

Civil liability of the radiologist in the diagnosis of breast cancer through mammography*

Responsabilidade civil do radiologista no diagnóstico do câncer de mama através do exame de mamografia

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Abstract The present study was aimed at analyzing civil liability for medical errors specifically for a radiologist's errors in the mammographic diagnosis of breast cancer. As examples, Court decisions were analyzed with the aim of showing the understanding of the Brazilian Courts of Law, among them the Supreme Federal Court that is responsible for reviewing, on appeal, judicial decisions affronting the Brazilian Constitution, as well as the Superior Court of Justice, that is competent to judge on appeals against decisions violating Federal Laws. The reviewed material demonstrates the Courts' view on the subject discussed on the present article, describing the consequences of radiologists' and radiological centers' errors in the sphere of the civil law that establishes monetary indemnity as a consequence of the existence of civil liability. That is to say that the duty to indemnify arises from the testifying of the existence of civil liability. Thus, once the civil liability is removed, the duty to indemnify comes to an end. Indemnity should not be confused with civil liability; the latter is the foundation of the former.

Keywords: Medical error; Mammography, Breast cancer; Civil liability.

Resumo O objetivo deste trabalho foi analisar a responsabilidade civil por erro médico no que tange, especificamente, à conduta do radiologista no diagnóstico do câncer através do exame mamográfico. Foram analisadas, para exemplificar, decisões judiciais com o objetivo de mostrar o entendimento dos tribunais nacionais, dentre eles, o Supremo Tribunal Federal, a quem compete revisar, em grau de recurso, as decisões judiciais que afrontam a Constituição Federal, bem como o Superior Tribunal de Justiça, que tem a competência de julgar em grau de recurso as decisões violadoras das leis federais. O material utilizado demonstra a visão dos tribunais acerca do tema objeto desta pesquisa, revelando as consequências do erro do médico radiologista e dos serviços de radiologia no âmbito do direito civil, que possui a indenização monetária como consequência da existência de responsabilidade civil. Ou seja, o dever de indenizar decorre da constatação da existência da responsabilidade civil. Assim, afastada a responsabilidade civil, fica afastado o dever de indenizar. Indenização não se confunde com a responsabilidade civil, esta é fundamento daquela.

Unitermos: Erro médico; Mamografia; Câncer de mama; Responsabilidade civil.

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INTRODUCTION

Internationally, one observes, as in some developed countries such as the United States of America, Canada, United King-

dom, Holland, Denmark and Norway, an increase in the incidence of breast cancer, followed by a decrease in mortality rates, a fact that is associated with early detection of the disease by means of the introduction of mammography as a screening method in association with the availability of appropriate treatment techniques. In Brazil, differently, the increased incidence of breast cancer has been followed by an increase in mortality rates, a fact that is primarily attributed to late diagnosis and consequential late adoption of appropriate therapeutics⁽¹⁾.

As the breast cancer mortality rates are increasing, with one of the causes for such

an increase being medical errors, which, by their turn, are a consequence of the increase in the number of mammography studies performed in Brazil, the number of lawsuits filed by patients allegedly victims of such errors in mammography and ultrasonography reports has been increasing substantially⁽²⁻⁴⁾.

Among the causes for alleged medical errors, is the late diagnosis of breast cancer, which may occur as a consequence of the lack of proper appreciation of abnormalities in the previous mammographic images, susceptible of generating a liability which is likely to result in the obligation of indemnifying the patients – and such indemnity can be many times very significant⁽⁵⁾ –, as for the establishment of an in-

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demnity obligation in the due course of the process, the existence of a liability must be duly demonstrated.

Thus the present study is intended to alert physicians of the consequences of such diagnosis errors, particularly in what concerns the decisions by the Brazilian Courts of Law on the legal liability of health professionals, particularly of radiologists and of radiology services in the analysis of mammographic images.

MATERIALS AND METHODS

The legal research was primarily based on literature and documents extracted from studies on the legislation, books on pertinent legal sciences, besides court decisions. Such contributions were mainly originated from the study of civil rights books, besides the decisions from the Brazilian Courts of Law, or jurisprudence.

In the legal field, the literature review is the method of choice available for the researcher, considering that a study approaching legal issues cannot be developed without mentioning the laws which regulate the theme, or the Court decisions that applied such laws to the conflicts of interest existing in society or, in the present study, to the conflicts between the radiologist and the patient.

