Evaluation of quality indicators of cervical cytopathology tests carried out in a municipality of Paraná, Brazil

Avaliação dos indicadores de qualidade dos exames citopatológicos do colo do útero realizados em um município do Paraná, Brasil

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ABSTRACT

Introduction: Although the criteria and recommendations are well defined to improve the quality of cervical cytopathology tests (Pap smear) in Brazil, the quality indicators of several laboratories are below the recommended standards. Objective: To evaluate the quality indicators of cervical cytopathology tests carried out by the Brazilian Unified Health System [Sistema Único de Saúde (SUS)]. Method: Cross-sectional study based on the results of cervical cytopathology tests conducted in the municipality of Cascavel, Paraná, Brazil, from January 2012 to December 2018. The study included 141,191 tests and the following variables were analyzed: sample suitability, cervical cytopathology tests result, and internal quality monitoring indicators recommended by the Brazilian Ministry of Health. Results: The percentage of unsatisfactory tests did not exceed 0.97%. The representation of the squamocolumnar junction ranged from 63% to 67.4%. The percentage of altered exams among the satisfactory samples ranged from 0.46% to 6.44%. The positivity index ranged from 0.46% to 6.44%, while the high-grade squamous intraepithelial lesion/satisfactory indicator ranged from 0.21% to 1.06%, atypical squamous cells of undetermined significance/altered ranged from 22.47% to 49.93%, atypical squamous cells of undetermined significance/satisfactory ranged from 0.1% to 2.57%: and atypical squamous cells of undetermined significance/squamous intraepithelial lesion/satisfactory and the positivity index indicators were below the recommended parameters, and in the remaining years, these indicators were within the parameters recommended. Consequently, a greater number of truly cancer precursor lesions were identified, demonstrating the importance of internal quality control in the prevention of cervical cancer.

Key words: cervical cancer; Pap smear; quality control; early detection of cancer.

RESUMO

Introdução: Ainda que critérios e recomendações estejam bem definidos para melboria da qualidade do exame citopatológico no Brasil, os indicadores de qualidade de vários laboratórios apresentam-se abaixo dos padrões recomendados. Objetivo: Avaliar os indicadores de qualidade dos exames citopatológicos do colo do útero realizados pelo Sistema Único de Saúde (SUS). Método: Estudo transversal com base nos resultados dos exames citopatológicos realizados no município de Cascavel, Paraná, Brasil, de janeiro de 2012 a dezembro de 2018. Foram incluídos 141.191 exames; as seguintes variáveis foram analisadas: adequabilidade da amostra, resultado do exame citopatológico e indicadores de monitoramento interno da qualidade recomendados pelo Ministério da Saúde. Resultados: A porcentagem de exames insatisfatórios não ultrapassou 0,97%. A representação da junção escamocolunar variou de 63% a 67,4%. A porcentagem de exames alterados entre as amostras satisfatórias variou de 0,46% a 6,44%, o índice de positividade variou de 0,46% a 6,44%, enquanto o indicador lesão intraepitelial de alto grau/satisfatórios, de

0,21% a 1,06%; atipias escamosas de significado indeterminado/alterados, de 22,47% a 49,93%; atipias escamosas de significado indeterminado/satisfatórios, de 0,1% a 2,57%; e razão atipias escamosas de significado indeterminado/lesões intraepiteliais escamosas, de 0,31 a 1,02. Conclusão: Em 2012 e 2013, os indicadores de lesão intraepitelial de alto grau/satisfatórios e índice de positividade encontravam-se abaixo dos parâmetros recomendados; nos demais anos, esses indicadores estavam dentro dos parâmetros recomendados. Consequentemente, foi identificado um maior número de lesões verdadeiramente precursoras do câncer, demonstrando a importância do controle interno da qualidade na prevenção do câncer do colo do útero.

Unitermos: câncer do colo do útero; exame colpocitológico; controle de qualidade; detecção precoce de câncer.

