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Diagnostic errors in surgical pathology

Erros diagnósticos em patologia cirúrgica

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ABSTRACT

Pathology must aim at a correct and complete diagnosis for the patient, timely, useful and understandable to the physician assistant. However, in daily practice, there are multiple possibilities of errors in the pathology laboratory, with several impacts on patient care and prognosis. In this review, we discuss the different concepts of error and diagnostic concordances in pathology, at which point in the diagnostic process the errors are more frequent, and propose solutions to minimize the chance of their occurrence.

Key words: medical errors; surgical pathology; pathology errors.

INTRODUCTION

In 1999, the formerly American Institute of Medicine (now the National Academy of Medicine) published the paper *To Err is Human: Building a Safer Health System*⁽¹⁾, which broadly defines medical error as the inability to complete a planned action, or the use of a wrong plan to achieve a goal. Sirota summarizes the document and its implications for pathology. In his article, the author considers that the efforts of professional societies, such as the College of American Pathologists (CAP), through the Laboratory Accreditation Program, as well as their councils and commissions, determine the quality standards for the practice of pathology. In professional training, the academic programs and the American Board of Pathology, with their certification mechanism, help to ensure the full competence of the practice of pathology⁽²⁾. In contrast to the numerous international publications, intensified in the last 10 years, in Brazil there is little data available on errors of pathology laboratories, their impacts and methods to minimize their occurrence. Nevertheless, the Brazilian Society of Pathology, through the editions of the Manual of Histopathological Report Standardization of the Quality Control Incentive Program [Programa de Incentivo ao Controle de Qualidade (PICQ)] and of the Brazilian National Accreditation and Quality in Pathology Program [Programa Nacional de Acreditação e Qualidade em Patologia (PACQ)] has promoted the continuous medical education and encouragement of daily practice improvement.

DIAGNOSTIC ERRORS AND CONCORDANCES IN PATHOLOGY

To discuss the error in pathology, it is essential to conceptualize their goals. Pathology should provide a correct and complete diagnosis, timely, in a useful and understandable way for the attending physician⁽³⁾. Since the goals of pathology are multifaceted, it is easy to understand that there are multiple possibilities for error. A correct result must be accurate, based on gold standards scientifically validated. But what is the gold standard of pathology? Morphology is subjective and affected by the observer's experience. Cytogenetic studies by *in situ* or molecular hybridization are not applicable to the most diseases routinely found in surgical pathology. Therefore, the most appropriate is to determine the accuracy, as a measure of diagnostic adequacy; it suggests that the majority of qualified pathologists will agree on a similar diagnosis when analyzing the same specimen. A main, major or unacceptable variation is the one that will have a great effect on therapy or prognosis, such as in classifying a benign tumor as malignant one. A smaller, acceptable or minor variation is the one that has no effect on the treatment that would alter the progression of the disease, with no effect on the prognosis, such as in some subclassifications of benign or malignant tumors. These definitions can be applied to the three pathology goals (correct, complete, timely)^(3, 4). The errors can be further divided into errors of accuracy, that is, how much the released diagnosis represents the true pathological

process, and precision errors, related to concordances among pathologists in the interpretation of a case⁽⁴⁾.

Meier *et al.* (2011)⁽⁵⁾ divide the errors of anatomopathological reports into four categories: errors of interpretation, of identification, of the specimen and related to the report. A study based on this classification evaluated 73 participating institutions of Q-Probes, of CAP, with 1,688 errors in 360,218 cases of surgical pathology, with a ratio of 4.7 errors/1000 cases. Rates were higher in institutions with pathology residency programs (8.5 vs. 5.0/1000, $p = 0.01$) or when a percentage of cases were reviewed after release (6.7 vs. 3.8/1000, $p = 0.10$). Interpretation errors were responsible for 14.6% of the cases, 13.3% were identification errors, 13.7% of the specimen, and 58.4% of other modalities. In general, errors were more detected by pathologists (47.4%) than by clinicians (22%). Incorrect interpretations and specimen errors were detected by pathologists (73.5% and 82.7%, respectively, with $p = 0.001$), while identification errors were more frequently detected by other physicians (44.6%, $p = 0.001$). The rates of identification errors were lower when the reports were reviewed by a second pathologist prior to their release (0.0 vs. 0.6/1000, $p < 0.001$) and errors related to the specimen were less reported when released after intradepartmental review of more difficult cases (0.0 vs. 0.4/1000, $p = 0.02$)⁽⁶⁾.

