studies, up to 95% of cases, the sufficient tissue sample is obtained in this way. In curettage method, in 46 cases (96%), the sufficient tissue was obtained for the study (12), but it should be noted that the negative results from the outpatient biopsy cannot be enough in all cases, so before an outpatient biopsy, a vaginal sonography is suggested, if necessary associated with the fluid injection (sonohysterography), and in case of increase in endometrial thickness, the other diagnostic methods such as hysteroscopy can be used along with biopsy and D&C. In case of continuation or recurrence of bleeding, following the negative results of the pathology from the outpatient biopsy, and in the people with high risks of for endometrial cancer such as the obese women, late menopause, people with diabetics, untreated estrogen therapy, tamoxifen therapy, and those who didn't give birth so far, and in atypical endometrial hyperplasia, a study with more accurate diagnostic methods, especially hysteroscopy with biopsy and D&C is suggested (13, 14)Saygili also focused on this issue. Therefore, the outpatient biopsy can be used in many cases instead of dilatation and curettage for diagnosis of possible endometrial lesions (15)

The same histologic results were in the pipelle biopsy and D&C in 46% of the study cases, so that in 23 patients of 50 patients, the histologic results were similar, and in 27 patients (54%), the histologic results were different, which was 77% in the Iranian study. It was shown in another study that in the endometrial sampling in 76% of cases, the results were similar with D&C, which was lower compared to other studies(16).

In none of the patients, the endometrial cancer was diagnosed using the pipelle and D&C, and with respect to prevalence of endometrial cancer where 1% or 2% of risk

is 0.7/1000, this is not abnormal. The susceptibility of diagnosis of endometrial cancer using pipelle is more than the benign lesions at 97.5% to 100%. In this way, in case of diagnosis of endometrial cancer in the patient, the D&C and two operations are not required, and immediately after diagnosis, the patient is merely undergoing laparotomy once for surgical staging.

In this study, 17 cases of polyps were diagnosed, which was not diagnosed by pipelle.

Although vaginal sonography is valuable in the diagnosis of polyps and submucous myoma, in such cases, the persistence of symptoms after outpatient sampling requires the need for D&C hysteroscopy.

In 2 patients (4%) of all the patients in D&C, the obtained tissues had been insufficient or incomprehensible, and the pipelle biopsy rate was in 17 patients (34%) from 50 patients.

Using the vaginal sonography in the patients with insufficient pathology sample results, the patients can be followed as outpatient. In such cases with the absence of a pathologic image in sonography scan with a thickness of less than or equal to 4 mm, even in some cases, the outpatient sampling is not required.

In various studies, the false negative rate is 10-15% for benign lesions, and 10% for D&C using the pipelle (17-19).

Conclusion:

Accordingly, this study showed that the pipelle is a cheap, fast, and low-risk, and outpatient technique with no need for anesthesia and operating room facilities, for diagnosis of proliferative and natural cases with lower susceptibility to D&C. Also, in the D&C with acceptable susceptibility and specificity, the pain was lower, number of insufficient samples was lower, and diagnosis of polyps was higher. However, in cases with strong clinical suspicion of focal lesions, with possibility of hysteroscopic examination, direct curettage can be considered.

Statement conflict of Interest:

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Tables and Charts:

Table 4.1: Distribution of patients by age group.

Age	Frequency	%
40-35	7	14%
45-40	14	28%
50-45	9	18%
55-50	7	14%
60-55	10	20%
65-60	3	6%

Table 4.2: Distribution of patients by thickness of the endometrium.

	Frequency	%
Below 8 mm	10	20%
8-10	15	30%
10-15	14	28%
15-20	11	22%
Above 20	0	0%

Table 4.3: Histological report on endometrial biopsy samples.

Pathology report	Pipelle		D&C		Probability value
	Frequency	%	Frequency	%	
Secrecy	14	28%	9	18%	0.075
Polyps	1	2%	19	38%	0.002
Hyperplasia	1	2%	3	6%	0.057
Atrophy	1	2%	5	10%	0.64
Insufficient sample	17	34%	2	4%	0.0345
Proliferative	14	28%	12	24%	0.061

Table 4.4: Histological results similar to two biopsy methods with pipelle and D&C.

Histological results similar to two methods	No.
Secretive	8
Polyps	1
Hyperplasia	1
Atrophy	1
Insufficient sample	2
Proliferative	10

Table 4.5: Assessment of average duration of operation in AUB patients in two sampling methods.

	Pipelle		D&C		Mann-Whitney U test	Approximation Z	Probability value
	Mean	Std	Mean	Std			
Duration of operation	8.65	3.123	14.63	4.584	204.500	-4.093	0.000

Table 4.6: Severity of pain in patients under two biopsy methods.

Severity of pain	Pipelle		Dilatation and curettage		Probability value
	Frequency	%	Frequency	%	
1	25	50	45	90	.000
2	5	10	5	10	
3	8	16	0	0.	
4	10	20	.0	0.	
5	2	4	0	0.	
Total	50	100.0	50	100.0	
Standard deviation ± mean	3.41±1.292		1.65±1.370		.000