

Spectrum of diagnostic errors in radiology

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Abstract

Diagnostic errors are important in all branches of medicine because they are an indication of poor patient care. Since the early 1970s, physicians have been subjected to an increasing number of medical malpractice claims. Radiology is one of the specialties most liable to claims of medical negligence. Most often, a plaintiff's complaint against a radiologist will focus on a failure to diagnose. The etiology of radiological error is multi-factorial. Errors fall into recurrent patterns. Errors arise from poor technique, failures of perception, lack of knowledge and misjudgments. The work of diagnostic radiology consists of the complete detection of all abnormalities in an imaging examination and their accurate diagnosis. Every radiologist should understand the sources of error in diagnostic radiology as well as the elements of negligence that form the basis of malpractice litigation. Error traps need to be uncovered and highlighted, in order to prevent repetition of the same mistakes. This article focuses on the spectrum of diagnostic errors in radiology, including a classification of the errors, and stresses the malpractice issues in mammography, chest radiology and obstetric sonography. Missed fractures in emergency and communication issues between radiologists and physicians are also discussed.

INTRODUCTION

A malpractice claim arises when a patient believes that improper medical care has resulted in bodily harm. An error in the interpretation of a radiograph, including misdiagnosis or failure to diagnose, is an example of a general type of claim in radiology. Robinson pointed out that radiology's Achilles heel is "error and variation in the interpretation of the Roentgen image"^[1].

The main reason for studying medical errors is to try to prevent them. Reducing errors will improve patient care, may reduce costs and will improve the image of the hospital.

Radiologic problems that have led to medical malpractice lawsuits most frequently have been due to "failure to diagnose". This means oversight of abnormalities or misinterpretation of radiologic images^[2-5]. These types of claims account for about 40%-54% of radiology-related medical malpractice cases^[2]. The three main categories of claims include misdiagnoses, complications, and miscellaneous. Radiologic "misses" typically are one of two types: either missed fractures or missed diagnosis of cancer. The most commonly missed fractures include those in the femur, the navicular bone, and the cervical spine. The

second type of “miss” is failure to diagnose cancer. Lack of appreciation of colorectal carcinoma on barium enema studies, lung nodules on chest radiographs, breast lesions on mammograms, and bone tumors on plain radiographs are the predominant problems^[2-4]. Informed consent for procedures related to interventional radiology is a relatively frequent source of legal problems as well^[6]. Types of procedures that prompt or contribute to litigation include biliary drainage, stone extraction, cholecystostomy, nephrostomy, abscess drainage, tract dilation, biopsy and contrast material administration^[6].

In addition to economic and social effects, malpractice lawsuits have often direct effects on a physician's health. Litigation for alleged malpractice is often associated with feelings of guilt and isolation. Medical professionals who have committed a severe error are open to a reduction in quality of life and an increase in the frequency of burn-out^[7]. Perceived stress is associated with an increase in the number of errors committed in the subsequent period, thus creating a vicious cycle whereby errors lead to stress, which in turn leads to new errors^[8]. Physicians may feel a sense of guilt resulting from the error and may fear suffering professional and economic consequences and being isolated by their own colleagues and clients^[9]. There is thus the need to analyze the extent and causes of the phenomenon, which would also help to identify the most effective measures in terms of clinical risk management. Identification and reduction of diagnostic error provides a measure of the efficacy of the healthcare system, as it reduces mortality, morbidity, length of hospital stay and additional healthcare costs^[10].

This article focuses on the spectrum of diagnostic errors in radiology, including a classification of the errors, and stresses the malpractice issues in mammography, chest radiology and obstetric sonography. Missed fractures in emergency and communication issues between radiologists and physicians are also discussed.

CHARACTERISTICS OF RADIOLOGY

Radiology offers a presumptive but neither a histological nor microbiological diagnosis^[11].

