SCREENING & BEYOND

MEDICAL IMAGING IN THE DETECTION, DIAGNOSIS AND MANAGEMENT OF BREAST DISEASES
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INTRODUCTION

Each year since 2012, as a part of its celebration of the International Day of Radiology (IDoR), the European Society of Radiology (ESR) has brought together several professional medical societies to create a special book to demonstrate the dedication, hard work and special skills of a particular radiological topic.

The ESR, together with the Radiological Society of North America (RSNA) and the American College of Radiology (ACR), introduced the IDoR as a way to raise general awareness of medical imaging and to help highlight the contribution of all the teams of experienced and highly-trained radiology professionals to improving the diagnostic opportunities for patients. Every IDoR so far has also had a main theme; one of the many "subspecialties" of radiology that focus on specific diseases or anatomical regions. Therefore, the purpose of this book you are reading is to highlight the people, methods, and technology involved in this year's main theme: breast imaging.

Breast cancer is the most common malignant tumour that affects women all over the world. Roughly one woman in every eight suffers from breast cancer during her lifetime, and over the years, the average age of women affected by breast cancer has been increasing. Most breast cancer patients are found in industrialised nations, but the number of affected patients in lesser developed countries is increasing.

Breast cancer is not a modern disease; it has been known about for a very long time. The first attempts to search for and establish imaging examinations to visualise and diagnose the breast are more than hundred years old. Since then, the enormous improvements made in this subspecialty field of radiology have resulted in a highly complex diagnostic approach that relies upon consultants with high levels of expertise to ensure the most accurate quality of detection, diagnosis, image-guided tissue sampling, pre-operative tumour location, intraoperative specimen radiography, and post therapy follow-up.

As the professions within the field of breast imaging have grown, so have the structures surrounding them, and naturally national and international breast imaging and senology societies have been founded, like the Society of Breast Imaging (SBI) in the US in 1985, and the European Society of Breast Imaging (EUSOBI) in 1998. Most of the authors of this book are board members of such national and international breast imaging or senology societies (including the SBI or EUSOBI), which exist to support the medical field of breast imaging. These societies are dedicated to promoting research, training, and the exchange of knowledge within the field. They organise conferences, forums, symposia, workshops and congresses, and publish journals, papers, and professional guidelines, all in the name of keeping the practitioners of the profession up to date with the full potential of their medical discipline. They also represent the interests of the field of breast imaging to public authorities, nationally and internationally, and work toward increasing public awareness of breast healthcare and the role that imaging plays within it.

We, as professionals working in breast radiology, are very happy to have the unique opportunity to share our working experience with you and explain the different aspects and developments of the wide spectrum of radiological methods for the diagnosis of breast cancer, including x-ray mammography, ultrasound, magnetic resonance imaging, and minimally invasive biopsies.

In this book we have tried to give you a broad look at the wide world of breast imaging, from the different aspects and controversies regarding breast cancer screening programmes and radiation therapy, to important points for achieving high quality in imaging, diagnosis and reports. We also provide an overview of the history of breast imaging, an insight into the research behind the technology, and recommendations for women’s information about the common breast imaging methods, in cooperation with Europa Donna, an independent non-profit organisation that represents the interests of European women regarding breast cancer.

As well as these articles, written by some of the most prominent experts in the field, we have also conducted interviews with data representatives of the breast imaging world from Australia, Europe, South Africa, South America, and different aspects of daily breast imaging practice in each region. Finally, the book is concluded with an interview with a radiographer, representing one of the most important professions involved in medical imaging, responsible for the correct interpretation of the various imaging examinations, and generating the radiological images that are used by radiologists to diagnose diseases.

We are delighted and proud to provide you with an insight into our daily work and expertise, and we hope that you will enjoy reading this book, improving your own knowledge of breast imaging, and getting to know the medical field that is dedicated to serving not only breast cancer patients, but all of the millions of women who undergo screening every year, throughout the world.
IT'S TIME TO STOP THE MISINFORMATION ABOUT BREAST CANCER SCREENING

END THE CONFUSION ON MAMMOGRAPHY SCREENING: COMMUNICATIONS TOOLS AND STRATEGIES USED BY THE SOCIETY OF BREAST IMAGING

BREAST DENSITY AND SUPPLEMENTAL SCREENING

IN SUPPORT OF BREAST CANCER SCREENING MAMMOGRAPHY

RADIOThERAPY IN BREAST CANCER
For unclear reasons, breast cancer screening has been one of the contentious medical issues of all time. The debate about its merits has been ongoing for more than fifty years. Much of the debate has been due to the publication of scientifically un- supportable concepts such as the falla- cious suggestion that invasive breast cancers would disappear if left unde- tected by screening. This has come to be known as “conventional wisdom” by some, even though there are virtually no credible reports of this ever happening, in the few cases that have been reported. Reports that breast cancer was sys- temic from the start and that early detection would have no benefit was a qualified recommendation while the data do not support this. By grouping and averaging data, ana- lysts made it appear as if there was a major change in the parameters of screening or that the benefit of screening was greater among older women, when the data do not support this. The qualification was not what the science showed, but reflected the individual biases of the panel and their guess (no science) at what the most lives are saved by screening starting at the age of 40. The randomised, controlled trials have proven this and observational studies have confirmed this, and this is why the age of 40 is the appropriate threshold. In fact, every major group in the U.S. now agrees that the most lives are saved by screening starting at the age of 40. The American Cancer Society, also relying on an inexpert panel, never- theless, clearly agreed that most lives are saved by annual screening start- ing at the age of 40: “Women should have the opportunity to begin annual screening between the ages of 40 and 44 years (qualified recommendation).” It was a qualified recommendation only because, as they state: “The majority of individuals in this situation would want the suggested course of action, but many would not.” In other words, the panel agreed that the most lives are saved by screening starting at the age of 40. The qualification was not what the science showed, but reflected the individual biases of the panel and their guess (no science) at what women might or might not ‘want’. In fact, the scientific evidence shows that breast cancer screening is one of the major advances in women’s health in the last fifty years. In the U.S. the death rate from breast cancer had been unchanged for fifty years dating back to at least 1940. Screening began in large numbers in the mid 1960s6 and soon after, the death rate began to fall. As more and more women have participated in screening it has con- tinued to fall, so that now there are more than 35% fewer women dying of breast cancer each year. Therapy has improved, but in women where screening has been introduced into the general population where women have access to modern therapy, the major decline in deaths is among women with access to screening7. There has never been a randomised, controlled trial comparing annual screening to biennial or longer, but...
Taber et al showed that the number of cancers detected between screens (interval cancers) as expected, increases with the time between screens.20 Computer modeling can be used to determine the importance of the time between screens (screening interval). The computer models of the National Cancer Institute’s Cancer Intervention and Surveillance Modeling Network (CISNET) all show that the most lives are saved by annual screening starting at the age of 40.21 Comparing women who are screened every year to those screened every two years, it is expected that the size and stage of the lesions is still important22 and that women screened with a shorter interval have more favourable tumour characteristics23,24.

The decline in deaths from screening was proven in the randomised controlled trials (RCT’s), and has been confirmed in multiple observational studies25,26. As has been seen in the United States, when screening is introduced into the general population, the death rate from breast cancer declines.27

Additional support for screening comes from evaluating women who have died from breast cancer. In two of Harvard’s main teaching hospitals, more than 70% of the women who died from breast cancer were among the 20% who were not participating in screening (this was true for women in their forties as well)28. As the value of mammography becomes clearer each year, the effort to reduce access has accelerated.

**‘OVERDIAGNOSIS’ - ‘OVERSTATING’: AN UNSUSTANCIATED PROBLEM**

As noted earlier, there are legitimate concerns about the management of ductal carcinoma in situ (DCIS), but these are not new, and there have been numerous efforts to try to ‘tailor’ treatment, but they have resulted in undeniable recurrence rates.20,22 These should be kept separate from discussions of invasive cancers, but, in an effort to confuse the issue, analysts have grouped DCIS with small invasive cancers.20 This is a ploy to dilute the results for the invasive lesions and should not be tolerated in publications.

There is not enough space here to address all of the misinformation that has been promulgated concerning the suggestion by a few that there are thousands of invasive cancers diagnosed each year as a result of mammography screening that would regress and even disappear if left undetected by screening. The prestigious New England Journal of Medicine published a paper that should have never passed peer review that claimed that in 2004 alone there were 70,000 breast cancers that would have regressed or disappeared if left undetected by mammography. It is astonishing that mammography was blamed, since the authors actually had no idea which cancers were found by mammography since they had no idea which women actually had mammograms. In addition, they based their claims on what they admitted, their “best guess” as to what the rate of cancers would have been had screening not begun in the 1980s! Based on the difference between the actual numbers of cancers diagnosed in 2004 and their guess (which was lower), they claimed that the numbers of cancers above their guess must not be real and would have disappeared had they not been detected by screening. In fact, actual data (and not a ‘best guess’) show that there has been no evidence of regression in interval cancers21. A paper in the New English Journal of Medicine that provided no data on mammography, and was based on a ‘best guess’ has been given great credibility, and, as a consequence it is now ‘common knowledge’ that mammography leads to massive overdiagnosis. This is sheer scientific nonsense. There are now two additional independent analyses of this paper that show that it is not scientifically supported21,26,27. It is repeatedly referenced in efforts to reduce access to screening.

Others have suggested huge numbers of interval breast cancers. All have suffered from scientific flaws.21,26. The treatment of lesions classified as DCIS had raised legitimate disagreement about management, but the data show that small invasive cancers will grow to become large invasive cancers and that early detection saves lives! When there is overdiagnosis, it is a challenge for pathologists just as ‘overtreatment’ is a challenge for oncologists, since the possibilities are not confined to mammographically detected cancers. At most, 10% of women who are treated for breast cancer actually benefit from systemic treatment26. Preventing overdiagnosis and overtreatment by denying women access to screening is like preventing car accidents by removing all the engines.

**‘VALUE BASED’ MEDICINE**

Knowing that they would lose if they argued that they did not want to spend the money to save those lives, those seeking to reduce access to screening have coined a new phrase ‘value based medicine’.6,7 As Harris has clearly stated: “... people need to understand that with this approach, there will be some women who die if we go to a high value approach rather than a maximal detection approach, we are going to miss some cancers. You have to give in to that”20. The effort to reduce access to screening is clearly about the money. Welch argued for the insurance companies by suggesting that they should no longer be rated based on the participation of their insured women in screening6. An article in the Annals of Internal Medicine claimed to compare the cost/benefit of annual screening starting at the age of 40 vs. biennial starting at the age of 50. They left out the benefit part, but claimed a $7 billion saving. What they left out was that premature death rate is not society’s concern. There is a great amount of money that is lost when women die unecessarily so that we can save women who might not have cancer20. The premature death of a woman in her forties costs $14 million, and the costs of care in the final year of life for a woman dying of breast cancer is an additional $260K. ‘Value based screening’ may not be as big a money saver20 as some would like us to believe. It is time to stop the misinformation.
During the last five years, breast imagers in the United States have been fighting an uphill battle to communicate the importance of life-saving mammographic screening to women. Despite the obvious advantages of mammography as a key component of preventive healthcare for women (breast cancer mortality in the United States has decreased by 35% since widespread screening mammography began in the 1980s), considerable variance in guidelines from researchers and stakeholders on when to start screening, and how frequently women should get mammograms, is leaving many women and their providers frustrated and confused. They are confused because they are receiving different recommendations from respectable experts and organisations. In addition, the American media do not always relay the information on mammography screening in a clear, understandable manner. Instead, they often focus on its controversies. The two biggest points of contention in this debate are when to begin screening and how often to get screened. The confusion began in 2009 when the United States Preventive Services Task Force (USPSTF) did not recommend that women aged 40 to 49 receive annual screenings and, furthermore, recommended that women aged 50 to 74 just be screened every other year. In 2015, the American Cancer Society also released new guidelines that stated that women should begin annual mammography screening at age 45 and could transition to biennial screening at age 55. The release of these guidelines has compounded the confusion created by academic journal articles, which argued that annual mammograms lead to overdiagnosis and overtreatment of breast cancer. Regardless of these studies’ scientific flaws, they receive significant media attention and have had a negative impact on women’s healthcare decisions. It is dangerous and deadly to let the confusion surrounding mammography continue. Breast imaging experts in the United States recommend that women begin annual mammography screening at 40 (and earlier if they are at high risk). Recognising the importance of these recommendations and that lives are at stake, the Society of Breast Imaging has implemented several communications methods to ensure women are getting accurate information on breast cancer screening. Below we describe these tactics, which can also easily be employed for other breast cancer screening issues.

The SBI’s strategies were developed and implemented to not only reach women directly but also indirectly through the media, advocates, policymakers and stakeholders. Communicating with all these groups maximises the chances of the message getting through to the intended audience. When developing a campaign, you need to target a multitude of audiences (especially ones your main audience trusts) in order to realise your goals.

One strategy the SBI executed was the creation and implementation of End the Confusion ([https://www.sbi-online.org/endtheconfusion/Home.aspx](https://www.sbi-online.org/endtheconfusion/Home.aspx)), a campaign and website built to inform and engage providers, stakeholders and the public so that the confusion associated with screening mammography is
CHAPTER 1: SCREENING & THERAPY

access a host of materials, including media, stakeholders and providers can to increased mortality. By visiting shows that these actions can lead on mammography, as science not want women to delay or forego screening mammography, as science is prepared to make informed deci- tion mammography screening so they can to make informed deci- sions about the importance of mammography screening. The SBI’s goal is to promote the campaign widely and target those who would most benefit from the infor- mation. Since the site launched at the beginning of 2016, it has been visited 4,149 times (as per September 30, 2016).

Given the insurance coverage implica- tions of the USPSTF’s recommendations, it is critical to make sure policymakers are aware of the benefits of mammography screening. A tactic that was successful for the SBI was to co-host, with a stake- holder organisation, a Capitol Hill Briefing, which targeted legislators and their staff. Panelists included experts in the field, as well as policymakers who champion this issue. The SBI used this formula success- fully, and partnering with other organisa- tions that have a stake in breast cancer issues, helped to amplify the message.

Creating engaging social media posts that communicate the importance of breast cancer screening has led to a substantial increase in the SBI’s follow- ers. As of September 2016, the SBI has attracted 962 followers on Twitter and 5,981 likes on Facebook. When appro- priate, the SBI responds to questions and engages in conversations started in response to a post. Multiple stakehold- ers and individuals have responded to social media posts, proving that the information has resonated with them.

Breast cancer has ended the lives of too many women and has devastated their families. It remains the second leading cause of cancer deaths among women in the United States, and the death rate is highest among women who are not screened regularly and present with advanced cancers.

From experience with our patients, breast imagers know that mammograms have detected cancers at an early stage when treatment is most effective. Patients are alive today because they practice the kind of preventive healthcare that is recommended by the Society of Breast Imaging, the American College of Radiology and other respected organ- isations. Ultimately, this is why the SBI has dedicated so much of its time and resources to communicating the impor- tance of screening mammography. It goes back to our mission: we want to save lives through early detection.

Although our efforts have been suc- cessful, it has not been an easy road, and the work is far from over. The SBI is committed to continuing to com- municate the importance of annual mammography screening using the techniques described in this article. As new techniques are developed, they will be explored, and the appropriate, disseminated (especially on social media). If you have questions about any of these tactics, including End the Confusion, please contact the Society of Breast Imaging at info@sbi-online.org. The SBI encourages you to visit the website (www.endtheconfusion.org) and share it with your colleagues. Most impor- tantly, continue to discuss breast cancer screening with your patients, their providers and your colleagues outside of breast imaging, and pro- vide them with appropriate informa- tion and recommendations. The SBI also encourages the use of any or all of these tactics with any breast can- cer screening issue you are trying to communi- cate. We have seen great success and believe you will too. Be persistent, be clear and be passionate.
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BREAST DENSITY AND SUPPLEMENTAL SCREENING

BY JENNIFER A. HARVEY AND WENDIE A. BERG

IMPORTANCE OF BREAST DENSITY

Dense breast tissue is common and normal.

About 40% of women over the age of 40 have dense breasts. Dense breasts are more common in younger women and the breasts tend to become more fatty after menopause. Dense breast tissue reduces the effectiveness of mammography and increases the risk for developing breast cancer.

Defining breast density

In clinical practice in the United States, Breast Imaging Reporting and Data System (BI-RADS) breast density categories are included in reports to indicate the degree of mammographic breast density (Figure 1). The “heterogeneously dense” and “extremely dense” categories are considered “dense.” In their early 40s, about 13% of women have extremely dense breasts and 44% have heterogeneously dense breasts; by the early 70s, 2% have extremely dense and 24% heterogeneously dense breasts1. Because radiologists vary in how they use BI-RADS density categories, computer-based methods have been developed to improve consistency.

Density and breast cancer risk

At least 15 studies have demonstrated a moderate to strong association between mammographic density and breast cancer risk2. Women in the extreme density group are about four times more likely to develop breast cancer than women with fatty breasts. Since most women are in the middle two categories of density, it is more appropriate to communicate that women with extremely dense breasts are about twice as likely to develop breast cancer as the average woman. Extreme breast density as the sole risk factor does not put women into a high lifetime or 10-year risk of breast cancer.

Density and masking

Breast cancers, which appear as white areas on the mammogram can be hidden by dense breast tissue; this is referred to as “masking.” Women with extremely dense breasts are four times more likely than women with fatty breasts (A) to develop breast cancer but twice as likely as the average woman to develop breast cancer. When there is a more focal area of density in an otherwise low density mammogram (E, arrow), the density should be classified as heterogeneous rather than scattered.

FIGURE 1

Bi-RADS breast density categories: A) the breasts are almost entirely fatty; B) there are scattered areas of fibroglandular density; C) the breasts are heterogeneously dense, which may obscure small masses; and D) the breasts are extremely dense, which lowers the sensitivity of mammography. Women with extremely dense breasts are four times more likely than women with fatty breasts to develop breast cancer but twice as likely as the average woman to develop breast cancer. When there is a more focal area of density in an otherwise low density mammogram (E, arrow), the density should be classified as heterogeneous rather than scattered.

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Dense breast tissue is at greater risk of having a cancer that is not detected by screening mammography. Because of this, women with dense tissue are at increased risk of having a cancer that presents due to symptoms, such as a lump. During the interval between recommended rounds of screening (one year in the U.S., but may be two or three years in other countries), which is considered an "interval cancer". These can represent up to one-third of the cancers diagnosed in women undergoing screening mammography.2

Even when breast cancer is detected at screening, women with dense tissue have cancers that are larger, more likely lymph node positive (i.e. cancer has spread to the lymph nodes), and of higher stage than women without dense tissue.4,5 A study from Sweden with 25-year follow-up showed an almost double risk of death for women with dense tissue compared with non-dense tissue.6

In the United States, the masking of cancer by dense tissue has become a political issue beginning with Connecticut, which became the first state to enact legislation requiring that supplemental screening in addition to mammography is increasingly utilised for women with dense tissue.7

**SUPPLEMENTAL SCREENING IN DENSE BREASTS**

Mammography is the only type of imaging that has been studied in long-term randomised trials and has been proven to reduce breast cancer deaths. Adding supplemental screening beyond mammography may allow earlier detection, thereby producing improved outcomes.

**TOMOSYNTHESIS**

Digital breast tomosynthesis (DBT), often referred to as 3D mammography, creates images 'slices' through the breast, reducing overlap of normal dense tissue and thereby allowing improved invasive cancer detection. DBT is associated with twice the amount of radiation exposure when used in combination with a standard mammogram, which is still low in comparison to background radiation. Some facilities have software to generate a 'synthetic' 2D mammogram from the same images used for tomosynthesis and the radiation exposure is then about the same as a standard mammogram.

Numerous studies have shown an improvement in invasive cancer detection with DBT in women with heterogeneously dense breasts, of 1 to 2 cancers per 1,000 women screened (Table 1). There is typically a lack of soft tissue contrast within slices of extremely dense breast tissue, which may still mask cancer detection even on DBT (Figure 2).

A reduction in the number of women recalled due to a detected cancer that was later found to be false (known as a "false positive") has been observed with DBT across all breast densities.4,8

**SCREENING ULTRASOUND**

Supplemental screening with ultrasound after mammography has been extensively studied in women with dense breasts. This can be performed by using traditional ultrasound, where the transducer is moved by hand over the entirety of both breasts (handheld ultrasound: HHUS), or using automated devices. Most studies used HHUS performed by radiologists, and showed a significant increase in cancer detection over mammography alone of 3 to 4 cancers per 1,000 women screened (Table 1, Figure 3) with the first, prevalent screen. This detection benefit persists with subsequent (incident) screening rounds.9 The vast majority of cancers seen only on ultrasound are invasive and have not spread to lymph nodes. Slightly lower cancer detection rates have been observed with ultrasound performed by technologists. About 13-15% more women will be recalled from screening the first year, and 7% in subsequent years, when screening ultrasound is added to mammography.10 About 4-5% of women screened with ultrasound may be recommended for biopsy of a benign mass due to multicentric invasive lobular carcinoma. B) Digital mammogram and DBT slice of a woman with extremely dense breasts demonstrating little improvement in visualisation of structures with DBT due to homogeneity of the dense tissue. Detection of cancer may not be improved when the breast tissue is of this extreme density.
Finding14,15, which is higher than for screening mammography, where 1-2% of women screened undergo biopsy. Adding ultrasound to mammography in women with dense breasts reduces the chance that cancer will be missed, as ultrasound can detect masses that mammography misses. A recent study in Italy, the United States, and Japan has shown that ultrasound improves screening mammography, where only 1–2% of women screened undergo biopsy.

Studies of AUS show slightly lower cancer detection rates and fewer benign biopsies16. Similar to HHUS, it takes about 15 minutes to acquire AUS images for most breasts. Most women with a finding on AUS require further evaluation with targeted HHUS.

As use of 3D-mammography for screening increases, an important question is whether or not screening ultrasound is still beneficial after 3D-mammography. For facilities that have not yet implemented 3D-mammography, ultrasound appears to show greater improvements in cancer detection than 3D-mammography when added to standard mammography in women with dense breasts. A large study including five centres in Italy evaluated screening ultrasound after DIB and reported a cancer detection rate of 7.3/10,000 for HHUS compared to a cancer detection rate of 4.0/1,000 for DBT. Only one cancer was seen on 3D-mammography but not ultrasound.

Magnetic resonance imaging (MRI) is recommended for supplemental annual screening in women of any breast density who are at high risk for breast cancer17. This requires intravenous injection of gadolinium-based contrast, a substance that helps to enhance the visibility of certain tissues in the resulting image. If MRI is performed, screening ultrasound is of no benefit. Not all women can tolerate MRI, due to claustrophobia, motion-related artefacts, or metallic implants. One study examined MRI in average-risk women of all breast densities, finding no benefit over screening ultrasound after a negative mammogram and HHUS. Among 1,705 MRI examinations, 54 (3.2%) showed suspicious findings and 18/54 (33%) were malignant, for an incremental cancer detection rate of 10.6 per 1,000 (Table 1). All cancers were lymph node negative. Importantly, in studies of high-risk women, MRI has been shown to shift stage at diagnosis to earlier, more curative stages and to reduce the number of findings categorised as late stage.

Although cost, patient tolerance, and accessibility are major barriers to breast MRI, the technique is still recommended for women with dense breasts and a history of breast cancer.

Screening MRI of a woman at high risk for breast cancer. There is a small enhancing mass in the left breast (arrow). Biopsy showed invasive lobular carcinoma; the lymph nodes were negative. When lifetime risk is >20–25%, typically due to known or suspected disease-causing genetic mutation, annual breast screening MRI is indicated, regardless of whether or not the breast tissue is dense.

Supplemental screening ultrasound detected breast cancer after negative mammogram (DBT). A) Bilateral digital mammogram image from the left breast shows an irregular mass (arrow), due to 1.4cm invasive ductal cancer. Lymph nodes were not involved by cancer. B) Handheld ultrasound image of the left breast shows a mass (arrow), due to 1.4cm invasive ductal cancer. Lymph nodes were not involved by cancer.

Images courtesy of Dr. Wendie A. Berg.
Contrast-enhanced mammography

Contrast-enhanced digital mammography (CEDM) is performed with a mammography machine adapted to obtain a low-energy and high-energy x-ray exposure within a few minutes after the intravenous injection of iodinated contrast (as is used in computed tomography). A subtraction image is then created, showing only areas enhanced by the contrast. The risk of a fatal contrast reaction is extremely low, estimated to be less than 1 in 150,000 examinations, but less severe contrast reactions such as flushing are more common. Based on diagnostic work in women with known cancer, sensitivity is likely comparable to MRI and specificity may be higher.

SUMMARY

In summary, about 40% of women having regular screening mammography have dense breasts. Dense breast tissue increases the risk of breast cancer and impairs detection of cancers on mammography, and this can result in later stage at diagnosis with worse prognosis. Digital mammography is better than film mammography in women with dense breasts. 3D-mammography improves cancer detection compared to standard digital mammography in women with heterogeneously dense breasts, but is less effective in women with extremely dense breasts due to lower internal contrast. MRI is recommended for supplemental screening in women at high risk of breast cancer, regardless of breast density, but the cost is prohibitive for general screening.

Cancers on contrast-enhanced digital mammography (CEDM). A) This 45-year-old woman had calcifications in the right breast (arrows) that were due to ductal carcinoma in situ. B) CEDM shows enhancement in the right breast at the known cancer (solid arrow), but also has a large area of enhancement in the left breast (dashed arrow) that was multi-focal invasive ductal carcinoma, not seen on digital or 3D-mammography (not shown).

Ultrasound improves detection of invasive breast cancer and is the most frequently used supplemental screening modality in women with dense breasts. It appears that screening ultrasound is of benefit even after 3D-mammography, provided the woman is willing to accept an increased risk of false positives.

Fast MRI, molecular breast imaging, and contrast-enhanced mammography all show promise in improved cancer detection after mammography in women with dense breasts, but require broader validation. Surrogate endpoints of shifting to lower stage disease, reduced node-positive disease, and reduced interval cancer rates should be accepted as proof of benefit of supplemental screening.

REFERENCES

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Images courtesy of Dr. Jennifer A. Harvey.
Images courtesy of Mayo Clinic.
IN SUPPORT OF SCREENING MAMMOGRAPHY

By Francesco Sardanelli et al. on behalf of EUSOBi and 30 National Breast Radiology Bodies

In recent years, the evidence in favour of screening mammography has recently been summarised by the International Agency for Research on Cancer (IARC)4. According to results from randomised controlled trials, the reduction in breast cancer mortality due to screening mammography has been confirmed for women between 50 and 69 years of age. From cohort studies, a mortality reduction has been estimated for women aged 40–49 and 70–74, with ‘limited evidence’. Available data did not allow the IARC working group to define an optimal screening interval. However, we should consider that the majority of European countries opted for biennial screening in women aged 50–69.

The average risk for a false positive recall was evaluated by the IARC working group to be about 20% for women aged 50–69 who have ten screens in 20 years while the needle biopsy rate for a false positive finding is lower than 1% per round. In addition, screening mammography allows for both downsizing of the clinico-pathological features of invasive breast cancers and reduction of loco-regional and adjuvant treatments1–4.

The IARC working group accepted the estimation of overdiagnosis provided by the Euroscreen Working Group7, equal to 6.5% (range 1–10%), calculated on the basis of the difference in the cumulative probability of a breast cancer diagnosis among women receiving or not receiving mammography. Notably, overdiagnosis (a radiological issue) should be distinguished from overdetection (a radiological issue) and should be more carefully considered and defined on the estimated magnitude of radiation induced breast cancers. Importantly, most radiation induced breast cancers will be cured8. The general conclusion of the IARC working group confirmed that the probability of avoiding a breast cancer death due to early detection via screening is at least 100 times greater than the risk of eventual death due to radiation exposure from mammography. The recent recommendations of the American Cancer Society9 can be a useful reference for the U.S. context: 1. regular screening mammography starting at age 45 (strong recommendation); 2. annual mammography from 45 to 54 (qualified recommendation); 3. from 55, transition to biennial or coning annually (quali- fied recommendation); 4. opportunity for annual screening from 40 to 49 (qualified recommendation); 5. to continue screening mammog- raphy as long as the subject’s overall health is good and they have a life expectancy of 10 years (qualified recommendation); 6. no suggestion for screening clini- cal breast examination at any age (qualified recommendation).
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The potential of digital breast tomosynthesis

EUSOIB and the 30 national European breast radiology bodies also consider the increasing evidence in favour of digital breast tomosynthesis (DBT) as a screening tool. Three prospective studies showed that DBT used as an adjunct[23-25] or alternative[26] to two-dimensional (2D) digital mammography (DM) allows for a superior diagnostic performance when compared to DM alone. Overall, DBT provides an increase in detection rate from 0.5 to 2.7 per 1,000 screened women, as well as a reduction in recall rate from 3.6 to 0.8 per 100 screened women[27]. DBT is now proposed along with synthetic 2D views, practically solving the problem of increased breast density impacting on radiation when DBT is performed as an adjunct to 2D DM[28-30]. All these aspects of DBT in screening, must be avoided. Initial results showing a reduction of 0.7 to 0.5 interval cancers per 100 screened women were recently reported[29], but further evidence is needed. Moreover, the probable increase in reading time associated with the use of DBT in screening[30] and its effects on the sustainability of screening programmes should be considered before routine implementation.

