Cyto-Histological Correlation Analysis in the Diagnosis of Cervical Lesions: Cancer Prevention Clinic – Venezuela (2020-2024)

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Análise de Correlação Cito-Histológica no Diagnóstico de Lesões Cervicais: Clínica de Prevenção do Câncer – Venezuela (2020-2024)

Análisis de Correlación Cito-Histológica en el Diagnóstico de Lesiones Cervicales: Clínica de Prevención del Cáncer – Venezuela (2020-2024)

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ABSTRACT

Introduction: Cervical cancer is a global public health problem, particularly in low- and middle-income countries such as Venezuela. Although global incidence has decreased thanks to screening programs and vaccination against the human papillomavirus (HPV), in Venezuela it remains one of the leading causes of female morbidity and mortality. **Objective:** Correlate the diagnosis of cervical cytology with the findings of cervical biopsy. **Method:** Descriptive, cross-sectional, and observational study conducted in patients treated at the "*Clínica de Prevención del Cáncer*" from January 2020 to December 2024. A total of 2,163 cytologies were performed, identifying 122 patients with simultaneous cervical biopsies, who formed the final sample of this analysis. **Results:** The mean age was 43.3±12.6 years; results showed that 4.06% of the total cytologies presented some type of cellular alteration, the most frequent was LSIL (low-grade squamous intraepithelial lesion). On the other hand, 50.82% of the biopsies presented pathological lesions, and 18% corresponded to invasive carcinoma. The correlation between cytology and cervical biopsy demonstrated a sensitivity of 85.48%, a specificity of 41.67%, a positive predictive value of 60.23%, and a negative predictive value of 73.53%. **Conclusion:** Cervical cytology maintains a valid diagnostic performance in the clinical setting. However, the standardization of auxiliary methods such as colposcopy and molecular typing tests is recommended to increase specificity, optimize clinical management, and reduce unnecessary procedures.
Key words: Cross-Sectional Studies; Papanicolaou Test; Biopsy; HPV; Venezuela.

RESUMO

Introdução: O câncer do colo do útero é um problema de saúde pública mundial, especialmente em países de baixa e média rendas, como a Venezuela. Embora a incidência global tenha diminuído graças aos programas de rastreamento e à vacinação contra o papilomavírus humano (HPV), na Venezuela continua sendo uma das principais causas de morbidade e mortalidade feminina. **Objetivo:** Correlacionar o diagnóstico da citologia cervical com os achados da biópsia do colo do útero. **Método:** Estudo descritivo, transversal e observacional em pacientes atendidas na Clínica de Prevenção do Câncer no período de janeiro de 2020 a dezembro de 2024. Foram realizadas 2.163 citologias, identificando-se 122 pacientes com biópsia cervical simultânea, as quais formaram a amostra definitiva desta análise. **Resultados:** A média de idade foi de 43,3±12,6 anos; os resultados mostraram que 4,06% do total das citologias apresentaram algum tipo de alteração celular, sendo a lesão intraepitelial de baixo grau (LIE-BG) a mais frequente. Por sua vez, 50,82% das biópsias apresentavam lesões patológicas e 18% correspondiam a carcinoma invasor. A correlação entre a citologia e a biópsia cervical resultou em sensibilidade de 85,48%, especificidade de 41,67%, valor preditivo positivo de 60,23% e valor preditivo negativo de 73,53%. **Conclusão:** A citologia cervical mantém um desempenho diagnóstico válido no contexto clínico. No entanto, recomenda-se a padronização de métodos auxiliares, como a colposcopia e testes de tipagem molecular para aumentar a especificidade, otimizar o manejo clínico e reduzir a realização de procedimentos desnecessários.
Palavras-chave: Estudos Transversais; Teste de Papanicolau; Biópsia; HPV; Venezuela.

