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REVIEW

Misdiagnosis in breast imaging: a statement paper from European Society Breast Imaging (EUSOBI)—Part 1: The role of common errors in radiology in missed breast cancer and implications of misdiagnosis

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Abstract

Importance Misdiagnosis in breast imaging can have significant implications for patients, healthcare providers, and the healthcare system as a whole.

Observations Some of the potential implications of misdiagnosis in breast imaging include delayed diagnosis or false reassurance, which can result in a delay in treatment and potentially a worse prognosis. Misdiagnosis can also lead to unnecessary procedures, which can cause physical discomfort, anxiety, and emotional distress for patients, as well as increased healthcare costs. All these events can erode patient trust in the healthcare system and in individual healthcare providers. This can have negative implications for patient compliance with screening and treatment recommendations, as well as overall health outcomes. Moreover, misdiagnosis can also result in legal consequences for healthcare providers, including medical malpractice lawsuits and disciplinary action by licensing boards.

Conclusion and relevance To minimize the risk of misdiagnosis in breast imaging, it is important for healthcare providers to use appropriate imaging techniques and interpret images accurately and consistently. This requires ongoing training and education for radiologists and other healthcare providers, as well as collaboration and communication among healthcare providers to ensure that patients receive appropriate and timely care. If a misdiagnosis does occur, it is important for healthcare providers to communicate with patients and provide appropriate follow-up care to minimize the potential implications of the misdiagnosis. This may include repeat imaging, additional biopsies or other procedures, and referral to specialists for further evaluation and management.

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Key Points

Question *What factors most contribute to and what implications stem from misdiagnosis in breast imaging?*

Findings *Ongoing training and education for radiologists and other healthcare providers, as well as interdisciplinary collaboration and communication, is paramount.*

Clinical relevance *Misdiagnosis in breast imaging can have significant implications for patients, healthcare providers, and the entire healthcare system.*

Keywords Misdiagnosis, Mammography, Ultrasonography, MRI, Artificial intelligence

Introduction

Some of the most notable implications of misdiagnosis are delayed or incorrect treatment that may exacerbate the patient's condition, cause unnecessary harm, and even result in death. Misdiagnoses are usually predictable events with readily identifiable contributing factors, resulting from technical, perceptual, and interpretive errors [1]. Identifying contributing factors is one of the key aspects of developing systematic processes that reduce or mitigate misdiagnosis [2].

Interventions to correct the initial misdiagnosis may cause a loss of trust in healthcare providers leading to decreased satisfaction with healthcare services and reluctance to seek medical care in the future, with legal consequences including medical malpractice lawsuits and disciplinary action by licensing boards. In breast imaging, modalities and procedures at the highest risk of litigation were mammography (risk ratio (RR) = 4.0) and breast ultrasound (RR = 2.8). In comparison, in general radiology, the risk of litigation was lower than in breast imaging with total magnetic resonance imaging (MRI) (RR = 3.4) or total CT (RR = 1.9) [3].

In addition, the increasing quality of artificial intelligence tools make the explanation of a cancer missed by human readers and detected by AI model but ignored much more complicated. On the other hand, many false-positive cases may alter the radiologist's judgment and cause unnecessary recalls for work up.

This paper will give an overview of the role of common errors in radiology in missed cancer and the implications of misdiagnosis on both the patient and the breast radiologist. In Part 2, the authors will detail the specific causes of errors in breast imaging, and the EUSOBI board will propose dedicated solutions.

Common errors in radiology and their role in missed breast cancer

In the literature, common radiological errors have been defined by different authors [1, 4–7] and classified according to the reporting process in pre-reporting errors, reporting, and post-reporting errors [8]. Pre-reporting errors mainly correspond to technical errors (such as poor image quality, including incomplete imaging, incorrect x-ray exposure, and poor patient positioning) [5], whereas post-reporting errors are mainly caused by communication errors between the radiologist and other healthcare providers or the patient. Reporting errors are directly related to the radiologist and include perceptual errors (when the radiologist fails to perceive abnormalities at the time of interpretation and that abnormality is "evident," in retrospect, at a later time) [9], cognitive or interpretive errors (when the radiologist misinterprets the nature or significance of the abnormality due to incomplete knowledge or faulty reasoning or judgment) [6], overlooking findings (especially when reviewing large volumes of images), and underestimation of lesions (either the significance or the severity) [8]. These errors can have significant implications for patient care, including delays in diagnosis, inappropriate treatment, increased healthcare costs, and patient harm. In this section, we will detail the common causes of errors in radiology and which efforts can be undertaken to minimize them. In Part 2, we will detail specific causes of errors in breast imaging, and the EUSOBI board will propose dedicated solutions.

