

Accuracy of Karman endometrial aspiration in comparison to conventional D and C in women with AUB at tertiary care hospital in North West Rajasthan

Ankur Nama, Swati Kochar, Neha Suthar, Arun Kumar, Kirti Solanki

Department of Obstetrics and Gynaecology, S.P. Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India

ABSTRACT

Background: Approximately 33% of all gynaecological consultations are associated with abnormal vaginal bleeding, and this proportion increases to 70% in the peri and postmenopausal years. **Aims and Objective:** To compare the diagnostic accuracy of Karman's cannula endometrial aspiration histopathology versus dilatation and curettage in patients with abnormal uterine bleeding. **Methodology:** In total 100 women of all age groups with a clinical diagnosis of AUB were included in this prospective comparative study. Endometrial aspiration with Karman cannula was performed in the operation theatre prior to curettage to maintain synchronization during sampling. **Results:** In our study, no significant difference was observed between Karman and D and C regarding sample adequacy ($P = 0.07$), HPE findings ($P = 1$) and concordance rate with hysterectomy specimen ($P = 1$). 95% of the samples obtained by Karman and 98% of those obtained by D and C were adequate. For obtaining an adequate sample by Karman the sensitivity and accuracy was 96.94% and 96% when compared with D and C. Karman and D and C had comparable concordance rates (95% and 95%) with hysterectomy specimen. Karman endometrial sampling is an easy procedure when compared to D and C ($P = 0.007$). With considering D and C as gold standard Karman endometrial sampling demonstrated 100% accuracy for diagnosing adenocarcinoma, endometrial hyperplasia. **Conclusion:** Endometrial aspiration with Karman cannula is an easy, safe, cost-effective, accurate, convenient method of achieving histopathological diagnosis. It can be done as an outpatient procedure without analgesia and anaesthesia when compared to D and C which is expensive and invasive method and requires hospitalization and general anaesthesia.

Keywords: Karman cannula, D and C, AUB, Endometrial aspiration, diagnostic accuracy

Introduction

Approximately 1/3rd of all gynaecological consultations are related to abnormal vaginal bleeding, and this proportion increases to 70% in the peri and postmenopausal ages.^[1] It also accounts for two third cases of hysterectomy. Most gynaecologist agree that abnormal vaginal bleeding after the age of 40 years requires further evaluation to exclude the presence of endometrial polyps, hyperplasia, fibroids or carcinoma.^[2]

Address for correspondence: Dr. Swati Kochar,
1 B 2 Pawanpuri, Bikaner, Rajasthan, India.
E-mail: swatikochar148@gmail.com

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There are various methods for endometrial assessment among women with abnormal uterine bleeding which include ultrasonography, endometrial curettage (D and C), Office based methods including biopsy by hysteroscopy or endometrial samplers like Karman cannula and pipelle.^[3,4] Dilatation and curettage (D and C) has for long been considered the "gold standard" in the diagnosis of endometrial pathology.^[5] One of the most commonly performed gynecological surgery, it accounts for a large proportion of hospital bed use and operating room time. The procedure is expensive, invasive and time consuming. The procedure carries the complications of anaesthesia and there is risk of uterine perforation, intra-uterine infection and cervical laceration.^[6,7] For these reasons, there is a need for a simple,

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accurate and good out-patient department (OPD) procedure as an alternative to D and C. Endometrial aspiration histopathology can be used as a safe, minimally invasive and reliable OPD procedure with minimum discomfort to the patient.^[8]

Karman's cannula is a soft, flexible cannula which works using a suction mechanism. It can be inserted into the cervical canal without dilatation making it an ideal outpatient endometrial biopsy procedure. It is safe, cheap and noninvasive, as well as its complication is too rare, it does not need operation theatre and anaesthesia. It can be used for the detection of a wide variety of benign lesions of endometrium and screening for malignancy.

Despite being an effective, minimal invasive, inexpensive method endometrial aspiration has not gained widespread acceptance for endometrial sampling so this study was undertaken to evaluate endometrial histopathology by Karman's cannula versus conventional dilatation and curettage in patients of AUB.

