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Üç Endoservikal Numune Alma Yönteminin Karşılaştırılması: Tanısal Doku Kalitesi İçin Hangi Yöntem Yeterlidir?

Comparing the Three Endocervical Sampling Methods: Which Method is Sufficient For Diagnostic Tissue Quality?

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ÖZ

Giriş: Endoservikal küretaj (ECC) yaygın olarak ayakta tedavi prosedürü olarak uygulanan ancak sıklıkla ağrı ve rahatsızlıkla ilişkilendirilen tanısal bir yöntemdir. Bu prospektif randomize gözlemsel çalışmada Novak küret, endoservikal fırça ve Pipelle kullanılarak elde edilen histolojik örneklerin kalitesinin yanı sıra bu işlemler sırasında yaşanan ağrı düzeylerinin değerlendirilmesi amaçlanmıştır.

Yöntem: Nisan 2018-Ağustos 2018 tarihleri arasında hastanemizde ECC uygulanan hastalar çalışmaya dahil edildi. Örnekleme aletleri olarak Novak küret, endoservikal fırça ve Pipelle kullanıldı. Hastalar işlemler sırasındaki ağrı düzeylerini görsel analog skala (VAS) kullanarak değerlendirdi. Histolojik materyal doku yeterliliği açısından bir patolog tarafından skorlanmıştır. Histolojik örneklerin kalitesi ile kullanılan cerrahi aletler arasındaki korelasyon analiz edildi.

Bulgular: Çalışmaya ortalama yaşı 41,9 ± 8.78 yıl, ortalama paritesi 2,7 ± 1,23, ortalama VKİ 30,9 ± 3,11 ve sigara içme prevalansı %22 olan hastalar dahil edildi. Ortalama patolojik inceleme skorları aşağıdaki gibidir: Novak küret, 3 ± 1,31; endoservikal fırça, 1,6 ± 1,14; ve Pipelle, 1,6 ± 1,13. Ortalama VAS ağrı skorları Novak küret için 3,7 ± 1,21, endoservikal fırça için 3,1 ± 1,18 ve Pipelle için 3,0 ± 1,02 idi.

Sonuç: Değerlendirilen aletler arasında Novak küret en yüksek düzeyde ağrıya neden olurken, endoservikal fırça ve Pipelle ile ilişkili ağrı düzeyleri benzerdi. Bu bulgular, Novak küretinin yüksek kaliteli örnekler sağlayabilmesine karşın, Pipelle ve endoservikal fırça gibi alternatif yöntemlerin potansiyel olarak daha iyi hasta konforu ile karşılaştırılabilir tanısal değer sunduğunu göstermektedir.

Anahtar Kelimeler: endoservikal küretaj, novak küret, pipelle, endoservikal fırça, kolposkopi

ABSTRACT

Objective: Endocervical curettage (ECC) is a diagnostic method commonly performed as an outpatient procedure but often associated with pain and discomfort. This prospective randomized observational study aimed to evaluate the quality of histological specimens obtained using Novak curette, endocervical brush, and Pipelle, as well as the pain levels experienced during these procedures.

Method: Between April 2018 and August 2018, patients undergoing ECC at our hospital were included in the study. Novak curette, endocervical brush, and Pipelle were used as sampling instruments. Patients rated their pain levels during the procedures using a visual analog scale (VAS). Histological material was scored by a pathologist for tissue adequacy. The correlation between the quality of histological specimens and the surgical instruments used was analyzed.

Results: The study included patients with a mean age of 41.9 ± 8.78 years, mean parity of 2.7 ± 1.23, mean BMI of 30.9 ± 3.11, and a smoking prevalence of 22%. The mean pathological examination scores were as follows: Novak curette, 3 ± 1.31; endocervical brush, 1.6 ± 1.14; and Pipelle, 1.6 ± 1.13. The mean VAS pain scores were 3.7 ± 1.21 for Novak curette, 3.1 ± 1.18 for endocervical brush, and 3.0 ± 1.02 for Pipelle.