Carelessness and satisfaction effect

Although the level of radiologist's satisfaction and motivation in the breast imaging field is similar to other fields of radiology [10], one of the most common causes of missed cancer is fatigue and inattention and not the lack of proper care per se (Fig. 1). Fatigue is a well-known factor in radiology departments affecting diagnostic performance, as shown in studies that used measures such as subjective self-report, measurements of eyestrain and records of reaction time [11].

Particularly in breast imaging, fatigue can result in the most common type of cognitive error (that is premature closing) and there is a tendency to accept a preliminary diagnosis before the final verification [12].

One study added low prevalence to the list of false negative causes, showing that most of the cancers that were missed at low prevalence were found in high-prevalence settings [13].

In healthcare, the need for constant communication and coordination causes a high frequency of interruptions,

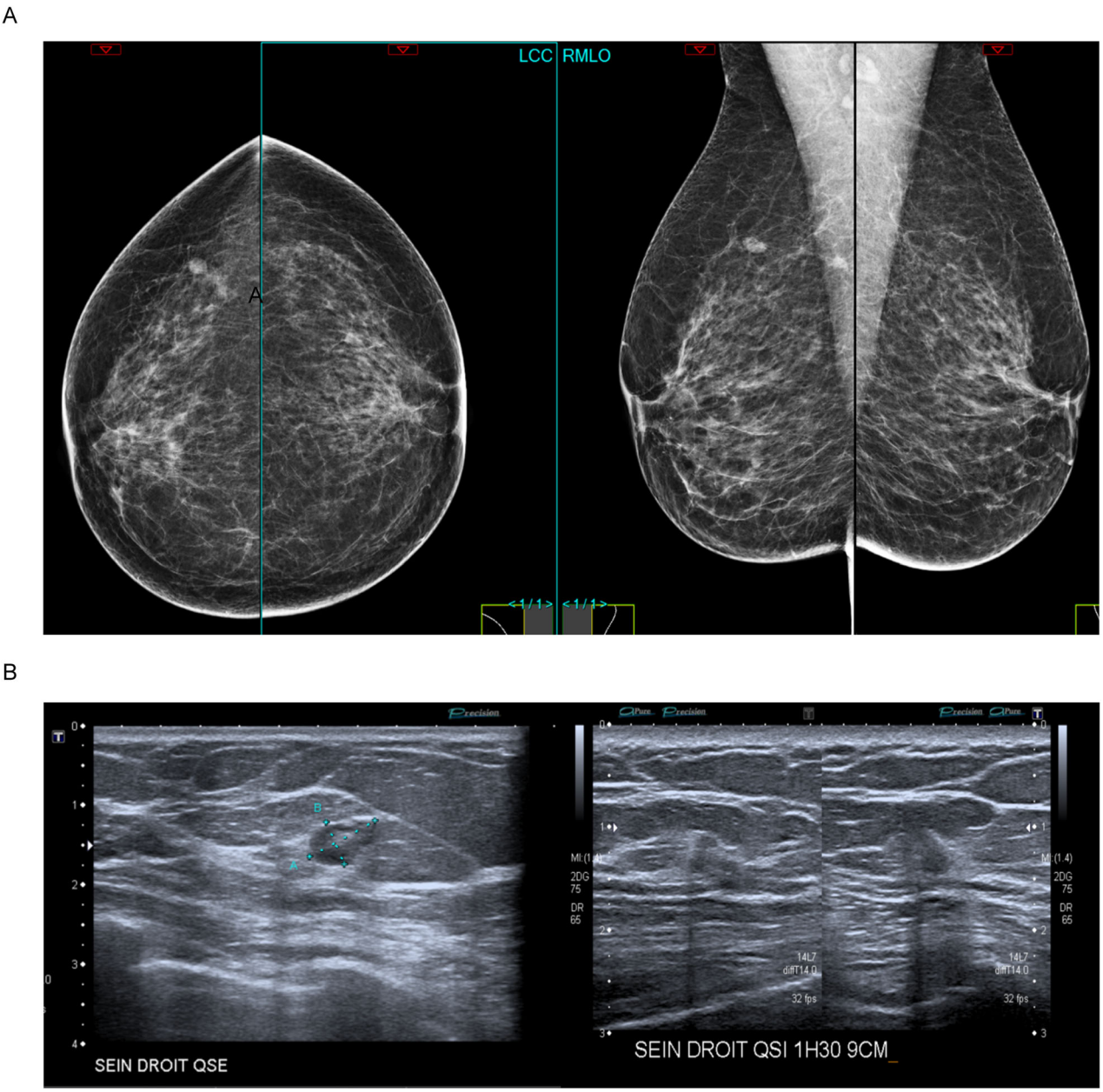

Fig. 1 Typical case of satisfaction of search effect. **A** Bilateral 2D mammography. **B** Breast ultrasonography. The first mass detected corresponded to a normal intramammary lymph node and hide the cancer which was behind (arrow)

distracting the radiologist and resulting in potential errors [14]. By combining evidence-based design, human factors, and architecture, some authors proposed a redesign of the radiology reading room that aims to create an optimal workspace for the radiologist to remove distractions and interruptions [15].

Satisfaction of search is also a well-known phenomenon, in which observation of an obvious finding misleads the radiologist into not looking carefully for other additional lesions. However, this can directly impact on failure to diagnose multifocal and multicentric breast cancers or even contralateral breast cancer, which can be seen in up to 9%–10% of patients at MR imaging [16]. Satisfaction of search can also occur in cases of an obvious benign lesion with a subtle cancer. The radiologist must not be satisfied with finding just one lesion, but must systematically search for others, whether benign or malignant.

Lack of proper training

Although mammography is regarded as the main tool for screening to reduce mortality from breast cancer, it has some limitations, including occult cancers. Amongst other factors, human error remains a major limitation to early breast cancer detection [17]. One of the most well-researched reader characteristics is the status of the training. Although the number of years reading mammograms did not show an association with diagnostic efficacy, studies showed that reading volume improved