RESUMEN

Introducción: El cáncer de cuello uterino es un problema de salud pública a nivel mundial, especialmente en países de ingresos bajos y medios como Venezuela. Aunque la incidencia global ha disminuido gracias a programas de investigación y vacunación contra el virus del papiloma humano (VPH), en Venezuela continúa siendo una de las principales causas de morbilidad y mortalidad femenina. **Objetivo:** Correlacionar el diagnóstico de la citología cervical con los hallazgos de la biopsia de cuello uterino. **Método:** Estudio descriptivo, transversal y observacional en pacientes atendidas en la Clínica de Prevención del Cáncer durante enero de 2020 a diciembre de 2024. Se realizaron 2163 citologías, identificando a 122 pacientes con biopsia cervical simultánea, las cuales conformaron la muestra definitiva de este análisis. **Resultados:** La edad media fue 43,3±12,6 años, los resultados mostraron que el 4,06% del total de las citologías presentó algún tipo de alteración celular, siendo la lesión intraepitelial de bajo grado (LIE-BG) la más frecuente. Por su parte, el 50,82% de las biopsias presentaba lesiones patológicas y el 18% correspondía a carcinoma invasor. La correlación entre la citología y la biopsia cervical resultó en sensibilidad del 85,48%, especificidad del 41,67%, valor predictivo positivo del 60,23% y valor predictivo negativo del 73,53%. **Conclusión:** La citología cervical mantiene un rendimiento diagnóstico válido en el entorno clínico. No obstante, se recomienda la estandarización de métodos auxiliares como la colposcopía y las pruebas de tipificación molecular para aumentar la especificidad, optimizar el manejo clínico y disminuir la ejecución de procedimientos innecesarios.
Palabras clave: Estudios Transversales; Prueba de Papanicolaou; Biopsia; VPH; Venezuela.

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INTRODUCTION

Cervical cancer remains a world public health problem. In the last decades, the World Health Organization (WHO) have fostered a global strategy grounded in three pillars: prevention through HPV vaccination (the goal is 90% of the girls), detection through high precision tests (coverage of 70%) and effective treatment of 90% of precancerous lesions and invasive cancers[1]. Despite these efforts, socioeconomic inequalities still persist: according to GLOBOCAN 2022[2], more than 660,000 new cases and 33,000 deaths have been recorded in Latin America and Caribbean. In Venezuela, the situation is alarming: this neoplasm is the second most incident and third in female mortality[3].

The investigation consists in an intervention in asymptomatic populations to identify individuals at high risk[4]. Cervical cancer is ideal for this approach since it presents a prolonged symptomatic and detectable phase whose timely treatment changes radically the course of the disease. The most important screening test continues to be cervical cytology (Pap Smear), which involves exfoliating cells from the transformation zone of the cervix to enable examination of these cells microscopically[5].

Given that the sensitivity of the cytology can vary significantly within a range from 38.9% to 89.4% in several studies[6,7], the conventional cytology continues to be the ideal test due to its low cost, reproducibility and capacity of early detection[8]. New technologies have been incorporated over time as liquid-based cytology and several FDA-approved HPV molecular tests (since ViraType in 1991 and self-collection systems expected for 2025) that improve the screening specificity[9-18]. Although these techniques attempt to improve the sensitivity and specificity, the principle of Papanicolaou continues to meet the criteria of Wilson and Jungner[19]. In despite of its effectiveness, the gold standard continues to be the biopsy to confirm the cytologic findings. The utilization of the novel technologies in Venezuela is restricted due to their high costs. Therefore, conventional cytology continues to be the standard of populational survey because of its low cost, safety and accessibility.

It appears to be imperative to analyze its effectiveness in the clinical environment. The present study aims to define the cyto-histologic correlation of cervical cytologies and biopsies in patients treated at "*Clínica de Prevención del Cáncer (CPC)*" between 2020 and 2024.

METHOD

Descriptive, cross-sectional cohort, observational study of diagnostic precision.

The inclusion criteria were all the patients older than 18 years who submitted to cervical biopsy and those who received a previous result of conventional cervical cytology treated at CPC in the investigational period (January 2020 to December 2024).

The exclusion criteria were all the patients younger than 18 years, confirmed diagnosis of cervical cytology for those who did not submit to cervical biopsy, patients with vaginal pool cytology, those who did not submit to cervical biopsy at CPC and the patients out of the investigational period.

The Ethics Committee, the gynecology service and the medical board of CPC have previously approved the study, all the patients have signed the informed consent form being ensured their anonymity and confidentiality. The clinical history of the patients registered in the institution treated by the gynecology service between January 2020 and December 2024 have been revised.

Based on the total cases evaluated in the gynecology visit from January 2020 to December 2024, 2,163 patients have been submitted to conventional cervical cytology (Papanicolaou test) at CPC, in the parish of Altagracia, municipality Libertador, Caracas, Venezuela. Of these, 122 patients have met the eligibility criteria.

For the present investigation, the positive cytologies reported as epithelial cells abnormalities were considered, such as ASC-H (atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion), LSIL (low-grade squamous intraepithelial lesion), HSIL (high-grade squamous intraepithelial lesion) and SCC (squamous cell carcinoma) while the negative cytologies were those that were negative for LSIL, atrophic, with mild, moderate, severe inflammation; the positive biopsies were those that presented the following histological findings: endocervical atypia, CIN (cervical intraepithelial neoplasia) 1, 2, 3 and SCC and the negative biopsies were those without pathological findings, metaplasia, cervicitis, polyps and cytopathic effects.

