

Concordance of Colposcopy-Directed Biopsy and Conization Results in Cervical Dysplasia

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ABSTRACT

OBJECTIVE: Cervical cancer prevention requires proper management of women with cervical intraepithelial neoplasia (CIN). A colposcopy is key to diagnosing CIN in women with abnormal cytology. Colposcopy identifies lesions, assesses grading, and guides biopsies. Excisional procedures like cold knife conization remove affected tissue for pathological examination and treat the CIN lesions. Some studies evaluate the consistency of conization and colposcopy-directed biopsy results. This study aimed to review the data of patients who had undergone conization retrospectively and to assess the consistency in predicting malignancy between preoperative cytology, biopsy, and/or Human papillomavirus (HPV) findings and conization pathologies.

STUDY DESIGN: This retrospective study included 114 women presenting to the gynecological oncology department between 2013 and 2024. The study included women with abnormal cytology and/or positive HPV 16/18 or persistent positivity for other high-risk HPV types. All of the women had undergone a colposcopy-directed biopsy and conization procedure. The kappa statistic (κ) was used to assess the correlation between colposcopy-directed biopsy and conization findings.

RESULTS: Among the patients, 46 (40.35%) had concordant colposcopy-directed biopsy and pathology results. The strength of agreement, as indicated by the Kappa statistic, was 0.237 ($p<0.001$). Colposcopy sensitivity for detecting high-grade cervical pathology was 93.2%, and specificity was 40%. of 77 patients (67.5%), an agreement between colposcopy-directed biopsy and cervical pathology for low and high-grade lesions was observed. The strength of agreement with the Kappa statistic was 0.338 ($p<0.001$).

CONCLUSION: This study showed that with a sensitivity of over 90%, colposcopy-directed biopsy plays an important role in detecting high-grade cervical lesions.

Keywords: Colposcopy; Conization; CIN

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Introduction

Proper management of women with cervical intraepithelial neoplasia (CIN) is a key part of preventing cervical cancer. If not managed correctly, this can lead to an increased risk of cervical cancer and the risk of complications from over-treatment,

such as preterm birth (1, 2). Colposcopy is probably the primary step in the accurate diagnosis of CIN in women with abnormal cytology (PAP smear) (3). The American Society for Colposcopy and Cervical Pathology (ASCCP) advises colposcopy for individuals who test positive for HPV types 16 and/or 18 (4). The most essential benefits of colposcopy are identifying the location of potential lesions, the first assessment of lesion grading, and the ability to perform colposcopically guided biopsies (5). CIN 1 lesions are commonly seen in younger women with a significant probability of spontaneous clinical regression (60-70%), whereas approximately 10% of the lesions may show progression to CIN 2 or 3. CIN 2 can also regress spontaneously, but there is a risk of progression to higher-grade dysplasia or carcinoma (22% of CIN 2 lesions may progress to CIN 3). CIN 3 may be persistent or show progression to carcinoma in about 12% of cases (6-8). Excisional procedures such as CNC were used to provide tissue samples for pathological examination and treatment of CIN lesions by removing affected tissue (9). However, the histopathological results of both biopsy and excisional methods can be inconsistent. There are differences in grading between the two histology results. Lately, large-scale studies have examined colposcopy-directed biopsy's precision (10-12). Conization has been regarded as the optimal procedure for both diagnosis and

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therapy (9). Because colposcopy is a subjective examination, its sensitivity and specificity for CIN 2+ lesions are 30-90 and 67-97%, respectively (13-16).

The literature includes studies that evaluate the consistency of conization and colposcopy-directed biopsy results (17-20). This study retrospectively examined the data of patients who underwent conization surgery to evaluate the consistency of malignancy prediction between preoperative cytology, biopsy, and/or HPV findings and conization pathologies.

Material and Method

Approval from the ethics committee for this retrospective study was obtained (Decision no: 2024/5233). The study was carried out within the framework of ethical rules by the Declaration of Helsinki. Since this was a retrospective study, informed consent was obtained from all patients at the time of admission, granting permission for their data to be used in scientific research. Women who applied to the gynecologic oncology department of our hospital during the period from January 2013 to September 2024 were included in the study. Women aged between 25 and 65 who did not smoke and had no systemic diseases were included in the study. Women with any diagnosis of malignancy, those using combined oral contraceptives, grand multiparous women, women who had undergone hysterectomy, and pregnant women were excluded from the study. Women included in the study were those with abnormal cytology and/or positive HPV 16/18 or persistent test positivity for other high-risk HPV types for 1 year. Referred women had either cytology-only or co-test results. Some of the women had undergone punch biopsy at another hospital. All of the women had undergone a conization procedure at our hospital. All biopsy specimens (punch biopsy and excisional biopsies) were studied, and the grade of the premalignant or malignant lesion was graded in every specimen. Since there was no LEEP device in our hospital when data were collected for the study, cold knife conization was performed on all patients as an excisional technique. The depth and width of the conization specimen were determined based on the type of transformation zone (TZ) and the degree of pathologic colposcopic appearance. In Cold Knife Conization (CKC), sutures were marked at the 12 o'clock cervical position and applied to control bleeding. After conization, the conical specimens were cut into tissue blocks, fixed in paraffin, and processed for Hematoxylin and Eosin (H&E) staining and light microscopy. All samples were graded based on the condition of the margins and the glandular involvement.

