



Evaluation of The Efficacy of Pipelle In Diagnosis of Endometrial Lesions in Cases of Perimenopausal Bleeding

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Abstract

One of the most common gynecologic complaint is irregular uterine bleeding. It is one of the most common problems in the perimenopausal and postmenopausal years. It has a direct impact on woman physical, social, emotional and material quality of life. While vaginal bleeding is the sign of endometrial cancer in more than 90% of postmenopausal women which is the sixth most common malignant neoplasm in women worldwide and is the most common gynecologic malignancy in developed countries, therefore, the diagnosis of AUB needs to be undertaken seriously. This study was implemented to evaluate the efficacy of suction pipelle-which is an endometrial sampling technique- in diagnosis of endometrial lesions in cases of abnormal uterine bleeding. It was designed as a cross sectional study and included 184 patients complaining of AUB. 2 samples were taken from all candidate women one by D&C and the other was by pipelle device and the results of histopathological examination of both were compared regarding that D&C was the gold standard. After statistical analysis of the present study by SPSS version 23 software, the 2 methods were 100% matched in diagnosis of secretory endometrium, hormone dependent endometrium, atypical hyperplasia and EEC grade 1. The pipelle succeeded to diagnose some cases of proliferative endometrial and simple hyperplasia which were missed by D&C (18.5% and 17.4% by pipelle versus 16.3% and 13% by D & C respectively). Unfortunately, there were cases the pipelle failed to diagnose, as in some cases of endometrial polyp and disordered endometrial hyperplasia which diagnosed by D&C (8.7% and 17.4% by pipelle versus 16.3% and 19.6% by D & C respectively).

Conclusion: Pipelle is an outpatient procedure which avoids general anesthesia and its related risks, does not need room or personnel in the operating theatre, is less painful, is more cost-effective and obtains an accurate specimen with consistent histopathology results compared to D&C. It would, however, have decreased sensitivity for endometrial polyp diagnosis and hyperplasia.

Introduction

Abnormal uterine bleeding (AUB) is a significant clinical entity complaint among women in reproductive age attending to an outpatient clinics [1] it may have a significant impact on woman physical, social, emotional and material quality of life along with the direct impact on the woman and her family, there are significant costs to both economy and health service [2]. AUB is an abnormal uterine bleeding that occurs in the absence of identifiable pathology. This represents a disturbance to the endometrial lining of the normal cyclic of ovulatory hormonal stimulation. In many cases, the bleeding is unpredictable. It can be too heavy or light and prolonged, irregular, or random [3].

The working group on menstrual disorders of the International Federation of Gynecology and Obstetrics, FIGO, has recently developed a classification system (PALM-COEIN) for AUB causes in non-gravid women of reproductive age. There are

nine main categories grouped under the acronym PALM-COEIN: polyp; adenomyosis; leiomyoma; malignancy and hyperplasia; coagulopathy; ovulatory dysfunction; endometrial; iatrogenic; and not yet classified [4]. Endometrium assessment methods are numerous in patients with abnormal uterine bleeding, these are ultrasonography, D&C, office-based methods as hysteroscopic biopsy or endometrial samplers such as suction pipelle [5]. In women with abnormal uterine bleeding, the main cause for performing endometrial biopsy is to confirm the benign nature of the problem by excluding endometrial carcinoma so appropriate management can be [6]. Throughout decades, the endometrial curettage is the gold standard endometrial sampling tool. However, in sixty percent of cases, it can lead to less than 50% curettage of endometrium and is also accompanied by infection risk and perforation. It also requires hospital admission and local or general anesthesia [5].

Aim of the Work

Evaluation of the efficacy of suction pipelle in diagnosis of endometrial lesions in patients with abnormal uterine bleeding

Patients and Methods

The study was Cross sectional study carried out at Gynecology and Obstetrics Department, Armed Forces Hospitals of South Region. Gazan, KSA. during the period from April 2017 to May 2019. 184 patients included in this study they had Abnormal vaginal bleeding although medical therapy.

Exclusion criteria:

- Lower genital tract infection.
- Local gynecological cause.
- Patients with bleeding disorders (Coagulopathy, thrombocytopenia (less than 100/000 platelet per mm³).
- Use of anti-coagulants.
- Bleeding due to endocrinological disorders (thyroid diseases and diabetes) or due to liver or renal impairment.
- An informed verbal and written consent were obtained from every subject.

