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Original Research Article

Office endometrial sampling: a comparison between Endosampler and Karman cannula number 4

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ABSTRACT

Background: Endometrial aspiration biopsy is one of the primary steps in diagnostic evaluation of a women presenting with suspected endometrial pathology. The aim of present study was to compare specimen adequacy, ease of doing the procedure, patient comfort and cost effectiveness in office endometrial sampling by endosampler vs Karman cannula number 4.

Methods: This was a prospective comparative study where 102 patients were included. In 50% of patients, endosampler was used and Karman cannula was used in the rest. All procedures were done in outpatient department and various parameters like specimen adequacy, pain score, ease of doing the procedure were noted, analysed and compared in both groups.

Results: The mean age of the patients was 37.1(±10) years with comparable distribution in the two groups. The parity was comparable in both groups. Authors further analysed the data on the basis of operator experience. The mean score of ease of insertion based on the experience of residents of <2 years and >2 years was 3.1±1.48; 4.0±1.96 and 3.5±1.5; 3.7±2 in endosampler and Karman cannula group respectively. This difference was significant in the endosampler group (P: <0.001). The difference in pain score in two groups was not significant. The specimen obtained was adequate in 32 (62.7 %) patients of the endosampler group and in 39 (76.4 %) patients of the Karman cannula group (p=0.07). Endosampler is five times costlier than Karman cannula.

Conclusions: Karman cannula is a good and cost-effective sampling device for endometrial biopsy.

Keywords: Abnormal uterine bleeding, Endometrial aspiration, Endometrial biopsy, Endosampler, Karman cannula

INTRODUCTION

Endometrial Biopsy is frequently required in gynaecological practice for the diagnosis of endometrial abnormalities in patients with abnormal uterine bleeding and infertility. Previously, dilatation and curettage (D and C) was performed for taking endometrial biopsy. The drawback of D and C is that in 60 % of cases less than half of the uterine cavity is curetted, needs anaesthesia

and there is risk of perforation and infection.¹⁻³ The various outpatient sampling devices for endometrial aspiration biopsy like Karman cannula, pipelle endometrial aspirator, vabra aspirator, endosampler, novak curette have been studied for their diagnostic accuracy.⁴⁻⁹ Comparison of various devices for detection of endometrial pathology have been done but the existing data is not enough which could advocate the use of an ideal method for endometrial sampling which obtains the

endometrium adequately, is comfortable for both doctor and patient and is also cost effective.

Authors planned a prospective comparative study at present institute to compare the efficacy, patient comfort, pain score and adequacy of specimen obtained by endosampler and Karman cannula number 4 both of which are readily available at their centre.

METHODS

This present prospective study was conducted at the Department of Obstetrics and Gynaecology, Vardhman Mahavir Medical College and Safdarjung hospital, New Delhi, India. The study protocol and consent form were reviewed and approved by the ethics committee of the hospital. Women having heavy menstrual bleeding, post-menopausal bleeding, infertility were included in this study. Pregnant females, women having vaginal infections, pelvic inflammatory disease and proven medical disorder accounting for abnormal uterine bleeding were excluded from the study. Clinical evaluation of each patient was done by a detailed history and clinical examination. Baseline investigations and a pelvic ultrasound was done and then they were subjected to endometrial sampling after an informed written consent. A total of 102 patients fulfilling the inclusion criteria were enrolled.

These patients were randomized according to computer generated numbers into two groups. Karman cannula number 4 was used in 51 patients and endosampler in rest.



Figure 1: Endosampler.

Endosampler, a low-pressure suction device is a semi rigid 3 mm curette with a single sharp slot on end (Figure 1). It is angulated and has markings on it. Negative pressure is created by a 10-cc syringe at the base of the device. There is a lock spring mechanism on syringe which prevents backflow of specimen. Karman cannula number 4 on the other hand is a higher-pressure device and is a flexible cannula made of latex free polypropylene plastic. It is 24 cm in length and has 4 mm diameter (Figure 2). Suction is created by a 10cc disposable syringe attached to the base of cannula.