Conclusion: Among the instruments evaluated, the Novak curette caused the highest levels of pain, while pain levels associated with the endocervical brush and Pipelle were comparable. These findings suggest that while the Novak curette may provide high-quality samples, alternative methods such as Pipelle and endocervical brush offer comparable diagnostic value with potentially improved patient comfort.

Keywords: endocervical curettage, novak curette, pipelle, endocervical brush, colposcopy

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INTRODUCTION

Endocervical sampling is a crucial component in the evaluation of the cervix, particularly in the assessment of preinvasive cervical lesions (1, 2). With increasing age, the squamocolumnar junction of the cervix tends to shift towards the endocervix, making the diagnosis of endocervical pathologies more challenging and potentially delaying their treatment (3).

There is no standardized method for endocervical sampling. Various instruments, including Novak curette, endocervical brush, Pipelle, Kevorkian curette, and Sims curette, are commonly used for this purpose (4). The choice of sampling technique often depends on the clinician's preference.

Although endocervical curettage (ECC) can be performed as part of outpatient care without hospitalization, it is a procedure that may cause pain and discomfort for the patient. Recent studies have focused on investigating techniques that reduce pain to enhance patient comfort and satisfaction, without compromising the efficacy of endocervical sampling methods or the adequacy of the obtained specimens (5, 6).

In this prospective randomized observational study, we aimed to evaluate the quality of histological material obtained using Novak curette, endocervical brush, and Pipelle, as well as the pain levels experienced during the procedure.

MATERIALS AND METHODS

This prospective randomized observational study was approved by the local ethics committee (Ethics Committee Approval No: 2018/514/128/7). Informed consent forms were prepared and obtained from all participants.

A total of 180 patients who visited our gynecologic oncology outpatient clinic between April 2018 and August 2018 were included in the study. Eligible participants included those with abnormal cervical cytology results requiring colposcopic examination, HPV positivity, or perimenopausal/postmenopausal patients with abnormal uterine bleeding undergoing probe curettage and ECC for suspected endometrial cancer. There was no upper age limit for participation; however, patients under the age of 18 were excluded.

Exclusion criteria included patients with a history of cervical ablative or excisional procedures, cervical masses, cervical stenosis, neurological disorders, significant cardiac or respiratory diseases, or markedly abnormal liver function tests. Pregnant women, patients unable to tolerate colposcopy without anesthesia, illiterate patients who could not score the visual pain scale, and those who did not consent to participate were also excluded from the study.

The randomization sequence was computer-generated (randomisation.com) and blinded to both the clinician performing the curettage and the pathologist evaluating the specimens. Only one nurse was aware of the sequence. Before each procedure, the nurse opened a sealed numbered envelope to reveal the assigned sampling method and informed the clinician accordingly. This ensured an equal distribution of patients across the three sampling methods: Novak curette, endocervical brush, and Pipelle. Before the procedure, a detailed medical history was obtained from each patient. Patients were positioned on a gynecological examination table, and a sterile speculum was inserted into the vagina to visualize the cervix. The cervix and vagina were irrigated with sterile saline. The cervix was stabilized with a single-tooth tenaculum to align the cervix-uterus axis.

Novak curette procedure: The Novak curette was inserted into the cervical canal up to the internal os and then retracted while rotating it to the right and left. Curettage was performed until sufficient material was obtained.

Pipelle procedure: The Pipelle was advanced into the cervical canal up to the internal os. The piston was withdrawn to create negative pressure, and back-and-forth and rotational movements were performed to aspirate sufficient tissue. The process was repeated 2–3 times if needed.

Endocervical brush procedure: The endocervical brush was advanced into the cervical canal up to the internal os and rotated to the right and left before being withdrawn. This process was repeated 2–3 times until adequate tissue was obtained.