DIAGNOSTIC DISCORDANCE AND THE EXAMPLE OF MAMMARY PATHOLOGY

In cases of breast pathology, some studies show that the review by specialists may considerably change the diagnosis of the first report issued. The study carried out by Romanoff *et al.* (2014)⁽⁷⁾ with 430 reports of breast biopsies observed a change of diagnosis in 17% ($n = 72$) of the cases, with a change in surgical management in 57% ($n = 41$) of these. Diagnostic changes were more frequent in patients originally identified with benign disease than in malignant ones (31% vs. 7%, $p < 0.001$). From 169, twelve (7%) specimens diagnosed as benign were reclassified as malignant, and four from 261 (2%) malignant cases were reclassified as benign. Diagnostic changes were significantly less frequent in private laboratories (8%), compared to teaching nonfederal hospitals (19%) or university hospitals (21%) ($p = 0.023$).

In a similar study of review of reports of breast pathology with 1,970 cases studied, 226 (11.47%) were considered as “significant discrepancy”, that is, non-compliance capable of affecting the patient care. In 418 resections (31.6%), there was no mandatory information in the report, according to CAP criteria. The main

non-compliance were observed in the histological category (33%, $n = 66$) and, among them, the most common were in intraductal lesions, lobular carcinoma, metaplastic carcinoma and phyllodes tumor. In 50 cases (25%), the discordances were identified in the biomarkers panels, and most of the discrepancies were of an interpretive nature⁽⁸⁾.

A study by Gomes *et al.* (2014)⁽⁹⁾ evaluated the interobserver concordances between general pathologists and pathologists specialized in mammary pathology in the diagnoses of lobular neoplasia, columnar cell lesions, atypical ductal hyperplasia and ductal carcinoma *in situ* with 610 cases. The authors observed moderate concordances for flat epithelial atypia ($k = 0.47$), good concordances for atypical lobular hyperplasia ($k = 0.62$) and lobular carcinoma *in situ* ($k = 0.66$). The worst concordances were observed for pleomorphic lobular carcinoma *in situ* ($k = 0.22$), columnar cell alterations ($k = 0.38$) and columnar cell hyperplasia ($k = 0.32$).

The cases of mammary pathology also show how the quality of the information provided in the histopathological report can directly influence the treatment of the patient. In women with breast cancer, the accelerated partial breast irradiation may be a therapeutic option in suitably selected patients, through criteria described in surgical reports. Pignol *et al.* (2012)⁽¹⁰⁾ identified, in 79 cases, lack of information on the margins of resection and presence of carcinoma *in situ* in 29.1% and 11.4% of the reports, respectively. When reviewing the concordances between the external reports reviewed by a pathologist specialized in mammary pathology, the main divergence was for the negative resection margins, with 34.4% ($n = 19$) of divergence, followed by the assessment of lymphatic invasion. Considering only the complete, initial and revised reports ($n = 43$), the review changed the eligibility of patients for radiotherapy in 18.6% of the cases. However, factors extrinsic to the experience of the pathologist may directly affect the diagnosis issued. In a review of breast lesions reports carried out in Barcelona⁽¹¹⁾, 102 thick needle biopsies, 88 surgical specimens and 18 lymphadenectomy were reviewed. The second opinion issued was based on a review of slides, cut-outs and selected cases, immunohistochemical panel for human epidermal growth factor receptor-type 2 (HER2), myoepithelial cells, thyroid transcription factor 1 (TTF-1), napsin A, S-100, HMB-45, podoplanin, E-cadherin, estrogen and progesterone, as well as molecular studies such as fluorescent *in situ* hybridization (FISH) and silver *in situ* hybridization (SISH). The cases were reclassified as the main change according to the impact on the prognosis or treatment of the patient and the others as minor change. In 52 cases (25.4%), the review revealed changes and from these, 33 (16%) were classified as major changes related to histological classification (12 cases), presence/absence of invasion in ductal carcinoma

(15 cases), results of hormone receptors assays (five cases) and HER2 (seven cases). In the changes of histological classification, two cases of invasive cancer were changed for benign lesions after the use of myoepithelial cells markers. In four patients, the diagnosis of invasive carcinoma was changed to metastatic lung cancer also after an immunohistochemical examination, and in one case of metastatic ductal carcinoma to axillary, after revision using S100 and HMB-45, the diagnosis was changed for metastatic melanoma. Clearly, we should consider the intrinsic limitations of routine staining when assessing diagnostic compliance in lesions of any nature. In many cases, the morphology alone cannot adequately define the nature of the tumor. Therefore, in order to avoid error, it is recommended to use techniques such as immunohistochemistry and molecular biology.