Direct digital over phosphor plate or film-screen mammography

Looking at the course of technological evolution of mammography in recent decades and at the current trend in favour of DBT, the adoption of direct digital mammography (DDM) implies many substantial advantages, including lower dose, higher image quality, the possibility of post-processing, digital archive, image transmission, and no chemical pollution. However, there should be evidence for a statistically significant and clinically relevant reduction in the interval cancer rate. An increase in overdiagnosis and costs, in the absence of the demonstration of the cost-effectiveness of DDM in screening, must be avoided.

Preference for core or vacuum-assisted biopsy

Preference should be given to needle sampling of breast lesions using core biopsy or vacuum-assisted biopsy instead of fine-needle aspiration. The advantages of core biopsy include a lower false-negative rate and/or inadequate sampling, unless strict cooperation with a cytologist allows for a demonstrable equally high diagnostic performance. This does not apply for sampling of lymph nodes suspected to be metastatic at ultrasound of axilla, where fine-needle aspiration has been shown to be effective[38].

TABLE 1

List of 30 national breast radiology bodies who signed a Memorandum of Understanding with the European Society of Breast Imaging and agreed on this paper

| Austria | Association of Radiology of Bosnia and Herzegovina |
| Belgium | Association of Breast Radiologists |
| Bosnia and Herzegovina | Association of Breast Radiologists |
| Bulgaria | Bulgarian Society of Breast Imaging |
| Croatia | Croatian Society of Radiology Working Group of Breast |
| Czech Republic | Association of Czech Breast Radiologists |
| Denmark | Danish Society of Breast Imaging |
| Estonia | Estonian Society of Breast Imaging |
| Finland | Radiological Society of Finland/Breast Radiologists of Finland |
| France | Section of imaging and imaging Pathology (SIDH) |
| Germany | Association of Breast Radiologists; German Breast Imaging Group |
| Greece | Hellenic Breast Imaging Society |
| Hungary | Hungarian Society of Breast Imaging |
| Iceland | The Icelandic Society of Breast Imaging |
| Ireland | Irish Society of Breast Radiologists |
| Italy | Italian College of Breast Radiologists by SIRM (Società Italiana di Radiologia Medica) |
| Israel | Breast Imaging Society |
| Latvia | Lithuanian Radiology Association |
| Lithuania | Department of Breast Imaging in the Society of Imagers of the Republic of Lithuania |
| The Netherlands | Dutch College of Breast Imaging (DCBI) |
| Norway | Norwegian Society of Breast Imaging |
| Poland | Polish Society of Breast Imaging (SPB) |
| Portugal | Portuguese Society of Radiology and Nuclear Medicine (SPRMN) |
| Romania | Romanian Society of Breast Imaging |
| Serbia | Serbian Society of Breast Imaging |
| Slovakia | The Slovakian Society of Breast Imaging |
| Spain | Spanish Society of Breast Imaging, Sociedad Española de Diagnóstico e Intervenciones de la Mama (SEDIIM) |
| Sweden | Swedish Breast Imaging Society |
| Switzerland | Breast Screening representative of the Swiss Radiological Society |
| Turkey | Turkish Society of Radiology Breast Imaging Working Group |

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Moreover, the masking effect of increased breast density impacting on the sensitivity of screening mammography has been demonstrated[28]. Finally, the role of breast density as an independent risk factor for breast cancer must be taken into consideration, although this factor is frequently overestimated[29]. In studies with a control group representative of the whole population, the relative risk for women with dense breasts dropped to two or less[30]. At any rate, these societies consider the generalised adoption of digital mammography as the first priority, also to improve sensitivity in women with increased breast density.
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WOMEN AT INCREASED RISK

The societies who endorse this paper are in favour of including, whenever possible, dedicated pathways for high-risk women (lifetime risk equal to or higher than 20%), offering breast MRI according to national or international guidelines and recommendations.

SUMMARY

EUSOBI and 30 national European breast radiology bodies strongly support mammography as a population-based mass screening tool which results in a relevant reduction in breast cancer mortality and leads to a favourable decrease in both loco-regional and distant treatments in women attending these programmes. People and institutions questioning its validity, despite a large body of evidence accumulated in more than three decades, put women's lives at risk. Preference should be given to population-based mass screening programmes on a regional/national basis. Adoption of direct digital mammography is a priority, also to improve sensitivity in breast tumors that are more difficult to detect. Digital breast tomosynthesis (DBT) will probably also become 'routine mammography' in the screening setting. Dedicated path- ways for offering breast MRI to high-risk women, according to national or international guidelines and recommendations, are encouraged.

The authors support the adoption of screening mammography by national governments, policy makers, institutions, family doctors, and - last but not least - the general population.

ACKNOWLEDGEMENTS

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Modification has become widespread in recent years, allowing the radiation dose to the opposite breast to be minimised. Adverse cosmetic results have been associated with the use of systemic therapy, higher total dose to the breast, and heart morbidity. Promising methods to reduce heart and lung dose include deep-inspiration breath hold, MLC, intensity-modulated radiation therapy (IMRT), and treatment in the prone position. In deep-inspiration breath hold, maximum inspiration is used to move the heart away from the chest wall, allowing the radiation beams to largely avoid the heart. Various commercial systems are available that allow the performance of deep-inspiration breath-hold techniques. However, it is unclear whether breath-holding techniques truly lead to a decrease in cardiac morbidity, given the lack of prospective data covering a sufficient follow-up period. MLC can be used to conform dose to avoid the heart, either alone or in addition to other complementary techniques.

Examining patients in the prone position has been shown to reduce heart and lung dose when compared to treatment in the supine position. A randomised trial of large-breasted women reported improved dose homogeneity and reduced acute skin toxicity and pain in the prone position compared to supine. Finally, prone positioning can also reduce the patients’ movement related to breathing during the radiation treatment. With the development of 3D treatment planning systems and the now widespread availability of linear accelerators with MLC capabilities, it has become possible to provide differential segmental blocking of the radiation beam through the treatment field to reduce hot spots in the dose distribution. This has led to an interest in administering radiation to the breast in several segmented fields. This technique has commonly been called breast IMRT. It is noteworthy that this relatively simple technique, which is intended primarily to improve dose homogeneity, may lead to decreased rates of dermatitis and oedema. Because tens of thousands of women each year continue to require adjuvant radiotherapy after breast-conserving surgery, various alternative approaches to minimise the burden of treatment have been sought. Traditionally, radiation treatment after breast-conserving surgery has targeted the whole breast with total doses of 45 to 50 Gy administered in 1.8- to 2-Gy daily fractions, followed in many centres by an additional 10- to 15-Gy boost dose to the tumour bed (the breast portion where the breast tumour was originally located before being excised by the surgeon) leading to a total of five to six weeks of daily treatment; in this case the radiation treatment is delivered in what is commonly referred to as ‘normal fractionation’.

‘Hypofractionation’ of radiation treatment involves the use of larger daily doses of radiation and decreases the total number of fractions that must be administered. Several trials have investigated the use of hypofractionated regimens of irradiation to the whole breast, concluding that the oncological outcome of patients treated with a hypofractionated approach (e.g. local control, overall survival) are similar compared to the standard treatment, with a considerable reduction of overall treatment time. A further effort to tailor even better post-operative radiation treatment for operated women affected by early breast cancer was inspired by evidence that the majority of failures after breast-conserving therapy occur in the vicinity of the tumour bed. The idea is that it is possible to identify patients who have a low risk of residual disease remote from the lumpectomy cavity. Investigators have also begun to explore the possibility that an even more radically accelerated schedule of hypofractionated radiation therapy might be feasible if one boosts only part of the breast. By further shortening treatment time, those developing these techniques of accelerated partial breast irradiation (APBI) hope that they may increase access to breast-conserving therapy for many women. Furthermore, it has been theorised that by decreasing the volume of irradiated tissue, these techniques might lead to a decrease in treatment-related toxicity. In addition, because chemotherapy is recommended for many patients with early stage breast cancer, the use of hypofractionated regimens for APBI so that neither radiation nor chemotherapy is delayed appears appealing. Recently, many techniques have been tested in an attempt to administer adjuvant RT while reducing the burden for patients and RT departments. Various techniques are currently available to deliver APBI and comprise intra-operative radiotherapy (IORT), multi-channel brachytherapy, and external beam radiotherapy delivered either with a 3D conformal technique or an intensity-modulated technique (Figure 1). Although definitive data from a large prospective randomised trial are still awaited, current evidence obtained from brachytherapy experiences and external beam radiotherapy encourages the use of APBI in appropriately selected patients.

An appropriate therapeutic choice for women operated for early breast cancer will be of utmost importance in the following years. The diagnosis of breast cancer is increasing, in part due to early detection of disease through imaging such as screening mammography; and this will inevitably lead to an increase in women operated for very low risk breast cancer, for whom a de-escalation of adjuvant therapies (both local and systemic) must be sought. In cases where mastectomy is unavoidable due to locally advanced breast cancer, patient selection for post-mastectomy radiotherapy is still debated. For patients at sufficient risk of harbouring residual disease in the chest wall and regional lymph nodes after mastectomy and systemic therapy, radiation therapy to the tumour bed. This led to the local recurrence but also may improve survival, presumably by eliminating an isolated microscopic reservoir of residual disease from which metastases may be seeded or reseeded after initial elimination by effective systemic therapy. The intrinsically molecular biology of breast cancer also plays a major role in determining the risk for both local and distant relapses of breast cancer. Therefore, a key subject of research has been to identify which patients are likely to benefit from this type of treatment.

In conclusion, breast cancer radiotherapy has been established as one of the pillars of the management of women affected by this very common solid cancer, and a growing body of evidence will help to tailor the most appropriate treatment for every single woman in the near future. Technical improvements over the last two decades have also helped to further minimise the risk of both acute and long-term toxicity, while maintaining the clear benefit demonstrated in the previous years.
In the 1980s, growing recognition of the value of screening mammography in reducing deaths from breast cancer led to increased use of mammography.

However, it was realised early on that a number of significant problems needed to be addressed before mammography as a screening and diagnostic tool could be universally adopted. In addition to sometimes poor image quality, mammogram reports were often long, rambling, and impossible to understand. This was partly because the appearance of the normal breast is very variable from one person to another. In addition, findings that might represent breast cancer, such as calcifications, are not found in other parts of the body and there was no experience in describing or dealing with these findings. This meant that mammogram reports often left the referring doctor with no idea whatsoever of what the mammogram showed or what to do for the patient.

In an effort to address this problem, the American College of Radiology Mammography Committee, headed by Dr. Gerald Dodd of MD Anderson Cancer Center in Houston, created a committee to develop a standardised reporting system. This committee was headed by Dr. Carl D’Orsi and included representatives from the National Cancer Institute, the Food and Drug Administration, the American Medical Association, the American College of Surgeons, and the College of American Pathologists. The result of the work of this committee was the Breast Imaging Reporting And Data System, known as BI-RADS. The BI-RADS atlas has revolutionised how breast imaging studies including mammography, breast ultrasound and breast magnetic resonance imaging are read and reported.

The first BI-RADS atlas was published in 1992 and was little more than a pamphlet. With time and experience, new editions refining the terms used and containing more information and detail were released. The 2nd edition was published in 1995 and the 3rd in 1998. In 2003 the 4th edition came out and for the first time included a lexicon of terms for breast ultrasound and breast MRI. Finally, in 2013, the 5th edition was published and for the first time an electronic version was available for download. This version attempts to be evidence-based and contains hyperlinks to references that refer to findings and their chances of representing cancer. The 5th edition also contains many actual images and is more than seven times larger than the 1st edition.

The BI-RADS atlas includes guidance on how the breast imaging report should be organised, a list of descriptions for findings seen on the exams, and a list of final assessment categories. The development of the descriptions for findings seen on mammography was done in a scientific manner that correlated imaging features with the likelihood of cancer. In the mammography lexicon, there are terms that should be used to describe mammographic findings such as masses, calcifications, asymmetries, and architectural distortion. For example, for masses, there are descriptions for the shape of the mass and for the edges of the mass (margins). For calcifications, there are descriptors for the way the calcifications are distributed in the breast and for the shape of the individual calcifications. Calcifications deposits in the breasts are extremely common and the vast majority of them are not a problem. The BI-RADS lexicon includes terms and descriptions of typically benign calcifications that do not need any further testing, such as calcium deposits in blood vessels, scar tissue, benign growths, or tiny cysts. This knowledge is as important as recognising which calcifications might represent a problem, in order to avoid unnecessary biopsies.

For masses and calcifications seen on mammography, there are some features that are more likely to be benign and some that are more likely to be malignant and therefore the radiologist, by using these standard terms to describe them, can come up with a...
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Masses

A: This mass (arrow) is round with circumscribed margins. These descriptions suggest that this mass is quite likely to be cancer.

B: This mass (arrow) is irregular with spiculated margins. These descriptions suggest that this mass is less likely to be cancer.

FIGURE 2

The development of BI-RADS has led to substantial improvements in the practice of breast imaging. By having standard terms to describe findings, research on how often these represent cancer has been possible. In addition, the descriptions of findings, when used correctly, help lead to the correct assessment and management recommendations. For example, if a mass seen on mammography is described...
as being irregular in shape with spiculated margins, which are suspicious features, the appropriate assessment would be BI-RADS 5 and the appropriate management would be biopsy. By the same token, an oval mass with circumscribed margins, which are benign features, could possibly be given a BI-RADS 3 assessment and followed rather than biopsied.

Standard terminology also improves communication. Radiologists all over the world who use BI-RADS understand instantly what ‘coarse calcifications’ or ‘milk of calcium’ means. Prior editions of BI-RADS have been translated into a number of different languages including French, Spanish, Portuguese, Croatian, German, Russian, Mandarin Chinese, and Romanian, and the latest edition is being translated into Japanese as well.

Having set terms also helps in teaching how to read mammograms. By being familiar with BI-RADS terms, those learning how to interpret mammograms and other breast imaging examinations are able to apply correct descriptions to findings and come up with appropriate assessment categories. Finally, having the lexicon and the final assessment categories allows radiologists and practices to track their results to see how they are performing in reading breast imaging examinations.

In summary, challenges in interpreting and reporting mammograms in the early days of mammography led to the development of the BI-RADS atlas which represents a remarkably useful tool that has improved the way mammograms, breast ultrasound, and breast MRI are read. By being familiar with BI-RADS terms, those learning how to interpret mammograms and other breast imaging examinations are able to apply correct descriptions to findings and come up with appropriate assessment categories. Finally, having the lexicon and the final assessment categories allows radiologists and practices to track their results to see how they are performing in reading breast imaging examinations.

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FIGURE 3

Calcifications
A: These are large rod-like calcifications that are not a sign of cancer.
B: This is a close-up of grouped calcifications that are fine linear branching. These have a high probability of being malignant.

THE IMPORTANCE OF THE MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)

By Priscilla F. Butler, American College of Radiology

In 1987, the American College of Radiology (ACR) developed the Mammography Accreditation Program to address documented concerns for inadequate and varying mammography quality and radiation dose in the United States. This voluntary programme provided a means for hospitals and clinics to demonstrate that they provided high-quality mammography by meeting the ACR’s standards for mammography personnel, equipment, quality assurance, clinical (patient) images, phantom images (a plastic breast simulator, see Figure 1), and dose. If a hospital or clinic could not pass the accreditation criteria, the ACR would provide feedback from experts in mammography to guide the facility in making improvements. The ACR’s accreditation programme gained wide acceptance among facilities and government agencies, even though it was voluntary. In 1991, approximately half of the estimated 10,000 mammography units in the United States had applied for accreditation; approximately one-quarter of the United States mammography units had successfully achieved accreditation.

Several U.S. states passed laws requiring mammography facilities to meet quality standards and submit to regular inspections by state inspectors. In 1990, the United States Congress passed a law authorising screening mammography to be covered by the national social insurance programme, Medicare. Facilities seeking Medicare reimbursement were required to register with the
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Health Care Financing Administration and most quality standards similar to those of the ACR’s Mammography Accreditation Program. Federal inspections of Medicare-registered screening facilities began in 1992. Although the goal of quality mammography was the same, this assortment of state, federal, and voluntary private efforts created a patchwork of mammography require-
mments across the United States, and much of the mammography being per-
formed at that time was not subject to quality regulations of any type. Conse-
quently, quality remained inconsistent.

Recognizing the need for uniform national standards that would apply to both screening and diagnostic facil-
ities, the U.S. Congress passed the Mammography Quality Standards Act (MQSA) in 1992. This act requires all
mammography facilities to meet minimum quality standards for per-
sonnel, equipment, and recordkeeping and to be certified by the U.S. Food
and Drug Administration (FDA) or an FDA-approved state certifying body
(CB) to legally operate in the United States. To become certified, facilities
must be accredited by FDA-approved accrediting bodies. All mammogra-
phy facilities in the United States had to be certified by October 1, 1994.

Although interim regulations were developed in time for the law to go into
effect, a massive effort by the FDA and its advisory committee produced final
MQSA regulations which were published on October 28, 1997. In brief, the final
rule established personnel requirements, strengthened equipment standards,
and outlined many performance-based equipment requirements for quality
assurance. Furthermore, the new regula-
tions required mammography facilities
to provide patients with written results
of their mammograms in language that
is easy to understand. Also known as
‘lay reports’, these communications
prevent situations where a woman
would fall through the cracks and never
receive the results of her mamo-
graphy examination as it was communica-
ted by the mammography provider to
her referring physician. The regulations
also required that the mammography
provider transfer original mammogra-
phy to the patient or the patient’s
physician at the patient’s request. Finally, each mammography facility is
required to have a consumer complaints
mechanism to provide patients with
a process for addressing any concerns.

The majority of the final regulations became effective on April 28, 1999.
Certain stincter equipment regulations became effective on October 28, 2002.
The FDA designated the ACR as one of four FDA-approved accrediting bodies.
The other three are the states of Iowa, Arkansas, and Texas. These states may only
accredit facilities within their own borders; facilities within these states
have the choice of accreditng with the ACR or with their states. The ACR is the only
body that accredits nationally.

The ACR’s Mammography Accredita-
Program process, which is directed
by radiologists and medical physicists
through the Committee on Mammogra-
hy Accreditation, is summarised by
the flowchart in Figure 2. A new mam-
ography facility must first complete
an online application to provide basic
information on the facility, equipment,
and personnel, and submit a sum-
mmary of the pass or fail results from its

FIGURE 1

American College of Radiology (ACR) mammography phantom

of the MQSA, along with the appropri-
ate results; and other requirements
must be accredited by October 1, 1994.
Academy of Radiology (ACR) mammography accreditation and the U.S. Food and Drug Administration (FDA) certification.
corrective action on its own. After corrective action, the facility may reapply for accreditation by repeating only the deficient test or tests (e.g., clinical, or phantom). Facilities may appeal any denial of accreditation. After two consecutive unsuccessful attempts, a facility fails accreditation, and the ACR strongly recommends that the facility take the unit out of service. The ACR works with each facility to help it improve its image and follow-up with documentation supporting this corrective action to reinstate. Once a facility has rein- stated, the FDA will send it a six-month letter of reinstatement to assess the facility’s independent corrective action and provide further advice on necessary improvements. This is an educational effort, and the ACR team works closely with the facility’s radiologists, technologists, and medical physicists to achieve these goals. The facility may reinstate only after taking all corrective action recommended by the survey team. On June 1, 2016, the FDA reported that there were more than 8,500 MQSA-certified facilities with more than 15,000 mammography units in the United States. Over 95% of the units are digital.

The ACR’s Mammography Accreditation Program has been one of the most successful quality improvement programmes in radiology. Since its inception as a voluntary programme in 1987, it has improved the quality of mammography performed at facilities throughout the United States, as illustrated by increasing accreditation pass rates and the closure of facilities that could not pass mammography accreditation. This ensures that all facilities in the United States have access to quality mammography services.

FURTHER READING


Breast cancer is the most commonly diagnosed cancer among women, accounting for 26% of all cancers, with increasing incidence. Iodising radiation is well known as a factor that can induce breast cancer. Therefore breast radiation protection is imperative for all health service providers.

Knowledge about radiation carcinogenesis (radiation causing cancer) in breast derives mainly from epidemiological studies of patients exposed to diagnostic or therapeutic medical radiation and of Japanese atomic bomb survivors, and supports a relationship in which the excess risk is proportional to radiation dose. Hence, breast cancer is a typical stochastic effect of radiation, and the ALARA (As Low As Reasonably Achievable) principle must be strictly adhered to when considering the dose of iodising radiation used in an examination. Radiation does not cause breast cancer immediately, but with a latency period of 10–12 years. The risk of breast cancer induction per unit dose depends on the age of the patient at the time of exposure to radiation. The susceptibility for carcinogenesis is increased when the mammary gland is not yet fully developed (intrauterine period, adolescence, pregnancy), with the second decade of life carrying the greatest risk. The risk for women exposed after the menopause is minimal. Age at first full-term birth, the number of viable pregnancies, history of benign breast disease, and genetic factors all influence the risk of radiation-related breast cancer. BRCA genes are involved in the repair of DNA damage caused by radiation, and exposure before 30 years of age during radiation therapy for Hodgkin’s disease is associated with an increased risk for women with BRCA 1 and 2 mutations. The breast can be exposed to radiation directly, during imaging or radiation treatment, or indirectly by scattered radiation during other imaging studies. In breast imaging the radiation dose should be optimised, while breast exposure to scatter radiation in other examinations should be minimised. Mammography is a large contributor to breast radiation exposure. Early detection is important for the successful treatment of breast cancer and a good prognosis.
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Mammography is a proven baseline technique which enables early detection in a large proportion of affected women, and is useful for diagnosis and screening mammography programmes. Unlike earlier machines, modern mammography machines use fairly low radiation doses to produce mammograms of high quality.

Breast radiation dose is not easily measured, and cannot be simply “read out” from the mammographic unit. For the individual patient it can be calculated from the exposure (x-ray beam output), compressed breast thickness and percentage of glandular tissue in the breast. The quantity mean glandular dose (MGD) is defined as the average dose to the glandular tissue, based on the assumption that the glandular tissue is the most radiosensitive part of the breast. The breast dose depends on the sensitivity of the image detector, technical parameters selected for the examination, and density of the patient’s breasts. To ensure the necessary image quality with the lowest possible radiation dose to the breasts, highly qualified radiographers select the optimum kV value (24 to 32 kVp) that provides a balance between breast penetration and absorbed dose. The mean glandular dose to the breast is adequately compressed to make it thinner, therefore requiring a lower dose of radiation.

Radiation dose is not an absolute criterion for the acceptability of the examination, and any encouragement for patients to go ‘dose shopping’ by searching for the facility with the lowest mammography dose should be avoided. Imaging with doses that are too low could result in missing cancers and having the risk of an additional radiation dose later on. The goal of the optimisation process – a compromise between the necessary image quality and as low a radiation dose as possible – can be achieved by systematic implementation of a quality assessment/control programme in a mammography unit.

Systematic monitoring of equipment, technique and organisation is necessary to ensure the correct balance between the quality of mammogram and the dose, which should comply with international standards (eg, MGSA, Mammography Quality Standards Act, see separate chapter by Penny Butler). Unnecessary radiation dose should also be minimised by ensuring that as few mammograms as possible are repeated.

Two-view digital mammography has MGD of 3.7 mGy, associated with a risk of fatal radiation-induced cancer of 1.3–1.7/100,000 women. The risk of malignancy related to radiation dose is expressed with the effective dose. Since different tissues and organs have varying sensitivity to radiation, the radiation exposure risk varies for different parts of the body. The term ‘effective dose’ is used when referring to the radiation risk averaged over the entire body. Knowledge of effective dose allows for the quantification of risk and comparison to more familiar sources of exposure that range from natural background radiation to radiographic medical procedures.

The effective dose for a two-view mammogram of each breast is 0.6 mGy for screen-film mammography (SFM) and 0.4 mGy for digital mammography (DM). People are exposed to an average effective dose from background radiation of 3 mGy/year; so the examination dose equals approximately two months of background radiation. For comparison, the dose from an airplane flight is 0.04 mGy, the annual dose from food is 0.3 mGy, and the annual limit for radiation workers is 50 mGy.

The effective dose of a chest x-ray is four times lower than that of mammography, while for abdominal CT it is up to 50 times higher, equivalent to several years of natural radiation (see Table 1).

Although radiation dose was much higher in the early stages of SFM, it has steadily decreased over time, especially after introducing full-field DM. The American College of Radiology Imaging Network (ACRIN) Digital Mammography Imaging Screening Trial showed breast doses from DM to be 22% lower than those from SFM, with MGD 3.7 mGy for two-view DM. With the use of 200 mGy kVp instead of 180 mGy, the breast dose was reduced to 1.3–1.7 mGy. The American College of Radiology has recommended reducing breast dose to 0.75 mGy. The effective dose of DBT is about 0.44 mGy.

Digital breast tomosynthesis (DBT) is a promising new DM technology with improved diagnostic performance that has benefits also the advantage of DBT is the elimination of the summation of shadows typical for conventional mammography and improved detection and characterisation of lesions in breasts with a high percentage of glandular tissue, improving sensitivity as well as specificity and decreasing recall rates, especially in patients with dense breasts who are younger than 50. It seems that the radiation dose with DBT may be up to two times the dose of DM only in women with predominantly fatty breasts with a low amount of glandular tissue, while in dense breasts the difference of the doses is lower. Radiation dose depends on whether DBT is implemented as one-view or two-view in addition to full-field digital mammography. Use of synthetic views reconstructed from original data sets of DBT could eliminate extra radiation dose due to mammography, and reduce the radiation dose by 40–50% without having an impact on diagnostic accuracy. In the future discussions of the role of DBT in screening, a moderate increase in radiation exposure per individual DBT exam must be weighted against the benefit of decreased recall rates (responsible for 10% of additional doses) which could reduce patient anxiety and radiation dose in general.

Nuclear medicine breast-specific gamma imaging (BSGI) and positron emission mammography (PEM) can be useful in the work-up of screen breast cancer, or in women with very dense breasts. These methods are not suitable for routine screening, as single BSGI or PEM exams expose patients to a risk of radiation-induced cancer comparable to the risk from an entire lifetime of protracted exposure starting at 40 years of age. The average effective dose from BSGI and PEM studies (6.2–9.4 mGy) equals to three years of background radiation. While DM has a lifetime risk of inducing 1.3 breast cancers per 100,000 women aged 40 at exposure, the median risk of BSGI and PEM is estimated to be 20 to 30 times greater.

In CT examinations where the breast is within the scanning volume, breast radiation dose is considerable. A chest CT examination for pulmonary embolism delivers 20–60 mGy to the breast, and CT coronary angiography 50–80 mGy. Even in abdominal CT, a breast dose of 10–20 mGy is considerable, seven times the dose of a standard two-view mammogram or equal to 50–100 chest radiographs. Since 1 mGy may induce five additional malignancies in 100,000 exposed people, a hundred additional cases of breast cancer can be assumed in 100,000 women exposed to chest CT. Especially for younger women, proper justification of procedures is strictly necessary, with shielding of the breasts with bismuth garments if feasible.