Radiology diverges from the normal path of other medical specialties, in that it depends entirely on visual perception and on the identification of specific characteristics on a radiograph. Mechanical, physiologic, and psychological factors contribute to an intricate interplay that has yet to be explained completely^[12]. Physicians should provide adequate clinical information to the radiology department. The technician and radiologist can both perform their jobs in a more efficient and focused manner if they have adequate information^[13].

Authors of previous studies^[14-20] have investigated the subject of radiologic errors in general and the frequency and clinical consequences of radiologic misinterpretations in a trauma setting. The average error rate among radiologists is around 30%, according to studies dating from 1949 to 1992^[21,22]. Wood pointed out that errors in

decision-making by inexperienced radiologists usually take the form of “pseudo-diagnostics” or premature diagnostic conclusions^[23]. Observations are interpreted on the basis of a single hypothesis, in the belief that a high true-positive rate of supportive evidence is diagnostic in itself. Such bias has been described as anchoring bias, where one locks on to a diagnosis early in the work-up of a case and undervalues data that would support another diagnosis or that refutes the favored diagnosis.

In recent surveys published by medical insurance agencies in North America^[24] and in the UK^[25], error in diagnosis was the most common cause of litigation against radiologists. The majority of such cases arose from failure to diagnose breast cancer on mammography, failure to diagnose lung cancer on chest radiographs, and failure to diagnose fractures on skeletal radiographs^[25,26].

CLASSIFICATION OF ERRORS IN RADIOLOGY

In general, there are four main reasons why radiologists are sued: observer errors, errors in interpretation, failure to suggest the next appropriate procedure and failure to communicate in a timely and clinically appropriate manner.

Observer errors

Kundel *et al.*^[27] described three types of observer error. Scanning error is the result of failure of the radiologist to fixate in the area of the lesion. Recognition error involves fixating in the territory of the lesion yet failing to detect the lesion. The most common error is decision-making error, which accounted for approximately 45% of observer error in the study by Kundel *et al.*^[27]. This error is due to incorrect interpretation of a malignant lesion as a normal structure after detection. Another form of observer error that may contribute to lesions being overlooked (a lung cancer, for example) is satisfaction of search (SOS) error^[28]. This error is the result of diversion of the radiologist's attention from a tumor by an eye-catching but unrelated finding. Another issue that may affect observer performance is intentional underreading, that is, a conscious tendency to interpret equivocal radiographic shadows as negative^[29]. Such a phenomenon may occur because of collegial pressure to reduce the number of false-positive interpretations, and thereby decrease unnecessary work-ups.

Failures of abnormality detection in film reading (i.e. perceptual errors) are subject to psychophysiological factors of human visual perception^[12,30]. They are common to visual perceptual tasks in general and are relevant to other professions (e.g. air traffic controllers, professional drivers) where active observation is a key part of professional activity. Perceptual errors, in general, are related to multiple psychophysiological factors, including level of observer alertness, observer fatigue, duration of the observation task, any distracting factors, conspicuity of the abnormality and many others^[31].

An additional source of error results from the influence a radiology report has over another radiologist. This type of perceptual error occurs because the radiologist reads the old report before looking at the films^[32]. If the first radiologist missed it, the next radiologist will likely miss it as well.

Errors in interpretation

There are many reasons why radiologists make errors in identifying and interpreting abnormalities. Factors such as clinical history, the presence or absence of previous studies, index of suspicion, the presence of an abnormality, the reading room environment, and the level of vigilance of the interpreter are various sources of error. Eye position studies have determined that obvious abnormalities on a radiograph are detected first and decrease vigilance for unrelated and subtle findings^[28].

Failure to suggest the next appropriate procedure

Most ordering physicians actually know the next appropriate procedure to suggest when an abnormality is found on the imaging study they originally ordered. However, if the patient becomes a plaintiff in a lawsuit against the ordering physician, the radiologist can almost be assured that the ordering physician will claim ignorance as to what to do next because the radiologist did not specify what to order next. Radiologists must ensure that their recommendations or suggestions for any additional radiologic procedures are appropriate and will add meaningful information to clarify, confirm, or rule out the initial impression. The American College of Radiology (ACR) "Practice Guideline for Communication of Diagnostic Imaging Findings"^[33] states that "follow-up or additional diagnostic studies to clarify or confirm the impression should be suggested when appropriate". The words "when appropriate" are not defined, and thus the circumstances under which radiologists should suggest additional radiologic studies are left to the radiologist's own judgment^[34].