RESUMEN

Introducción: Aunque criterios y recomendaciones están bien definidos para la mejora de calidad de las pruebas citopatológicas en Brasil, los indicadores de calidad de varios laboratorios se encuentran por debajo de los estándares recomendados. Objetivo: Evaluar los indicadores de calidad de las pruebas citopatológicas de cuello uterino realizadas por el sistema público de salud en Brasil (SUS). Método: Estudio transversal basado en los resultados de pruebas colpocitológicas llevadas a cabo en el municipio de Cascavel, Paraná, Brasil, de enero de 2012 a diciembre de 2018. Se incluyeron 141.191 pruebas; las siguientes variables se analizaron: adecuación de la muestra, resultado de la prueba citopatológica e indicadores de monitoreo interno de calidad recomendados por el Ministerio de Salud. Resultados: El porcentaje de pruebas insatisfactorias no superó 0,97%. La representación de la unión escamo-columnar varió de 63% a 67,4%. El porcentaje de pruebas alteradas entre las muestras satisfactorias varió de 0,46% a 6,44%. El índice de positividad varió de 0,46% a 6,44%, mientras el indicador de lesión intraepitelial de alto grado/satisfactorios, de 0,21% a 1,06%; atipias escamosas de significado indeterminado/alterados, de 22,47% a 49,93%; atipias escamosas de significado indeterminado/satisfactorios, de 0,1% a 2,57%; y razón atipias escamosas de significado indeterminado/lesiones intraepiteliales escamosas, de 0,31 a 1,02. Conclusión: En 2012 y 2013, los indicadores de lesión epitelial de alto grado/satisfactorios e índice de positividad se encontraban por debajo de los parámetros recomendados; en los otros años, esos indicadores estaban dentro de los parámetros recomendados. Por consiguiente, se identificó mayor número de lesiones realmente precursoras del cáncer, demostrando la importancia del control interno de calidad en la prevención del cáncer de cuello uterino.

Palabras clave: cáncer del cuello uterino; prueba de Papanicolaou; control de calidad; detección precoz del cáncer.

INTRODUCTION

Cancer is a worldwide public health concern. Cervical cancer (CC) is the fourth most common cancer among women — it stands out for both incidence and mortality —, followed by breast, colorectal and lung cancer⁽¹⁾. The estimate of the Brazilian National Cancer Institute [Instituto Nacional do Câncer (Inca)] for Brazil in 2020 indicate the occurrence of 297,261 new cases among women, among which more than 17,030 will be new cases of CC⁽²⁾.

When early diagnosed, CC can reach 100% cure. In this regard, the cervical cytopathology test, when performed with quality, is the test of choice for detecting this cancer in Brazil⁽³⁾. Variables in the pre-analytical phase and in the analytical phase of cervical cytopathology testing, such as representation of the epithelium in the collection, correct fixation, identification of the material,

cytologist's experience level, appropriate working conditions, implementation of standard operating procedures, in addition to qualification and periodic training of professionals, may impair their sensitivity^(4,5).

In cytopathology, quality control is based on the detection, correction and reduction of deficiency in the execution proceedings within the laboratory, resulting in cytopathology tests with greater quality and reliability, minimizing diagnostic errors as much as possible and collaborating to improve the preanalytical and analytical phases, in addition to contributing to public health⁽⁶⁾.

In Brazil, the quality control of cytopathology tests was recommended from 2001 onwards through Ordinance SPS/SAS no. 92 of the Brazilian Ministry of Health (MH)⁽⁷⁾. This ordinance was ratified by Ordinance MH no. 3.388 of December 30, 2013, which instituted the Brazilian national qualification

in cytopathology in preventing cervical cancer [Qualificação nacional em citopatologia na prevenção do câncer do colo do útero (Qualicito)], which consists of the definition of standards and criteria in the evaluation of the quality of the cytopathology test by monitoring public and private Brazilian Unified Health System [Sistema Único de Saúde (SUS)]. service providers, classified as type I and type II laboratories. Type I laboratories are public and private laboratories that provide services to SUS and perform cytopathology tests; type II are the public laboratories responsible for performing cytopathology tests within the scope of External Quality Monitoring (EQM)⁽⁸⁾.