Interpretation of concepts

The idea of civil liability is connected with the existence of a wrongful conduct, which is configured whenever imprudence, malpractice or neglect are present. With respect to the physician, whenever he or she is the agent causing damage to the patient, by acting in a reckless manner, that is, without the required care, he/she will also be acting with imprudence. When the professional does not possess enough technical knowledge in order to diagnose, or his knowledge is outdated, the case will be a malpractice one. On the other hand, neglect is configured when the medicine professional reveals lack of attention in the utilization of the usual care required in the diagnosis of the patient's disorder⁽⁶⁾.

Once the above expressions were analyzed, in order to achieve a comprehension of the civil liability concept, one should refer to the teachings by Pontes de Miranda⁽⁷⁾:

“Whenever we do what we do not have the right to do, it is certain that we commit an injurious act, as we reduce, against one's will, the assets represented by one's rights, or increase one's liabilities, which generally means the same”.

Indeed, in most of cases, the legal duty of responsibility arises from a contract, a fact or omission, originating from the agreement between the parties or from the rule of Law⁽⁸⁾. Therefore, civil liability can be simply defined as the obligation to repair the damage caused to someone⁽⁹⁾.

In this sense, the understanding and conceptualization of civil liability from Maria Helena Diniz⁽¹⁰⁾ is very helpful: “Civil liability is the application of measures that oblige a person to repair moral or patrimonial damage caused to third parties, on account of one's actions, or actions by persons one is responsible for, by something that one owns, or simply by the rule of Law”.

As explained above, the physician's obligation to indemnify is characterized whenever the occurrence of damages borne by the patient, as well as the physician's wrongful action or omission, and the causation, i.e., the causal relationship between the wrongful action or omission and the damage caused to the patient are sufficiently demonstrated.

At radiology services, the relationship established between the patient and the radiologist is generally governed by a contract, which is subject to the regulations established by the Brazilian Consumer Protection Code (Código de Defesa do Consumidor) (Law No. 8.048/1990). This is due to the fact that the provider of radiology services, whether such provider is an individual or a legal entity, is presented as a provider of medical exam services, thus characterizing a consumer relationship as the patient is presented as the consumer of such services. The Consumer Protection Code, on the *caput* of Article 3, describes the concept of provider: “Provider is any individual or legal entity, either public or private, national or foreign, as well as the unincorporated entities which develop the activities of (...) providing services”. On Article 2, the Consumer Protection Code defines the consumer as: “...any individual or legal entity that acquires or utilizes a product or service as its final recipient”.

Thus, the patient who is submitted to radiological examination is a consumer of such service, i.e., the patient is the final recipient, therefore the consumer of a service utilized to establish a diagnosis, or even a treatment, for his eventual health problem.

The Court decisions are uniform with respect to the objectiveness of the liability of legal entities providing radiology services for eventual damages caused to patients, objective liabilities being those that are characterized independently from guilt by the agent. On the other hand, the personal liability of professionals, among them the radiologist, will be investigated by means of verification of guilt⁽¹¹⁾.

Therefore, when analyzing the civil liability of a legal entity provider of health services in imaging diagnosis before considering such a liability as objective, there must be an investigation in Court, on whether there was subjective liability (presence of guilt in the action of the professional) of the professional that may have caused damage to a patient. Only then, once it is proven that the eventual damage resulted from a wrongful act by the physician, the radiology service may be considered liable in Court.

As a rule, radiology services are liable for damages caused by errors from radiologists and other professionals in the practice of their professional activities at such medical services, characterizing the *vicarious* liability. As regards liabilities, Rui Stoco⁽¹²⁾ explains: “*Vicarious* guilt originates from the poor choice of the representative or agent”. On the same concept, Caio Mário da Silva Pereira⁽¹³⁾ explains: “...*vicarious* guilt, when there is a bad choice by a person to whom a certain task is assigned”.

Following the same reasoning, in spite of not mentioning that the liability is objective, but rather assuming the guilt in the act of the employer or constituent, the Supremo Tribunal Federal (STF) (Brazilian Supreme Court) issued the 341 Precedent: “The employer or constituent is guilty for wrongful act performed by the employee or agent”.

Therefore, radiology services may be considered liable in Court by the damages caused to patients as a consequence of the procedures to which the patients are sub-

mitted. Such liability may occur even in cases where the damages are caused to patients by employees or agents of such services.

And, in what concerns the physicians, even in cases where they are not employed by the radiology service, the Courts will not reject the responsibility for indemnity to patients to whom damages were caused on account of the professional activities developed at such health centers. This is because the agent, or the radiologist, will always perform the activities with a specific purpose: to perform specialized clinical examinations in the field of radiology that are offered by such medical entities.

