Analysis of The Reasons for Unsatisfactory Cervical Histopathological Exams in the Unified Health System, Brazil, 2014 to 2017

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Análise dos Motivos de Insatisfatoriedade dos Exames Histopatológicos do Colo do Útero no Sistema Único de Saúde, Brasil, 2014 a 2017

Análisis de las Causas de los Exámenes Histopatológicos Cervicales Insatisfactorios en el Sistema Único de Salud, Brasil, 2014 a 2017

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ABSTRACT

Introduction: Cervical cancer is still an important public health problem in Brazil and worldwide. The quality of screening and diagnostic confirmation tests are essential for cancer control actions to achieve an effective impact on mortality. **Objective:** The aim of this study was to analyze the information registered in the description field of the motives for the unsatisfactoriness of the histopathological exams of the cervix. **Method:** Descriptive study using data of the Cancer Information System (SISCAN) of women who underwent histopathological examination of the cervix in the Unified Health System (SUS) in the period from 2014 to 2017. 1,236 histopathological examinations of the cervix were analyzed. The reasons for unsatisfactoriness specified in the description field were analyzed and reclassified and, when relevant, were reassigned to the existing fields for satisfactory exams. **Results:** 262 exams (21.2%) were incorrectly classified as 'unsatisfactory', in which 11.25% were reclassified as a benign lesion, 5.91% as a high-grade lesion, 1.46% as carcinoma, 0.24% as adenocarcinoma and 0.24% as adenocarcinoma *in situ*. **Conclusion:** The study showed a significant percentage of errors in reports classified as unsatisfactory in SUS, pointing out the need to train professionals who issue histopathological reports in order to avoid diagnostic errors.

Key words: Uterine Cervical Neoplasms; Unified Health System; Teste de Papanicolaou; Mass Screening; Pathology, Clinical.

RESUMO

Introdução: O câncer do colo do útero é ainda um importante problema de saúde pública no Brasil e no mundo. A qualidade dos exames de rastreio e de confirmação diagnóstica são fundamentais para que as ações de controle do câncer alcancem efetivo impacto sobre a mortalidade. **Objetivo**: Analisar as informações registradas no campo descritivo dos motivos da insatisfatoriedade dos exames histopatológicos do colo do útero. **Método:** Estudo descritivo com dados do Sistema de Informação do Câncer (SISCAN) de mulheres que realizaram exame histopatológico do colo do útero no Sistema Único de Saúde (SUS) no período de 2014 a 2017. Foram analisados 1.236 exames histopatológicos do colo do útero. Os motivos de insatisfatoriedade especificados no campo descritivo foram analisados, reclassificados e, quando pertinente, foram redistribuídos nos campos existentes para exames satisfatórios. **Resultados:** Foram classificados incorretamente como 'insatisfatório' 262 exames (21,2%), dos quais, 11,25% foram reclassificados como lesão de caráter benigno, 5,91% como lesão de alto grau, 1,46% como carcinoma, 0,24% como adenocarcinoma e 0,24% como adenocarcinoma *in situ*. **Conclusão**: O estudo demonstrou um percentual expressivo de erros nos laudos classificados como insatisfatórios no SUS, apontando a necessidade de capacitar profissionais que emitem laudo histopatológico de forma a evitar erros diagnósticos.

Palavras-chave: Neoplasias do Colo do Útero; Sistema Único de Saúde; Teste de Papanicolaou; Programas de Rastreamento; Patologia Clínica.