Failure to communicate in a timely and clinically appropriate manner

In addition to rendering an official interpretation (a final written report), the radiologist is responsible for communicating these findings directly to the referring physician. Errors in communication are the fourth most frequent allegation against radiologists in medical malpractice claims^[35]. Failure to communicate is one area in which the radiologist can take a direct role in reducing the risk of malpractice. When communication is not documented, the radiologist risks losing a lawsuit when there are adverse or unexpected clinical outcomes. Documentation should include the date, time, name of the person spoken to, and what was discussed^[36].

America in 1995 and in 1997 (the latter in association with the ACR), found that radiologists had become the specialists most frequently sued in malpractice lawsuits involving breast cancer, that mammography had become the most prevalent procedure involved in malpractice lawsuits filed against radiologists, and that the allegation of an error in the diagnosis of breast cancer had become the most prevalent condition precipitating medical malpractice lawsuits against all physicians^[37]. The radiology literature is replete with articles that document error rates among competent radiologists in the interpretation of mammograms^[37]. The literature also describes the large number of breast carcinomas seen retrospectively on mammograms originally interpreted as having normal findings once subsequent mammograms reveal a tumor^[37]. An article published in the ACR Bulletin showed that 30%-70% of breast cancers detected at follow-up mammography are retrospectively seen on first mammograms interpreted as showing normal findings^[37]. The most common lesion types reported in studies of missed breast cancers are mass or density in 19%-64%, calcifications in 18%-28%, mass with calcifications in 2%, and architectural distortion in 4%-12%^[38-41].

MISSED LUNG CANCER ON CHEST RADIOGRAPHS

Lung cancer has become the primary cause of cancer-related deaths worldwide^[42]. However, early detection of lung cancer at a surgically curable stage is difficult with conventional screening methods^[43-45]. Missed lung cancer remains a serious medico-legal issue despite widespread awareness of the problem by radiologists. Most overlooked lung cancers on chest radiographs are solitary pulmonary nodules. Missed cancer usually has a substantial upper lobe predilection^[46,47]. This predominance probably reflects the tendency of bronchogenic carcinoma to involve the upper lobes more frequently than other regions^[48]. The perihilar regions are an important but somewhat less common site of overlooked lung cancer. There are many sources of error in the radiographic diagnosis of lung cancer, including image quality, detection of the lesion, recognition of the lesion, and communication of the information to the referring physician. Any one of these may serve as a basis for malpractice litigation^[49]. Lesion size is an important factor of detectability on chest radiographs. Several studies have shown that only 50% of 1-cm lesions are detected^[50]. Lesion shape may also influence detectability. In general, lesions that are sharply margined are found more easily than spiculated or poorly defined cancers. Technical features also play a role in failure to diagnose lung carcinoma^[50]. On chest radiography, film contrast, density, and kVP all influence the detection of a lesion^[48].

Manning *et al.*^[51] reported that the majority of errors related to missed lung cancer from the posteroanterior chest radiograph were failures of decision rather than detection, supporting the idea that the complexity of the visual information in chest imaging makes it difficult for observers

MALPRACTICE ISSUES IN MAMMOGRAPHY

Reports issued by the Physician Insurers Association of

to discriminate between normal anatomical structures and nodular pathological features, even when such features have been made visually obvious by the imaging process. Such difficulties do not imply reader incompetence but suggest that perceptual rather than imaging limits may be the fundamental problem in some image interpretation tasks.

The role of the lateral radiograph in detection of lung cancer at chest radiography has been in dispute for over 30 years^[52-54]. Only the lateral radiograph revealed cancer retrospectively in two patients (5%) in the series by Shah *et al.*^[55], and the cancer was seen better on the lateral radiograph than on the frontal projection in one other patient (2%) in the same series. These results are comparable to those of other series, which indicate a 2%-4% detection rate for lung cancer on the lateral compared with the frontal chest radiograph^[52,56,57].