All cases who met inclusion criteria were subjected to the following:

History

Full history was taking including: personal, present, past, family, obstetric, history of drug intake, contraceptive and menstrual history.

Detailed History about duration, amount and pattern of bleeding.

Examination

General examination: Including Blood pressure, pulse, temperature and respiratory rate.

Abdominal examination: Evaluation of fundal level. Presence of any scars of previous operations.

Laboratory investigation: CBC will be conducted, coagulation profile, hormonal assay consisting of thyroid function tests, serum prolactin, liver and kidney function tests. Transvaginal ultrasonography TVS for assessment of myometrium, endometrial thickness and uterine cavity. On the day of operation and after vaginal washing and speculum placement in lithotomy place, patients are moved to the operating room. the sampling was performed preceding to anesthesia, dilatation and using of suction pipelle. The sheath piston was drowned back to make negative gradient after the pipelle was inserted into the uterine cavity and then the pipelle was slowly removed. The procedure was repeated more than one as much if the sample was insufficient. In container A, the samples were collected. Using the curette number 3 or 4 and the samples were assembled in container B. The samples were sent

to the same pathologist for histopathological evaluation. Patients and pathologists were blinded about the sampling sequence and the sampling method used for each sample.

Results

The mean of 54.8 years, parity of the studied group ranged from 0 to 5 times, and 48.9% of them were obese and 31.5% were overweight (Table 1). The mean duration of bleeding ranged from 7 days up to 90 days with mean of 23.8 days, endometrial thickness of the studied group ranged from 6 to 15mm, and 76.1% of them were pre-menopause (Table 2). The most common presented symptoms among the studied group was menorrhagia among 42.4% of them, then 30.4% presented with poly-menorrhagia and 16.3% with metrorrhagia (Table 3). The results of D & C and pipelle device, they were matched in detection of secretory endometrium, hormone dependent endometrium, atypical hyperplasia and EEC grade 1, while there was over estimation of positive proliferative endometrial cases and simple hyperplasia by pipelle device (18.5% and 17.4% versus 16.3% and 13% respectively by D&C), also it miss cases of endometrial polyp and disordered endometrial hyperplasia (8.7% and 17.4% versus 16.3% and 19.6% respectively by D& C) (Table4).

Table 1: General characteristics of the studied group.

Variables	Cases N=184	
Age \years		
Mean ±SD	54.8 ± 10.2	
Range	40-66	
Parity number		
Mean ±SD	1.8 ± 1.21	
Range	0-5	
Variables	(N=184)	Percent %
BMI		
Normal	36	19.6
Overweight	58	31.5
Obese	90	48.9

Table 2: Clinical data of the studied group.

Variables	Cases N=184	
Duration of Bleeding (days)		
Mean ± SD	23.8 ± 15.8	
Range	7-90	
Endometrial Thickness (mm)		
Mean ±SD	11.2 ± 2.71	
Range	6-15	
Variables	(N=92)	Percent %
Menopausal Status		
Pre-menopause	140	76.1

Post-menopause	44	23.9
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Table 3: Symptoms presented among the studied group.

Symptoms	Cases	
	N=92	
	N	Percent %
Menorrhagia	78	42.4
Poly-menorrhoea	56	30.4
Metrorrhagia	30	16.3
Post-menopausal bleeding	20	10.9

Table 4: Results obtained by D & C and pipelle device.

Symptoms	Cases N=92	
	D & C N (%)	Pipelle N (%)
Proliferative endometrium	30 (16.3)	34 (18.5)
Secretory endometrium	28 (15.2)	28 (15.2)
Endometrial polyp	30 (16.3)	16 (8.7)
Disordered proliferative endometrium	36 (19.6)	32 (17.4)
Hormone dependent endometrium	18 (9.8)	18 (9.8)
Simple endometrial hyperplasia	24 (13)	32 (17.4)
Atypical endometrial hyperplasia	8 (4.3)	8 (4.3)
EEC grade 1	6 (3.3)	6 (3.3)
Insufficient sample	4 (2.2)	10 (5.4)

The sensitivity of pipelle sampling was 100% in detecting proliferative, secretory, hormonal dependent endometrium, simple and atypical hyperplasia and EEC grade 1, while it was 89% for the detection of disordered endometrium and 53.3% only for detection of polyp (Table 5).

Table 5: Data of pipelle device results in comparison to D & C results.

