Original Article

A Randomized Comparative Study to Compare Karman's Cannula and Pipelle Biopsy for Evaluation of Abnormal Uterine Bleeding

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Abstract

Objectives: This study aimed to compare the diagnostic accuracy, inadequate sampling, pain during the procedure (Visual Analog Scale [VAS] score), and ease of insertion of the Karman's cannula and Pipelle biopsy for patients with abnormal uterine bleeding (AUB). **Methods:** This prospective observational randomized comparative study included women of age more than 40 years with complaints of AUB. Two hundred and fifty women were randomly divided into two groups: (1) Group A (n = 125) who underwent endometrial aspiration using Karman's cannula and (2) Group B (n = 125) who underwent Pipelle endometrial sampling. Both the groups were followed by conventional dilation and curettage (D and C) which was considered the gold standard. Sensitivity, specificity, positive predictive value, and negative predictive value for differentiating benign and malignant conditions of endometrium were calculated. **Results:** Group B had a sensitivity of 89.29% followed by Group A (86.36%); on the other hand, Group A had a specificity of 96.08% followed by Group B (95.74%) ($P > 0.05$). Inadequacy was comparable among the two groups with 1 inadequate in Group A and 3 inadequate in Group B. Mean VAS score was significantly lesser in Group A than Group B (4.5 ± 2 vs. 5.8 ± 2.1, $P < 0.0001$). Ease of insertion was similar in Groups A and B ($P = 0.345$). **Conclusion:** Both procedures were equivalent in diagnostic accuracy, inadequacy, and ease of insertion. However, the use of Karman cannula resulted in less pain and is a much cheaper option in comparison to Pipelle. Overall, either procedure can be performed on an outpatient basis without cervical dilation and anesthesia and thus may be routinely used for women presenting with AUB.

Keywords: *Abnormal uterine bleeding, Karman's cannula, Pipelle*

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Introduction

Abnormal uterine bleeding (AUB) is an increasing health problem in the reproductive age group affecting nearly 9%–14% of women[1] with a significant impact on their quality of life.[2] AUB may be a part of disturbance in the menstrual cycle or sudden nonmenstrual bleeding, both of which require medical investigation in the form of endometrial sampling primarily to differentiate benign causes like hyperplasia from malignant causes like carcinoma.[3]

Invariably, dilatation and curettage (D and C) has been considered the gold standard for AUB investigation.[4] Besides, there are other methods for assessing the troubled endometrium which include ultrasonography (USG), hysteroscopic biopsy, and endometrial sampling using the Vabra aspirator, Tao brush, SAP-1 brush sampler, Pipelle, or Karman cannula.[3,5] These devices are gaining importance due to the certain disadvantages of D and C such as time of procedure, cost, and invasiveness. In addition, D and C has an inherent risk of anesthesia-related complications, uterine infections, uterine perforations, and lacerations of the cervix.[6]

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Karman's cannula is "a soft, flexible cannula" that works under the principle of suction. Its insertion involves no dilatation or anesthesia, making it a safe, feasible office procedure with minimal procedure time.[5]

Pipelle device, "a silastic flexible curette," is also a similar noninvasive method of endometrial sampling which does not require straightening of cervical fundus axis.[7] By its rotatory method, it samples around 5%–15% of the surface of the endometrium, thus establishing its use mainly in the global lesions rather than focal lesions.[8]

As both of them are effective and minimally invasive methods of endometrial aspiration, each of these methods has been studied individually in comparison with D and C, with results being in favor of their clinical use.[1,3,5,8-11] However, till date, there has been no head-to-head trial comparing both of them.

Hence, this study was planned to compare Karman's cannula versus Pipelle biopsy against the gold standard of conventional dilatation and curettage among patients of AUB. The study was done with an objective to compare the diagnostic accuracy, inadequate sampling, pain during the procedure, and ease of insertion of the devices.

Methods

A prospective observational randomized comparative study was conducted for a duration of 15 months from January 2019 to March 2020, which included women of age more than 40 years who presented to the outpatient department with complaints of AUB and underwent evaluation of the endometrium.

Any woman with pregnancy, pelvic inflammatory disease, gynecological malignancy, menopause or endometrial thickness <4 mm on transvaginal sonography (TVS) were excluded from the study. The institutional ethical clearance was obtained for the study from the institutional committee. The patients were explained about the procedure and written informed consent was obtained from them before enrolling them into the study.

