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Efficacy of Endosampler in Endometrial Sampling for Diagnosis of Endometrial Cancer

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Abstract:
Objective: To evaluate the efficacy and operator satisfaction of Endosampler in endometrial sampling for the diagnosis of endometrial cancer.

Study Design: A Non Randomized Experimental Trial.

Place and Duration of Study: The Department of Obstetrics and Gynecology Bahawal Victoria Hospital, Bahawalpur. From 15 July 2015 to 10 December 2017

Methodology: overall 300 patients were selected for study. Data was collected regarding demographic informations like age, parity and outcome variable as operator satisfaction, positive and negative sampling. Collected data information was entered in SPSS version 24 for mean ± SD calculation of numerical data (age and parity) frequency percentages of categorical variables operator satisfaction, positive and negative sampling was calculated. Student t test was applied on data and p value ≤0.05 was considered as significance.

Results: Among studied patents operative satisfaction score (ranged 1-5) was 1-2 73.7% well accepted. While, Operative satisfaction score was ranged 3-5, 26.3% poorly accepted. Positive sampling was 82.7%.While negative sampling was 17.3%. No association was found between operative satisfaction score and sampling.

Conclusion: Our results revealed that Endosampler is a useful device for endometrial sampling for the diagnosis of endometrial cancer with high rate of operator satisfaction.

Keywords: Endosampler, Endomatrial cancer, Hystrectomy, Gynaecology.

Introduction:

In case of endometrial cancers Dilatation and curettage (D and C) is a useful technique for solicitation of endometrium for severe uterine bleeding[1]. From a long time this technique considered as gold standard among lot of modalities for this purpose[2]. When someone concern about its disadvantages, use of Operation Theater and requirement of general and regional anesthesia are main disadvantages of D and C. D and C is a time taking procedure with consequent cost and has lot of complications from local anesthetics[3]. Taking these complications in consideration D and C was replaced with many other outpatient techniques.

Abnormal uterine bleeding is an initial sign in suspected cases of endometrial cancer patients, for diagnostic purpose transvaginal ultrasound to measure the endometrial thickness is an primaey investigation and procedure[4]. Endometrial thickness of 5 mm in postmenopausal women is a standard but in non menopausal ladies endometrial thickness is under debate and time of ultrasound is also fixed as close to bleeding episode as possible. in patients with history of recurrent bleeding[5], diagnosed polyps and endometrial thickness above these values (4,5 mm in non menopausal women) histipathology must be performed for confirmation of diagnosis. Point to be noted that advance endometrial cancer was noted in patients whom endometrial thickness is ≤ 5 mm, such patients must have histological sampling[6].

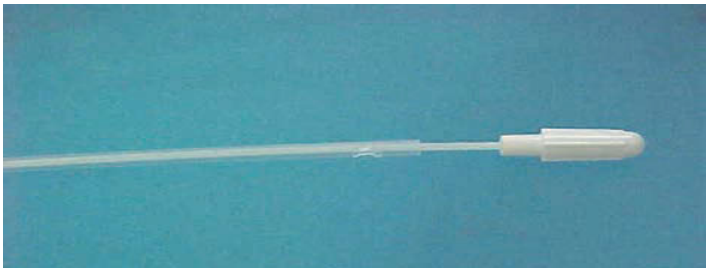
Sampling of endometrium was performed in previous days with disposable devices and these studies were conducted to evaluate their effectiveness[7]. Due to time limitations and small number of patients for studies efficacy of one method not declared over other[8]. Superiority of these techniques needs more investigation and large sample scale studies. Not all available studies conducted for diagnostic accuracy of sampling technique[9]. In recent era a new technique famous with name of endosampler is available in form of disposable device which is a joint venture of Lombard ILL and MedGynand easy to use for sampling of endometrium [10]. In our study we aim to investigate the diagnostic yield of Endosampler for endometrial sampling in suspected cases of endometrial cancer.

Methodology:

This non randomized trial was conducted in the department of Obstetrics and Gynecology Bahawal Victoria Hospital, Bahawalpur. From 15 July 2015 to 10 December 2017 under supervision of senior Hospital and Department staff. Non probability consecutive sampling technique was used. Total number of 300 patients who were suspected cases of endometrial cancer selected for study. Endometrial samples were obtained before decision of hysterectomy. Patients with previous history of endometrial sampling and who were refused to give consent were excluded from the study.

