

## Efficacy of Endosampler in Endometrial Sampling for Diagnosis of Endometrial Cancer

Iqra Younus<sup>1</sup>, Tahreem Bashir<sup>2</sup>, Muhammad Ali Raza<sup>3</sup>

1,3 Department of Gynaecology and Obstetrics, Bahawal Victoria Hospital, Bahawalpur.

2. Department of Gynaecology and Obstetrics, Jinnah Hospital, Lahore.

Email of Corresponding author: [iqrayounus363@hotmail.com](mailto:iqrayounus363@hotmail.com)

### 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  $\pm$  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  $\leq 0.05$  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, Endometrial 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<sup>1</sup>. From a long time this technique considered as gold standard among lot of modalities for this purpose<sup>2</sup>. 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<sup>3</sup>. 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 primary investigation and procedure<sup>4</sup>. 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<sup>5</sup>, diagnosed polyps and endometrial thickness above these values (4,5 mm in non menopausal women) histopathology must be performed for confirmation of diagnosis. Point to be noted that advance endometrial cancer was noted in patients whom endometrial thickness is  $\leq 5$  mm, such patients must have histological sampling<sup>6</sup>.

Sampling of endometrium was performed in previous days with disposable devices and these studies were conducted to evaluate their effectiveness<sup>7</sup>. Due to time limitations and small number of patients for studies efficacy of one method not declared over other<sup>8</sup>. Superiority of these techniques needs more investigation and large sample scale studies. Not all available studies conducted for diagnostic accuracy of sampling technique<sup>9</sup>. 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<sup>10</sup>. 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  $\pm$  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  $\leq 0.05$  was considered as significance.

**Results:**

Overall, 300 patients were enrolled in this study. The mean age and parity of the patients was  $44.03 \pm 2.38$  years and  $1.95 \pm 0.95$  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 $\pm$ 5.40	t=0.325, p=0.745
Parity	1.95 $\pm$ 0.95	t=-0.236, p=0.814

**Table. II**

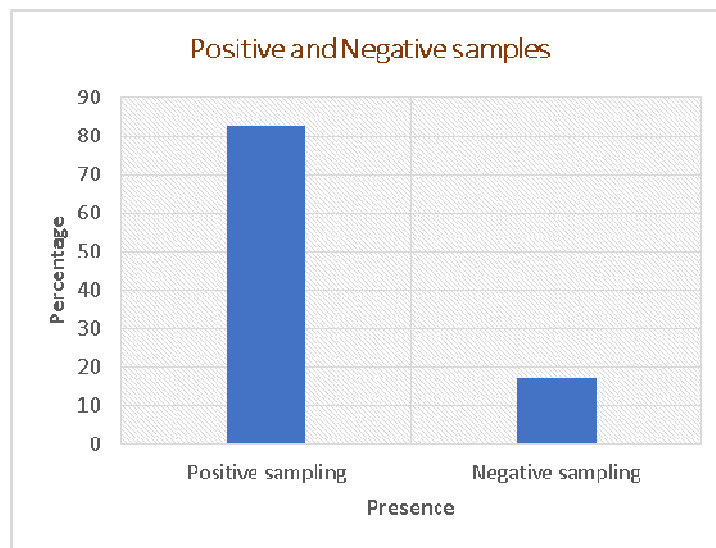
**Operator satisfaction score**

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

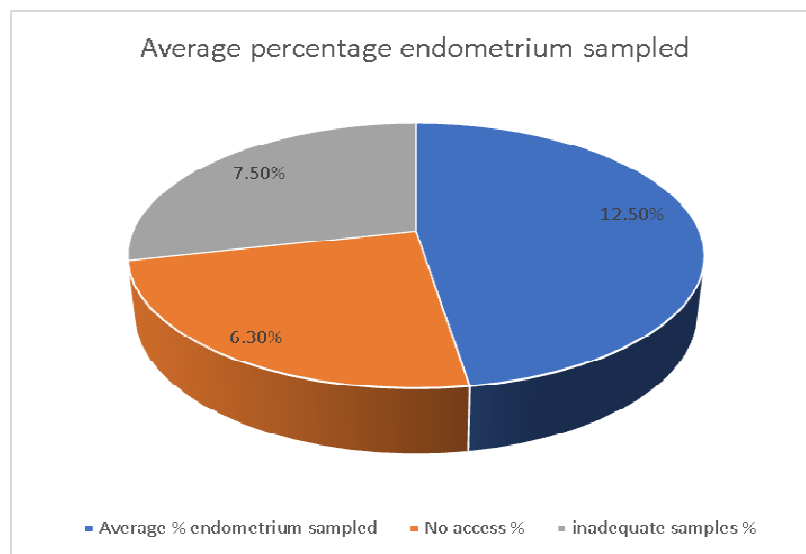
**Table. III**  
**Association of Operator satisfaction score and sampling**

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	
<b>Total</b>	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<sup>11</sup>. Moreover, the efficacy of endometrial devices commonly calculated as yield for endometrial carcinoma and hyperplasia is almost comparable to the classical D and C<sup>12</sup>. 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  $44.03 \pm 2.38$  years and  $1.95 \pm 0.95$  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<sup>13</sup>. 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<sup>14,15,16,17</sup>.