In addition to the liability for wrongful action by agents, radiology services are also liable for damages caused by things. Extending the interpretation of “things” to medicines or drugs that may cause damage to patients, such damages may also generate liabilities to those who prescribed or administered them⁽¹⁴⁾.

At this point, it is important to highlight the fact that radiological contrast agents, among other similar substances utilized in imaging examinations, are considered as medicines at our positive law under Federal Decree No. 79.094/77, item II of Article 3: “Medicine is the technically obtained or elaborated pharmaceutical with prophylactic, curative, palliative, or for diagnostic purposes”⁽¹⁵⁾.

Thus, based on the aforementioned considerations, one concludes that radiology services must undertake all necessary care to avoid any kind of damage to patients, performing the activities without exposing the patients to risks, particularly those risks that are unnecessary. Moreover, one should always take into consideration the risk-benefit factor related to the procedures that are beneficial to patients, with respect to the basic ethical principles of medical practice, that is to say, the principle of beneficence, the principle of non-maleficence and the principle of justice⁽¹⁶⁾.

Grounds for litigation between patients and radiology services

It is important to mention that the main aspects of breast cancer diagnosis that may provide grounds for litigation among physicians, radiology services and patients are

the false-positive diagnosis, false-negative diagnosis and failure in communication.

Diagnosis

False-negative diagnosis

In general, false-negative diagnoses almost always provide grounds for litigation against radiology services and radiologists. Some decades ago, undiagnosed fractures represented the most common cause of litigation. Late In the 1980's, false-negative diagnoses of malignant tumors, particularly lung cancer and colon cancer, became a more significant cause for litigation.

As an example, the failure to diagnose breast neoplasias was pointed out in 2002 by the report from the Physicians Insurers Association of America (PIAA – an organization comprising 26 medical professional liability insurance companies) as the most common and second most costly condition related to litigation between patients and physicians among the most diverse specialties, with radiologists being the most commonly sued specialists⁽¹⁶⁾.

Indeed, diagnostic errors may be caused by perception failures or misjudgment. Perception failures occur as an abnormal finding is not perceived. Misjudgment errors are related to a detected abnormality that is not correctly interpreted. Both hypotheses provide a cause of action for a judicial proceeding seeking indemnity. However, it is important to remind that differentiating a simple error from a transgression of a code of conduct is not always a simple matter.

Another point that should not be forgotten is the reality that some breast tumors become noticeable only by means of retrospective studies, even in cases where the initial imaging study has been appropriately analyzed. Indeed, not infrequently, it has been observed that some tumors may be considered as not suspicious, even by the most experienced radiologists, with the malignancy of such tumors becoming noticeable only after a comparative analysis with subsequent studies. An important fact to be taken into consideration in the comparison between studies is that slow-growing tumors may present very small variations between mammograms; this may lead the radiologist to minimize the finding, and thus achieve a false-negative diagnosis⁽¹⁷⁾.

This happens because mammography presents a sensitivity of approximately 90% for dense breasts, increasing to 96.5% for predominantly fatty breasts, which leads to the understanding that lesions that are not detected by the method should not even be considered as possible grounds for litigation⁽¹⁷⁾.

False-positive diagnoses

As it is widely known, false-negative diagnoses receive more attention than the false-positive ones, as these, in spite of causing many inconveniences to the patient, such inconveniences are not comparable to the consequences of a false-negative diagnosis that hides the presence or malignancy of a tumor, not rarely leading to the death of the patient.

On the other hand, false-positive diagnoses may cause problems related to excessive use of medications, unnecessary biopsies, frequent and excessive exposure to radiation, which may constitute grounds for litigation with unpredictable results. The specificity is directly related to the number of false-positive diagnoses: the cumulative risk of a false-positive result after 10 mammographic studies is of 50%. In a study developed by Elmore et al.⁽¹⁸⁾ with 2,169 women, the rate of false-positive results was higher for radiologists with less than 15 years of experience than for those with longer professional experience. Currently, the total number of mammograms recommended for a radiologist to analyze is 480 mammograms/year⁽¹⁷⁾.

One must also take into consideration the fact that the health status of a patient goes through changes when she is informed that in her mammography study a suspected cancer has been found and a biopsy will be necessary. Radiologists can immediately induce a change in the patient's mood or, depending on the case, even in the patient's health as the presence of a cancer that in reality does not exist is suggested.