The sample size calculation for the study was based on the values seen in the study by Vijay Zutshi *et al*.,[10] who observed that the adequacy of Karman cannula was 76.4%. Considering these values as reference and assuming a difference of 15% in the adequacy rate of Karman cannula group and Pipelle biopsy group, the minimum required sample size with 90% power of study and 5% level of significance is 121 patients in each study group. To reduce margin of error, total sample size taken was 250 (125 patients/group).

A clinical history about the age, parity, and any continuing hormone therapy was taken. Per speculum examination and per vaginal examination were done in detail of all the patients. TVS was done to evaluate the endometrial thickness before any intervention was planned.

The study population of 250 women were randomly divided into two groups: (1) Group A (n = 125) who underwent endometrial aspiration using Karman's cannula (size of 4 mm without anesthesia and without cervical dilation) which was attached to the aspiration syringe and (2) Group B (n = 125) who underwent Pipelle endometrial sampling under aseptic conditions without anesthesia or cervical dilation. After the insertion of the Pipelle device, the piston was fully withdrawn (to cause vacuum-assisted suction) and rotated to get the sample. The sample was collected in the initial part of the tube which was cut and sent for histopathology. The procedures were done by the principal investigator without blinding.

The block randomization for the two groups was done with sealed envelope system. In this method, ten sealed opaque envelopes were assigned A and B in 5 envelopes each, where A represented Karman cannula group and B represented Pipelle biopsy group. Once a patient agreed to enter the trial, an envelope was opened, and the patient was then offered the allocated group. In this technique, patients were randomized in a series of blocks of ten. A consort diagram of the randomization and patient flow is shown in Figure 1.

After the collection of the primary sample in both the groups, patients (of both the groups) further underwent cervical dilation and curettage under the use of 1% Xylocaine. The samples of Karman's cannula (Group A), Pipelle biopsy (Group B), and conventional D and C were collected separately in 10% formalin bottles and sent to laboratory for histopathological examination. For accuracy of the diagnosis, the histopathology reports of the D and C sample was considered to be the gold standard.

The primary outcome measures of our study were diagnostic accuracy of Karman endometrial aspiration versus Pipelle aspiration for differentiating benign and malignant conditions of endometrium. The secondary outcomes of the study were sample adequacy, ease of procedure, and pain score.

Standards, definitions, and criteria

Endometrial lesions consisting of proliferative endometrium, secretory endometrium, endometritis, and hyperplasia without atypia were labeled as benign; while lesions consisting of hyperplasia with atypia,

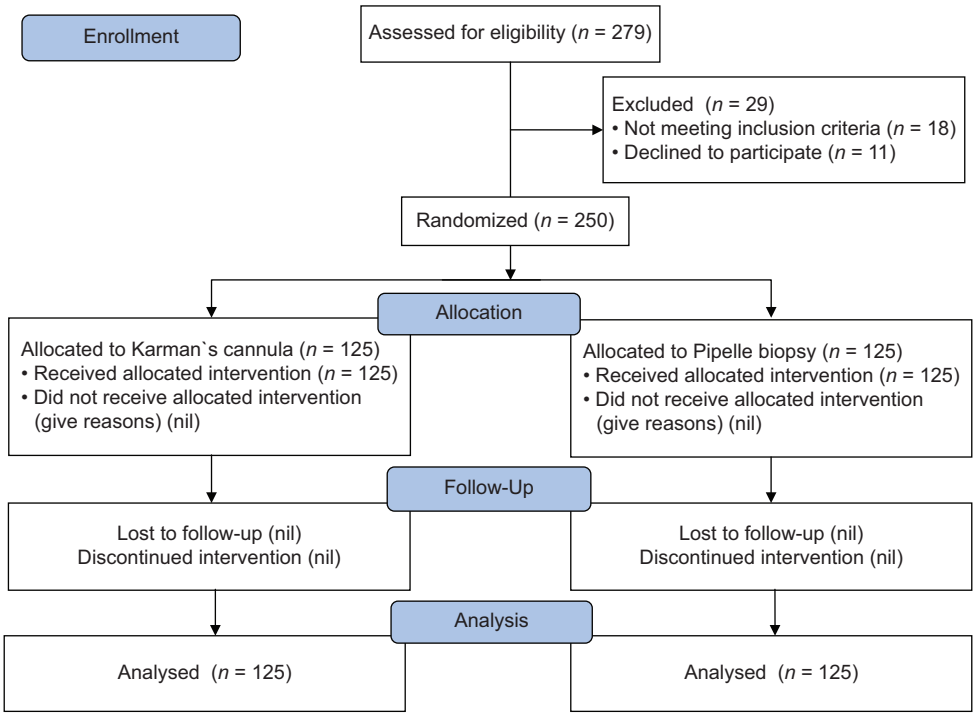

Figure 1: Consort flow diagram

endometrial intraepithelial neoplasia, and endometrial carcinoma were labeled as malignant. The sample adequacy depended on the microscopic presence of intact endometrial glands in the background of stroma.[5] The ease of the procedure was adjudged by the clinician performing the procedure on a scale of 1–5. Pain was calculated using the Visual Analog Scale (VAS).