Material and Methods

The present observational clinical correlational diagnostic study was carried out in the Department of Obstetrics and Gynaecology at S.P. Medical College and Associated Group of Hospitals, Bikaner, Rajasthan, India over a period of 1 year from June 2018 to May 2019. Aims and Objective: To compare the diagnostic accuracy of Karman's cannula endometrial aspiration histopathology versus dilatation and curettage in patients with abnormal uterine bleeding. Total 100 women of all age group with a clinical diagnosis of AUB were recruited in the study. Patients having acute inflammatory disorders of the genital tract, a viable pregnancy and cervical carcinoma will be excluded from the study. After obtaining a detailed clinical history, the patients went through a physical examination, Ultrasonography for endometrial thickness and all relevant investigations were carried out. The procedure was well-explained to the patients, and their consent was taken.

Method of sample collection

Under all aseptic conditions, endometrial aspiration was carried out in the operation theater prior to curettage. Endometrial aspiration was performed by a plastic disposable Karman's cannula measuring 4 mm by the gynaecologist in the operation theater and without administering an aesthesia. The cannula was inserted into the endometrial cavity and connected to 20cc disposable syringe. Negative pressure was then created by withdrawing the piston and maintained, while the mucosa was uniformly aspirated. The suction was released after aspiration and the cannula was withdrawn. Material obtained was saved in container A. In the same sitting, immediately after aspiration all the patients went for D and C under intravenous sedation, the sample was collected in container B. Both samples obtained were fixed in 10% formaldehyde and sent to the Department of Pathology in the same institute. After the biopsy, the patient was observed and evaluated for vaginal bleeding at least for

15 min. Hysterectomy done in patients where it was indicated. With considering D and C as the gold standard, histopathological results of Karman sample were compared.

Outcome measures

Primary outcome of our study was diagnostic accuracy of Karman endometrial aspiration for different endometrial pathologies especially for endometrial hyperplasia and malignancy, and concordance rate with hysterectomy specimen. Secondary outcome of our study was to compare sample adequacy, ease of procedure, and duration of procedure, pain score and associated complications of the procedure.

Sample adequacy was defined by pathologist as presence of intact endometrial glands and stroma on microscopic examination. Endometrial sampling procedure was termed as easy or not easy by the clinician who did the procedure; subjectively taking into consideration the time taken for the procedure to negotiate the cervix, the time taken for the whole procedure. Duration of procedure was calculated for both methods. It starts from holding of upper lip of cervix with vulsellum to the end by obtaining a sample for both methods. Pain was calculated using verbal categorical rating scale (VRS). In Karman endometrial sampling pain was calculated during the procedure while in D and C pain was calculated half an hour after the procedure to nullify the effect of sedation on VRS.

Statistical analysis

Epi-info statistical software (Epi-info., USA) by Centre for Disease Control and prevention, USA was used for data analysis. Quantitative data were analyzed by Student's *t* test for comparison of 2 groups and revealed as mean and SD. Qualitative data were analyzed implementing the Chi-square test and revealed as number and percentage. If one cell had expected number < 5 than Fisher's exact test was applied for a 2 × 2 table. *P* value < 0.05 considered statistically significant.

Results

In our study, 100 women with a clinical diagnosis of AUB were included. The baseline characteristics such as mean age, mean parity, mean endometrial thickness, mean BMI, mean PBAC score, mean Hb level of the studied subjects were 43.14 ± 10.44 years, 3.22 ± 1.55, 7.59 ± 3.16 mm, 23.60 ± 2.67 kg/m², 203.03 ± 39.64, 10.19 ± 0.18 gm/dl [Table 1].

Women with AUB had menometrorrhagia (28%) as their chief complaint followed by postmenopausal bleeding (26%) menorrhagia (19%), polymenorrhoea (19%), and metrorrhagia (8%).

