

Study of endomed sampler for endometrial biopsy, by comparing the histopathology reports as gold standard

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Abstract

Background: Abnormal uterine bleeding (AUB) is a major clinical problem in women of peri and post-menopausal age group. It accounts for 30% of outpatient population coming to a gynaecologist. Evaluation of AUB is important for ruling out endometrial carcinoma and its precursors. Endomed biopsy is an ideal method for obtaining endometrial sample with ease, low cost and without anaesthesia. To determine sensitivity, specificity, positive predictive value and negative predictive value of Endomed sampler, by comparing the histopathology reports of endometrial samplings with that of hysterectomy specimen, taken as gold standard. **Methods:** This study is carried out in 76 patients with abnormal uterine bleeding posted for hysterectomy. Endometrial sampling was done with Endomed in all patients. The histopathology report of endomed sample is compared with that of hysterectomy sample. **Results:** The mean age of study population in our study was 45.75 ± 7.19 years. The most common complaint was menorrhagia (39.5%), followed by polymenorrhagia (17.1%), dysmenorrhoea and lower abdominal pain (14.5% each). Endomed sample was found to be adequate for 94.7% of the study population. Among the adequate samples, proliferative endometrium contributed to a 28.9%, followed by secretory endometrium (22.4%) and the least was hyperplasia with atypia (3.9%). Among the study population, 8 (10.5%) of them were found to have carcinoma endometrium with histopathology (HPR) report of hysterectomy specimen whereas 6 (7.9%) using Endomed sampling. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was found to be 100%, 88.2%, 96.97%, 100% and 97.22% respectively for Carcinoma Endometrium. **Conclusion:** Endometrial sampling by endomed method is safe, easy to perform, highly sensitive and specific for diagnosis of endometrial carcinoma and its precursors. Endomed sampling can be used as an alternative to D&C for sampling of endometrium.

Keywords: AUB, Endometrial sampling, Endomed, endometrial carcinoma, D&C

Introduction

Abnormal uterine bleeding is one of the most frequent menstrual problems that constitute

about 70% of patients attending gynaecology outpatient department ^[1]. It includes heavy and prolonged bleeding or any form of irregular bleeding per vaginum ^[2]. It warrants thorough evaluation in pre and postmenopausal women to rule out serious pathology like endometrial cancer and its precursors.

Histopathological interpretation of endometrial tissue is the gold standard investigation for AUB. Since many years Dilatation and curettage has been the procedure of choice for endometrial tissue sampling. But because of associated surgical risks, expense, postoperative pain and need for operative anaesthesia other substitutes were evaluated ^[3].

Endo Med, the Indian version of endometrial pipelle is gaining popularity, owing to its reduced cost & easy availability. There is no need for cervical dilatation and decreased risks of hemorrhage, infection and perforation. It is made up of a clean, flexible, polypropylene sheath with a syringe for suction. The device is disposable, easy to use and well tolerated by patients. The endomed enables quick sampling of the endometrium and entire procedure is completed within seconds ^[4].

Present study was aimed to determine sensitivity, specificity, positive predictive value and negative predictive value of Endomed sampler, by comparing the histopathology reports of endometrial samplings with that of hysterectomy specimen, taken as gold standard.

Materials and Methods

Present study was single-center, diagnostic test evaluation study, conducted in Department of OBG, KMCT Medical College, Manassery, Kozhikode, India. Study duration was of 1 year (January 2020 to December 2021). Informed written consent of the patients and ethical committee approval from our institution were obtained.

Inclusion criteria

- Women of pre and postmenopausal, 35-70 years of age group with abnormal uterine bleeding scheduled for hysterectomy, Not on hormone therapy & No evidence of any hematological disorder.

Exclusion criteria

- Unwilling patients.
- With suspected pelvic infection.
- Premalignant and malignant lesions of cervix.

76 women with abnormal uterine bleeding who meets the inclusion and exclusion criteria, scheduled for hysterectomy were selected. Patient related data such as history, general physical examination, local examination and ultrasonography findings were noted. Ultrasonography was done before endometrial sampling in all cases. After hysterectomy, endometrial sampling was done using Endomed sampler, specimen sent for histopathology. Hysterectomy specimens are sent for histopathology. The histopathology reports of endomed sample was compared with that of hysterectomy sample.