RESUMEN

Introducción: El cáncer de cuello uterino sigue siendo un importante problema de salud pública en Brasil y en todo el mundo. La calidad de las pruebas de cribado y las de confirmación diagnóstica son fundamentales para que las acciones de control del cáncer logren un impacto efectivo en la mortalidad. **Objetivo:** El objetivo de este estudio fue analizar la información registrada en el campo descriptivo de las razones de la insatisfacción de los exámenes histopatológicos del cuello uterino. **Método:** Estudio descriptivo que utilizó datos del Sistema de Información del Cáncer (SISCAN) de mujeres a las que se les realizó examen histopatológico cervicouterino en el Sistema Único de Salud (SUS) de 2014 a 2017. Se analizaron 1.236 exámenes histopatológicos cervicouterino. útero. Los motivos de insatisfacción especificados en el campo descriptivo se analizaron y reclasificaron y, cuando fue relevante, se redistribuyeron en los campos existentes de satisfacción con el examen. **Resultados:** 262 exámenes (21,2%) se clasificaron incorrectamente como 'insatisfactorios', en los que el 11,25% se reclasificó como lesión benigna, el 5,91% como lesión de alto grado, el 1,46% como carcinoma, 0,24 % como adenocarcinoma y 0,24% como adenocarcinoma *in situ*. **Conclusión**: El estudio mostró un porcentaje significativo de errores en informes calificados como insatisfactorios en el SUS, señalando la necesidad de formar profesionales que emitan informes histopatológicos para evitar errores diagnósticos.

Palabras clave: Neoplasias del Cuello Uterino; Sistema Único de Salud; Prueba de Papanicolaou; Tamizaje Masivo; Patología Clínica.

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INTRODUCTION

Cervical cancer is still an important public health problem worldwide. Its incidence and mortality are higher in low-income countries[1], where screening characterized as opportunistic are predominant, offered when women seek health services for other reasons[2]. Therefore, no screening programme where women are formally invited to participate exists with age and periodicity defined. This opportunistic model is less effective on the impact over morbimortality and uses to be burdensome for the health system[3,4].

Brazil still presents elevated incidence and mortality by cervical cancer with estimated risk of 12.6 per 100,000 women in 2020 corresponding to 16,590 new cases, it is the third most frequent neoplasm, except non-melanoma skin cancer[5]. Despite being a highly curable cancer, in 2018, 6,526 deaths were registered by this neoplasm in the country[6]. There is a steady stability of the mortality rates along the last decades despite the drop in the capitals[7]. However, a recent study about the tendency of mortality by cancer points out a drop of the mortality rate by cervical cancer in the whole country, except in the rural area of the Northern Region, which brings the reflection on whether the control actions are being conducted correctly. The reduction of the incidence and mortality are achieved with effective actions of primary prevention (HPV vaccine), early detection and treatment of precursor lesions and timely referral to treat the cancer cases diagnosed[9].

The quality of the diagnosis of the cytopathological exams, the screening modality adopted in Brazil, and of the histopathological exams of the cervix are essential to achieve the expected success of cancer control actions. For such, it is necessary to reduce the percentage of false-negative, false-positive, and unsatisfactory exams. Professional qualification to prepare the slide is a *sine qua non* requisite because, further to the correct collection, the smear must be well distributed and adequately fixed for better visualization when the slide is stained. The ideal for the histopathological exam is the smear to portray the squamous, glandular and/or metaplastic epithelium. However, to be considered satisfactory for analysis, it may only contain squamous epithelium cells[10,11].

The activities of control and quality assurance of the cytopathologic exam are of critical importance for the screening actions and the clinical and cyto-histologic correlations are part of the different strategies utilized[11,12]. The histopathological exam is based in architectural and cellular morphologic criteria, it is the golden-standard of the morphologic diagnosis[13].

The histopathological exam is necessary to rule out diagnostic errors and establish the appropriate conduct[14] and constitutes the main instrument for the diagnosis confirmation of a malignant or pre-malignant neoplasm. It is performed from a sample of tissue obtained through biopsy after referring the woman to colposcopy. It enables the diagnosis of lesions non visualized in colposcopy and sometimes, can issue a diagnosis different from the cytopathological exam; this is why it is important that the histopathological results are expressed according to a nomenclature that allows the cyto-histological correlation. In the microscopic analysis, the lesion is identified, specifying the benign, the pre-neoplastic or neoplastic lesions, defining the degree of differentiation, the extension of the tumor and the surgical margins[15,16] whenever possible.