Radiation treatment to the chest for malignancy in childhood or adolescence substantially increases the risk of breast cancer. Young women irradiated for Hodgkin’s lymphoma have three to seven times the risk of breast cancer compared to women with Hodgkin never treated with radiation. Altho with very dense breasts, this increases the risk of breast cancer later in life, the benefits of its use in the
CHAPTER 2: STANDARDS & QUALITY

The increased carcinogenesis risk at younger ages, the limited accuracy of mammography in dense breasts, and the high risk of cancer in BRCA-positive women, raises a dilemma about whether it is justified to begin with screening before the age of 40. Early screening of high-risk women might seem justifiable because many will develop breast cancer in their 30s or 40s, and early detection may save their lives. However, women with BRCA mutations who were exposed to radiation before the age of 20 had 2.5 times the risk of breast cancer even low doses associated with early annual screening mammography could jeopardise women with BRCA-mutations, as radiation exposure before the age of 30 increases the risk of breast cancers in a dose-dependent manner.

In conclusion, mammography is a fast, widely available, accurate, cheap and acceptability harmful method for diagnostic screening of breast cancer. The main aim of mammographic screening is to reduce the mortality from breast cancer. The benefit of early diagnosis and treatment of breast cancer far outweighs the risk of the small amount of radiation received during a screening mammogram. The general conclusion of the IARC (International Agency on Research of Cancer) working group confirmed that the probability of saving a life by early detection with screening is at least 100 times greater than the probability of death caused by the radiation from screening. The possibility of inducing cancer by radiation is often sensationalised in the media, resulting in anxiety, and occasionally delays or avoidance of mammography, which may subsequently result in late diagnosed cancer. Many people overestimate the levels of exposure and the risks of ionising radiation from mammography, and fear radiation more than necessary — including some radiologists or referring physicians. Mammography screening has been considered one of the major medical advances of the past decades, and women need to be provided with the important information that mammography saves lives and that the radiation risk is minimal.

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The European Commission Initiative on Breast Cancer (ECBIC) is a person-centred sustainable initiative aiming to improve and harmonise breast cancer care in Europe.

ECBIC is coordinated by the Commission’s Joint Research Centre (JRC) under the auspices of the Directorate General for Health and Food Safety. The JRC is the European Commission’s in-house science service and provides an inclusive and transparent platform for engaging stakeholders.

The JRC is independent of any national, commercial or private interests.

WHY IS THE ECBIC NEEDED?

According to WHO 2012 estimates, each year there are 2.6 million new cases of cancer in Europe (excluding non-melanoma skin cancers). Breast cancer is the most frequently diagnosed cancer in Europe, with 364,000 new cases each year. In women this figure represents almost one third of all diagnosed cancers. It is also estimated that breast cancer causes 91,000 deaths each year in Europe. Even though the prognosis of breast cancer is significantly better, one out of every six women can and will still die from breast cancer.

Incidence rates (the number of new cases in a given period in a specified population) and mortality rates (the number of deaths in a given period in a specified population) for breast cancer vary widely between countries.

REFERENCES
See page 103.
Although a higher mortality rate in some countries may be due to a higher incidence rate, in others it may be due to lower rates of survival of breast cancer patients. This lower survival rate may reflect major health inequalities, including those related to different health policies, but also those related to lower quality of care. Hence, there is considerable potential to reduce the burden of cancer, and inequalities in cancer diagnosis and care, at the European level.

The European Union Members acknowledged the need for a coordinated action to tackle the burden of cancer via the Council Conclusions of 2008. As a consequence, the European Commission launched the ECIBC in 2012. It aims to ensure that all breast cancer care processes are performed with quality and appropriateness, based on the best available evidence, and are accessible to all citizens. The ECIBC is working towards this crucial harmonisation goal with the support of clinical and scientific experts, patients, and other stakeholders, and taking into account the existing guidelines and schemes.

ECIBC OBJECTIVES

The ECIBC covers all breast cancer care processes from screening of breast cancer until end-of-life care. The following six processes have been identified along the breast cancer care pathway (see also Figure 2):

1. screening
2. diagnosis
3. treatment
4. rehabilitation
5. follow-up and survivorship care
6. palliative care

The four specific objectives of the ECIBC are to establish:

1. A voluntary European quality assurance scheme for breast cancer services (the European QA scheme) addressing all care processes.
   • The European QA scheme will define a common set of quality and safety requirements for breast cancer services in Europe.
   • The scheme will cover all the relevant areas of healthcare provision for breast cancer and all processes of breast cancer care.
   • It will be piloted among participating services in Europe in 2017, and thereafter it will be available to all by 2018.

2. Evidence-based recommendations supporting the European QA Scheme:
   a. The European guidelines for breast cancer screening and diagnosis (the European Breast Guidelines)
      • The European Breast Guidelines will provide recommendations for the screening and diagnostic processes of breast cancer services.
      • Whenever possible and appropriate, the evidence-based approach is applied.
      • The European Breast Guidelines will have a web-based format, and will be publicly available starting from 2016.
   b. A platform of guidelines covering all care processes (the Guidelines Platform)
      • Breast cancer guidelines produced by different entities and stakeholder organisations, such as professional societies, are being collected.
      • Only those trustworthy guidelines fulfilling the carefully defined eligibility criteria will be included in the web-based platform hosted on the ECIBC website.
      • This platform can be foreseen as a valuable resource of guidelines for professionals, policy makers, researchers, and guideline developers, as well as for citizens and patients, and will be available by 2017.

3. A European training template on digital breast screening for the competence and training requirements of the European QA scheme
   • A concept for training on digital breast screening to be developed will be aimed at health professionals involved in screening programmes.
   • The digital screening training template will include the essential requirements
for professionals working for services adhering to the European QA scheme. It will be designed and disseminated in coordination with European key stakeholders.

- The digital screening template is expected to be ready by 2016. Thereafter, the model would be available and applicable to other professional profiles covered by the European QA scheme.

4. A web interface, the ECIBC web hub (ecibc.jrc.ec.europa.eu) offering complete public information on the ECIBC and its deliverables.

- The site will host all the ECIBC objectives in the most updated version.
- It will also provide a map of the certified breast cancer services accredited with the European QA scheme.
- Key information will be available in all official EU languages.

THE IMPACT OF THE ECIBC ON TRAINING – WITH SPECIAL EMPHASIS ON RADIOLOGY

Of particular importance from the radiological point of view is the screening and diagnosis of breast cancer, where different imaging methods and radiological interventions are needed. The schematic presentation of the screening pathway is shown in Figure 3.

The crucial importance of the correct and timely diagnosis is also emphasised by the ECIBC, of which one of the key objectives is related to development of the competence and training requirements for breast screening in general, and for digital breast screening in particular.

In fact, the European training template for digital screening will set essential training requirements for professionals working in breast screening activities, initially by developing a template tailored for radiologists and radiographers.

This training template will ensure that citizens going through breast screening will have it provided only by healthcare providers who have received adequate training. Moreover, the healthcare providers will be asked to fulfil some specific indicators which show that their work is admissible.

ECIBC TIMELINES

At the end of 2018 all key objectives will be fulfilled. The ECIBC will build on sustainable approach, and all project deliverables will be updated based on need. The timelines of the ECIBC are provided in Figure 4.

ECIBC WORKING MODALITY

To achieve these crucial objectives, the ECIBC does not work in isolation but counts on working groups consisting of professional and scientific experts, as well as citizens and patients, who work for the project voluntarily. The working group members have been selected through a transparent open call process.

To produce reliable outcomes, the requirements and the recommendations established within the project will be developed based on the best available evidence using explicit and transparent approaches. Thus, the outcomes will be based solely on scientific evaluation of the available data, independent of any national, commercial or private interests.

Other stakeholders, including patient organisations, professional societies and individual citizens, are able to contribute through public calls for feedback. This multidisciplinary, inclusive and transparent working method ensures feasible and wide implementation to truly impact on the quality of care.

ECIBC EXPECTED BENEFITS

By ensuring an essential level of quality and safety in breast cancer care, the ECIBC is expected to reduce inequalities in healthcare services, and hence, to improve the outcomes of breast cancer patients in terms of morbidity, mortality, and quality of life.

More information: ecibc.jrc.ec.europa.eu
HISTORY OF BREAST IMAGING

FROM ‘MAMMOGRAPHY’ TO ‘BREAST IMAGING’: A HISTORY
FROM ‘MAMMOGRAPHY’ TO ‘BREAST IMAGING’: A HISTORY

BY BONNIE N. JOE AND EDWARD A. SICKLES

What began as ‘mammography’ in the early days of x-ray technology has now evolved into the field of ‘breast imaging.’

WHY DID THE NAME CHANGE? The history of breast imaging encompasses many years of improvement in mammographic techniques, entry into the digital age, and now includes breast ultrasound and magnetic resonance imaging as a standard part of breast imaging practice across the globe. The scope of this article allows only a brief glimpse into the rich history of breast imaging. Innovation, leadership, and commitment on the part of many over the past decades have contributed to making breast imaging the exciting field it is today.

Chapter 3: History of Breast Imaging

MAMMOGRAPHY – THE BEGINNING

In 1913, Dr. Albert Salomon, a surgeon at the University of Berlin, first published his work using x-rays to study breast cancer ex vivo in 3,000 mastectomy specimens. During the following decades, early attempts at in vivo imaging of the breast did not sustain interest, mainly due to poor visualisation of breast tissues (Figure 1). Fortunately, there were radiologists who continued to work on improving mammography techniques.

Dr. Stafford Warren was able to successfully use direct x-ray technology to image the breast in vivo (Figure 2) and in 1930, published results of pre-operative evaluation of breast lesions for malignancy. In 1948, Dr. Jacob Gershon-Cohen was able to demonstrate the feasibility of mammography to detect occult breast cancer thus introducing the concept of screening mammography. In 1951 Dr. Raul Leborgne described the importance of the relationships between calcifications and breast cancers. In 1960, Dr. Robert Egan’s description of a standardised direct-exposure mammographic technique sparked renewed interest in mammography. Egan is credited with disseminating his direct x-ray technique for mammographic positioning and imaging, facilitating more widespread adoption of mammography. Around this time, Dr. Charles Marie Gros, in Strasbourg, France, developed the first dedicated mammography unit.

The CGR Senographe, which became available in the 1960s,6

By today’s standards, direct-exposure film images (Figure 3a) are not considered of diagnostic quality. Nevertheless, the landmark results of the Health Insurance Plan of Greater New York, published in 1973 and known as the ‘HIP study’, showed a statistically significant reduction in breast cancer deaths among women offered screening compared with a control group of women not offered screening7. Subsequent randomised controlled trials and results of population-based service screening confirm the lifesaving benefit of mammography screening. Additional information can be found in the article devoted to screening mammography in Chapter 1.

XEROMAMMOGRAPHY

During the 1970s, thanks primarily to the efforts of Dr. John Wolfe, working closely with the Xerox Corporation, a...
CHAPTER 3: HISTORY OF BREAST IMAGING


There were problems with xerographic image processing such as paper jams and non-uniform toner (similar to those seen with modern-day copiers), and given the paucity of continuing innovation, xeromammography was ultimately replaced by screen-film mammography.

SCREEN-FILM MAMMOGRAPHY

Another major technological advance, screen-film mammography, was first introduced in 1973 by DuPont. Screen-film techniques allowed faster imaging times, improved contrast, and reduced radiation dose compared with direct x-ray and xeromammography. With the addition of uniform thickness breast compression, breast tissue was spread out more evenly, allowing further reduction of radiation dose and better visualization due to fewer motion artifacts.

Continued technological improvements in the screen-film process and advances in dedicated units for performing mammography led to continued improvements in breast image quality during the 1980s and 1990s (Figure 3c).

DIGITAL MAMMOGRAPHY AND DIGITAL BREAST TOMOSYNTHESIS

Breast imaging experienced another significant technological advance with the transition from analogue (film-based) mammography to digital mammography (Figure 3d). From the radiologist’s perspective, digital mammography is performed the same as analogue mammography. However, because the images are ‘read’ from electronic signals by a computer rather than developed on x-ray film by a technologist, images are available to the radiologist in a much shorter time.

Digital mammography has the added benefit of lower radiation dose compared with analogue (film-based) mammography. As radiologists traded in their light boxes for computers and workstations, the digital transition allowed workflow improvements such as integration of imaging with the electronic medical record and reporting systems.

Building on advances in digital mammography, digital breast tomosynthesis (DBT) was the next major technological development in mammographic imaging. DBT acquires multiple low-dose mammographic projections through the breast thereby improving the visualization of overlapping tissues. DBT has been shown in studies to reduce false positive findings and improve detection of invasive cancers12-14. As a result, DBT is often called ‘a better mammogram’ and may soon become the standard for mammographic screening.

BREAST ULTRASOUND

Breast ultrasound is an indispensable tool in current breast imaging practice and provides complementary information to mammography. Similar to early mammo film, early ultrasound images would seem crude by modern standards (Figure 4a) but served to distinguish a mass as solid or cystic. Just as mammography has seen technological improvements, so has breast ultrasound.

MAMMOGRAPHY OF TODAY: DIGITAL MAMMOGRAPHY AND DIGITAL BREAST TOMOSYNTHESIS

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Adding ultrasound to mammography improves a radiologist’s ability to distinguish benign from suspicious lesions, thus reducing the number of biopsy procedures, for example, in the case of the simple cyst shown in Figure 4b15. Breast ultrasound for whole breast screening has been shown to detect small cancers that are not palpable and cannot be seen by mammography, particularly in dense breasts20. A high rate of false positive biopsies and operator dependency are acknowledged limitations of hand-held screening ultrasound.

**BREAST MRI**

Breast MRI was not considered useful for breast cancer evaluation until gadolinium contrast became available. In the mid-1980s, Werner Kaiser and Sylvia Heywang-Köbrunner reported on the potential for contrast-enhanced MRI in the clinical evaluation of breast cancer21. During the next two decades, clinical applications for breast MRI expanded from diagnostic applications such as evaluation for unknown primary cancer in a patient with axillary adenopathy, extent of disease evaluation, and pre-surgical planning.

Breast MRI is the most sensitive means of detecting breast cancer (Figure 5) but is much more costly than mammography and results in more false positive biopsies than mammography. Thus, breast MRI is not currently recommended for screening the general population but reserved for supplemental screening (in addition to mammography) of high risk populations such as BRCA mutation carriers and patients with very strong family history of breast cancer.

**BREAST INTERVENTIONAL PROCEDURES**

**Wire localisation**

Breast localisation and minimally invasive biopsy procedures developed alongside mammography and other breast imaging technologies. Prior to the 1970s, suspicious breast lesions required surgical excision to obtain a diagnosis. As a result, several benign surgeries were performed to diagnose one cancer. For non-palpable lesions seen at mammography, a large amount of breast tissue was removed to ensure the lesion was included in the specimen. Pioneers such as Gerald D. Dodd, Jr. initially placed needles ‘freehand’ into the breast to guide surgeons to non-palpable lesions seen by mammography, but the needles could easily fall out22. Radiologist Peter Hall, along with surgeon Howard Frank, reported a technique for hookwire localisation through a needle in 1976. The hook-wire held in place within the breast better than a straight needle. Additional improvements came with the development of needle localisation systems that allowed repositioning for more accurate placement of the wire, for example as developed by Daniel Kopans and Harry Homer23. Development of grid localisation devices, which allowed needle placement parallel to the chest wall (Figure 6), created a safer procedure for patients compared with the freehand technique, in which the needle pointed towards the chest wall and thus caused a risk of pneumothorax. The increased accuracy of wire localisation techniques allowed surgeons to remove less breast tissue and provide better cosmetic results for patients. Currently, localisation is performed under mammographic, ultrasound or MRI guidance, even using localising devices other than wires, for example, radioactive seed localisation24,25.

**Percutaneous Biopsy**

Development of image-guided percutaneous breast biopsy allowed a more rapid, less invasive, less expensive way to obtain a tissue diagnosis for suspicious findings and provided excellent cosmetic results for the patient with little, if any, scarring26. The role of the breast imaging radiologist now expanded to include biopsies with stereo-rectic guidance for non-palpable breast lesions began in 1976 at the Karolinska Hospital in Sweden27. Fine needle aspiration biopsy was attractive as a minimally invasive procedure but suffered from a high rate of insufficient sampling under general use and also required available cytology expertise. Ultrasound-guided core biopsy was described by Carl D’Onofrio and Ellen Mendelson in their 1989 review28. Core biopsy has advantages over fine needle aspiration biopsy in terms of larger tissue sample and ability to diagnose invasive disease based on histology. Currently, core biopsy is successfully performed under mammographic, ultrasound or MRI guidance. This minimally invasive technique is currently considered the ‘first line’ approach to obtain a diagnosis rather than surgical excision.

**SUMMARY**

Breast imaging radiologists today have more tools at their disposal and are a more integral part of patient care than ever before. Image-guided minimally invasive needle biopsies of the breast have virtually eliminated the need for surgical biopsies, decreasing patient morbidity and reducing healthcare costs for society. Advanced mammography remains central to early detection efforts and lower mortality rates from breast cancer.
BREAST CANCER PATIENTS TO BENEFIT FROM EIBIR’S EU-FUNDED IMAGING RESEARCH PROJECTS
CHAPTER 4: RESEARCH

Breast cancer is the second most common cancer in the world, and kills more women than any other cancer type. Between 2007 and 2013, the European Union (EU) invested €160 million in breast cancer research and treatment. EIBIR is a non-profit organisation founded by the European Society of Radiology which has coordinated and managed three major EU projects on Biomedical Imaging Research (EIBIR) has coordinated and managed three major EU projects on biomedical imaging research throughout Europe and beyond. EIBIR provides expert advice, professional project management, coordination, dissemination (informing people of the results) and exploitation (ensuring the results are used) services for international collaborative research projects and clinical studies.

EIBIR’s mission is to coordinate and support the development of biomedical imaging technologies and the dissemination of knowledge with the ultimate goal of improving the diagnosis, treatment and prevention of disease. EIBIR’s support for several breast cancer research projects over the last decade is integral to this mission and this article presents three EU-funded and EIBIR-coordinated projects, highlighting their innovative ideas and results, as well as their potential benefits for patients across Europe.

The three-year (2008-2012) project Highly Accurate Breast Cancer Diagnosis through Integration of Biological Knowledge, Novel Imaging Modalities and Modelling (HAMAM) had the ambitious goal of improving methods for the early detection and accurate diagnosis of breast cancer and suspicious breast tissue. The aim was to tailor treatment procedures to the individual patient by integrating various types of medical images and patient information together into one clinical workstation.

When investigating a suspected case of breast cancer, clinicians prefer to use a range of imaging methods, which can include techniques such as mammography, 2D ultrasound, dynamic contrast-enhanced magnetic resonance imaging, digital breast tomosynthesis, positron emission mammography and automated 3D breast ultrasound. The HAMAM project set out to develop a new patient-centric workstation that incorporates these diverse and advanced image acquisition and corresponding image analysis methods into one user-friendly interface. This makes it quicker and easier to access the wide range of information needed for physicians to make accurate, early diagnosis of breast malignancy as a basis for reliable treatment decisions.

A team of nine scientific institutes and companies from five European countries, plus the USA, contributed to the project, coordinated by EIBIR.

Among the key outcomes of the project were a number of tools designed to automatically correlate and interpret information from different sources. With conventional imaging workstations, extensive training is required before readers are able to identify instances of suspicious structures in 2D projection images, like mammography and 3D modalities. A major result of the HAMAM project is a set of new techniques that can automatically map corresponding anatomical structures across different types of medical imaging. The images can then be presented such that sizes, positions, and orientations match between these various types of imaging, giving the human reader a more complete and accurate picture of the lesion.

A new system was also developed to classify lesions as either benign or malignant using image descriptors from mammography with kinetic and morphological descriptors from magnetic resonance imaging (MRI).

A second computer-aided diagnosis (CAD) system assists radiologists in characterising suspicious lesions in automated breast ultrasound (ABUS), a promising technology for screening women with dense breasts. In a reader performance study, this new CAD system outperformed most radiologists and, when used by radiology residents, significantly improved their performance compared to conventional ABUS reading. In addition, HAMAM generated improved knowledge of how the genetic risk of breast cancer can be used in clinical practice.

The methodological innovations were integrated into the patient-centric HAMAM workstation (see Figure 1), which enables readers to quickly access the various imaging studies, plus non-imaging information, and make fully informed, computer-assisted decisions about diagnosis and treatment. This offers the potential to dramatically improve the efficiency of breast cancer care.

The results from HAMAM encouraged the project team to apply for further EU funding and this led to the project Virtual Physiological Human: Personalised, Predictive Breast Cancer Therapy Through Integrated Tissue Microstructure Modelling (VPH-PRISM), which has continued with much of the work of HAMAM. VPH-PRISM aimed to develop personalised and predictive modelling of breast cancer which would allow treatment.
also have their own specific ‘language’ when it comes to their findings.

The aim of the VPH-PRISM project was to develop a way to allow these specialists to essentially speak the same language. The team was made up of leading organisations in the fields of pathological imaging, radiological imaging, image processing and biophysical and statistical modelling from four European countries and two partner organisations from the United States. Researchers created a unique database that allows image data from a range of technologies such as MRI, mammography and ultrasound to be combined with pathology data and other information like patient age, patient lifestyle and genetics. This means the clinician would

FIGURE 1

The HAMAM Workstation which gives users access to various imaging studies and non-imaging data in one platform.

FIGURE 2

Surgeon using VPH-PRISM surgery planning iPad application in the operating room.

stratification and prevent unnecessary and unsuccessful treatment. The rationale behind the VPH-PRISM project is that detecting breast cancer early and getting the right treatment started as soon as possible requires input and expertise from a number of medical specialists. These specialists include radiologists, gynaecologists, pathologists, surgeons, radiotherapists and oncologists, who all use different sets of tools in the diagnosis and treatment of breast cancer. For instance, radiologists read images from scans and pathologists examine tissue samples for signs of cancer. Surgeons and clinicians then use this information for diagnosis, as well as treatment and surgery planning, but they tend to receive this information separately from the various specialist disciplines, which

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CHAPTER 4: RESEARCH

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SCREENING & BEYOND | MEDICAL IMAGING IN THE DETECTION, DIAGNOSIS AND MANAGEMENT OF BREAST DISEASES

CHAPTER 4: RESEARCH
These new tools will also have a significant impact on breast cancer care as they will facilitate earlier and more accurate diagnosis, leading to improved outcomes, as well as better surgical outcomes through more accurate and efficient surgical planning.

The project team is confident that the project has served as a successful proof of concept for facilitating the development of improved surgery planning tools in breast cancer and enhanced treatment decision support for clinicians. The data collected during the course of the project will also be made available to other researchers and the unique data hosting platform developed for the purposes of the VPH-PRISM project will be of value to other research projects which plan to collect a range of multimodal data. This means that the project will have a lasting impact on research in the field of breast cancer and eventually clinical practice, which will benefit from improved surgery planning and support in the treatment decision-support process.

In early 2016, yet another breast cancer-related project was launched. The Digital Hybrid Breast PET/MRI for Enhanced Diagnosis of Breast Cancer (HYPMED) Project will develop a hybrid system of two medical imaging modalities (MRI and PET) for improved diagnosis of breast cancer and personalised therapy control. A team of nine organisations coordinated by EIBIR, including major universities, research organisations and industries, are working to develop a device that can transform conventional MRI scanners into high-resolution PET/MRI hybrid systems (see Figure 3). This system can then be used to identify even the smallest breast tumours and better characterise the cancer, as well as its response to therapy. This new device will allow for vastly improved imaging of breast cancer and allow minimally invasive MRI and PET-guided targeted biopsy. The impact of this technology on outcomes is clear; diagnosis, and monitoring of treatment response in breast cancer will also be assessed through a clinical study with 250 patients. Imaging data will be correlated with established and new molecular biomarkers and the results will be compared to those obtained from more conventional whole-body PET/MRI and PET/CT. Patients will clearly benefit as the radiation dose of PET/MRI and PET/CT is lower and comparable to a regular digital mammogram. Moreover, the HYPMED approach is also likely to be transferrable to other clinical applications, such as prostate cancer detection and hybrid cardiac imaging. This groundbreaking concept convinced the reviewers of the EU Horizon 2020 funding programme, who awarded the HYPMED project’s proposal the highest evaluation score possible.

Medical imaging is an indispensable partner in the fight against breast cancer. Its technology and methods allow clinicians to find breast cancer earlier and less invasively, which gives them and their patients more options and a better chance of survival. This makes it vital that investment in biomedical research imaging continues and that the researchers get the support they need. The projects covered in this article may have taken different approaches to improving breast cancer care, from integrating clinical decision aids to develop new tools for clinicians to developing new PET/MRI technology. However, they all share the goal of equipping clinicians throughout Europe with new and improved tools to diagnose and treat breast cancer earlier and more effectively. Despite the funding for all of these projects, more research and innovation is needed to ensure that they are brought into clinical practice and their full potential is realised. To ensure that happens, the EIBIR team remains committed to helping imaging researchers get more innovative projects funded through the Horizon 2020 programme, and it will continue to offer its support beyond the next decade.
EUSOBI
RECOMMENDATIONS
FOR WOMEN’S
INFORMATION

MAMMOGRAPHY
BREAST ULTRASOUND
BREAST MRI
IMAGE-GUIDED BREAST BIOPSIES
MAMMOGRAPHY

BY FRANCESCO SARDEANELI, EVA M. FALLENBERG, PAOLA CLAUSSER, RUBINA H. TRIMBOLI, JULIA CAMPS-HERRERO, THOMAS H. HÉLBICH, GABOR FORRAI, ON BEHALF OF THE EUROPEAN SOCIETY OF BREAST IMAGING (EUSOBI)

INTRODUCTION

Malignant tumours (cancers) and benign diseases are very common in the breast.

Aside from clinical history (disorders in the family, previous breast diseases/ surgery, hormone therapy, personal well-being and complaints), inspection (external viewing) and palpation, which compose the so-called clinical breast examination, imaging procedures and especially mammography are of crucial importance in the detection and diagnosis of breast cancer and other breast diseases. Mammography is a specialised radiography of the breast using x-rays to generate images of the breast. Its purposes are: first, early detection of breast cancer before symptoms (screening mammography); and second, diagnosis in patients with symptoms such as a palpable lump (diagnostic mammography), also named clinical mammography.

This article – specifically aimed at summarising the most important information to be offered to women about mammography – updates a previous article published in 2012 by the European Society of Breast Imaging (EUSOBI), taking into consideration the most recent evidence in favour of mammography and of two mammographic techniques now available for clinical practice: digital breast tomosynthesis (or simply tomosynthesis) and contrast-enhanced spectral mammography (CESM). Here we also took into account the recent position paper on screening for breast cancer by EUSOBI and 29 national breast radiology bodies, which should be considered complementary to this article.

SCREENING AND DIAGNOSTIC MAMMOGRAPHY

Mammography is the most important imaging procedure for breast cancer detection and diagnosis. The general aim is to enable early treatment of breast cancer to improve survival rates and to reduce the need for aggressive treatment such as mastectomy. It can be performed in a screening setting or a diagnostic setting. In both settings, whenever something suspicious is found, the woman is recalled for a tailored further assessment, including ways of reporting, are considered complementary to this article.

Screening mammography

Screening is performed periodically in order to find small cancers before they are detected through self-examination or clinical breast examination. Mammography is performed every one, two, or three years from the age of 40-50 years until around 70-75, depending on regional screening programmes. Relevant differences in screening programmes across European countries, including ways of reporting, are due to differences in culture, technical circumstances, biopsy options, financial restrictions, and breast cancer prevalence. Women with a high frequency of breast cancer in their family should start even earlier with periodic imaging, possibly with protocols including contrast-enhanced magnetic resonance imaging (MRI), after consulting specialised centres, since mammograms in those conditions may have very limited diagnostic power.

Screening mammography is a standardised procedure composed of four views (also named projections), two for each breast: the craniocaudal projection and the medio-lateral oblique projection. In some countries, clinical breast examination is a part of the procedure, even though it added value in the screening setting, when mammography is performed, is negligible. Screening mammography can be performed by a radiographer alone; the resulting images are usually read by two radiologists, independently, in separate sessions. If the exam is judged to not reveal any abnormally suspicious for malignancy, the woman receives a letter communicating this result. If something suspicious is found, the woman is recalled for a tailored further assessment that can be variably composed of additional mammographic views, tomosynthesis, ultrasound, MRI, CESM, or needle biopsy. When this assessment is concluded, a formal written report will be prepared by the radiologist and given to the woman during a dedicated interview.