Data was entered in Excel and analyzed using SPSS trial version. Descriptive statistics is used to analyze the data. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of the endomed are calculated by comparing the histopathology reports of endomed sample with that of hysterectomy specimen which is considered as gold standard.

Results

Among 76 patients, the mean age was 45.75 ± 7.19 years, minimum age was 33 and maximum age was 67 in the study population. The mean of Duration of symptoms was 1.55 ± 1.5 years & mean of BMI was 25.08 ± 2.68 in the study population. Among the study population, 61 (80.3%) participants were Multiparas.

Table 1: General characteristics (N=76)

Parameter	Frequency/Mean \pm SD	Percentages
Age (In Years)	45.75 ± 7.19	
Duration of symptoms (In Years)	1.55 ± 1.5	
BMI (kg/m^2)	25.08 ± 2.68	
Parity		
Nulli	6	7.9%
Primi	9	11.8%
Multi	61	80.3%

Among the study population, common complaints were Menorrhagia (39.5%), followed by Polymenorrhagia (17.1%), Dysmenorrhagia & lower abdominal pain (14.5% each).

Table 2: Descriptive analysis of complaints

Complaints	Frequency	Percentages
Dysmenorrhagia	11	14.5%
Menorrhagia	30	39.5%
Polymenorrhagia	13	17.1%
Lower abdominal pain	11	14.5%
Postmenopausal bleeding	6	7.9%
Metrorrhagia	5	6.6%

In present study population, majority patients had past history of Diabetes mellitus (9.2%), Hypertension (7.9%), Hypothyroidism (6.6%), Hypertension with Diabetes mellitus (5.3%) & coronary artery disease (3.9%).

Table 3: Past history in the study population (N=76)

Past History	Frequency	Percentages
Diabetes mellitus	7	9.2%
Hypertension	6	7.9%
Hypothyroidism	5	6.6%
Dyslipidaemia	4	5.3%
Hypertension, Diabetes mellitus	4	5.3%
Coronary artery disease	3	3.9%
No significant history	47	61.8%

The mean of endometrial thickness was 9.9 ± 4.45 mm in the study population, minimum was 1.10 and maximum was 20.00 in the study population.

Table 4: Descriptive analysis of endometrial thickness in study population (N=76)

Parameter	Mean \pm SD	Median	Minimum	Maximum	95% C.I	
					Lower	Upper
Endometrial thickness	9.9 ± 4.45	9.00	1.10	20.00	8.88	10.91

Among the study population, 72 (94.7%) participants samples were adequate and 4 (5.3%) were not adequate. Among the HPR endometrium by endomed 27% were proliferative endometrium, 19% secretory endometrium, 10.5% atrophic endometrium, 9.2% disordered proliferative endometrium.6.6% came as endometrial hyperplasia, 5.3% hyperplasia with atypia. 7.9% came as carcinoma endometrium.

Table 5: Descriptive analysis of HPR endomed in the study population (N=76)

HPR-Endomed	Frequency	Percentages
Proliferative endometrium	21	27.6%
Secretory endometrium	15	19.7%
Atrophic endometrium	8	10.5%
Disordered proliferative endometrium	7	9.2%
Carcinoma endometrium	6	7.9%
Cystic glandular hyperplasia	6	7.9%
Endometrial hyperplasia	5	6.6%
Complex hyperplasia with atypia	4	5.3%
NA(not adequate)	4	5.3%

Among the 76 patients 28.9% was proliferative endometrium, 22.4% had secretory endometrium, 10.5% atrophic endometrium, 6.6% endometrial hyperplasia. 10.5% came as carcinoma endometrium.

Table 6: HPR hysterectomy in the study population (N=76)

HPR hysterectomy	Frequency	Percentages
Proliferative endometrium	22	28.9%
Atrophic endometrium	8	10.5%
Secretory endometrium	17	22.4%
Carcinoma endometrium	8	10.5%
Cystic glandular hyperplasia	6	7.9%
Endometrial hyperplasia	5	6.6%
Disordered proliferative endometrium	7	9.2%
Complex hyperplasia with atypia	3	3.9%

The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was found to be 98.51%,86.5%,98.51%,80%,97.22% respectively for Endometrial Hyperplasia. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was found to be 98.55%, 92.8%, 100%, 75% and 98.61% respectively for Hyperplasia with atypia. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was found to be 100%, 88.2%, 96.97%, 100% and 97.22% respectively for Carcinoma Endometrium.