The result of the histopathological exam guides the decisions of treatment and clinical follow-up and, for this, the quality of the entire diagnostic process needs to be ensured and the difficulties to improve the accuracy of the exam, reduced. Factors as subjectivity and experience of the histopathologist, orientation and thickness of the cut can influence the interpretation of the exam.

The objective of this study was to analyze the information described in the field of motives of unsatisfactoriness of the histopathological exams of the cervix registered in the System of Cancer Information (SISCAN) from 2014 to 2017 in Brazil.

METHOD

Descriptive, cross-sectional study about the causes of unsatisfactoriness associated with the histopathological exams of the cervix registered in SISCAN from 2014 to 2017.

The results of the histopathological exams of the cervix are registered in a national standard form to capture data to be entered in SISCAN. In this form, there are no pre-selected specifications for unsatisfactoriness of the material as occurs in the cytopathological exam[16]. For recording the cytopathological exams when the material is considered unsatisfactory for oncotic evaluation, it is possible to select the motive for non-adequacy among the fields available: acellular or hypocellular material in less than 10% of the smear; blood in more than 75% of the smear; piocytes in more than 75% of the smear; artifacts desiccation in more than 75% of the smear; external contaminants in more than 75% of the smear; intense cellular superposition in more than 75% of the smear and still specify other possible causes unlisted[17].

In the field titled results of the histopathological exam the anatomopathologist needs to specify the type of surgical procedure that generated the sample: biopsy, exeresis of the transformation zone, conization, simple hysterectomy, hysterectomy with unilateral or bilateral

adnexectomy or classify as others and write the description (Figure 1).

In the result of the macroscopy (Figure 2), it must be reported the type of material received, whether biopsy or surgical piece; location of the tumor (ectocervix, endocervix or squamocolumnar junction) and adequacy of the material (satisfactory or unsatisfactory). If satisfactory, the microscopy analysis will be performed where the type of benign, neoplastic, or pre-neoplastic lesion will be specified. If unsatisfactory, the professional should specify the motive for unsatisfactoriness in the open field since there are no pre-categorized specifications in the form of this exam.

In this article the motives for unsatisfactoriness specified in the descriptive field were analyzed. The motives described were categorized and when errors in the descriptive field were detected, with description of diagnosis instead of motives of unsatisfactoriness, these were reclassified and, when applicable, redistributed to the existing fields of satisfactoriness of the exam with matching description. The search occurred in 2018 when the study began, considering the availability of the consolidated database, and all the histopathological registries informed in SISCAN in this period were utilized.

The histopathological registries with information of unsatisfactoriness were extracted from SISCAN database, utilizing the software R, version 3.5.3, package tidyverse[18], organized in Excel and reclassified.

The Institutional Review Board of the National Cancer Institute José Alencar Gomes da Silva (INCA), CAAE: 26944219.5.0000.5274 approved the study

RESULTS

In the period of the study, there were 137,893 histopathological exams of the cervix registered in SISCAN, 0.89% of which with unsatisfactory adequacy. 1,236 descriptions of all the exams registered in SISCAN in the field of "Unsatisfactory" were reviewed. After orthographic revision, 882 different descriptions of unsatisfactoriness remained.

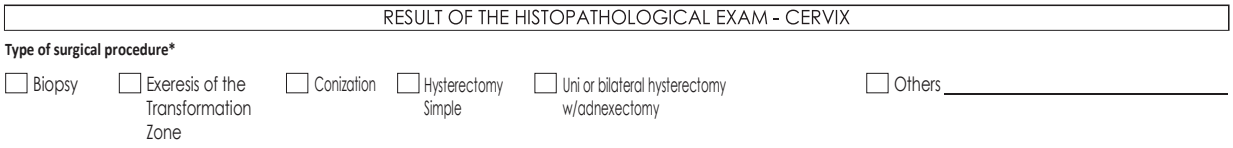
Many synonyms to reflect the same cause of unsatisfactoriness were utilized, as for instance, 30 references to evaluate the size of the sample as motive for unsatisfactoriness (Chart 1). Among them, the most common were: exiguous sample (39), scanty material (28), insufficient material (22) and scarce sample (15).