All the endometrial samples were obtained in the minor operation theatre in outpatient department as an office procedure by the residents. The experience of the gynaecologist doing endometrial sampling was taken into

account to reduce the operator bias and was classified as those having less than 2 years of experience and others with 2-4 years of experience into the field of gynaecology.



Figure 2: Karman cannula number 4 used in present study.

The tissue obtained was sent for histopathology in 10% formalin. The pathologists were blinded to the method used. Various parameters like ease of insertion, pain score and time taken to do the procedure, were recorded in a preset proforma.

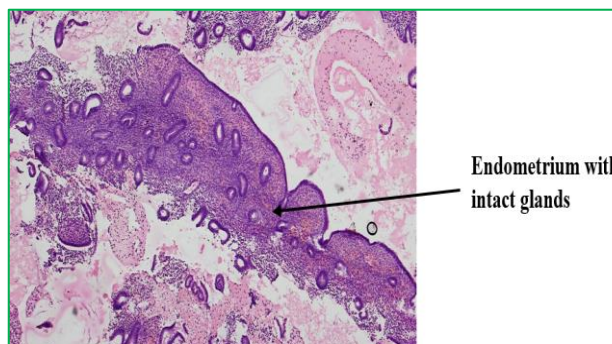


Figure 3: Adequate specimen showing proliferative phase endometrium with intact glands.

The ease of insertion was defined as the ease with which the operator could negotiate the internal os with the respective cannula. This score was measured subjectively by the clinician on a score of 1-5 with 5 being very easy. Women were asked about the pain experienced during the procedure which was documented from a score of 0-10 with 10 being worst pain according to the visual analogue scale.¹⁰ Pathologist commented on the adequacy of the tissue which was defined as the presence of intact endometrial glands and stroma on microscopic examination. Figure 3 depicts histopathology slide showing an adequate specimen with presence of intact glands and Figure 4 shows inadequate specimen slide with broken glands, blood and mucus (Figures 3, 4). Patients in whom inadequate tissue was obtained were taken up for repeat procedure at a later date. The cost of the two sampling devices was also taken.

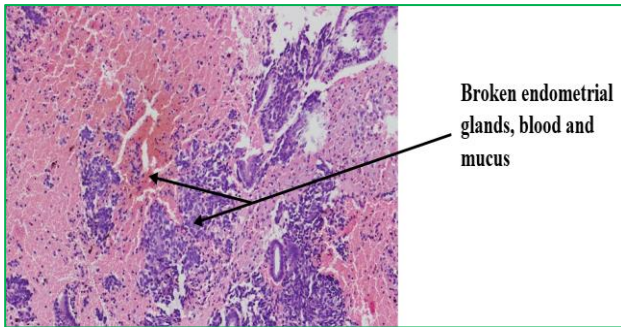


Figure 4: Inadequate endometrial biopsy sample slide showing broken endometrial glands, blood and mucus.

Statistical analysis

Data was statistically analysed using Epi info software by Centre for Disease control and Prevention, USA; Open Epi software by Dean and Sullivan; and Microsoft Office Excel 2016. P value of <0.05 has been considered statistically significant and is reported throughout.

RESULTS

The overall mean age of the patients was 37.1(±10) years. 63 (61.67 %) patients had parity more than 2 and 39 (38.2 %) patients had parity less than 2. The parity was comparable in the two groups with 34 (66.6 %) patients with parity >2 in endosampler group and 29 (56.88 %) in the Karman cannula group (P - 0.15).

Table 1: Comparison on basis of ease of insertion.

Variables	Score	Endosampler (n)	Karman cannula (n)
Ease of insertion	1	1	2
	2	3	3
	3	14	15
	4	22	25
	5	11	6
<2 years' experience	Mean score	3.1±1.48	3.56 ±1.5
>2 years' experience	Mean score	4.0±1.96	3.77±2
P value		0.0003	0.16

n-Number of patients

Table 1 shows the comparison between ease of insertion score in the two study groups. The mean score of ease of insertion in endosampler group by those with <2 years of experience was 3.1±1.48 and those with >2 years of experience was 4.0±1.96. This difference was statistically significant (P-0.0003). On the other hand, this difference in mean score for ease of insertion in Karman group was not significant (p-0.16). The difference in pain score in two groups was not statistically significant (p-0.24).

