Successful development of a breast cancer detection algorithm using Artificial Intelligence

CT in the diagnosis of COVID-19 infection
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COVID-19 and the role of CT

In fast-developing situations such as those of the current world-wide coronavirus infections it is hard to put the daily statistics into perspective. At the time of writing, the official World Health Organisation data show that, world-wide there have been a total of 90933 confirmed COVID-19 cases (the extent of underreporting in countries such as Iran remains unknown). Of these cases, so far a total of 3119 deaths have been reported. The vast majority of these cases and deaths have occurred in China, but the daily number of new Chinese cases is steadily decreasing while now there appears to be nine times more new cases being reported outside of China than within the country. Currently at least, the four countries outside of China giving the WHO most concern are Korea, Italy, Iran and Japan (although if the hapless cruise liner the Diamond Princess moored in Japan had been a country, it would have been included in the top four).

Amongst all the constant analysis and repeated attempts to interpret the data to determine the on-going rate and possible future direction of the number of cases, one date stands out. This was February 12th when in Hubei, the county in China where the outbreak was first detected, a huge surge in the number of newly diagnosed COVID-19 cases was reported. This prompted many ill-informedcommentators to unfairly interpret the surge in new cases as evidence of the unreliability of the Chinese epidemiological data. In fact, the simple reason for the sudden increase in reported cases was that the Chinese authorities had introduced new diagnostic criteria which for the first time included CT-derived evidence of pathological changes in the lungs. The new diagnostic criteria were employed to ensure timely treatment and isolation measures, because of the delays associated with laboratory testing and a large number of patients presenting with respiratory symptoms in the province. As a group of researchers from the Diagnostic Radiology Department of the University of Hong Kong point out (Lee, Ng, Khong. COVID -19 what has CT taught us?. Lancet Infectious Diseases Feb 24 2020 doi 10.1016/ S1473-3099(20)30134-1), since the predominant pattern seen in COVID-19 pneumonia is ground-glass opacification, the detection of COVID-19 using the much more accessible modality of chest X-ray of chest radiography—on which this type of abnormality is often imperceptible, particularly in patients with few symptoms or low severity—is likely to be challenging. The raw data on which these conclusions were based came from a group of radiologists right in the heart of the Chinese outbreak, namely Wuhan City in Hubei province (Shi H et al. Radiological findings from 81 patients with COVID-19. pneumonia in Wuhan, China: a descriptive study Lancet Infect Dis 2020 Published Online February 24, 2020 https://doi.org/10.1016/ S1473-3099(20)30086-4) The Wuhan group showed that COVID-19 pneumonia tends to manifest on lung CT scans as bilateral, subpleural, ground-glass opacities with air bronchograms, ill-defined margins, and a slight predominance in the right lower lobe. Importantly abnormal lung CT findings can be present even in asymptomatic patients, and lesions can rapidly evolve into a diffuse ground-glass opacity predominance or consolidation pattern within 1–3 weeks after onset of symptoms, peaking at around 2 weeks after onset. Combining assessment of imaging features with clinical and laboratory findings could facilitate early diagnosis of COVID-19 pneumonia.

Alarmingly, another group of Chinese workers (Xie X, et al. Chest CT for typical 2019–nCoV pneumonia: relationship to negative RT-PCR testing. Radiology 2020; Feb 12. doi:10.1148/radiol.2020200343) reported that some patients with positive chest CT findings may present with negative results from real time reverse-transcription–polymerase chain- reaction (RT-PCR) tests for the virus.

The conclusion was that, in the context of typical clinical presentation and exposure to other individuals with the viral infection, CT features of viral pneumonia may be strongly suspicious for COVID-19 infection even with negative RT-PCR results.

Of course more research and data are needed to determine the lack of concordance of the RT-PCR results with those of CT.

In the meantime the general population should focus on basic hygiene measures such as scrupulous washing and disinfection of hands, avoiding viral hot-spots and isolating suspected carriers.
CT PROVIDES BEST DIAGNOSIS FOR COVID-19 INFECTION

In a recent study of 1,014 patients, chest CT was found to be more effective than RT-PCR lab testing in the detection of COVID-19 infection. The results showed that 59% of patients examined had positive RT-PCR results, while 88% had positive chest CT scans. The low sensitivity of RT-PCR implies that many COVID-19 patients may not receive appropriate treatment and risk infecting a larger population. ... 30

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COMING IN THE NEXT ISSUE:
Cardiovascular imaging
Risk of Acute Kidney Injury from CT contrast media “overstated” according to new consensus statements

The risk of administering modern intravenous iodinated contrast media in patients with reduced kidney function has been overstated, according to new consensus statements from the American College of Radiology (ACR) and the USA National Kidney Foundation (NKF), (Davenport MS, Perazella MA, Yee J, Dillman JR, Fine D, McDonald R, Rodby RA, Wang CL, Weinreb JC. Use of Intravenous Iodinated Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation. Radiology. 2020 Mar;294(3):660-668. doi: 10.1148/radiol.2019192094)

Intravenous iodinated contrast media are commonly used in CT to evaluate disease and to determine treatment response. Although patients have benefited from their use, iodinated contrast media have been denied or delayed in patients with reduced kidney function due to the perceived risks of contrast-induced acute kidney injury. This practice can hinder a timely and accurate diagnosis in these patients.

“The historical fears of kidney injury from contrast-enhanced CT have led to unmeasured harms related to diagnostic error and diagnostic delay,” said lead author Dr MS. Davenport, “Modern data clarify that this perceived risk has been overstated. Our intent is to provide multi-disciplinary guidance regarding the true risk to patients and how to apply a consideration of that risk to modern clinical practice.”

These consensus statements were developed to improve and standardize the care of patients with impaired kidney function who may need to undergo exams that require intravenous iodinated contrast media to provide the clearest images and allow for the most informed diagnosis.

In clinical practice, many factors are used to determine whether intravenous contrast media should be administered. These include probability of an accurate diagnosis, alternative methods of diagnosis, risks of misdiagnosis, expectations about kidney function recovery, and risk of allergic reaction. Decisions are rarely based on a single consideration, such as risk of an adverse event specifically related to kidney impairment. Consequently, the authors advise that these statements be considered in the context of the entire clinical scenario.

Importantly, the report outlines the key differences between contrast-induced acute kidney injury (CI-AKI) and contrast-associated acute kidney injury (CA-AKI). In CI-AKI, a causal relationship exists between contrast media and kidney injury, whereas in CA-AKI, a direct causal relationship has not been demonstrated. The authors suggest that studies that have not properly distinguished the two have contributed to the overstatement of risk.

“A primary explanation for the exaggerated perceived nephrotoxic risk of contrast-enhanced CT is nomenclature,” Dr. Davenport said. “‘Contrast-induced acute kidney injury implies a causal relationship. However, in many circumstances, the diagnosis of CI-AKI in clinical care and in research is made in a way that prevents causal attribution. Disentangling contrast-induced AKI (causal AKI) from contrast-associated AKI (correlated AKI) is a critical step forward in improving understanding of the true risk to patients.”

The statements answer key questions and provide recommendations for use of intravenous contrast media in treating patients with varying degrees of impaired kidney function.

Although the true risk of CI-AKI remains unknown, the authors recommend intravenous normal saline for patients without contraindication, such as heart failure, who have acute kidney injury or an estimated glomerular filtration rate (eGFR) less than 30 mL/min per 1.73 m2 who are not undergoing maintenance dialysis. In individual and unusual high-risk circumstances (patients with multiple comorbid risk factors), prophylaxis may be considered in patients with an eGFR of 30-44 mL/min per 1.73 m2 at the discretion of the ordering clinician.

The presence of a solitary kidney should not independently influence decision making regarding the risk of CI-AKI. Lowering of contrast media dose below a known diagnostic threshold should be avoided due to the risk of lowering diagnostic accuracy. Also, when feasible, medications that are toxic to the kidneys should be withheld by the referring clinician in patients at high risk. However, renal replacement therapy should not be initiated or altered solely based on contrast media administration. The authors recommend that renal replacement therapy should not be initiated or altered solely based on contrast media administration.

The authors emphasize that prospective controlled data are needed in adult and pediatric populations to clarify the risk of CI-AKI.

doi: 10.1148/radiol.2019192094
Portable MRIs bring diagnostics to stroke patients’ bedside

A portable, low-field MRI system may become a safe and practical way to get accurate brain images at a patient’s bedside, according to preliminary research presented at the American Stroke Association’s International Stroke Conference 2020.

“We’ve flipped the concept from having to get patients to the MRI to bringing the MRI to the patients,” said Kevin Sheth, M.D., senior author and chief physician, Division of Neurocritical Care and Emergency Neurology at Yale School of Medicine and Yale New Haven Hospital in Connecticut, USA. “This early work suggests our approach is safe and viable in a complex clinical care environment.”

Eighty-five stroke patients (46% women, age 18-96, 46% ischemic stroke, 34% intracerebral hemorrhage, 20% subarachnoid hemorrhage) received bedside, low-field MRI within seven days of symptom onset. The exam time averaged about 30 minutes, and most patients were able to complete the entire exam. However, five patients could not fit into the 30-centimeter opening of the MRI machine, and six patients experienced claustrophobia, factors which halted their test.

“We started this research several years ago because obtaining accessible, meaningful brain imaging for patients has been a major worldwide health care gap for decades,” Sheth said. “The whole thing works because we are using low-field magnets to acquire brain images after a stroke.”

Currently, patients must travel to the location of a high-field MRI device. However, advances in low-field MRI have enabled acquisition of clinically useful images using a portable device at bedside.

“High-field magnets are the cornerstone of commercial MRIs. The portable, low-field MRI could be used at hospitals that currently have a high-field MRI and in any other setting where an MRI is currently not available.”

He added that the portable MRI devices will also decrease need for a special power supply, cooling requirements, cost and other barriers that currently limit easy patient access.

In addition, the low-field, bedside MRI scanner did not interfere with other equipment, and metals did not need to be removed from the room. No significant adverse events were reported.

“There’s a lot of work to do, however, we’ve cracked the door open for bringing this technology to any setting anywhere. In rural settings, urban advanced hospitals and in remote villages in areas of the world where it’s hard to get an MRI - not anymore,” Sheth said.

Sheth said next steps include scanning more patients, improving image quality, using the devices in multiple settings and using machine learning to extract as much meaningful information as possible.

The new portable MRI system was developed by Hyperfine Research www.hyperfine.io

O-RADS MRI in difficult cases of ovarian cancer

A recently published study (Thomassin-Nagagara I et al. Ovarian-Adnexal Reporting Data System Magnetic Resonance Imaging (O-RADS MRI) Score for Risk Stratification of Sonographically Indeterminate Adnexal Masses. JAMA Netw Open. 2020 Jan 3;3(1):e1919896. doi: 10.1001/jamanetworkopen.2019.19896.) has shown that a new MRI tool, known as Ovarian-Adnexal Reporting Data System Magnetic Resonance Imaging (O-RADS MRI), produces encouraging results. The tool is able to distinguish between malignant and benign ovarian cysts with 90 per cent accuracy, in cases that cannot be distinguished on ultrasound. It was developed by researchers led by Professor Isabelle Thomassin-Nagagara at the APHP-Sorbonne Université, Paris, France with Professor Andrea Rockall at Imperial College London, UK.

Currently, to investigate potential cases of ovarian cancer ultrasound scanning and blood tests are used. However, in a quarter of cases these methods cannot identify with confidence whether a patient’s cyst is benign or malignant. This leads to surgical investigations, which are invasive and carry risks, such as potential loss of fertility. In most cases women are then diagnosed as having benign cysts.

The team of researchers believes that the new tool can be used as a triage test to decide whether patients need further follow up or treatment. They also believe that the findings from the study could help stratify patients who are high risk so they can be given treatment at a much earlier stage.

Professor Andrea Rockall, senior author of the study and Chair of Radiology at Imperial College London, said: “Ovarian cancer is referred to as a ‘silent killer’ as cases are often diagnosed at an advanced stage of the disease. When it is diagnosed earlier the chance of survival is much improved.

There is a real unmet clinical need to find less invasive ways to identify women at risk of ovarian cancer. Our tool has the potential to help triage patients who are low risk so they can have less invasive treatment options, as well as identifying high risk patients so they can receive treatment at an earlier stage and have a better chance of long-term survival.”
Ovarian cancer is the sixth most common cancer in women and usually affects women after the menopause or those with a family history of the disease. There are 6,000 new cases of ovarian cancer a year in the UK but the long-term survival rate is just 35-40 per cent as the disease is often diagnosed at a late stage once symptoms such as bloating are noticeable. Early detection of the disease could improve survival rates.

Currently, to investigate potential cases of ovarian cancer clinicians use an ultrasound of the pelvis which shows the ovaries, womb and surrounding structures. The clinicians then look for cysts in the ovaries and if these appear suspicious, women are referred for additional investigations. Clinicians also use a blood test to look for the tumour marker CA125. These methods are effective at differentiating most benign cysts from those that are malignant. However, in 20-25 per cent of cases the ultrasound is unable to confidently characterise whether a cyst is malignant or benign.

When this occurs, patients may need to undergo surgery in order to confirm if the cyst is malignant or benign. This is invasive and the majority turn out to be benign. In some cases, this can also lead to a loss of fertility in younger patients.

If the nature of the cysts could be known before surgery, patients would potentially benefit from a more limited surgical approach or follow-up, saving the patients from additional risks as well as cutting unnecessary costs.

In the new study, researchers looked at the effectiveness of Ovarian-Adnexal Imaging-Reporting-Data System Magnetic Resonance Imaging (O-RADS MRI) in identifying the risk of malignancy in ovarian cysts that could not be categorised by ultrasound in 1340 women. The study took place from March 2013 to March 2016 at 15 centres across Europe. Each patient underwent a routine pelvic MRI examination which looked for particular features in cysts that could not be identified during an ultrasound examination such as changes to tissue structure. The researchers developed a risk stratification score based on five categories. Radiologists then used this tool to score the cysts.

A score of one to three was identified as no mass or benign and a score between four and five was deemed high risk. The women then underwent appropriate standard care, such as surgery if they were identified as high risk or a two year follow-up if their cysts were benign.

A team of radiologists also analysed patients’ medical records and ultrasound scans to compare the tool.

The team found that the system outperformed current methods and was 90 per cent accurate at identifying malignant and benign cysts.

The team also found that in patients who scored two or three the risk of a malignant tumour was very low. The researchers believe that these patients can make an informed decision, with the support of their physicians, to undergo a minimally invasive approach towards their treatment such as close monitoring and follow-up rather than surgery.

Deep learning approach differentiates small renal masses on multiphase CT


Between 2012 and 2016, researchers at Japan’s Okayama University studied 1807 image sets from 168 pathologically diagnosed small (<4 cm) solid renal masses with four CT phases — unenhanced, corticomedullary, nephrogenic, and excretory — in 159 patients. Masses were classified as malignant (n = 136) or benign (n = 32) using a 5-point scale, and this dataset was then randomly divided into five subsets.

As lead author Takashi Tanaka explained, “four were used for augmentation and supervised training (48,832 images), and one was used for testing (281 images).”

Utilizing the Inception-v3 architecture CNN model, the AUC for malignancy and accuracy at optimal cutoff values of output data were evaluated in six different CNN models.

Finding no significant size difference between malignant and benign lesions, Tanaka’s team did find that the Area Under the Curve (AUC) value of the corticomedullary phase was higher than that of other phases (corticomedullary vs excretory, p = 0.022).

Additionally, the highest accuracy (88%) was achieved in the corticomedullary phase images.

Multivariate analysis revealed that the CNN model of corticomedullary phase was thus a significant predictor for malignancy, “compared with other CNN models, age, sex, and lesion size,” Tanaka concluded.
Abnormal imaging findings key to EVALI diagnosis

Images show electronic cigarette or vaping product use-associated lung injury in a 52-year-old man with history of vaping who presented with fevers and night sweats for 1 week. (a) Coronal maximum intensity projection image shows diffuse centrilobular nodularity. (b) Histologic sections of his transbronchial cryobiopsy showed distinctive micronodular pattern of airway-centered organizing pneumonia, corresponding to centrilobular nodularity seen at CT. Similar imaging and pathologic findings have been described in patients with smoke of airway-centered organizing pneumonia, corresponding to centrilobular nodularity seen at CT. Similar imaging and pathologic findings have been described in patients with smoke.

Pulmonary imaging is important in the diagnosis of the acute lung injury associated with vaping, known as electronic cigarette or vaping product use-associated lung injury (EVALI), according to a special review article (Kligerman et al. Radiologic, Pathologic, Clinical, and Physiologic Findings of Electronic Cigarette or Vaping Product Use-associated Lung Injury (EVALI): Evolving Knowledge and Remaining Questions. Radiology. 2020 Mar;294(3):491-505. doi: 10.1148/radiol.2020192585). The report outlines what is currently known about this condition and discusses remaining questions. Although e-cigarettes have been often marketed as a safer alternative to traditional cigarettes, EVALI has emerged as a serious and sometimes fatal complication of vaping. Radiologists play a key role in the evaluation of suspected EVALI. Accurate identification of the condition allows for prompt medical treatment, which may decrease the severity of injury in some patients. “Rapid clinical and/or radiologic recognition of EVALI allows clinicians to treat patients expeditiously and provide supportive care,” said Dr. S Kligerman. “Although detailed clinical studies are lacking, some patients with EVALI rapidly improve after the administration of corticosteroids. Additionally, making the correct diagnosis may prevent unnecessary therapies and procedures, which themselves can lead to complications.” Despite ongoing investigations by public health officials, the exact cause of EVALI remains unclear. Over 80% of EVALI patients report vaping tetrahydrocannabinol (THC) or cannabidiol CBD containing compounds. Chest CT findings in EVALI can be variable but most commonly show a pattern of diffuse lung injury with sparing of the periphery of the lungs. EVALI is a diagnosis of exclusion. The patient must have a history of vaping within 90 days and abnormal findings on chest imaging, but other possible causes for the patient’s symptoms must be eliminated. “If EVALI is not diagnosed in a timely manner, patients may continue vaping after leaving the doctor’s office, clinic or emergency department which could lead to worsening lung injury,” he said.

“Right now, we do not know the long-term effects of vaping, as it is still a relatively new method of nicotine and THC delivery, and there are countless variables involved which further confound our understanding of what is happening on a patient-specific level.”

He added that while recent studies have shown an association between vaping and the development of asthma, chronic bronchitis and chronic obstructive pulmonary disease, these studies have only shown an association and not causation.

“I would not be surprised if vaping is directly linked to many of the chronic pulmonary and cardiovascular diseases commonly associated with traditional cigarette smoking,” Dr. Kligerman said. “The link between vaping and lung cancer is unknown at this point,” he noted.

doi: 10.1148/radiol.2020192585

Low back pain accounts for a third of new emergency department imaging

The use of imaging for the initial evaluation of patients with low back pain in the emergency department (ED) continues to occur at a high rate—one in three new emergency visits for low back pain in the United States—according to a recent article (Pakpoor J, Raad M, Harris A, Puvanesarajah V, Canner JK, Nadgir R, Jain A. Use of Imaging During Emergency Department Visits for Low Back Pain. AJR Am J Roentgenol. 2020 Feb;214(2):395-399. doi: 10.2214/AJR.19.21674). “Although there has been a modest decline,” wrote Dr. Jina Pakpoor of the University of Pennsylvania, “in 2016, approximately one in three patients still continued to receive imaging in the ED.”