The MH/Inca prepared the Quality Management Manual for Cytopathology Laboratories, aiming to guide the SUS laboratories service provider on the implementation of Internal Quality Monitoring (IQM) and EQM⁽⁶⁾. The Manual and Qualicito encourage increased coverage of the target audience (women aged 25 to 64 years), and the monitoring of internal quality indicators promotes permanent education of health professionals, encourages and establishes parameters for SUS service providers' contracting and cancelation of agreement⁽⁶⁻⁸⁾.

The continuous monitoring of the results is an important action that should be performed by the cytopathology laboratory, based on the estimated indicators found in the Quality Management Manual to assess the professionals' global and individual performance⁽⁶⁾. Some of these indicators are: positivity index (PI), percentage of tests compatible with high-grade squamous intraepithelial lesions (HSIL) in satisfactory tests, percentage of atypical squamous cells (ASC) of undetermined significance in altered and/or satisfactory tests and squamous atypia's of undetermined significance and squamous intraepithelial lesions ratio⁽⁶⁾.

Despite these efforts, studies show results that are not recommended by the MH, such as the percentage of tests performed outside the recommended age range⁽⁹⁾. In the state of Minas Gerais, Brazil, laboratories providing services to the SUS presented PI below the recommended by the MH, since several laboratories did not detect or detected a low number of CC precursor lesions⁽¹⁰⁾; another study results show that the quality indicators for laboratories that provide services to SUS in several states and regions of Brazil are, for the most part, outside the parameters recommended by the MH^(11,12).

Although criteria and recommendations are well defined for improving the quality of cytopathology test in Brazil, the quality indicators of several laboratories are below the standards recommended by the MH. Therefore, the objective of this study was to evaluate the quality indicators of cervical cytopathology tests performed by SUS in a municipality in the state of Paraná state, Brazil.

METHOD

Cross-sectional study based on the results of cervical cytopathology tests performed by the female population using SUS in the municipality of Cascavel, Paraná, included in the cancer information system between January 2012 and December 2018. This study was approved by the Research Ethics Committee of the Universidade Paranaense (UNIPAR) under protocol number 892452/2014.

We included 20,115 tests from 2012; 19.500 from 2013; 15,859 from 2014; 22,546 from 2015; 20,377 from 2016; 21,586 from 2017; and 21,208 from 2018, totaling141,191 cervical cytopathology tests in the sample. The information from 2012 and 2013 tests was collected from the Cervical Cancer Information System [Sistema de Informação do Câncer do Colo do Útero (SISCOLO)], and from 2014 and 2018, from the Cancer Information System [Sistema de Informação do Câncer (SISCAN)].

The variables analyzed were: sample suitability, result of the cytopathology test, and internal quality monitoring indicators.

Information on the results of cytopathology tests, including the suitability of the sample and the representativeness of the squamocolumnar junction (SCJ) were extracted from the cytopathological reports contained in SISCOLO and SISCAN and classified according to the Brazilian nomenclature for cervical reports and recommended conduct $^{(13)}$.

The evaluation of the indicators for internal monitoring of the quality of the cytopathology test was carried out based on five indicators, which are described below with their respective formulas, as recommended by the MH⁽¹⁴⁾:

a) PI-PI expresses the prevalence of cellular changes and characterizes the sensitivity of screening to detect lesions in the population examined, according to the Brazilian nomenclature for cervical reports and recommended conduct⁽¹⁴⁾.

Calculation method:

Total cytopathology tests with altered results in a specific place and period × 100

Total satisfactory cytopathology tests performed in the same place and period

For the critical analysis of laboratories registered in SISCOLO/SISCAN, the PI categorization was determined as follows: very low – below 2%; low – between 2% and 2.9%; expected – between

3% and 10%; above the expected – above 10%. It is necessary to consider that these providers can assist secondary referral services for cervical pathology.

b) percentage of tests compatible with HSIL/satisfactory tests: HSIL represent the CC truly precursor lesions, that is, those that actually have the potential for progression. Its detection is the main objective of secondary prevention of CC. It is recommended that the indicated value is greater than or equal to 0.4%.