The obtained specimens were placed in sterile containers with formalin and sent to the pathology department for evaluation.

After the procedure, patients were asked to rate the pain they experienced using a visual analog scale (VAS).

The pathologist assessed the quality of the specimens, in addition to routine pathological evaluation, using the following scoring system:

G0: No endocervical cells observed.

G1: Individual endocervical cells observed.

G2: Partial endocervical gland observed.

G3: One complete endocervical gland observed.

G4: Multiple endocervical glands observe

Statistical Analysis

The statistical analyses in this study were conducted using the IBM-SPSS (Statistical Package for the Social Sciences) software. Data evaluation was performed in two stages: descriptive statistics and statistical analyses. Descriptive statistics included calculations of mean, standard deviation, median, frequency, minimum, and maximum values, as well as the presentation of data in tables and graphs.

The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess the normality of data distribution. For groups not following a normal distribution, the Kruskal-Wallis H test was employed to evaluate the significance of differences among more than two groups. For comparisons between two groups, the Mann-Whitney U test was utilized. The Spearman correlation analysis was applied to examine relationships between variables that did not exhibit normal distribution.

All statistical tests were evaluated at 95% or 99% confidence levels (significance levels of $p < 0.05$ or $p < 0.01$).

RESULTS

Demographic Characteristics of Participants

A total of 180 patients participated in the study, with an age range of

24 to 65 years (mean: 41.9 ± 8.78 years). The mean parity was 2.7 ± 1.23, and the average BMI was 30.9 ± 3.11. Among the participants, 22% were smokers. The demographic characteristics of the study population are summarized in Table 1. The study flow diagram is shown in Figure 1.

Diagnostic Tissue Adequacy

The histopathological adequacy scores varied significantly among the instruments used. Novak curette achieved the highest mean pathological examination score (3 ± 1.31), followed by Pipelle (1.6 ± 1.13) and endocervical brush (1.6 ± 1.14). As shown in Table 2, Novak curette yielded significantly more diagnostic tissue compared to the other instruments ($p<0.05$).

Pairwise comparisons between the instruments revealed that Novak curette significantly outperformed both Pipelle and endocervical brush, while no significant difference was observed between the latter two (Table 3).

The distribution of pathological examination scores by instrument is visually summarized in Figure 2.

These findings highlight that Novak curette is the most effective instrument for obtaining diagnostic-quality tissue samples, while Pipelle and endocervical brush demonstrated similar levels of adequacy.

Pain Levels During Procedures

Pain scores differed significantly based on the instrument used. The Novak curette caused the most pain, with a mean VAS score of 3.7 ± 1.21, followed by endocervical brush (3.1 ± 1.18) and Pipelle (3.0 ± 1.02). These differences were statistically significant and are detailed in Table 4.

Despite causing more pain, the Novak curette's superior diagnostic adequacy makes it a valuable tool in clinical practice, especially when tissue quality is critical. Conversely, Pipelle and endocervical brush are less painful alternatives with comparable diagnostic performance.

Table 1. The Demographic Characteristics of the Study Population

Age (years)	Min-Max (Median)	24-65(42)
	Mean ± Standard Deviation	41.9±8,78
Pathological Examination Score (n,%)	Min-Max (Median)	0-4(1)
	Mean ± Standard Deviation	2.0±1.36
	0: Absent endocervical cells	14(8%)
	1: Individual endocervical cells	79(44%)
	2: Partial endocervical gland	18(10%)
	3: One complete endocervical gland	27(15%)
	4: Multiple endocervical glands	42(23%)
Surgical Instrument (n,%)	Min-Max (Median)	1-3(2)
	Mean ± Standard Deviation	2±0.82
	1: Novak Curette	20(33,3%)
	2: Endocervical Brush	20(33,3%)
	3: Pipelle	20(33,3%)
Infection (n, %)	0: Absent	180(100%)
	1: Present	0(0%)
Smoking Status (n, %)	0: Absent	141(78%)
	1: Present	39(22%)
Body Mass Index (BMI) (kg/m²) (n, %)	Min-Max (Median)	22.9-36.7(31.1)
	Mean ± Standard Deviation	30.9±3.11
Number of Deliveries (n, %)	Min-Max (Median)	1-6(3)
	Mean ± Standard Deviation	2.7±1.23
	1 delivery	28(16%)
	2 delivery	60(33%)
	3 delivery	56(31%)
	>3 deliveries	36(20%)
Delivery Method (n, %)	Cesarean Section (C/S)	53(29%)
	Normal Spontaneous Delivery (NSD)	127(71%)