Endosampler is a 23 cm long plastic portable device with 3 mm external diameter. At the round tip of device there is 4 mm hole which represents its mouth opening. Shape of this end is like curette (not round not flushed with tube).

Fig-A



Endosampler Device

An angle of 160 degree is also given from the tip to adjust according the anatomy of uterus. This angle is six cm from the tip of device. A base point is given to attach 5 ml syringe to create negative pressure. Negative pressure can be maintained on detaching syringe by locking the spring structure made inside. Once negative pressure was maintained device can be detached from the cavity. It is very important to measure the uterine length before insertion of device to unlock the piston. Contents in the piston pushed into the container filled with formalin solution. All samples were analyzed by the same person who was unaware of device used for sampling. After that samples were confirmed with histopathology. Collected data information was entered in SPSS version 24 for mean ± SD calculation of numerical data (age and parity) frequency percentages of categorical variables (operator satisfaction, positive and negative sampling) was calculated. Chi square test was applied on data and p value ≤0.05 was considered as significance.

Results:

Overall, 300 patients were enrolled in this study. The mean age and parity of the patients was 44.03±2.38 years and 1.95±0.95 respectively. The difference was statistically insignificant. (Table. I).

Operative satisfaction score (ranged 1-5) was 1-2 73.7% well accepted. While, Operative satisfaction score was 3-5, 26.3% poorly accepted. (Table.II). Positive sampling was 82.7%, while, negative sampling was 17.3%. (Figure.I). No association was found between operative satisfaction score and sampling. (Table.III).

Table-I

Demographic characteristics of the patients

Variable	Presence	Test of Sig.
Age (years)	44.36±5.40	**t=0.325, p=0.745**
Parity	1.95±0.95	**t=-0.236, p=0.814**

Table. II

Operator satisfaction score

Variable	Frequency	Percentage
1-2 well accepted	**221**	**73.7**
3-5 poorly accepted	**79**	**26.3**
Total	**300**	**100.0**

Table. III

Association of Operator satisfaction score and sampling

Operative satisfaction score	Sampling		Total	Chi-Square P-value
	Positive sampling	Negative sampling		
well accepted	182	39	221	0.810
poorly accepted	66	13	79	
Total	248	52	300	

Figure. I

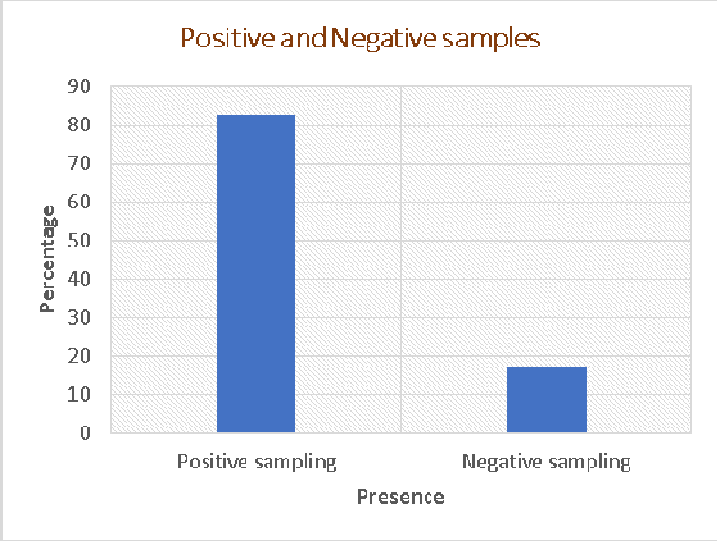
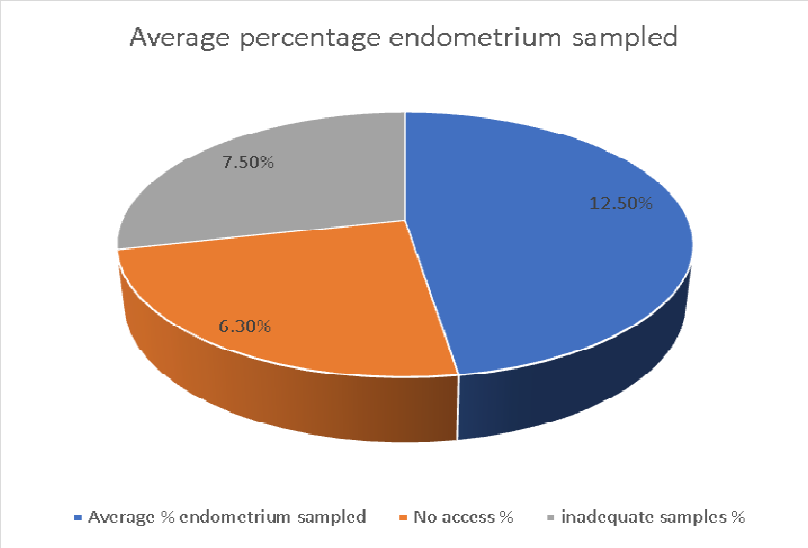