cancer detection rate (CDR) and sensitivity but also that older readers make fewer false-positive errors. In contrast, specialization in breast imaging alone, with or without affiliation with an academic medical center, is associated with better performance [18, 19]. The number of years reading mammograms does not necessarily improve detection, but a combination of readers' characteristics such as feedback, lifetime mammograms read, number of CME credits, and practice type does improve performance [20]. Improved performance with higher reading volume may be related to increased exposure to normal and abnormal features, and to their ability to discriminate normal mammograms [21].

Although the literature on the relationship between breast fellowship and performance is inconsistent due to the differences between countries, most of the studies showed that breast specialists had better CDR, sensitivity, specificity, as well as higher positive predictive value of recall and lower abnormal interpretation rates [22]. Studies show that the number of breast cancers diagnosed increased by 50% after general radiologists took dedicated breast imaging courses [23].

Official, obligatory special breast license exams, requirements for a minimum number of reads per year, and regular clinical performance assessments exist in most countries and can help radiologists evaluate their own level of knowledge and motivate them to continuously update their professional knowledge. In the UK, for example, breast screening readers are recommended to read 5000 mammograms per year [24], which equates to approximately 3 cancers per year. PERsonal perFORmance in Mammographic Screening (PERFORMS) has been developed as a UK nationwide self-assessment scheme [25], which is now mandated by Public Health England and has been shown to improve readers' skills at detecting malignancy. Other examples exist in many other countries, which are beyond the scope of this paper to discuss.

Systematic personal analysis of the daily routine work's results (output control) and feedback is also an important factor in self-estimation and continuous learning and must be encouraged both at a personal and institutional level [26].

Diagnostic laboratory errors

Breast radiologists can contribute to preanalytical laboratory errors that occur before the specimens are measured, mostly involving biopsies [27]. These errors may affect the reliability of the test results and patients' safety and furthermore, they can cause serious harm to patients through significant diagnostic delays and inappropriate treatments [28]. One study published in 2007 showed that many labeling errors occurred in biopsy specimens most commonly involving breast, skin, and colon [29].