In total 95 subjects (95%) of the samples obtained by Karman and 98 subjects (98%) of those obtained by D and C were adequate (*P* = 0.07). The samples were adequate in both methods in 95 subjects (95%) and were inadequate in both

methods in 1 subject (1%). In one subject (1%) the Karman sample was adequate but in D and C sample was inadequate. Three subjects (3%) had adequate sample by D and C whereas inadequate sample by Karman. In 1 patient both Karman and D and C failed to get an adequate sample for histopathological diagnosis. In this patient, Karman and curette both failed to negotiate endometrial cavity due to big cervical fibroid[Table 2].

The histopathological examination of samples by conventional D and C revealed proliferative endometrium (67%) was the most common endometrial pattern followed by secretory endometrium (18%), endometrial hyperplasia (7%), adenocarcinoma (3%), atrophic endometrium (2%), and pseudo decidual reaction (1%). Out of total subjects, in 2 (2%) subjects, no histopathologic pattern was observed because of inadequate sample [Table 2].

The comparison of histopathological results of Karman and D and C are demonstrated in Table 2.

In the present study, 11% of procedures were termed as not easy in D and C when compared to Karman endometrial sampling in which 1% of procedure were termed not easy by the clinician suggesting that Karman endometrial sampling is an easy procedure when compared to D and C ($P = 0.007$).

In our study, duration of Karman endometrial biopsy was less (3 ± 0.62 min) when compared with D and C (4.91 ± 0.87 min).

In the present study, during Karman endometrial sampling 25% of the subjects felt no pain, 66% of the subjects felt mild pain, and 9% of the subjects experienced moderate pain on VRS. None of the subjects felt worst imaginable pain during Karman endometrial sampling. After D and C 23% of the subjects felt mild pain, 62% of the subjects felt moderate pain and 15% of the subjects experienced worst imaginable pain.

With considering D and C as gold standard Karman endometrial sampling demonstrated 100% sensitivity, specificity, PPV, NPV, and accuracy with regards to diagnosis of adenocarcinoma, endometrial hyperplasia, atrophic endometrium and pseudo decidual reaction. For secretory endometrium the corresponding values were 88.88%, 100%, 100%, 97.62%, and 98%, respectively. With regards to proliferative endometrium sensitivity, specificity, PPV, NPV, and accuracy were 98.50%, 100%, 100%, 97.05%, and 99%, respectively[Table 3].

In our study, 20 out of 100 subjects with AUB went for hysterectomy. Both Karman and D and C had comparable concordance rates with hysterectomy specimen. Karman and D and C both had concordance rate of 95% ($P = 1$)[Table 4].

Discussion

Dilatation and curettage is the most commonly used endometrial sampling method. The capability to recognize endometrial

Table 1: Baseline characteristics of studied subjects

Baseline characteristics	Mean	SD
Age (years)	43.14	10.44
Parity	3.22	1.55
Endometrial thickness (mm)	7.59	3.16
BMI (kg/m ²)	23.60	2.67
PBAC score	203.03	39.64
Hb level (gm/dl)	10.19	0.18

Table 2: Comparison of endometrial patterns on histopathology

Endometrial pattern	Karman	D&C
Proliferative phase	66(66%)	67(67%)
Secretory phase	16(16%)	18(18%)
Pseudo decidual reaction	1(1%)	1(1%)
Endometrial hyperplasia	7(7%)	7(7%)
Adenocarcinoma	3(3%)	3(3%)
Atrophic endometrium	2(2%)	2(2%)
Unsatisfactory tissue	5(5%)	2(2%)
Total	100(100%)	100(100%)

Table 3: Statistical analysis of endometrial patterns obtained by Karman's cannula in comparison to D&C

	Sensitivity	Specificity	PPV	NPV	Accuracy
Proliferative endometrium	98.50%	100%	100%	97.05%	99%
Secretory endometrium	88.88%	100%	100%	97.62%	98%
Endometrial hyperplasia	100%	100%	100%	100%	100%
Adenocarcinoma	100%	100%	100%	100%	100%
Pseudo decidual reaction	100%	100%	100%	100%	100%
Atrophic endometrium	100%	100%	100%	100%	100%

Table 4: Concordance between the results of the Karman and D&C with hysterectomy specimen

	Hysterectomy (total n=20)		Concordance rates
	Comparable	Not comparable	
Karman	19	1	95%
D&C	19	1	95%

carcinoma and hyperplasia is used as a scale to estimate the success rate of each method, as suggested by majority of studies. D and C is an invasive procedure which needs anaesthesia and has morbidity in term of pain and hospitalization so there is a need for alternative methods which are less invasive, cost effective and as efficient as D and C for endometrial sampling.