Excluding patients with concomitant encounter diagnoses suggesting trauma, as well as those with previous visits for back pain, Current Procedural Terminology codes were used to identify three imaging modalities: radiography, CT, and MRI.

Of the 134,624 total encounters meeting Pakpoor’s inclusion criteria, imaging was obtained in 44,405 (33.7%) visits and decreased from 34.4% to 31.9% between 2011 and 2016 (odds ratio per year, 0.98 [95% CI, 0.98-0.99]; p < 0.001).

During the five-year study period, 30.9% of patients underwent radiography, 2.7% of patients underwent CT, and 0.8% of patients underwent MRI for evaluation of low back pain. Imaging utilization varied significantly by geographic region (p < 0.001), with patients in the southern U.S. undergoing 10% more imaging than patients in the western U.S.

Acknowledging further research is necessary “to understand the underlying reasons for persistent use of potentially unwarranted imaging in the emergency setting,” as Pakpoor concluded, “our results indicate that the use of imaging for the evaluation of patients with low back pain in the ED is moderately declining but continues to occur at an overall high rate.”
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For more information about the course and our Society, please visit: icimagingssociety.org.uk
Reduced lung-cancer Mortality with volume CT screening in a randomized trial

The joint Dutch-Belgian Nelson trial was set up to address the issue of the limited amount of data available from randomized trials as to whether volume-based, low-dose computed tomographic (CT) screening can reduce lung-cancer mortality among male former and current smokers. The results have now been published (de Koning HJ et al Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial. N Engl J Med. 2020 Jan 29. doi: 10.1056/NEJMoia1911793). In the trial, a total of 13,195 men (primary analysis) and 2594 women (subgroup analysis) between the ages of 50 and 74 were randomly assigned to undergo CT screening at T0 (baseline), year 1, year 3, and year 5.5 or undergo no screening. It was found that, at year 3, and year 5.5 or undergo CT screening at T0 (baseline), year 1, year 3, and year 5.5 or undergo no screening. There were low rates of follow-up procedures for results suggestive of lung cancer. doi: 10.1056/NEJMoia1911793.

BJR celebrates 125 years of publishing radiological research

This year, the British Institute of Radiology’s flagship research journal, BJR (British Journal of Radiology), celebrates 125 years of publishing radiological research. To celebrate this significant milestone, the BJR has announced a special anniversary article series that will feature invited articles from leading international experts published throughout the year.

BJR Editor-in-Chief (medical) Dr Simon Jackson said, "This is an exciting time for our prestigious journal – BJR has reached a significant landmark and is going from strength to strength. We are delighted to be able to celebrate this important milestone with such an outstanding collection of articles from some of the world’s foremost experts on medical imaging and the related sciences."

BJR is the oldest radiology journal in the world, with roots dating back to 1896. Founding editor Sidney Rowland, a medical student at St Bartholomew’s Hospital in London, launched the new journal, the Archives of Clinical Skiagraphy, in April 1896, just months after Wilhelm Roentgen discovered the X-ray in 1895. The primary objective of the new publication was, "to put on record in permanent form some of the most striking applications of the New Photography to the needs of Medicine and Surgery" as Rowland noted in his preface to the first issue. In 1928, following several name changes and an initial period of evolution, the publication re-launched as the British Journal of Radiology. The figures show a timeline of BJR’s history and some examples of the journal’s front cover from launch to present day. BJR’s history is radiology’s history, and the journal has gone on to publish landmark papers such as the 1953 seminal paper from L.H. Gray and Sir Oliver Scott, defining the importance of oxygen in radiotherapy, and the first description of CT “Computerized transverse axial tomography” by Sir Godfrey Hounsfield in 1973.

The specially commissioned and forward-facing commemorative collection of articles spans the breadth of BJR’s scope, from diagnostic radiology to radiotherapy and the underpinning sciences. The series will focus on developments and future directions across different areas and imaging modalities as well as revisiting some key seminal papers from BJR’s extensive and prestigious archive.

BJR Editor-in-Chief (scientific) Professor Kevin Prise said, “The themes and topics being tackled in this superb collection highlight the state-of-the-art underpinning the work undertaken by clinicians and researchers who specialise in medical imaging, medical physics and radiation research. We expect these articles to have a broad and significant impact on the community we serve and its future development.”

This important collection of Review articles will be essential reading for the whole of the imaging community. The articles will be published in BJR issues throughout 2020 and as a curated collection towards the end of the year.

The January issue of BJR, containing two introductory Editorials to mark the start of the anniversary year, can be accessed via: www.birpublications.org/toc/bjr/93/1105. The first Review article of the series, “Artificial Intelligence: reshaping the practice of radiological sciences in the 21st century”, by Professor Issam El Naqa and colleagues, published in BJR’s February issue, can be read here: https://doi.org/10.1259/bjr.20190855.

The collection itself, which will be added to as the year goes on, can be found on the BJR publications website: www.birpublications.org/BJR125.
The University Hospital Zurich (USZ) is one of Switzerland’s largest and most renowned university hospitals, with a world-wide reputation for clinical excellence and technological innovation. For the last six months the USZ Radiology Department has been involved in the intensive evaluation of a newly launched CT scanner, the Somatom X.cite system from Siemens Healthineers.

We wanted to find out more about the new system and its performance in real-life clinical practice, so we spoke to Prof. Hatem Alkadhi, head of cardiovascular imaging and CT in the diagnostic and interventional radiology department.

Q Before we get on to the specifics of the new system, please give us some general background about radiology in USZ.

In total we see around 150,000 patients per year in the radiology department of USZ, of whom approximately 60% are out-patients. The majority of our patients come from Zurich and the surrounding area, but we do have some referrals from the rest of Switzerland, particularly for special imaging examinations such as cardiac imaging, dual-energy CT and others.

Each year we carry out approximately 35,000 CT examinations and approximately 13,000 MRIs. To handle such a workload, we have three X-ray systems (Fuji and Siemens); for CT we have three scanners (Siemens SOMATOM Force, Edge Plus and Flash) as well as a CT from nu-view dedicated to breast imaging; for MRI, we have two 3.0 Tesla scanners (Siemens Skyra) and two 1.5 Tesla Scanners (GE Healthcare). We also have one mammography unit from Siemens and three ultrasound systems from GE and Philips. In addition to all this we have two fluoroscopy units from Siemens for interventional radiology. And to efficiently run all this we have a total of 120 radiologists and technologists in the department.

Q And now let’s focus on your experience with the Somatom X.cite.

We have had the new CT scanner since September 2019. It is physically located in the Neuroradiology Clinic of the hospital so we share it with our neuroradiology colleagues. We have access to the system several days a week and we use it as an all-rounder CT, scanning all cases, including cardiovascular and dual-energy applications.

After the usual training period of three days our technologists felt comfortable with the new CT, including the new software platform so there was no significant learning curve. This was mainly due to the fact that the new user interface has been specifically designed to improve usability, using a visual logic that is easy to understand and follow even for less experienced users. Traditional interfaces can often be very technical since they tend to be designed by engineers for engineers. In contrast, the new user interface was designed by engineers in close cooperation with clinical staff who could express the real-life requirements of clinical operation.

Q One of the features of the new system is the “myExam Companion” software, which optimizes scanning results by providing customized “decision trees”. In practice how does this work?

Basically the system works by proposing several questions which have been derived from the analysis of thousands of previous scans, in order to suggest the optimal scanning parameters.
The idea is that the software enables individualization of scanning parameters as a function of the patient’s characteristics, so guaranteeing optimal scanning performance.

Thus myExam Companion is a new approach to scanner operation, that has been designed to make work easier for us users, to personalize procedures for patients and to deliver fast, reliable and comprehensive results for radiologists. The system takes patient-specific input from the RIS and from smart sensors such as the 3D Camera on the scanner (which determines the optimal height positioning of the table) as well as other variables such as the patient’s ECG. All this information is then translated into a personalized protocol for the individual patient.

To create the system, thousands of scanning processes were analyzed and using artificial intelligence, key parameters were identified that enable optimized scanning results to be achieved. The outcome of all this research work was the development of decision trees which now work automatically in every exam by identifying the appropriate patient input and by putting relevant questions to the technologists at each stage of the procedure, for instance “can the patient hold breath longer than 5 seconds?”, thus guiding the technologist through the scan set-up without any complication.

Decision trees in themselves are of course not new and are to be found in almost every hospital, but up till now they have been typically sketched roughly out on paper and posted at an individual department level. Now they are integrated into the scanner software and directly available via the WiFi - connected tablet at the time of the scan.

The effect of the Fast 3D camera on patient positioning. There is a statistically significant difference in the off-centering between manual patient positioning by technologist and by the automatic Fast 3D camera. Image adapted from Saltybaeva et al. Invest.Radiol 2018; 53: 641

Q You mentioned the Fast 3D camera which automatically adjusts the height of the table as a function of the patient. Just how big a problem is sub-optimal patient centering?

This is actually a serious problem in clinical routine. Previous studies have shown that when positioning is done manually by the technologists, up to 95% of patients are suboptimally centred in the scanner gantry. Such mis-centering has negative effects, not just on image quality but also — and perhaps more importantly — on radiation dose. Depending on the position of the patient in the scanner gantry, the organ doses may be increased by more than 40% compared to the optimal dose level when the patient is positioned at the iso-center of the gantry. The technologists had no problems or resentment in adopting the new system. On the contrary, they appreciate the entire new workflow, the proof being that they readily changed their habits after a few days.

Q Thanks to hand-held tablet computers connected by Wi-fi to the scanner, the technologists can spend more time being right next to the patient while setting up the scan instead of being at the operating console behind a shield. Do they use this facility in practice?

Yes they do. The benefits of the tablet operation are two-fold: first the tablet allows the technologist the flexibility of being mobile and able to set up the whole preparation of the scan while still being next to the patient. In addition, the tablet offers a simplified and touch-based, haptic user interface that is based on visual logic, very similar to the apps in our smartphones or tablets, so very user-friendly. Our technologists perceive this new usability concept as being very positive, since the interface is intuitive and modern. As you might expect, our younger technologists in particular adapted very quickly to the use of the tablet.

Q How useful is the 82 cm. wide gantry?

We — and even more so our colleagues in Neuroradiology — often use the scanner to examine patients from the neurological...
The system has a particularly powerful Vectron X-ray tube. This means that the Tin Filter can be also used in obese patients, so low-dose techniques which were previously restricted to non-obese patients are now available to a broader range of the population. The power of the tube also enables low kV imaging in more patients and hence at lower dose. Imaging at 70 kVp and 80 kVp can be carried out even for bigger patients, not only without any detrimental effect on image quality but also an improvement in iodine contrast. As a result, contrast media doses can be reduced, so allowing the imaging of critical patients with renal insufficiency for whom the administration of contrast media might otherwise have been contra-indicated.

With the CAREkV algorithm of the system, the tube voltage is automatically tailored to each individual patient and clinical indication. Tube voltage levels can be adjusted at intervals of 10 kV for lower dose and high contrast resolution and are aligned with the respective tube currents. This keeps the radiation dose low, while the image quality stays high.

All these features are equally useful in the two basic clinical scenarios in which we use the new system: as a routine work-horse but also for more advanced, more complex imaging such as cardiac or dual-energy CT.

**Q** **And the effect of all these features on throughput and work-flow?**

Many of the repetitive tasks and quality checks that are necessary for successful CT scans and which were previously carried out manually are now automated through the myExam Companion and the FAST 3D Camera system. Since most of this preparatory work can now be done at the patient’s side, the techs are much more efficient because they no longer have to walk back and forth several times to the control room. Although the actual scan time itself remains roughly the same as before, preparation time is optimized, which has a considerable impact on the overall workflow, potentially leading to shorter total room times.

Previous studies of the go.Platform, which was the previous version of the mobile workflow now incorporated in the Somatom X-cite, and is the basis for the current myExam Companion showed that patient preparation times were 20% faster [Wetzl M et al. Mobile Workflow in Computed Tomography of the Chest. Journal of Medical Systems. 2018; 43: 14. doi: 10.1007/s10916-018-1131-2].

**Q** **Radiation dose?**

The Tin Filter (Sn) which is incorporated in the system cuts out lower energy photons (which don’t contribute positively to the image acquisition) and so reduces overall dose and also optimizes contrast between soft tissue and air. This has benefits for imaging body areas such as the lungs, colon, and sinuses. In addition, clinical experience has shown that the Tin Filter reduces beam-hardening artifacts as well as improving image quality of bony structures, so it is particularly useful in orthopedic CT.
Do not lower the image quality and working speed due to budget constraints. The new VIVIX series offers superior image quality through enhanced DQE and advanced image processing technology. Presenting a cassette-size DR detector offered in 3 sizes – 25x30cm (VIVIX-S 2530V), 36x43cm (VIVIX-S 3643V), and 43x43cm (VIVIX-S 4343V).
Before we get into the various ultrasound elastography applications, please describe your clinic.

Echomed is a medical company that was founded in 1985 and since its foundation has always been uniquely specialized in ultrasound (US). We examine approximately 40,000 patients every year in Echomed, with the number increasing by approximately 10% every year. Our patients are referred to us from all over Greece, but some patients come from neighboring and Eastern European countries (e.g. Cyprus, Albania, Bulgaria, Kosovo, Ukraine and Moldova).

Echomed is a reference center for the imaging of patients with chronic liver disease and prostate cancer, so many hospital hepatology and urology departments refer their patients to us. In particular we have special associations with the hepatology departments of Laiko University Hospital, Athens and of the Ippokrateio hospital, in Thessalonika as well as with the Patras Oncology University Hospital which is specialized in prostate cancer.

Nearly 50% of our activities concern the liver and involve not only US and shear wave elastography (SWE) but also contrast-enhanced ultrasound (CEUS). We see approximately 50-70 patients with chronic liver disease of various causes per week. Nearly half of these are suitable for inclusion in the many clinical trials that we undertake, since Fibroscan or Fibrotest analytical data are available and/or the patients have undergone liver biopsy. As for biopsies, we carry out 8-12 US/SWE guided prostate biopsies and US/MRI Fusion guided prostate biopsies per week. We also perform approximately 4-6 US-guided fine needle thyroid biopsies per week.

Since we are focussed completely on US, all of the medical staff at Echomed are specialized in the modality regardless of their original medical specialty. In total we have 11 medically qualified clinicians (6 radiologists, 2 gastroenterologists, 1 cardiologist, 1 gynecologist, 1 pathologist, 1 anesthesiologist). Each clinician is specialized in US and Elastography analysis of one of the various anatomical organs: abdomen, pelvis, GI, urogenital, Gyn/Obst, MSK, thyroid and lymph nodes, small parts, vessels.

Other personnel at Echomed include a software developer, who handles RIS/PACS system support; a medical physicist who is mainly involved in our research activity and collaboration with the R&D departments of US equipment constructors. We also have a data scientist supervising and co-ordinating the collection of data, clinical trials, research projects and scientific publications. Echomed employs five administrative staff to support its activities.

What imaging equipment do you have?

Since the founding of Echomed in 1985 we have had many US systems from various manufacturers. Many of the high-end US systems that we installed even
some time ago are still operational. For example, we have a B&K system, which we use mainly for TRUS-guided biopsies, a GE Logiq 9 with six transducers which we use mainly for cardiac applications but also as a general-purpose system, as well as a Philips IU22 system, with six probes, which we mainly use for vascular applications.

Ultrasonography, however, is always evolving, which means that continuing investment in new technologies is essential. Thus, we have two SuperSonic Imagine Aixplorer US systems with five probes each which are mainly used for US and Shear Wave Elastography (SWE) in abdominal, prostate and small organ examinations.

Most recently we acquired a Resona 7 system from Mindray with six probes which we use as a multipurpose system for US and STE examinations in small and abdominal organs, as well as for TRUS-guided biopsies and CEUS.

Q **Why did you choose Mindray Resona 7?**

We were looking for a system satisfying several requirements:

To be able to carry out abdominal and pelvic exams with high quality B-Mode and color Doppler;

- to provide high quality B-Mode for small organs (including the possibility of US-guided breast biopsies and thyroid FNA);

- to generate reliable SWE for the liver, reliable strain and SW elastography for the breast and the prostate with the possibility of guided prostate biopsies.

In short we needed a heavy-use multi-purpose US system able to perform all US exams for all organs.

SWE can provide stiffness measurements in virtually all US-accessible organs. As far as the liver is concerned, we are no longer in the era of the single-line, non-guided elastography measurement offered by Fibroscan.

With modern high-end US/SWE systems, the physician or clinician can simultaneously carry out:

1. high-definition B-Mode examination to yield a precise anatomical morphologic imaging of all organs.

2. High quality Color and Pulsed Doppler for reliable hemodynamic assessment of the vasculature of all organs.

3. Nowadays, elastography must be added as the third vital feature for modern US. In practice, for elastography to be applicable to every organ and in difficult anatomic regions, it is frequently incorporated in an US/SWE system already fitted with robust B-Mode and Color Doppler. Used together, the three technologies form a powerful multi-parameter US/CD/SWE imaging tool.

Although the technique of elastography may not have equal importance in all organs and pathologies, it undoubtedly contributes additional information in every US application. The usefulness of liver and breast elastography has long been established and can now be considered as a “sine qua non” tool for Chronic Liver Diseases and breast tumors.

Simultaneously, the scientific community is increasingly focussing on the applicability of elastography in the thyroid, lymph nodes, testis, kidney, ovary, endometrium, MSK, and blood vessels, as evidenced by increasing...
numbers of publications in these fields. The current surge in the number of elastography applications is understandable since the underlying principle of the technique, namely the evaluation of tissue stiffness, provides very useful additional information in the US diagnosis of practically all organs.

Q Some people have the perception that elastography is difficult to carry out and that the results are difficult to interpret. Is this impression correct?

Elastography should always be carried out carefully and using well-established techniques, since it’s true that acquiring reliable data from many US elastographic applications can be difficult and the data sometimes difficult to interpret. Thus the person carrying out the examination should use all visual, mental and hand reflexes for each frame to avoid obstacles, create reliable shear-waves at the appropriate tissue depth and acquire meaningful color/stiffness maps.

However the starting point for a successful elastography examination is always to have a perfect B-mode image—a clear B/W B-Mode image is the prerequisite for every reliable elastogram. Of course awareness of existing guidelines and compliance with the equipment manufacturer’s instructions are mandatory—but not sufficient—for assuring consistent elastographic measurements. Basic knowledge of the principles of acoustics/physics as well as the underlying technology is also useful so that the user understands how to optimally produce stable ShearWaves and avoid any artefacts.

Q Every day there seems to be news of Artificial Intelligence/Machine learning algorithms being used in some imaging modality or another. Are there any AI applications being developed for the interpretation of ultrasound elastography results?

Artificial Intelligence seems indeed to have important applications such as identifying suspicious lesions in mammography, in identifying lung cancers in CT examinations of the thorax and in MRI examinations for the detection of central nervous system tumors.