Statistical analysis

The presentation of the categorical variables was done in the form of number and percentage (%). On the other hand, the presentation of the continuous variables was done as mean ± standard deviation. The comparison of the variables which were quantitative in nature was analyzed using independent *t*-test (for the two groups) and for those which were qualitative in nature was analyzed using Chi-square test.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each group, and McNemar test was used for comparison of sensitivity and specificity. The final analysis was done with the use of the Statistical Package for the Social Sciences, IBM manufacturer, Chicago, USA, version 21.0. For statistical purposes, $P < 0.05$ was considered statistically significant.

Results

The mean age of the patients was comparable in Groups A and B (45.73 ± 9.7 vs. 43.57 ± 9.1, $P = 0.07$). In both Groups A and B, most of the women were Para 1 (68% vs. 64%), followed by Para 2 (28% vs. 32%) and Para 3 (4% vs. 4%) ($P = 0.785$) [Table 1].

Inadequacy was comparable among the two groups, with 1 (0.97%) inadequate in Group A and 3 (2.4%) inadequate in Group B ($P = 0.622$), as shown in Figure 2.

Among the benign, 4 cases were incorrectly diagnosed as malignant in each Groups A and B, whereas among the malignant, 4 cases were incorrectly diagnosed as benign in each Groups A and B [Table 2].

Interpretation of the area under the receiver operating characteristic curve showed that the performance of Group A (area under the curve [AUC]: 0.91; 95% confidence interval [CI]: 0.85–0.96) and Group B (AUC: 0.93; 95% CI: 0.86–0.96) was outstanding. Group B had a sensitivity of 89.29% followed by Group A (86.36%). On the other hand, Group A had a specificity of 96.08% followed by Group B (95.74%). The highest PPV was found in Group B (86.21%) and the highest NPV was found in Group A (97.03%). There was no significant difference in sensitivity and specificity of Groups A and B ($P > 0.05$) [Table 3].

The mean VAS score of the patients was lesser in Group A as compared to Group B (4.5 ± 2 vs. 5.8 ± 2.1, $P < 0.0001$). Ease of insertion was similar in Groups A and B as most of the patients have score

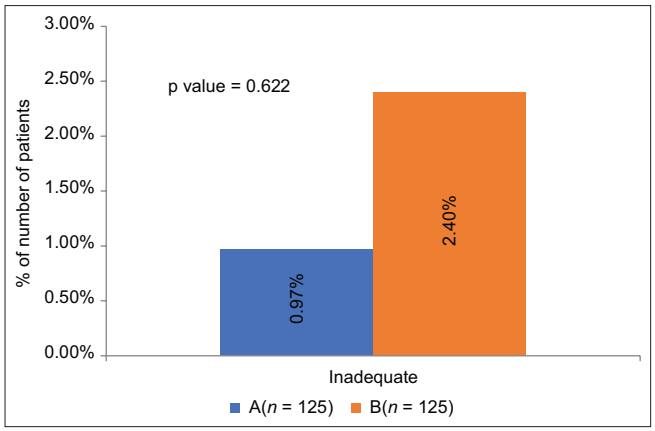

Figure 2: Comparison of inadequacy between Groups A and B

4 (43.20% vs. 48.80%, $P = 0.345$) [Table 4]. There were no complications in either group.

Discussion

One of the important steps in evaluating the AUB for ruling out endometrial carcinoma is the endometrial biopsy; it is helpful in providing medical or conservative surgery and therefore unwarranted radical surgery can be prevented.

In the present study, we found that the diagnostic accuracy of both Karman cannula and Pipelle biopsy was comparable, with none of the procedures showing superiority over others.

The sensitivity, specificity, PPV, and NPV of Karman cannula were 86.36%, 96.08%, 82.61%, and 97.03%, respectively, for diagnosing malignant lesions. Among other studies which compared Karman with others, Tomar *et al.*[1] reported that Karman cannula had a sensitivity of 92.3%, specificity of 100%, PPV of 100%, and NPV of 99.56% for diagnosis of endometrial pathology, which was slightly higher than that of our study.