Labeling errors can occur at any step of the process and can range from unlabeled specimens to misidentification of the patient, wrong biopsy site and laterality. Luckily, although specimen labeling errors have a baseline rate of 4.2% in interventional radiology departments, in the end, just a small fraction of these errors can affect the patient's outcome due to additional verification in the pathology department [30, 31].

At this date, one of the most efficient methods to minimize labeling errors is to implement two unique patient identifiers and that the specimen containers be labeled in the presence of the patient, before leaving the room [32]. Schwartz et al also showed that double-checking of specimen labels can be used efficiently in radiology departments [33].

The pathology request or report form that accompanies biopsy specimens should indicate the date the biopsy was taken, the location of the lesion and laterality, the indication (for example, microcalcifications or mass), BI-RADS category (for radiological-pathology concordance), the image-guidance method, size of needle and number of cores used [34].

It is crucial for a concordant imaging-pathology result to have adequate targeting and sampling. The number of samples is influenced by the type of biopsy performed, which is determined by the lesion type. It is generally recommended at least three (preferably five) for 14-gauge core needle biopsy, twelve for 11-gauge, and six for 9-gauge vacuum-assisted biopsy [35]. An intact specimen that is more than 1 cm in length and sinks to the bottom of the liquid fixative is considered adequate sampling. Adequate targeting should be confirmed by obtaining ultrasound images of the entire length of the needle passing through the lesion, specimen radiography after biopsy of calcifications, or additional imaging after MRI biopsy to verify the position of a released marker clip. It is important, if inserted, to document the location of the tissue marker after biopsy with a mammogram, and to document any marker clip migration. Any discordant results between imaging and pathology must be quickly acknowledged to revise the previous imaging studies and