Pathology	Pipelle Device results N=92			
	Sensitivity	Specificity	PVP	PVN
Proliferative endometrium	100%	97%	88%	100%
Secretory endometrium	100%	100%	100%	100%
Endometrial polyp	53.30%	100%	100%	91.70%
Disordered proliferative endometrium	89%	100%	100%	97.40%
Hormone dependent endometrium	100%	100%	100%	100%
Simple endometrial hyperplasia	100%	95%	75%	95%
Atypical endometrial hyperplasia	100%	100%	100%	100%
EEC grade 1	100%	100%	100%	100%

Discussion

Abnormal bleeding is the presenting sign in more than 90%

of perimenopausal women with cancer of the endometrium [7]. Endometrial cancer is the sixth most common malignant neoplasm in women worldwide and is the most common gynecologic malignancy in developed countries [8]. Therefore, the management of AUB needs to be undertaken seriously. There are many methods of endometrial assessment in patients with abnormal uterine bleeding, including ultrasonography, D&C, office-based methods, including hysteroscopic biopsy or endometrial samplers such as suction pipelle [6]. The D & C is the most conventional method of endometrial sampling which is in vogue since many decades. Though, it offers a high degree of sensitivity in diagnosis of endometrial lesions, the associated surgical risks, postoperative pain, higher costs due to hospitalization and anesthesia have necessitated the search for a suitable substitute which is simpler, cheaper, non-invasive, free of complications and offers good diagnostic accuracy [6]. The advent of non-invasive office procedures like pipelle endometrial sampling has posed a challenge to the whole range of conventional invasive techniques. It is now widely accepted by the clinicians and patients, since its safe and economical. It can sample about 5-15% of the total endometrial surface area. It is especially useful in global lesions involving in large surface area of the endometrium than in focal lesions [7]. Hence, our study was proposed to evaluate the efficacy of Pipelle sampling in diagnosing endometrial pathologies in comparison with gold standard D and C method. The aim of this study was to Compare between the histopathological findings of pipelle endometrial biopsy and D&C biopsy (the gold standard).

Regarding the clinical features of the study population; we work on 184 cases their age was ranged from 44 years up to 66 years with mean of 54.8 years, their parity is ranged from 1 to 5 with mean of 1.8, and according to BMI, 36 cases (19.6%) were normal (BMI; 18-25), 58 cases (31.5%) are overweight (BMI; 25-30) and rest of cases (90 case, 48.9%) are obese (BMI: more than 30) from that it seems that most of patients were obese. In comparison with a study performed in Iran by Moradan et al., 2015 on 130 patients, similar data have been observed, as the mean age of the study group was 46.19 years. The mean parity was 2.9 ranging from 1 to 5 time [9,10]. Our data is also agreed with data obtained from a study performed in Kuwait by Abdelazim et al. [11] on 143 cases as it shows that, the mean age of the study group was 46.3 years ranging from 40 to 49. The mean parity was 4.7 ranging from 1 to 6 time. Regarding to menopausal state of our studied group, most of cases were pre-menopause with percentage of 76.1%, the rest of cases were post-menopause. It was to somehow consistent with that in another study as the percentage of pre- menopause was 62.3%.

The most common presenting symptoms among our studied group was menorrhagia 78 cases (42.4%), 56 cases (30.4%) presented with Polymenorrhoea, 30 cases (16.3%) presented with metrorrhagia and finally 20 cases (10.9%) presented with Post-menopausal bleeding [9]. There were slight differences in the percentage of the common presentation among patients included in the above study as Menorrhagia was the most common presenting complaint seen in 116 cases (55.24%), but against to our findings it was followed by metrorrhagia in 48 (22.86%) cases, then Polymenorrhoea in 28 (13.33%) cases and postmenopausal

bleeding in 18 (8.57%) cases. In comparison with the study by Abdelazim et al. [11], the presenting symptoms were menorrhagia 37%, poly-menorrhagia 25.8%, metrorrhagia 18.1% and Post-menopausal bleeding 16.7%, like our results.

In our study tissues obtained for histopathology were mostly enough in both methods, sample sufficiency was 97.9% for D & C as there were only 4 insufficient samples while in pipelle sampling it was 94.6%, 5 samples are in insufficient. In comparison with the study by Alliratnam AS et al. [12] Sample sufficiency was 96% for D & C versus 93% for Pipelle. While in Moradan et al., 2015 study 84.6% of the samples obtained by Pipelle and 90% of those obtained by D& C were enough. Similar results have been observed in Abdelazim et al. [11]. study, Sample sufficiency was 100% for D & C versus 97.9% for Pipelle.