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<sup>18</sup>. 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  $< 0.001$ <sup>19</sup>.

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<sup>20,21</sup>. Detection of polyps by Blind endometrial sampling is unreliable<sup>22</sup>. 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.<sup>11</sup>

## 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

## References:

1. Du J, Li Y, Lv S, et al. Endometrial sampling devices for early diagnosis of endometrial lesions. *J Cancer Res Clin Oncol*. 2016;142(12):2515-22.

2. Kaiyrylkyzy A, Freese KE, Elishaev E, Bovbjerg DH, Ramanathan R, Hamad GG et al. Endometrial histology in severely obese bariatric surgery candidates: an exploratory analysis. *Surg Obes Relat Dis.* 2015;11(3):653-8.
3. Gkrozou F, Dimakopoulos G, Vrekoussis T, Lavasidis L, Koutlas A, Navrozoglou I et al. Hysteroscopy in women with abnormal uterine bleeding: a meta-analysis on four major endometrial pathologies. *Arch Gynecol Obstet.* 2015;291(6):1347-54.
4. Russell M., Choudhary M, Roberts M. *Gynecol Surg.* 2016;13:193.
5. Jindal A, Mohi MK, Kaur M, Kaur B, Singla R, Singh S. Endometrial evaluation by ultrasonography, hysteroscopy and histopathology in cases of breast carcinoma on Tamoxifen therapy. *J Mid-Life Health.* 2015;6(2):59-65.
6. Jacques Donnez, Marie-Madeleine Dolmans; Uterine fibroid management: from the present to the future, *Human Repro.* 2016;22(6):665–86.
7. Werner M.D, Forman EJ, Hong KH. *J Assist Repro Genet.* 2015;32:557.
8. Sivalingam VN, Kitson S, McVey R, et al. Measuring the biological effect of presurgical metformin treatment in endometrial cancer. *Br J Cancer.* 2016;114(3):281-289.
9. Ma T, Readman E, Hicks L, Porter J, Cameron M, Ellett L et al. Is outpatient hysteroscopy the new gold standard? Results from an 11 year prospective observational study. *Aust NZ J Obstet Gynaecol.* 2017;57:74–80.
10. Bonger, M, Brölmann H, Gupta J *Gynecol Surg.* 2015;12:61.
11. Peacock LM, Thomasee ME, Williams VL, Young AE. Transition to office-based obstetric and gynecologic procedures: safety, technical, and financial considerations. *Clin obstet and gynecol.* 2015;58(2):418-33.
12. Sundar S, Balega J, Crosbie E, Drake A, Edmondson R, Fotopoulou C, et al. BGCS uterine cancer guidelines: Recommendations for practice. *Eur J Obstet Gynecol Reprod Biol.* 2017;213:71-97.
13. Clark TJ, Gupta JK. Endometrial sampling of gynaecological pathology. *The Obstet & Gynaecol.* 2002;4(3):169-74.
14. Clark TJ. Outpatient hysteroscopy and ultrasonography in the management of endometrial disease. *Current Opinion in Obstet Gynecol.* 2004;16(4):305-11.
15. Amant F, Moerman P, Neven P, Timmerman D, Van Limbergen E, Vergote I. Endometrial cancer. *The Lancet.* 2005;366(9484):491-505.
16. Dreisler E, Poulsen LG, Antonsen SL, Ceausu I, Depypere H, Erel CT, et al. EMAS clinical guide: assessment of the endometrium in peri and postmenopausal women. *Maturitas.* 2013;75(2):181-90.
17. Dueholm M, Hjorth IMD. Structured imaging technique in the gynecologic office for the diagnosis of abnormal uterine bleeding. *J Res Clin Obstet & Gynaecol.* 2017;40:23-43.
18. Soeters R, Whittaker J, Dehaeck K. Endometrial sampling: a comparison between the Pipelle® endometrial sampler and the Endosampler®. *South Afric J Gynaecol Oncol.* 2011;3(1):34-8.
19. Rodriguez GC, Yaqub N, King ME. A comparison of the Pipelle device and the Vabra aspirator as measured by endometrial denudation in hysterectomy specimens: the Pipelle device samples significantly less of the endometrial surface than the Vabra aspirator. *Am J Obstet Gynecol.* 1993;168(1):55-9.
20. Moodley M, Roberts C. Clinical pathway for the evaluation of postmenopausal bleeding with an emphasis on endometrial cancer detection. *J Obstet Gynaecol.* 2004;24(7):736-41.
21. van Hanegem N, Prins MM, Bongers MY, Opmeer BC, Sahota DS, Mol BWJ, et al. The accuracy of endometrial sampling in women with postmenopausal bleeding: a systematic review and meta-analysis. *E J Obstet Gynecol.* 2016;197:147-55.
22. Levy-Zauberman Y, Pourcelot A-G, Capmas P, Fernandez H. Update on the management of abnormal uterine bleeding. *J gynecol obstet human repro.* 2017;46(8):613-2.