The failure to detect a lung cancer, under any conditions, would be considered negligent. This line of reasoning is referred to as *res ipsa loquitur* ("the facts speak for themselves"), which means that the fact that a lung cancer was missed on a chest radiograph is sufficient evidence of negligence without requiring that someone establish standards of care. Negligence is a legal term that requires specific elements to be a cause of action in tort. These must be proved to a finder of fact, either a jury or a judge. The following elements constitute negligence: (1) a duty is present, for example, practice to the standard of care; (2) a breach of duty occurs, such as failure to the standard of care; and the breach of duty is (3) a proximate cause of (4) substantial injury to the patient^[49].

MISSED FRACTURES IN EMERGENCY RADIOLOGY

Trauma care creates a "perfect storm" for medical errors: unstable patients, incomplete histories, time-critical decisions, concurrent tasks, involvement of many disciplines, and often junior personnel working after-hours in busy emergency departments^[58,59].

Patients with multiple injuries often require a series of radiographs to examine all injured sites. The frequency of missed lesions in such patients is high. Physicians have long been aware that an injury may draw and hold their attention, diverting it from other injuries^[60]. A "SOS" effect has been demonstrated in which the discovery of a fracture on one image interfered with the detection of a subtle fracture on another image of the same patient^[61].

The frequency of reported "missed diagnoses" depends on how the frequency of error was assessed; based on trauma registries, error rates were approximately 2%^[62]; retrospective chart review found approximately 40%^[63]; and retrospective review of all admissions revealed missed or delayed diagnoses of approximately 8%-10%^[62-64]. Fractures in some complicated anatomical locations are difficult to detect on plain radiographs that remain the primary imaging modality used in the Emergency Department. Other factors may also affect the accuracy of

diagnosing fractures, such as imaging quality, insufficient clinical information and fracture type^[65-68]. To interpret a radiograph of a patient with clinically suspected skeletal fracture, the radiologist must be aware of the circumstances of the injury, the patient's symptoms, and the clinical findings^[69-72]. Plain radiographs are still the main imaging tool in the Emergency Department for detecting bony fractures in patients sustaining trauma. Failure to identify fractures is the most common diagnostic error, which may account for 41%-80% of diagnostic errors in the Emergency Department^[73-75]. Orthopedic injuries predominate, constituting 75% of missed diagnoses^[76-80]. Detection of orthopedic injuries can be substantially improved with imaging search patterns directed at areas of recognized clinical abnormalities, resulting in a decrease in delayed or missed diagnoses of approximately 70% in otherwise occult injuries^[81]. Missed orthopedic injuries are most common in the periarticular regions, shoulder girdle, and feet. Spine injuries constitute approximately 10% of all initially missed diagnoses. These are especially common at the cranio-cervical junction and at the cervico-thoracic junction^[77]. Compared to extremity fractures, missed visceral injuries to the chest and abdomen are less common, with the liver and the spleen each contributing 10%-15%^[77]. Although diaphragmatic injuries are not particularly common, they represent about 5% of all delayed diagnoses, and a third to half are not diagnosed in the first 24 h^[82].

MALPRACTICE ISSUES IN OBSTETRIC SONOGRAPHY

Performing obstetric sonography carries significant medico-legal risk^[83], because missing a detectable fetal abnormality because of negligence often results in the largest indemnification payments in medical malpractice. Whether radiologists perform the examination themselves or rely on a technologist to obtain the images, it is the radiologist who is responsible for the quality of the examination. The radiologist must make sure that basic anatomy is depicted appropriately and that all measurements are accurate^[84,85]. Reports of sonographic studies should be completed in a timely manner. The attending physician should be called if significant abnormalities or fetal anomalies are suspected. General radiologists who miss subtle fetal abnormalities on sonography and claim malpractice immunity because they are not "sonographic specialists" cannot escape liability any more than those who miss a subarachnoid hemorrhage on a CT scan and claim malpractice immunity because they are not neuroradiologists.