In our study, the Sn, Sp, PPV, and NPV of Pipelle biopsy were 89.29%, 95.74%, 86.21%, and 96.77%, respectively, for diagnosing malignant lesions. Compared to the present study, higher values were reported in a study done by Yasmin *et al.*,[12] as sensitivity, specificity, PPV, and NPV of Pipelle were 100%, 84%, 100%, and 95%, respectively. Abdelazim *et al.*[7] reported a 100% diagnostic accuracy for endometrial carcinoma for Pipelle device. Rachamallu *et al.*[13] reported that endometrial aspiration by Pipelle had a sensitivity of 93.4%, specificity of 100%, PPV of 100%, and NPV of 92.3%. Machado *et al.*[14] concluded that endometrial aspiration with Pipelle was 84.2% sensitive, 99.1% specific, and 96.9% accurate with 94.1% PPV and 93.7% NPV. However, lesser accuracy of Pipelle was reported by Ilavarasi *et al.*[15] Similarly, less accuracy of Pipelle was reported by Demirkiran *et al.*,[16] as sensitivity in detection of hyperplasia and atypia was 67% and 75%, respectively.

The varying diagnostic accuracy can be ascribed to the technique itself whereby many endometrial glands may be deformed or the aspirated sample might be inadequate for reporting.

Reason for inadequacy with Pipelle may be because of the less expertise as the procedure is relatively new and not used in routine.[3] However, literature review

Table 1: Demographic characteristics in Groups A and B

Demographic characteristics	A (*n*=125)	B (*n*=125)
Age (years), mean±SD	45.73±9.7	43.57±9.1
Parity, *n* (%)		
Para 1	85 (68)	80 (64)
Para 2	35 (28)	40 (32)
Para 3	5 (4)	5 (4)

SD: Standard deviation

Table 2: Comparison of diagnosis in the two groups

Variables	A (*n*=125), *n* (%)	B (*n*=125), *n* (%)
Benign	103 (82.40)	96 (76.80)
Malignant	22 (17.60)	29 (23.20)

Table 3: Sensitivity, specificity, positive predictive value, and negative predictive value of Groups A and B for predicting malignancy and comparison of sensitivity and specificity

Malignancy	Group A	Group B
Sensitivity (95% CI)	86.36 (65.09-97.09)	89.29 (71.77-97.73)
Specificity (95% CI)	96.08 (90.26-98.92)	95.74 (89.46-98.83)
AUC (95% CI)	0.91 (0.85-0.96)	0.93 (0.86-0.96)
PPV (95% CI)	82.61 (61.22-95.05)	86.21 (68.34-96.11)
NPV (95% CI)	97.03 (91.56-99.38)	96.77 (90.86-99.33)
Diagnostic accuracy (%)	93.60	92.00
P value of sensitivity	0.607*	
P value of specificity	0.854*	

*McNemar test. PPV: Positive predictive value, NPV: Negative predictive value, CI: Confidence interval, AUC: Area under the curve

Table 4: Comparison of outcome between Groups A and B

Variables	A (*n*=125)	B (*n*=125)	*P**
VAS score, mean±SD	4.5±2	5.8±2.1	<0.0001
Ease of insertion, *n* (%)			
1	3 (2.40)	5 (4)	0.345
2	7 (5.60)	7 (5.60)	
3	34 (27.20)	37 (29.60)	
4	54 (43.20)	61 (48.80)	
5	27 (21.60)	15 (12)	

*Independent *t*-test, SD: Standard deviation, VAS: Visual Analog Scale

shows that factors that affect the insufficient sampling are rarely evaluated. As per our experience, it can be said that the chances of obtaining a sufficient sample are higher in correlation with increasing endometrial thickness. As reported by Bakour *et al*.,[17] endometrial thickness of <5 mm on USG forms a standard cutoff for insufficient sampling.[18]

In the present study, one case (0.97%) was inadequate in the Karman cannula group and three cases (2.4%) in the Pipelle group. Among other studies on Karman, the inadequacy rate has been reported to range from 2% to 24%,[1,5,10,19-22] and for Pipelle, it has been reported in the range of 2% to 28.8%.[13,23-27] Since we frequently use Karman cannula, the inadequacy was lower in that group. Moreover, there has been an increasing use of Pipelle at our institute because of increasing awareness and demand which might have accounted for a lower inadequacy in that group as well. We propose the regular use of these endometrial aspiration devices as they are safe with good accuracy and low inadequacy.