Calculation method:

Number of HSIL tests × 100

Total satisfactory tests

c) percentage of ASC/altered tests — PI must be analyzed together with the ASC/altered tests indicator, as this index, apparently adequate, may contain a high percentage of tests compatible with ASC. It is recommended that the indicated value is below 60% of the altered tests.

Calculation method:

Number of tests with atypical squamous cell of undetermined significance probably not neoplasic (ASC-US) and atypical squamous cell of undetermined significance, cannot exclude high-grade lesion (ASC-H) × 100

Total altered tests

d) percentage of atypical squamous cells of undetermined significance (ASC)/satisfactory tests — a maximum of 4%-5% of all tests are expected to be classified as ASC. Higher values deserve evaluation and may indicate the need for training laboratory professionals.

Calculation method:

Number of tests with ASC-US and ASC-H \times 100 Total satisfactory tests

e) ASC/squamous intraepithelial lesions (SIL) ratio — assists in the identification of alteration that are low-grade squamous intraepithelial lesions (LSIL) and HSIL. It is recommended that this ratio should not exceed 34.

Calculation method:

Number of ASC-US and ASC-H tests
Number of tests with LSIL and HSIL

Data analysis was performed using descriptive statistics (calculation of absolute and relative frequencies), using the Microsoft Excel software.

RESULTS

The results of this study showed that about 15,859 and 22,546 tests were performed per year; the percentage of unsatisfactory tests did not exceed 0.97%. Over the years, the SCJ representation varied from 63% to 67.4% of the tests (**Table 1**).

The total of satisfactory samples ranged from 15,701 to 22,147 tests per year, the largest number of altered tests in 2017, with 1,364 cytopathological results. Among the altered exams, the results that presented ASC-US ranged from 0.08% to 2.22%; those with ASC-H, from 0.02% to 0.53%; those with LSIL, from 0.12% to 2.58%; and those with HSIL, from 0.21% to 1.06%. From 2015 to 2018, results of invasive carcinoma were also identified (**Table 2**).

The results show that PI ranged from 0.46% to 6.44% (value within the recommended parameter, between 3% and 10%) in five of the seven years of study. Regarding the HSIL/satisfactory tests indicator, the index ranged from 0.21% to 1.06% – value within the recommended ($\geq 0.4\%$) in five from the seven years of study. Regarding the ASC/altered tests indicator, the index ranged from 22.47% to 49.93% – a value within the recommended range (< 60%) in all years of the study. The ASC/satisfactory exams indicator ranged from 0.1% to 2.57%, a value within the recommended range (< 5%) in all years of the study. Finally, the ASC/SIL ratio indicator ranged from 0.31 to 1.02, a value within the recommended range (< 3) in all years of the study (**Table 3**).

DISCUSSION

The results of this study show that, over the years, there has been an increase in the detection of HSIL and HSIL with suspicious invasion characteristics (HSIL micro). The high-grade lesion is considered the true precursor lesion of the CC; its detection and treatment are important to avoid evolution to cancer⁽¹⁵⁾.

The increase in HSIL detection directly impacts the HSIL/satisfactory tests and PI indicators. The HSIL/satisfactory tests indicator measures the ability to detect precursor lesions, and the PI, the prevalence of cellular changes in tests, as well as the sensitivity of the screening process to detect lesions in the examined population. A low PI can indicate that malignant changes are not being identified, which causes false-negative

TABLE 1 – Adequacy of the sample of cervical cytopathological exams, according to the recommendations of the MH, underwent by the female population using SUS in the municipality of Cascavel, Paraná, between 2012 and 2018