In our study, menometrorrhagia was the most common presenting complaint (28%). In the study by Tansathit T *et al.* they reported metrorrhagia (45.1%) was the most common presenting complaint.^[9] Singh M *et al.* reported menorrhagia (54.2%) as the most common presentation of AUB.^[10]

In our study, 95% of the samples obtained by Karman and 98% of those achieved by D and C were adequate. Various studies reported fluctuating sample adequacy rate to vary from 76.4% to 98% by using different endometrial aspiration method. Anyhow, variation in methodology did not alter the sensitivity and specificity of the histopathological result. This alteration may be due to different instruments, techniques and as well as gynaecologist's and pathologist's skill.

Abdelazim *et al.* in their study achieved a sample adequacy rate of 97.9% and 98.2% by endometrial aspiration with Pipelle and Tao brush respectively, that is higher in comparison to our study.^[11,12] By using Karman cannula Handa *et al.*, Saikia *et al.*, Tansathit *et al.*, Kenchappa *et al.*, and Kaur *et al.* achieved a sample adequacy rate of 89%, 93.06%, 87.2%, 92%, and 95%, respectively.^[9,13-16] These studies have a comparable sample adequacy rate with our study. The study by Zutshi *et al.* reported a sample adequacy rate of 76.4% with Karman cannula that is lower than our study [Table 5].^[17]

In the present study, 11% of subjects was termed as not easy in D and C when compared to Karman endometrial sampling in which 1% of subjects termed not easy. In the study by Navakumar N *et al.* they reported 98 subjects as easy and 52 subjects as not easy.^[18]

In the present study, duration of Karman endometrial biopsy was less (3 ± 0.62 min) when compared with D and C (4.91 ± 0.87 min). Sanam *et al.* reported that duration of pipelle biopsy (3.38 ± 0.98 min) was less when compared with conventional D and C (7.12 ± 1.01 min).^[19] This study had comparable result with our study.

In our study, no complications occurred during Karman endometrial sampling procedure. In D and C 4 patients were complicated with bleeding. All patients were admitted for observation but no serious consequences occurred. Tansathit *et al.* reported no complication during aspiration procedure while during D and C 3 patients were complicated with uterine perforation.^[9] In the study by Rezk *et al.* uterine perforation occurred in 3 patients with D and C however, no complication reported during aspiration procedure.^[20]

Table 5: Comparison of sample adequacy of different studies

Study	Year	Method of endometrial aspiration	Sample adequacy
Handa U <i>et al.</i> ^[13]	2018	Karman cannula	89%
Zutshi V <i>et al.</i> ^[17]	2018	Karman cannula	76.4%
Kenchappa S <i>et al.</i> ^[15]	2017	Karman cannula	92%
Saikia JB <i>et al.</i> ^[14]	2016	Karman cannula	93.06%
Abdelazim IA <i>et al.</i> ^[12]	2015	Tao brush	98.2%
Kaur N <i>et al.</i> ^[16]	2014	Karman cannula	95%
Abdelazim IA <i>et al.</i> ^[11]	2013	Pipelle	97.9%
Tansathit T <i>et al.</i> ^[9]	2005	Karman cannula	87.2%
Present study	2019	Karman cannula	95%

In our study, with considering D and C as gold standard Karman endometrial sampling demonstrated 100% sensitivity, specificity, PPV, NPV, and accuracy with regards to diagnosis of adenocarcinoma, endometrial hyperplasia, atrophic endometrium and pseudo decidual reaction.