Malignant tumours (cancers) and benign diseases are very common in the breast.
Diagnostic mammography is performed in patients presenting with clinical symptoms such as a palpable lump, nipple discharge, skin thickening or retraction, oripple retraction, in order to diagnose or exclude breast cancer. Diagnostic mammography is usually performed by a radiographer and images are immediately available for the radiologist to assess. Before or after the lateral acutation of the two standard projections already mentioned for screening mammography, a full clinical breast examination is performed by the radiologist. This is particularly important when results of a full clinical breast examination recently performed by another doctor are not available. According to the radiologist's preference, palpable lumps, scars from previous surgeries or other abnormalities can be highlighted by positioning the patient in a specific way, and the radiologist may ask for additional views or images to be acquired. The standard mammographic projections are the mediolateral oblique (MLO) and the craniocaudal (CC) views. Additional views may be acquired at the radiographer's discretion for a more accurate assessment.

When interpreting mammogram images, it is important to consider the patient's medical history, including previous mammograms, as well as any symptoms the patient may be experiencing. Image interpretation is a collaborative process between the radiographer and the radiologist, who work together to ensure that all relevant findings are identified and communicated to the patient. The radiologist will provide a detailed report that includes all significant findings, along with recommendations for further evaluation or treatment.

After the procedure, the patient is usually discharged and instructed on what to expect in terms of any potential discomfort or side effects. Follow-up appointments may be scheduled to monitor the patient's progress and ensure that any necessary interventions are in place.

In summary, mammography is a critical tool in the early detection and management of breast cancer, and it is important for patients to be fully informed about the procedure and its potential implications. Regular mammograms can help detect breast cancer at an early stage, improving the chances of successful treatment and survival.
CHAPTER 5: EUSOBI RECOMMENDATIONS FOR WOMEN'S INFORMATION

WITH RECOMMENDATIONS

In many European countries, standardised classification systems are used for the conclusions of mammography reports. A European system uses the five-level scale from R1 to R5, where R1 stands for radiology. R1 means no abnormalities, R2 benign findings, R3 equivocal findings, R4 suspected cancer, R5 strongly suspected cancer. A system developed in the United States – the Breast Imaging Reporting and Data System (BI-RADS) – but also used in many European countries, includes a similar scale, from BI-RADS 1 to BI-RADS 5.

The main difference is for BI-RADS 3, which implies a very low probability of cancer (less than 2%), allowing the possibility of waiting for a short interval (usually three to six months) before a repeat mammogram. Conversely, the R3 category indicates a probability of cancer that is higher than that of BI-RADS 3. Moreover, the BI-RADS score system also includes BI-RADS 0 (examination insufficient for a diagnostic conclusion; further work-up needed) and BI-RADS 6 (evaluation of an already diagnosed cancer).

Note B. In practice, if you have an R4–R5 or a BI-RADS 4–5 finding, needle biopsy is recommended. In case of R3 or BI-RADS 3, meet your radiologist and ask for a detailed explanation of this result, the risks, and of the probabilities associated with different options.

DIAGNOSTIC PERFORMANCE OF MAMMOGRAPHY

No diagnostic test is perfect. This rule also applies to mammography. When thinking about screening, women should be aware that about 28% of cancers can be missed10, especially in pre-menopausal women and in those with dense breasts. This means that if we consider 1,000 women getting a screening mammogram, if eight to ten cancers are present, then two or three can be missed, mostly because they are not well distinguishable from normal breast tissue. Still, mammography is the best proven method for screening average risk women.

Note B. Do not underestimate the importance of breast symptoms (especially a new palpable lump, skin/nipple retraction or nipple discharge) regardless of the timing of your last negative mammogram. Go to your radiologist and ask for a full exam.

RADIATION EXPOSURE FROM MAMMOGRAPHY

The radiation exposure for a mammogram is low. A study11 reported that undergoing repeated mammograms over a time period of 34 years (annually from age 40 to 55 by mammography from 56 to 74) entails a risk of radiation-induced breast cancer equal to one in 1,000 women screened. The risk of breast cancer in the female population of western countries is equal to that of one in every ten women. The first risk is 100 times smaller than the second, while the reduction in breast cancer mortality thanks to early detection with screening mammography is about 40%. Another study12, applying the mortality reduction of 43% as an effect of screening mammography, also considering the ‘minimal’ risk of radiation-induced breast cancer, found that biannual screening mammography performed in 100,000 women age 50–69 saves 350 lives. Anyway, for the 40–49 age range, the problem of radiation effects depends on the estimated magnitude of radiation-induced breast cancer in this younger age interval and must be more carefully considered. Importantly, even in the rare case of radiation-induced breast cancer, in a screening setting most of these will be detected early and treated.

OVERDIAGNOSIS

Not all the breast cancers diagnosed with screening are aggressive and fatal cancers. In the absence of screening mammography, some breast cancers – estimated to be about 6.5%, with a range from 1% to 10% – would have remained totally free of symptoms, due to the very slow growth of these types of lesions, that do not tend to advance outside the breast13. However, these cancers cannot be distinguished from those that, if left undiagnosed and untreated, would be fatal. Thus, if we want to reduce breast cancer mortality, we must accept a rate of overdiagnosed cancers with the consequence of a rate of unnecessary treatment, mainly including surgery and radiation therapy. An effective representation of the balance between early diagnosis and overdiagnosis has been provided by the Euroscreen working group14: for every 1,000 women screened from 50 to 69 years of age, seven to nine breast cancers as deaths are avoided, four breast cancers are overdiagnosed. 170 women have at least one recall followed by non-invasive assessment with a negative result, 30 women have at least one recall followed by invasive procedures with a negative result. In practice, the probability of a life being saved is double that of a breast cancer being overdiagnosed.

NEW MAMMOGRAPHIC TECHNIQUES: TOMOSYNTHESIS AND CONTRAST-ENHANCED SPECTRAL MAMMOGRAPHY

Two further developments of digital mammography have recently been introduced into clinical practice: tomosynthesis and contrast-enhanced spectral mammography (CESM). Both techniques are intended to overcome some limitations of mammography by reducing summation effects (tomsynthesis) or by increasing contrast differences (CESM), especially (but not only) in women with dense breast tissue. These women, tumours can be masked due to overlying breast tissue, leading to underdiagnosis of contrast to the adjacent normal breast tissue is common. So far, these techniques have mainly been proposed as an adjunct to mammography in women with inconclusive findings in their initial mammograms, with interesting results.

Tomosynthesis has also been positively evaluated as a screening tool.

Tomosynthesis is carried out with a mammographic unit that allows acquisition of either usual digital mammograms or tomosynthesis studies. The same crano-caudal and medio-lateral views are acquired for both examinations and the patient's preparation

FIGURE 3

An asymmetry is seen in the supero quadrants of the right breast in a 66-year-old woman undergoing screening mammography (only MLO view shown) (A). On digital breast tomosynthesis (MLO view) a mass associated with architectural distortion is clearly visible (B). The lesion was identified on ultrasound (not shown) and image-guided biopsy was performed. Histology showed an invasive ductal carcinoma.
Tomosynthesis can be acquired as an addition to the usual mammograms or it can be acquired alone. Because very similar images to the usual mammograms can be reconstructed from the tomosynthesis dataset, this so-called synthetic mammograms can avoid the need to acquire the original usual mammograms\(^1\). Depending on the device used, the radiation exposure is slightly higher than mammography, but it is still within the limits recommended by international radiation safety guidelines\(^2\). The results of different studies comparing mammography on its own against mammography with tomosynthesis have demonstrated that tomosynthesis is able to significantly increase cancer detection up to 30–40\(^\%\)\(^3\).

Tomosynthesis is already used as a screening modality in the United States. In Europe, only few centres perform tomosynthesis in organised screening programmes, mostly in the context of research programmes approved by ethical committees. The results of these studies are promising. Three prospective studies showed that digital breast tomosynthesis (DBT) used as an adjunct\(^4\)\(^5\) or alternative\(^6\) to the usual digital mammograms allows for a superior diagnostic performance when compared to mammography alone; tomosynthesis provides an increase in detection rate in the range from 0.5 to 2.7 per 1,000 screened women as well as a reduction in recall rate in the range from 0.8 to 3.6 per 100 screened women\(^7\). All these aspects probably mean tomosynthesis will become a routine procedure in screening, just as mammography is now.

However, before introducing tomosynthesis in breast cancer screening outside ethical-approved trials, there should be evidence for a statistically significant and clinically relevant reduction in the interval cancer rate. This caution is due to the need to avoid an increase in overdiagnosis and costs. Initial results showing a reduction from 0.7 to 0.5 interval cancers per 100 screened women were recently reported from a large study in the United States\(^8\), but further evidence is needed.

Note: During a breast examination performed outside the screening setting, it is up to the radiologist whether to perform only mammography, to associate tomosynthesis or ultrasound, or to perform tomosynthesis without mammography. By obtaining reconstructed synthetic mammograms, this decision is based on various issues: the characteristics of the breast, the availability of previous examinations, the availability of technology, and also the radiologist’s preference in relation to the specific case.

Note 1. If you are invited to attend a screening programme where tomosynthesis is proposed in the context of a study, or as routine practice, consider that the potential advantages of tomosynthesis in terms of increased cancer detection and reduced recall rate should overcome the modest increase in radiation dose.

Contrast enhanced spectral mammography

As is the case for contrast-enhanced MRI, the basis of contrast-enhanced mammography is the fact that during the development and growth of a tumour, it develops its own new blood vessels, which can be a bit leaky, allowing an intravenously injected contrast agent to enrich the tumour. This enhances the contrast of the tumour compared to the surrounding tissue. To be able to show this tumour contrast uptake in a mammographic image, you have to acquire two exposures of the breast within the time of one compression, each of them with a different x-ray energy composition, a technical possibility available with some new mammographic units. This results in a low-energy image, identical to a normal mammogram, and a high-energy image containing information about contrast agent distribution in the breast; the use of different energies is the reason for the denomination spectral mammography. Depending on breast composition and thickness, this causes an extra radiation dose of approximately 20\%, but both images together still imply an x-ray dose below the recommended dose for mammography\(^9\)\(^10\).

Before the acquisition of the two images starts, iodinated contrast agent has to be intravenously injected. This is usually done while the patient is seated near the mammographic unit. Two minutes after the start of the injection, the patient is guided to the mammography system and positioned similarly to contrast-enhanced MRI. Within roughly five minutes, the usual cranio-caudal and medio-lateral oblique views of both breasts are taken bilaterally, each of them composed of a low-energy image and a high-energy image. The two images are combined using special software, creating a new image where the presence of contrast uptake is easily seen. The diagnostic performance of CESM has recently been summarised by a systematic review and meta-analysis\(^11\), i.e. a combination of the results of previous studies on CESM. The authors identified eight studies (four prospective and four retrospective) for a total of 920 patients, and showed that the ability to detect existing cancers (sensitivity), estimated from all studies, was about 98\% while the ability to recognise the normal condition in the absence of any false positive findings (specificity), estimated from six studies reporting mammography, was about 58\%. The majority of included studies were judged to have studied very selected populations. The mean cancer size, reported only in three studies, was 21.2mm. The authors concluded that high-quality studies are required to assess the CESM accuracy. In practice, CESM still deserves evaluation and the results of this meta-analysis cannot be considered conclusive. Interestingly, two recent studies confirmed a high sensitivity of CESM (94–95\%) with higher values of specificity: 81\% in the symptomatic setting\(^12\) and 74\% in the post-screening assessment\(^13\).

On the basis of preliminary results, CESM can be considered an alternative to contrast-enhanced MRI in the case of contraindications to MRI (including the presence of MRI-unuitable devices in the patient’s body, claustrophobia, and obesity) that prevents the patient from entering the magnet or to perform a reduced contrast injection as well as local conditions of limited MRI availability\(^14\), due to interesting results obtained by comparing CESM and MRI in the same condition\(^15\).

Note 2. It is important to note that contrast-enhanced agents are frequently used in clinical practice, mostly intravenously injected for contrast-enhanced screening & beyond | medical imaging in the detection, diagnosis and management of breast diseases

screening & beyond | medical imaging in the detection, diagnosis and management of breast diseases
CHAPTER 5: EUSOBI RECOMMENDATIONS FOR WOMEN’S INFORMATION

B

computed tomography. There are contra-
indications (history of allergic reactions,
renal failure) and possible side effects
that require discussion with the patient
and the signing of an informed written
consent. Thus, the injection of iodinated
contrast agents for mammography
requires the same precautions used for
other contrast-enhanced x-ray based
examinations\(^3\). Before the examination,
the radiologist will clarify the risks and
benefits associated with the intravenous
injection of iodinated contrast agents.

FREQUENTLY ASKED QUESTIONS (FAQs)

1. How painful is breast compres-
sion for mammography? Mammmography is well tolerated by the
vast majority of women. In particular, it
is painless for about 40–50% of women,
a little painful for 40%, rather painful for
12%, and very painful only for 4%. Pain
disappears immediately after the proce-
dure for 76% of the women, while it lasts
several minutes for 13%, several hours for
7%, and more than a day for 4\(^\circ\). How-
ever, the advantages of compression are
clear, and unnecessary pain may someti-
times be avoided by suitable scheduling
(see Note C). The radiographer will guide
you through all the steps of the examina-
tion, and will take care of minimising the
discomfort during breast compression.

2. When should the first mammo-
graphy be done? Women aged 40 to 70
years of age, with a time interval
depending on several factors described
above. Extension from about 40–45
years is now adopted by several
screening programmes. When starting
at 40, a one-year interval can be recom-
mended up to 45–50, considering the
probable higher density of the tissue and
the possible faster growth of the tumour.
After 50, the optimal interval may be
decided based on personal history and
breast density. If you have symptoms,
mammography may be necessary for
you at any age. If you are a woman
with an increased risk of breast cancer
gene (mutation carrier, multiple breast/
ovarian cancers in the family), screen-
ing should start before the age of 40,
according to your personal calculated
risk level, access to special screen-
ning programmes, and other factors.

Note K. If you are invited to attend
an organised screening programme, fol-
low the programme’s planned interval.
If you have any doubts about this time
interval, or the usefulness of ultrasound
as a supplemental screening method,
consult your radiologist. If there are a
high number of incidences of breast
cancer in your family, especially at a
young age and before menopause, you
may need to be screened with MRI\(^4\).
Consult your radiologist or a special-
ised centre (e.g. a family cancer clinic).
Information on reasons to have an MRI
scan is available in a special EUSOBI paper\(^1\).

3. What about screening mammog-
raphy for women over 75? The
continuous increase in life expec-
tancy prevents us making a clear cut
definition of an upper age limit for
screening mammography. A general
suggestion is to continue screening with
mammography for elderly women as
long as their health is not significantly
compromised by illness that drastically
reduces life expectancy\(^4\). Discuss
this decision with your radiologist.

4. Can women with breast
implants or breast reconstruc-
tion undergo mammography?
Yes, in the majority of cases they can.
Special views with back placement of
the implant are commonly needed,
as well as specific technical expertise
from the radiographer. Exceptions
where mammography cannot be
performed are breast reconstructions
after complete gland tissue removal.
Limitations of mammography due to
the presence of an implant can be coun-
teracted by an accurate clinical breast
examination and breast ultrasound.

Note L. Always tell the radi-
ologist and the radiographer if
you have breast implants.

5. Is x-ray radiation from mammog-
raphy dangerous? The x-ray radiation
associated with mammography is low. See the Section
‘Radiation exposure from mammog-
raphy’ in this article for a comparison
between the risk of radiation-induced
breast cancer and the reduction of breast
cancer mortality due to mammography.

6. What is the role of new technolo-
gies like tomosynthesis and CESM?
The role of these new technologies is to
help in the detection and diagnosis of
breast cancers. Tomosynthesis is com-
monly accepted as an effective tool for
the evaluation of symptomatic patients
and suspicious findings at screening
mammography. Large studies in the
screening setting have shown that
tomosynthesis allows the identification
of more cancers than mammography
and potentially reduces the number of
women recalled for benign findings.
So far, CESM has been evaluated in a
limited number of small studies. It pro-
vides useful information on suspicious
lesions, increasing the visibility of malign-
ant lesions, particularly in women with
dense breasts, and can be used as an
alternative to contrast-enhanced MRI
especially in the case of contraindica-
tions to MRI or to gadolinium-based contrast
injection, or when MRI is not available.
INTRODUCTION

Breast ultrasound is one of the four main methods for diagnosing breast diseases, together with mammography, magnetic resonance imaging (MRI) and image-guided needle biopsy.

The ultrasound probe is moved around the breast with the aid of contact gel, with the patient lying on their back or side. It does not require pressure, so ultrasound is usually painless. In terms of invasive cancer detection, the performance of ultrasound is similar to that of mammography and is less hampered by dense breast tissue. It may therefore be particularly helpful in younger women, who tend to have dense breasts. However, it doesn’t mean that ultrasound can replace mammography. Ultrasound is less sensitive than mammography at detecting breast microcalcifications, hence the sensitivity of ultrasound for the detection of ductal carcinoma in situ (DCIS) is less than that seen with mammography. Benign breast disease is very common, and ultrasound also detects benign lesions that may otherwise have gone unnoticed. Ultrasound is very useful in differentiating cysts from solid breast masses. Breast ultrasound examinations sometimes use Doppler and elastography, which are automated applications used to detect and measure blood flow and tissue stiffness respectively. However, these are not obligatory elements of a breast ultrasound examination. Breast ultrasound is expensive compared to mammography. However, compared to mammography, ultrasound of both breasts is time consuming and false positive test results are common. For this reason breast ultrasound examinations are often restricted to the breast of concern or even to the part of the breast, which is symptomatic. Interventional procedures are easy to perform under ultrasound control, so biopsy of solid breast masses, even if they are palpable, are often performed under ultrasound guidance. Automated whole breast ultrasound is being developed and provides images which can be reported by a radiologist at a later time.

An impediment to the more widespread use of breast ultrasound for screening is the fact that with breast ultrasound - unlike all other breast imaging methods such as mammography, tomosynthesis and breast MRI - the vast majority of the examination is not captured, i.e. the images are not stored for later review, or for review by other breast imaging specialists. Usually, the examiner will only document abnormalities that they have noticed during the scanning process. If an examiner overlooks an abnormality during the ultrasound examination, that abnormality will not be visible on later review of the ultrasound study documentation. This, in turn, means that quality assurance for ultrasound is more challenging than it is for other breast imaging methods, where third parties have a chance to review the images of a given study and thus may identify insufficient ultrasound examination performance. This is not, however, true for examinations using automated whole breast ultrasound, where the whole examination is recorded.

CONTRAINdications and INDICATIONs

For breast ultrasound there are no absolute contraindications (reasons a patient could not undergo the procedure). The examination can be suboptimal in patients who cannot lie still, lie flat or move onto the examination couch. Examinations can be difficult in women with open wounds or damaged skin, and tissue behind breast implants is often obscured. The total examination time ranges from five to twenty minutes. In women with a suspected breast cancer, the whole of the affected breast and the axilla (underarm area) of the same side are usually examined. Ultrasound of the opposite breast in women with breast cancer is performed in some centres as there is a small chance of picking up a cancer in the opposite breast not seen on the mammogram. Definite indications for breast ultrasound are listed in table 1. Possible indications and non-indications are listed in tables 2 and 3 respectively.

TABLE 1

<table>
<thead>
<tr>
<th>Definite indications for breast ultrasound</th>
<th>Possible indications for breast ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focal palpable abnormality</td>
<td>% risk of breast cancer, especially if local staging of a known breast cancer</td>
</tr>
<tr>
<td>Mammographic abnormality which is not detected</td>
<td>Recent nipple inversion</td>
</tr>
<tr>
<td>Breast lesion detected on MRI which is not definitely benign</td>
<td>Single duct nipple discharge</td>
</tr>
<tr>
<td>Local staging of a known breast cancer</td>
<td>Recurrent nipple inversion</td>
</tr>
<tr>
<td>Single duct nipple discharge</td>
<td>Palpable breast lesion</td>
</tr>
<tr>
<td>Recent nipple inversion</td>
<td>To guide biopsy/triage/localisation of a breast lesion</td>
</tr>
<tr>
<td>Palpable breast lesion</td>
<td>Follow-up of women receiving neo-adjuvant systemic therapy for breast cancer</td>
</tr>
<tr>
<td>Breast inflammation</td>
<td>First examination for any abnormality in young breast-feeding women</td>
</tr>
<tr>
<td>To guide biopsy/triage/localisation of a breast lesion</td>
<td>First examination for any abnormality in young women</td>
</tr>
</tbody>
</table>

TABLE 2

<table>
<thead>
<tr>
<th>Possible indications for breast ultrasound</th>
<th>Closest recent breast pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound &amp; women aged 40+ with dense breasts (in addition to mammography)</td>
<td>Screening in women with previous mammographically occult breast cancer diagnosed with breast-conserving surgery</td>
</tr>
<tr>
<td>Ultrasound &amp; women with previous mammographically occult breast cancer diagnosed with breast-conserving surgery</td>
<td>Differentiation between hamartoliod and other abnormalities in women with breast implants</td>
</tr>
<tr>
<td>Screening high-risk women, especially if the patient is unable to have MRI</td>
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TABLE 3

<table>
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<tr>
<th>Non-indications for breast ultrasound</th>
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</tr>
</tbody>
</table>

Technique/Procedure

Breast ultrasound is performed using a clinical ultrasound scanner using probes of 10-13MHz. Clear instructions and explanation regarding the entire procedure are provided by the operator performing the investigation. Breast ultrasound is usually performed with a chaperone in the room who will also be present.
The sensitivity of breast ultrasound for breast cancer is approximately 85%, which implies that a fraction of cancers may be missed by an ultrasound examination. Invasive cancers that are missed are in general either very small, directly behind the nipple or are difficult to distinguish from normal tissue or fibrocystic change. This is particularly true of lobular cancers, which account for about 15% of invasive cancers. Ductal carcinoma in situ (DCIS), a possible precursor of invasive breast cancer that is treated similarly to invasive cancers, is frequently not seen on ultrasound. DCIS is commonly depicted on mammograms as a cluster of microcalcifications. This means that significant clinical, mammographic or MRI findings should not be dismissed because an ultrasound scan is normal.

The sensitivity of mammography is less sensitive in younger women. There is some evidence that ultrasound too is less sensitive in women with dense breasts but the effect of breast density on sensitivity appears to be less for ultrasound than for mammography.4

Benign/malignant differentiation of solid breast nodules Solid masses that have clear benign characteristics are probably benign (BI-RADS 3), and have a less than 2% risk of being a cancer, so short term follow-up is often performed rather than immediate biopsy.5 New ultrasound techniques such as shear wave elastography may further improve ultrasound’s ability to differentiate benign from malignant breast masses.6

BREAST ULTRASOUND FOR SCREENING

Many studies have shown that in women with mammographically dense breasts, adding bilateral whole breast ultrasound to mammography can help to identify additional invasive cancers, which tend to be small and node-negative.7 Most of these studies have been performed in women at increased risk of breast cancer so the additional cancer detection in women of normal risk is unclear8 and the few studies which have been carried out are from Asia, so their findings may not be valid in European populations. Nonetheless, the additional cancer yield in women with non-dense breasts is low.

The down side of ultrasound screening is that it is very non-specific. Less than one in ten of biopsies prompted by ultrasound screening are malignant.9 This means that ultrasound screening is less specific than both mammography and MRI. Ultrasound screening is also more time consuming than mammography for the patient and the radiologist. It takes about 20–30 minutes to perform. Mammography takes about 5–10 minutes to perform and two minutes to interpret.

In the future, additional ultrasound techniques, such as shear wave elastography, may reduce the number of ultrasound-detected lesions that require either short term follow-up or biopsy.10 This may make adjunctive ultrasound screening more attractive.

Automated whole breast ultrasound analyses ultrasound images of both breasts to be acquired in about 15–20 minutes. These images can then be read by a radiologist later. Reading such an examination takes about 15 minutes.11 It is unclear if the sensitivity of this technique equals that of hand held ultrasound.
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The false positive rate increases with automated whole breast ultrasound15,16.

BREAST ULTRASOUND FOR BREAST CANCER DIAGNOSIS AND STAGING

Most breast cancers are detected by screening mammography or due to clinical symptoms. The standard way to assess suspicious lesions is with the so-called triple assessment: mammography, clinical symptom assessment and breast ultrasound. Image-guided needle biopsy is reserved for those cancers not seen on ultrasound, as the procedure is more uncomfortable and more time consuming than ultrasound guided biopsy.

Tumour size and focality

Ultrasound is superior to mammography or clinical examination in assessing the size of invasive cancers and how focally invasive is the tumour. Ultrasound is not as useful as mammography in detecting and sizing DCIS. MRI is the best method of assessing size and focality of breast cancer, but because of cost, availability, and the number of false positive results, MRI is reserved for those women where assessing tumour size is difficult.

Sometimes extra foci of cancer may be found in first-look ultrasound imaging than ultrasound guided biopsy. MRI is typically useful for assessing cancer that has spread from a tumour mass into a duct (intraductal extension).

In breast cancer patients, ultrasound of the contralateral breast is performed to identify synchronous bilateral cancers (appearing in both breasts at the same time). Because false positive findings are common with whole breast ultrasound, whether contralateral ultrasound should be performed in women with a new diagnosis of breast cancer is debatable17.

Second-look ultrasound

When a patient undergoes an MRI exam to stage a breast cancer, it is possible that MRI may detect additional lesions that have not been detected by an earlier staging ultrasound. Therefore a second ultrasound exam, referred to as a ‘second look’ is indicated. This does not mean that the first staging ultrasound exam was not correctly performed, but it is the most expert hands, small nodules or intraductal extensions can go unnoticed, and MRI, due to its superior sensitivity to breast cancer, depicts these lesions. In those cases in which these additional lesions are deemed important to characterise, because they may change the surgical treatment, a second-look ultrasound is indicated. This procedure will be most useful in additional mass lesions that are malignant and much less useful in non-mass lesions. If an additional lesion is not found in second-look ultrasound, the radiologist, together with a multi-disciplinary team, will decide the next step, such as MRI biopsy or follow up.

Assessing the axilla

Until recently, instead of the perilateral axilla was routinely performed in all women suspected or proven to have invasive breast cancer. If lymph nodes had a thickened cortex, were lobulated or were round rather than oval an ultrasound-guided biopsy was performed. Recent evidence suggests that core biopsy is more accurate than fine needle aspiration in this clinical situation18. This allowed the pre-operative identification of nodal metastases in about 50% of cases. Most women with proven nodal metastases then underwent a surgical axillary clearance while those women without proven axillary nodes metastases would have had a biopsy of the sentinel node, i.e. the closest node or nodes that filter fluid draining from that specific area of the breast. A recent study has cast into doubt the need to treat all involved axillary nodes with surgery. So clinical practice in this area is in a state of flux. Research is underway to try and accurately identify the sentinel node(s) pre-operatively and remove them percutaneously (through the skin). In women with very large involved axillary lymph nodes, the supraclavicular and infraclavicular fossae (areas above and below the collarbone) should also be scanned to look for enlarged nodes.

BREAST ULTRASOUND IN PATIENTS WITH IMPLANTS

Breast ultrasound is usually the first imaging test performed on women with implants who develop a palpable breast lump. As well as benign and malignant sold breast masses and cysts, women with implants can have silicone granulomas as a consequence of extra-capsular rupture19. Such granulomas have a characteristic ‘snow storm’ appearance on breast ultrasound images and this finding can be confirmed by ultrasound-guided biopsy.

Almost all ultrasound-guided intervention (biopsy, preoperative localisation) may be performed on implanted breasts. Cancers arising behind implants and false silicone areas may be missed by ultrasound. Ultrasound is not an accurate tool for identifying intra-capsular rupture (where the silicone is contained by a pseudo-capsule of fibrous tissue). MRI is the best imaging modality for identifying intra-capsular rupture.