However Artificial Intelligence has not (yet) been applied to the interpretation of US and SWE data, principally because, as explained above, it can be difficult to acquire diagnostic images suitable for AI. Only selected images that have been acquired following precise guidelines and under ideal anatomical conditions are suitable for applying Machine Learning technology and generating Artificial Intelligence-derived algorithms.

Q Most of your work is in liver. Any special requirements for this application?

We use SWE elastography for all types of Chronic Liver Disease (CLD). It should be noted however that elastography is not suitable for differentiating HepatoCellular Carcinoma (HCC) from other focal liver lesions. For examination of HCC, CEUS is the modality of choice. Likewise, CEUS is the optimal choice for the monitoring of progression or the effect of treatment of all focal liver lesions.

Elastography data can also result in a decrease in the need for liver biopsies, at least for the more frequent causes of CLD such as Hepatitis B and Hepatitis C and nonalcoholic steatohepatitis (NASH).

Studies have shown that a direct approach based on the measurement of the speed of sound (SSI) on the B-Mode image in a solid tissue correlates with the histology. The SSI technology, exclusively proposed by Mindray in the Resona7 system, is currently in clinical trials in order to prove its reliability in the assessment liver steatosis.

Q What about US/SWE in other organs?

While our main focus is on the liver, we also carry out US/SWE examinations in other organs.

Apart from the breast where strain elastography has proven its reliability and reproducibility, in general SWE is preferred for the estimation of stiffness in other organs.

Prostate. We perform 8-10 prostate biopsies per week. Elastography is crucial to confirm that a hypoechoic lesion in the peripheral zone is stiffer than the neighboring prostate parenchyma. This is useful not just to guide the taking of biopsies in stiff lesions but also to avoid the need for performing biopsies in the first place and, thus to reduce the number of false negatives.

On the other hand, strain and SWE have some limitations in prostate applications particularly in the transition zone of the prostate where the technique is faced with many acoustic obstacles in the differentiation of lesions. SWE is thus not suitable in guiding biopsies in that anatomical part of the prostate, (actually only 20% of the prostate cancers are located in the transition zone). Such lesions are better visualized by multiparametric MRI, so the tool of choice is transrectal ultrasound guided mpMRI, or TRUSmpMRI.

Thyroid. The echogenicity of thyroid nodules shown on the B-Mode thyroid examination is the main US feature used to guide Fine Needle Aspiration (FNA) biopsy. The stiffness of the solid tissue as estimated by elastography is rarely of added value in performing FNAs and elastography does not result in fewer false-negative results.

STE technology has already been applied in breast patients, albeit in a trial that was not very large. The technique showed highly significant results, with the potential of being able to differentiate malign from benign tumors.

Further extensive clinical research using STE technology is expected to provide more accurate critical values for the improvement of diagnosis.

Q We have talked about mainly about elastography as though that was the only development of US, but there are others. What role/potential do you see for Contrast-Enhanced US?

The applications of CEUS are expanding continuously since tumor vascularization is often the feature that can differentiate benign from malignant lesions in all organs. CEUS also has an important role in traumatology as a first examination to detect any hemorrhage of the abdominal organs. Likewise CEUS has an important role
to play in diagnosing and following up intestinal disorders such as Crohn's disease, as well as complications in Crohn's and in monitoring response to medical treatment.

**Q** Your institute is an active participant in clinical trials. Can you tell us about these?

Yes, we are currently carrying out comparative studies of different SWE technologies from different manufacturers for the assessment of liver fibrosis in CLD patients. We are also performing a monocentric trial on the usefulness of SWE in diagnosing prostate cancer and on the ability to carry out SWE-guided prostate biopsies in comparison with mpMRI/TRUS fusion guided biopsies.

**Q** Finally, how do you see the future development of elastography both in your center and in general?

Elastography is a game changer that is revolutionizing US technology and practice. From its original applications in liver and breast, US Elastography is expanding its applicability to virtually all organs and pathologies, so is dramatically changing US diagnostic protocols and challenging existing gold standard methods including mammography and histology. Recognizing the potential of the technique, all manufacturers of US system now offer strain and SWE probes.

For the liver, US Elastography is the first, and often the only, examination able to establish the final diagnosis and guide and monitor subsequent therapeutic decision.

"... Elastography is a game changer that is revolutionizing US technology and practice ..."

In the future it looks certain that liver elastography will evolve by overcoming current issues of applicability in difficult patients and in challenging anatomical conditions.

The evaluation of liver steatosis using a non-invasive method, is a very important need — and a large and expanding market — since obesity and Type II diabetes look set to grow rapidly in the years to come.

In this context, the Speed of Sound (SSI), proposed by Mindray in the Resona 7, is already showing promising results in liver steatosis. Other manufacturers are evaluating other parameters (US beam attenuation (CAP), dispersion, etc.) in order to grade liver steatosis and inflammatory process. Thus in the near future US will be upgraded as a non-invasive, cost-effective tool, able to provide a holistic diagnostic and prognostic evaluation of any CLD patient, grading Fibrosis, Steatosis and Portal Hypertension in a single exam lasting only a few minutes.

Ultimately this could lead to the replacement of other costly and invasive examinations such as liver biopsy exam and gastric endoscopy, that are widely used today.

**Spleen** elastography could be confirmed as a reliable parameter of portal hypertension, which is a severe complication of CLD. If such Elastography applications are accompanied with progress on B-Mode US signal pre-and post-processing, this could lead to the ability to stage not only liver fibrosis, but also liver steatosis.

**Prostate.** We foresee that elastography will also evolve as a complementary method to Transrectal US (TRUS) in the diagnosis of prostate cancer and also in guiding prostate biopsies. The current protocol of guiding prostate biopsies is mainly driven by multiparametric MRI and there are many methods of carrying out TRUS/mpMRI-fusion guided biopsies either transrectally or transperineally. SWE performs better than strain elastography in the prostate in both the peripheral and transition zones. Although there are still some unresolved issues connected with interfering acoustic obstacles in the prostate, I believe that SW Elastography-guided prostate biopsies will in the future be considered as the cost/effective method of choice for most of prostate biopsies. The relatively long learning curve associated with TRUS and Elastography will remain an issue but can be resolved through specific courses and training.

**Thyroid** Elastography will play a role in diagnosing diffused and focal thyroid lesions, as well as thyroid cancer. This role may not be as important as that of elastography in the liver and the prostate, but nevertheless elastography looks set to become an integral part of a standard thyroid US examination.

It may be possible to avoid the need for many US guided thyroid biopsies since US, Color Doppler and SWE can be conclusive the diagnosis of practically all benign thyroid lesions. Elastography may also play a role in guiding and assessing the result of thyroid cryo-, thermo- or laser- ablations.
Promising AI-based approach to lung pathology and foreign body detection in the chest

By Dr. D Blinov, Dr. E Zhukov, Dr. V Leontiev & Dr. E Blinova

INTRODUCTION.
Chest X-ray is the most common radiological diagnostic procedure worldwide, accounting for up to 45% of all radiological studies [1]. The wide availability of the method is due to its low cost and great diagnostic potential in relation to such socially significant pathologies as tuberculosis, lung cancer, pneumonia [2]. However, at the same time, chest radiography is an example of diagnostic ambiguity, because an apparently straightforward image is formed as a result of the overlay of anatomical areas with different structure, composition and density. Hence, the image may contain dozens of signs encountered in hundreds of pathological processes and conditions [2]. This makes it difficult to read and interpret chest plain radiograph correctly. Discrepancies between radiologists frequently occur and ultimately lead to often unreasonable additional patient examinations to clarify the discrepancies.

The last few years have been marked by breakthrough advances in the field of computer-aided processing of medical data, including diagnostic images. In particular, neural networks, parabolic, vector regression models have been proposed for the diagnosis of lung diseases [3]. Algorithms for the detection of tuberculosis, lung cancer and pneumonia based on decision tree, Bayesian principle have been developed [4].

Figure 1. The principle behind the development of the models.
of neural network capabilities to solve the problems of detecting individual pathological conditions in medical images has allowed the development of high-performance models [7, 8].

The aim of our work was to develop a promising approach to lung pathology and foreign body detection on straightforward chest radiographs.

MATERIAL AND METHODS.

Our proposed approach is aimed at detecting whether the patient has a pathology or not and is based on the analysis of straightforward lung X-ray images using an ensemble of 15 neural networks (Inception V3 and ResNet-50).

Some of these networks were trained to analyze different parts of the chest area, e.g., heart, diaphragm, lungs and related parts. The remaining networks were trained to describe another meta-dataset associated with X-rays, such as patient position (laying or standing), quality of image, etc. The set of outputs of each model is then aggregated with XGBBoost boosting model [Figure 1]. The result of the predictive model is the probability of the patient having a lung pathology.

We also developed two further models for the detection of foreign bodies. The first of these models was trained to detect on an X-ray image whether or not there was any foreign body located within the chest area. If the first model indicated that there was indeed a foreign body present, the second model which had been trained to identify which kind of foreign body was present, was then applied.

To train the models a total of 276840 frontal X-ray images were used. Those images were labelled independently by two experienced radiologists using software specifically developed for labeling purpose. Each individual model was trained independently of other models. Thus, preprocessing workflow was a little bit different from model to model. For example, some subsets of models required a special image size compared to other models. The size settings used were: 224 x 224; 299 x 299 and 512 x 512 pixels. Also different normalization algorithms were applied to different models.

For the models to make a final decision it is necessary to set an appropriate threshold value. In our work, the threshold was set to find the optimal balance between the receiver operating characteristics area under the curve (ROC AUC), the recall score for the pathology category and the precision score for the healthy category. After several experiments the threshold for the normal/pathology binary classification was set to 0.4 to achieve a satisfactory balance.

RESULTS

All outcomes of the quality metrics described above were greater then 0.7. They were calculated related to the default decision threshold set at 0.5 for the foreign body detection models and at 0.4 for the normal/pathology binary classification model. Thus in the model we consider the patient to have a lung pathology if the model outcome is equal or greater than 0.4.

The ROC curve is another way to demonstrate the model’s ability to distinguish different classes in binary classification tasks. ROC curves for the models developed are shown in Figure 2.

DISCUSSION

In this development a set of models were developed to analyze lung radiographs. A whole set of models were aggregated to form one binary classification model capable of detecting whether the patient had any lung disease or not. As described above, a threshold value of 0.4 was chosen to get a satisfactory balance between recall rates in the positive category and the precision in the negative category. An appropriately set balance minimizes the number of patients wrongly considered to be healthy, while at the same time maximizing the number of patients identified as probably having a lung pathology. As a result, fewer patients were categorized as being in the “normal” class, and more patients were categorized as being in the “pathologic” class. Despite the possibility that it may lead to overdiagnosis, such an approach is required to avoid false negatives where patients with some pathology are wrongly attributed to the normal category.

Another two models were used to detect whether any foreign body could be visualized on the X-ray image and then to identify it. We observed that both the foreign body detection model and the classification model gave acceptably good results. The weak part of both models is the level of precision in the negative category (those categories are “non-medical body” for one model and “foreign body not visualized” for the other).

As for quality analysis using the ROC curve, we observed that the results of the foreign bodies model were very good, as judged by a large area under ROC curve - the top-left corner of the curve is closer to the y-axis of the True Positive Rate. The Pathology/Normal model is not of such high quality as can be seen from the smooth curve which yields a smaller area under the curve.

As an example to demonstrate how the neural network operates on X-ray images with and without foreign bodies, Class Activation Maps (CAM) were applied for two random images [Figure 3]. As can be seen from the images in Figure 3 the...
neural network showed higher activation values in areas which were not normal in a normal lung state.

To classify a foreign body, we used a 2-step approach. In the first step we detect if any foreign body can be visualized on the X-ray image, and in the second step we classify the foreign body.

In the future it could be of interest to investigate other approaches. For example, we could try two separate models: one of which can detect whether any medical material or equipment is detected on the image. The other model could be trained to check whether any non-medical foreign body is detected.

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How imaging can support healthcare’s circular economy

By Kees Wesdorp

Faced with rising costs, increasing patient volumes, staff shortages, and the pressures of value-based care, healthcare organizations often feel they must ‘do more with less.’ Rather than framing our approach to care as one that feels stretched beyond its means, what if we flipped our mindset to ‘do better with what we have’?

This is the perspective of the circular economy, an evolution from today’s linear model of production and consumption of ‘make, use, and dispose’ to a circular model of ‘make, use, return.’ In this model, healthcare organizations effectively partner with vendors for a mutually beneficial exchange of solutions, including reimbursable trade-ins, structured upgrades and same-as-new refurbished products at a lower cost. The circular economy is part of a groundswell of new business models taking root in healthcare purchasing. Instead of business models marked by massive capital investments in expensive medical equipment, such as brand-new MRI or CT machines, healthcare organizations are moving towards more predictable, flexible models that avoid huge cost spikes, and help mitigate risk by shifting some responsibility to their technology partners.

In the name of sustainability, a cyclical approach to imaging innovation redefines our traditional sense of ‘ownership.’ It helps to future-proof a healthcare organization’s operations by driving high-quality care with advanced medical equipment at a lower total-cost-of-ownership – and ultimately makes what is the right business decision the right choice for the planet as well.

CIRCULAR ECONOMY IN PRACTICE

In addition to tackling the economic pressures of value-based care to maintain profitability, healthcare organizations must also address the environmental pressures that stem from our planet’s limitations. A growing demand for healthcare from an expanding population and overconsumption of resources have played a role in placing unsustainable burdens on our ecosystems. For the health of both our environment and healthcare’s financial bottom line, the transition to a circular economy is essential. We need different ways of looking at the global business model of healthcare to find sustainable solutions that meet clinical, operational and financial concerns, while providing patient value and business efficiency in tandem.

This means we need to rethink what ‘new’ means. In other industries such as automotive or retail, there could be natural skepticism when buying refurbished products, with preconceived notions about its performance or worth. However, there is value in repurposing. The vendors who meticulously restore their solutions and make them nearly indistinguishable from new – at a more accessible cost for buyers – will prove to be worthwhile partners in the age of the circular economy. To fulfill the promises of the circular economy, healthcare organizations need to identify a seasoned vendor partner that professionally and stringently refurbishes solutions to maintain the highest utility throughout its lifespan.

For example, at Philips, we actively ‘close the loop’ with customers who have made that capital expenditure years ago; they no longer have to hold onto an older machine that they may be ready to replace. We pursue trade-ins of equipment such as MRI, CT, ultrasound, and interventional and diagnostic X-ray systems, taking full control to ensure that all materials are repurposed or recycled in a responsible way. Through our

The Author
Kees Wesdorp,
General Manager, Diagnostic Imaging.
Kees Wesdorp joined Philips in 2017 to lead Philips’ largest business group, Diagnostic Imaging (DI).
DI includes:
Magnetic Resonance Imaging (MRI); Computed Tomography (CT);
Advanced Molecular Imaging (AMI); Diagnostic X-ray;
Circular Equipment.
**Diamond Select** refurbished systems program, traded-in imaging systems undergo a stringent refurbishment process, and are brought back to full performance, or its parts are otherwise reused or fully recycled. Using Philips’ Technology Maximizer service, healthcare organizations can also receive regular upgrades to ensure they have the latest software and hardware updates, while maintaining cost efficiency through a predictable fee.

At Philips, ‘used’ does not equate to ‘worse.’ Through this integrated ecosystem, customers gain access to the same advanced technology that offers high-quality clinical and operational performance at a lower cost.

**RISK MANAGEMENT IN THE NAME OF SUSTAINABILITY**

The balancing act of cost and value is playing an increasing role in purchasing decisions of imaging technology. With the shift to value-based care, radiology departments often operate more like a business within a hospital, with efficiency-driven performance metrics that they are measured against. From a business standpoint, healthcare organizations must remain competitive and profitable to survive with increasing consolidation in the market. This creates greater focus on increasing patient volumes and referrals to bring in revenue while, at the same time, lowering operating costs.

Consequently, imaging technology purchases are becoming more strategic decisions with increased attention on how these solutions can improve clinical decision-making and patient outcomes, and less on their functionality or technical claims. Beyond finding the right technology for your specific needs, it is now arguably equally as important to identify a forward-thinking partner who is invested in your operational strategy long-term.

For example, Philips recently replaced an old Philips digital radiography system at Reinier de Graaf Ziekenhuis in the Netherlands with the latest ceiling-mounted system, the **DigitalDiagnost C90**, while refurbishing some of the system. The hospital was under pressure to keep operational costs as low as possible while keeping diagnostic confidence high, so this was an ideal solution. Reza Karimzadeh, head of the hospital’s radiology department said, “Our hospital supports and encourages the transition to a circular economy, so we are pleased that Philips shares this objective of sustainability.”

When considering a significant investment, such as a CT scanner, customers increasingly vet the value of a purchase versus the cost, not only in terms of acquisition costs but also integration, personnel, maintenance and replacement costs. With **Philips Incisive CT**, for example, hospitals can keep control of operational replacement costs such as tube life that can then be reinvested into patient care. Incisive CT also offers upgradeable systems technology so that hospitals can purchase what they need now with an easy path to add up-to-date features as their clinical needs evolve. In this way, vendors can provide reliable, scalable solutions, while proving their ability to reduce total cost of ownership end-to-end for healthcare systems.

Similarly, other imaging innovations, such as Philips’ **Compressed SENSE**, enable health systems to get the most value out of existing imaging equipment in terms of productivity and streamlining workflows. With Compressed SENSE, a breakthrough acceleration technique, imaging departments can shorten MRI sequences and full MRI exams by up to 50 percent without compromising imaging quality [1]. This gives imaging departments the flexibility to use this time to advance patient care in a multitude of ways such as managing a higher patient volume, spending more time with patients prior to their exam, reducing staff overtime or even scanning at significantly higher spatial resolution. The time gained with Compressed SENSE allows health systems to increase productivity and diagnostic confidence while enhancing patient comfort without buying a new MRI scanner.

**INNOVATION ALIGNED WITH THE QUADRUPLE AIM**

The circular economy allows healthcare organizations to profit from and contribute to a cyclical, sustainable business model that helps them achieve the Quadruple Aim of better health outcomes, improved patient and staff experience, and lower cost of care. With the cost savings that comes with a circular approach to healthcare
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AI and Machine Learning in Cancer Imaging

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Seong Ki Mun, Arlington, USA (Organising committee)
For example, Philips recently supported the Advanced Cardiac and Vascular Amputation Prevention Centers (ACV), an independent endovascular center in Grand Rapids, Michigan, USA, which aims to support underserved patients with critical limb ischemia (CLI). The independent center was concerned it would not have access to the same advanced technology found in a hospital environment. Working with Philips as a partner, ACV was able to receive a refurbished, high-performance interventional x-ray system via Philips’ Diamond Select program that was tailored to fit the budgetary and clinical needs of AVC’s office-based labs.

ACV’s CEO and Co-founder, Dr. Jihad A. Mustapha, FACC, said, "What really matters is that critical components inside the system have been completely refurbished. We’re pretty much getting a like-new device for less cost, but yet the highest quality imaging, which in the end is what we want. The Diamond Select system has lived up to its promise—100%.”