Data analysis was performed with SPSS version 22.0 (SPSS, Chicago, IL, USA). Categorical data were compared using the chi-squared test, and continuous variables were compared using the independent samples t-test or Mann-Whitney test. The correlation between the histopathological findings of colposcopy-directed biopsy and conization was assessed using the Kappa statistic (κ). Univariable and multi-

variable analyses were used to test the association between clinical variables and diagnoses. Univariable logistic regression was performed for all independent variables, and the results were presented as odds ratios (OR) with 95% confidence intervals. Differences with a p-value of less than 0.05 were considered statistically significant.

Results

The study involved 433 cases that underwent conization during the study period. When the archival records of the patients were examined, the results of Pap-smear, HPV, colposcopy-directed biopsy, and conization pathology of 114 patients were reached. There was no normal distribution in the sample in terms of descriptive data. The median age of women was 38 (min 25-max 70), and the median parity was 2 (min 0-max 5). Patient characteristics are shown in Table I. The most

Table I: Characteristics of the study group

Variables	n=114 (%)
Age (year)	
<30	11 (9.6)
30-39	47 (41.2)
40-49	40 (35.1)
50-59	12 (10.5)
≥60	4 (3.5)
Menopausal status	
No menopause	91 (79.8)
Menopause	23 (20.2)
Pap test	
Normal	66 (57.9)
ASCUS	12 (10.5)
HSIL	20 (17.5)
LSIL	14 (12.3)
ASC-H	2 (1.8)
HPV	
16	58 (50.9)
18	2 (1.8)
Other hr-HPV	32 (28.1)
16 +18	4 (3.5)
16 + other hr-HPV	12 (10.5)
18 + other hr-HPV	2 (1.8)
16, 18 + other hr-HPV	3 (2.6)
HPV negative	1 (0.9)
Diagnosis of colposcopic biopsy	
Normal	2 (1.8)
CIN 1	24 (21.1)
CIN 2	46 (40.4)
CIN 3	41 (36.0)
CIS	1 (0.9)
SCC	0 (0)
Diagnosis of conization	
Normal	37 (32.5)
CIN 1	18 (15.8)
CIN 2	21 (18.4)
CIN 3	33 (28.9)
CIS	3 (2.6)
SCC	2 (1.8)

ASCUS: Atypical squamous cells of undetermined significance, ASC-H: Atypical squamous cells, HSIL cannot be excluded, LSIL: low-grade squamous intraepithelial lesion, HSIL: high-grade

frequent Pap smear outcome was normal (57.9%), second was HSIL (17.5%). In total, 67.5% of the patients were HPV16, 9.7% were HPV 18, and 43% were other high-risk-HPV positive. The colposcopy-directed biopsy revealed one carcinoma in situ. Conization was performed in 2 patients with normal colposcopy-directed biopsy results due to HSIL as a Pap-smear result. Conization was performed in 24 patients diagnosed with CIN 1 on colposcopy-directed biopsy. This was because the squamocolumnar junction could not be observed in 17 patients with persistent postcoital bleeding, and in 5 patients' cytological biopsy incompatibility was found.

The diagnosis obtained by cold knife conization showed that 28.9% of the women were diagnosed with CIN 3, and 32.4% had no squamous intraepithelial lesions. CKC revealed two SCCs and three in situ SCCs.