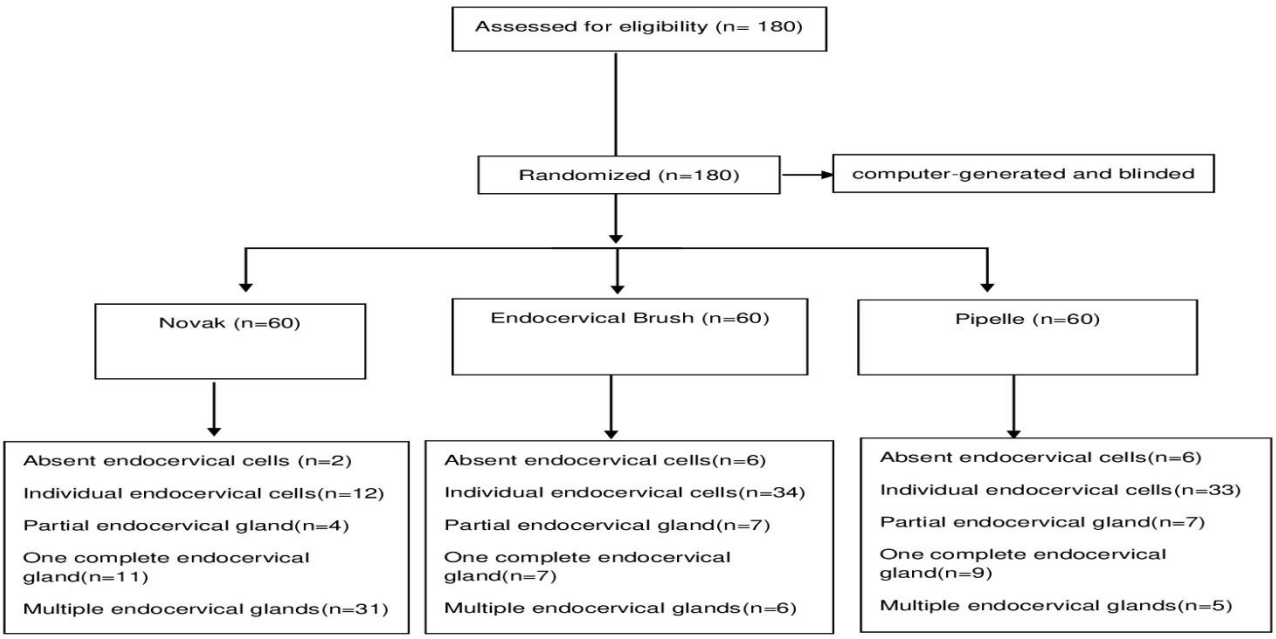

Figure 1. The study flow diagram.