Figure. II



Discussion:

Office endometrial sampling is a preferable and commonly accepted procedure used to diagnose endometrial pathology, mainly due to its economical cost, minimal theatre time and ward admission [11]. Moreover, the efficacy of endometrial devices commonly calculated as yield for endometrial carcinoma and hyperplasia is almost comparable to the classical D and C [12]. General anesthesia required for D & C is avoidable by using office endometrial sampling techniques which can be carried out with or without local anesthesia. Last but not the least, the ease of its use during first clinical visit helps in reducing the time to reach at a diagnosis. The best device competition for office endometrial sampling has been a tough race and a hot topic of many researchers. The parameters used to reach a conclusion regarding this race include the simplicity in use, comfort level of the patient, low cost e minimal major complications and good tissue yield for histopathological evaluation.

In our study, the mean age and parity of the patients was 44.03±2.38 years and 1.95±0.95 respectively. Operative satisfaction score was ranked on a range of 1-5. In 73.7% cases it was well accepted and poorly accepted in remaining 26.3% of cases. Positive sampling was 82.7% while, negative sampling was 17.3%. No association was found between operative satisfaction score and sampling.

Accuracy of a positive test result is high but that of a negative test result is of limited value. Thus, a negative test is not accurate enough to rule out the need of further diagnostic testing, thereby reducing the utility of outpatient biopsy in isolation for excluding disease [13]. Poor patient compliance or biopsy technique can give rise to inadequate endometrial samples and may lead to non-representative sampling. Endometrial carcinoma can be missed in outpatient biopsy. Therefore, if intrauterine structural abnormalities are suspected or symptoms persist than transvaginal ultrasonography, outpatient hysteroscopy and further endometrial sampling or a combination of these can be used to reach at a confirmed diagnosis [14,15,16,17].

Most other studies give a comparison of Pipelle with the Endosampler in a randomised fashion. Endosampler seem to be easier to use than pipelle. No major complications are associated with any of this device. Efficacy of any endometrial sampler device seems to be in direct relation with the size of the endometrium excised as biopsy, making the Endosampler a better device than the Pipelle with a p-value of 0.03 [18]. A study done by Rodriguez et al showed that the percentage of sampled endometrium obtained by using Vabra aspirator was also higher than that of Pipelle with p-value of < 0.001 [19].

A formal D and C can also fail to detect malignant change of the endometrium. This failure to detect malignancy is not limited to patients undergoing outpatient sampling [20,21]. Detection of polyps by Blind endometrial sampling is unreliable[22]. Endometrial samples obtained by endosampler showed no noticeable abnormalities.

If clinician correlates the clinical findings with the endometrial sampling findings, especially the endosampler owing to its higher adequacy of sample size, can pick up the missed endometrial carcinoma by repeated sampling through a different technique.[11]

Conclusion:

Our results revealed that Endosampler is a useful device for endometrial sampling for the diagnosis of endometrial cancer with high rate of operator satisfaction.

Conflict of interest: Nil

Funding Source: Nil

Authors Contribution:
IY – Conceived Idea, Designed Study
TB- Data Collection, Manuscript writing
MAR- Data Collection, Literature Review

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