Statistical analyzes were performed on an Excel (Windows 11) database while the software Rstudio[20] (version 2024.04.2+764. pro1) was applied for the statistical tests and data analyzes. Key performance indicators (KPI) such as sensitivity, specificity, PPV (positive predictive value), NPV (negative predictive value) were calculated in addition to weighted Kappa index for the diagnostic agreement according to the scale proposed by Landis and Koch[21]. The results are presented as tables.

The Ethics Committee of "*Departamento de Educación de la Sociedad Anticancerosa de Venezuela (SAV)*" approved the study that was classified as risk-free because it was based on a review of secondary data (medical charts), being

ensured the anonymity of the participants in compliance with the Declaration of Helsinki[22], with the guidelines of the "*Centro Nacional de Bioética (CENABI, Venezuela)*[23] and the "*Código de Ética para la Vida*" of the "*Ministerio del Poder Popular para Ciencia y Tecnología de Venezuela (*edition 2010*)*[24].

RESULTS

Upon the review of clinical history and consistent with CPC medical procedures, 2,163 cervical cytologies have been performed in the gynecological visit at CPC. Of these, 122 (5.6%) required histological confirmation with cervical biopsy due to cytologic and/or colposcopy alterations. There was a progressive increase of altered cytologies in 2023 and most of the lesions were diagnosed in 2022-2023. Utilizing cytology as investigation method, the majority was negative as expected in a populational investigation, only 4.06% required additional histologic confirmation because of cyto-colposcopy alterations (Table 1). The age-range included patients aged 18-82 years old, with higher frequency in the 36-55 age range (57.3%), considered as the highest risk range for precursor and invasive lesions (Table 2).

Table 3 shows the results obtained from the 122 cytological samples and the most frequent alteration was LSIL in 59 cytologies (48.36%), followed by squamous cell carcinoma (SCC) in 14 cytologies (11.48%). Among the findings of the biopsies, 62 were positive for preinvasive and invasive lesions (50.82%) and, of these, 22 (18.03%) were squamous cell carcinoma (SCC).

According to table 4, the most common cytologic alterations were LSIL in 59 cytologies (48.36%); regarding the histopathological results, 39 biopsies (31.96%) corresponded to some grade of cervical intraepithelial neoplasm (CIN), of these, CIN grade 1 (CIN I) represented the major group with 33 biopsies, while 22 biopsies (18.03%) confirmed the diagnosis of SCC.

The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated through the correlation between cervical cytologies and cervical biopsies with high sensitivity of 85.48%, specificity of 41.67%, PPV of 60.23% and NPV of 73.53% (Table 5). Based on the scale proposed by Landis and Koch[21] the Kappa index was evaluated, where 0.273 represents an acceptable or discreet agreement with confidence interval of 95% (CI95%) (0.103 -0.443) and the correlation cytology-biopsy with odds ratio 4.21 with CI95% (1.76-10.07) demonstrating that positive cytologies are 4-fold more propense to associate with positive biopsy than negative biopsies.

DISCUSSION

Considering the objective of determining the diagnostic efficacy of conventional cervical cytology through its correlation with the histopathological study of a Venezuelan cohort between 2020-2024, it has been found that cytology keeps a high sensitivity of 85.48%, consolidating itself as a fundamental tool of primary screening in the clinical setting investigated. However, a relevant diagnostic discrepancy was observed: only 4.06% of the total cytologies showed alterations and the analyzes of the patients who submitted to biopsies revealed a high disease burden. This initial interpretation suggests that cytology is an effective screening tool to identify risk groups but presents moderate capacity for accurate prediction, reinforcing the necessity of histologic confirmation to favor a proper definitive clinical management.

The mean age of 43 years old and higher proportion of cases in the age range of 36-55 years are similar to the results obtained by Berrios et al.[25], where the age range of 26-55 years accounted for 72.8% of their sample. The cytologic evaluation revealed a prevalence of 48.36% of LSIL consistent with the results obtained by Mayorga-Bautista et al. [26] and Riviera[27] with 46.4%.