WHERE IS THE POSSIBILITY OF ERROR?

The most common classification of errors is based on the time and place of the laboratory where they occurred: in the pre-analytical, analytical and post-analytical phases⁽¹²⁾. This division is commonly used in clinical analysis laboratories and, since they are based on similar work processes, they may be used to evaluate work in pathology (**Table**).

During the material reception, gross examination and processing there are many possibilities of error, from exchange of samples or labels, absence or excessive cut in the block, to cross-contamination with tissues foreign to the specimen included in the final slide. Cognitive errors, such as inadequate or incomplete macroscopic descriptions, inadequate representation of the lesion or of relevant areas necessary for its characterization, may also occur, and although some are beyond the pathologist's control, the responsibility will fall directly on him, with very serious damage to the patient⁽³⁾.

A study carried out in Pennsylvania, in a teaching hospital with Pathology residency training identified 491 errors. From these, 88% ($n = 432$) in the pre-analytical phase, regarding the order, identification, collection, transportation, material reception and processing in the laboratory. The authors identified 20% ($n = 4$) analytical errors and 39% ($n = 8$) post-analytical, as shown in Table⁽¹³⁾.

Layfield and Anderson⁽¹⁴⁾ evaluated for 18 months the experience with samples labeling errors in 29,749 cases and 248,013 slides. In patient identification errors, a sample is labeled with the incorrect name or identification number. In the case of samples identification errors, a specimen is incorrectly identified as to the site of origin at the time of collection. The authors identified 75 errors; of which, 55 (73%) were related to the patient's name and 18 (24%), to the anatomical site. Most of the mistakes (69%,

TABLE – Distribution of errors according to the operating process phase and examples^(13, 15)

Pre-analytical phase: 53.3%⁽¹⁵⁾ to 88%⁽¹³⁾
Deliver and registration of material
Incomplete/error in order
Order does not correspond to specimen
Sample quantity does not correspond to order
Specimen without previous marking/incorrect orientation
Incorrect anatomical site
Incomplete/inaccurate clinical information
No material in sample sent
Inappropriate packaging/fixing conditions
Specimen loss
Integrity not preserved
Malfunction of equipment
Freezing error
Analytical phase: 4%⁽¹³⁾ to 42.1%⁽¹⁵⁾
Quality of the slides
Repetition of coloration
Foreign tissue in the specimen
Incorrect block identification
Interpretation errors
Delayed results
Work environment (eg, refrigeration failure and other equipment failures)
Post-analytical phase: 5.6%⁽¹⁵⁾ to 8%⁽¹³⁾
Correlation errors of freezing biopsy with conventional histology
Specimen discarded during routine examination
Patients exchange
Transcription errors
Delayed results
Malfunction of laboratory information systems

$n = 52$) occurred in the gross examination room, 19 (25%) in the histology laboratory and four (6%) were related to the pathologist's errors. From the errors, 73% ($n = 55$) resulted in slides assigned to non-corresponding patients. The majority of identification errors occurred in skin, esophagus, kidney and colon biopsies, reflecting the distribution of types of cases received in surgical pathology, with small samples from endoscopy and dermatology.