EVALUATION OF THE EFFECT OF NEOADJUVANT CHEMOTHERAPY

In advanced breast cancer, many centres have adopted protocols that include the reduction of tumour load with neoadjuvant chemotherapy before surgical treatment. In this setting, MRI and ultrasound are often performed to monitor early treatment response and for pre-surgical evaluation20.
**TABLE 1**

<table>
<thead>
<tr>
<th>Reasons/indications for breast MRI exams</th>
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<tbody>
<tr>
<td>Occult primary breast carcinoma (searching for breast cancer in patients with mastectomies and negative mammography and ultrasonography)</td>
</tr>
<tr>
<td>Scenarios when evaluation is needed (searching for breast cancer in patients with mastectomies and negative mammography and ultrasonography)</td>
</tr>
<tr>
<td>Reassessment of those previously referred for mammography/ultrasoundography</td>
</tr>
<tr>
<td>Surveillance of women at high risk for breast cancer</td>
</tr>
<tr>
<td>Evaluation of women with breast implants</td>
</tr>
<tr>
<td>Other new indications have recently been proposed, such as nipple discharge and evaluation of lesions with uncertain malignant potential (so-called high-risk or B3 lesions) detected with mammography or ultrasound and needle biopsy under their guidance</td>
</tr>
</tbody>
</table>

**REASONS FOR BREAST MRI EXAMS**

Women's information is important not only for patient awareness about advantages and disadvantages of breast MRI, but also to be prepared for the examination. Patients need to be aware of the possible benefits and risks associated with breast MRI and of potential further investigations prompted by this exam. Moreover, technical quality of breast MRI is dependent on patient compliance.

In terms of cancer detection, MRI outperforms (but does not entirely substitute) both mammography and ultrasound. Its valuable diagnostic performance has been confirmed by many studies. However, benign lesions that would otherwise have gone unnoticed may be detected with MRI, leading to additional, otherwise unnecessary work-up. Costs must also be considered, as MRI is more expensive than mammography and ultrasound.

The main reasons/indications for breast MRI exams** are listed in Table 1.

*Note: When needle biopsy cannot be performed, a core biopsy should be performed.*
CHAPTER 5: EUSOBI RECOMMENDATIONS FOR WOMEN'S INFORMATION

PRECAUTIONS/CONTRAINDICATIONS

An MRI system is a relatively narrow tube in which the woman lies face-down during a breast examination for 15 to 30 minutes. Patients with claustrophobia are unable to undergo the exam unless they are psychologically/psychopharmacologically prepared or sedated. 

Contraindications to MRI are magnetic fields and radiofrequency waves, the presence of non-MRI compatible intracranial ferromagnetic clips for aneurysms and iron splinters in the eyes are absolute contraindications to MRI. In cases of doubt, an x-ray examination of the orbits can be performed to rule out the presence of iron splinters. Moreover, MRI is also contraindicated in patients with implanted electronic devices such as MR-inactive pacemakers, implantable cardioverter defibrillators, and neurostimulators.

The patient should inform the radiologist or the staff physician (technicians/nurses) if she has any allergy or permanent medication. These may contain iron pigments, and especially when loop-shaped (like an antenna), they may heat up and cause local burns. Tissue expanders (e.g. for breast reconstruction) may not be MRI-compatible. Women with tattoos or permanent makeup, metal screws or plates for osteosynthesis can safely have a breast MRI six weeks after implantation. A list of acceptable and unacceptable implantable devices and precautions needed for MRI imaging can be found on the internet.

As stated above, breast MRI without contrast material cannot be used to answer clinical questions18,19, with the evaluation of breast implant integrity as the only exception. Women with allergic predispositions or earlier allergic reactions to any CM have a higher risk for allergic reactions to CM. It is important to inform the patient well in advance of the examination. In individual cases, with very low kidney function (estimated glomerular filtration rate lower than 30 ml/min × 1.73 m²), contrast injection implies a real, but very low risk of a rare disease called nephrogenic systemic fibrosit20; contrast-enhanced MRI is also generally contraindicated in pregnant women, but this condition should be evaluated on a case-by-case basis.

Before entering the MRI room, the patient is asked to fill out a detailed questionnaire to rule out any contraindication to examination and to contrast media injection.

Note A: If you think you may be claustrophobic, you can go to the MRI centre and ask to see the MRI scanner to get practical information. If you are seriously claustrophobic, discuss this with the referring physician, radiologist, and personnel of the institution where MRI is scheduled. This issue should be discussed before the MRI examination. In any case, consult your radiologist before the scheduled MRI date. We recommend informing the personnel of the institution where MRI is scheduled. This issue should be discussed before MRI takes place.

Note B: To avoid a risk from MRI CM in the presence of renal failure, different regimens are adopted in European countries. Your renal function can be checked and reviewed before attending the examination. The use of a simple sedative medication to relieve the symptoms might be indicated.

Note C: If you have an important allergic predisposition (e.g. bronchial asthma) or you have had allergic reactions to any CM, you may consult your radiologist, and Personnel of the institution where MRI is scheduled, this with your referring physician. This issue should be discussed before your examination. In cases of serious allergic symptoms, a balance between the potential advantages of MRI and the risk of allergic reactions has to be made. Where MRI has to be performed, precautions need to be taken, including the administration of corticosteroids and antihistaminic drugs prior to the investigation. In any case, consult your radiologist before the scheduled MRI date. This issue should be discussed before MRI takes place.

Note D: If you have a history of breast biopsy, mammography, or surgical treatment, MRI should not be performed in cases where these procedures have been done in the last 30 days. To avoid interference, CM will be injected using an automated injector. Note E: If you have a history of breast biopsy, mammography, or surgical treatment, MRI should not be performed in cases where these procedures have been done in the last 30 days. To avoid interference, CM will be injected using an automated injector.

CONTRAINDICATIONS

In premenopausal women, contrast-enhanced MRI is preferably performed between the seventh and fourteenth days of the menstrual cycle, when the background enhancement of the fibroglandular breast tissue is low, and hence abnormalities are better detected and false positives less frequent21. In any case, scheduling the exam during the most suitable phase of the cycle may cause both false positives (findings suggesting a lesion but turn out to be benign) and false negatives (apparently normal or benign findings when a lesion is present). Cycle-related scheduling is not required for the assessment of breast implants, and CM administration is not usually required in breast implants.

SCHEDULING

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TECHNIQUE/PROCEDURE

Breast MRI is performed using MRI scanners with at least 1.5 T strength, which refers to the strength of the magnet within the machine. Clear instructions and explanation regarding the procedure are provided by a technician or a nurse. After a possible interaction with the radiologist on duty and completion of questionnaires, a simple puncture comparable to that for blood sampling will be performed. After the procedure and the puncture site will be briefly compressed to stop bleeding.

The woman should keep still during the entire examination as patient movement can cause disturbances in the resulting images as well as artifacts, which strongly reduce image quality and make interpretation difficult and sometimes impossible. A warm and sometimes tingling sensation can be felt in the arm that has received the injection. This may be more extensive and can possibly be felt throughout the body. A metallic taste may be noticed in the mouth, and a transient headache or nausea may occur in rare cases.

The procedure is performed with the capriun band removed. Any clothing containing metal, any jewellery, and other foreign objects must be removed. Some centres may require complete undressing and provide disposable clothing. The woman lies face-down on the MRI table with her breasts hanging free. The specific device used specifically for breast imaging, known as a ‘breast coil’, which contains the signal receiver. A technician or a nurse positions the breasts, avoiding folding of breast tissue on the edges of the coil. In some centres, slight breast compression is applied to reduce motion artefacts. Rubber ear plugs or headphones are
provided to reduce the scanner noise during image acquisition. Radiologists and technicians are able to commu- nicate with the woman during the examination. An alarm bell is provided; when it is rung by the woman, the examination will be terminated im- mediately and she will be removed from the magnet. Thus, the woman can be sure that if needed, she will be assisted.

When the woman is optimally posi- tioned, table and patient are moved into the magnet bore. MRI images are in the centre of the tube; the mag- netic field is most homogeneous at that position allowing for optimal image quality. The procedure is noisy, even though ear plugs or headphones attenuate noise perception. During the examination, the staff are encour- aged from talking to the woman, as this frequently induces movements and should be done only when really needed. Scan sequences produce different noises and different noise levels, more relevant being those for CE imaging (continuous buzzing sound), and for so-called diffusion-weighted imaging (continuous buzzing sound), which should be described. Lymph node evaluation is not a specific aim of breast MRI, but it is possible that the exam renews an unsuspected nodal metastasis.

Each report should end with a con- clusion, commonly associated with a diagnostic category and recommen- dations. In many European countries, a structured reporting and classifica- tion system is in use. The most com- monly applied system is the Breast Imaging Reporting and Data System (BI-RADS®) developed by the Ameri- can College of Radiology, also used with high-resolution 3 Tesla systems

### Conclusion

Bi-RADS diagnostic categories are used as follows:

- **0**: incomplete, additional imag- ing evaluation is needed
- **1**: negative, no abnormalities
- **2**: benign findings
- **3**: probably benign findings (short- term follow-up within six months recommended)
- **4**: suspected malignancy (nee- dice biopsy recommended)
- **5**: highly suspected malignancy (needle biopsy recommended)
- **6**: already histologically proven can- cer (typically reserved for MRI scans made for cancer staging or in the case of neoadjuvant chemotherapy)

Reported image findings should include breast density, the amount of paren- chymal background enhancement, and a usually structured description of relevant abnormalities, including those in the axilla (underarm area) or inci- dential findings in the image material of the thorax and abdomen, when visible. The side and location of any breast lesions should be described. Lymph node evaluation is not a specific aim of breast MRI, but it is possible that the examination renews an unsuspected nodal metastasis.

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Bi-RADS 3 findings form a special diagnostic category, with a chance of malignancy below 2%. However, the actual chance of an MRI-detected BI-RADS 3 lesion being malignant is sometimes higher, especially in high-risk women. For a BI-RADS 3 lesion, short- term follow-up is recommended instead of biopsy due to the low probability of malignancy and the likelihood that the efficacy of treatment will not be reduced due to a slightly delayed diagnosis. This entails repeat MRI examinations within six months and potential further repeat MRI at one year and two years after initial detection. When, at MRI follow-up, an MRI-detected lesion has disappeared, Shank, or remained unchanged in size, and does not show any new sign of malignancy, it can be downgraded to benign (BI-RADS 2). However, in some cases, mostly when the patient prefers an immediate con- clusion of the diagnostic pathway, a needle biopsy should be performed. The recommendation of needle biopsy should be performed for isolated, newly diagnosed lesions. It could not be performed in the case of a lesion adjacent to or close to a lesion already known to be cancer. Around 60% of lesions initially detected at MRI are identified using second-look targeted ultrasound, even though this rate varies among studies. The term ‘second-look’ refers to the common event that a lesion undetected in a first ultrasound examination is detected at the ‘second look’, when the radiologist knows from patient MRI where to look. In that case, needle biopsy is performed under ultrasound guidance; a faster, less invasive, and cheaper pro- cedure than MR-guided biopsy. When the lesion is not detected with ultrasound and the indication for biopsy still stands, an MRI-guided biopsy is indicated. It takes longer than a diagnostic breast MRI, and it is a special procedure, requiring dedic- ated targeting and sampling equipment, as well as trained personnel. In some countries it is necessary to apply for a specific remuneration (this is a rela- tively new and expensive procedure). However, in cases where MRI-guided biopsy cannot be performed or is a ded- icated equipment is not available, or the lesion site is not accessible, such as in large breasts (fat wall), computed tomography-guided biopsy or MRI-guided pre-surgical localisation may be performed.

Note H. When a needle biopsy is indicated for an MRI-detected finding, this doesn’t mean you have cancer. Up to 50-70% of MRI findings that require biopsy turn out to be benign targeted ultrasound, re-evaluation of mammo- grams, targeted mammographic views, or images obtained with digital breast tomosynthesis are useful, offering the possibility of a biopsy under ultrasound or mammography guidance. Thus, if a suspicious lesion (BI-RADS 4 or 5) is detected with MRI, an image-guided needle biopsy should be performed in almost all cases. Definition of the benign nature of a MRI-detected suspi- cious finding, using only other targeted imaging modalities, without biopsy, is only possible in very few cases. A suspicious lesion is detected at MRI, the lesion is not detected with ultrasound and the indication for biopsy still stands, an MRI-guided biopsy is indicated. It takes longer than a diagnostic breast MRI, and it is a special procedure, requiring dedic- ated targeting and sampling equipment, as well as trained personnel. In some countries it is necessary to apply for a specific remuneration (this is a rela- tively new and expensive procedure). However, in cases where MRI-guided biopsy cannot be performed or is a ded- icated equipment is not available, or the lesion site is not accessible, such as in large breasts (fat wall), computed tomography-guided biopsy or MRI-guided pre-surgical localisation may be performed.
these women a BI-RADS 3 finding has a higher probability of malignancy and biopsy is more frequently performed.

Sensitivity of breast MRI

Overall sensitivity of breast MRI for breast cancer is approximately 90%, which implies that 10% of cancers may be missed. Missed cancers are in general either very small or do not have enough contrast enhancement.

Sensitivity for ductal carcinoma in situ (DCIS), a non-invasive lesion, possibly a precursor of invasive cancer and similarly treated, is variable; some of them, especially those with a lower pathological grade (G0) can be missed30-32. Occasionally, invasive cancers can also be hidden at MRI. DCIS may be depicted on mammograms as a cluster of microcalcifications, even if, in some cases, MRI findings are negative. This implies that findings from clinical examination, mammography, or ultrasound, even if only probably benign (i.e. BI-RADS 3), should be reviewed when MRI findings are negative. Generally, if a needle biopsy is correctly indicated, a negative MRI finding cannot be considered an alternative to biopsy. Sensitivity also depends upon technical prerequisites, clinical indication, and reader experience.

Note K. If a needle biopsy based upon palpable abnormalities or mammography/ultrasound is indicated, you should have a needle biopsy to rule out cancer. Even though highly sensitive, breast MRI is not a perfect test and should not be used as an alternative for biopsy. Needle biopsies are performed to exclude the presence of cancer, as a consequence, when a biopsy is recommended, this does not mean that you have a cancer.

BREAST MRI FOR SCREENING

Due to its high sensitivity, breast MRI is an excellent screening tool (Figure 1). In cohorts of women with a familial increased risk for breast cancer, and of women who are carriers of BRCA1, BRCA2, or other rare genetic mutations, the superior sensitivity of breast MRI compared to other breast imaging techniques has been shown19,30-32. However, MRI also has a very high sensitivity for benign breast disease. This leads to additional investigations, including repeat MRI scans, targeted ultrasound, and biopsy, as stated above. This additional burden from MRI screening is greater in women with a prior lower breast cancer risk. Moreover, MRI is a relatively expensive examination, and the need for additional investigations further increases the cost. Consequently, the cost-effectiveness of MRI screening has been questioned for women who are not at increased risk40. Note that healthcare reimbursement of breast MRI screening varies from country to country.

Evidence for the substantial added value of MRI as a screening tool exists for women with proven BRCA1, BRCA2, or other rare genetic mutations30-32,44-45 for a proportion of women with an elevated risk based upon their family history, and for those patients who received thoracic radiotherapy before the age of 3044-45. A recent individual patient-data meta-analysis showed that for BRCA mutation carriers, the gain in sensitivity is also relevant over the age of 5044. Guidelines throughout Europe and the United States differ substantially in the risk level deserving breast MRI screening, and the age for starting and ending MRI screening.

Note L. If you have multiple cases of breast or ovarian cancer in your family, discuss the possibility of MRI screening with your referring physician, radiation therapist, and radiologist. There are risk assessment systems available to estimate your risk. The referring physician or your radiologist could decide to refer you to a specialised centre for risk evaluation. The results thereof can subsequently be matched to your local or national guidelines. Note that healthcare reimbursement is variable among countries.

BREAST MRI FOR BREAST CANCER STAGING

Most breast cancers are detected due to clinical symptoms or by screening mammography. The standard way to assess suspicious lesions is with the so-called triple assessment: mammography, an image-guided needle biopsy. MRI is not yet involved in initial cancer detection except in those women, usually at high risk, screened with MRI. When a breast cancer is detected, MRI may be performed to assess the extent of the disease, look for satellite lesions, and screen for other FIGURE 1

Small screen detected ductal carcinoma in situ (DCIS) in the right breast.

FIGURE 2

Large screen detected ductal carcinoma in situ (DCIS) in the left breast. Large area of non-mass enhancement in the lateral and posterior aspect of the left breast (arrows).
cancers either in the affected breast or in the contralateral (other) breast (Figure 2). MRI is much more useful for tumour extent evaluation than either mammography or ultrasound, even though overestimation and underestimation of tumour size still occur in up to 15% of patients. Although better documentation of tumour size and extent could lead to a better tailored surgery with a lower likelihood for positive margin resections for positive resection margins, randomised studies that evaluated the surgical outcome of preoperative MRI with subsequent resection have yielded conflicting results. In patients with invasive lobular carcinoma (a specific diffuse growing tumour type notably underestimated when seen with mammography and ultrasound) a reduction of re-excisions from 18% to 11% was observed, although this was not statistically significant in a meta-analysis. Other suggested indications are discrepancy in tumour size among different modalities (including clinical examination) that may change the treatment strategy, breast cancer found in a high-risk woman, and eligibility for partial breast irradiation.

Preoperative MRI is also used to detect many additional enhancing lesions unseen with mammography and ultrasound, since up to 50% of them are cancerous (increased up to 75% in the breast harbouring an already known malignancy), indicating that pathological verification is necessary, especially when additional lesions are distant from the already diagnosed tumour. If no additional disease is detected, this logically leads to more extensive surgery. However, this must be regarded with caution. It should be understood that breast conserving surgery in breast cancer in over 40% of patients is primarily aimed at reducing disease extent rather than being completely curative. This information should be presented to patients: treatment is mostly completed by radiation therapy, chemotherapy, and/or hormonal therapy. Consequently, additional MRI-detected foci may be effectively treated by these adjuvant therapies. Extension of a lumpectomy indicated by MRI might, therefore, be unnecessary. So far, there is a lack of evidence of improved overall or disease-free survival due to preoperative MRI. In any case, the possible patient gain from preoperative MRI is also dependent on the experience of the radiologist reporting the MRI, the accuracy of mapping MRI-detected additional tumour extent, the capabilities of the treating surgeon using the results of this imaging technique, and thus on the interface between radiology and surgery.

In addition, MRI may reveal unsuspected cancer in the contralateral breast in approximately 3% of all women with unilateral cancer as found by conventional imaging, even though higher rates of undetected contralateral cancers were reported. Since no radiation therapy is given to the contralateral breast, the detection of unsuspected contralateral cancer may be more relevant than detection of additional disease in the ipsilateral breast (the breast where cancer is already known to be). Although in most circumstances the eventual prognosis is mainly dictated by the size and grade of the largest cancer, early detection of additional cancers can be very accurately depicted with MRI. MRI is able to confirm or exclude rupture when mammography or ultrasound are inconclusive. This may facilitate the decision of the surgeon to make a revision or to change the implants.

The presence of implants does not affect the sensitivity of MRI for breast cancer detection other indications for CE breast MRI remain valid in the presence of implants.

In the case of a newly diagnosed breast cancer, preoperative MRI is a possibility for improving treatment of the already diagnosed cancer and also detecting cancer in the contralateral breast. This must be balanced against a risk that more extensive unnecessary surgery may be performed (e.g. mastectomy instead of a lumpectomy) as a consequence of MRI. Your radiologist and your surgeon can discuss with you potential advantages and disadvantages of preoperative MRI considering your particular case.

Breast MRI in Patients with Implants

MRI is the most sensitive technique for detecting breast implant ruptures when an appropriate protocol is performed. This protocol includes specialised sequences without CM administration. Notably, the breast’s usual reaction to augmentation is to form a fibrous capsule around the implant. This capsule frequently keeps the silicone in place even after an implant rupture. In fact, up to 50% of old implants are leaky ten years after implantation, usually without any symptoms. Thus, screening for implant rupture is not needed. In symptomatic patients, for example, those with an extracapsular rupture (i.e. with silicone outside the fibrous capsule), the leakage and spread of silicone in the breast can be very accurately depicted with MRI. MRI is able to confirm or exclude rupture when mammography or ultrasound are inconclusive. This may facilitate the decision of the surgeon to make a revision or to change the implants.

Breast MRI in Patients with Implants

Once breast MRI has been performed prior to neoadjuvant chemotherapy, as MRI images cannot be compared to initial mammography or ultrasound studies. For both early response prediction and pre-surgical evaluation, MRI seems to be a better test than clinical examination, mammography, or ultrasound. However, women should be aware that if MRI is used to guide surgery at the end of chemotherapy, a fraction of patients (10–20%) may have clinically relevant underestimation or overestimation of residual cancer.

OCCULT PRIMARY BREAST CARCINOMA

After the initial detection of metastasis, breast cancer may be suspected, especially when axillary nodes are involved. However, in a small fraction of patients, in whom needle biopsy of lymph nodes confirms the breast origin of the disease, mammography and ultrasound may be negative. This is occult primary breast cancer, accounting for up to 1% of breast cancers. In this clinical setting, MRI can be used to identify the primary breast cancer in about two thirds of cases, allowing for breast conserving surgery. If breast MRI is negative, immediate surgery may be avoided. In cases of axillary metastases, patients are usually treated with radiotherapy to the ipsilateral breast. Follow-up MRI can be proposed.

FREQUENTLY ASKED QUESTIONS

1. Is MRI screening harmful? MRI does not use ionising radiation, and consequently does not cause damage to cells. Therefore, the use of MRI is not associated with magnetic fields and radiofrequency waves applied in MRI are harmful to pregnant women and children. However, this is by law restricted to a maximum of one degree core temperature. This potential effect is harmless. However, detection or exclusion of malignancy is only possible by intravenous injection of contrast media, which can lead to rare but severe side effects including life-threatening allergic reactions or nephrogenic systemic fibrosis (see above).

2. Should I bring my prior examinations and mammograms? The availability of prior examinations improves the accuracy of the interpretation of breast MRI, resulting in increased sensitivity and decreased false positive rates. Therefore it is very important to take prior examinations and mammograms (by mammogram, ultrasound, histopathology results of needle biopsy, printed or on an electronic device) with you to the appointment for breast MRI. Unless these are already present at thecentre/hospital. This holds true for prior MRI examinations and for prior mammograms, ultrasound, histopathology results of needle biopsy or surgical interventions, and any clinical records relevant to your case. All

SCREENING & BEYOND | MEDICAL IMAGING IN THE DETECTION, DIAGNOSIS AND MANAGEMENT OF BREAST DISEASES

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this information creates the basis for obtaining the most detailed diagnosis and proper recommendations from your current breast MRI examination.

3. When should MRI screening in high-risk women start? How often should MRI screening be repeated?

The onset of MRI screening is highly dependent on the indication for MRI screening. In women with a strong family history of breast or ovarian cancer, in particular those with BRCA1 or BRCA2 mutations, MRI screening should start between the ages of 25 and 30. The proposed screening schedule is once yearly. This is more frequent than population-based mammographic screening due to the more rapid growth of breast cancers at a young age. Please note that one single case of breast cancer among your relatives, especially if it occurred after the age of 50, does not mean that you are at high risk. If you have any concerns in this regard, consult your family doctor or your breast radiologist. They will decide whether or not they should refer you to a specialist centre to evaluate your risk.

4. Does preoperative MRI also detect additional cancers in women with very fatty breasts and in women over 60 or 70? Does preoperative MRI also detect additional cancers in women with very dense breasts? MRI detects additional cancers unseen by mammography and ultrasound in a proportion of women with breast cancer, among your relatives, especially if it occurred after the age of 50, does not mean that you are at high risk. If you have any concerns in this regard, consult your family doctor or your breast radiologist. They will decide whether or not they should refer you to a specialist centre to evaluate your risk.

5. Is there any special indication for breast MRI when partial breast irradiation is under consideration? If you are offered partial breast irradiation in the context of or outside a clinical trial, the possibility of having a breast MRI in order to verify that you really qualify for reduction of the field treated with radiation therapy (i.e., that no tumour foci remain outside the treated field), should be evaluated by your physicians in a multidisciplinary meeting. Note that the reported rate of patients who are deemed not suitable for partial breast irradiation after a breast MRI is about 1%.

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REFERENCES

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INTRODUCTION

Increasing efforts to improve the early detection of breast cancer along with improved adjuvant therapy have led to a steady decrease in breast cancer mortality over the last three decades, despite a significant increase in breast cancer incidence over the same time period. Before the introduction of mammography screening more than 40 years ago, breast cancer was only found when palpable or when other clinical signs were present and was therefore traditionally treated with mastectomy. Imaging-based early detection has made it possible to find breast cancer at an early, preclinical stage, which in the majority of cases can be treated with breast-conserving therapy. However, both clinical breast exams as well as imaging-based early detection efforts will also find some breast abnormalities that are benign and do not require further treatment. To avoid unnecessary surgery for benign abnormalities and to allow optimal treatment planning, suspicious imaging findings detected in screening or during assessment of clinical abnormalities should therefore – if possible – first be subjected to minimally invasive percutaneous biopsy. In their fourth edition from 2006, the European guidelines for quality assurance in breast cancer screening and diagnosis specify that at least 70% of patients with a clinically occult breast cancer should have the diagnosis confirmed preoperatively by percutaneous biopsy. Ideally, this proportion should be much higher. The more recent European Society of Breast Cancer Specialists (EUSOMA) guidelines specify a target rate of 90% of women with breast cancer (invasive or in situ) with a definitive preoperative diagnosis.

A variety of different techniques are now available for this purpose. Depending on the circumstances, the biopsy may be performed using different guidance techniques and needle types, all of which have specific strengths and disadvantages. It is important that the person choosing the optimal biopsy technique...
is well versed in the full spectrum of available methods to be able to choose the optimal strategy for the specific patient. This article will discuss the strengths and weaknesses of the different biopsy techniques, including diagnostic accuracy and potential side effects.

RATIONALE BEHIND OBTAINING A DEFINITIVE PREOPERATIVE DIAGNOSIS THROUGH PERCUTANEOUS BIOPSY

Even with all the recent advances in imaging, a definitive diagnosis of malignancy can only be made through obtaining cells or tissue for microscopic histopathologic evaluation. There are a variety of benign abnormalities which can mimic malignancy on imaging and even the most suspicious imaging findings will never reach a positive predictive value of 100%. So the most obvious reason for performing a percutaneous biopsy prior to surgery is to prevent surgery, with all its associated morbidity and costs, for abnormalities that eventually turn out to be benign and which would not have required surgical treatment. However, in recent years another aspect has increased in importance. A whole range of surgical options, various primary and postoperative adjuvant systemic therapy concepts, and different local radiation therapy treatments are currently available for breast cancer patients. Adequate patient counselling and treatment planning is only possible if a definitive diagnosis of malignancy, including the type of cancer (e.g., in situ or invasive) and the biological tumour characteristics, is available prior to commencement of therapy.

CHOOSING THE OPTIMAL BIOPSY GUIDANCE TECHNIQUE

Percutaneous biopsy can either be performed freehand without imaging guidance or with the assistance of imaging techniques such as mammography, ultrasound or MRI, which are used to control the placement of the needle. Freehand biopsy is the least expensive and easiest method to perform, but it is the least accurate technique. It is usually reserved for performing fine-needle aspiration cytology (FNAC) on larger palpable abnormalities and ultrasound-guided biopsy is performed as core needle biopsy (CNB) using a specialised biopsy gun, but ultrasound is also suited to guidance for VAB or advanced breast lesion excision systems.

Specimen radiography at vacuum-assisted breast biopsy of pleomorphic microcalcifications for verification of adequate lesion sampling.

Stereotactic biopsy using mammographic guidance is the method of choice for lesions detected with screening mammography which do not have a corresponding finding on ultrasound. The majority of these lesions will represent microcalcifications and to a lesser extent architectural distortions and small masses. Stereotactic biopsies can be performed with dedicated prone tables or with upright mammographic add-on systems, with the patient usually sitting or lying on their side during the procedure. With the dedicated prone systems, vasovagal reactions can be avoided, but the upright add-on systems may have better access to lesions close to the chest wall. All stereotactic biopsies performed for microcalcifications should be followed by specimen radiography to document adequate sampling of the microcalcifications. A recent addition to mammographic biopsy options are systems which allow biopsies under tomosynthesis guidance.
FIGURE 5

MRI guided biopsy

A) Trocar in place.
B) MR image of trocar (black) in place in the left breast.
C) Biopsy with hand-held vacuum-assisted device.
D) Specimen (at needle tip) to be placed in tissue collection box.

Difficult cases may require a second look ultrasound to detect findings.

In the case of localisation by ultrasound or mammography, a repeat biopsy may be necessary, guided by the original imaging findings and pathology.

If the correlation between the imaging and pathology is doubtful, a repeat biopsy may be necessary, guided by the original imaging findings.