During procedure of endometrial aspiration with Karman cannula and Pipelle biopsy, pain can be experienced due to cramping.[5] In our study, the mean VAS score of the patients was lesser in the Karman cannula group compared to the Pipelle group (4.5 ± 2 vs. 5.8 ± 2.1, $P < 0.0001$). Although both the techniques are done without dilation and anesthesia, both are considered nonpainful. However, individuals may experience different levels of pain as per the threshold. Interestingly, in both the groups, the pain intensity was termed to be mild. In the study by Gupta *et al*.,[3] median VAS score in nulligravida and multigravida was 4 and 2 after the use of Pipelle, which is almost similar to the present study. They also stressed that VAS scores in the Pipelle group were less than the D and C group, suggesting that it is a less painful procedure as compared to the standard D and C. Rauf *et al*.[24] compared Pipelle device and D and C and reported that Pipelle caused significantly less pain. Balaram *et al*.[28] also reported similar findings as, during Pipelle curettage, very few patients experienced mild pain that was well tolerated.

In the study by Zutshi *et al*.,[10] no significant difference in pain score was observed in Karman cannula and Endosampler groups, with both showing less pain. Mathew and Thomas[29] observed that most of the patients required no analgesics after Karman cannula use. Thus, it can be said that Karman cannula and Pipelle use is associated with less pain, however, between both of them, we advocate Karman cannula in terms of pain threshold. Future studies are required to find the factors affecting the pain during these procedures and maneuvers to further reduce the pain below the level of 5 VAS score.

Another aspect that carries importance during the procedure is the ease of insertion. In the present study, ease of insertion was similar in both the Karman cannula and Pipelle groups. Indirectly, other studies have shown that the use of these devices provides ease of procedure in comparison to the conventional D and C.

Nama *et al*.[5] compared D and C and Karman endometrial sampling and found that in D and C, 11% of patients were termed as not easy and 1% in Karman endometrial sampling were termed not easy. In a study, Navakumar *et al*.[30] reported that Pipelle aspiration was easy in most of the patients when compared with D and C. Zutshi *et al*.[10] did not observe any difference in terms of ease of insertion in the Karman cannula group on the basis of experience of residents, while residents with >2 years' experience can more easily perform D and C. Even Balaram *et al*.[28] found ease of doing procedure with Pipelle as much easier than D and C. Findings of the studies indicate that Karman cannula and Pipelle are much easy to use than other devices/methods. The experience of the treating physician carries paramount importance while performing the procedure.

There is a requirement of an accurate and low-cost device for endometrial aspiration with specimen adequacy and higher sensitivity for diagnosis. In India, the cost of Karman cannula is Rupees 8–15/piece, and the average cost of a Pipelle sampling is Rs. 250.[31] Tansathit *et al*.[22] reported that the use of Karman cannula for aspiration decreases the cost of the diagnostic workup for AUB. Zutshi *et al*.[10] also found Karman cannula to be five times cheaper than Endosampler for endometrial biopsy.

Although we found no complications with either procedure, literature reports the possibility of prolonged bleeding and slight chances of infection with Karman cannula[22] and concerns related to adequacy of the sample and nonsampling of focal intrauterine lesions with Pipelle.[3]

The study had certain limitations. First, the cost of the procedure was not taken into account as the devices were procured from the hospital without any additional cost for the patient. However, the high cost of Pipelle in comparison to Karman cannula can be a limiting factor for its use. Second, the diagnostic accuracy of both aspirators was compared against conventional D and C rather than endometrial biopsy or hysterectomy. Third, the experience of the physician performing the procedure was not compared since it may significantly affect the inadequacy of the procedure.

In spite of the limitations, the strength of the study was that it was a prospective study and a single-center

study where samples were collected by an experienced physician and evaluated by an experienced pathologist. Furthermore, to the best of our knowledge, this seems to be the first study that compared the efficacy of Karman cannula and Pipelle.

Conclusion

It can be concluded that endometrial aspiration with Karman cannula resulted in no significant difference with respect to diagnostic accuracy, inadequacy, and ease of insertion in comparison with Pipelle biopsy. However, the use of Karman cannula resulted in less pain and is a much cheaper option in comparison to Pipelle.

Overall, either procedure may be routinely used for endometrial aspiration for a histopathological diagnosis. These procedures can be performed on an outpatient basis without cervical dilation and anesthesia. Therefore, women presenting with AUB can be evaluated by a family physician who can provide primary care without hospitalization.

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Conflicts of interest

There are no conflicts of interest.

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