396 exams (32%) were classified erroneously as "unsatisfactory" in relation to the adequacy of the material. Among them, 11.25% were reclassified as benign lesion, 5.91% as high-grade lesion, 1.46% as carcinoma, 0.24% as adenocarcinoma and 0.24% as adenocarcinoma *in situ*, being possible to distinguish 22 categories (Table 1).

DISCUSSION

The histopathological exam plays a fundamental role in the diagnosis of cervical cancer and immunohistochemistry can be useful to differentiate benign and malignant cervical cancer and to classify its various subtypes[19].

The identification of unsatisfactory histopathological exam happens when the histopathologist, while conducting the microscopic analysis of a tissue to detect possible


RESULT OF THE HISTOPATHOLOGICAL EXAM - CERVIX

Type of surgical procedure*

☐ Biopsy ☐ Exeresis of the Transformation Zone ☐ Conization ☐ Hysterectomy Simple ☐ Uni or bilateral hysterectomy w/adnexectomy ☐ Others _____

Figure 1. Form of Histopathological Exam of the Cervix. Type of surgical procedure.
Source: INCA/Ministry of Health


MACROSCOPY

_____

_____

_____

Type of material received:

☐ Biopsy, Number of fragments _____

☐ Surgical piece, size of the tumor _____ x _____ cm

Distance from the nearest margin _____ mm

location of the tumor: ☐ Ectocervix ☐ Endocervix ☐ Squamocolumnar junction

*Adequacy of the material ☐ Satisfactory ☐ Unsatisfactory. Specify _____

Figure 2. Form of Histological exam of the cervix. Macroscopy.
Source: INCA/Ministry of Health

Chart 1. Sample size dimension classification in the histopathological examination of the cervix. Brazil, 2014-2017

CLASSIFICATION	SPECIFICATION
1. Sample	- of very reduced size
	- diminutive
	- scarce
	- exiguous
	- insufficient
	- very scarce
	- small
2. Very small biopsy	-
3. Diminutive fragment	-
4. Scarcity	- of the sample
	- of elements
	- of the tissue
	- of the material
5. Exiguous specimen	-
6. Exiguity	- of the sample
	- of the material
	- fragment
7. Fragment	- scant
	- exiguous
	- minuscule
	- unrepresentative
8. Material	- diminutive
	- scant
	- exiguous
	- very exiguous
	- too small
	- unrepresentative
	- small
9. Very exiguous	-
10. Reduced size	-

Source: SISCAN.

Table 1. Diagnoses after reclassification. Brazil, 2014-2017

CATEGORIES	QUANTITY	%
Adenocarcinoma	3	0.24
Adenocarcinoma *in situ*	3	0.24
Unsatisfactory sample without justification	34	2.75
Unsatisfactory sample/ acellular	218	17.64
Unsatisfactory sample/ absence of epithelium	112	9.06
Unsatisfactory sample / with atypia	14	1.13
Unsatisfactory sample/ fixation	30	2.43
Unsatisfactory sample / fulguration	37	2.99
Unsatisfactory sample / hemorrhagic	31	2.51
Unsatisfactory sample / laboratory	11	0.89
Unsatisfactory sample / scarce material	266	21.52
Absence of one of the epitheliums of SCJ	76	6.15
Carcinoma	18	1.46
Pre-analytical error	27	2.18
Exams of other than cervical areas	58	4.69
Inconclusive exams	60	4.85
Benign lesion	139	11.25
CIN I	14	1.13
CIN II/III	73	5.91
CIN ungraded	3	0.24
Other malignant neoplasms	2	0.16
Suggestive CIN	7	0.58
Total	1,236	100.00

Source: SISCAN.
Captions: SCJ: Squamocolumnar junction; CIN: Cervical intraepithelial neoplasia.

alterations or lesion is unable to specify the nature, the severity of the extension of the sample's lesions, hindering the diagnostic conclusion that would uphold the definition of the correct treatment of the lesion[11].