	_	Rejected samples						Unsatisfactory samples							Satisfactory samples		SCJ Representation	
Year	Total de exams	Total		Absence or misidentification	Slide damaged or missing	Other causes	: 1	Total	Drying artifacts	Thick	Blood	White blood cells	Acellular or hypocellular material	External contaminants	174401	10141	Vac	651
	\overline{n}	n	%	n	n	n	n	%	n	n	n	n	n	n	n	%	n	%
2012	20,115	10	0.05	1	9	0	11	0.05	0	0	4	0	7	0	20,094	99.9	13,302	66.2
2013	19,500	5	0.03	0	5	0	21	0.11	2	2	10	0	9	0	19,474	99.87	12,269	63
2014	15,859	137	0.86	119	8	10	21	0.13	0	3	7	0	13	0	15,701	99	10,567	67.3
2015	22,546	274	1.22	253	19	2	125	0.55	63	0	11	4	44	0	22,147	98.23	14,750	66.6
2016	20,377	267	1.31	251	0	16	164	0.8	84	7	4	7	62	0	19,946	97.88	13,444	67.4
2017	21,586	204	0.95	187	5	12	209	0.97	39	6	15	7	141	1	21,173	98.09	13,995	66.1
2018	21,208	176	0.83	143	32	1	170	0.8	25	2	10	14	119	0	20,854	98.33	13,618	65.3

MH: Brazilian Ministry of Health; SUS: Brazilian Unified Health System (Sistema Único de Saúde); SCJ: squamocolumnar junction; 'the same exam showed more than one unsatisfactory factor.

TABLE 2 – Result of cervical cytopathological exams, according to the Brazilian Nomenclature for Cytopathological Reports, underwent by the female population using SUS, in the municipality of Cascavel, Paraná, between 2012 and 2018

Year	Total satisfactory samples	Monditud for and monditude	Negative for manginality		Auereu exams	011 001	ASC-US		ASC-H	140 1	TOT		HSIL		HSIL micro		invasive SCC	[cal	cells and glandular lesions
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2012	20,094	19,709	98.08	385	1.92	156	0.78	26	0.13	111	0.55	67	0.33	0	0	0	0	25	0.12
2013	19,474	19,385	99.54	89	0.46	16	0.08	4	0.02	24	0.12	41	0.21	0	0	0	0	4	0.02
2014	15,701	14,934	95.11	767	4.89	331	2.11	52	0.33	262	1.67	110	0.7	6	0.04	0	0	6	0.04
2015	22,147	21,091	95.23	1,056	4.77	416	1.88	50	0.23	412	1.86	149	0.67	5	0.02	4	0.02	20	0.09
2016	19,946	18,765	94.08	1,181	5.92	420	2.11	92	0.46	476	2.39	161	0.81	3	0.02	3	0.02	26	0.13
2017	21,173	19,809	93.56	1,364	6.44	407	1.92	113	0.53	547	2.58	225	1.06	16	0.08	6	0.03	50	0.24
2018	20,854	19,588	93.93	1,266	6.07	463	2.22	79	0.38	537	2.58	154	0.74	11	0.05	1	0	21	0.1

SUS: Brazilian Unified Health System (Sistema Único de Saúde); ASC-US: atypical squamous cells of undetermined significance; ASC-H: atypical squamous cells cannot exclude an HSIL; LSIL: low-grade squamous intraepithelial lesion; HSIL: high-grade squamous intraepithelial lesion; HSIL micro: high-grade squamous intraepithelial lesion with features suspicious for invasion; invasive SCC: squamous cell carcinoma; atypical glandular cells and glandular lesions: may include atypical endocervical cells not otherwise specified, atypical endocervical cells, favor neoplastic and/or endocervical adenocarcinoma in situ.