Staff also reap the benefits of same-as-new advanced technology that allows for custom configurations and workflow optimization. For example, at ACV, clinicians have access to the superior imaging needed for the complex nature of its CLI patients with technology that is indistinguishable from a brand-new system. This partnership with Philips helped provide access to high-quality care for their patient population’s needs in an environment that is equivalent or superior to a hospital while reducing any risk associated with their investment.

“...What really matters is that critical components inside the system have been completely refurbished. We’re pretty much getting a like-new device for less cost, but yet the highest quality imaging, which in the end is what we want. The Diamond Select system has lived up to its promise—100%...”

Dr JA Mustapha, CEO of AVC

RETHINKING OWNERSHIP TO UNCOVER OPPORTUNITIES

The circular economy enables hospitals to stay clinically advanced while maximizing their imaging investment with a right-sized solution. On average, Philips’ Diamond Select customers achieve 25% cost savings on technology with the same clinical capabilities and upgradable software to add the latest features as their clinical needs evolve, future-proofing their investment. By adopting innovative business models and maximizing the lifetime value of our products and solutions, we open up new opportunities for providers, including growth and cost savings, reducing resource risk, and facilitating smart asset management. By participating in such integrated, closed-loop ecosystems, healthcare organizations can safeguard their investments, while contributing to a sustainable economy. When we rethink ownership, we expand our ability to ‘do better with what we have.’

FOOTNOTE
1. Compared to Philips scans without Compressed SENSE.
Radiologists Describe Coronavirus Imaging Features

In a special report [1] published in the journal Radiology, researchers describe CT imaging features that aid in the early detection and diagnosis of Wuhan coronavirus.

“Early disease recognition is important not only for prompt implementation of treatment, but also for patient isolation and effective public health surveillance, containment and response,” said the study’s lead author, Michael Chung, M.D., assistant professor in the Department of Diagnostic, Interventional and Molecular Radiology in the Mount Sinai Health System in New York, N.Y.

BACKGROUND

On December 31, 2019, the World Health Organization (WHO) learned of several cases of a respiratory illness clinically resembling viral pneumonia and manifesting as fever, cough, and shortness of breath. The newly discovered virus emerging from Wuhan City, Hubei Province of China, has been temporarily named “novel coronavirus” (2019-nCoV). This new coronavirus belongs to a family of viruses that include Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).

The outbreak is escalating quickly, with thousands of confirmed 2019-nCoV cases reported globally. On January 30, the U.S. reported the first confirmed instance of person-to-person spread of the virus.

In this retrospective case series, Dr. Chung and colleagues set out to characterize the key chest CT imaging findings in a group of patients infected with 2019-nCoV in China with the goal of familiarizing radiologists and clinical teams with the imaging manifestations of this new outbreak.

From January 18, 2020, until January 27, 2020, 21 patients admitted to three hospitals in three provinces in China with confirmed 2019-nCoV infection underwent chest CT. The 21 patients consisted of 13 men and 8 women ranging in age from 29 to 77 years old, with a mean age of 51.2 years. All patients were confirmed positive for infection via laboratory testing of respiratory secretions.

EVALUATION OF CT IMAGES

For each of the 21 patients, initial CT scans were evaluated for the following characteristics:

1. Presence of ground-glass opacities
2. Presence of consolidation
3. Number of lobes affected by ground-glass or consolidative opacities
4. Degree of lobe involvement in addition to overall lung “total severity score”
5. Presence of nodules
6. Presence of a pleural effusion
7. Presence of thoracic lymphadenopathy (lymph nodes of abnormal size or morphology)
8. Presence of underlying lung disease such as emphysema or fibrosis. Any other thoracic abnormalities were also noted.

Figure 1. 29-year old male with unknown exposure history, presenting with fever and cough, ultimately requiring intensive care unit admission. (a) Axial thin-section non-contrast CT scan shows diffuse bilateral confluent and patchy ground-glass (solid arrows) and consolidative (dashed arrows) pulmonary opacities. (b) The disease in the right middle and lower lobes has a striking peripheral distribution (arrow).

Figure 2. 36-year old male with history of recent travel to Wuhan, presenting with fever, fatigue and myalgias. Coronal thin-section non-contrast CT image shows ground-glass opacities with a rounded morphology in both upper lobes (arrows).
The analysis showed that 2019-nCoV typically manifests on CT with bilateral ground-glass and consolidative pulmonary opacities. Nodular opacities, crazy-paving pattern, and a peripheral distribution of disease may be additional features helpful in early diagnosis. The researchers also noted that lung cavitation, discrete pulmonary nodules, pleural effusions and lymphadenopathy are characteristically absent in cases of 2019-nCoV.

Follow-up imaging in seven of eight patients showed mild or moderate progression of disease as manifested by increasing extent and density of airspace opacities. Dr. Chung cautioned that absence of abnormal CT findings upon initial examination does not rule out the presence of 2019-nCoV.

“He added that a second patient had a normal follow-up chest CT four days after her initial normal imaging exam.

“This suggests that chest CT lacks complete sensitivity and does not have a perfect negative predictive value,” Dr. Chung said. “We can’t rely on CT alone to fully exclude presence of the virus.”

This finding may be related to the fact that infection with 2019-nCoV is characterized by an incubation period of several days, and there may be a phase where viral infection manifests with symptoms prior to visible abnormalities on CT.

The researchers note that further study is required to understand how patients fare after treatment but suggest that experience and imaging findings from MERS and SARS epidemics might be helpful in managing the current outbreak.

Dr. Chung’s colleagues at Mount Sinai include cardiothoracic radiologist Adam Bernheim, M.D., and Ph.D. candidate Xueyan Mei. Colleagues in China, including Hong Shan, M.D., from Guangdong Provincial Key Laboratory of Biomedical Imaging, The Fifth Affiliated Hospital of Sun Yat-sen University in Zhuhai (Guangdong Province) were also instrumental in this work.

SUMMARY

In summary, this work represents an early investigation of chest CT findings in the 2019 Novel Coronavirus (2019-nCoV) and has the intention of creating familiarity with common imaging manifestations of the disease. The radiologist plays a crucial role in the rapid identification and early diagnosis of new cases, which can be of great benefit not only to the patient but to the larger public health surveillance and response systems. As new cases are identified, other unique pulmonary CT imaging manifestations may emerge as potential points for discernment in this patient population.

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CT Provides Best Diagnosis for COVID-19

- In a recent study [1] of 1,014 patients, chest CT was more effective than RT-PCR lab testing in detection of COVID-19.

- The results showed that 601 patients (59%) had positive RT-PCR results, while 888 (88%) had positive chest CT scans.

- The low sensitivity of RT-PCR implies that many COVID-19 patients may not receive appropriate treatment and risk infecting a larger population.

In a recent study [1] of more than 1,000 patients published in the journal Radiology, chest CT outperformed lab testing in the diagnosis of 2019 novel coronavirus disease (COVID-19).

Starting December 2019, a number of cases of “unknown viral pneumonia” related to a local Seafood Wholesale Market were reported in Wuhan City, Hubei Province, China [2]. A novel coronavirus (SARS-CoV-2) was suspected to be the etiology with the Phinolophus bat as the alleged origin. In just two months, the virus has spread from Wuhan to the whole China, and another 33 countries.

The researchers of the recent study [1] conclude that CT should be used as the primary screening tool for COVID-19.

In the absence of specific therapeutic drugs or vaccines for COVID-19, it is essential to detect the disease at an early stage and immediately isolate an infected patient from the healthy population.

According to the latest guidelines published by the Chinese government, the diagnosis of COVID-19 must be confirmed by reverse-transcription polymerase chain reaction (RT-PCR) or gene sequencing for respiratory or blood specimens, as the key indicator for hospitalization. However, with limitations of sample collection and transportation, as well as kit performance, the total positive rate of RT-PCR for throat swab samples has been reported to be about 30% to 60% at initial presentation.

In the current public health emergency, the low sensitivity of RT-PCR implies that a large number of COVID-19 patients won’t be identified quickly and may not receive appropriate treatment. In addition, given the highly contagious nature of the virus, they carry a risk of infecting a larger population.

"Early diagnosis of COVID-19 is crucial for disease treatment and control. Compared to RT-PCR, chest CT imaging may be a more reliable, practical and rapid method to diagnose and assess COVID-19, especially in the epidemic area," the authors wrote.

Chest CT, a routine imaging tool for pneumonia diagnosis, is fast and relatively easy to perform. Recent research found that the sensitivity of CT for COVID-19 infection was 98% compared to RT-PCR sensitivity of 71%.

For the current study, researchers at Tongji Hospital in Wuhan, China, set out to investigate the diagnostic value and consistency of chest CT imaging in comparison to RT-PCR assay in COVID-19.

Included in the study were 1,014 patients who underwent both chest CT and RT-PCR tests between January 6 and February 6, 2020. With...
RT-PCR as reference standard, the performance of chest CT in diagnosing COVID-19 was assessed. For patients with multiple RT-PCR assays, the dynamic conversion of RT-PCR test results (negative to positive, and positive to negative, respectively) was also analyzed as compared with serial chest CT scans.

The results showed that 601 patients (59%) had positive RT-PCR results, and 888 (88%) had positive chest CT scans. The sensitivity of chest CT in suggesting COVID-19 was 97%, based on positive RT-PCR results. In patients with negative RT-PCR results, 75% (308 of 413 patients) had positive chest CT findings. Of these, 48% were considered as highly likely cases, with 33% as probable cases. By analysis of serial RT-PCR assays and CT scans, the interval between the initial negative to positive RT-PCR results was 4 to 8 days.

“About 81% of the patients with negative RT-PCR results but positive chest CT scans were re-classified as highly likely or probable cases with COVID-19, by the comprehensive analysis of clinical symptoms, typical CT manifestations and dynamic CT follow-ups,” the authors wrote.

LIMITATIONS

There are several limitations in the present study. For example, by using RT-PCR assays with relatively low positive rate as reference, the sensitivity of chest CT for COVID-19 may be overestimated while the specificity underestimated. In epidemic area, negative RT-PCR but positive CT features can still be highly suggestive of COVID-19. This has important clinical and societal implications.

CONCLUSION

Despite the limitations of the current study, it can be concluded that chest CT imaging has high sensitivity for diagnosis of COVID-19. Our data and analysis suggest that chest CT should be considered for COVID-19 screening, comprehensive evaluation, and follow-up, especially in epidemic areas with high pre-test probability for disease.

REFERENCE


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In December 2019, a lower respiratory tract febrile illness of unknown origin was reported in a cluster of patients in Wuhan City, Hubei Province, China. A novel strain of coronavirus isolated from the bronchoalveolar lavage of the patients was determined to be responsible for the outbreak. The pulmonary syndrome was later named coronavirus disease 2019 (COVID-19) by the World Health Organization.

COVID-19’s imaging features are variable and nonspecific, but the imaging findings reported thus far do show “significant overlap” with those of severe acute respiratory syndrome and Middle East respiratory syndrome. Although the imaging features of novel coronavirus disease 2019 (COVID-19) are variable and nonspecific, the findings reported thus far do show “significant overlap” with those of severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), according to an ahead-of-print article [1] in the American Journal of Roentgenology (AJR).

COVID-19 is diagnosed on the presence of pneumonia symptoms (e.g., dry cough, fatigue, myalgia, fever, dyspnea), as well as recent travel to China or known exposure, and chest imaging plays a vital role in both assessment of disease extent and follow-up.

As per her review of the present clinical literature concerning COVID-19, Melina Hosseiny of the University of California at Los Angeles concluded: “Early evidence suggests that initial chest imaging will show abnormality in at least 85% of patients, with 75% of patients having bilateral lung involvement initially that most often manifests as subpleural and peripheral areas of ground-glass opacity and consolidation.”

Furthermore, “older age and progressive consolidation” may imply an overall poorer prognosis.

Unlike SARS and MERS--where initial chest imaging abnormalities are more frequently unilateral--COVID-19 is more likely to involve both lungs on initial imaging.

“To our knowledge,” Hosseiny et al. continued, “pleural effusion, cavitary, pulmonary nodules, and lymphadenopathy have not been reported in patients with COVID-19.”

Ultimately, the authors of this AJR article recommended CT for follow-up in patients recovering from COVID-19 to evaluate long-term or even permanent pulmonary damage, including fibrosis--as seen in SARS and MERS infections.

Besides the acute phase, CT is recommended for follow-up in individuals who are recovering from COVID-19 to evaluate long-term or permanent lung damage including fibrosis, as is seen with SARS and MERS infections.

REFERENCE
**Fujifilm acquires Hitachi’s diagnostic imaging-related business**

Last December, FUJIFILM announced that it was acquiring Hitachi’s diagnostic imaging-related business. The purchase price is expected to be approximately $1.66 billion.

By applying its proprietary image processing and AI technologies to Hitachi’s extensive product lineup, Fujifilm hopes to further expand its medical systems business and to create new values around the world.

Fujifilm will be able to enhance its relationships with medical institutions and medical specialists, and access to high-quality diagnostic images and operation data. By leveraging such data, Fujifilm will be able to expand into new areas, including “AI-supported Diagnosis” and “AI-supported Maintenance”.

1. Providing one-stop total solutions through comprehensive product line-up. By acquiring Hitachi’s Diagnostic Imaging Systems business, Fujifilm will be able to provide a one-stop total solution that includes CT, MRI, X-ray, and ultrasound systems. The business not only serves as a stable revenue base, but also shows potential for further growth.

Since its launch of an X-ray system in 1953, Hitachi has been providing solutions using diagnostics imaging system, IT and electronic health records to enhance the quality of care and efficiency. Its diagnostic imaging systems business has a strong global presence, providing a comprehensive suite of products including CT, MRI, X-ray, and ultrasound systems. The business not only serves as a stable revenue base, but also shows potential for further growth. Especially with its ultrasound systems, Hitachi is one of the global leaders offering a wide range of products with high image quality and excellent operability.

Fujifilm has been actively investing its management resources in the business to become a comprehensive healthcare company. Its medical systems business is leading the company’s overall healthcare business, offering a wide variety of medical diagnostic products and services with medical IT at its core, ranging from X-ray, endoscopy, ultrasound to in-vitro diagnostics systems.

Fujifilm identified several synergies coming out of the acquisition:

1. Providing one-stop total solutions through comprehensive product line-up. By acquiring Hitachi’s Diagnostic Imaging Systems business, Fujifilm will be able to provide a one-stop total solution that includes CT, MRI diagnostics imaging, medical IT, in-vitro diagnostics and endoscopy. This will dramatically enhance its capability to offer a comprehensive solution to medical institutions.

2. Providing innovative solutions by leveraging Fujifilm’s proprietary image processing and AI technologies. By leveraging Fujifilm’s unique image processing technologies utilized in picture archiving communication systems (PACS) and AI technologies, Fujifilm will be able to provide new value-added solutions. For example, the use of AI technology on CT images can reduce noise and offer better image quality in low-dose examinations.

In addition, through its extensive portfolio, Fujifilm will be able to expand its relationships with medical institutions and medical specialists, and access to high-quality diagnostic images and operation data. By leveraging such data, Fujifilm will be able to expand into new areas, including “AI-supported Diagnosis” and “AI-supported Maintenance”.

3. Expanding sales capability through cross-selling. Fujifilm will further expand the business in the global market through cross-selling, utilizing the extensive sales channels of both companies. Fujifilm will continue to develop and provide a wide range of products and services that can meet the needs in clinical settings, contributing to even more efficient medical diagnosis and high-quality medical care, leading to the maintenance and improvement of people’s health.

According to U.K. market researcher Evaluate, the top three medical imaging companies Siemens, Philips and GE Healthcare hold a combined 65% share of the global market. In 2016, Fujifilm offered to buy Toshiba Medical Systems, but was beaten out by Japanese rival Canon, which won the exclusive right to negotiate a buyout and successfully completed the acquisition.

As of last year, Fujifilm held a 5.5% share of the worldwide diagnostic imaging market. The purchase of Hitachi’s diagnostic imaging operations, which are believed to account for another 2.9% of the market, will bring Fujifilm close to Canon’s 9.5% share.

[https://www.fujifilm.com](https://www.fujifilm.com)

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**Canon acquires Swiss MRI R&D company**

Canon Medical Systems has concluded a contract to acquire all shares of Skope Magnetic Resonance Technologies AG, headquartered in Zurich, Switzerland. With a unique research and development team, Skope is a company devoted to providing MRI users with unprecedented imaging quality and performance. Skope’s expertise in MRI sensorics, signal-processing and image reconstruction covers the entire chain from signal acquisition to image generation. As a result, reproducible image quality, great image detail and time-saving MRI scanning can be achieved. Skope is equipping leading MRI research sites with its high-precision magnetic field monitoring systems and sophisticated image reconstruction software to facilitate next-generation MR imaging and diagnostics.

Canon Medical Systems succeeded in developing and introducing the first Japanese MRI in 1983, and has been devoting itself to research and development of innovative MRI technologies such as Pianissimo, Canon Medical’s unique acoustic noise reduction technology, which provides extraordinary patient comfort.

Canon Medical Systems said that it will leverage Skope’s talent to promote advanced research and development of MRI systems, committing to innovative MRI solutions for uncompromised patient care.

Canon offers a full range of diagnostic medical imaging solutions including CT, X-Ray, Ultrasound and MR, as well as a full suite of Healthcare IT solutions, across the globe. The company’s goal is to deliver optimum health opportunities for patients through uncompromised performance, comfort and safety features.

[https://global.medical.canon/](https://global.medical.canon/)
AI healthtech firm Lunit secures additional funds to drive global sales

The Korean medical AI startup Lunit, which is already backed by SoftBank has raised US$26 million in a series C round led by a Korean brokerage and investment firm. Other investors such as InterVest, alternative asset investment company IMM Investment, Kakao Ventures, and Lenovo Group’s Legend Capital also participated in the round, which pushed the startup's total capital raised to US$50 million.

The company previously secured US$4.3 million in investment from Fujifilm and US$15 million in series B funding last year. Lunit, abbreviated from “learning unit,” develops advanced software for medical data analysis and interpretation through deep-learning technology. Its solutions, which mainly target cancer, provide precise diagnostics and therapeutics to help patients find the right treatment.

The company plans to use the new funds to accelerate the global sales of its AI software for chest and breast radiology and help drive its research and development efforts in oncology and pathology.

“Our dedication to combat cancer through AI has shaped some tangible, meaningful outcomes,” said Lunit CEO Brandon Suh. “We have been actively adopting customer needs and feedback into our products, upgrading the software to improve clinical workflow.”

Founded in 2013, Lunit said its products are now being used in Mexico, the United Arab Emirates, China, Thailand, Taiwan, and Korea. It also claims that its public demo has analyzed more than 2.5 million radiology images, reaching 80 countries.

https://lunit.io

GE-sponsored study shows AI may be making healthcare more human

Artificial Intelligence (AI) is widely expected to drive important benefits across the health system, from increasing efficiency to improving patient outcomes, but it also may be key to making healthcare more human. Benefits range from increasing the amount of time clinicians can spend with patients and on cross-care team collaboration to enhancing the ability to deliver preventative care.