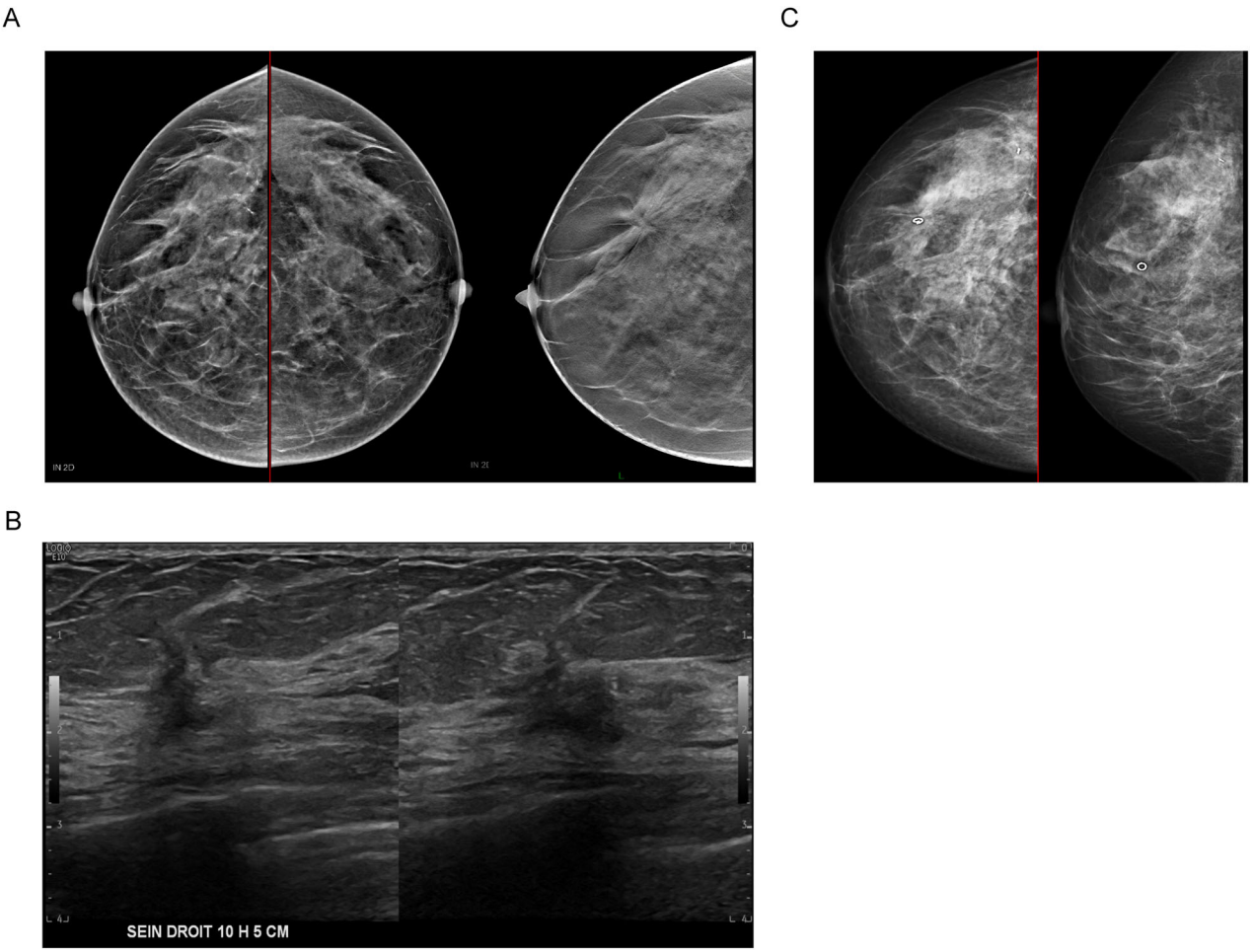

Fig. 2 Management errors 53-year-old, familial history (mother: 50-year-old and sister: 48-year-old), referred for palpable mass. Architectural distortion is mainly seen on digital breast tomosynthesis acquisition (**A**) and corresponded to a echoic nodule BI-RADS 4C (**B**). A CNB under US guidance was performed and revealed radial scar. This result was not concordant as a radial scar that is usually non palpable mass. Six months later FU was performed and a VABS followed by a marker was indicated and revealed a radial scar with FEA. On MG after biopsy (**C**), the marker did not correspond to the architectural distortion. Thus, a surgery was indicated and finally revealed a IDC grade 1 measuring 8 mm

to further recommend a second biopsy or surgical excision [36] (Fig. 2).

Artificial intelligence implementation: automatization bias and AI risk model

The implementation of artificial intelligence is the future. After the initial excitement and enthusiasm for the benefits of traditional CAD, the overall reading accuracy of radiologists was demonstrated to be reduced [37] with a decreasing specificity by increasing recall rates, with no increase in sensitivity or invasive tumor characteristics [38]. With new AI CAD systems, the diagnostic performance of AI combined with human readers is better than humans alone [39, 40]. However, the automatization bias is the propensity for humans to favor suggestions from automated decision-making systems, and it is a known source of cognitive error in human-machine interactions. With the increasing role of artificial intelligence in breast imaging, recent studies evaluate the impact of the interaction between the radiologist and the machine. Dratsch et al demonstrated that a reader of any experience is worse at assigning the correct BI-RADS scores for cases in which the purported AI suggested an incorrect BI-RADS category [41]. This phenomenon was particularly significant in inexperienced readers, with a decrease in reading time and an increase in false-positive cases. False-positive cases should not be considered "better safe than sorry", as approximately 40% of women experiencing a false-positive mammogram labeled the experience as "very scary" or the "scariest time of my life [42]. The reaction of the patient is variable, and some patients will be more likely to return for subsequent screening [43, 44],

while others become less interested in future screening with lower screening reattendance rates after false-positive mammography findings [45, 46]. False-positive diagnosis can lead to skepticism and reduced public trust in breast cancer screening programs Some individuals may opt out of screening altogether, fearing the potential consequences of overdiagnosis and overtreatment. Lower reattendance is particularly observed in women who underwent a false-positive biopsy [47].