COMMUNICATION OF FINDINGS TO REFERRING PHYSICIAN

About 10% of the patients in Renfrew's series were victims of communication errors, such as radiological examinations obtained on the wrong patients, incorrect examinations obtained on patients, laterality errors of

findings in radiology reports, delay in diagnosis because radiological images were allowed to be removed from the radiology department before they were interpreted, and failure to alert referring clinicians of important but unsuspected findings^[22]. A common cause of incidents related to a wrong patient examined is the misidentification of a patient with the same name of one who is intended to undergo the procedure, or a patient responding to the wrong name. However, the number of such incidents has been reduced by adoption of procedures in which the patient is required to give their name and date of birth.

The standard of communication between the radiologist and the referring clinician has become an important issue^[86]. Traditionally radiologists have believed their duty to communicate results did not extend beyond dictating and signing their report. In the USA, and more recently in Europe, an increasing onus is being placed on radiologists to ensure reports are communicated to the referring clinician, particularly when an urgent or unexpected diagnosis is made. Diagnosis provided by a written report does not conclude the responsibilities of the radiologist: direct communication by telephone has been an adjunct reserved for emergencies or for unusual and often unexpected findings^[86]. Kline *et al*^[86] report the case related to *Keene v Methodist Hospital* in which the court found both the hospital and the involved radiologist negligent for failure to communicate radiographic findings directly to the attending physician. The patient was examined in the emergency room for possible head injuries after a fight and then was discharged after an unremarkable physical examination. That day, the radiologist reviewed the skull radiographs and noted a possible fracture. Rather than communicate immediately with the clinician, the radiologist dictated his conclusions, which were transcribed 2 d later. The same evening, however, the patient became comatose and died. The court ruled that not only was the hospital negligent for failure to require adequate notification procedures, but also the radiologist was "...negligent in failing to immediately bring his report to the attention of the proper persons...". As stated by the ACR: "if there are urgent or significant unexpected findings, radiologists should communicate directly with the referring physician..."^[33]. Moreover, registration policies should be rigidly followed, particularly in situations in which breakdowns in policies are likely to occur, such as when patients are members of the medical staff. In such situations, to avoid that physicians themselves interpret the radiologic examination, radiologists should review all policies regarding registration and processing of patients to ensure that all radiologic examinations are accurately identified and presented to the radiologist for interpretation^[87].

COMMUNICATION BETWEEN RADIOLOGISTS AND PATIENTS

The Council of the ACR adopted Resolution 5: ACR Standard for Communication - Diagnostic Radiology. It recognizes that "...communication is a critical component of

the art and science of medicine and is especially important in diagnostic radiology"^[86]. Patients have the right to know of errors that have adversely affected the management of their care^[21,88]. Communication of this information to the patient must be undertaken in a sensitive manner after discussion between the radiologist and the clinical team^[89,90]. The Royal College of Radiologists have produced a suggested list of radiological clinical incidents for mandatory reporting, e.g. missed fracture implicated in subsequent permanent severe disability, missed cancer not identified until the tumor is judged to be at a higher stage than at the time of the miss^[89].

CONCLUSION

Radiology-related litigation occurs most often because of objective or subjective patient injuries. Obviously, radiologists do not intend to injure patients. In the longer term, if diagnostic errors are to be reduced, the system should change to allow patients to be seen by better trained doctors. Ideally, the legal system should help compensate injured persons without creating an atmosphere of distrust between patient and radiologist. Radiologic malpractice in the future will be affected by several factors: new imaging techniques, innovations in the processing of radiologic images, new standards published by scientific societies, as well as clinical guidelines issued by medical professional organizations.

We need to develop a safety culture within radiology departments where, every time we come across an error made by a colleague, we bring that error to our colleague's attention in a sensitive and constructive fashion. A radiology safety culture will only exist when the radiologist who made the error views such feedback positively as a learning experience.

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