According to a new study of more than 900 healthcare professionals in the U.S. and the U.K. conducted by MIT Technology Review Insights with GE Healthcare, nearly half of medical professionals surveyed said AI is already increasing their ability to spend time with and provide care to patients. Additionally, more than 78 percent of healthcare business leaders who reported they have deployed AI in their operations also reported that AI has helped drive workflow improvements, streamlining operational and administrative activities and delivering significant efficiencies toward transforming the future of healthcare.

“One of any industry, AI could have the most profound benefits on human lives if we can effectively harness it across the healthcare system,” said Kieran Murphy, President and CEO, GE Healthcare. Based on the study, which examines how AI is currently impacting healthcare professionals and the patients they serve today, roadblocks to adoption and opportunities for the future, GE Healthcare and MIT Technology Review Insights found that AI implementation is pervasive with 7 out of 10 healthcare providers already adopting or considering adopting AI. Among those surveyed, 81 percent believe AI will improve their performance by making them more competitive, and 80 percent believe it is already helping or will help them improve revenues. Even more notably, institutions that have already implemented AI technologies reported that it is playing a key part in rebalancing physician workload from administrative to patient-focused tasks, resulting in more time with patients and collaborating with colleagues across healthcare disciplines.

AI has also helped alleviate a significant challenge for healthcare providers and institutions facing a rise in health worker burnout over the past decade. In fact, 80 percent of those surveyed indicated that AI has been instrumental in helping to remove barriers and reduce worker burnout. This paves the way for future improvements as AI-enabled technology scales across organizations to help improve data analysis, enable better diagnoses and treatment predictions, and further free medical staff from administrative burdens. Additionally, the vast majority of survey respondents believe AI represents the extension – not extinction – of professional capabilities in healthcare.

Other key survey findings include:

• Medical professionals using AI applications are seeing immediate gains in reducing clinical error
• 75% of medical staff who have AI stated it has enabled better predictions in the treatment of disease
• 78% have reported that their AI deployments have already created workflow improvements
• 60% of AI-empowered medical staff expect to spend more time performing procedures versus administrative or other work
• 68% spend more time collaborating with other staff and across clinical care areas, leading to potential benefits in patient care and precision health

These trends are only expected to grow with survey results indicating that nearly 80 percent of healthcare institutions plan to increase their spending on AI in the next two years, including diverse technologies ranging from medical imaging and diagnostics to patient data and risk analytics. Further, nearly three in four healthcare institutions that use or plan to use AI will develop their own AI algorithms in the next two years.

Detailed survey findings and methodology can be found at: https://www.technologyreview.com/hub/ai-effect/
Advanced Philips CT systems support precision diagnosis in the capital region of Denmark

Philips and the capital region of Denmark have signed a significant agreement for Philips’ advanced IQon CT systems, supporting the delivery of a precision diagnosis for each patient and enabling the transition to a value-based care model.

Philips provides flexible and scalable enterprise imaging solutions that support hospitals and imaging centers who seek to step up their performance by simultaneously improving the patient experience, health outcomes, and staff experience, while lowering the cost of care.

“The new scanners will be a clear improvement for patients in the Capital Region, supporting us in taking advantage of the diagnostic benefits associated with this new technology,” said Jens Brøndberg, regional capital procurement manager, Capital Region of Denmark. “The systems will contribute to a faster and better diagnosis for patients, which ultimately contributes to a better patient experience.”

As a result of the agreement, 10 IQon CT systems will be installed at hospitals in Bispebjerg, Bornholm, Frederiksberg, Gentofte, Herlev, Hvidovre and Rigshospitalet. The IQon Spectral CT is the world’s first and only detector-based spectral CT, delivering multiple layers of retrospective data in a single, low-dose scan. This advanced technology combines with simplified workflows and strong clinical capabilities, empowering healthcare providers to provide a precision diagnosis, leading to targeted therapies with predictable outcomes.

Philips
Eindhoven, The Netherlands
www.philips.com

Use Cases published by COCIR on Artificial Intelligence in Healthcare

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

The use of Artificial Intelligence (AI) in clinical settings is already a reality, one that has brought benefits to patients, healthcare stakeholders and wider society. These developments have now been highlighted in a library of use cases on ‘Artificial Intelligence in Healthcare’, published by COCIR.

COCIR’s Secretary General, Nicole Denjoy says, “It is clear from this initial collection of use cases that AI in healthcare is already generating diagnosis and treatment opportunities that were not previously possible. The examples cover an incredibly diverse range of topics; diagnosing psychiatric multimorbidities, diagnosing lung and skin lesions; detecting calcium in coronary arteries; documenting the anatomy of the foetal brain - even preventing deaths from snakebites”.

This first set of use cases highlight the range of benefits that AI can bring to healthcare; however, this is only a fraction of the available potential. This is why COCIR is urging the creation of the optimum conditions for stimulating further growth and expansion of AI into further clinical fields, which will substantially improve both access to healthcare and health outcomes on a large scale.

The current COCIR library of use cases can be accessed COCIR’s website (www.cocir.org/media/centre/publications/article/cocir-use-cases-artificial-intelligence-in-healthcare.html) This collection will be enriched periodically with new use cases to reflect further developments of AI in healthcare and provide interested parties with a centralised library.

COCIR
Brussels, Belgium
www.cocir.org
Scientists study what women know — and don’t know — about breast density and cancer risk

Breast density is a risk factor for cancer, but until now, no study has asked women what they actually know about breast density in relation to screening that they have had. A new three-state-wide study out of Dartmouth’s Norris Cotton Cancer Center reveals varying knowledge on the topic.

In the United States, a number of states have notification laws which compel a radiologist to inform a woman if she has dense breasts and the significance of her dense breasts. However in practice, these state laws vary. In a new qualitative study, a team of scientists at Dartmouth and Dartmouth-Hitchcock’s Norris Cotton Cancer Center and the Breast Cancer Surveillance Consortium led by Dr. Karen Schifferdecker and Dr. Anna Tosteson, sought to explore women’s knowledge and perceptions of breast density and experiences of breast cancer screening across three states with and without notification laws.

The recently published focus group study (Schifferdecker KE et al. Knowledge and Perception of Breast Density, Screening Mammography, and Supplemental Screening: in Search of “Informed” Journal of General Internal Medicine (2019)) found that women from all states had varying knowledge about their own breast density and breast density in general. A number of women were aware of the difficulty of detecting cancer with dense breasts, but only one woman knew that density actually increased breast cancer risk. “We found that very few women received information about breast density during healthcare visits although some were encouraged to get supplemental imaging or to pay for new types of mammography such as breast tomosynthesis,” says Schifferdecker. “Women who were offered more imaging or different technology usually thought these were ‘better,’ even though they were given little information about the effectiveness or harms.”

The study also found, importantly, that women from all states expressed a strong desire for more information about breast density. “The findings in this paper are exciting because no research on dense breasts has explored women’s knowledge and experiences in their own words and compared this across different states,” says Schifferdecker. “We partnered with the national Breast Cancer Surveillance Consortium to identify and recruit women who had a recent screening and also had dense breasts. In this way, we knew all women had dense breasts and could explore what they knew or did not know, including their own personal breast density.”

The conclusions also identify opportunities for improvements in educating women so they may make informed decisions related to mammography and supplemental screening. “Women want—and deserve—more usable information about breast cancer risk” says Schifferdecker. “More research needs to be done to understand how the medical community can better assist women in making informed decisions related to breast density and screening.”

Study examines causes of death in US breast cancer survivors


Of 754,270 U.S. women diagnosed with breast cancer from 2000 to 2015, 24.3 percent died by the end of 2015. The highest number of deaths (46.2 percent) occurred within one to five years following diagnosis, and most were caused by breast cancer or other cancers. Breast cancer-related deaths decreased as years passed, however, and were eventually overcome by non-breast cancer causes of death. Within five to 10 years following diagnosis, about half of patients died of non-breast cancer causes, whereas the majority of those who survived beyond 10 years died of non-breast cancer causes.

The most common non-cancer causes of death within 10 years of diagnosis were heart diseases, followed by cerebrovascular diseases. After more than 10 years following diagnosis, the most common non-cancer causes of death were heart diseases, followed by Alzheimer’s disease.

Compared with the general population, patients had a higher risk of dying from chronic liver diseases within 5-10 years following diagnosis, and from Alzheimer’s disease and heart diseases after more than 10 years following diagnosis.

“Non-cancer diseases, such as heart diseases, contribute to a significant number of deaths in patients with breast cancer, even higher than in the general population,” said senior author Dr. Mohamad Bassam Sonbol of Mayo Clinic in Phoenix, Arizona. “Cancers other than breast cancer are also an important cause of death in patients with a history of breast cancer.”

The results will be informative for survivors in discussions with physicians about their future health. “Our findings emphasize the importance of counseling patients about their survivorship and risk of developing other cancers, with a focus on proper screening or preventive measures for other cancers and diseases,” added Dr. Sonbol.

doi: 10.1002/cncr.32648
Predicting 10-year breast cancer recurrence with MRI - based radiomics

Diverse diseases like breast cancer can present challenges for clinicians, specifically on a cellular level.

According to a new study [1], MRI and the emerging field of radiomics — which uses algorithms to extract a large amount of features from medical images — could help to characterize the heterogeneity of cancer cells within a tumor and allow for a better understanding of the causes and progression of a person's individual disease.

“If we’re only taking out a little piece of a tissue from one part of a tumor, that does not give the full picture of a person’s disease and of his or her response to specific therapies,” said principal investigator Dr. D Kontos, an associate professor of Radiology in the Perelman School of Medicine at the University of Pennsylvania. “The method we currently have for choosing the appropriate treatment for patients with breast cancer is not perfect, so the more steps we can take toward more personalized treatment approaches, the better.”

Kontos and her colleagues wanted to determine whether they could use imaging and radiomics for more personalized tumor characterization. Using MRI, the researchers extracted 60 radiomic features, or biomarkers, from 95 women with primary invasive breast cancer. After following up with the patients 10 years later, the group found that a scan that showed high tumor heterogeneity at the time of diagnosis could successfully predict a cancer recurrence.

“Our study shows that imaging has the potential to capture the whole tumor’s behavior without doing a procedure that is invasive or limited by sampling error,” said the study’s lead author Rhea Chitalia, a PhD candidate in the School of Engineering and Applied Science at the University of Pennsylvania. “Women who had more heterogeneous tumors tended to have a greater risk of tumor recurrence.”

The researchers retrospectively analyzed patient scans from a 2002-2006 clinical trial conducted at Penn Medicine. For each woman, the group generated a “signal enhancement ratio” (SER) map and from it, extracted various imaging features in order to understand the relationship between those features and conventional biomarkers (such as gene mutations or hormone receptor status) and patient outcomes.

While imaging may not completely replace the need for tumor biopsies, radiologic methods could augment what is currently the “gold standard” of care, Kontos said, by giving a more detailed profile of a patient’s disease and guiding personalized treatment. Next steps for the research team will include expanding the analysis to a larger patient cohort and also further exploring which specific markers are more predictive of particular outcomes.

“We’ve just touched the tip of the iceberg,” Kontos said. “Our results and the validation study give us confidence that there are many opportunities for these markers to be used in a prognostic and potentially a predictive setting.”

REFERENCE

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Findings of the DENSE study acclaimed: supplemental MRI screening for women with ultra dense breasts

The first results of the Dutch DENSE study were published November last year [1]. The objective of the study was to provide data on the use of supplemental MR imaging to improve early detection and reduce interval breast cancers in patients with extremely dense breast. Women with extremely dense breast tissue have an increased risk of breast cancer, and their cancers are also less likely to be detected on mammography. Such patients may benefit from a tailored breast-screening strategy, supplemented with more sensitive imaging methods. However the precise benefit of supplemental imaging is the subject of a worldwide debate.

Spanning an eight-year period, the DENSE trial is the first randomized controlled study on the clinical utility of breast MRI supplemental screening for women with extremely dense breasts. The study involved Dutch researchers, led by epidemiologist Professor Carla van Gils of the University Medical Center Utrecht. The findings of the trial showed that the use of supplemental MRI screening in women with extremely dense breast tissue and normal results on mammography resulted in the diagnosis of significantly fewer interval cancers than mammography alone during a 2-year screening period.

The MRI cancer-detection rate among the women who actually underwent MRI screening was 16.5 per 1000 screenings (95% CI, 13.3 to 20.5).

The data from incident screening rounds and longer follow-up are needed in combination with simulation studies to assess the effect on the rate of advanced cancers and, eventually, on mortality.

In the study, breast density was determined by the Volpara Breast Density software package.

Commenting on the results, Dr. R. Highnam, CEO of Volpara Health Technologies said “Volpara is thrilled to see these results. The evidence from this study is quite clear: using VolparaDensity to automate the assessment of breast density as a triage to breast MRI screening resulted in a remarkable reduction in interval cancers.”

Results show that women with extremely dense breast tissue above a Volpara volumetric breast density (VBD%) of 15.5%, which correlates to the densest BI-RADS category, could benefit from MRI supplemental screening.

REFERENCES
DOI: 10.1056/NEJMoai1903986
The potential of Diffusion-Weighted MRI as an unenhanced breast cancer screening tool

by Dr. N Amornsiripanitch and Dr. SC Partridge

This article provides an overview of the potential role of diffusion-weighted magnetic resonance imaging (DW-MRI) as a breast cancer screening tool independent of dynamic contrast-enhancement. The article aims to summarize evidence to date of DW-MRI in cancer detection and present optimal approaches and future considerations.

Due to well-documented limitations of mammography in the settings of women with dense breasts and high-risk women [1], there has been great interest in identifying imaging techniques to supplement mammography in breast cancer screening. Dynamic contrast-enhanced (DCE) MRI is endorsed by multinational organizations as a supplemental screening tool for women at high risk for breast cancer [2, 3] due to high sensitivity and cancer detection rate [4, 5]. Screening with DCE-MRI has also been shown to decrease incidental cancer rate in women with extremely dense breast [6]. However, widespread implementation of DCE-MRI is limited by cost. And given the unknown long-term effects of gadolinium retention after administration for contrast-enhanced MRI [7], caution may be warranted against repeated administrations in a healthy population such as women undergoing breast cancer screening.

Considering the constraints of contrast-enhanced breast MRI, there is great clinical value in identifying an unenhanced MRI modality. Diffusion-weighted (DW) MRI is a technique that does not require external contrast administration—instead, image contrast is generated from endogenous water movement, reflecting multiple tissue factors such as cellular membrane integrity, density, and organization. DW-MRI has been investigated for a variety of breast imaging applications, most commonly as an adjunct tool for lesion assessment in multiparametric breast MRI examinations and for evaluating response to neoadjuvant chemotherapy. However, a growing number of studies are evaluating the role of DW-MRI as a stand-alone tool for breast cancer detection.

The goal of this article is to provide an overview of DW-MRI’s potential as a breast cancer screening tool, which is outlined in greater detail in a recent publication [8]. Summary of evidence to date of DW-MRI in cancer detection, optimal approaches, and future considerations are presented.

CURRENT EVIDENCE FOR DW-MRI IN BREAST CANCER

The following equation describes DW-MRI signal intensity in relation to water mobility within a voxel: $SD=S_0e^{-b\cdot ADC}$, where SD is defined as diffusion weighted signal intensity, $S_0$ the signal intensity without diffusion weighting, $b$ or ‘b-value’ the diffusion sensitization factor, which is dependent on applied gradient’s strength and timing (s/mm²), and the apparent diffusion coefficient (ADC) the rate of diffusion or average area occupied by a water molecule per unit time (mm²/s) [9].

Compared to normal surrounding tissue, breast malignancies typically exhibit impeded water diffusion, appearing dark on ADC map and bright on DW-MRI sequences [10] [Figure 1]. A meta-analysis of 73 studies demonstrated that, using only ADC measurements, DW-MRI could differentiate benign versus malignant lesions with comparable sensitivity and specificity to DCE-MRI (sensitivity=89% vs. 93% and specificity=82% vs. 71%, respectively) [11]. In another study, 89% of mammographically occult cancers were visually detected on DW-MRI,

<table>
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<th>ABBREVIATIONS</th>
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<tr>
<td>ADC – apparent diffusion coefficient</td>
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<td>DCE – dynamic contrast-enhanced</td>
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<td>DCIS – ductal carcinoma in situ</td>
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<td>DW – diffusion-weighted</td>
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<tr>
<td>EPI – echo planar imaging</td>
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<td>MIP – maximum intensity projection</td>
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suggesting that DW-MRI may be superior to mammogram in cancer detection [12]. However, readers in these studies were not blinded to DCE-MRI images when identifying cancers with DW-MRI. Therefore, these study designs do not approximate a clinical setting where DW-MRI is potentially used as a stand-alone unenhanced modality to supplement mammogram in screening for breast cancer.

**Blinded DW-MRI reader studies**

Several studies to-date have explored the use of DW-MRI in study designs simulating a clinical screening setting [13-19]. Readers in these studies retrospectively reviewed only DW-MRI and other unenhanced MRI sequences without access to contrast-enhanced sequences. Readers assessed exams for level of suspicion for malignancy (assigning a numeric score or positive versus negative assessment). Study designs ranged from inclusion of only asymptomatic intermediate-to-high risk patients (cancer prevalence 1.4-2.5%) [13, 19], enriched asymptomatic cancer population (prevalence 25-67%) [15, 18], to inclusion of symptomatic and/or known cancer patients [14, 16, 17]. However, to simulate a screening experience, readers in the latter study design did not have access to clinical history and other imaging modalities, and, therefore, were not privy to prevalence of cancer in the study populations (prevalence 27-46%) [14, 16, 17].

DW-MRI performances in these seven studies are summarized in Table 1. Briefly, mean sensitivity was 76% (range 45-100%) and mean specificity 90% (range 79-95%). Variation in reported sensitivities is likely due to inclusion criteria and interpretation protocol: the study with the lowest sensitivity included only mammographically occult cancer and did not exclude studies with suboptimal image quality [15], whereas the study with the highest sensitivity performed double reading [19]. A variety of imaging acquisition techniques were also used.