Table 7: Predictive validity of ENDOMED (N=76)

Parameter	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Diagnostic accuracy
Proliferative endometrium	98.08%	100.00%	100.00%	95.24%	98.61%
Atrophic endometrium	100.00%	100.00%	100.00%	100.00%	100.00%
Secretory endometrium	100 %	100 %	100%	100 %	100 %
Carcinoma endometrium	100.00%	88.20%	96.97%	100.00%	97.22%
Cystic glandular hyperplasia	100.00%	100.00%	100.00%	100.00%	100.00%
Endometrial hyperplasia	98.51%	86.50%	98.51%	80.00%	97.22%
Disordered proliferative endometrium	100.00%	100.00%	100.00%	100.00%	100.00%

Complex hyperplasia with atypia	98.55%	92.80%	100.00%	75.00%	98.61%
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Discussion

Endomed, the Indian version of endometrial pipelle is gaining popularity, owing to its reduced cost, easy availability and there is no need for cervical dilatation and decreased risks of hemorrhage, infection and perforation. It is made up of a clean, flexible, polypropylene sheath with a syringe for suction. The device is disposable, easy to use and well tolerated by patients. The endomed enables quick sampling of the endometrium and entire procedure is completed within seconds. This study is intended to establish the reliability of Endomed sampler so that the number of traditional Dilatation and Curettage could be reduced to minimum.

Endomed sample was found to be adequate for 94.7% of the study population. Among the adequate samples, proliferative endometrium contributed to a 28.9%, followed by secretory endometrium (22.4%) and the least was hyperplasia with atypia (3.9%, i.e. 3 samples out of 72). Among the study population, 8 (10.5%) of them were found to have carcinoma endometrium with histopathology (HPR) report of hysterectomy specimen whereas 6 (7.9%) using Endomed sampling. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was found to be 100%, 88.2%, 96.97%, 100% and 97.22% respectively for Carcinoma Endometrium.

Endomed sampling is known to be a highly specific and highly sensitive test for the diagnosis of endometrial disorders mainly carcinoma and its precursors. Endomed procedure is easy to perform. However, it requires experienced pathologists for accurate results. It was found that pipelle sampling using Endomed was highly sensitive (100%) and specific (88%) in screening carcinoma endometrium and similarly, its precursor stages like endometrial hyperplasia and hyperplasia with atypia.

In present study, we compared the histopathology report of Endomed sampling to with that of HPR report of hysterectomy specimen post-surgery. We found that endomed sampling results were highly similar to the results of HPR hysterectomy biopsy reports. The results were found to be consistent with other studies [5, 6, 7]. These results were on par with the results of D&CHPR reports in a similar study done by Chandrakumari *et al.*, [8] and hence can be one of the alternatives to D&C. It is less painful, less expensive, easy to perform and does not require anaesthesia when compared to D&C [9, 10].

Similar studies found similar results with respect to mean age, presenting complaints, parity, past medical history, and pattern of endometrium [11, 12]. Proliferative and Secretory endometrium were more common than other patterns especially carcinoma [11]. Abnormal uterine bleeding was common among middle aged women (44-47 years) in their perimenopausal period. Most of the women with AUB presented with menorrhagia. This result was found to be consistent with other studies [8, 12]. In our study, we found adequate sample adequacy i.e. 94.4% which may have contributed to high accuracy of our results (97-100%).

Endomed biopsy is valuable in diagnosing endometrial pathology of AUB cases. It is safe, easy to perform, highly sensitive and specific for diagnosis of endometrial carcinoma and its precursors. With the additional benefit of high sample adequacy it can be used as an alternative to D&C for sampling of endometrium.

Conclusion

Endomed biopsy is valuable in diagnosing endometrial pathology of AUB cases. It is safe, easy to perform, highly sensitive and specific for diagnosis of endometrial carcinoma and its precursors. With the additional benefit of high sample adequacy it can be used as an alternative to D & C for sampling of endometrium.

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