It is emphasized that 50.82% of the biopsies revealed pathological lesions. In comparison with the international literature, specifically the multicenter study of Ouh et al.[28]

Table 1. Distribution of cytologies and biopsies performed, 2020-2024

Year	Cytologies	Altered cytology	% of altered cytologies of the total cytologies	Cervical biopsies	% biopsies performed
2020	138	7	5.07	7	5.07
2021	397	6	1.51	8	2.01
2022	538	22	4.08	27	5.01
2023	576	34	5.90	49	8.5
2024	514	19	3.69	31	6.03
Total	**2,163**	**88**	**4.06**	**122**	**5.64**

Captions: Altered cytology: altered cytologies of the total cytologies performed. % altered cytologies of the total cytologies: percent of altered cytologies of the total cytologies evaluated. Cervical biopsies: biopsies performed. % biopsies performed: percent of biopsies performed of the total cytologies/year.

Table 2. Distribution of patients with cervical biopsy by age, 2020-2024

N = 122		
Age = 43.30± 12.62 (18-82 years)		
Age-range (years)	**N**	**%**
18-25	11	9.02%
26-35	23	18.85%
36-45	37	30.33%
46-55	33	27.05%
56-65	13	10.66%
66-85	5	4.10%
Total	122	**100.00%**

where 3,798 cases were analyzed, resulting in a histological positivity of some type of CIN of 36.07% of the samples, it has been shown that the present investigation presents a prevalence of invasive disease such as SCC in 18.03% of the positive biopsies. This result is higher than reported in the international literature on preventive screening where it is expected a higher concentration of preinvasive lesions.

The high incidence of SCC of the sample in the present investigation suggests late diagnosis in an important portion of the sample, contextualizing the limitations of access to continuous investigation programs in the country; this difference can be explained by selection bias of prevention clinic because women with samples of cervical biopsy have been selected but it also reflects the aggressiveness of the lesions of the local population who seeks medical assistance.

Finally, the weighted Kappa index of 0.27 translates an acceptable/discreet agreement between cytology and biopsy. This result is consistent with the value of 0.33 reported by Mayorga-Bautista[26]. The technical explication lies on the operator-depending nature of the conventional cytology and the limitations of the exfoliative sample compared with biopsy. The index of 0.27 reinforces that, although cytology is a reliable survey method, it should not replace biopsy for definitive diagnostic confirmation.

Table 3. Results of cervical cytology in patients with cervical biopsy, 2020-2024

Results of cervical cytology	**N**	**%**
Negative for SIL or malignancy	18	14.75%
Abnormality of epithelial cells	1	0.82%
Atrophic associated with unspecified moderate inflammation	1	0.82%
Mild inflammation	7	5.74%
Moderate inflammation	3	2.46%
Severe inflammation	5	4.10%
ASC-H	1	0.82%
LSIL	59	48.36%
HSIL	13	10.66%
Infiltrative squamous cell carcinoma	14	11.48%
Total	**122**	**100.00%**
Findings of cervical biopsy	**N**	**%**
No pathological findings	4	3.28%
Mature squamous metaplasia	7	5.74%
Immature squamous metaplasia	4	3.28%
Tubal metaplasia	1	0.82%
Cervicitis	26	21.31%
Endocervical polyp	2	1.64%
Endocervical atypia	1	0.82%
Cytopathologic effects associated with HPV infection	16	13.11%
CIN 1	33	27.05%
CIN 2	1	0.82%
CIN 3	5	4.10%
Keratinizing squamous cell carcinoma	3	2.46%
Non-keratinizing squamous cell carcinoma	19	15.57%
Total	**122**	**100.00%**

Captions: SIL: squamous intraepithelial lesion. ASC-H: atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesions. LSIL: low grade squamous intraepithelial lesion. HSIL: high-grade squamous intraepithelial lesion. HPV: human papillomavirus. CIN 1: cervical intraepithelial lesion grade I, CIN 2: cervical intraepithelial lesion grade 2, CIN 3: cervical intraepithelial lesion grade III.

CONCLUSION

The current investigation has shown that conventional cervical cytology continues to be a robust primary detection tool and essential in the Venezuelan clinical setting, especially in limited resources scenarios. The study reaches its objective of correlating cytological findings with cervical biopsy, concluding that the method has high diagnostic sensitivity. This characteristic is vital for public health since it ensures a high rate of detection of truly positive cases in a population where the incidence of precursor and invasive lesions shows a rising trend post-pandemic.