Performance of DW-MRI versus other imaging modalities was reported in some of the studies [13-18]. Compared to mammography, one study found DW-MRI to be more accurate and sensitive in cancer detection (area under the receiver operating characteristic curve=0.73 vs. 0.64 and sensitivity=69% vs. 40%) [18], and all malignancies detected by DW-MRI in

<table>
<thead>
<tr>
<th>Study</th>
<th>Total Women</th>
<th>Cancer Prevalence</th>
<th>Field Strength (mT/m)</th>
<th>Max b-value (s/mm²)</th>
<th>Study Population</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yabuuchi 2011</td>
<td>63</td>
<td>67% (42/63)</td>
<td>1.5</td>
<td>1000</td>
<td>Asymptomatic women with DCE-MRI detected malignancy + negative and benign controls</td>
<td>50</td>
<td>95</td>
</tr>
<tr>
<td>Kazama 2012</td>
<td>46</td>
<td>27% (25/62)</td>
<td>1.5</td>
<td>500</td>
<td>Patients &lt;50 years with known malignancy + normal controls</td>
<td>74</td>
<td>93</td>
</tr>
<tr>
<td>Trimboli 2014</td>
<td>67</td>
<td>32% (37/116)</td>
<td>1.5</td>
<td>1000</td>
<td>Patients with known malignancy, suspicious mammographic or US findings, and intermediate-to-high risk screening (asymptomatic)</td>
<td>77% (70-79%)</td>
<td>90% (90-90%)</td>
</tr>
<tr>
<td>Teigrafo 2016</td>
<td>280</td>
<td>46% (129/240)</td>
<td>1.5</td>
<td>1000</td>
<td>Patients with suspicious mammographic or US findings and high-risk screening (asymptomatic)</td>
<td>94</td>
<td>79</td>
</tr>
<tr>
<td>McDaid 2016</td>
<td>48</td>
<td>25% (24/95)</td>
<td>1.5</td>
<td>300</td>
<td>Asymptomatic high-risk women with dense breast tissue: 50% with mammographically occult cancer + 50% matched negative controls</td>
<td>45</td>
<td>91</td>
</tr>
<tr>
<td>Kang 2017</td>
<td>343</td>
<td>2.5% (8/335)</td>
<td>3</td>
<td>1000</td>
<td>Asymptomatic women with history of breast cancer and no known active malignancy</td>
<td>93% (83-100%)</td>
<td>90% (83-95%)</td>
</tr>
<tr>
<td>Reitil 2020</td>
<td>158</td>
<td>1.4% (4/295)</td>
<td>1.5</td>
<td>1000</td>
<td>High-risk screening (asymptomatic)</td>
<td>100%</td>
<td>90%</td>
</tr>
</tbody>
</table>

Table 1: Blinded reader studies evaluating DW-MRI performance for breast cancer screening.
Lastly, cancers ≤10mm were more likely characterized this pathological subtype [16]. A 100% false negative rate in one study that carcinoma, a malignancy with high ADC, had difficult to detect on DW-MRI. Mucinous carcinoma (mean false negative rate of 32% vs. 15%, respectively) [15-17, 19]. Examples of a complicated/proteinaceous cyst, fibroadenomas, and artifactual “lesions” [14-17]. In one study, all seven DW-MRI false positives were found to represent complicated cysts [16]. Fibroadenomas can present with a wide range of ADC values; a study reported that 37% of fibroadenomas exhibited ADCs in the same range as those of malignancies (all below an ADC cut-off of 1.81 ×10⁻³ mm²/s) [22]. Examples of a complicated cyst and fibroadenoma on DW-MRI are shown in Figure 3. Figure 2b also demonstrates an example of artifactual lesion at the nipple from field inhomogeneity-related distortion, which could be mistaken as a suspicious lesion.

CHALLENGES AND FUTURE DIRECTIONS

More studies directly evaluating DW-MRI as a screening tool are warranted before clinical implementation. One main consideration in future studies should be standardization of acquisition protocol and interpretation approach. Recently established expert consensus from the European Society of Breast Radiology provided a number of recommendations towards standardizing breast DW-MRI [23]. Because in vivo ADCs vary with applied b-value, a maximum b-value of 800 s/mm² is recommended for calculating ADC in order to optimize both diagnostic specificity and image quality (i.e., signal-to-noise ratio). Standardization of optimal diagnostic ADC cut-offs is also warranted. A recent multicenter trial suggested that an ADC cutoff of 1.68 ×10⁻³ mm²/s using a maximum b-value of 800 s/mm² could avoid 21% of unnecessary breast biopsies prompted by DW-MRI without compromising sensitivity [24]. Specific to screening applications where both sensitivity and specificity are a major consideration, there is also benefit in acquiring an additional very high b-value (1200 – 1500 s/mm²) as lesion conspicuity increases with b-value [8]. High diffusion-weighting can also be achieved with computed DW-MRI, a technique that uses images acquired at low b-values to synthesize ones at higher b-values. The technique has been shown to generate high image quality and lesion conspicuity without compromising scan times [25].

DW-MRI’s performance as a screening tool could be further amplified by advanced techniques, which are described in depth in a prior review article [10]. Namely, high-resolution acquisition techniques including multi-shot (e.g., readout-segmented) and reduced field-of-view echo planar imaging (EPI) could improve lesion conspicuity and produce sharper images, allowing for better assessment of tumor shape and margin. Post-processing techniques can improve image quality by reducing magnetic field inhomogeneity-related EPI distortions and spatial inaccuracies and artifacts due...
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to eddy-currents and motion, as well as correcting b-value inaccuracies due to gradient nonlinearities. Display enhancing techniques such as maximum intensity projections (MIPs), which renders a 3-dimensional display of DW-MRI, and fusion of DW-MR images to unenhanced T1- or T2-weighted images may also improve cancer detection accuracy and reduce reading time [13,16].

CONCLUSION
Several studies to date suggest that DW-MRI may be more sensitive than mammography in breast cancer detection and support further investigation into DW-MRI as an unenhanced option for supplemental breast cancer screening. Moreover, DW-MRI’s potential to detect clinically and mammographically occult cancer may be further enhanced by protocol optimization and advanced techniques. Larger standardized multicenter trials are warranted to confirm DW-MRI’s potential as a safe and convenient alternative to conventional contrast-enhanced MRI for breast screening.

REFERENCES
Global Roundtable on Risk-Based Breast Cancer Screening

Breast cancer screening is conducted differently in virtually every country in the world. Despite evidence-based research regarding the effectiveness of breast cancer screening, there is significant variation in screening guidelines across global imaging societies. As a result, there are no consistent protocols for the initiation and frequency of screening, let alone for breast density assessment, risk-based triage or supplemental imaging. At a users’ meeting during the recent RSNA conference, Volpara Solutions asked leading breast imaging experts from around the world to answer questions on the implications of these variations as it relates to consistent and equitable screening and best practices moving forward.

Q Given the differences in how breast cancer screening is implemented worldwide, what do you think the consistent protocol for the initiation and frequency of screening should be?

Dr Vourtsis: A consistent protocol would be to implement mammography starting from age 40. Because cancers in younger women tend to grow faster, annual mammography may diagnose breast cancer at an earlier stage, reducing the rate of interval cancers and improving the chances of survival in younger women. Additionally, to overcome the limitations of mammography due to breast density, the utilization of supplemental breast ultrasound should be suggested, whereas in high-risk women, an annual MRI should also be performed.

Dr Kraemer: I think the American Society of Breast Surgeons has done an excellent job regarding a modern imaging protocol with its foundation of early risk assessment and multimodality imaging based on risk and density.

Dr Rickard: There is unlikely to be one perfect model for screening, as the variations on guidelines around the world would indicate. In Australia, women 40 years of age and over are eligible for government funded screening with mammography every two years. However, women aged 50 to 74 years are actively recruited to the National Program, BreastScreen Australia. While changes to lower the age or reduce the screening interval could potentially positively impact outcomes, they would do so at a significant cost. Making these changes based on increased cancer risk may be a more cost-effective option.

Q Do you think that patient advocacy makes a difference in driving an effective screening protocol?

Dr Vourtsis: I believe that advocacy has made a tremendous difference because advocacy groups are mainly focusing on supplemental screening independent of the government-sponsored screening programs and the cost-effectiveness discussions that have been hampering the further adoption of risk stratified screening globally. Continuous awareness of risk stratification screening and its benefits will help women make informed decisions.

Dr Kraemer: Advocacy in the age of social media influencers is in its infancy in medicine. For patients to influence decision making, the screening protocol needs to be easy to understand and accessible to the population, not only at specialized centers. However, there are dangers in ceding leadership to certain influencers, as opposed to expert consensus, as we’ve seen with the pseudoscience of vaccinations and autism.

Dr Russo: Research shows that women with insurance coverage are twice as likely to obtain the yearly mammograms and it stands to reason that this number is higher for adjunct screening.

ROUND TABLE PARTICIPANTS

Dr Mary Rickard MBBS, BScMed (Hons II), DRACR, DDU, MPH, RANZCR, Consultant Radiologist, BreastScreen NSW, Australia.

Athina Vourtsis, MD, PhD, Radiologist and President of the Hellenic Breast Imaging Society in Greece.

Joseph Russo, MD, Section Chief of Women’s Imaging at St. Luke’s University Health Network in Bethlehem, PA, USA.

Eric J. Kraemer, MD, Radiologist at Reno Diagnostic Centers, Reno, NV, USA.
screening. If physicians are interested in delivering the appropriate screening adjuncts to patients, it will have to be driven through the legislative process. We, for example, have been working with densebreastinfo.org to finalize insurance coverage for dense breast patients in Pennsylvania.

What have you found has the most impact in educating patients about their breast health?

Dr Rickard: The process for changes to health practice is not easy or rapid. Patients need access to understandable and consistent information via a range of sources. Doctors are important sources of information, but the public increasingly is seeking to access information from a variety of media sources.

Dr Vourtsis: Social media is usually an important source of information for women. It’s important that this includes medically sourced educational websites such as densebreastinfo.org website, which is the most up-to-date comprehensive site about breast density.

Dr Kramer: We’ve instituted a process where the technologist who performs a woman’s mammogram explains her density score and Tyrer-Cuzick lifetime risk, along with the personalized screening recommendations. The technologist has a relationship with the patient from that exam process, and the information is timely. The patients report this has improved their understanding of breast density and supplemental screening options.

What do healthcare professionals around the world need to know about breast density?

Dr Rickard: There is strong established evidence that mammographic breast density increases breast cancer risk and the risk of missing a cancer diagnosis on mammography. Many health professionals are not aware of these two facts. They are also often unaware of the difficulties of accurate measurement of density by visual assessment.

Dr Kraemer: Large portions of our referring population don’t appreciate density as a risk factor, or know there are supplemental screening methods for improving cancer detection in women with dense breasts. There is still a lot of work to do in this area.

Dr Russo: We should be proud of the strides in survival that promoting screening mammography has made ... but breast density is the next frontier. Patients, providers, politicians and insurers must understand that breast density - and consequent adjunct screening - is what will provide the next leap in breast cancer survival.

What role can automated breast density assessment and risk-based screening play in advancing personalized screening approaches?

Dr Vourtsis: Automated density software has played an important role in the precise assessment of breast density and the utilization of risk based screening programs. Ongoing research on the existing risk models and the various risk factors will provide further evidence.

Dr Rickard: Risk based screening cannot be implemented effectively without the routine use of automated breast density assessment, which offers an independent, reliable and repeatable measure of density. This accuracy of measurement is a key starting point for the use of density measurements in personalized screening. Other data such as family history and personal breast history also are required for risk assessment and collection of this information needs to be accurate and complete.

Dr Russo: When we initiated a supplemental screening algorithm for patients, we realized the importance of determining breast cancer risk. So all of our patients receive a “screening risk assessment” with Tyrer Cuzick. This allows both clinicians and radiologists to take the temperature of the patients’ risk.

What are the next steps needed to move towards consistent implementation of automated breast density assessment and risk-based screening?

Dr Russo: There are now numerous health systems that have implemented some form of high risk or dense breast screening regimens with multiple modalities. We need to get together and start comparing the outcomes for these different regimens.

Dr Kraemer: Incorporating risk based screening at the EMR level would help compliance. When treated as ‘breast vital sign’ patients and primary care providers will better understand that patients have different risk, and therefore may need different screening procedures.

Dr Vourtsis: Application of deep learning methods to the current volumetric quantitative density measurements will help in moving towards more consistent and reproducible automated breast density assessment. Additionally, this accurate density measurement will improve the distribution of existing supplemental screening resources and the shift toward personalized breast screening in the near future.

What is your wish list for the future of breast cancer screening?

Dr Vourtsis: My wish for the near future is to adopt personalized assessment based on individual risk factors and also to routinely offer supplemental ultrasound screening in women with heterogeneously or extremely dense breasts. For women with a personal history of breast cancer and women at high risk, MRI screening should be provided in addition to mammography, regardless of breast density.

Dr Rickard: Recent studies have highlighted the fact that there is a wealth of ‘hidden’ and unrecognized information in mammographic images. Future breast cancer screening should be greatly enhanced by use of this information to improve risk assessment and guide protocols.

Dr Kraemer: I think the next five years will see great improvements in risk models with density, tissue texture analysis and incorporation of genomic data becoming standard. With larger data sets and better risk determination, we may be able to refine screening recommendation intervals, as our 12 month standard is convenient for patient compliance, but not personalized to the individual level.

Dr Russo: I would like to see increased breast imaging collaboration to determine the best algorithm for high risk and dense breast patients. There are so many more tools available to screen for breast cancer. Women should not be discouraged by the media’s scrutiny of screening mammograms, but should be encouraged by the new screening tools in the arsenal that were not available to their mothers and grandmothers.
Successful development of a breast cancer detection algorithm using Artificial Intelligence

By Dr. Ki Hwan Kim

Breast cancer is the most common cancer and the leading cause of cancer-related deaths among women around the world. Screening programs using mammography have been adopted in many countries to reduce breast cancer mortality. Although screening plays a vital role in terms of breast cancer management, it still requires further improvement. It is well known that 10-30% of breast cancers may be missed in mammography. This can be attributed, but not limited to dense parenchyma obscuring lesions, perception error, and interpretation error in screening mammography.

Efforts not to miss breast cancer can sometimes lead to excessive false-positive recalls. About 40% of radiologists who read screening mammography make recall decisions at rates higher than recommended. This is confirmed by the statistics of histologically-confirmed cancer in biopsies being less than 30% [1].

All this shows that the interpretation of mammograms is difficult and that extensive reading experience is required to achieve a high level of reading performance.

The development of software to aid in reading mammography has long been in great demand. Computer-Aided Detection (CAD) for Mammography was developed 20 years ago to aid the detection of breast cancer on mammograms. However, recent large-scale clinical trials found CAD to be ineffective. The main limitation of traditional CAD is that CAD was developed to detect several mammographic features of breast cancers defined by radiologists. In the process of changing high-level information related to the morphology of breast cancers in the mammograms into relatively simple descriptors defined by the radiologists, a loss of information is inevitable.

ARTIFICIAL INTELLIGENCE

Very much in the spotlight currently, Artificial Intelligence can overcome such problems of traditional CAD. AI does not need radiologist-defined features, but instead defines important features on its own, based on an analysis developed from a large amount of data during the training process. This novel approach allows AI to better extract important information from images, resulting in improved performance of AI in comparison to humans in image analysis.

Many researchers have recently been applying AI to medical image analysis, but several factors should be considered when conducting these studies. First, a large number of data must be collected to train the AI models. Since AI has the ability to learn by itself from the data, the performance of a trained AI algorithm is directly related to the quantity of data used to train it. This is similar to the human learning process—the same principle which means that a person who has studied a lot usually knows more.

Secondly, it is not only the amount but also the quality of the data which is an important factor determining the performance of AI. The definition of “quality” may vary from task to task, but in general, one aspect is that it should be able to reflect the data distribution of the environment where AI is to be used. In addition, to achieve high performance, the ground truth of the basic task should be clearly defined. Third, the problem to be addressed should be clinically meaningful, and the appropriate information must be extracted faithfully and well from the image data. The ultimate value of solving the clinical problem being addressed should be absolutely clear to justify the effort of developing novel AI algorithms and collecting high-quality big data. All these factors must therefore be taken into account when using AI to solve specific problems.

AI IN THE DETECTION OF BREAST CANCER IN MAMMOGRAMS

Four years ago at Lunit, we set off on a long journey to develop a new AI algorithm for breast cancer detection on mammograms. The importance of this challenge has been described above: improving the performance of breast cancer screening using AI could ultimately have a positive impact on patient survival. This has been the underlying objective of our efforts carried out over the last four years to solve the problem using AI.

First of all, we tried to collect sufficient breast cancer data since AI requires learning from a variety of mammographic features of breast cancers.

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Naturally, we had to collect a large number of mammograms of breast cancer patients, reflecting various histopathological features of breast cancer. We were successful in collecting mammography exams of more than 35,000 biopsy-proven cancers in screening and diagnostic environments, both early and late-stage cancer. Since the distinction between benign lesions and malignancy is one of the most difficult tasks in the interpretation of mammograms, we collected approximately 60,000 benign exams confirmed by biopsy or through follow-up imaging after more than one year. Considering that difficult cases such as biopsy-proven benign cases are more likely to have abnormal areas suspicious for malignancy, we also trained our AI system on these cases to effectively improve AI performance.

We also took into consideration the distribution of the collected data in terms of hospitals, countries, ethnicities, and the systems used to acquire the images. In our study, which has been recently published in Lancet Digital Health, data were collected from five hospitals throughout Korea, the USA, and the UK [2]. This diversity in data distribution allows AI to extract various morphologic features from the data. In order to use the data more effectively, the location of malignant and benign lesions were annotated by multiple dedicated breast radiologists. These superior data, both in quantity and quality, gave AI the opportunity to achieve higher-level performance.

Another critical factor that determines the successful outcome of algorithms for medical image analysis is the development of an AI algorithm that is optimally suited for the particular task at hand. Preliminary studies to confirm feasibility often use algorithms that are publicly available for general image data. However, developing an AI algorithm suitable for mammography interpretation requires a great deal of effort, since interpreting mammograms is entirely different in several ways from interpreting general images. For example, the image size is very large, exceeding 3000 x 4000 pixels. Also, one mammography examination consists of four views of two breasts.

To specifically deal with mammograms, we designed two sequential learning stages for the training of our AI. The first stage was intended to learn low-level features of mammograms by patch-level training. The second stage was to learn high-level context using full-size images. This method of training was developed through multiple experiments in search of the optimal condition that can efficiently deal with four-view mammograms.

In addition, highly qualified annotations were used to train the AI algorithm in a semi-supervised learning manner for pixel-level training. Supervised training with location annotations is known to be superior to unsupervised learning without the location information, and it can contribute to the generation of accurate heatmaps. A downside to supervised learning is the high cost of creating annotations. Despite this, we used this approach in order to ensure excellent performance.

In medical image analysis, the performance of AI algorithms is sometimes affected by domain differences between training and test datasets, which are typically caused by differences in the image acquisition device, scan protocol, ethnicity, and age of the patient.

We developed a new AI technology, batch-instance normalization method, to overcome this problem, proving its effectiveness not only in mammography but also in general images [3] [Figure 1]. Thanks to these technical efforts, our AI algorithm can effectively utilize a large amount of collected data.

**RESULTS**

Using the AI technology described above and high-quality data, we have developed a high-performance AI algorithm for breast cancer detection in mammography. The system was validated in multiple datasets collected from Korea, the USA, and the UK. The values of 0.938–0.970 of the Area Under the Receiver Operating Characteristics (AUROC) in those datasets indicate that the AI algorithm works well across data from different countries. Ours is the first study to demonstrate the performance of AI-derived algorithms in Western and Asian populations — it is well-known that breast parenchymal patterns on mammograms vary greatly between Asian and Western populations. Also, the detection of cancerous lesions in the breast is more difficult in dense breasts than in fatty breasts, and the proportion of dense breasts is significantly

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**Figure 1:** AI-based diagnostic support software
higher among Asians than the Western population. For global use, the performance of AI-derived algorithms must be validated in diverse populations.

Another important result of this study is that the AI-derived algorithm outperformed both specialized breast radiologists and general radiologists [Figure 2]. Since this evaluation was conducted with a cancer-enriched dataset, the results of the experiment do not necessarily indicate that AI is superior to radiologists—however, it does show the feasibility of AI improving breast cancer screening. The diagnostic performance of radiologists was significantly enhanced by using AI. Furthermore, it should also be noted that AI improves both sensitivity and specificity. These results allow us to expect that the AI would improve the cancer detection rate and reduce false-positive recall in mammography screening, though this has to be confirmed by a prospective study.