Table 2. Findings Related to Surgical Instruments Used

		Surgical Instrument Type			
		Novak	Endocervical Brush	Pipelle	*p*
Pathological Examination Score	Min-Max (Median)	0-4(4)	0-4(1)	0-4(1)	0.000
(n,%)	Mean ± Standard Deviation	3±1.31	1.6±1.14	1.6±1.13	
Absent endocervical cells		2(3%)	6(10%)	6(10%)	
Individual endocervical cells		12(20%)	34(56%)	33(55%)	
Partial endocervical gland		4(7%)	7(12%)	7(12%)	
One complete endocervical gland		11(18%)	7(12%)	9(15%)	
Multiple endocervical glands		31(52%)	6(10%)	5(8%)	
Visual Pain Score	Min-Max (Median)	1-6(4)	1-6(3)	1-5(3)	
	Mean ± Standard Deviation	3.7±1.21	3.1±1.18	3.0±1.02	0,001

Table 3. Comparison of Administered Surgical Instruments

Surgical Instruments	*p*
Novak Curette vs. Endocervical Brush	0,000
Endocervical Brush vs. Pipelle	1,000
Pipelle vs. Novak Curette	0,000

Table 4. Findings Related to Pathological Examination Scores

		Pathological Examination Score (n=180)					
		Absent endocervical cells (n=14)	Individual endocervical cells (n=79)	Partial endocervical gland (n=18)	One complete endocervical gland (n=27)	Multiple endocervical glands (n=42)	
Smoking Status (n,%)	0: Absent	11(79%)	59(75%)	15(83%)	20(74%)	36(86%)	0.292*
	1: Present	3(21%)	20(25%)	3(17%)	7(26%)	6(14%)	
Number of Deliveries (n,%)	Min-Max (Median)	1-4(1)	1-5(2)	1-5(2.5)	1-4(3)	2-6(3)	0.000**
	Mean ± SD	1.7±1,07	2.2±0.88	2.5±1.04	2.9±0.91	3.8±1.33	
	1 delivery	9(64%)	15(18%)	3(17%)	1(4%)	0(0%)	
	2 delivery	1(7%)	37(47%)	6(33%)	10(37%)	6(14%)	
	3 delivery	3(22%)	21(27%)	7(39%)	8(30%)	17(41%)	
	>3 deliveries	1(7%)	6(8%)	2(11%)	8(29%)	19(45%)	
Body Mass Index (BMI) (kg/m²)	Min-Max (Median)	24.1-35.4 (31.2)	23.6-36.1 (30.8)	27.2-35.1 (30.6)	25.2-34.7 (31.6)	22.9-36.7 (30.4)	0.795***
	Mean ± Standard Deviation	30.6±3.53	31.1±2.92	30.7±2.37	31.4±2.59	30.5±3.86	

*Mann Whitney U test;
**Spearman Correlation Analysis;
***Kruskal Wallis-H Test

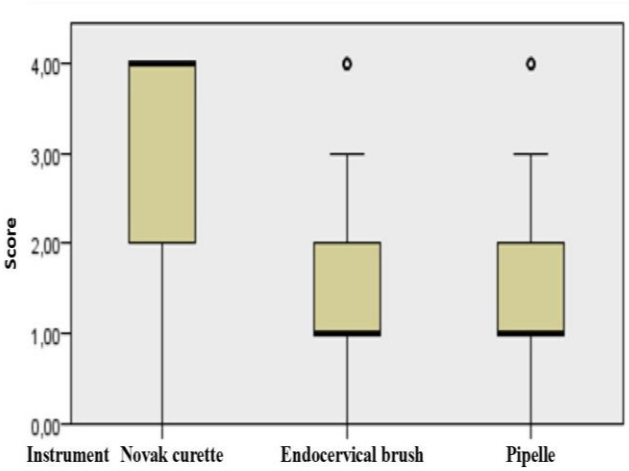

Figure 2. Relationship between instruments and pathological examination scores.

DISCUSSION

Endocervical sampling is a crucial diagnostic procedure for evaluating patients suspected of having cervical cancer. While colposcopy effectively assesses the ectocervix in patients with abnormal cervical cytology and a macroscopically normal cervix, it often falls short in evaluating the endocervix. In such cases, endocervical curettage (ECC) provides valuable diagnostic insights (7-9). ECC is associated with high rates of insufficient sampling and increased false positive and false negative results, which further highlights the need for careful consideration in clinical practice(4, 10-13). In our study, patients with no observed endocervical cells during ECC tended to have lower parity, whereas higher pathological examination scores and better tissue sampling were observed in patients with higher parity. This may be explained by anatomical changes in the cervix associated with increased parity.

