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Research Article

Diagnostic Performance of Cytocolposcopy versus Biopsy for Premalignant and Malignant Lesions in a Women's Hospital Dysplasia Clinic

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ABSTRACT

Background: Cervical cancer (CRC) is a public health problem because it is the fourth most common gynecologic neoplasm worldwide. The screening tests used to diagnose this pathology are cervical cytology, which in suspected malignancy or with malignancy requires colposcopy to identify the affected area and thus guide the biopsy, which is the gold standard for diagnosis. Therefore, these tests are complementary, and a high diagnostic concordance is required to make a confident diagnosis.

Subjects and Methods: A retrospective, cross-sectional, observational, and analytical study was performed. A total of 1470 medical records were analyzed, of which 175 patients met the inclusion criteria. The cyto-colposcopic diagnostic yield was compared with the histopathologic yield. The concordance between screening tests and the gold standard was calculated using Cohen's kappa coefficient

Results: The sample comprised 175 subjects who met the selection criteria (11.9%). The mean age was 34.59 + 11.01 years, ranging from 17 to 65 years. The mean sexual debut was 16.6 years, with a mean of 3.1 ± 2 sexual partners. When patients were classified according to lesion type, the highest percentages were found in low-grade squamous intraepithelial lesions (LSIL). With 45.71, 61.14, and 49.14% for cytologic, colposcopic, and histopathologic examination, respectively. The highest concordance between histopathology and cytology was found in the high-grade squamous intraepithelial lesion (HSIL) with 0.41, and the concordance between histopathology and colposcopy in HSIL and cancer was 0.55 and 0.74, respectively.

Conclusions: Papanicolaou tests and colposcopy showed moderate concordance with histopathologic findings; the diagnostic accuracy of colposcopy is superior to that of cytology.

Introduction

Cervical cancer (CRC) is a public health problem as it is the fourth most common gynecologic neoplasm worldwide. In developing countries, it is the second leading cause of cancer-related death among women.(1) It is also considered a preventable disease due to its prolonged pre-invasive stage, which facilitates its early detection by cytology, colposcopy, and histology and the treatment of pre-invasive lesions2. In the United States, even with screening programs in place with appropriate protocols, the odds of developing CRC at some point

in life are estimated to be 1:128, and up to 30% of CRC cases occur in patients who have undergone cervical cytology (Pap smear).(2)
Screening tests include vaginal cytology, which is performed to evaluate cervical cytologic abnormalities or dysplasia. It is recommended to be performed every three years, as annual tests have similar results to those performed every three years.(3) In addition, the incidence of high-grade cytologic abnormalities in the three years following a normal test is very low (10-66 per 10,000).(4) Colposcopy is also used to diagnose CRC and detect precancerous and cancerous lesions. It is used as a secondary test when abnormal cervical cytology is detected.(5)
CRC is one of the easiest gynecologic malignancies to detect and stage early, provided a culture of routine screening allows for early treatment. Worldwide, according to the International Agency for Research on Cancer, it is the fourth most common gynecologic neoplasm, with a prevalence of 5.8% in 2020, surpassed by breast (30.3%), colorectal (9.3%), and thyroid (6%). Likewise, in our country, the estimated prevalence rate is 560.8-1321.5 per 100,000 inhabitants, being the second cause of death in women in Mexico, surpassed only by breast cancer (6).
The 5-year survival rate, according to the American Cancer Society, is related to the initial staging, which is why screening tests are vital, as mentioned above, since CRC is one of the most common neoplasms and is highly preventable and curable in its early stages.(6-8)
In Sinaloa, Mexico, according to the last CRC report obtained from epidemiological week 18, 2 new cases were reported, with a cumulative total of 60 cases from epidemiological week 1 to 18 of 2022. It is more prevalent in women of reproductive age in 76% of the cases between 20 and 49 years but less frequent in women over 65 years.(9) Our study aimed to determine the diagnostic yield of cyto-colposcopy versus biopsy for premalignant and malignant lesions in a dysplasia clinic of a women's hospital in northwestern Mexico.