CONCLUSION

The basic rationale of this study was to see how AI can help radiologists. To answer this question, we first needed to find the difference between the characteristics of AI-detected cancers and those of radiologist-detected cancers. Although additional clinical studies are needed, we found that AI is relatively sensitive in cancers with asymmetry or architectural distortion and also sensitive in early-stage breast cancer. Analyses to describe the characteristics of AI-based algorithms are necessary and helpful for radiologists to understand and apply the results of the AI algorithms and make final decisions. Without this information, radiologists can sometimes be confused in understanding the output of AI-derived algorithms. Therefore, the AI-based software must provide not only the final analytical result but also a variety of clinical data that can be helpful for radiologists in utilizing the AI result. This is why medical AI algorithms need to be rigorously tested, accumulating clinical evidence in different clinical and experimental environments. The only way to make a good user guide in medicine is to create sufficient clinical evidence.

In summary, the AI algorithm we developed showed better diagnostic performance than radiologists in detecting breast cancer in mammograms. Such high performance was obtained by the use of large numbers of high-quality data and superior AI technology. It was also demonstrated that AI could significantly improve the radiologist’s diagnostic performance. These early findings suggest the possibility that AI could be used as an effective diagnostic support tool for breast cancer detection in the future, which shows that it is worth further evaluation in prospective clinical trials.

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Breast MRI at reduced gadolinium dose

By Dr. A Melsaether

This review is a synopsis of previously reported work on reduced-dose contrast-enhanced breast MRI, originally published in the Journal of Clinical Imaging in FEB/MARCH 2020 [1] and includes a brief summary of work by other authors who have also investigated reduced-dose MRI.

**BREAST CANCER SCREENING AND MRI**

Breast cancer is widely prevalent, affecting one in eight women over their lifetimes, and is second only to lung cancer in causing cancer-related deaths in women [2]. Although imaging screening for breast cancer, specifically mammography, has been shown to improve survival [3,4], there has been pushback recently, with many bodies recommending reduced mammographic screening or eventually even no mammographic screening at all, such as is the case in Switzerland, in deference to the potential harms of mammography, such as the stress caused by the need for additional imaging and biopsies that turn out to be benign [5,6]. The improved survival in patients who are screened is in part because imaging-detected cancers are smaller in size and are less likely to have metastasized to the axilla or systemically than cancers that are detected by palpation or physical exam. These smaller node-negative cancers have higher long-term disease-free survival rates and also necessitate less invasive treatments than their larger counterparts [1,7]. However, mammographic sensitivity is relatively low, especially in dense breasts, being consistently reported at around 40% [8,9]. This low sensitivity may be a reason for some discontent with mammography, as many women who are routinely screened by mammography end up later by having interval cancers detected.

Breast imaging technologies have improved since mammography was widely tested as a screening tool. Dynamic contrast enhanced (DCE) breast magnetic resonance imaging (MRI) specifically has been shown to double the cancer detection rates compared to mammography and ultrasound combined in elevated risk women [8,9]. DCE-MRI has demonstrated incremental cancer detection rates of up to 22.6 per 1000 MRIs in normal risk women, with cancer yields among all four breast densities, even fatty breasts [10]. The sensitivity of screening MRI routinely approaches 100% and interval cancers in such screened populations are rare [10,11]. Further, MRI detects cancers of average smaller sizes and lower rates of nodal metastases than cancers detected on physical exam, mammography, or ultrasound [8-10].

DCE breast MRI screening was initially reserved for breast cancer screening in women with a 20% or greater lifetime risk of breast cancer. Thankfully, recommendations have recently expanded, with the ACR now recommending MRI for many more women, including those with a personal history of early-onset breast cancer (before 50) and those with a personal history of breast cancer and dense breasts [12-15]. A trial in dense breast women recently reported significantly fewer interval cancers in MRI-screened women [11]. Eventually, MRI may be able to replace more conventional screening tools, much as cross-sectional imaging has replaced conventional x-rays in searching for lung cancers.

**GADOLINIUM-BASED CONTRAST AGENTS**

At least for now, gadolinium-based contrast agents (GBCA)s are integral to screening with DCE-MRI, but they present an obstacle to widespread screening since GBCAs have been shown to deposit gadolinium in the bodies of imaged patients [16,17] and to persist in the environment (e.g. streams, tap water) in areas with robust advanced imaging [18,19]. Other obstacles such as the time and cost of MRI are being addressed by several groups, who show that DCE-MRI protocols including a single pre- and post-contrast T1-weighted sequence have sensitivity nearly equivalent to the current ACR protocol [20-22]. Whether deposited GBCAs could be harmful is an open question. In its free form, gadolinium is toxic because it interferes with calcium channels and protein binding sites [23,24]. Gadolinium ions are therefore chelated to a conjugate base into linear or macroyclic GBCAs, which can be renally excreted. Recent studies have demonstrated, however, that clearance in many patients is incomplete, and that gadolinium accumulates in the brain and bone [16,17]. These accumulations have been shown with repeated administrations,

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Such as would be necessary in a gadolinium-based screening program. Although accumulation appears to be related to the chelate, for example, linear agents demonstrate greater deposition than macrocyclic contrast agents (25,26), with repeated administration, macrocyclic agents have also demonstrated some Gd accumulation in the brain (27,28). As of yet, no toxic effects have been demonstrated. However, the United States Food and Drug Administration (USFDA) comments, “health care professionals should limit GBCA use to circumstances in which additional information provided by the contrast agent is necessary and assess the necessity of repetitive MRIs with GBCAs.”

In Europe, linear GBCAs have been withdrawn from the market. Further, GBCAs have been shown to cause minor allergic and even rare anaphylactic reactions (29,30). In patients with renal failure (likely to be rare in a screening population), gadolinium administration may lead to nephrogenic systemic fibrosis [31]. Finally, and importantly, increasing concentrations of excreted gadolinium have been documented in environmental water including tap water, with highest concentrations in places with high volume advanced medical imaging [18,19].

**STUDY RATIONALE**

Regardless of whether gadolinium eventually proves to have negative effects, it makes sense to titrate down to a minimal effective dose, rather than using a maximum tolerable dose. As in many things, an “as low as reasonably achievable (ALARA)” approach is a good model. This was the motivation behind our study that imaged breast cancers with a half dose of Gadobutrol [1]. This idea has been approached by a few research groups who work with lower GBCA doses in MRI exams of the brain [32], prostate [33], and heart [34] and have yielded promising results. In the breast, two older studies looked at GBCA dose: one investigated multiple doses of linear GBCAs [35] of variable relaxivities and another compared our now standard 0.1mmol GBCA dose with a higher dose [36], but both were performed without the object of finding a minimal effective dose.

More recently, our study and one by Pineda et al at the University of Chicago investigated the ability of breast MRI to detect lesions with reduced GBCA doses. The Pineda study showed improved visualization of nine benign-appearing lesions at a 15% GBCA dose [37] and our study showed visualization of breast cancers as small as 3mm with a 50% GBCA dose.

**STUDY DESIGN**

We didn’t have strong referral support for the ideal study design, which would be women with known untreated, biopsy-proven breast cancers who were undergoing PET/MRI of the breast and whole body. These women received a 0.05mM (half-dose) of Gadovist for the breast portion of their exam and a second half-dose for the later, whole body portion of their exam and formed our patient population.

**INCLUSION AND EXCLUSION CRITERIA**

The inclusion criteria for the PET/MRI study in which these women took part, were that a patient needed to have a core biopsy-proven untreated breast cancer that measured at least 2cm, was multi-focal or multi-centric, had metastasized to the axilla, or involved the skin. For a cancer to be included in our study, it had to be biopsy-proven, either by core biopsy, by fine needle aspiration biopsy if in the same breast as the index cancer. Alternatively the lesion had to demonstrate suspicious imaging characteristics on the initial breast MRI and been shown on MRI to decrease in size which was the most commonly met requirement for study inclusion. Exclusion criteria were exam failure, for clear reasons, and gadolinium injection within 24 hours of the study to avoid residual enhancement. Because in most cases we couldn’t directly compare the breast cancer.
sizes or conspicuities between a low dose and standard dose exam, we instead had two radiologists to read the exams. One radiologist had minimal experience and one had a decade of experience. Each radiologist recorded, on a 4-point scale, whether the cancers could be seen and measured the cancer sizes. The radiologist also characterized the cancers as a mass, nonmass enhancement (NME) or a focus, as masses could be easier to discern than NME and documenting inclusion of NME could strengthen the implications of the work.

DATA ANALYSIS
We assessed inter-reader agreement with the idea that if both radiologists could see the cancers confidently and measured them similarly, this would suggest the MRI was clearly depicting the abnormality. We also correlated size on half-dose MRI with size on mammography (available in nearly all cases), ultrasound (available in all cases), standard-dose MRI (available in about a quarter of cases), and with the gold-standard size at surgical pathology (available in about a quarter of cases). For comparison, we correlated size on mammogram and ultrasound with gold-standard size on surgical pathology as well.

RESULTS
Cancer characteristics and detection
Cancers ranged in size from 0.4-9.2 cm with 5 cancers 1 cm or less and 13 cancers 2 cm or less. There were 35 masses, 13 areas of NME, and 1 focus. All 49 cancers were seen by both readers, with average conspicuity scores of 2.9 on a scale of 0-3. No cancers were rated as 0 not seen or 1 questionably seen by either reader. Readers measured cancers similarly, with a concordance of 1.0, i.e. nearly perfect.

Comparison with mammography, ultrasound images and pathology
For the subsets of these cancers imaged with mammogram and ultrasound, but not from size at surgical pathology or standard-dose MRI, the cancer size on half-dose MRI correlated with size at surgical pathology while the cancer size determined on mammogram and ultrasound did not.

IMPLICATIONS
Our results indicate that breast cancers as small as 4 mm and of all morphologies (mass, NME, focus) can be well seen on breast DCE-MRI with a half dose of GBCA by both experienced and relatively inexperienced breast radiologists. Further, our study suggests that the cancer borders are clear at this reduced dose, as there was near perfect concordance in size measurements between the two radiologists. That there was also significant correlation between size on the half-dose MRI and size at pathology corroborates that half-dose MRI accurately depicts tumor margins. As significant correlations were not seen between size on mammogram or ultrasound and size on pathology, it appears half-dose MRI outperforms mammogram and ultrasound, even in this group of larger cancers. A similar recent study, published the same month as our study, provides similar results in benign lesions at an even lower contrast dose. The authors looked at 10 lesions with imaging features compatible with fibroadenomas- first at a 0.015 mmol GBCA dose and, 10 minutes later, at a 0.085 mmol GBCA dose [37]. This study showed that 9 of the 10 lesions were seen on both image sets and that lesion conspicuity and enhancement rate were higher on the lower dose images. This study is exciting since it suggests that these benign lesions may preferentially recruit contrast, so that at lower doses, more contrast agent would go to the lesion and at higher doses, there may be more contrast angiogenesis. Thus it is likely that preferential contrast recruitment by malignant lesions would be even greater than that seen by benign lesions in this study. This suggests this low dose, or even a lower contrast dose, may be sufficient. Another recent study looked at inter- and intra-observer agreement in assessment of tumor volumes prior to neoadjuvant radiation therapy and found similar agreement in half- and full-dose groups [38]. As a result, this team changed to half-dose...
dose screening DCE-MRI.
With continuous advances in artificial intelligence (AI), another hope is that small changes in signal intensity could be detected and augmented artificially, potentiating even smaller contrast doses. Eventually, non-contrast MRI may become useful for breast cancer screening. Until that happens, though, we hope to see continued focus on “minimal necessary” rather than “maximal tolerated” doses.

REFERENCES
Over the past few years there has been a significant surge of interest in the use of contrast-enhanced spectral mammography (CESM). The reasons for the recent interest in CESM are mainly the high sensitivity of this breast imaging modality and the absence of any effect of breast density on the sensitivity. However, despite the many benefits of CESM, up until now the technique had the inconvenience that taking a biopsy of any suspicious lesion detected by CESM meant that the biopsy guidance had to be carried out using another imaging modality. This situation has now been addressed with the introduction of the Serena Bright CESM biopsy solution from GE Healthcare.

We wanted to find out more about CESM in general and the new CESM-guided biopsy system in particular, so we spoke to Dr. Rodrigo Alcantara, head of Breast Imaging at the Hospital del Mar in Barcelona, Spain. Dr. Alcantara has a long experience of CESM and is actively involved in the evaluation of the new CESM biopsy system.

**Q** Before we get on to CESM, please tell us a bit about your clinic and the patients you see.

Hospital del Mar is part of an extensive public health complex in Barcelona (Parc de Salut Mar) and is the fourth biggest hospital in the city. We operate a large and well established breast screening program in which we carry out 17,000 mammograms per year. Screening represents almost 70% of all our breast examinations. In Spain the breast cancer screening program covers asymptomatic women aged from 50 to 70 years, who are invited every two years for a suggested mammogram appointment. Covering two of the five administrative areas in Barcelona, our hospital del Mar operates the biggest screening program in town.

The average participation rate of the women who are invited to participate in our screening program is 55-60%.

In addition to all this screening activity, on average we carry out a further 7000 mammograms per year for diagnostic/symptomatic patients, for follow-up and for examining high-risk patients. These symptomatic patients are mostly referred to us from primary care centers in our area and also from the surgical and gynecological departments associated with our breast unit.

Regarding screening, it is of course important for us to always keep in mind that women in the screening setting are not only asymptomatic but also usually have no increased risk of breast cancer. We, as radiologists, must therefore always strive to find the optimal balance between diagnostic performance and recall rate in order to minimize unnecessary interventions while keeping the level of false positives as low as possible. In contrast, when we are dealing with a symptomatic or a high-risk patient, we can, and should favor diagnostic accuracy in order to be able to reliably answer the key clinical question as to whether we can rule out or confirm any suspected malignancy.

**Q** What breast imaging equipment do you have and from which manufacturers?

We have now 3 mammography systems, one Senographe Pristina from GE Healthcare and two Amulet Innovality from Fujifilm, all of them fully equipped with tomosynthesis and biopsy add-ons, stereo and tomo-guided unit. We previously had a Senographe Essential system (GE Healthcare), equipped with contrast enhanced mammography (Senobright) which provided us with our first contact with the remarkable technique of CESM. Nowadays, we perform our CESM examinations with the new Senographe Pristina system (Senobright HD). We have also two dedicated ultrasound systems (GE Logiq S8) and access to a 1.5 T Signa Explorer MRI (GE Healthcare).
What is the typical work-up of a woman with a suspicious lesion on mamm/tomo?

The typical work-up procedure in our department is compliant with the appropriate international recommendations and guidelines. For BI-RADS 5 non-calcified lesions in non-dense breasts, we can proceed with an ultrasound core-needle biopsy. Initial evaluation of the extent of disease is usually carried out with FFDM or DBT plus ultrasound. However, for some cases of asymmetries and distortions, we prefer to carry out CESM, given the established value of the technique as a problem-solving tool. Thus, by adding CESM to the work-up we gain further functional information which can help to avoid unnecessary biopsies. This is especially important for patients recalled from the breast cancer screening program. For example for patients with a BI-RADS 4-5 mass in a dense breast, performing CESM increases the overall diagnostic accuracy and improves the detection of additional unexpected lesions. In addition, this approach minimizes the need for second-look ultrasound in case of further MRI. Cases with calcifications are considered for stereotactic or DBT-guided vacuum-assisted biopsy. In these cases and, depending on the breast composition, we may consider further evaluation with CESM or MRI.

And what about symptomatic women with a suspicious lesion detected on clinical examination?

Such cases are usually referred to us from primary care centers. We have introduced CESM as an initial diagnostic technique in our institute for patients with clinically suspicious breast abnormalities. Thus, CESM is our first-line imaging modality in symptomatic women over 40 years of age and as a second-line modality in patients under 40 years with suspicious findings on ultrasound. The good correlation between the tumor size as determined by CESM with that determined by MRI and also with the final size shown on pathology increases the radiologist’s confidence in establishing the local staging.

And high breast density?

Dense breasts have been shown to be an independent risk factor for breast cancer and the most important cause of false negatives on mammography. In contrast to mammography, the sensitivity of CESM is not compromised by breast density. Indeed, some reports describe a statistically significant increase in CESM sensitivity in patients with dense breasts. Several different imaging approaches for the work-up of women with dense breasts are currently being evaluated by various groups of investigators.

The procedures we use in our hospital are as follows. First of all in our department we currently determine breast density by visual assessment, although we have a collaboration with a Spanish IT group which is likely to result in the installation of a dedicated breast density software in our unit in the near future.

For the evaluation of women with dense or highly dense breasts in the clinical/symptomatic setting, we usually use tomosynthesis plus ultrasound. On the other hand, for women with dense breasts in the population-based screening program, the method is FFDM only, despite the associated density issues.

Our unit is currently involved as a collaborator center in a multicentric trial evaluating different approaches to personalized breast screening. In this context, I am personally very interested in the possibilities of a rigorous evaluation of CESM vs. other imaging modalities. In fact this is the objective of a large and innovative trial that is currently being organized in the USA, namely the Contrast Enhanced Mammography Imaging Screening Trial (CMIST). The trial is designed to compare the performance of CESM in the screening of women with dense breasts with that of the combination of digital breast tomosynthesis (DBT) and whole breast ultrasound (WBUS). Managed by the American College of Radiology (ACR) with support from the Breast Cancer Research Foundation and GE Healthcare, the CMIST study is planned to start in the second quarter of 2020.

As for women with high genetic risk such as those with BRCA mutations, we generally direct them to MRI, where we use a full, standard 1.5 T MRI protocol for the initial examination and then abbreviated MRI protocols for subsequent acquisitions. As in most hospitals, our MRI system is not solely dedicated to breast examinations so in practice there is a waiting list of several weeks for our cases. The waiting list for MRI-guided biopsy is even longer. For cases where MRI is contra-indicated, e.g. because of claustrophobia, we offer CESM as an alternative.

All in all, how many CESM examinations have you carried out?

So far we have performed more than 1300 CESM examinations, the first 200 using the first generation of the Senobright system from GE but nowadays our contrast mammograms are carried
out with GE’s latest Pristina system. The performance of the system based on the initial 329 cases showed a sensitivity of 94.0%, specificity 75%, PPV 70% and NPV 95.6%. There was an average of 16% false positive results, but this was in the beginning of our experience with the technique and we expect that those results have considerably improved by now. Indeed, the image quality has increased significantly with the updates available in the latest generation equipment and software.

The impressive performance of CESM can be explained by its underlying principle which relies on the detection of tumor vascularization. CESM detects angiogenesis by tracking the uptake of iodine-based contrast media in breast cancer, similar to the principle of breast MRI with gadolinium-based contrast. Both imaging techniques are thus based on increases in enhancement after contrast agent administration due to angiogenesis in neoplastic lesions.