Regarding the adequacy of histological material, Gibson et al. conducted a study on 547 patients to identify the most effective technique for endocervical sampling (6). They compared ECC performed with an endocervical brush, a curette, or both, and evaluated sample adequacy using a scoring system. Their results indicated that the endocervical brush group had the highest rates of insufficient or limited samples and the lowest rates of stromal sampling compared to the curette or combined

groups (6). In our study, Novak curette yielded the highest pathological examination scores (2–4), with most samples containing partial or complete endocervical glands or multiple endocervical glands. Conversely, samples obtained using the endocervical brush and Pipelle predominantly consisted of individual endocervical cells or partial glands (1–2). These findings suggest that while Novak curette provides superior diagnostic adequacy, the performance of Pipelle and endocervical brush is comparable.

In terms of pain levels, our findings are consistent with previous studies. Rust et al. found that ECC performed with a sharp Duncan curette resulted in higher pain scores compared to a plastic Milex curette (VAS mean: 1.62 vs. 1.30) (14). Similarly, Göksedef et al. compared endocervical brush and Kevorkian curette in 208 patients, finding that pain levels were significantly higher with the Kevorkian curette (VAS mean: 2.55 ± 1.12) compared to the endocervical brush (VAS mean: 1.99 ± 0.87, $p < 0.001$) (15). In line with these studies, Novak curette caused the highest pain levels in our study, while Pipelle and endocervical brush showed no statistically significant differences in pain levels. Oliveira et al. compared Kevorkian curette and Pipelle in 52 patients, reporting significantly lower pain scores for Pipelle (VAS mean: 27 ± 5) compared to Kevorkian curette (VAS mean: 48.5 ± 7, $p = 0.02$) (5). While Pipelle caused the least pain in our study as well (VAS mean: 3.0 ± 1.02), Novak curette was associated with the highest pain levels (VAS mean: 3.7 ± 1.21) (5). Unlike Oliveira et al., who reported no significant difference in diagnostic tissue adequacy between the instruments, our study demonstrated superior diagnostic adequacy with Novak curette. Eken et al. evaluated ECC using Kevorkian curette, Pipelle, and Karman cannula in 318 patients, comparing pain levels and the quality of histological material (16). They reported the lowest VAS scores for Pipelle (VAS mean: 1.85 ± 0.84) and the highest for Kevorkian curette (VAS mean: 5.88 ± 1.43). Similarly, our study identified Pipelle as the least painful instrument, while Novak curette caused the highest pain levels (VAS mean: 3.7 ± 1.21). No significant differences in pathological examination scores were found between smokers and non-smokers in our study, suggesting that smoking status does not influence the quality of histological samples obtained.

CONCLUSION

In conclusion, Novak curette demonstrated superior diagnostic adequacy but at the cost of higher pain levels. Pipelle and endocervical brush, while less diagnostic, provided comparable results with lower pain, making them valuable alternatives for patient comfort. Considering individual patient factors, such as parity, clinicians should weigh diagnostic efficacy against patient comfort when choosing an instrument for endocervical sampling.

Ethics Committee Approval: The study was approved by Health Sciences University Kartal Dr. Lütfi Kırdar Training and Research Hospital Ethics Committee, Protocol No: 2018/514/128/7. This research adhered to the ethical standards outlined in the Helsinki Declaration and its subsequent amendments.

Authors' contributions: HS and MSC designed the study. HS and ADA collected data. AAT and ADA performed the data analysis, interpreted the analysis, and reviewed the literature. HS and AAT wrote the manuscript, then critically reviewed and made significant corrections. All authors read and approved the final version of the manuscript.

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Informed Consent: Informed consent forms were prepared and obtained from all participants.

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