However, the negative impact of a "false-positive" biopsy may be discussed as a personal history of breast biopsy could be information regarding the risk of developing breast cancer in the future. The cumulative effect of a biopsy describing benign or atypical breast pathology with other factors, such as breast density, on the risk of breast cancer was proven in a large cohort [48]. Many models of breast cancer risk include a "false-positive" biopsy that may impact a personalized breast cancer screening strategy [49]. In this setting, the negative value of a "false-positive" breast biopsy should be reconsidered as this event may help to detect breast cancer in the future and be included in some AI models that evaluate the risk of a woman developing future breast cancer. Depending on this level of risk, a personalized prevention plan and/or supplemental or more frequent imaging would be proposed. Thus, based on an AI model, we could increase or decrease the interval between screening, or opt for a breast MR screening instead of a digital mammography. If the model is not adapted or insufficiently validated on a representative population, this could increase the number of missed cancers or overdiagnosis. Radiologists and researchers should recognize the limits of AI algorithms in order to prevent misuse or overuse, which could otherwise sow distrust and cause patient harm [50].

A recent paper related to women's perceptions and attitudes to the use of AI in breast cancer screening reveals that most of the females undergoing screening approve of the introduction of AI, although only as a support to the radiologist and not in substitution [51]. Accountability in case of AI errors is still unsolved and ethics recommendations are required. The performance of AI solutions (software) shows significant differences [52]. Because of its economic impact, decision-makers and AI companies are forcing the introduction of human + AI screening solutions, instead of double human reading.

Actually, there are neither established international standards for the regularized evaluation process of these software nor precise standard indicators, e.g., detection rate and false-positive/negative rate, although retrospective studies have compared the standalone tool to the first reader of a double reading system. The Newnham report, which proposes criteria for international evaluation, has recently been published [53]. However, without consensus, the strength of marketing efforts could influence AI software selections for public screening programs. Informed decision-making should be undertaken by professionals to avoid diagnostic failures and an adverse effect on the public's trust in AI for mammography screening.

Implications of misdiagnosis on clinical practice

Misdiagnosis of diagnostic studies (perceptual and interpretative error) is the leading cause of diagnostic delays, which is more common than the delay of failure in ordering diagnostic tests or delay in consultation (49% of the cases vs. 27% and 17%) [54]. False negative mammograms are one of the principal reasons for delay in the diagnosis of breast cancers, mostly because they give physicians and patients a false sense of reassurance. Between 23–34% of the breast cancers detected on a mammogram are, in fact, false negatives on previous mammography, with a higher prevalence in younger women with dense breasts. Interval cancers are more frequently associated with nodal involvement, partly because these types of cancers are often more histologically aggressive [55, 56].

Delay in diagnosis is the most cited reason for claimed negligence in medical malpractice [57–59]. Regarding breast cancer malpractice litigation, delay in diagnosis was cited as a reason for claimed negligence in 82% of cases with a length of delay between 4 and 30 months [58]. The study also showed that claimants tended to be younger than the median age at diagnosis for breast cancer. Besides diagnostic delay, the other factors related to claimant payments are lack of surgical referral and lack of recommended follow-up.

Breast radiology is the most frequently sued subspeciality in malpractice lawsuits and mammography is the most prevalent procedure involved in medical malpractices against radiologists [60]. This is partly due to three combined factors of public misconceptions [61]: (1) That women have a very high risk of dying from breast cancer, (2) that mammography has the ability to detect 100% of breast cancers, (3) that detecting cancer at a very early stage guarantees a cure. The radiology community is virtually unanimous in its recognition that the accuracy of mammography is considerably less than 100%, and, in fact, radiologists acknowledge that a review of mammograms interpreted initially as normal in women who later develop breast cancer that many of the cancers can be seen retrospectively [60].

When a woman is referred for a palpable mass and cancer is missed, the risk of malpractice lawsuits is the highest; The National Institutes of Health blames a "triad of errors" that involves young patients, self-discovered

breast lumps, and negative mammograms. The malpractice phenomenon in breast radiology is differently represented worldwide. Studies have documented that a delay in diagnosis of breast cancer is the most common malpractice claim within the United States, with breast radiologists among the most cited defendants [62]. In England, a retrospective study showed that the largest number of medicolegal claims concerned delayed or missed diagnoses of cancer, the majority related to breast radiology [63]. A study from the Netherlands highlighted that the interpretation of screening mammography represents one of the most difficult tasks in radiology, and the discrepancy between actual sensitivity and the public's perception of efficacy has the potential for major legal consequences for the screening radiologist [64].

