

Error and Discrepancy in Radiological Diagnosis

Erro e Discrepância no Diagnóstico Radiológico

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Abstract

Discrepancies between Radiology reports and their subsequent patient outcomes are not necessarily considered error or malpractice. The Portuguese College of Radiology makes some pertinent considerations on these sensitive themes, intending to frame both European and North American concepts and visions for our national reality.

Keywords

Error; Discrepancy; Radiology exams; Medico-legal.

Resumo

Discrepâncias entre relatórios dos exames da Radiologia e seus subsequentes desfechos nos pacientes não são necessariamente considerados erro ou má prática. O Colégio de Radiologia Português tece algumas considerações pertinentes sobre estas sensíveis temáticas pretendendo enquadrar conceitos e visões quer europeias quer norte-americanas para a nossa realidade nacional.

Palavras-chave

Erro; Discrepância; Exames da radiologia; Medico-legal.

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- Discrepancies between reports of Radiology exams and their subsequent patient outcomes are not necessarily considered error or malpractice.
- The performance, evaluated by the report and interpretation of the findings by the Radiology specialist, may not be perfect or outstanding, and some discrepancies, or even errors, are inevitable.
- The error or discrepancy, in the interpretation and reporting of the findings by the Radiology specialist, is not in itself equivalent or equal to negligence or malpractice.
- The error or discrepancy can occur for intrinsic (human) or extrinsic (technical or systemic) reasons.

These are, currently and in general, the 4 key points or the understanding, in a summarized way, assumed by the European Society of Radiology (ESR) - and with which

the College of Radiology is in line - published in an official journal of that European society and the usual repository of their statements or official positions.^{1,2}

Below we develop some points for a better understanding of the unique aspects and vicissitudes inherent to the interpretive art in the specialty of Radiology.

I)

Although not always well understood or appreciated by the general public, or even by physicians in other specialties who request radiological examinations, radiologists' reports are not always expected to be definitive or uncontroversial. According to Adrian P. Brady, current 1st Vice President of the ESR Board of Directors, and a recognized prominent expert on this subject, the reports represent specific medical consultations, resulting in opinions that are conclusions

reached after weighing evidence; opinion, which can be defined as a view held on a particular subject or point; a formed judgment; a belief. Sometimes it is possible to be definitive in radiological diagnoses, but in most cases, radiological interpretation is strongly influenced by the clinical circumstances, the patient, the relevant past history and previous imaging studies, among a myriad of other factors, including cognitive biases of which we may not be aware of.²

Radiological studies do not come with built-in labels denoting the most significant changes, and interpreting them is not, in most cases, a binary process (normal vs. abnormal, cancer vs. no cancer).

In this context, radiological error can assume two legal-conceptual dimensions: the reporting radiologist should be able to make the correct diagnosis or report, but did not do so (obligation of result); or the radiologist is only required to act diligently, regardless of error verification (obligation of means) when faced with cases where there is room for different opinions, discrepant diagnoses or erratic perceptions.

Depending on the specific case, the relevance of radiological error will be greater the simpler and more certain the conditions of diagnosis and perception are, and vice versa.

II)

How frequent can discrepancies or errors occur in Radiology and Medicine in general?

Usually, contrary to what happens either with the findings of the physical examination of patients, or with the findings in surgery or endoscopy, the imaging evidence of a radiological examination remains available for future scrutiny, and can be used to study the variance of interpretations or of imaging reports. A two-decade scientific literature review in 2001 suggested that the level of major or clinically significant error in Radiology would be in the range of 2-20%, and varies depending on the technique or modality.^{2,3}

Comparative studies of other medical specialties found a similar prevalence of inaccuracy, failure or omission in clinical assessment or physical examination. A Mayo Clinic autopsy study published in 2000, which compared clinical diagnoses with postmortem diagnoses, found that in 26% of cases, an important diagnosis was not made pre-mortem.⁴

The large amount of data available in the scientific literature thus leads us to the inevitable conclusion that discrepancy or error (radiological and/or clinical) is inevitable. Therefore, the concept of fallibility must be accepted. At the same time, a threshold of competence is required of all radiologists.^{2,5}

III)

Hindsight bias

A major influence on the determination or assumption that an initially undiagnosed or reported disorder should have been previously identified comes in the form of hindsight cognitive bias, defined as the tendency for people with knowledge of the actual outcome or end result of an event to believe, falsely or fallaciously, that they would have foreseen the result in time. This underlying determinism involves the automatic and immediate integration of information about the outcome or end result into their knowledge of events preceding the outcome.^{2,6}

Thereby, it can be understood that the retrospective analysis of, for example, a subtle asymmetry in a mammogram can be considered fallaciously “easy” to identify, knowing in advance that the patient is being followed up for breast cancer recently operated or treated.