The histopathological comparison of the colposcopy-directed biopsy and conization is shown in Table II. The agreement between colposcopy-directed biopsy and cervical pathology was observed in 46 patients (40.35%). The strength of agreement with the Kappa statistic was 0.237 ($p<0.001$). The colposcopy-directed biopsy was overestimated in 52 patients (45.6%) and underestimated in 16 patients (14%). The agreement of colposcopy-directed biopsy and conization

pathology within 1 grade was found in 69 patients (60.5%). Table III shows concordance, sensitivity, and specificity for the diagnosis of the colposcopy-directed biopsy and conization. As shown in Table IV, the Positive Predictive Value (PPV) of high-grade colposcopic diagnosis or more was (55/88) 62.5%, and the Negative Predictive Value (NPV) of low-grade colposcopic diagnosis or less was (22/26) 84.6%. The sensitivity of colposcopic diagnosis to detect high-grade cervical pathology or more was (55/59) 93.2%, and the specificity of colposcopy (when negative was defined as a low-grade lesion or less) was (22/55) 40%. The false-positive rate for high-grade colposcopy or higher was (33/55) 60%, and the false-negative rate for low-grade colposcopy or higher was (4/59) 6.8%. The agreement between colposcopy-directed biopsy and cervical pathology was found in 77 patients (67.5%) for low- and high-grade lesions. The strength of agreement with the Kappa statistic was 0.338 ($p<0.001$). The accuracy of detecting high-grade lesions was 67.54%.

In 37.5% of patients with colposcopy-directed biopsy results showing CIN of 2/3 or cancer, the conization pathology result was reported as CIN 1 or normal. All of the SCC cases revealed in conization pathology were graded as CIN 2/3 or more in the colposcopy-directed biopsy.

Table II: Histopathologic comparison of the colposcopy guided biopsy and conization ($n=114$)

Colposcopic biopsy	Conization pathology						The Agreement between Colposcopic Biopsy and Cervical Pathology	
	Normal	CIN 1	CIN 2	CIN 3	CIS	SCC	Total	χ^2 (p-value)
Normal	1	1	0	0	0	0	2	75.645(<0.001)
CIN 1	14	6	0	4	0	0	24	
CIN 2	13	8	16	7	1	1	46	
CIN 3	9	3	5	22	1	1	41	
CIS	0	0	0	0	1	0	1	
SCC	0	0	0	0	0	0	0	
Total	37	18	21	33	3	2		

CIN: Cervical intraepithelial neoplasia, CIS: Carcinoma in situ, SCC: Squamous cell carcinoma

Table III: Concordance, sensitivity, and specificity for diagnosis of the colposcopic biopsy and conization

Variables	CI %95	Sensitivity (%)	Specificity (%)	Concordance %
Normal	0.246-0.471	62.2	13	2.7
CIN1	0.243-0.532	66.7	18.7	33.3
CIN2	0.393-0.615	23.8	58.1	76.2
CIN3	0.572-0.792	87.9	24.7	66.7
SCC	0.464-0.916	60	62.4	20

CIN: cervical intraepithelial neoplasia, SCC: squamous cell carcinoma

Table IV: The Colposcopic diagnosis and cervical pathology in low-grade and high-grade lesions

Colposcopy guided biopsy	Conization pathology		
	Normal/Low-grade	High-grade	Total
Low-grade	22 (84.6%) (40%)	4 (15.4%) (6.8%)	26 (100%)
High-grade	33 (37.5%) (60%)	55 (62.5%) (93.2%)	88 (100%)
Total	55 (100%)	59 (100%)	114

On univariable analysis, age, Pap test, menopausal status, number of vaginal delivery, and HPV type were not significantly associated with the final diagnosis ($p=0.449$, 0.509 , 0.229 , 0.085 , and 0.286 , respectively).

There was no correlation between smear and conization pathology in the diagnosis of normal/low-grade and high-grade/cancer-grade lesions (Kappa statistic was 0.09 , $p=0.214$).

Discussion

This current study aims to assess pathological discrepancies between colposcopy-directed biopsy and cold knife conization pathology. We found a concordance rate of 40.35% in total. Comparing final pathology with biopsy, CIN 2+ lesions were detected in 51.7% and 77.3% of CKC and colposcopic biopsies, respectively. In 45.6% of cases with CIN 2+ on biopsy, the CKC was reported as CIN 1 or less. In our study, the Kappa statistic strength of agreement between colposcopic diagnosis and cervical pathology was 0.237 and 0.338 for all pathological diagnoses and by lesion grade (low vs. high), respectively ($p<0.001$ for both).

CIN2 and CIN3 should be handled appropriately, as they are the most likely precancerous lesions that develop into cervical carcinoma (19). Colposcopic visual findings with the highest degree of abnormality are used to determine the biopsy site to diagnose cervical precancerous lesions (21). In the literature, there are different results for agreement of colposcopy and conization. Tatiyachonwiphat et al. showed an intermediate level of concordance ($k=0.494$, $p<0.001$), and Petousis et al. showed similar results to them ($k=0.34$, $p<0.005$) (18, 22). This current study found a Kappa value close to these studies for diagnosing low/high-grade lesions ($k=0.338$). Akhter et al. and Boonlikit et al. found higher agreement in their studies ($k=0.65$, $p<0.001$; $k=0.66$, $p<0.05$, respectively) (23, 24). Whereas Massad et al. showed a poorer agreement between colposcopy and conization pathology ($k=0.20$) (25). We also found a Kappa value for identifying all grades of CIN close to that of this study ($k=0.237$).