Analytical errors generally have greater evidence of impact on patient care, with potentially devastating consequences for them and the responsible pathologist. Troxel (2005)⁽¹⁶⁾ reviewed records of lawsuits against pathologists for diagnostic negligence at a US insurance company responsible for the insurance of 1,100 pathologists. The pathology presented a low frequency of complaints (8.3% per year), however with a great financial impact, measured by the amount of indemnities paid per claim, since many claims against pathologists result from the lack of diagnosis. False negative and false positive results for cancer accounted for 63% and 22% of claims, respectively. The highest values were related to diagnostic errors in melanomas (US\$ 757,146; 95% false negatives), cervicovaginal cytology (US\$ 686,599; 98% false negatives) and breast cancers (US\$ 203,192, with the

same proportion of false negatives and positives). Also about analytical errors, Genta (2014)⁽¹⁷⁾ argues that there are external or “suprahistological” elements that interfere with the pathologist’s decision which can be divided into two categories: the evidence-based ones (such as age, sex, ethnicity and epidemiology) and the elements that arise from emotional perceptions, not rooted in objective evidence, named emotional elements, directly related to inter and intraobserver variability. Faced with a colon adenoma with high-grade dysplasia, the pathologist may believe that surgeons will interpret the presence of dysplasia as a license for an unnecessary surgical resection and feel inclined to omit such information from the report. Even the errors of pathologists, when discovered, they may modify their decision-making behaviors. Biases such as visual anticipation, first impression, and preconceived judgments influence the critical decision-making processes⁽¹⁸⁾, however, to what extent such elements may interfere with the pathologist’s diagnostic decision-making is uncertain.

Delays in the result release may be considered as an error in the post-analytical⁽¹³⁾ or analytical phase⁽¹⁵⁾ and the turn-around time (TAT) should be used as an important quality measure in laboratories⁽¹⁹⁾. It is not uncommon for the pathologist to miss the perception that there is a patient waiting for his result; therefore, the cases should not remain for longer than necessary on the pathologist’s desk⁽²⁰⁾. Delays in TAT may be considered, during the pre-analysis, as delays in reception, gross examination and material processing; during the analysis (in the diagnostic interpretation of the pathologist); or after the analysis, as the delay in typing and release of the reports to the patient. In a study performed with 713 cases of surgical pathology, 551 (77%) were released in two days and 162 (23%) in three days or more. From these, the majority was cases of lung, gastrointestinal tract, breast and samples of the genitourinary tract. Diagnosis of malignancy (including staging), consultations with other pathologists, freezing and immunohistochemical analysis were associated with increased TAT, in univariate analysis. In the multivariate analysis, the consultation with other pathologists, the diagnosis of malignancy, the use of immunohistochemistry and the number of slides evaluated (11.3 when TAT > 2 days and 4.8 when TAT ≤ 2 days), remain as significantly associated with increased TAT. Despite CAP recommendation of an analytical response time of two days or less for most routine cases, the authors conclude that cancer care institutions should have a TAT longer than other services⁽²¹⁾.

LOOKING FOR SOLUTIONS

Perkins (2016)⁽²²⁾ considers that the disclosure of errors in pathology is complicated by factors intrinsic to the specialty. The first barrier, as already mentioned, is the definition of error.

Another concern is that the patient does not understand the nature of the error or even that the clinician is unable to explain it adequately to the patient. Even more complex is the situation that involves the discovery of the error of another individual: when the pathologist or the head of the laboratory discovers an error of a technician/another pathologist in their laboratory or of external laboratories, or even when the pathologist discovers an error of a clinician from the same organization. Therefore, when disclosing an error, the pathologist must consider the potential impact on their professional relationships.

One factor conferred to the increase in the number of medical errors is the excessive decentralization of patient care. Since the patient may have several professionals working in different contexts and none with access to the complete information, the physician would work in a situation of greater susceptibility to error⁽¹⁾. The lack of complete information is critical in pathology, where many cases depend on correct, clear and complete clinical information for adequate clinical-pathological correlation.

In 2016, CAP, the Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology convened a panel of experts to develop a guideline to help to define the role of case reviews in surgical pathology and cytology. The main recommendations cited in the document, with strong agreement among the participants were: 1) pathologists should develop procedures for the evaluation of selected cases in order to detect divergences and possible interpretation errors; 2) pathologists should conduct case reviews timely to prevent negative impacts on patient care; 3) pathologists should have review procedures of cases relevant to their practice, as well as continuously monitor and document the results of case reviews; and 4) if case reviews show unsatisfactory concordances for a defined case type, the pathologists should take actions to improve diagnostic compliance. The situation may become a little more problematic in places where only one pathologist is responsible for all cases; almost all published data refer to situations in which there is a second pathologist responsible for the review. The authors understand that there may be value when the pathologist himself revises his cases in a second moment; however, there are not enough data in the literature. Each laboratory should develop written procedures and record the results of its departmental review studies⁽²³⁾.