Malignant lesions are sampled. Depending on the system setup, these tissue cores will allow for accurate histopathological diagnosis including immunohistological tumour characteristics.

Different options for tissue sampling:

There are several different types of needles and other tissue sampling devices which can be used for percutaneous biopsy, which primarily differ in the amount of tissue obtained during biopsy.

The least invasive technique is fine-needle aspiration cytology (FNAC), where very thin needles - typically with needle diameters between 21 and 25G - attached to a syringe are used to aspirate cells for cytological examination. This procedure is easy and fast to perform, with the associated costs being low, and with a cytopathologist on site, results may be available immediately after the procedure. However, the success of the technique is highly dependent on the skills of the physician performing the procedure as well as the pathologist interpreting the results, and even in experienced hands, this technique has a high rate of inadequate or false-negative results.

In addition, FNAC cannot be used to reliably distinguish between in situ and invasive malignant changes, and immunohistological tumour characteristics required for optimal treatment planning are largely unavailable.

This is the reason why FNAC has in recent years increasingly been replaced by core needle biopsy (CNB).

With CNB, needles with a diameter ranging between 12 and 18G (most commonly 14G) mounted on a reusable or disposable, spring-loaded biopsy device (or ‘gun’) are used to obtain cylindrical tissue samples (‘cores’), with a length of somewhere between 11 and 22mm, depending on the system setup. These tissue cores will allow for accurate histopathological diagnosis including biological markers necessary for treatment planning.

CNB is the most common type of biopsy in solid lesions under ultrasound guidance. Although in principle a single high-quality core obtained from the lesion in question is sufficient for making the diagnosis, usually multiple cores (at least three) are obtained to assure accurate sampling.

CNB has a low false-negative rate, but there is a certain risk of underestimating lesions due to the fact that only a small portion of the lesion is sampled. Depending on the underlying histological abnormality, 10–50% of lesions characterised as high-risk by CNB will eventually turn out to be malignant, and around 25% of lesions diagnosed as in situ by CNB will have an invasive component at final surgery.

To reduce this underestimation rate, especially for lesions associated with microcalcifications, new vacuum-assisted biopsy devices using needle diameters between 7 and 12G have been developed. These allow for rapid removal of much larger amounts of tissue (more than one gram or cubic centimetre) of tissue per biopsy) to reduce the risk of underestimation. With VAB systems, multiple (usually at least 12 for a needle size of 10G or 11G) consecutive tissue cores can be obtained just by rotating the needle without the need for needle removal and reintroduction as in CNB.

Small lesions (e.g. less than 1cm in size) may be completely removed by VAB, in which case a marker should be placed in the biopsy cavity to allow for subsequent surgery if necessary. In addition to reducing the underestimation rate, the larger amount of tissue removed with VAB is able to compensate for possible slight inaccuracies in targeting and needle placement in stereotactic and MRI-guided biopsies, where real-time supervision of correct needle placement is not possible.

In the past, several attempts have been made to develop systems which allow the complete removal of small lesions in one single contiguous specimen under
POTENTIAL SIDE-EFFECTS AND COMPLICATIONS

Percutaneous breast biopsies in general are a very safe procedure and severe complications requiring treatment are exceedingly rare. The most common side effect of a biopsy is some degree of bleeding or haematoma formation at the biopsy site. The risk of bleeding will increase somewhat with the needle diameter and the amount of tissue sampled. Bleeding after biopsy is usually self-limited and may not be present at the site of biopsy for several days. Severe bleeding requiring surgical intervention can be prevented almost completely by careful screening for bleeding disorders in preparation for the biopsy, avoidance of aspirin, especially aspirinlike vessels when choosing the needle track, and by adequate compression of the biopsy site after the procedure. As with any percutaneous intervention, a certain risk of infection exists and adherence to sterile working conditions is important. The risk of infection may be higher in patients with diabetes or a compromised immune system.

Although studies have shown that mechanical displacement of malignant cells along the biopsy tract can occur with percutaneous biopsy, reports of actual recurrences along the needle tract from biopsy, reports of actual mechanical displacement of malignant cells, and new tumour foci are exceedingly rare. The most common complications requiring treatment are almost completely by careful screening for bleeding disorders in preparation for the biopsy, avoidance of aspirin, especially aspirin-like vessels when choosing the needle track, and by adequate compression of the biopsy site after the procedure. As with any percutaneous intervention, a certain risk of infection exists and adherence to sterile working conditions is important. The risk of infection may be higher in patients with diabetes or a compromised immune system.

Aspiring for MRI-compatible implants, prior imaging guidance to further increase imaging guidance to further increase biopsy accuracy. These include the earlier advanced breast biopsy instrumentation (ABBI) system29 and the SiteSelectTM system30, both of which are no longer marketed and were designed as add-ons to regular stereotactic biopsy tables, as well as the newer Intact™ breast lesion excision system (BLIES), which uses radiofrequency to facilitate the excision of the specimens and can be performed under ultrasound or stereotactic guidance31,32. So far however, none of these systems have shown clear advantages over existing VAB systems.

To reduce the risk of bleeding, patients scheduled for percutaneous breast biopsy should be screened for bleeding disorders and any anticoagulation medication should preferably – if medically safe – be discontinued prior to biopsy, even though breast biopsies can safely be performed in patients receiving anticoagulation treatment, if necessary. Stereotactic and MRI-guided biopsies are usually not performed during pregnancy and patients planned for MRI-guided biopsy should undergo the usual precautions including screening for MRI-incompatible implants, prior contrast reaction, or renal function impairment. The planned procedure, including the rationale for performing the biopsy, possible complications and the likely outcomes, should be explained in detail to the patient and (usually written) informed consent should be obtained.

The patients should also be informed about the possible necessity of placing a marker clip in the biopsy cavity (and its associated anxiety) and the rare need for re-biopsy or surgical excision in cases with poor radiological-pathological concordance or for certain risk lesions with uncertain malignant potential. Efforts should be made to reduce the patient’s anxiety prior to the biopsy, as the anticipated pain correlates with the level of pain experienced by the patient during the procedure. No other special safeguards are necessary prior to the procedure and the patients do not have to fast prior to the procedure. Patients undergoing breast biopsy should be informed that the administration of local anaesthesia may, in rare cases, impair reaction times and the patients should be encouraged not to drive themselves home after the procedure.

PREPARATION FOR BIOPSY

Following the biopsy, a marker clip may be placed in the biopsy cavity to facilitate future localisation, if surgery will be necessary based on the histological results of the biopsy. This is especially important for MRI-guided biopsies and in cases where the imaging finding is small and the risk exists that the lesion will no longer be visible after biopsy. Upon conclusion of the biopsy, direct compression as well as cooling may be applied to the biopsy site to achieve haemostasis and to minimise the amount of bleeding. In addition, the application of a circular compression bandage (for VAB only) after the procedure, which should stay in place until the next morning, can reduce the risk of bleeding. For all biopsies with clip placement, a post-biopsy mammogram has to be performed, either immediately following the procedure or later, e.g. at the time when the biopsy results are discussed. This mammogram is useful for confirming correct lesion targeting and clip placement and serves as a companion for future follow-up exams.

PATIENT EXPERIENCE DURING BIOPSY

After selecting the best and safest needle access route to the lesion, the patient is properly positioned for biopsy, which in the case of stereotactic or MRI-guided biopsy will include mild compression of the breast for immobilisation. Next, the skin in the area of the planned needle entrance will be cleaned and disinfected. Whereas for FNAC the use of local anaesthesia is optional, since the size of the needle used is similar to an anasthesia needle, all other types of percutaneous breast biopsy are usually performed under local anaesthesia. For superficial anasthesia, lidocaine buffered in sodium bicarbonate may be used to reduce the initial stinging sensation of the lidocaine injection and for the deep anaesthesia, a local anaesthetic may be added to reduce the risk of bleeding. Even with optimal local anaesthesia, some discomfort or pain may be felt during needle insertion and tissue sampling, which will vary significantly from patient to patient.

Following the biopsy, a marker clip may be placed in the biopsy cavity to facilitate future localisation, if surgery will be necessary based on the histological results of the biopsy. This is especially important for MRI-guided biopsies and in cases where the imaging finding is small and the risk exists that the lesion will no longer be visible after biopsy. Upon conclusion of the biopsy, direct compression as well as cooling may be applied to the biopsy site to achieve haemostasis and to minimise the amount of bleeding. In addition, the application of a circular compression bandage (for VAB only) after the procedure, which should stay in place until the next morning, can reduce the risk of bleeding. For all biopsies with clip placement, a post-biopsy mammogram has to be performed, either immediately following the procedure or later, e.g. at the time when the biopsy results are discussed. This mammogram is useful for confirming correct lesion targeting and clip placement and serves as a companion for future follow-up exams.

POST-PROCEDURAL RECCOMENDATIONS AND COMMUNICATION OF RESULTS

Following the biopsy procedure and after achieving haemostasis, the patients can be discharged from the department with appropriate instructions, which should include the need to avoid strenuous exercise, notably swimming and in water (e.g. tub bath, swimming) as well as strenuous exercise should be avoided for at least three days following the biopsy. Possible biopsy results as well as recommendations for further management (e.g. treatment, follow-up) should be discussed with the patient in person. With the exception of FNAC, where biopsy results may be available immediately after the biopsy, this will occur during a second follow-up visit. Timing of the follow-up visit must strike a balance between minimising the waiting time for the patient and also allowing for enough time to have final pathology results (if necessary, including additional immune-histological stains) available at the time of the follow-up visit. Ideally, the follow-up visit should – if applicable – already include the results from the multidisciplinary conference, at which concordance of imaging and histological findings is confirmed.
WHY IS BREAST HEALTH SO IMPORTANT?

• How we live our lives affects our health in the long term and certain lifestyle factors have been shown to increase the risk of getting cancer. WHO has reported that at least one-third of all cancer cases are preventable and up to 30% of cancers are probably related to diet and nutrition.
• Breast cancer is the most common cancer in women worldwide. In Europe it still claims the lives of more women than any other cancer.
• Although much remains to be learned about the causes of breast cancer*, some specific factors have been shown to influence risk:
  • Living a healthy, active lifestyle, avoiding weight gain and obesity can help maintain healthy breasts. Studies show that about one-third of breast cancer cases can be attributed to increased weight and physical inactivity.
  • Limiting alcohol intake can help keep breasts healthy, since high alcohol consumption can double the risk of breast cancer.
  • Having children at a younger age, having several and breast-feeding the risk of breast cancer.
  • Combined hormone replacement therapy (HRT) is associated with an increased risk of breast cancer. Seriously considering the pros and cons of using HRT can have a future influence on breast health.
  • Participating in vaccination programmes can help detect potential problems early. Studies show that women who attend screening have a greater chance of surviving a breast cancer diagnosis; deaths from breast cancer are reduced by about 35% in women aged 50–69 who participate in screening.
  • While studies have shown that breast self-examination is not necessarily effective, being aware of our breasts and changes in them can alert us to potential problems.
  • Above all, paying attention to specific lifestyle factors, being breast aware and participating in a screening programme set up according to EU guidelines are the first steps toward prolonged breast health.

EUROPA DONNA GUIDE TO BREAST HEALTH

EUROPA DONNA – The European Breast Cancer Coalition is an independent, non-profit organisations whose members are affiliated groups from throughout Europe. The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research. EUROPA DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the European Union.

*Genetic factors account for approximately 5–10% of breast cancer

Source of above data: IARC and WHO

EUROPEAN CODE AGAINST CANCER

EUROPA DONNA encourages women to follow the recommendations resulting from the study supported by the European Union’s Europe Against Cancer programme. Individual lifestyle choices may influence our health and decrease our chances of developing cancer. Certain cancers may be avoided and general health improved if you adopt a healthier lifestyle

• Do not smoke; if you smoke, stop doing so. If you fail to stop, do not smoke in the presence of non-smokers.
• Avoid obesity
• Undertake some brisk, physical activity every day
• Increase your daily intake and variety of vegetables and fruits: eat at least five servings daily. Limit your intake of foods containing fats from animal sources
• If you drink alcohol, whether beer, wine or spirits, moderate your consumption to two drinks per day if you are a man and one drink per day if you are a woman
• Care must be taken to avoid excessive sun exposure. It is specifically important to protect children and adolescents. For individuals who have a tendency to burn in the sun active protective measures must be taken throughout life
• Apply strictly regulations aimed at preventing any exposure to known cancer-causing substances. Follow advice of national radiation protection offices
• Women from 25 years of age should participate in cervical screening. This should be within programmes with quality control procedures in compliance with European Union Guidelines for Quality Assurance in Cervical Screening
• Women from 50 years of age should participate in breast screening. This should be within programmes with quality control procedures in compliance with European Union Guidelines for Quality Assurance in Mammography Screening
• Men and women from 50 years of age should participate in colorectal screening. This should be within programmes with built-in quality assurance procedures
• Participate in vaccination programmes against Hepatitis B Virus infection

CHAPTER 6: EUROPA DONNA GUIDE TO BREAST HEALTH

LIFESTYLE AND BREAST CANCER

There is growing evidence of the link between lifestyle factors and breast cancer. EUROPA DONNA encourages women to take charge of their own health and to make lifestyle choices now that could protect them later. Healthy living helps protect us against numerous diseases.

Women should pursue a health strategy that will reduce the known breast cancer risk factors as much as possible, including avoiding obesity and weight gain, increasing physical activity and managing lifestyle choices. IARC estimates that excess body weight and physical inactivity account for approximately 25–33% of breast cancer cases.

Obesity and weight gain

Recent studies indicate that women who avoid being overweight reduce their risk of postmenopausal breast cancer. This risk is independent of the effect of physical activity. It is important for women to limit their weight gain in adult life and maintain a body mass index (BMI) of 18.5–24.99 (see BMI chart below). Postmenopausal overweight/obesity is associated with an increased risk of breast cancer.

- A large amount of abdominal fat may increase the risk of breast cancer.
- Obese women tend to have more abnormal mammography readings than non-obese women.

Body mass index (BMI)

- Being overweight with a BMI (see chart below) of 25 or greater, or obese with a BMI of 30 or greater, points to an increased risk of developing postmenopausal breast cancer.
- Women who have already had breast cancer may help reduce the risk of further problems by keeping their weight within the normal range.

Physical activity

Growing evidence supports that there is a protective association between physical activity and breast cancer, preferably over a lifetime, but probably beneficial even if begun after menopause.

- Regular physical activity reduces the risk of breast cancer.
- Inactivity is estimated to cause 10–16% of all breast cancer cases.
- Inactivity coupled with excess body weight accounts for nearly 33% of all breast cancer cases.

Women should:

- Stay healthy and active
- Engage in moderate exercise for at least 30–60 minutes every day

TABLE 1: Calculating your body mass index

<table>
<thead>
<tr>
<th>Weight status</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.50</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.50 – 24.99</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥25.00</td>
</tr>
</tbody>
</table>

Restricting alcohol intake

- Restrict alcohol intake to not more than one drink per day (i.e., 10 grams or less per day). A glass of beer, wine or spirits corresponds to 8–10 grams of ethanol.

Nutrition

Women should limit specific dietary fat to breast cancer risk factors as much as possible, including:

- Include fresh fruit and vegetables in your daily food choices.
- Eat the right amount to maintain a healthy weight.
- Limit red meat consumption.

Other considerations

While there has not been a direct link found between active smoking and breast cancer, not smoking cigarettes and minimizing exposure to second-hand smoke is beneficial for multiple health reasons. Smoking is directly linked to numerous types of cancer and other illnesses.

About HRT

Hormonal Replacement Therapy (HRT) is a common therapy offered to women to treat menopausal symptoms. HRT reduces the symptoms that are caused by menopause, maintains bone density in postmenopausal women and decreases the risk of bone fractures caused by osteoporosis during period of use.

HRT and breast cancer risk

Based on evidence from various studies, the Women’s Health Initiative (see www.nih.gov/NTP/whi/) and the Million Women Study (www.millionwomenstudy.org), there is a very clear connection between HRT and the risk of developing breast cancer. The Million Women Study found that current users of HRT at recruitment were more likely than never users to develop breast cancer (adjusted relative risk 1.66) (see Lancet 2003; 362: 419-27). The above-mentioned studies indicate that the breast cancer risk increases the longer HRT is taken.

An IARC evaluation of cancer risk and HRT concluded that combined estrogen-progestogen therapy is carcinogenic. This is based on the numerous studies consistently reporting increased risk of breast cancer in women who currently use or have recently used combined estrogen-progestogen therapy.

For women who do not have a history of breast cancer it is advisable to discuss the risks and benefits of taking HRT with your doctor in order to make an informed decision as to whether HRT is right for you. It is recommended that you review your current treatments with your doctor on a regular basis to know if they are still your best option. If you opt for HRT, ask to take the lowest effective dose for the shortest amount of time needed to treat your symptoms.

HRT is generally not recommended if you have a history of breast cancer. In this case HRT may increase your risk of a recurrence of breast cancer (see Lancet 2004; 362: 453-5). Any decision to take HRT should, therefore, be discussed in detail with your physician.

Oral contraceptives and breast cancer

An IARC evaluation of the cancer risk with oral contraceptive use concluded: “There is sufficient evidence in humans for the carcinogenicity of combined oral estrogen-progestogen contraceptives. This evaluation was made on the basis of increased risks for cancer of the breast among current and recent users only.”

ABOUT MAMMOGRAPHY SCREENING

EUROPA DONNA advocates for population-based mammography screening programmes adhering to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. Use of mammograms in women less than 50 years of age has been shown to reduce the number of deaths from breast cancer up to 53% for women between the ages of 50 and 69.

Mammography is widely accepted as the best method to spot breast cancer early, before it becomes detectable to the touch. When you have a mammogram, a radiographer
places your breast between two large plates on the mammography machine. These plates compress the breast which is then X-rayed. Although compression can be uncomfortable, it is necessary to create good, readable images, to reduce blur, to spread out the tissue and to reduce the dose of radiation. The radiographer should take two pictures of each breast, one from top to bottom and the other from side to side.

Once the mammograms are taken, they are read by a radiologist. The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis recommend that each mammogram should be read by two separate radiologists.

Mammograms can be taken on film, as a photograph, or using a digital system, where your files can be stored in a computer. If you have already had a mammogram, the radiologist should compare the previous films or files with the current ones to check for any changes in your breasts.

Ultrasound may also be used to obtain further images, particularly if you are uncomfortable, it is necessary to inform your physician of any changes without delay. Starting at an early age you should have regular clinical breast exams performed by a health care professional. A younger woman’s body has hormonal and biological characteristics which differ from those of older women. A typical consequence of this is denser breast tissue, which makes mammography less sensitive and specific for detecting early cancer. Ultrasound might be more effective in the diagnosis of breast cancer in younger women.

Some questions women should ask when having a mammogram:

1. Does the mammography facility follow a quality assurance programme, that meets EU quality standards* or the equivalent?
2. How many mammograms does this facility perform each year?
3. Will my mammogram be conventional (x-ray film) or digital?
4. Are all mammograms read by two separate radiologists?
5. Is the person who takes the mammogram a registered radiographer specialised in mammography?
6. Does the radiologist who reads the mammograms have extensive experience, i.e., does he/she read at least 5,000 mammograms per year?
7. Is the mammography equipment technically controlled and calibrated on a regular basis (i.e., at least once a year)?
8. How and when will the results be available? (Ideally they should be ready in less than 5 working days)
9. If the results indicate a problem, I will be notified, and if so, within what time frame? (Ideally this information should be provided in less than 5 working days in person in the presence of a nurse counsellor)
10. Is there another procedure, other than a mammogram, that is more reliable for my specific situation (e.g., pregnancy, breast implants, under the age of 35)?

Many countries in Europe have mammography programmes running or being established in 22 EU Member States (Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom). The full report can be found at http://ec.europa.eu/health/lhp/declarations/geraads/documents/cancer_screening.pdf

If population-based mammography screening does not yet exist in your country or area, you should discuss your options with your physician.

WOMEN UNDER 40 AND BREAST CANCER

EUROPA DONNA recognises the need to raise awareness concerning younger women and breast cancer.

Since approximately 5–7% of breast cancers occur in women younger than 40 years of age, young women should be informed about the risks of breast cancer and be aware of the recommendations listed in the European Code Against Cancer.

It is important that women, from an early age, become breast aware (see Breast Aware section). You can take convenient opportunities such as bathing or dressing to become familiar with your breasts by looking at them and touching them. This will help in noticing any changes or abnormalities (usually a lump) sooner. Even though most breast lumps are harmless, it is important to inform your physician of any changes without delay.

The most common clinical breast exam is the breast self-exam. The Coalition strongly recommends each woman learn how to do a breast self-exam and participate in one every month.

If your results indicate a problem, you should be informed, and if so, within what time frame. It is important that women, from an early age, become breast aware (see Breast Aware section). You can take convenient opportunities such as bathing or dressing to become familiar with your breasts by looking at them and touching them. This will help in noticing any changes or abnormalities (usually a lump) sooner. Even though most breast lumps are harmless, it is important to inform your physician of any changes without delay.

If you have already had mammograms, they are read by a radiologist. The radiologist should take two pictures of each breast, one from top to bottom and the other from side to side. This is stipulated in the European Guidelines and is kept in both IARC recommendations and the European Council Recommendation on Breast Screening.

Mammography screening should be carried out in conjunction with a specialist breast unit, as stipulated in the European Guidelines, to ensure access to a multidisciplinary team for diagnosis and treatment if necessary.

The First Report on the Implementation of the Council Recommendation on Cancer Screening published in June 2008 states that in 2007 population-based screening programmes were running or being established in 22 EU Member States (Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom). The full report can be found at http://ec.europa.eu/health/lhp/declarations/geraads/documents/cancer_screening.pdf

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2. How many mammograms does this facility perform each year?
3. Will my mammogram be conventional (x-ray film) or digital?
4. Are all mammograms read by two separate radiologists?

6. Does the radiologist who reads the mammograms have extensive experience, i.e., does he/she read at least 5,000 mammograms per year?
7. Is the mammography equipment technically controlled and calibrated on a regular basis (i.e., at least once a year)?
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9. If the results indicate a problem, I will be notified, and if so, within what time frame? (Ideally this information should be provided in less than 5 working days in person in the presence of a nurse counsellor)
10. Is there another procedure, other than a mammogram, that is more reliable for my specific situation (e.g., pregnancy, breast implants, under the age of 35)?

If you are between the ages of 50 and 69, you should receive an invitation for breast cancer screening every two years as part of a screening programme offered by your public health system. This is stipulated in the European Guidelines and is kept in both IARC recommendations and the European Council Recommendation on Breast Screening.

Mammography screening should be carried out in conjunction with a specialist breast unit, as stipulated in the European Guidelines, to ensure access to a multidisciplinary team for diagnosis and treatment if necessary.

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ABOUT EUROPA DONNA – THE EUROPEAN BREAST CANCER COALITION

By Susan Knox, CEO Executive Director EUROPA DONNA – The European Breast Cancer Coalition (EC) is an independent, non-profit organisation whose members are affiliated groups from countries throughout Europe. The Coalition works to raise awareness of breast cancer and to mobilise the support of European women in pressing for improved breast cancer education, appropriate screening, optimal treatment and care and increased funding for research, EUROPA
DONNA represents the interests of European women regarding breast cancer to local and national authorities as well as to institutions of the European Union. ED was founded in 1994 and now has 47 fora (national country organisations) across Europe. The strength of our organisation lies in uniting women of many countries, cultures, and backgrounds in fighting breast cancer and seeking common goals toward that end.

EUROPA DONNA ten goals
1. To promote the dissemination and exchange of factual, up-to-date information on breast cancer throughout Europe
2. To promote breast awareness
3. To emphasise the need for appropriate screening and early detection
4. To campaign for the provision of optimum treatment
5. To ensure provision of quality supportive care throughout and after treatment
6. To advocate appropriate training for health professionals
7. To acknowledge good practice and promote its development
8. To demand regular quality assessment of medical equipment
9. To ensure that all women understand fully any proposed treatment options, including entry into clinical trials and their right to a second opinion
10. To promote the advancement of breast cancer research

EUROPA DONNA is an evidence based advocacy organisation and all our information and advocacy programmes are based on scientific evidence that has been agreed upon by European scientific experts in all the specialist fields. Since 2000 we have worked with the European Breast Cancer Network and EUSOMA – The European Society of Breast Specialists and these partnerships have resulted in the publication in 2006 by the European Commission of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. This document now forms the basis for much of our advocacy work as it outlines the breast cancer services that all women should have a right to receive. ED has published a ‘Short Guide’ to these guidelines to enable women and the lay public to understand the main points contained in this scientific document. These can be downloaded from our website http://www.europadonna.org/short-guide/ and have been translated into 16 languages in addition to English so far.
INTERVIEWS

BREAST IMAGING TODAY: A ROUNDTABLE INTERVIEW
European Society of Radiology: Breast imaging is widely known for its role in the detection of breast cancer. Could you please briefly outline the advantages and disadvantages of the various modalities used in this regard?

Michelle Reintals: Breast imaging is widely known for its role in the detection of breast cancer. If an abnormality is found on a mammogram or a woman has a symptom, then ultrasound should be performed in combination with mammography and the test itself to assess the abnormality by determin-
ing for example if it is solid, cystic, infiltrating or vascular.

Mammograms can be used to identify mass lesions, distortion of normal structures and calcifications, whereas ultrasound is used to characterise the abnormality by determin-
ing for example if it is solid, cystic, infiltrating or vascular.

Another limitation of mammography that is becoming topical amongst breast professionals is breast density. As it is operator dependent and time consuming, ultrasound may not detect pre-malignant calcifications in the breast that may only be seen on mammography, and some small cancers may be missed. In addition, ultrasound may detect many benign lesions such as inflamed cysts and this may result in the patient hav-
ing unnecessary biopsies to prove they are benign. As with any technology, there are advantages and disadvantages.

The pitfalls of mammography include slow growing lesions where stability is reassuring for a benign lesion and lack of detection of certain types of breast cancers, which may be difficult to perceive due to the nature of their biology and growth pattern. The disadvantage is the extra radiation dose if it is performed routinely every year for women at high risk of breast cancer and in many circumstances from a young age (e.g. 25 years old) if known BRCA gene carriers, this has raised concerns. As a consequence of these recent find-
ings, it is recommended that a cyclic structure gadolinium chelate is used in preference to a linear structure agent.

Elizabeth Morris: Breast imaging is rapidly evolving. Our microbiologists reading time is significantly increased, as over 400 images are typically generated, compared with the standard four images with a mammogram. Breast MRI is not the only imaging technology that relies upon both the character of the tissue and the blood supply and enhancement pattern of an abnormality within the breast. It is highly sensitive in the detection of breast cancer. The disadvantages of MRI are that it may detect many benign lesions that require further work-up with ultrasound and the possibility of biopsy, all contributing to patient anxiety. It requires an intravenous injection of contrast media and is therefore an invasive procedure. Also, recent reports have shown that the intravenous contrast medium used has the potential to accumulate in certain parts of the brain. Whilst gadolinium injection is not specific to breast MRI, the dilemma is that it is as yet unknown if this is sig-
nificant or has long-term repercussions for the patient, and if so, what they may be. Given breast MRI is often performed routinely every year for women at high risk of breast cancer and in many circumstances from a young age (e.g. 25 years old) if known BRCA gene carriers, this has raised concerns. As a consequence of these recent find-
ings, it is recommended that a cyclic structure gadolinium chelate is used in preference to a linear structure agent.

Miguel Angel Pichetch: Currently, mammography is still the most important technique when it comes to the early diagnosis of breast cancer. The technological advances of 2D and 3D digital mammography (tomosynthesis) have allowed an increase of sensitivity at the time of detection. The great disadvantage in Latin America is its implementation. Ultrasonic is highly accessible and used in daily medical practice. Its use in the region is very important in diag-
osing lesions where stability is reassuring for a benign lesion and lack of detection of certain types of breast cancers, which may be difficult to perceive due to the nature of their biology and growth pattern. The disadvantage is the extra radiation dose if it is performed routinely every year for women at high risk of breast cancer and in many circumstances from a young age (e.g. 25 years old) if known BRCA gene carriers, this has raised concerns. As a consequence of these recent find-
ings, it is recommended that a cyclic structure gadolinium chelate is used in preference to a linear structure agent.