However, the diagnostic agreement (Kappa index 0.27) and the moderate specificity suggest that although cytology is effective to detect the disease, it has limitations to define precisely the histologic severity alone. The main clinical implication of the present study is that the cytology should be connected with colposcopy and targeted biopsy to avoid unnecessary or underdiagnosed procedures. As contribution to the report of local data, the findings underpin that the

Table 4. Description of cervical cytology and histopathological results of cervical biopsy, 2020-2024

	Cervical biopsy																					
	No pathological findings		Metaplasia		Polyps		Cytopathic effects		Cervicitis		Atypical		CIN 1		CIN 2		CIN 3		SCC		Total	
Cervical cytology	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Negative for SIL	1	5.55	3	16.66	1	5.55	5	27.77	5	27.77	0	0	3	16.66	0	0	0	0	0	0	18	14.75
Atrophic	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	100.00	1	0.82
Inflammation (mild-moderate-severe)	2	13.33	2	13.33	0	0	4	26.66	1	6.66	0	0	5	33.33	0	0	0	0	1	6.66	15	12.29
Abnormalities of epithelial cells	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	100.00	1	0.82
ASC-H	0	0	0	0	0	0	0	0	1	100.00	0	0	0	0	0	0	0	0	0	0	1	0.82
LSIL	1	1.69	6	10.17	1	1.69	5	8.47	18	30.51	1	1.69	25	42.37	0	0	1	1.69	1	1.69	59	48.36
HSIL	0	0	0	0	0	0	2	15.38	1	7.69	0	0	0	0	1	7.69	3	23.08	6	46.15	13	10.65
SCC	0	0	1	7.14	0	0	0	0	0	0	0	0	0	0	0	0	1	7.14	12	85.71	14	11.47
Total	**4**	**3.27**	**12**	**9.84**	**2**	**1.64**	**16**	**13.11**	**26**	**21.31**	**1**	**0.82**	**33**	**27.04**	**1**	**0.82**	**5**	**4.10**	**22**	**18.03**	**122**	**100.00**

Captions: ASC-H: atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesions. LSIL: low-grade squamous intraepithelial lesion. HSIL: high-grade squamous intraepithelial lesion. SCC: squamous cell carcinoma. CIN 1, 2 and 3: Cervical intraepithelial neoplasia grades I, II and III.

Table 5. Comparison of cervical cytology and cervical biopsy, 2020-2024

		Biopsy + N	Biopsy - N	Total	Weighted Kappa index	CI 95%
Cytology +		VP 53	FP 35	88		
Cytology -		FN 9	VN 25	34	0.273	(0.103– 0.443)
Total		**62**	**60**	**122**		
Results	**Sensitivity**	**Specificity**	**PPV**	**NPV**		
	85.48%	**41.67%**	**60.23%**	**73.53%**		
CI 95%	**(74.21– 93.14%)**	**(29.11 – 55.06%)**	**(49.18– 70.54%)**	**(56.63-87.12%)**		

Captions: Biopsy +: positive biopsy. Biopsy -: negative biopsy. Cytology+: positive cytology. Cytology-: Negative cytology. TP: true positive. FP: False positive. FN: False negative. TN: true negative. PPV: positive predictive value. NPV: negative predictive value. CI 95%: confidence interval.

optimization of the detection in Venezuela depends not only on the introduction of novel technologies, but on the standardization of processes such as pathology auditing and integration of HPV-HR (high-risk human papillomavirus) molecular tests when possible in order to improve the precision of the detection for the population.

One of the most outstanding methodological qualities of the present study is the analysis of a large sample of 2,163 cytologies in the period 2020-2024, which allows to observe the dynamics of the disease in a critical epidemiologic transition phase. The robustness of the study relies on the use of complete diagnostic key performance indexes (sensitivity, specificity, PPV, NPV and Kappa index), ensuring a rigorous statistical base to evaluate the actual clinical practice in CPC.

Nevertheless, the results should be interpreted in light of its limitations, mostly the selection bias; while concentrating the correlation analysis exclusively on patients who had submitted to cytology-biopsy, the sample is limited to high clinically suspected cases or with previous cyto-colposcopy alterations. This phenomenon explains the high prevalence of confirmed pathology (50.82%) and the remarkable incidence of SCC (18.03%), results that likely overestimate the disease burden if generalized to the general asymptomatic population. In despite of this restriction, the investigation represents a methodological achievement while reflecting accurately the performance of the diagnosis in second level attention centers where the priority is the histologic confirmation of high-risk patients.

CONTRIBUTIONS

All the authors contributed substantially to the study conception and design, acquisition, analysis and interpretation of the data, writing and critical review. They approved the final version for publication.

DECLARATION OF CONFLICT OF INTEREST

There is no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

All the content underlying the text is contained in the manuscript.

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