According to the authors, the causes for low agreement within and among anatomopathological groups are multiple, but two factors need to be discussed. Some diagnoses have intrinsically greater variation between observers and these differences should be considered. Furthermore, the histological diagnosis is dynamic and different terminologies can be used for the same disease. If a poor interobserver agreement is evidenced, methods for improvement

should be implemented, such as consensus conferences, images for comparison, etc., however the quality of evidence is very low in regard to the best method of improvement. The authors consider that best practices may differ according to the characteristics of the disease, individual practices and complementary tests available⁽²³⁾.

Smith and Raab (2012)⁽⁴⁾ describe how to use the Lean A3 quality control method in surgical pathology. Under the Lean method, a management philosophy developed by Toyota Motor Corp., pathologists develop activities, i.e., examination of slides, diagnostics and preparation of reports from paths through the sequential flow of the sample, with connections, represented by the individuals with whom the pathologist communicates. At all stages, there is the possibility of error, and quality improvements should focus on repairing these failures. The A3 method is based on defining a problem, analyzing its causes, aiming at an ideal practice, and providing an improvement plan. Other authors have also used industrial techniques, such as the Six Sigma, with excellent results in error reduction. Examples of their measures were: meetings with the clinical teams responsible for delivering the material to correct the inadequacy of the samples and intradepartmental meetings, in which employees actively participated in the discussions about the errors and their solutions. In the pre-analytical phase, the authors established a double-check system of the material, with the work divided into successive stages, and at each stage, all specimens were listed and checked by two team members, from receipt to material processing, and were subjected to the supervision of a quality control unit⁽¹⁵⁾.

In a review article by Ellis and Srigley (2016)⁽²⁴⁾, the authors emphasized the importance of structured and standardized reports for the improvement of diagnostic quality. Standardized reports can provide data that contribute to quality improvement programs in health care and, when combined with other health data sources, provide important information for monitoring, improvement, possible interventions and benefit analyzes in services offered to the population. The standardization of reports has proved to be particularly important in oncological diagnoses, which can generate

a large number of information with epidemiological impacts. The International Collaboration on Cancer Reporting maintains at <http://www.iccr-cancer.org/datasets> the guidelines and all the necessary parameters in the histopathological report, in order to guide clinical management, as well as to provide prognostic information for several cancers; the guidelines panel results from a six-week public consultation conducted by a Dataset Authoring Committee, with multidisciplinary experts. Lehr and Bosman (2016)⁽²⁰⁾, in an article about the communication skills of pathologists, discourage the excess of additional notes on artifacts from improper pre-laboratory handling, such as incorrect fixation due to electrocautery, etc. The authors advise that if the problems become recurrent, a letter to the material source services with guidelines may help to improve the specimens.

Nakhleh *et al.* (2016)⁽²³⁾ state that it is natural to wish to use data from case reviews to measure the quality of a pathology laboratory, however, now, it is not clear what best way to interpret these results, which should not be used to compare the quality between two different laboratories. There are some limitations that may explain such facts: the sources of error, as well as their definitions, and the methods used for their measurement, which may differ between laboratories. Its clinical impacts may be different. The sensitivity of the evaluation method is not controlled and is unknown; in addition, the expected performance points are not well defined.

CONCLUSION

The taboo around the diagnostic error in the pathology should be broken. It is not possible to discuss the quality controls of laboratories without admitting the possibility of error. Investing in continuing medical education, with emphasis on patient safety, as well as on the training of new pathologists, with a critical view aimed at reducing errors, is an obligatory path in improving the pathology practice.

RESUMO

A patologia deve ter como meta um diagnóstico correto e completo para o paciente, em tempo hábil, de maneira útil e compreensível para o médico assistente. No entanto, na prática diária, são múltiplas as possibilidades de erros no laboratório de patologia, com diversos impactos na assistência e no prognóstico do paciente. Nesta revisão, serão abordados os diferentes conceitos de erros e concordância diagnóstica em patologia, em que momento do processo diagnóstico os erros são mais frequentes, bem como a proposta de soluções para minimizar a chance de sua ocorrência.

Unitermos: erros médicos; patologia cirúrgica; erros em patologia.

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