Many studies in the literature examine the concordance rate of colposcopy and conization. A review of the literature found a 42% to 57% concordance rate of diagnostic pathology between colposcopy-guided biopsy and conization, and the overall sensitivity was $50\text{-}70\%$ and $55\text{-}90\%$ for CIN 1 and CIN 2/3, respectively, and overall specificity was 80% and 96% for CIN 1 and CIN 2/3, respectively (26). Zuchna et al. found sensitivity, specificity, and PPV and NPV; 66.2% , 95.0% , 98.5% , and 35.5% , respectively, for detecting CIN 2+ lesions (27). The sensitivity for detecting high-grade lesions was 93.2% in our study. Specificity was 40% , positive and negative predictive values were 62.5% and 84.6% , respectively. The concordance rate of our study was 40.35% in total. Our study's sensitivity, specificity, NPV, and PPV for detect-

ing high/low-grade lesions were 93.2% , 40% , 84.6% , and 62.5% , respectively.

Colposcopy remains the standard for cervical intraepithelial dysplasia, although the accuracy of some studies supporting it is questionable (28). This situation was explained by the small volume of biopsy material, possible regression due to a triggered inflammatory process, or insufficient conization. In $10\text{-}33\%$ of cases, low-grade lesions cannot be identified (11). Also, the ALTS trial (Atypical Squamous Cells of Undetermined Significance/Low-Grade Squamous Intraepithelial Lesion (ASCUS/LSIL) Triage Study) showed that the number of biopsies in colposcopy is important for final diagnosis. Gynecologic oncologists prefer to take fewer biopsies, while gynecologists take more. In this study, the detection rate of HSIL in colposcopy was 73.5% , which is higher than that reported in the literature. This result may be due to the lack of gynecologic oncologists among the colposcopists (29). In our study, the detection rate for HSIL was 66.6% , both gynecologic oncologists and gynecologists performed colposcopies.

In our study, 33 patients (29%) whose colposcopy-directed biopsy results were CIN 2/3 had a final diagnosis of CIN 1/normal in conization pathology. This situation may be due to the total excision of a higher-grade lesion in colposcopy-directed biopsy.

The main risk factor for developing cervical cancer and precancerous lesions of the cervix is persistent infection with oncogenic HPV types (30). All patients except one patient were positive for HPV 16,18 or other high-risk HPV types in our study. However, there was no statistically significant difference between the patients regarding Pap-smear, colposcopy, or conization pathology according to the HPV type they carry.

The experience of cytologists, collection of specimens, monitoring of laboratory diagnostic rates, and quality control under better conditions affect the diagnosis of ASCUS with the Bethesda system. Following the new definitions, the ASCUS/SIL ratio should be decreased to nearly 1 (28). In our study, all patients diagnosed as ASCUS in Pap-smear have a CIN lesion in colposcopy-directed biopsy (4 patients CIN 1, 6 patients CIN 2, and $+$ patients CIN 3). The same patients' conization pathology results were as follows: 5 patients normal, 1 patient CIN 1, 2 patients CIN 2, 5 patients CIN 3, and 1 patient *in situ* cancer.

This study has some limitations. The fact that it is a single-center retrospective study with a limited sample can be counted among them. Interobserver biases cannot be neglected. Colposcopic examinations were not blinded; colposcopists were aware of cytology and HPV results and had no specific colposcopy certifications. Different pathologists evaluated the biopsies and surgical material. Since the study was conducted at a university hospital where patients were referred

for further examination and treatment, the rate of high-grade lesions may have been higher than in the normal population.

Conclusion

In conclusion, despite its limitations, this study showed that with a sensitivity of over 90%, colposcopy-directed biopsy plays an important role in detecting high-grade cervical lesions. Colposcopy-directed biopsy sensitivity was the highest for HSIL among all cervical intraepithelial lesions, exceeding 85%. Further research is still needed to determine the precise diagnostic accuracy of methods based on the final histology of surgically treated cases.

Declarations

Ethics approval and consent to participate: Necmettin Erbakan University Ethics committee approved this retrospective study (Decision no: 2024/5233). Since it was a retrospective study, informed consent was obtained from all patients at the time of admission so that their data could be used in scientific studies. All procedures were performed according to the Declaration of Helsinki.

Availability of data and materials: The data supporting this study is available through the corresponding author upon reasonable request.

Competing interests: The authors declare that they have no competing interests.

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