Subjects and Methods

A retrospective, cross-sectional, observational, and analytical study was conducted in which 1470 files of women between 15 and 65 years of age were reviewed, registered, and attended in the Gynecology and Obstetrics Outpatient Clinic and referred to the Dysplasia Clinic of the Women's Hospital from January 1, 2020, to September 30, 2022.
The inclusion criteria were compliance with the epidemiologic clinical follow-up protocol, suspicious cervical cytology results, having undergone colposcopy and having the diagnostic conclusion by histopathology. All patients who did not meet the above inclusion criteria were excluded from the study.
Operative Definitions.
The Bethesda system was used for cervical cytology reporting.[10] This is the World Health Organisation (WHO) recommended classification for cytology reporting and is as follows (Figure 1); Normal: Any result that does not fall within the range of epithelial abnormalities or abnormal cytology: according to Bethesda System terminology,[10] cytology with abnormalities were those with results of atypical squamous cells of uncertain significance (ASC-US), Atypical squamous cells cannot exclude high-grade squamous intraepithelial lesion (ASC-H), low grade squamous intraepithelial lesion (LSIL), High grade squamous intraepithelial lesion (HSIL), invasive carcinoma, atypical glandular cells (AGC), adenocarcinoma in situ, or adenocarcinoma. Indeterminate: Atypical squamous cell carcinoma of undetermined significance and/or atypical squamous cell carcinoma cannot exclude HSIL. Low-grade squamous intraepithelial lesion (LSIL): Includes cellular changes associated with the cytopathic effect of human papillomavirus (HPV) infection (known as pilocytic atypia), usually confined to the superficial layers. High-grade squamous intraepithelial lesion (HSIL): Cellular changes involving two-thirds or more of the thickness of the squamous epithelium. This type of lesion corresponds to those classified above as moderate and severe dysplasia and cancer in situ. Cancer: Malignant tumor caused by loss of control of cell growth that may invade adjacent structures or spread to distant sites, resulting in death.
Statistical Analysis
Cyto-colposcopic diagnostic yield was compared with histopathologic yield. Cohen's kappa coefficient calculated the agreement between screening tests and the gold standard. Data were analyzed using Stata Intercooled version 13.1, College Station, Texas. Sensitivity and specificity estimates for colposcopic diagnosis were calculated by cross-tabulation. Forest plots with corresponding 95% confidence intervals (95% CI) were generated for each test. Pooled estimates of test accuracy are presented graphically with summary receiver operating characteristic (SROC) curves.
Variables assessed
Chronological age, sexual partners, cervical cytology, colposcopy, and histopathology.
Patient and public involvement
Participants were not directly involved in designing or implementing the study**.**

Results

A review of 1,470 medical records of patients seen between January 1, 2020, and September 30, 2022, was performed, of which 175 subjects (11.9%) met the selection criteria. The mean age was 34.59 + 11.01 years, with a range of 17 to 65 years, and the median age was 33. The mean age of sexual debut was 16.6 years, with a mean of 3.1 ± 2 sexual partners.
When patients were classified according to lesion type, the highest percentages were found in LSIL, with 45.71, 61.14, and 49.14% for cytology, colposcopy, and histopathology, respectively (Table 1, Figure 1)

Table 1. Percentage distribution of cytology, colposcopy, and histopathology results in patients in the dysplasia clinic.

Diagnosis	Normal	Indeterminate	LSIL	HSIL	Cancer	n
Cytology	6(3.43)	41(23.43)	80(45.71)	48(27.43)	0(0.00)	175
Colposcopy	14(8)	6(3.43)	107(61.14)	38(21.71)	10(5.71)	175
Histopathology	26(14.86)	0(0.00)	86(49.14)	52(29.71)	11(6.29)	175

Low-grade squamous intraepithelial lesion (LSIL). High-grade squamous intraepithelial lesion (HSIL); **n:** sample