IV)

Radiology: an obligation of means or of result?

The treatment obligation imposed on the doctor is, fundamentally, an obligation of means or diligence and, exceptionally, an obligation of result. Physicians will be responsible for prudently and diligently developing, bearing in mind the current scientific stage of the *leges artis*, a certain activity to obtain a certain useful effect, which translates into using their science in the treatment of the patient, without requiring the binding to a certain result. If an examination is configured for a complex pathology, subject to delicate interpretation, as it happens in a more demanding radiological or ultrasound examination, in which medical thought admits, even if scientifically, a margin for error, the hypothesis will point to the existence of an obligation of means and not of result.⁷

V)

Other peculiar aspects in radiodiagnosis

It is not always simple to distinguish objectionable conduct from adverse results or misfortunes resulting from diagnostic failures inherent even to the “average, careful and diligent professional”. Vicissitudes in this definition of mean or median must be taken into account (Fig. 1).

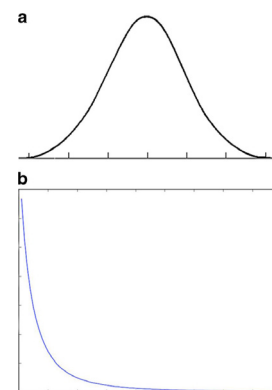


Figure 1 – If we assume that radiodiagnostic acuity has a Gaussian distribution (a), then about half of this performance must be below average. Individual performance may rather follow a Paretian distribution (b), where more performance is clustered on the left side of the reverse exponential curve, where most feats have been achieved by a small number of super-performers; in this model, most performers are below average and therefore will be less productive or more likely to make mistakes than super-performers; the median of this distribution is also skewed towards the high end of performance. In Radiology, it is transversal to all practices and modalities, that the diagnostic accuracy between different observers very rarely reaches 100.0%, decade after decade, whatever the nationality or environment, academic or not, whether in published or unpublished studies in scientific journals, whether indexed or not. [Figure taken from reference 2 – Open Access: Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>)]

It is important to emphasize that even in nations perhaps considered to be more litigious on these issues, such as the USA, there are instructions from judges to juries that “there is an absolutely inevitable ‘human factor’ at work in the interpretation of radiological studies; some alterations may go unnoticed, even those considered “obvious”; the mere fact that a radiologist overlooks a change in a radiograph does not mean that he or she has committed negligence; and not all radiographic failures are excusable. Therefore, the focus of attention should be on issues such as proof of competence, practice habits and the use of proper techniques.”⁸

In these circumstances, a technical analysis with a risk matrix as recommended by Adrian P. Brady et al.,⁵ can be performed, resulting in a score that may give a little more objectivity to the analysis of the cases in question.

Also remember that the famous Practice Parameters and Technical Standards of the American College of Radiology are not inflexible rules or requirements of practice and are not intended, nor should they be used to establish a medico-legal standard of care. For all these reasons, we warn against using them tout court in legal or medico-legal disputes where the clinical decisions of a professional are questioned.⁹

In this way, errors, failures, omissions or inaccuracies in Radiology result mostly from a doctor’s diligent action (obligation of means), diluting the impact of the error within the scope of medical responsibility; or, exceptionally, the

adverse event occurs in a simple clinical context, with no margin for error (result obligation), implying a breach of the duty of care and generating that responsibility.

According to Schwalm, “a medical error that has not been the result of a breach of duty of care, and despite all the possible diligence of the doctor, has occurred, cannot be criminally or civilly relevant, due to the lack of the respective assumptions of responsibility”.¹⁰

VI) Solutions

The regular holding of Service meetings on the Prevention of Errors and Failures is considered a fundamental aspect in modern radiological practice. A positive culture of development and continuous learning (peer-learning) is important to prevent new adverse events, errors or failures detected in previous exams. The cases must be anonymized and subject to analysis by the radiology medical staff, always including, of course, the radiologist(s) involved in the target case. Holding these meetings virtually instead of face-to-face can ensure better avoidance of feelings of shame or blame among peers.¹¹

“I would give great praise to the physician whose mistakes are small, for perfect accuracy is seldom to be seen.”

Hippocrates, On Ancient Medicine, IX

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Protection of human and animal subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

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