Although missing a breast cancer is often difficult for a breast radiologist both emotionally and professionally, it is not uncommon, with an estimated 10–20% of all cancer cases misdiagnosed [65]. Understanding and reviewing the missed cancers may decrease the number of errors, but sometimes errors are still unavoidable. It is well-documented that a lawsuit can be one of the most emotionally damaging experiences for a radiologist [65]. Even just the potential for litigation is one of the biggest stressors that radiologists face and is cited as one of the major reasons as to why trainees would not consider pursuing a career in breast radiology, which has implications for the already diminishing workforce of breast radiologists [66]. It can lead to the practice of so-called "defensive medicine", and the concern over litigation from errors has led to a reduction in the number of radiologists willing to read mammograms in the ultrasonography (US), which puts increased pressure on those radiologists remaining [67].

Medical malpractice suits are time-consuming, drawn-out, and sometimes confrontational processes that can have significant impacts on the radiologist. More than 95% of physicians react to being sued by experiencing periods of emotional distress during all or portions of the lengthy process of litigation [68, 69]. Intense feelings of incompetence, inadequacy, or guilt may occur throughout this period, including symptoms of major depressive disorder and the onset or exacerbation of a physical illness. These emotional effects can last for weeks or up to several years, depending on several factors. Indeed, a post-traumatic-type stress reaction is well-documented and serious enough to be dubbed "medical malpractice stress syndrome (MMSS)" in the US [70]. Psychology studies have compared the stress of being involved in a medical malpractice case to that of victims involved in a major disaster, which will inevitably have an impact on the performance of the individual radiologists to perform their role, as well as increased pressure on their colleagues who may have to take on additional work.

The term second victim was initially coined by Wu et al in their description of the impact of errors on professionals [71]. Second victims are healthcare providers who are involved in an unanticipated adverse patient event, in a medical error and/or a patient-related injury, and become victimized in the sense that the provider is traumatized by the event. Frequently, these individuals feel personally responsible for the patient outcome. Many feel as though they have failed the patient, second-guessing their clinical skills and knowledge base. Scott et al identified and named six stages of recovery and stage characteristics in response to medical errors [72].

The outcome is influenced by several factors, one of which is the support given by the professional's institution. A survey of more than 3000 physicians validated that, when involved in medical errors, support was needed but was largely unaddressed [73]. Seeking help can sometimes be perceived as a sign of professional/personal weakness and vulnerability. Scott et al concluded that in the early stages, trained supervisors and colleagues would be ideal for providing support, and in the later stages, mental health professionals could be beneficial [72]. Hospitals publish clear guidelines for handling adverse events and should share their institutional policy on open disclosure. The implications for clinical practice should be creating a strategy to enable supporting networks at individual, organizational, and national levels.

Conclusion

Overall, misdiagnosis can have far-reaching consequences for patients, healthcare providers, and the healthcare system. Individual radiologists also risk significant implications from legal processes. Therefore, it is critical to prevent and address misdiagnosis promptly to ensure the best health outcomes for patients. There is enhanced public attention in breast screening with the expectation of perfect performance. Many controversies and misconceptions still exist regarding breast screening which risks eroding public trust in screening.

Clearer statements and explanations are needed to improve communication for patients with the limitations, advantages, and disadvantages of this method openly discussed. A general consensus would be advantageous regarding screening side effects and limitations in order to avoid considering them as medical faults.

Introduction of AI in screening is a very critical process as artificial intelligence may have a role to play to potentially reduce this error by 20% [74]. Without the existence of a generally accepted, independent, standardized evaluation method of the real figures of the performance, other influences including commercial factors could affect the selection among the different AI software options. This is

the responsibility of decision-makers, which affects the detection rate and misdiagnosis numbers as well.

Careful and precise documentation, communication among specialties, and patient information are essential, as a screening-diagnostic workup consists of several steps, and any discordance could lead to inadequate treatment.

Abbreviations

AI	Artificial intelligence
MRI	Magnetic resonance imaging
US	Ultrasonography

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Compliance with ethical standards

Guarantor

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Conflict of interest

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Statistics and biometry

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Informed consent

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Ethical approval

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Study subjects or cohorts overlap

Not applicable.

Methodology

- Review

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