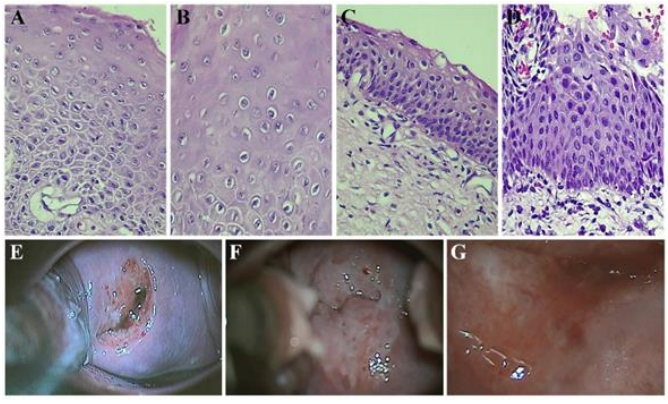

Figure 1. Representative images of cervical tissue stained with haematoxylin and eosin (A to D) and colposcopic examination of the cervix (E to G). Hematoxylin and eosin staining, A) Squamous epithelium with changes associated with a low-grade squamous epithelial lesion (LSIL), B) Squamous epithelium with cytopathic changes (koilocytes), C) Squamous epithelium with LSIL, borderline changes towards a low-grade squamous epithelial lesion (HSIL), D) Squamous epithelium with HSIL-related changes; Colposcopy, E) Eutrophic cervix with type I vascular pattern, type 1 transformation zone, visible squamocolumnar junction, mature squamous epithelium, negative Hiselman test, no lesions, F) Hypertrophic cervix with type I vascular pattern, type 1 transformation zone, visible squamocolumnar junction, mature squamous epithelium, positive Hiselman's test for dense acetowhite epithelium with glandular infiltration at 10 to 12 o'clock and 5 to 8 o'clock, well defined and raised borders, high-grade lesion, G) Eutrophic cervix with type II vascular pattern, type 3 transformation zone, invisible squamocolumnar junction, mature squamous epithelium and positive Hiselman's test for dense acetowhite epithelium. Hemorrhagic endocervical neoformation is observed, with high-grade HPV-associated lesions.

Table 2 shows that cytopathology reports have low sensitivity compared with histopathology reports. However, specificity and negative predictive values (NPV) were higher for HSIL; colposcopy was better in specificity, positive predictive values (PPV), and negative predictive values for LSIL and cancer. A high NPV indicates the probability that the patient is healthy. Similarly, a high PPV suggests that there is an actual probability that she has the disease.

For indeterminate lesions (ASC-US, ASC-H) by cytology and colposcopy, the false positive rate was 21.47% and 1.34%, respectively, and the false negative rate was 12.68% and 14.96%, respectively. The diagnostic accuracy for this type of lesion was 72% and 86.2% for cytology and colposcopy, respectively.

Cytology showed a diagnostic accuracy of 76% and 62.28% for high- and low-grade lesions, respectively; colposcopy showed an accuracy of 82.85%, 76.57%, and 97.14% for LSIL, HSIL, and CANCER, respectively. The likelihood ratio found for colposcopy in LSIL and cancer is high, as is the area under the curve, which was 0.76 and 0.85, respectively (Table 2).

The highest concordance between histopathology and cytology was in HSIL, with 0.41, and the concordance between histopathology and colposcopy in HSIL and cancer was 0.55 and 0.74, respectively, see Table 3.

Table 2. Diagnostic yield of cytology and colposcopy in the dysplasia clinic**.**

Diagnostic test	S	E	VPP	VPN	LR+	LR-	ABC
Cytology for LSIL	62.5	62.1	58.1	66.2	1.72	0.63	0.6
Cytology for HSIL	55.7	84.5	60	81.8	3.59	0.18	0.70
Colposcopy for LSIL	57.69	93.49	78.94	83.94	8.86	0.45	0.76
Colposcopy for HSIL	88.37	65.16	71.02	50	2.53	0.17	0.75
Colposcopy for Cancer	72.72	98.78	80	98.18	59.6	0.27	0.85

LSIL: low-grade intraepithelial lesions; HSIL: high-grade intraepithelial lesions; S: sensitivity, E: specificity, PPV and NPV: positive and negative predictive values; LR+: positive likelihood ratio; LR-: negative likelihood ratio; ABC: area under the curve.
The positive and negative predictive values (PPV and NPV, respectively)

Table 3. Diagnostic concordance between cytology and colposcopy compared to histopathology.

Diagnostic test	Normal	indeterminate	LSIL	HSIL	Cáncer
Cytology	0.14	0.00	0.24	0.41	0
Colposcopy	0.49	0.00	0.53	0.55	0.74

LSIL: low-grade intraepithelial lesions; **HSIL:** high-grade intraepithelial lesions.

Discussion

Knowing the concordance between different screening tests and the gold standard is essential to reduce unnecessary procedures and make timely decisions when needed, thus optimizing the resources available in public institutions. This is the first study performed at the Women's Hospital to determine the performance and concordance of diagnostic tests with histopathologic results.

Our results indicate that cytology was more specific and had an adequate negative predictive value for HSIL but inferior to colposcopy. That colposcopy was more sensitive and had a proper positive predictive value for HSIL compared to cytology.

We can say that our hospital diagnostic screening for premalignant and malignant lesions demonstrates and confirms that colposcopy has better accuracy than cytology, as already established by other authors, although according to the guidelines updated by the International Federation for Colposcopy and Cervical Pathology in its recently published meta-analysis of 15 articles with 22. 000 participants reported a sensitivity of 92% and a specificity of 51% for detecting LSIL, a sensitivity of 68%, and a specificity of 93% for LSIL, which are very high figures. Like those found in the present study.(11) The concordance was moderate according to the Landis J scale for assessing the degree of concordance.(12)

A study conducted by Barut et al. in 2015 (13) aimed to correlate diagnostic tests in detecting malignant and premalignant lesions of the cervix, given the significant variability in the sensitivity of cytology reported by other authors and the cost of it. In the analysis of abnormal cervical lesions, colposcopy, and biopsy invasiveness found in their research at the tertiary level of care in women with a low

socioeconomic level, they reported a cytology sensitivity of 57%, which is much lower than the result obtained in our study; a specificity of 76%, much lower than that reported in our study, as well as a PPV of 26% and NPV of 92%.(13)