The results encountered stood out not only because of the variation of the macroscopic descriptions, corroborating the lack of a suitable pattern, but mainly because of the expressive percentage of exams with results erroneously classified as unsatisfactory, most of the times presenting descriptions of high degree lesions or even cancer which would require immediate referral to the reference unit for the correct treatment[13]. It was not found in the literature any similar analysis that can serve as comparison for the data of the present study. However, studies with data of the breast histopathological exams at the National Health System – SUS indicate that an expressive amount of breast cancer histopathological

exams were classified as "others" instead of having its histological type described, which may also call for issues of quality of the histopathological exams or record of the information in the system[20].

The histopathology provides the final diagnosis and is the golden standard for quality control of cytology and colposcopy[21]. The histopathological exams together with the clinical findings is mandatory for an accurate and early diagnosis to allow timely treatment[22]. However, the accuracy of the histopathological diagnosis of the tissue samples depends on adequate samples, correct macroscopic diagnosis, technical processing, microscopic interpretation, and quality control correlating the cytological and histological diagnosis[19]. In addition to the lack of a pattern to specify the dimension of the sample, the current study makes clear that actions to improve the quality control of the exams are necessary and training the professionals responsible for reporting to not classify satisfactory exams as unsatisfactory incorrectly, compromising the continuity of the care to the patients.

The problems identified in unsatisfactory reports in the present article compromise the care provided to the woman, most of all for neoplasms with still great magnitude of occurrence in the country. Unsatisfactory exams need additional material collection, which increases the likelihood of loss to follow-up for these women. The problems identified in women's follow-up go from picking up the cytopathological result and a new exam, if needed, to the adherence to the continuity of diagnostic investigation actions (colposcopy and histopathological)[23-25]. A specific study addressing the repetition of the histopathological exam in cases of unsatisfactoriness was not identified, however, all the factors involved in the line of care of this cancer requiring the necessity of a new repetition for that cause should be minimized to ensure more adherence to the necessary conducts, avoid delays of diagnosis and harms of unnecessary procedures.

The data are related to the services utilizing SISCAN and do not represent the totality of the exams of all the service providers of SUS. Recent data showing the level of implementation of SISCAN in the country indicate that in 2017, 74% of the laboratories reported cervical histopathological exams in this system[4]. The scope of the study did not include the analysis per state or service provider but can contribute for targeted actions.

CONCLUSION

It is of great relevance that histopathological patterns are monitored and reported in internationally acknowledged terminology because the results of the histopathological analysis are the source of diagnostic data field in cancer registries which are utilized to evaluate the screening programmes.

Although the standardization of the field of motives for unsatisfactoriness may diminish part of the problem, it is necessary to understand why the professional concludes the exam is unsatisfactory due to the adequacy of the material and simultaneously include the existing diagnosis in the specifications in the field of microscopy for lesions. Most of all because not checking the type neoplastic or pre-neoplastic may hinder the timely diagnosis, leading to delay of the treatment or even loss to follow-up.

Problems in the description of unsatisfactory histopathological exams and register of diagnosis of cervical neoplasms were found in this field. These diagnoses are not counted nationally as satisfactory exams and these women are unaware of the actual diagnosis. The study indicates the urgent necessity to capacitate the professionals who issue the histopathological report in order to avoid the loss to follow-up of the woman with altered cytopathological exam.

CONTRIBUTIONS

Itamar Bento Claro, Mário Lúcio Cordeiro Araújo Junior and Jeane Glaucia Tomazelli contributed substantially for the study conception and design, analysis and interpretation of the data, wording, and critical review with intellectual contribution. Arn Migowski contributed for the interpretation of the data and critical review with intellectual contribution. All the authors approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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