Handa *et al.* in their study reported 100% sensitivity, specificity and accuracy in diagnosing adenocarcinoma by using Karman cannula which was comparable to our study.^[13] The study by Kenchappa S *et al.* reported diagnostic accuracy of Karman cannula for diagnosing malignancy was 100%.^[15] By using Karman cannula Saikia *et al.* reported 100% accuracy in diagnosing endometrial adenocarcinoma.^[14]

Kaur N *et al.* reported 87.5%, 100%, 100%, 96.1%, and 96.94% of sensitivity, specificity, PPV, NPV and accuracy in diagnosing endometrial hyperplasia with Karman cannula.^[16] Sanam M *et al.* reported 92.3%, 100%, 100%, 98.10%, and 98.50% of sensitivity, specificity, PPV, NPV, and accuracy in diagnosing endometrial hyperplasia with endometrial aspiration using Pipelle.^[19]

The results of our study were comparable to the results of Kaur *et al.* and Sanam *et al.* in case of atrophic endometrium.^[16,19] Kaur N *et al.* reported 97.94% of accuracy in diagnosing atrophic endometrium with Karman cannula.^[16] Sanam *et al.* demonstrated 98.50% of accuracy in diagnosing atrophic endometrium with endometrial aspiration using Pipelle.^[19]

In our study, Karman endometrial sampling reported 98.50%, 100%, 100%, 97.05%, and 99% of sensitivity, specificity, PPV, NPV, and accuracy with regards to diagnosis of proliferative endometrium. Our results were similar to the study by Kaur N *et al.*, Saikia JB *et al.*, Kenchappa S *et al.*^[14-16] Kaur N *et al.* reported 100%, 96%, 86.96%, 100%, and 96.84% of sensitivity, specificity, PPV, NPV, and accuracy, respectively in diagnosing proliferative endometrium with Karman cannula.^[16] Saikia *et al.* reported 90.90% accuracy in diagnosing proliferative endometrium by using Karman cannula.^[14] Kenchappa *et al.* reported 88% of accuracy in diagnosing proliferative endometrium by Karman cannula.^[15]

In our study, Karman endometrial sampling showed 88.88%, 100%, 100%, 97.62%, and 98% of sensitivity, specificity, PPV, NPV, and accuracy respectively for diagnosing secretory endometrium. Kaur *et al.* reported 94.44%, 100%, 100%, 98.73%, and 98.96% of sensitivity, specificity, PPV, NPV, and accuracy, respectively in diagnosing secretory endometrium with Karman cannula.^[16] Saikia *et al.* reported 100% accuracy in diagnosing secretory endometrium by using Karman cannula.^[14] Kenchappa *et al.* reported 92% of accuracy in diagnosing secretory endometrium by Karman cannula.^[15] These results were comparable with our study.

Table 6 shows summary of Karman endometrial aspiration procedure.

Table 6: Summary of the Karman endometrial aspiration procedure

Findings	n(%)
Total number of patients under the study	100
Successful entry into the endometrial cavity	99(99%)
Difficult negotiation of Karman into the uterine cavity	5(5%)
No samples obtained	Nil
Material adequate for histopathological analysis	95(95%)
Material inadequate for histopathological analysis	5(5%)

However, the ease of procedure and pain assessment during Karman sampling and in D and C 30 min after the procedure to alleviate the effect of IV sedation are subjective phenomenon which might have produced unintentional observer's bias in our study. It was reported as the limitation of our study. Another study limitation was that cost could not be compared because this study was done in Govt. setup where every procedure is free of cost.

Despite the limitations the power of our study was that it was prospective study and performed in a single institute where samples are analysed by experienced pathologist. Synchronisation of sampling which is needed for comparison provides added strength to our study.

Endometrial aspiration with Karman cannula is an easy, convenient and OPD method so a Family physician can provide primary care and evaluate women presenting with AUB.

Conclusion

From our study, it was concluded that endometrial aspiration with Karman cannula showed no significant difference in terms of sample adequacy, HPE findings when compared to D and C. Also no significant difference with hysterectomy specimen was observed. Endometrial aspiration with Karman cannula is an easy and convenient method of achieving histopathological diagnosis. It can be done as an outpatient procedure without analgesia and anaesthesia when compared to D and C which is expensive and invasive method and requires hospitalization and general anaesthesia.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Ethical approval

The study was approved by Institutional Ethical Committee of our institute on dated 6/12/19.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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