The overall mean time taken to do endometrial sampling was 5±3.4 min and 5.4±3.0 min with endosampler and Karman cannula respectively. Those having less than 2 years of experience took less time to do the procedure with endosampler (4.9±3.2 min) as compared to Karman cannula (mean: 5.6±3.2 min) Those with > 2 years of experience took almost same time with either of the cannula (mean: 5±3.6 min with endosampler and 4.9±2.0 min with Karman cannula). However, this difference was not statistically significant (P value: 0.86).

The mean time taken for the procedure based on parity in the endosampler group showed that in parity more than 2, it was 4.6±2.8 min which was significantly less than the time taken in patients with parity less than 2 (5.7±4.2) (p value-0.02). This difference was not significant in the Karman cannula group. Mean time taken for the procedure with Karman cannula number 4 in parity more than 2 was 5.4±3.2 min and in women with parity less than 2 was 5.3±2.6 min (P value-0.8).

The specimen obtained was found to be adequate in 32 (62.7 %) patients in endosampler group as compared to 39 (76.4 %) in Karman group which although statistically insignificant was close to significant p value (P- 0.07). This accounted for repeat procedure in total of 19 patients in endosampler group and 11 in Karman cannula group.

Finally, the cost of two sampling devices was compared. Karman cannula costed only 1 USD to the patient as against 5 USD for an endosampler.

DISCUSSION

An endometrial sampling procedure is the gold standard for diagnostic evaluation of women with suspected endometrial pathology. The demographic variables like age and parity were comparable in the two study groups. In present study authors did not find any difference regarding ease of insertion in Karman cannula group depending upon resident experience. However, in endosampler group this was statistically significant. Soeters R et al had compared the use of endosampler and pipelle endometrial sampler in 68 patients and they found endosampler to be easier to use as compared to pipelle device (P- 0.0005).⁶ Another study by O.S. Bajouh et al evaluated the use of pipelle endometrial sampler in 463 patients by residents in training and found it to be easy to use and accurate in 70% of the cases.¹¹

There was no statistically significant difference in pain score in present study groups. Rauf et al studied the use of pipelle device vs D and C in 203 women and found Pipelle to produce significantly less pain than D and C. They also concluded that pipelle was acceptable in 98% of patients as compared to 34 % in D and C group.¹² Although authors feel that this comparison between pipelle and D and C procedure in terms of pain score is not feasible as sampling by pipelle is an office procedure

which does not require any anaesthesia unlike D and C procedure which is an inpatient procedure.

The mean time taken in present study to do endometrial sampling was 5 ± 3.4 min and 5.4 ± 3.0 min with endosampler and Karman cannula respectively. Sanam M et al evaluated 130 patients and compared the diagnostic value of D and C with pipelle which has a diameter of 3.1 mm. They reported the duration of procedure for endometrial sampling by pipelle method to be 3.38 ± 0.98 min.¹³ This difference from present study could be explained as Karman cannula had a diameter of 4 mm. However, in case of endosampler, difference in time taken could probably be attributed to the fact that procedure in present study was done by residents.

Authors obtained adequate specimen in 62.7% and 76.4% in endosampler and Karman cannula group respectively. Soeters R et al compared endosampler with pipelle in 68 women and they found endosampler to have sampled significantly more endometrial tissue as compared to pipelle device.⁶ Recently, Jiang Du et al reviewed the literature of a period of 15 years related to various endometrial sampling devices and found the need of an accurate and low-cost endometrial sampler which has specimen adequacy and higher sensitivity for diagnosing endometrial lesions.¹⁴ In present study, authors found Karman cannula to be better than endosampler in terms of specimen adequacy.

When comparing the cost factor, Karman cannula was more cost effective to present patients. There have been studies in literature comparing cost factor of office sampling devices with D and C.^{12,13} But no study has been done so far comparing this parameter in office sampling devices.

CONCLUSION

Karman cannula number 4 is a good office endometrial sampling device for suspected endometrial lesions and is also cost effective.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Ethical Committee of the Hospital

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