Finally, a false-positive diagnosis may cause great emotional distress that momentarily and psychologically incapacitates the patient for working. Not rarely, such type of diagnosis can lead to unnecessary surgery, a fact that undoubtedly constitutes strong foundations for the filing of lawsuits⁽¹⁷⁾.

Failure in communication

The efficient communication of the findings at mammography studies is indispensable for the correct use of the data obtained through such study, as the identification of an abnormality, if not followed by timely and appropriate clinical treatment, will not result in benefits to the patient.

It is an undeniable fact that even when the communication with the patient is satisfactory and efficient, i.e., by means of a printed report and/or a telephone call, delays in beginning the treatment or follow-up still may occur. On the other hand, when such a communication is not appropriate, effective damages may occur, possibly being attributed to both the physician and other health professional.

In this scenario, it is possible to understand that radiologists may be considered negligent in the event of failure in notifying the assisting physician, on a timely basis, on the relevant mammographic findings. Therefore, one should bear in mind that one of the radiologists' duties is the effective and timely communication of mammographic findings.

ANALYSIS OF ACTUAL CASES (JURISPRUDENCE)

With the purpose of better illustrating the present work, as well as bringing to the objective reality the concepts developed on the previous paragraphs and facilitate the understanding of the theme in discussion, the analysis of some actual cases taken to Court is necessary.

The first case concerns a lawsuit claiming a compensation for moral damages, arising from an error in breast cancer diagnosis, in which the physician was condemned to indemnify the heirs of the patient in the sum of R\$ 72,000.00 (seventy two thousand Reais). After the initial consultations with the physician, the patient presented to the assisting physician a mammogram whose report indicated the need for a biopsy. However, the physician did not request the performance of such biopsy, which impaired the early diagnosis of the disease. On account of this wrongful conduct, the patient was properly diagnosed with breast cancer only two years later, by another professional. The patient

died in the course of the legal proceedings⁽¹⁹⁾.

In the second case, the court rejected responsibility by the physician and by the hospital on account of the sole responsibility of a third party that performed an equivocal biopsy. The assisting physician instituted the appropriate treatment as per results of biopsy performed by a third party laboratory, which indicated breast dysplasia (a benign abnormality), ruling out the cancer diagnosis. However, when a second biopsy was performed by a specialized institution that detected the previous misdiagnosis and identified breast cancer, it was already too late. The patients underwent radical mastectomy, and the patient died as a consequence of the disease⁽²⁰⁾.

In the third case, a defective service was proven. The wrong diagnosis led to the right mastectomy and subsequent chemotherapy for treatment of cancer. The institution was condemned to pay indemnity of R\$ 20,000.00 (twenty thousands Reais) for moral damages, besides bearing the costs of restorative plastic surgery. In this case, the patient was submitted to mammography on September 21st, 2005 and breast ultrasonography on February 2nd, 2006. Both studies were performed at the defendant institution, with reports negative for breast cyst. At a breast ultrasonography performed by another institution on February 13th, 2006, a solid mass was found in the right breast of the patient. The forensic expert's report produced as part of the legal proceedings concluded that both clinical imaging studies performed by the defendant institution presented defective reports. The forensic expert's analysis of the same images diagnosed the presence of a highly suspicious mass on the study performed on September 21st, 2005. The wrong diagnosis caused exclusively by the defective mammographic report provided by the defendant institution generated the obligation to indemnify⁽²¹⁾.

FINAL CONSIDERATIONS

As previously discussed in the present article, radiology services are sometimes the stage where actions that cause damages to certain patients take place, because such centers are the place where radiologists and

other health professionals perform their duties in assisting patients with technologically appropriate equipment and installations in cases that undoubtedly tend to be more complex for requiring attention in health care in a hospital environment.

The present review discussed the way by which our legal system approaches the civil liabilities of physicians and radiology centers and on how the Brazilian courts have dealt with such demands. It is strongly recommended that poor quality images should not be interpreted, and as much information as possible should be obtained from the patient by means of a form for classification of risk factors for breast cancer.

In addition to the images review by another radiologist, the interaction with the assisting physician is of paramount importance. Whenever possible, the report should always convey all the necessary detailed information to the assisting physician, informing the findings at the clinical examination of the breasts, reporting the presence of asymmetries, abnormalities on the skin and in the subcutaneous breast tissue, the type of breast parenchyma, the imaging findings (microcalcifications, masses, architectural distortion), describing the accurate location of such findings as well as the BI-RADS classification. Such recommendations are aimed at minimizing medical errors, thus avoiding civil liabilities and the payment of huge indemnities.

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