Screening Australia has been providing mammographic screening for over 20 years, with proven benefits shown by improved survival rates from the early detection of breast cancer. If an abnormality is found on a mam-
mogram or a woman has a symptom, then ultrasound is routinely performed for further investigation. Mammograms can be used to identify mass lesions, distortion of normal structures and calcifications, whereas ultrasound is used to characterise the abnormality by determin-
ing for example if it is solid, cystic, infiltrating or vascular.

The disadvantages of MRI are that it may detect many benign lesions that require further work-up with ultrasound and the possibility of biopsy, all contributing to patient anxiety. It requires an intravenous injection of contrast media and is therefore an invasive procedure. Also, recent reports have shown that the intravenous contrast medium used has the potential to accumulate in certain parts of the brain. Whilst gadolinium injection is not specific to breast MRI, the dilemma is that it is as yet unknown if this is sig-
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ings, it is recommended that a cyclic structure gadolinium chelate is used in preference to a linear structure agent.

Elizabeth Morris: Breast imaging is rapidly evolving. Our ability to detect breast cancer has improved markedly.

A panel of renowned breast imagers from all over the world took part in IDoR 2016 to make the benefits of medical imaging clearer to the public. They explained what exactly imaging can do in the detection, diagnosis and treatment of breast diseases, the role played by radiologists in healthcare and what patients should know before undergoing a breast examination.

Breast imaging is widely known for its role in the detection of breast cancer. Could you please briefly outline the advantages and disadvantages of the various modalities used in this regard?
CHAPTER 7: BREAST IMAGING TODAY: A ROUNDTABLE INTERVIEW

Australia has six states, and each state provides an individual screening programme, which is held accountable to a high standard of practice by the National Accreditation Standards, under the jurisdiction of the national screening programme BSA. The challenges that a population-based screening programme faces are numerous, and a country the size of Australia introduces many additional challenges that are unique, including access for rural and indigenous populations and satisfactory participation among the target-aged, resident female population.

Mobile bus units travel around Australia, which assists in breaking down the barriers of accessibility. Participation is centred around breast cancer awareness, which the Australian government promotes through the national screening programme. Participation rates are typically around 55% for the screening target group.

Other non-government programmes, such as the McGrath Foundation, contribute significantly to the awareness of breast cancer through sponsored events and October Breast Cancer Awareness month. The benefits of a screening programme have been demonstrated with a reduction in mortality rates, but potential disadvantages of a population-based screening programme also exist. These include reduced accuracy of cancer detection in women with high mammographic breast density. It is recognised that women with a high risk of breast cancer due to their family history or those women who are BRCA gene carriers, are eligible for annual mammographic screening. So this raises the question, should we be reporting routinely on breast density? Should we be offering personalised screening pathways, incorporating family history, breast density etc.? Should we be offering magnetic resonance imaging to women with high mammographic breast density? This is a complex issue, with concerns relating to funding and resources, and patient anxiety.

Elizabeth Morris: In the United States, there is no national screening programme, which is different than many European countries. Therefore, it is up to the woman to remember to have her mammogram as she does not receive a reminder letter in the mail. It is estimated that approximately 60-70% of American women undergo screening mammography. Screening guidelines are recommended by many societies. The Society of Breast Imaging recommends that women be screened every one to two years starting at the age of 40, to obtain the maximal benefit of screening mammography. It is recommended that the patient continues screening as long as she has at least a ten-year life expectancy.

Miguel Angel Pinchot Tejada: In Latin America, there are no screening programmes for the population as in Europe. The only programmes performed are opportunistic screening programmes, which can be found in Mexico, Brazil, and Ecuador. The biggest challenge is to raise awareness among government for the implementation of screening programmes for the population.

ESR: The most common method for breast examination is mammography. When detecting a possible malignancy, which steps are taken next? Are other modalities used for confirmation?

Miguel Angel Pinchot Tejada: Once a possible malignant lesion has been detected with mammography, a crucial step is to perform an ultrasound study to define the lesion and locate any other associated findings. Then, a percutaneous biopsy (core biopsy, stereotactic biopsy) is performed to evaluate if it is cost-effective. Once breast cancer has been diagnosed, an MRI examination must be performed to stage the tumour, evaluate its size, extent, multicentricity, and biologically to apply the most effective treatment.

Gabor Forrai: Hungary was among the first countries to introduce nationwide organised screening, in 2001. The programme operates on an invitation basis and is free for all women. One special advantage is the lower-than-usual starting age (45), and a disadvantage is the quite low upper limit (65). Physical examination (palpation) is included, and is performed by trained radiographers. The goal of the programme is also to raise awareness, as well as to avoid as many invasive lobular carcinomas and non-calcified ductal carcinomas in situ as possible. The 15 years of practice have made the screening system robust, but it still needs continuous feedback and fine-tuning: this is a very important task in every country in order to achieve even better treatment selection (surgery, radiation therapy, chemotherapy, hormone therapy, etc.) and results.

Michelle Reintals: Australia’s population-based screening programme, Breast. Screen Australia (BSA) has been in existence since 1991, when BSA commenced. 68 women per 100,000 died from breast cancer, compared with 4.4 per 100,000 in 2012. The BSA Evaluation 2009 programme report demonstrated mortality reduction of 22-28% in the target aged women, in line with earlier randomised controlled trials undertaken in Europe.

ESR: Early detection of breast cancer is the most important issue for reducing mortality. What is one reason for large-scale screening programmes? What kind of programmes are in place in your country and where do you see the advantages and possible disadvantages?

Gabor Forrai: It is exquisitely sensitive in the detection of breast cancer and allows better characterisation of known cancers and enables early detection of early cancer in high risk groups of women.

Dr. Morris is considered one of the leaders in the field of breast imaging both nationally and internationally and has been an invited speaker at more than 500 meetings throughout the world and has authored or co-authored more than 100 papers. Her bestselling book on breast MRI has become the standard in the field. Dr. Morris hopes that one day breast cancer can be detected early enough to be treated without radical therapies. Her future research will be in this direction.
CHAPTER 7: BREAST IMAGING TODAY: A ROUNDTABLE INTERVIEW

Potential further findings and to assess the option of ultrasound-guided biopsy, which can be performed for any lesion visible on ultrasound. Biopsy with ultrasound guidance is a short procedure which is performed with the patient lying on their back. If the lesion is only visible with mammography (microlithifications), biopsy will be performed through stereotactic guidance. Because of scanner availability, duration and costs, MRI-guided breast biopsy is only performed for lesions detected with MRI.

Eugene Jostes: Additional views are obtained in order to confirm or exclude the presence of suspicious findings. Ultrasound will be performed in order to obtain additional information and to do guided biopsy if required. Breast MRI can be performed to further characterise the abnormality and to assess the area of involvement and possible additional abnormalities (including in the other breast).

Michelle Reintals: The imaging guidelines recommended for standard practice include the use of multiple modalities, and the individual application depends upon many factors, including the nature of the lesion detected. A standard mammogram that reveals a lesion will be further investigated with spot compression views if the abnormality is a mass, density or distortion, or with magnification views if calcification. Typically ultrasound will then be performed to assess for a mass or infiltrative lesion, evidence of skin or chest wall involvement and if there is lymph node spread. Fine needle aspiration or core biopsy may be performed, usually under ultrasound guidance, however, if the abnormality is not visualised on ultrasound (e.g. calcifications), then it is common practice to perform vacuum-assisted core biopsy on calcifications under mammogram guidance. A radio-opaque site marker may then be placed at the time of biopsy, where appropriate, in order to mark the site of biopsy and assist in localisation if excision of the lesion is required. They are typically used when a lesion is almost completely excised at biopsy or difficult to see under all imaging modalities. The site marker is a few millimetres in size, typically made of titanium or stainless steel, and is safe to remain within the breast from the time of diagnosis. Once the diagnosis of breast cancer is made, staging investigations are carried out to identify any spread of disease to lymph nodes or organs. The treatment will depend upon this pre-operative staging. The staging investigations depend upon the size of the primary breast cancer.

1. Breast MRI may be performed for staging the size, extent and type of breast tumour burden which is multifocal (multiple lesions within a breast quadrant) or multicentric (multiple lesions scattered throughout the breast), and if there is involve ment in the contralateral (opposite) breast.

2. Chest x-ray, liver ultrasound or CT scan of the chest, abdomen and pelvis may be performed for any spread to bone or liver.

3. Whole body bone scan (WBBS) to assess for spread to bones.

4. Sentinel Node Biopsy (SNB) is performed on the day of surgery to identify the draining node from the site of the cancer, and this or the group of nodes are removed at the time of mastectomy or partial mastectomy. If these nodes prove to be malignant, then a second operation is required to remove any remaining nodes accessible in the axilla.

Michelle Reintals: Imaging is used for screening for breast cancer and the diagnosis and staging of the extent of disease. There are circumstances where non-surgical treatment is administered. Neo-adjuvant treatment is used in advanced cancers where the size of the tumour or the extent of lymph node spread is reduced with chemotherapy prior to surgery. This approach may also be used to reduce tumour size to allow breast conserving surgery. Similarly, in frail or elderly patients who are not amenable to surgery, neo-adjuvant treatment, where the tumour is hormone sensitive (ER, PR positive), an aromatase inhibitor is used to locally control or reduce the primary cancer. In all these instances, the tumour burden and extent of nodal disease is monitored at regular intervals, to ensure that the treatment is effective and the disease is responding to the chemotherapy or hormone treatment. If the tumour burden is increasing, then hormonal or chemotherapy agents can be altered. The imaging options available to closely monitor the tumour and nodal response are mammography, ultrasound and MRI. If there is distant spread of disease to common sites such as liver, bone, lung, or brain, then tumour response is typically monitored by CT scans.
CHAPTER 7: BREAST IMAGING TODAY: A ROUNDTABLE INTERVIEW

Dr. Miguel Angel Pinochet Tejos: Breast imaging is a team approach and influenced by three professionals, we are trained to recognise and manage patient anxiety, and show a personal yet professional side to the patient, and express empathy. It is important to be aware that some women experience significant discomfort during the mammogram and biopsy. It is important to explain the process and describe the experience when obtaining the patient’s consent, allowing time for any questions the patient may have regarding the procedure. There are some suggestions that can be made when a patient book in for a routine screening mammogram, which may reduce the physical discomfort. This applies to pre-menopausal women, where exams may be better tolerated between days 7 to 14 of their menstrual cycle. If the study is being performed for symptoms, then timing with the menstrual cycle is unimportant, and imaging as soon as possible is optimal. It is vital that the health professional shows guidance and knowledge of the patient’s circumstance and gives advice on the diagnosis and management.

Eugene Jooste: Fear of the unknown generally adds to the anxiety associated with breast imaging. Anecdotally, feedback from patients is that the procedure was not as uncomfortable as expected and that other stories are exaggerated. Ultrasound is associated with cold jelly on the skin. Warming the jelly goes a long way to making the investigation more manageable.

Michelle Reintals: A patient undergoing a breast imaging exam will usually be anxious about the process and the possible outcome. As health professionals, we are trained to recognise and manage patient anxiety, and show a personal yet professional side to the patient, and express empathy. It is important to be aware that some women experience significant discomfort during the mammogram and biopsy. It is important to explain the process and describe the experience when obtaining the patient’s consent, allowing time for any questions the patient may have regarding the procedure. There are some suggestions that can be made when a woman books in for a routine screening mammogram, which may reduce the physical discomfort. This applies to pre-menopausal women, where exams may be better tolerated between days 7 to 14 of their menstrual cycle. If the study is being performed for symptoms, then timing with the menstrual cycle is unimportant, and imaging as soon as possible is optimal. It is vital that the health professional shows guidance and knowledge of the patient’s circumstance and gives advice on the diagnosis and management.

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CHAPTER 7: BREAST IMAGING TODAY: A ROUNDTABLE INTERVIEW

Michelle Reintals: Imaging should only ever be performed if there is likely to be a clear benefit, and that the potential benefit outweighs any possible risk from the procedure. There has been a clear benefit shown in the Australian screening programme, with a reduction in breast cancer deaths between 21-28%. Whilst this is significant, there is the potential issue of over-diagnosis. This refers to those cancers which may not result in patient death if untreated. Whilst a discussion point, it remains a dilemma, as currently there is no way of accurately determining pre-operatively which cancers are harmful versus those that are not harmful, if left untreated.

Eugene Jooste: CT is rarely performed for local diagnosis of breast cancer, but rather for staging prior to definitive therapy or re-staging at follow-up. Mammography comes with radiation exposure, although it uses the lowest dose among all radiological methods and the risks associated with radiation are by far outweighed by the benefits. Most currently used equipment is digital, which means dose is reduced by approximately 30% compared to the previously used film technique. Patients’ safety can furthermore be assured by adequate training of radiographers to avoid repeat mammography examinations due to positioning errors.

Michelle Reintals: The internet provides general information on a range of topics, including medical information, and therefore many patients will research what procedure their doctor has recommended, and inform themselves prior to their appointment. Radiation risk versus benefit is topical and is the subject of many discussions from patients attending for a mammogram. It is the health provider’s role to explain these risks and benefits and to allow the patient to ultimately decide what their preference is. The Royal Australian and New Zealand College of Radiologists has a teaching portal available to members and also a general consumer section for the public, called Inside Radiology, where there is information on such topics. Breast imaging information at Inside Radiology is searched by approximately 200,000 visits per month. The optimal service is one where the principle of ALARA (As Low As Reasonably Achievable) refers to the practice of keeping radiation doses as low as is practical to achieve a useful quality image.

ESR: How much interaction do you usually have with your patients? Could this be improved and, if yes, how?

Michelle Reintals: The greatest joy in my job is having interactions with patients. In our practice we have a lot of interaction with patients and enjoy this enormously. We discuss abnormal findings with all of our patients and inform them of results from any needle biopsies. We have many patients who return year after year for their mammograms, and many others who return to us after a diagnosis and inform us of any new developments. One of the greatest joys is hearing the histological results. We always make sure we treat patients with a very human and personalised approach.

ESR: How do you address the issue with them?

Michelle Reintals: We will not perform mammography on a patient who may be pregnant, in order to protect the foetus. Most patients are aware of radiation exposure. If there are any concerns, we are happy to discuss with them the relative degree of radiation. For example, in the United States, the radiation from a mammogram would be akin to taking an airline trip from New York to San Francisco.

Elizabeth Morris: Most patients are aware of the general risks associated with exposure to radiation. We follow the ALARA (As Low As Reasonably Achievable) principle with regard to radiation dose, but we do also reassure patients that the radiation associated with mammography is very low and the radiation is comparable with that of taking a flight from New York to San Francisco. It is the health provider’s role to explain these risks and benefits and to allow the patient to ultimately decide what their preference is. The Royal Australian and New Zealand College of Radiologists has a teaching portal available to members and also a general consumer section for the public, called Inside Radiology, where there is information on such topics. Breast imaging information at Inside Radiology is searched by approximately 200,000 visits per month. The optimal service is one where the principle of ALARA is adopted; ALARA is the acronym for the phrase ‘As Low As Reasonably Achievable’, which refers to the practice of keeping radiation doses as low as is practical to achieve a useful quality image.

ESR: What is the patient’s role in the breast screening process?

Michelle Reintals: Of young breast radiologists.

Michelle Reintals, MBBS, FRANZCR, is an Australian radiologist, specialised in breast imaging, having undertaken fellowships at BreastScreen South Australia and Western Australia BreastScreen and subsequendy at BreastScreen Victoria. She is currently based in Brussels, where she is the Chair of the Breast Imaging Reference Group (BIRG) of the Royal Australian College of Radiologists and a Committee member of the Breast Imaging Group (BIG) and Mammographic Quality Assurance Program (MQAP) of the Royal Australian College of Radiologists and Australian Society for Breast Diseases (ASBD). She has recently relocated to Brisbane to work for IMED Queensland as Director of Breast. Currently she is the Chair of the Breast Imaging Reference Group (BIRG) of the Royal Australian College of Radiologists and a Committee member of the Breast Imaging Group (BIG) and Mammographic Quality Assurance Program (MQAP) of the Royal Australian College of Radiologists and Australian Society for Breast Diseases (ASBD). She has authored numerous papers on breast diagnostics and imaging techniques for Australian conference presentations and mentoring young radiologists.
Michelle Reintals: There is a distinction in service provision between population and personalised private breast screening. In a population screening programme, there is no individualised service based on risk factors or personal contact with the patient. The patient undergoes a routine mammogram and receives her result via mail. If there is an abnormality seen by two readers interpreting the image, then the patient is recalled for assessment, at which time she will be given the results by a health professional in a results clinic setting. In a personalised private breast screening programme, there is typically a clinical breast exam done by either a breast physician or breast surgeon and a mammogram read by a breast radiologist. If there is a symptom then further diagnostic workup will be done, which may include ultrasound, MRI, and biopsy.

Gabor Forrai: Breast imaging is one of the radiological subspecialties with the most pronounced personal interaction with patients, particularly for breast ultrasound and image-guided breast interventions, which even require the presence of a radiologist at all times. Furthermore, the radiologist is usually the first doctor who discusses the findings of diagnostic imaging procedures, as well as histopathology results after biopsy, with patients. Therefore, breast radiologists should be sufficiently empathetic in order to deal with these psychologically difficult situations, and should have profound knowledge of breast pathology and oncology.

Elisabeth Morris: Over the next few years, the breast imagers will take on a more central role in the care of breast patients. As cancers are diagnosed at an earlier stage, traditional surgery, chemotherapy and radiation therapy may not be necessary. Percutaneous treatment is likely possible in the near future, changing breast cancer from a surgical disease to a nonsurgical disease.

Miguel Angel Pinchiet Tejos: The future of breast imaging is in sight: a blood test that will let you select the group that needs breast imaging. Customised studies and therapies according to the molecular biology of the tumour will improve. Radiologists will continue to actively participate in research together with pathologists, oncologists, pathologists, radiotherapists, surgeons, gynaecologists and all others on the multidisciplinary breast team.

Michelle Reintals: Breast imaging is continually undergoing significant changes, improvements and upgrades. For many years analogue mammography and ultrasonography were routine. In recent years there has been a transition to digital mammography (DR) and more recently to tomosynthesis and magnetic resonance imaging (MRI). We have also seen the transition from fine needle aspiration biopsy (FNA) to core biopsy and vacuum-assisted core biopsy, due to advances in technology and biopsy equipment, and changes in management that require histopathology and receptor status of the tumour prior to the decision on surgery. There are also software programmes available that assess the mammographic breast density, and with this awareness comes a consideration for adjunct screening such as tomosynthesis, MRI or ultrasound where deemed appropriate. These adjunct imaging techniques are also used in the setting of known risk factors such as family history and gene carrier status. Screening imaging techniques are used to detect early, small, curable cancers. Ultimately, despite these efforts, there remains a relatively high interval cancer rate, where cancers present between screening mammograms. Whilst the mortality rates from breast cancer are decreasing, the incidence of breast cancer is increasing. Perhaps the future developments will look at how to reduce the interval cancer rates, by determining which are the cancers that cause this. We are already moving towards screening women based upon their breast density, having recognised this is a separate risk factor as well as a confounding factor in the reduced sensitivity of mammographic screening. Should we be offering personalised screening pathways, incorporating family history, genetics, breast density, etc?

Eugene Jooste: I believe that imaging modalities will become more comfortable for the patient in the future. Increased accuracy will lead to fewer false positives. Risk management and genetic counseling will play progressively more important roles as the different characteristics of breast cancers are identified, and this will also result in tailored approaches to treatment and follow-up options.
THE ROLE OF RADIOGRAPHERS IN BREAST IMAGING: A BRITISH PERSPECTIVE

INTRODUCTION AND BACKGROUND

INTERVIEW
INTRODUCTION AND BACKGROUND

As in all aspects of contemporary healthcare, the aim in breast imaging is to deliver evidence-based care to underpin pathways and inform decisions in the management of breast problems.

The UK National Health Service Breast Screening Programme (NHSBSP) currently invites all women aged 50 to 70 for a screening mammogram once every three years. The NHSBSP has published detailed and specific guidance for all professionals involved, based on the most recent evidence, and this enables standardised care to be delivered nationally.

The role of radiographers in breast imaging is central and extends to the following areas: patient safety, patient care and image quality optimisation.

The involvement of x-ray radiation in mammography, albeit at much lower levels compared to other conventional x-ray imaging examinations, makes the minimisation of radiation dose delivered to patients imperative and involves important decision making regarding the compression technique and imaging parameters used for each patient. There are great synergies here with the team of medical physicists, who have an influence on optimising the dose. Compression of the breast also needs to be tailored to the patient’s pain threshold to allow for useful diagnostic images, a skill that is perfected in close collaboration and multidisciplinary team meetings with the consultant breast radiologists. Knowledge of the different projections, and the ability to thoughtfully use these to demonstrate the lesion, is not only science but radiography art and can impact on the diagnosis and therapeutic scheme. Radiographers, like all healthcare professionals, work to deliver the best evidence-based care, and therefore they actively participate in and often lead research projects in their areas of expertise, closely collaborating with other healthcare professionals in the field. Their involvement with research ensures the radiographers know and can apply the most relevant techniques for the benefit of their patients.

There are different agreed protocols in different departments but generally two-view mammography (mediolateral oblique and craniocaudal projections) is recommended. Digital mammography is the standard modality, due to its increased cancer detection performance, and double reading by suitably trained readers is recommended.

Ultrasound alone is not an effective screening tool but is associated with an increased cancer detection rate in women with dense breasts. However, it is considered to have poor specificity, so is not recommended routinely. It is a valuable adjunct in the workup of mammographically detected lesions. As in the case of mammography, radiographers are central in delivering evidence-based care and optimal image quality.

Women in high risk groups often undergo additional screening with magnetic resonance imaging (MRI) due to its increased sensitivity and ability to detect mammographically occult lesions with an acceptable specificity. MRI may also be subsequently performed for the delineation of additional disease. As a technique it is extremely sensitive to soft tissue changes; however, it demands deep knowledge and understanding of MRI principles and techniques, which may extend beyond structure to function, such as diffusion MRI. As this is a fast expanding imaging capability, breast radiographers often attend and participate in continuing professional development activities to ensure they keep abreast of recent developments and offer the best service to their patients.

Breast radiographers therefore have a central role as ambassadors of patient safety, champions of personalised patient care and gatekeepers of image quality with regard to all breast imaging examination techniques: mammography, ultrasound and breast MR imaging. Teamwork in breast imaging, as in all other aspects of medical Imaging, is vital in achieving the best patient outcomes.

REFERENCES

See page 171.
Breast imaging is widely known for its role in the detection of breast cancer. Could you please briefly outline the advantages and disadvantages of the various modalities used in this regard, with emphasis on the radiology aspects, such as patient safety, patient care and technical complexity?

There are many advantages of mammographic screening, which is currently a first line imaging screening technique. Mammography, which is currently a first line imaging screening technique, as compressing the breast to improve the sensitivity of detection, allows for a speedy identification of abnormalities and allows for a speedy identification of abnormalities. It is ideal for imaging soft tissue and for further assessment of other abnormalities and allows for a speedy examination when performed by experienced hands. It may, however, be subject to the operator-dependent operator-dependent nature, not suitable for mass screening but helpful as an adjunct imaging tool to x-ray mammography. Although still unable to detect fine microcalcifications, which may be indicative of early invasive disease.

Lastly, and more recently, MRI has gained ground and is currently in place in the UK, involving all women between the ages of 50 and 70 for breast screening once every three years. Breast screening facilitates the early detection of breast cancer, and it requires a multidisciplinary team of highly experienced healthcare professionals, so it is resource-intensive. In the UK, screening, including the use of MRI, is in place for all women deemed to be at high risk either due to family history or previous radiotherapy treatment.

Do you know how many women take part (per-cent)? Do patients have to pay for this?

In the NHSBSP the average is 65–70% of 50–70 year-olds across the UK taking part and it is paid for by the NHS, without incurring any charge to individual patients. What should patients keep in mind before undergoing an imaging exam? Do patients undergoing radiological examinations generally experience anxiety, and increased costs to healthcare providers, and it can cause unnecessary morbidity and mortality rates, and it allows for high-risk patients to be screened and followed up. However, it may also carry the possibility of false positives, it can cause unnecessary morbidity and mortality, and increased costs to healthcare providers, and it requires a multidisciplinary team of highly experienced healthcare professionals, so it is resource-intensive. In the UK, screening, including the use of MRI, is in place for all women deemed to be at high risk either due to family history or previous radiotherapy treatment.

Do you see the advantages and possible disadvantages?
**CHAPTER 8: THE ROLE OF RADIOGRAPHERS IN BREAST IMAGING: A BRITISH PERSPECTIVE**

**Screening & Beyond | Medical Imaging in the Detection, Diagnosis and Management of Breast Diseases**

Some imaging technology, such as x-ray and CT, uses ionising radiation. How do the risks associated with radiation exposure compare with the benefits? How can patient safety be ensured when using these modalities and how can radiographers contribute?

Any radiological test requested should be justified in terms of answering a clinical question or as a screening tool. Radiographers checking patient identity and clinical information can further enhance safety measures. There are also departmental protocols for patient imaging pathways, which should be followed closely. Additionally, all equipment should adhere to all QA procedures and protocols and all radiographers should have up-to-date training to use the available equipment resourcefully and for optimal patient care and image quality examinations.

How aware are patients of the risks of radiation exposure? How do you address the issue with them as a radiographer?

It vastly depends on the patient. Overall there should be an honest and trusting environment established between healthcare professionals and patients. Many patients are aware of issues because of the abundance of information online. As radiographers we are in position to explain the benefits of the imaging methods and that everything possible is done to ensure the test is as reliable and safe as possible. We also need to keep continuing professional development to stay up to date with recent advances in our professional field, to ensure all staff are well trained in radiation awareness, patient care and image quality optimisation.

How much interaction do you usually have with your patients? Could this be improved and, if yes, how?

In diagnostic breast imaging, interaction is usually focused and intense, but short. It is difficult, though, to see how this could be improved, given the workforce shortages and demanding everyday schedule. This interaction often involves helping patients feel comfortable during positioning, explaining the procedure, and creating a trusting environment, but very often in the UK the interaction of radiographers might involve breaking bad news, so advanced communication and counselling skills are frequently used, since many patients are highly anxious. Many patients also have a fear of further biopsies or procedures, so calm and competent reassurance by the radiographer is key to guiding them through a safe examination. Effective communication is important not only for improving the patient experience but also for ensuring the quality of the images which will be reviewed. Communication between radiographers and patients lies therefore in the heart of breast imaging procedures.

How do you think breast imaging will evolve over the next decade and how will this change patient care? How involved are radiographers in these developments and which other healthcare professionals are involved in the process?

I believe screening will be more tailored to individual needs – for example for those with fatty or dense breasts – for the normal risk population (as well as those at high risk). Additionally, image-guided interventional techniques will dramatically reduce the need for open surgical procedures as equipment becomes more refined. As radiographers remain at the forefront of communication with the patients for each breast imaging technique and capability, it is imperative to keep up to date with recent technological developments, to manage expectations, and to achieve high image quality standards and optimal patient care.
ABOUT THE AUTHORS
CHAPTER 9: ABOUT THE AUTHORS

Massimo Ambrosio
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Massimo Ambrosio, MSc, graduated in Food Science and Technology in 1988. He has worked in the European Commission for eight years and joined the EC Initiative on Breast Cancer (ECIBC) in 2015. He has worked in accredited laboratories, including the European Reference Laboratory for Mycotoxins, and as an analyst, inspector, and has experience in the management of projects in the areas of food safety and toxicology.

Wendie A. Berg
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Wendie A. Berg, MD, PhD, FACS, is Professor of Radiology at Magee-Womens Hospital of UPMC, University of Pittsburgh School of Medicine, and is well known for her role as Study Chair and PI of the American College of Radiology Imaging Network Protocol 6666. Screening Breast Ultrasound and MRI High Risk Women. She has authored or co-authored more than 60 peer-reviewed publications, co-written and edited the book, Diagnostic Imaging: Breast (now in its second edition) and has given over 500 national and international invited lectures and referee courses. Dr. Berg has also led or authored prospective multicentre studies of position emission mammography and shear-wave elastography and is currently conducting a study of screening ultrasound after tomosynthesis. She has received multiple national and international awards for her work on improving screening for women with dense breasts. Dr. Berg is Chief Scientific Advisor to www.DenseBreast-info.org.