Also, similar results were reported in a study by Naderi et al. [13] the sufficiency rates were 91.6% and 98.3% by Pipelle and D & C respectively. Regarding pathology of endometrial tissue obtained by D&C and pipelle; our study showed that, the 2 methods were matched in detection of secretory endometrium, hormone dependent endometrium, atypical hyperplasia and EEC grade 1, while there was over estimation of positive proliferative endometrial cases and simple hyperplasia by pipelle device (18.5% and 17.4% versus 16.3% and 13% respectively by D&C), also it miss cases of endometrial polyp and disordered endometrial hyperplasia (8.7% and 17.4% versus 16.3% and 19.6% respectively by D&C).

The results of endometrial sampling were also to somehow similar to Alliratnam et al. (12). study, Histopathological examination revealed that both methods agreed in all cases of secretory endometrium and adenocarcinoma, and there was over estimation of positive in diagnosis of proliferative endometrium by pipelle device, only 1 missed case by pipelle in diagnosis of disordered endometrium, but it failed to diagnose any case of endometrial polyp, thus polyp is rarely to be detected by pipelle in this study and proliferative endometrium is the commonest cause of peri-menopausal bleeding in this study.

In Moradan et al., 2015 study, the pipelle missed only few cases in diagnosis of secretory endometrium and endometrial hyperplasia without atypia (27.7% and 16.9% versus 28.5% and 18.5% by D&C), but they were agreed in diagnosis of malignant endometrium, and pipelle positively overestimated the diagnosis of proliferative endometrium [10]. The results were similar to Abdelazim et al [11]. study who found that there was positive correlation between 2 methods in diagnosis of proliferative endometrium, secretory endometrium, endometrial hyperplasia with atypia and malignant endometrium, but the pipelle missed the diagnosis of some cases of endometrial hyperplasia without atypia and endometrial polyps (34.3% and 2.1% versus 31.4% and 0.7% by D&C). Our study disagrees with Demirkiran et al. [14]. study on 478 patients. Histopathological examination of D & C biopsy showed normal endometrium in 330 cases (69%), hyperplasia in 21 cases (4.4%), hyperplasia with atypia in 20 cases (4.2%), focal lesions in 89 cases (18.6%), atrophy in 9 cases (1.9%) and insufficient in 9 cases (1.9%), while Pipelle method showed; normal endometrium in 356 cases (74.5%), hyperplasia in 22 cases (4.6%), hyperplasia

with atypia in 18 cases (3.8%), focal lesions in 59 cases (12.3%), atrophy in 7 cases (1.5%) and insufficient in 16 cases (3.3%).

Regarding validity; Our study showed good agreement between Pipelle and D&C in detection of endometrial abnormalities; the sensitivity of pipelle sampling was 100% in detecting proliferative, secretory, hormonal dependent endometrium, simple and atypical hyperplasia and EEC grade 1, while it was 89% for the detection of endometrium disorders and 53.3% only for detection of polyp.

In support of our finding's validity of Pipelle in Alliratnam et al. [12] study was as following; Pipelle has sensitivity of 100% in proliferative endometrium, secretory endometrium and Adenocarcinoma, while it had 90% sensitivity in disordered proliferative endometrium diagnosis and only 16% in endometrial polyp detection. Similar results have been observed in Moradan et al., 2015 study as following; pipelle has sensitivity in proliferative endometrium (94.4%), secretory endometrium (97.4), simple endometrial hyperplasia without atypia (92.3%), endometrial cancer (100%) and atrophic endometrium (50%) (10).

Our results are also consistent to somehow with Abdelazim et al. [11] study results as pipelle showed sensitivity of 100% in proliferative endometrium, secretory endometrium, endometrial hyperplasia and endometrial carcinoma and only 60% in detection of endometrial polyp. On the other hand, the current study disagrees with Demirkiran et al. [14]. In the detection of endometrial hyperplasia, which was lower than our study, they reported a sensitivity level of 67% for Pipelle biopsy. The source of discrepancies is the recognition of different age groups as criteria for inclusion in this and another research. The other probable cause is difference in curette and Pipelle that is used by different studies.

Conclusion

With regard to the facility to perform sampling as an outpatient procedure and without anesthesia and with short duration and less cost, it is recommended that this device be used instead of D & C. lesion like polyps and focal lesions may missed by pipelle. Negative biopsy must therefore be followed in a symptomatic patient by other diagnostic methods such as D&C or hysteroscopy.

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