TABLE 3 – Internal quality monitoring indicators of the of cervical cytopathological exams underwent by the female population using SUS, in the municipality of Cascavel, Paraná, between 2012 and 2018

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Year	PI (%)	HSIL/satisfactory tests (%)	ASC/altered tests (%)	ASC/satisfactory tests (%)	ASC/SIL (%)
2012	1.92	0.33	47.27*	0.9*	1.02*
2013	0.46	0.21	22.47*	0.1^{*}	0.31*
2014	4.89*	0.7*	49.93*	2.44^{*}	1.01*
2015	4.77*	0.67*	44.13*	2.1^{*}	0.82^{*}
2016	5.92*	0.81*	43.35*	2.57*	0.8*
2017	6.44*	1.06^{*}	38.12*	2.46^{*}	0.66^{*}
2018	6.07*	0.74^{*}	42.81*	2.6^{*}	0.77*

SUS: Brazilian Unified Health System (Sistema Único de Saúde); Pl: positivity index; ASC/satisfactory tests: rate of atypical squamous cells of undetermined significance among satisfactory tests; ASC/sll: ratio of atypical squamous cells of undetermined significance among the altered tests; ASC/sll: ratio of atypical squamous cells of undetermined significance among the altered tests; ASC/sll: ratio of atypical squamous cells of undetermined significance among the altered tests; ASC/sll: ratio of atypical squamous cells of undetermined significance among the altered tests; as a significance among satisfactory tests; within the recommended parameters values.

results⁽⁶⁾. In this study, we noticed that, as of 2014, these indicators were within the recommended parameters, differently from the years 2012 and 2013, whose values were much lower than the recommended. We can infer that this scenario occurred due to the strict internal quality control in 2014, which was implemented in the laboratory service provider for SUS, which contributed to the standardization of cytomorphological criteria and, consequently, to the improvement in quality indicators.

The ASC/altered tests, ASC/satisfactory tests, and ASC/SIL indicators were within the recommended parameters in all years of the study. The ASC/altered tests indicators should be analyzed together with the PI, as an apparently suitable PI contains a high percentage of ASC. A large number of borderline atypia may point to problems, both in sample collection and/or preparation and in the cytopathological analysis. Overall, this demonstrates the need for professionals continuing education for, especially for the review of ASC diagnostic criteria⁽⁶⁾.

The year 2013 was the one with the lowest detection of malignant changes and, consequently, the lowest rates. In part, this can be justified by the lower representation of SCJ in the analyzed samples. The SCJ representation in cytological smears is very important, as it is recognized as the region most likely to develop CC precursor lesions⁽¹⁶⁾.

Less severe changes, ASC-US and LSIL, were the most frequent, except in 2013. ASC-US are correlated with low severity disease for most women, so the expected clinical management is conservative⁽¹⁷⁾, as with low-grade lesion, which has a significant spontaneous regression rate⁽¹⁸⁾ and is considered the least likely lesion to progress to invasive carcinoma⁽¹⁹⁾.

Regarding the sample suitability, the number of unsatisfactory samples did not exceed the 5% recommended by the MH⁽⁶⁾ and its main causes were acellular or hypocellular material

and desiccation artifacts. Among the rejected samples, the main reason was identification absence or error. These findings corroborate those found by Galvão *et al.* (2015)⁽²⁰⁾: from the unsatisfactory samples, 34% were due to acellular or hypocellular material; 21% were rejected due to identification absence or error; and 14% showed desiccation artifacts.

The quality of the cytopathology test is closely linked to factors such as information on anamnesis data, collection performed properly, good smear fixation, adequate color and careful analysis of the sample. Any mistake in one of these factors may lead to false-negative or false-positive results and harm not only women, but society as a whole.

In order to improve the quality control of the cytopathology test, the MH, in 2013, published ordinance 3,388 called Qualicito⁽⁸⁾. Among the recommendations of the ordinance, as a quality criterion, the laboratories may have an annual production of 15,000 tests, which was demonstrated in this study.

As limitations of this work, we highlight the lack of information on the population profile. This data would contribute to explain the prevalence of less severe changes and other possible variables that influence the PI.

CONCLUSION

The results of this study show that, in 2012 and 2013, the HSIL/satisfactory tests and PI indicators were below the parameters recommended by the MH. In the remaining years, these indicators were within the recommended parameter. Consequently, a greater number of CC truly precursor lesions was identified. Therefore, we demonstrate the importance of implementing internal quality control of cytopathology tests for CC screening and prevention.

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