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Prof. Ulrich Bick is Professor of Radiology and Vice-Chairman of the Department of Radiology at the Charité Berlin. He is an internationally renowned expert in breast imaging and spokesperson of the European Society of Breast Imaging and the European Society of Urogenital Radiology. He is an honorary member of the Hungarian Society of Radiology and sits on the International Editorial Board of Ultraschall in der Medizin and the Cardiovascular and Interventional Radiological Society of Europe. Moreover, he is a fellow of the European Federation of Societies for Ultrasound in Medicine and Biology (2004–2015) and has been Head of the Advisory Board of the Croatian National Breast Cancer Screening Programme since 2005. He is a fellow of the European Society of Urogenital Radiology and a fellow of the European Society of Breast Imaging and the Cardiovascular and Interventional Radiological Society of Europe. Moreover, he has held numerous invited lectures internationally. He is a fellow of the European Society of Breast Imaging and the Cardiovascular and Interventional Radiological Society of Europe. Moreover, he is an honorary member of the Hungarian Society of Radiology. He is editor-in-chief of the Journal of Ultrasound and sits on the International Editorial Board of Ultraschall in der Medizin. He has published two textbooks, 56 chapters in textbooks and books, 101 papers in peer-reviewed journals and has given more than 20 invited lectures internationally. His work focuses on breast imaging, cardiovascular and interventional radiology, and urogenital radiology.

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Giulia Bocchi, MA, graduated in Communications and holds a master’s degree in European Affairs. She has worked in the area of public and institutional communication and as a Communication and Press Officer in various European Commission services between Brussels and Italy.

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Boris Brkljačić
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Dr. Boris Brkljačić is Professor of Radiology and Vice-Dean at the University of Zagreb School of Medicine (UZSM), Croatia. He graduated from UZSM in 1984 and has been a board certified radiologist since 1986. He completed educational programmes at the Thomas Jefferson University, Philadelphia and the Memorial Sloan Kettering Cancer Center, New York. Since 2001 he has been the chairman of the Department of Radiology at the University Hospital Clinical Centre Zagreb, Croatia. He was President of the Croatian Society of Radiology from 2004 to 2010. Since 2013 he has been a member of the Croatian Medical Association and since 2014 he has served as Chairman of the Communications and External Affairs Committee of the European Society of Radiology (ESR). He has also served as Chairman of the ESR’s Finance and Internal Affairs Committee (2011–2014) and a member of the Education and Professional Standards Committee of the European Federation of Societies for Ultrasound in Medicine and Biology (2004–2015), he has been head of the Advisory Board of the Croatian National Breast Cancer Screening Programme since 2005. He is a fellow of the European Society of Urogenital Radiology and member of the European Society of Breast Imaging and the Cardiovascular and Interventional Radiological Society of Europe. Moreover, he is an honorary member of the Hungarian Society of Radiology. He is editor-in-chief of the Journal of Ultrasound and sits on the International Editorial Board of Ultraschall in der Medizin. He has published two textbooks, 56 chapters in textbooks and books, 101 papers in peer-reviewed journals and has given more than 20 invited lectures internationally. His work focuses on breast imaging, cardiovascular and interventional radiology, and urogenital radiology.

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Dr. Zoran Brnić is Head of the Clinical Department of Diagnostic and Interventional Radiology at University Hospital Center Zagreb, Croatia. He is Professor of Radiology and radiation protection in medicine. He is involved in the organisation of the Croatian National Breast Screening Programme and quality control service. Dr. Brnić is a member of the Croatian Society of Radiology and an active participant at many international congresses. He has authored 65 publications, five book chapters, and three books. His research interests include radiation exposure in medicine, ultrasound and radiation protection in medicine. He is involved in the organisation of the Croatian National Breast Screening Programme and quality control service.

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Joy Burwell is the Director of Communications for Policy, Practice Improvement and Consulting at the US National Council for Behavioral Health, where she manages communications for the Policy, Practice Improvement and Consulting portfolio. She uses her experience and expertise in health policy, communication strategies, traditional and innovative public affairs strategies and stakeholder relations to help the National Council influence decision-makers and the public to improve the state of mental healthcare and addiction services. Prior to this, she was Assistant Vice President of Public Affairs and Director of Public Affairs at Amplify Public Affairs. In these roles, she developed communication and education strategies, media outreach initiatives and managed third-party stakeholder outreach and support for a variety of clients. Before her roles at Amplify, she was a Program Associate for the American Academy of Nursing (AAN), where she monitored health policy trends including health information technology, workforce issues and nursing research for the AAN and advocated for nursing’s contributions to health reform.

She is a graduate of James Madison University (BSW) and received her Master’s Degree in Public Administration at Georgetown University’s Public Policy Institute. She is a member of the Health Care Policy and Politics Council of the American Public Health Association. She has received awards at national and international congresses.

Priscilla F. Butler

Priscilla F. Butler, MS, FAAPM, FACR, has devoted her career to quality breast imaging and assessment of patient radiation dose. She has been with the American College of Radiology since 1998, is currently Senior Director and Medical Physicist in the ACR’s Department of Quality and Safety, and is responsible for a growing number of dose-related projects (e.g. Image Gently and Image Wisely) as well as physics-related activities (e.g. quality control manuals) and BI-RADS®. For over 15 years, she was the Senior Director for the ACR’s Breast Imaging Accreditation Programs, including Mammography, Stereotactic Breast Biopsy, Breast Ultrasound and Breast MRI. Ms. Butler served on the original FDA National Mammography Quality Assurance Advisory Committee during the development of the Mammography Quality Standards Act (MQSA) final regulations.

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Dr. Julia Campo-Herrero

Dr. Julia Campo-Herrero is a breast radiologist and head of the Radiology Department at University Hospital de Arisbon in Valencia, Spain. She trained in Alcoy (Alicante) in general radiology and also in breast (Mammography, Stereotactic Breast Biopsy, Breast Imaging, 140 Ultrasound and Breast MRI). She has recently been appointed as a special interest in MRI. Under her supervision, the diagnostic breast section became the first unit in the Valencian community to set up breast MRI. She is also works in collaboration with other research centres specialising in breast imaging. She is currently a committee member of the European Society of Breast Imaging and the Italian College of Breast Radiologists of SRM (Societa Italiana di Radiologia Medica). Her main goal in these societies is to increase the number of initiatives dedicated to young radiologists in training and to favour their interest in research and collaborations. She has co-authored several peer-reviewed papers and conference abstracts, some of which have received awards at national and international congresses.

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Dr. Paola Clauser, MD, is a board-certified radiologist currently working at the Medical University of Vienna, Austria. Her interest in breast imaging grew during her residency at the Institute of Radiology of the University of Biitello, Italy. As a researcher, her main topics of interest are tomosynthesis and multiparametric breast MRI. She also works in collaboration with her former University and other Italian research centres specialising in breast imaging. She is currently a committee member of the European Society of Breast Imaging and the Italian College of Breast Radiologists of SRM (Societa Italiana di Radiologia Medica). Her main goal in these societies is to increase the number of initiatives dedicated to young radiologists in training and to favour their interest in research and collaborations. She has co-authored several peer-reviewed papers and conference abstracts, some of which have received awards at national and international congresses.

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Michael Crean is the project manager at the European Institute for Biomedical Imaging Research (EIBIR) and has been involved in two of EIBIR’s three breast cancer projects. He was project manager on the European Human-Personalised, Predictive Breast Cancer Therapy Through Integrated Tissue Microstructure Imager (VTHM-IMI) project and is currently involved in the Digital Hybrid Breast RD (DHBRD) for Enhanced Diagnosis of Breast Cancer (HYPMED) project as work package leader for dissemination, as well as assisting with project management.
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Dr. Silvia Deandrea graduated in Medicine specialisation in Public Health and obtained her Bachelor’s in Public Health in 2003. She has worked in healthcare quality consultancy, in cancer epidemiology research and in organising and evaluating population-based cancer screening programmes as Quality Manager. She is the author of more than 20 research papers published in international peer-reviewed journals.

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Dr. Irico Desideri completed his medical studies in 2009 and specialised in Radiation Oncology in 2013 at the University of Florence, Italy. During his specialisation, he performed a gamma-knife radiotherapy fellowship at the Roswell Park Cancer Institute in Buffalo, USA. He became Assistant Professor in Radiation Oncology at the University of Florence in 2016, where he currently works as a Clinical Oncologist. His major fields of interest are radiotherapy, head and neck cancer, breast cancer research. He has published more than 15 papers in peer-reviewed journals. He is an active member of the European Society for Radiotherapy and Oncology (ESTRO), the European Organisation for Research and Treatment of Cancer (EORTC), the Italian Association for Radiology Oncology (AIRO), and the Italian Association for Radiology Oncology (AIR). He has served as a clinical consultant of the non-profit Florence Foundation for Radiation Oncology (FFRO) since 2016.

Prof. Andy Evans

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Prof. Andy Evans is Professor of Breast Imaging at Dundee University. He is a world leading authority on shear-wave elastography of the breast. His other fields of expertise include breast cancer screening and ductal carcinoma in situ. He is a past chairman of the British Society of Breast Radiology, a member of the scientific committees of the European Society of Breast Imaging (EUSOBI) and a member of the Breast Imaging Subcommittee of the European Congress of Radiology. His research outputs include 152 peer-reviewed publications, 17 book chapters and three books. He also plays the French horn and is a successful composer of classical music.

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Dr. Eva M. Fallenberg undertook her general radiology training from 1999 to 2005 at the University of Münster, where she went on to work as the responsible consultant of breast imaging, organising the first courses for the German Breast Screening programme. Held in the Reference Centre for Mammography Screening in Münster. Since 2007 she has worked as a consultant and team manager in breast imaging at Charité University Hospital, Berlin. Her main research interests are conventional mammography and MRI in which she has performed several studies both in Berlin and also in collaboration with Clarisse Dromain and the Institute Gustave Roussy in Paris, which have been published in several peer-reviewed journals including Radiology, Investigative Radiology, European Radiology, Breast Cancer Research and Treatment.

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Gábor Forrai MD, PhD, completed his studies at Semmelweis Medical University, Budapest, Hungary. He later served as a staff radiologist for ten years at the National Institute of Oncology, Hungary (1997-2007), as assistant professor and head of department at the Haynal Imre Postgraduate Education University, Budapest (1996-2001) and as Head of the Department of Radiology at the Military Hospital/State Health Center/Teaching hospital University Semmelweis (2007-2016). He is currently head of the Department of Mammography at Duxa Medical Center & Budapest Hospital and head of the breast screening centres in Vac and Éger County Hospitals.

He also gained experience abroad in Köln, Hamb erg, and Erlangen, Germany (1996), as well as in the United Kingdom (1998-1999) and Dundee, United Kingdom (1999-2001), and was a visiting radiologist at the hospital Tenon, Paris, France (1994-1998). An experienced lecturer (with 227 presentations in French, English and Hungarian), Prof. Forrai has published numerous book chapters. In addition, he wrote his PhD thesis on the subjects of breast core biopsy and breast MRI.

Dr. Forrai has been the president of several national and international courses and congresses, such as the French-Hungarian Radiology Symposium (annually since 2001), Central European PACS School, Central European Endo-Analysis, EUSOBI schools and ESOR events.

He is the current President of EUSOBI (2015-2018) and was Chair of the Breast Subcommitte of the European Congress of Radiology 2016, Secretary General of the Hungarian Section of Breast Diagnostics of the Hungarian Radiological Society, and vice-president of the French-speaking Radiology Educators’ Society (SGRM). His contributions to French-Hungarian scientific cooperation have been recognised by the French Republic, which awarded him Knight of National Order of Merit (2012).

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Prof. Fornari has been the president and organiser of several national and international courses and congresses, such as the French-Hungarian Radiology Symposium (annually since 2001), Central European PACS School, Central European Endo-Analysis, EUSOBI schools and ESOR events.

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Chair of the Department of Radiology at the Medical University of Graz. Dr. Fuchsjäger received his MD degree from the University of Vienna and completed his residency at the Medical University of Vienna’s Department of Radiology and was a research scholar at the Department of Radiology at the Horváth-Stall-Karolinska Center, New York. He also served as Chair of the Clinical Imaging Institute at the Al Ain hospital in Abu Dhabi, UAE. Dr. Fuchsjäger’s clinical work and research is dedicated to diagnostic and interventional breast radiology. He serves on various committees for national and international radiology and oncology societies, first and foremost the European Society of Radiology, where he is the Committee Chair for Finance and Internal Affairs on the Executive Council, as well as chair of evaluation on the Editorial Council, as well as chair of evaluation on the Scientific Council. His primary research interest is the influence of breast density on breast cancer risk. He has more than 60 peer-reviewed publications to his name, is co-author of the textbook Making the Diagnosis: A Practical Guide to Breast Imaging, and is co-author of the popular text Imaging the Breasts: A Problem-Based Approach. He is currently project manager of a Horizon 2020 project on dementia and stroke co-occurrence.

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Jennifer A. Harvey, MD, FACR, is Professor and Vice-Chair of Faculty Development at the Department of Radiology and Medical Imaging at the University of Virginia in Charlottesville, Virginia. Her primary research interest is the influence of breast density on breast cancer risk. She has more than 60 peer-reviewed publications to her name, is co-author of the textbook Making the Diagnosis: A Practical Guide to Breast Imaging, serves on many national committees and editorial boards, and has been invited to speak worldwide on breast imaging and breast density. She has received many awards and is a fellow of the American College of Radiology and the Society of Breast Imaging.

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Thomas H. Heidt, MD, MSc, MBA, Professor of Radiology, received his medical degree at the Medical University of Vienna in 1988. From 1996 until 1999 he was trained as a radiologist at the Department of Radiology at the Medical University of Vienna. He was a research fellow at the Department of Radiology, Center of Molecular Imaging of the University of California in San Francisco from 1996 to 1998. In 1999 he became Associate Professor of Radiology. In 2004 he became Vice Chairman of the Department of Radiology/Gastrointestinal Division. From 2007 to 2004 he was Division Head of the Breast Imaging Department of the University of Toronto and Full Professor of Radiology of the University of Toronto. Since October 1, 2006 he has been Professor of Molecular Imaging and Vice-Chair of the Department of Radiology of the Medical University of Vienna. His main fields of research interest are clinical and experimental investigation on a cellular and sub-cellular level to diagnose cancer, in particular breast cancer. His working group has developed and optimised several methods on the basis of MRI, various molecular imaging tools, as well as minimally invasive diagnostic techniques. He is author or co-author of more than 200 scientific articles. He is an advisor to both the Minister of Health of Austria and the Mayor of the city of Vienna for the national breast screening programme, and has been honoured with several national and international awards. He was President of the European Society of Breast Imaging (EUSBI) from 2010 to 2012.

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Medicine

New England Journal of a landmark article in the ing, which is its highest honour.

He has received numerous awards and honours, including the Gold Medal from the Society of Breast Imaging Division from 1978 to 2006. He has been at the Harvard Medical School and founded the Graduate Hospital, where he was Director of the Breast Imaging Division from 1978 to 2004. He has trained numerous residents and is one of the leading textbooks to his field, Dr. Kopans helped develop breast imaging as a specialty.

He invented a guide wire and techniques that made it possible to accurately direct surgeries to areas of concern found by mammography, making it possible to aggressively pursue small lesions with a minimum of trauma to the patient using local anaesthesia in an outpatient setting with a high degree of accuracy. Accurate localisation and early intervention facilitated the diagnosis of very small cancers that led to the major decrease in breast cancer deaths that has been seen in the United States since 1990.

He was co-chairman of the original BI-RADS committee and his organised approach to image interpretation and reporting is the basis for the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS). Dr. Kopans is the leading expert on screening for women in their forties and it is in large part due to his efforts in defining the scientific issues, analysing the data, and presenting the National Cancer Institute in the 1980s that women aged 40–49 have access to routine mammography screening. He continues to support the fundamental scientific basis of screening while exposing the flawed analyses that are being generated to try to reduce access to screening.

Dr. Kopans holds several patents on devices to improve breast cancer detection and diagnosis. He is the inventor and patent holder of Digital Breast Tomosynthesis (DBT), sometimes called 3D mammography. DBT permits high resolution tomographic breast evaluation that has been shown to significantly increase the detection of small cancers while also reducing the recall (false positive) rate.

Dr. Kopans is a clinician, educator, investigator, author and inventor. He is a member and Fellow of the American College of Radiology (ACR) and a Chairmen of the Fellows Committee of the Society of Breast Imaging.

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Dr. Katharina Krischak, MD, is a project manager at the European Institute for Biomedical Imaging Research (EIBIR) with past experience working at the European Commission and the Council of Europe in Strasbourg. She is currently involved in the management of two Horizon 2020 projects on better thyroid cancer screening and an innovative glucose-based imaging method for cancer.

She coordinates the European Commission Committee of the Council of Europe and the European Institute for Biomedical Imaging Research (EIBIR) with past experience working at the European Commission in the 1990s that women aged 40–49 have access to routine mammography screening. She continues to support the fundamental scientific basis of screening while exposing the flawed analyses that are being generated to try to reduce access to screening.

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Carol H. Lee New York, USA

Dr. Carol H. Lee, MD, is attending radiologist at Memorial Sloan Kettering Cancer Center in New York and is also Professor of Radiology at Weill Cornell Medical College. Dr. Lee has specialized in breast imaging for more than 30 years and has served as Chair of the American College of Radiology (ACR) Breast Commission and as President of the Society of Breast Imaging. She is currently a member of the National/Mammography Quality Assurance Advisory Committee, which advises the Food and Drug Administration on regulatory issues. She is also Head of the ACR Breast Imaging Reporting and Data Systems (BI-RADS) Committee. She is a recent recipient of the Gold Medal from the Society of Breast Imaging.

Dr. Lee is the leading expert on screening for women in their forties and it is in large part due to his efforts in defining the scientific issues, analysing the data, and presenting the National Cancer Institute in the 1980s that women aged 40–49 have access to routine mammography screening. He continues to support the fundamental scientific basis of screening while exposing the flawed analyses that are being generated to try to reduce access to screening.

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Donata Lenda Monza, Italy

Dr. Donata Lenda graduated in Dentistry in 1987. She worked in public administration in Italy for more than 20 years and started working at the European Commission in 2007. She is an expert in quality assurance, accreditation, auditing and management of network; she also has a deep knowledge of the European Commission working rules. She coordinates the European Commission Initiative on Breast Cancer.

She is a recent recipient of the Gold Medal from the European Commission Committee of the Council of Europe and the European Institute for Biomedical Imaging Research (EIBIR) with past experience working at the European Commission in the 1990s that women aged 40–49 have access to routine mammography screening. She continues to support the fundamental scientific basis of screening while exposing the flawed analyses that are being generated to try to reduce access to screening.

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Dr. Lorenzo Livi graduated in Medicine and Surgery in 1997. He specialized in radiation oncology in 2000 and in medical oncology in 2002. He served as Assistant Professor of Radiation Oncology at the University of Florence from 2002 to 2011. In 2012 he became Full Professor of Radiation Oncology and since 2015 he has been Chair of the Radiation Oncology Department at the Florence University Hospital. He has an extensive interest in radiation oncology and its interplay with systemic therapies, in particular breast cancer, urogenital cancer and soft tissue sarcoma. He has been listed as an author or co-author in more than 100 peer-reviewed papers and is also the author of various book chapters. He is an active member of the Italian Association of Radiation Oncology (AIRO), the European Society for Radiotherapy and Oncology (ESTRO), and the European Organisation for Research and Treatment of Cancer (EORTC).
CHAPTER 9: ABOUT THE AUTHORS

Jesús López Alcalde, MD, graduated in Medicine in 2004 and specialised in Preventive Medicine, Epidemiology and Public Health in 2006. He is an expert in guideline development methodologies and the implementation and dissemination of research findings.

Ritse Mann, MD, PhD, is an academic breast and interventional radiologist at the Radboud University Medical Centre in Nijmegen, the Netherlands, and the Director of the Radboud University Medical Centre’s Breast Imaging and Interventional Radiology Department. Mann is a member of the executive board of the European Society of Breast Imaging (EUSOBI) and its scientific and young club committees. In addition to being a member of the Euroaim working-group on evidence-based radiology, he is course director of the Nijmegen advanced breast imaging course aimed at clinical validation of novel strategies for breast cancer detection and treatment. Mann is also a member of the executive board of the European Society of Radiology (EUSOBI) 2013–2018. Dr. Mann is breast section editor of the European Journal of Radiology, and a member of the e-learning editorial board of the European Journal of Radiology, and actively involved in numerous other teaching courses. Ritse Mann is a breast section editor of the European Journal of Radiology, and a member of the e-learning editorial board of the European Society of Radiology.

Iiro Neutelis, MD, PhD, is a board-certified radiologist and Professor of Diagnostic Radiology and Molecular Imaging at Oakland University William Beaumont School of Medicine. He is also the Director of the Division of Breast Imaging at Beaumont Health System’s Royal Oak Campus in Royal Oak, Michigan.

Ritse Mann, MD, PhD, is an academic breast and interventional radiologist at the Radboud University Medical Centre in Nijmegen, the Netherlands. He is an active researcher, and counsellor of the non-profit Florence Foundation. Mann has focused on breast cancer (including screening programmes and regional population based cancer registry in her own country). He is a member of the executive board of the Estro Young Club, the Italian Society of Breast Imaging.

Luciana Neamțiu, PhD, graduated in Mathematics and Physics in 1996 and obtained her PhD in mathematical biophysics in 2001. Neamțiu is an active researcher, and in different management positions both in academia and the pharmaceutical industry. Since 2012 she has worked as Chief Medical Officer at the Cancer Society of Finland. Her scientific interests have focused on breast cancer (including screening) prostate cancer, bone active compounds and patient support.

Liisa Pylkkäsen, MD, studied in Turku, Finland. She is a specialist in Clinical Oncology (1995), Health Administration (2001) and Palliative Medicine (2010) and has held an Adjunct Professor position since 2001. She has worked in clinical oncology for more than 25 years and in different management positions both in academia and the pharmaceutical industry. Since 2005, Liisa Pylkkäsen has worked as Chief Medical Officer at the Cancer Society of Finland. She is a specialist in Clinical Oncology (1995), Health Administration (2001) and Palliative Medicine (2010) and has held an Adjunct Professor position since 2001. She has worked in clinical oncology for more than 25 years and in different management positions both in academia and the pharmaceutical industry. Since 2005, Liisa Pylkkäsen has worked as Chief Medical Officer at the Cancer Society of Finland.

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Luciana Neamțiu, PhD, graduated in Mathematics and Physics in 1996 and obtained her PhD in mathematical biophysics in 2001. Neamțiu is an active researcher, and in different management positions both in academia and the pharmaceutical industry. Since 2012 she has worked as Chief Medical Officer at the Cancer Society of Finland. Her scientific interests have focused on breast cancer (including screening) prostate cancer, bone active compounds and patient support.
CHAPTER 9: ABOUT THE AUTHORS

**Francesco Sardanelli**
Milan, Italy

Dr. Francesco Sardanelli is Professor of Radiology and Director of the Postgraduate School in Radiodiagnostic at the University of Milan. He received his Medicine Graduation in 1982 and Postgraduate Diploma in Radiodiagnostic at the University of Genova. He was staff radiologist at the San Martino Hospital, Genoa from 1987 to 1999 and Adjunct Professor of the Postgraduate Course in Radiodiagnostic at the University of Genova from 1992 to 2000. From 1999, he was Director of the Radiology Department at the Research hospital Policlinico San Donato, Milan, then Adjunct Professor of the Postgraduate Course in Radiodiagnostic, University of Milan from 2001 to 2005. He became Associate Professor of Radiology (2006–2014), then Full Professor of Radiology (from 2015) at the University of Milan. He was Director of the Postgraduate School in Nuclear Medicine at the University of Milan (2008–2012). In 2015 he became Director of the Postgraduate School in Radiodiagnostic at the University of Milan. He was a consultant for the Attitude Supervisor di Sanità (Italian Health Government Department) for the national radiological coordination of multicentre studies on MRI, including screening and diagnostic studies, and has served a reviewer for almost 60 other medical journals. He is currently on the research Committee of the European Society of Radiology and the Advisory Board of the European Institute for Biomedical Imaging Research (EIBIR). He is Director of the EIBIR/European Network for Assessment of Imaging in Medicine (from 2009), Past President of the European Society of Breast Imaging and President of the Italian College of Breast Radiologists of the Italian Society of Medical Radiology.

He has received honorary membership of the British Society of Breast Radiology and the Human Society of Radiology, he has published ten books and 96 book chapters, more than 250 full articles, and more than 200 congress abstracts; he has also given more than 140 oral presentations and lectures at medical congresses and courses, and Clinical and Translational Imaging; he is the Editor-in-Chief of the forthcoming journal European Radiology, Experimental, and has served as a reviewer for almost 60 other medical journals. He is currently on the Board of Directors of Breast Imaging committee of the American College of Radiology since 1999, and has co-chaired the ACR Committee on Mammography Interpretative Services Assessment since its inception in 1992, and currently chairs the ACR BI-RADS Management Subcommittees. In his commitment to improving the science and art of breast imaging, he has also served in a leadership position in 10 other professional societies and organizations and on over 40 committees both nationally and internationally. He is a founding member and past president of the Society of Breast Imaging. He has been the recipient of numerous awards and special recognitions for his dedication, service, and contributions to breast imaging, including the Gold Medal of the Society of Breast Imaging and honorary membership in four international radiologic societies.

**Zulka Sari Parkinson**
Luton, United Kingdom

Dr. Zulka Sari Parkinson. PhD, graduated and received a master’s degree in biochemistry in 1994 and 1996, respectively. She obtained her PhD in Preventive Medicine and Public Health in 2005. She has worked in Health Technology Assessment, with a particular interest in screening, cancer and genetics, for over ten years and also has ample experience in Research Management and Quality Management gained in working at the Spanish National Cancer Research Centre and also a health-research institute in Madrid.

**Edward A. Sickles**
San Francisco, USA

Edward A. Sickles, MD, is Professor Emeritus of Radiology at the University of California, San Francisco (UCSF). School of Medicine and served as chief of the Breast Imaging Section at the UCSF Medical Center for almost 30 years. He is a prolific contributor to breast imaging education and the scientific literature; he has provided editorial services to twelve professional journals. He has been the author or co-author of ten books and monographs, approximately 250 scientific articles, and almost 100 other scientific communications. He has presented papers at more than 250 scientific meetings and has been an invited speaker at more than 150 educational seminars and medical institutions in 42 states in the United States and in 32 other countries. He has also served on many breast imaging committees of the American College of Radiology (ACR) since 1980; he chaired the ACR Committee on Mammography Interpretative Services Assessment since its inception in 1992, and currently chairs the ACR BI-RADS Management Subcommittee. In his commitment to improving the science and art of breast imaging, he has also served in a leadership position in 10 other professional societies and organizations and on over 40 committees both nationally and internationally. He is a founding member and past president of the Society of Breast Imaging. He has been the recipient of numerous awards and special recognitions for his dedication, service, and contributions to breast imaging, including the Gold Medal of the Society of Breast Imaging and honorary membership in four international radiologic societies.

**Rubina Manuela Trimboli**
Milan, Italy

Dr. Rubina Manuela Trimboli, MD, is a radiologist at IRCCS Policlinico San Donato, University of Milan, her main area of interest is breast radiology. She is involved in mammography, ultrason but breast MRI, and needle biopsy under stereotactic and US guidance; and is an active researcher in breast cancer prevention and diagnostics, focusing on screening in high and intermediate risk women. She also holds a PhD in Biomedical Imaging and Research and acts as a tutor of medical-students and residents in radiodiagnostic. She is a fellow of the European Society of Breast Imaging (EUSOBI). She has co-authored 14 peer reviewed papers and more than 20 conference abstracts, and given ten invited lectures.

**Asli Uluturk**
Istanbul, Turkey

Dr. Asli Uluturk graduated in Medicine in 2000 and received her specialist degree in radiology in 2007. She has worked in the field of breast imaging, in particular within a screening and early diagnosis programme, in the breast ultrasound field.
Dr. Pamela Zolda is a former assistant professor at the University of Vienna with highly valuable and in-depth experience of international research projects. She is a senior European research project manager at the European Institute for Biomedical Imaging Research (EIBIR) and has coordinated and managed several Framework 7 projects. She is currently the coordinator of the Digital Hybrid Breast PET/MRI for Enhanced Diagnosis of Breast Cancer (HYPMED) project.
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