In the study conducted by Singhal et al. in 2019, where they compared the diagnostic concordance, the diagnostic accuracy of cytology and colposcopy for HSIL was 100% and 91.3%, respectively, where the mean age was 34 years. However, the highest percentage was centered in the group from 26 to 35 years, unlike our study, where we found an age range from 16 to 65 years, although the accuracy of our tests was 72% for cytology and 86% for colposcopy.(14)

According to the authors, the poor results obtained are most likely because the specific diagnosis in these techniques is highly operator-dependent and subjective. Therefore, the severity of the lesions tends to be underdiagnosed.(15)

Scales are recommended to reduce intra-operator error, as proposed by the International Federation of Cervical Pathology (IFCPC 2011).(16) In a study by Rema Prabhakaran Nair et al. in 2020, comparing several colposcopic visual scales, they concluded that the best one proposed by the IFCPC 2011 compared with histopathologic findings, reporting a correlation of 65. 7% for squamous intraepithelial lesions regardless of grade, compared to our study where the colposcopic-histopathologic correlation was demonstrated for HSIL, LSIL, and CANCER with an accuracy of 82.85%, 76.57%, and 97.14%, respectively.(17, 18)

Fadi W. Abdul-Karim et al., published 2017 the results of a study that aimed to compare the discrepancy between diagnostic tests for CRC (19). They reported a histopathologic prevalence of 29% for LSIL in the control group and 2.2% in the group in which colposcopy was used. Compared to our study, the percentage was 21.7% for colposcopy and 29.7% for histopathologic results, with a sensitivity of 88.37 and specificity of 65.1, reporting a lower diagnostic discrepancy in our study.(19)

In a study published by Juan Li Wei Wang et al., whose aim was to analyze the agreement between colposcopic impression and histopathological diagnosis of cervical biopsy, they reported a perfect agreement between colposcopy and histopathology of 46.9%, with a kappa concordance of 0.23. With a PPV of 93.1%, NPV of 57.8%, and sensitivity and specificity of 80.9% and 93.9%, respectively, for LSIL or higher.(20) Our study reported higher concordance for both LSIL and HSIL, as previously discussed; in terms of sensitivity, specificity, PPV, and NPV, the results were very similar (Table 2), the diagnostic performance of cytology and colposcopy in the dysplasia clinic. They also conclude by pointing out that the experience of the colposcopist is an integral part of the underdiagnosis factor of HSIL.(20)

Peng Xuw et al., in 2020, reported that the diagnostic accuracy of colposcopy-guided cervical biopsy for the detection of squamous intraepithelial lesions is relatively low, ranging from 30% to 70%, attributing it to the lack of capacity of colposcopy services in low- and middle-income countries.(21) In comparison, in our study, colposcopy showed a diagnostic accuracy for HSIL, LSIL, and CANCER of 82.85%, 76.57%, and 97.14%, respectively. The training and quality of the teams in our dysplasia center can effectively justify this.(21)

Women with a clinical diagnosis of cervical dysplasia should be evaluated by cytology to detect premalignant or malignant lesions. It has been concluded that cytology, colposcopy, and histopathology should be evaluated to assess cervical findings in low socioeconomic regions.(13) On the other hand, it is essential that when a result is found, whether positive or negative, the patient is referred as soon as possible for timely follow-up and treatment.(22)

The diagnostic tests evaluated in our study are complementary in arriving at a diagnosis of CRC. Currently, the screening method is cervical cytology; however, we must remember that it may be subject to false bias due to the person taking the samples and the patient's condition at the time of screening. If it is positive or suspicious of malignancy, or if the result is equivocal, the ideal is to send the patient to a dysplasia center for colposcopic examination and biopsy to increase our diagnostic certainty since this is the gold standard.(23, 24)

Conclusions

Cytology and colposcopy showed moderate agreement with the histopathology report; however, the sensitivity of the tests was low for cytology. Although the diagnostic accuracy of colposcopy is superior to that of cytology, the high rate of false negatives and positives must be considered due to quality issues, as cytology samples were taken and read by personnel from outside our hospital in different laboratories, so the expertise of each professional plays a key role in the diagnosis. Therefore, diagnosis should be complemented by more effective tests, such as molecular tests (hybrid capture and PCR), which promote early diagnosis and treatment of the disease to prevent HPV infection from progressing to cervical cancer.

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Conflict of Interest

The authors declare that they have no conflicts of interest.

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request

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