Several studies have shown that CESM has similar diagnostic performance to that of MRI for detecting breast cancer and evaluation of the extent of the disease. In a systematic review and meta-analysis Tagliafico et al [doi 10.1016/j.breast.2016.04.008], reported sensitivity to be 98% with a post recalculation specificity estimated as 78%.

CESM has several advantages compared to MRI, for example shorter procedure times, lower cost, suitability for claustrophobic patients and no need to schedule according to menstrual cycle.

As has been described in several papers in the literature, the use of CESM instead of a normal mammogram can increase the sensitivity and the negative predictive value of the first imaging approach in symptomatic patients. The technique improves the detection for additional disease and has the potential to reduce the need of additional work up such as second look ultrasound in the case of MRI.

CESM is an outstanding problem-solving tool, so we nowadays use it often when we have doubts about previous mammogram or DBT findings, as well as for some recalls from the screening program.

The CESM technique is very well accepted by the patients and in our experience is better tolerated by them than MRI, mainly due to ambiance and positioning factors. The enhancing (and non-enhancing) lesions are easily recognizable, even by the patients, so they can sometimes participate and fully understand the diagnostic process.

In practice, a CESM study consists of a set of 2 images per view, so the radiation dose is higher than FFDM, with literature reports of an increase of 20 to 54% of the Average Glandular Dose compared to mammography. Despite this, the overall CESM radiation dose is still within internationally accepted radiation dose limits. In addition, replacing a conventional FFDM by CESM study for an initial examination, e.g. in the case of symptomatic patients makes it possible to eliminate 60% of the increase in radiation dose.

Q Now what about biopsies?

In our department we carry out an average of 630 core needle biopsies and 200 Vacuum-Assisted Biopsies (VAB) annually. All our core needle cases are ultrasound guided. For mammographic-guided (stereotactic, DBT and CESM) and MRI-guided biopsies we always use a vacuum assisted needle in order to optimize sampling, avoid false negatives and minimize underestimation.

Both CESM and MRI can detect breast lesions that were initially occult by other techniques. The majority of the published data on these cases involves MRI, with the level of additional enhancing lesions being reported as between 16% and 29% of the women undergoing breast MR imaging.

Prior to the arrival of the Serena Bright biopsy system, whenever CESM showed a mammographically occult lesion, we proceeded with a targetted ultrasound, carried out on the same day. Similar to second-look ultrasounds after a MRI, we are able to localize on average of 50-60% of the findings that had initially gone unnoticed. This biopsy is usually performed under sonographic guidance. There are also a few cases that are associated with a tomosynthesis finding, for example a distortion, which we work up with a DBT-guided procedure. When there is no sonographic or mammographic correlation, until now a biopsy had to be performed under MRI guidance.

Q When did you install the Serena Bright system?

We have had this technology available in our department since last October 2019, using it under board approval and in a context of clinical validation. Our radiologists have extensive experience in the routine carrying out of mammography-guided breast biopsies, so the learning curve and implementation for CESM-guided biopsy was easy, particularly since the software interface is very intuitive. Technically, the CESM-guided biopsy is a procedure similar to a standard stereotactic biopsy (one scout and a pair of stereo images). The main difference is the additional step of contrast agent injection two minutes before starting to image. As in routine CESM examinations, each acquisition is composed of a low-energy and high-energy exposure, with the lesion being able...
to be targeted on either the low energy or recombined view. Our procedures last for around 12 to 16 minutes, from the first compression to the clip placement, which our patients still find acceptable.

As far as the advantages of using this approach are concerned, in the first place there is the benefit of using the same modality to guide the biopsy as was used to detect the lesion in the first place.

The waiting list for a MRI-guided biopsy can be as long as several weeks, whereas the CESM-guided biopsies can be scheduled sooner, for example in our center in less than one week after the initial CESM.

The CESM-guided biopsy procedure itself is fast and easy to perform, and typically doesn’t last more than 12-15 minutes, which compares favorably with the 40-60 minutes of a MRI biopsy. Overall, CESM biopsy costs less than a MRI-guided intervention. Last, but not least, for most doctors and radiographers, preparing for and carrying out MRI-guided biopsy procedures can be quite stressful. The technique is not used routinely and sometimes the lesion can be difficult to approach, making the whole procedure last longer than desirable.

So far, we have carried out 15 CESM-biopsies, all of them using a 10g VAB needle. Considering that we are still operating in a clinical validation context, our initial findings with CESM-guided biopsies have been very promising as concerns the reliable targeting of enhancing lesions. We have observed an average of 45% of malignancies in the cases selected, i.e. more than the malignancies rates reported for MRI guidance (22-33%). This is probably related to the higher specificity of CESM compared to MRI. Also, MRI detects more non-malignant enhancing foci and seems to be more affected by background parenchymal enhancement (BPE).

The software interface of the Serena Bright is particularly appreciated since it is very intuitive and user friendly. During the targeting, it is easy to go from the low energy image to the recombined image, favoring image correlation. In addition, the possibility of easily switching between different biopsy modalities, e.g. from CESM to conventional stereo or DBT during the procedure, is very useful. For example, this can be done to carry out extra imaging, such as a DBT scout after clip placement. Given that enhancing information is not available after 10 minutes, performing a final DBT scout may avoid additional unnecessary radiation.

So far overall patient feedback to the CESM biopsy procedure has been very good — the patients usually state that the procedure was much less onerous than they expected. Of course, having a scheduled breast biopsy intervention always involves some stress for the patient, so being able to carry it out in a fast, efficient and easy way is of help.

In contrast, MRI-biopsy positioning can be a major issue for the patients and can be painful and uncomfortable. Since it is a complicated and limited technique, we always reserve MRI biopsy only for cases where there are really no alternatives.

Unlike MRI-biopsy, CESM-guided biopsy is a relatively simple technique and the procedure is fast. We foresee increasing use of the technique in the future. For dubious ultrasound or mammogram cases, CESM-guided biopsy clearly has the potential to increase the success rate and avoid equivocal biopsies.

Q And the future of breast imaging in general?

The role of the breast radiologist has evolved from simply cancer screening and detection to a more complete diagnosis and management role with the widespread adoption of image-guided percutaneous procedures. One of the challenges in the near future is to find the balance between lesion detection and overtreatment, something that depends on a multidisciplinary commitment. In this context, the implementation of AI-based software could help us to improve the overall diagnostic performance, decrease false negatives and positives, while freeing us up to deal with more complex human-facing tasks.

All this means that we may be at the beginning of a whole new era where the profile of breast radiologists will be even more integrated in the clinical setting, participative and interventional.
Assessment of benefit from screening women ages 40–49 years: elements of the controversy

By Dr. S A Feig

The debate regarding screening women ages 40-49 began around 1976 and continues today, making it one of the longest and most heated of all medical controversies. The controversy goes on, even though reduction in deaths has now been proven through randomized clinical trials and the hypothetical radiation risk from mammography has been shown to be negligible or non-existent compared to the known substantial benefits.

EPIDEMIOLOGIC PERSPECTIVE

Among the requirements for the performance of any screening test is that the disease being screened must have adequate prevalence in the intended screening population. For example, the likelihood of developing breast cancer over the next decade for average risk women at age 20, 30, 40, and 50 is 0.06% (1/1760), 0.44% (1/229), 1.44% (1/69), and 2.39% (1/42), respectively [1]. To many observers, these data support starting screening at age 40 rather than at age 50 or later.

Population data reflects not only incidence (cases/1,000 women in each age group), but also the relative distribution of age groups in the U.S. population. From this perspective, the percentages of breast cancers in the entire population diagnosed at ages 40-44, 45-49, 50-54, and 55-59 are 6%, 10%, 13%, and 12%, respectively.

The percentages of deaths from breast cancer diagnosed during these ages are 7%, 10%, 11%, and 11%. For each of these age groups, the percentages of all years of life lost from breast cancer in the entire U.S. population diagnosed during these ages would be 12%, 15%, 15%, and 13% respectively. Breast cancer diagnosed between ages 40-49 accounts for 17% of all deaths attributable to breast cancer, but because normal life expectancy is highest for younger women, breast cancers diagnosed in this age group account for fully 27% of all years of life expectancy lost to breast cancer [1].

ORIGINS OF THE CONTROVERSY REGARDING SCREENING WOMEN IN THEIR FORTIES

The first randomized trial of screening mammography was the Health Insurance Plan of Greater New York (HIP Study), which began in 1963 [2]. A difference in breast cancer deaths between study and control groups age 50-64 years old at entry became apparent by year 4, but did not emerge until 7-8 years of follow-up for women age 40-49 years at entry. The first screening controversy started in 1976 when John Bailar, then editor of Journal of the National Cancer Institute, claimed that evidence of benefit from screening women in their 40’s was uncertain at 7 year follow-up and that the radiation risk from mammography might exceed the benefit [3,4].

Nevertheless, subsequent follow-up of the HIP study in 1998 found that mortality reduction from screening women ages 40-49 was equal to or greater than that from screening women ages 50-64, 24% vs 21% [2]. Moreover, subsequent studies of newer low dose mammography technology showed no evidence of radiation risk [5, 6]. A report from the US National Council on Radiation Protection and Measurements (NCRP) concluded that even at a 1% mortality reduction, benefit would greatly exceed risk.

NATIONAL BREAST SCREENING STUDY OF CANADA (NBSSC)

The controversy intensified in 1992 with publication of results from the National Breast Screening Study of Canada (NBSSC), which found no evidence of benefit among study group women ages 40-49 offered five annual screenings with mammography and clinical examination versus control group women [7]. However NBSSC had poor mammographic technical quality due to faulty film processing, inadequate breast positioning, and no mammography grids. Additionally, there were other serious flaws in trial implementation. NBSSC was a trial of volunteers rather than a population-based trial. It had been enriched with women having palpable breast masses. These women may have been preferentially assigned to the study group by facility clerks, rather than being placed randomly in both groups. As a consequence, NBSSC was the only screening...
trial ever to find more advanced cancers in the study group than in the control group. For these reasons, NBSSC should be excluded from the list of studies used to calculate benefit for screening women ages 40-49 years [8-12].

STATISTICALLY SIGNIFICANT BENEFIT FOR WOMEN AGES 40-49

Because there were relatively few women ages 40-49 in the randomized trials, it was necessary to combine results from all 7 population-based trials for a meta-analysis. However, early meta-analysis performed between 1993-1995 suggested little if any benefit [13]. Subsequent meta-analysis published by Smart et al. in 1995, the Falun Sweden Meeting Committee in 1996, and Hendrick et al. in 1997 found a statistically significant 24% mortality reduction for women aged 40-49 years at entry into the seven population-based trials: HIP, Swedish Two-County (Dalarma and Ostergotland), and three Swedish Trials in Malmo, Stockholm, and Gothenburg [14-16].

Subsequently, two other individual randomized trials besides HIP were each able to show statistically significant benefit for women ages 40-49 years. Bjurstam and co-workers reported a statistically significant 45% mortality reduction for women ages 39-49 years at randomization in the Gothenburg Sweden trial [17]. Andersson and Janzon reported on 35% breast cancer mortality reduction in the Malmo “Age Trial” who began screening mammography at age 45-49 years [18].

Unfortunately, the UK Age Trial, which began in 1990, was not able to show long term mortality reduction for women ages 40-49. Explanations for the results include restriction to only single view mammography on incidence screens, a relatively low 68-70% compliance rate, contamination of the control population by women who obtained screening outside the trial, and failure of radiologists to advise biopsy for many suspicious microcalcifications [19-22].

SERVICE SCREENING STUDIES

We now have data from several “service screening” studies, each showing statistically significant mortality reduction from screening women age 40-49 years. Unlike randomized trials, service screening compares mortality rates to historic data from the same areas or the contemporaneous non-screened women from the screened or adjacent areas [23]. Such data may require adjustment for potential biases.

An expansion of the Swedish Two-County randomized trial as a service screening study found breast cancer mortality reduction of 48% for women ages 40-49 years and 44% for all women ages 40-69 years [24].

In a service screening study conducted in British Columbia Canada, Coldman et al. found that breast cancer deaths were reduced 39% among women ages 40-49 vs 40% for all women ages 40-79 years [25]. A follow-up report from this Pan-Canadian study published in 2014 confirmed a 40% reduction in mortality [26]. In a service screening study conducted in the northern Swedish counties of Vasternorrland and Norbotten, breast cancer deaths were reduced 30%-38% for women ages 40-49 years and 30% for all women 40-79 years [27].

WHY DO MANY STUDIES UNDERESTIMATE BENEFIT FROM CURRENT IMAGING METHODS?

There have been many limitations in the design and conduct of most randomized trials and service screening studies that allow under-estimation of the benefit from screening. These include excessively long screening intervals (1.5-2.0 years or longer) between screens, extremely high biopsy thresholds, and an insufficient length of the screening trial [28,29]. Additionally, most of the earlier trials did not utilize modern imaging technology that have allowed earlier detection. These advances include film-screen mammography, digital mammography [30] and digital tomosynthesis [31], high-frequency x-ray generators, improved x-ray focal spots, beam filtration, improved breast compression devices, and mammographic grids.

More recently, ultrasound screening has been shown to improve detection rates beyond those of digital mammography for invasive cancers in dense breasts by 54% using hand-held high resolution transducers and 55% using automated breast ultrasound (ABUS) [32,33]. These studies suggest that substantially greater mortality reductions will result from advances in mammographic equipment as well as from use of supplementary screening ultrasound for younger women and dense breasts. Supporting this expectation is a recent study by Kim et al. which found that cancers detected by screening ultrasound have a 5 year survival rate of 98% [34]. All of these studies suggest that advances in mammography and breast ultrasound may be reasonably expected to allow further decreases in breast cancer mortality, which could be far greater than those shown in prior randomized trials and service studies.

ADVANCES IN TREATMENT HAVE NOT REDUCED THE IMPORTANCE OF SCREENING WOMEN AGES 40-49 YEARS

There has been a 32.7% decrease in breast cancer deaths in the U.S. since 1980 [35]. Several mathematical models suggest that earlier detection through screening as well as advances in chemotherapy, hormonal therapy, radiation therapy, and surgery have all contributed toward reduction in breast cancer mortality [36-38]. However, modeling provides fairly inaccurate estimates for the relative contributions of screening versus treatment [36]. Moreover, there is evidence that chemotherapy works best when used on smaller breast cancers [35]. A study by Hellquist et al. clearly showed a substantial mortality reduction for women ages 40-49 screened in Sweden that was independent of advances in treatment...
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of Swedish counties offered screening to women ages 40-49, while the other counties did not due to budgetary restraints. Yet all counties offered women ages 40-49 the same options in chemotherapy. At a mean follow-up of 16 years, there was an incremental 29% mortality reduction for those who attended screening [39]. Another large observational study on the relative benefits of screening and chemotherpay was conducted at Massachusetts General and Brigham and Women’s Hospitals, where 80% of patients received screening mammography [40]. Among women ages 40-49 years, 70% of all deaths from breast cancer were in women who had not been screened, 12% in screen-detected cancers, 11% in interval cancers, and 7% off-program. These results support a central role of mammographic screening and early detection in declining mortality from breast cancer. All women, screened and unscreened, had access to contemporary adjuvant chemotherapy.

NUMBER NEEDED TO SCREEN

The number of women needed to be screened (NNS) to detect one cancer, prevent one cancer death, or gain one year of life expectancy represents a new and arguably more valid way of comparing absolute benefit from screening at different ages. Traditionally, benefit has been measured in relative terms; percent mortality reduction from breast cancer deaths expected in the absence of screening. By comparison, NNS is affected by differences in breast cancer incidence and the sensitivity of mammography in different age groups. Older women have a higher breast cancer incidence and generally have more fatty breasts [41].

The U.S. Preventive Services Task Force [42,43] made two major mistakes in their portrayal of NNS for women in their 40’s to detect one cancer, prevent one death, or gain one year of life expectancy. First, they calculated the number of women needed to be invited to screening (NNI) rather than the actual number needed to be screened (NNS) to prevent one death. NNI is always higher than NNS, often considerably because many invited women do not accept the offer to be screened. In some trials, as few as 32% of enrolled women have attended all screening rounds. USPSTF calculations based on randomized trial data found that NNI at ages 39-49, 50-59, and 60-69 was 1904, 1339, and 377, respectively.

USPSTF’s second mistake was inclusion of results from NBSSC, the only trial not to show benefit for any age group. If data from only the other trials had been used, the NNI to prevent one death among women screened between ages 40-49, 50-59, and 60-69 years would have been 950, 670, and 377, respectively. These values are sufficient to recommend screening of all the age groups according to USPSTF’s own criteria. Furthermore, using Cancer Intervention and Surveillance Modeling Network (CISNET), Hendrick and Helvie calculated NNS for women actually screened in the RCTs, not just invited to be screened; and, for women ages 40-49, 50-59, and 60-69, NNS was 746, 351, and 233, respectively [44]. In a subsequent paper, Hendrick et al. calculated that by using digital mammography, NNS for annual screening of women ages 40-49 would be even lower, 588 compared to 746 for analog mammography [45].

Estimation of the NNS will be influenced by the size of the mortality reduction, the number of screening rounds, and the length of follow-up. For example, the Swedish Two-County Trial, which screened women ages 40-69 years for 7 screening rounds and 30 years follow-up, achieved more than 30% mortality reduction. For these women who were screened, Tabar et al estimated that NNS would have been 181 [46]. It should not be surprising that NNS is larger for younger women because their breast cancer incidence is lower. NNS is inversely proportional to the incidence rate. Recent interest in NNS is because it is an indirect indication of the harms and costs of screening compared to the absolute benefits. For each age group, the more women needed to be screened to prevent one death, the greater the number of women who are recalled for diagnostic imaging or biopsy to prevent that death. Thus, a greater number of women may experience “harms” for each cancer detected. There is no consensus among “experts” regarding the value for NNS needed to recommend screening of women ages 40-49.

SCREENING GUIDELINES FOR WOMEN AGES 40-49 YEARS

The main differences among various guidelines include the age to begin screening, the recommended screening frequency, and the age to stop screening. The American Cancer Society (ACS) revised its Screening Mammography Guidelines in October 2015, [47] moving their recommendations away from those of the American College of Radiology (ACR), Society of Breast Imaging (SBI), American College of Obstetricians and Gynecologists (ACOG), American Medical Association (AMA), and National Comprehensive Cancer Network (NCCN), as well as away from the 2003 ACS Guidelines but closer to the 2009 and now the 2016 US Preventive Services Task Force (USPSTF) guidelines [48,49-50].

The ACS as well as the American Society of Breast Surgeons (ASBS) and the American Society of Clinical Oncology (ASCO) now recommend starting screening mammography at age 45 with the option to start at age 40. ACR/SBI, ACOG, AMA, and NCCN continue to recommend starting at age 40 [51]. USPSTF, American Academy of Family Practice (AAFP), and American College of Physicians (ACP) advise starting at age 50 years, with a decision to begin screening between ages 40-49 years individualized on the basis of risk factors and personal choice [48,50].

For women who choose to begin screening at age 40, ACS, ASBS, and ASCO advise annual screening between ages 40-45 and biennial screening above age 55, with the option to continue annual frequency above age 55. For all women being screened, ACR/SBI, ACOG, NCCN, and NCBC recommend annual intervals whereas USPSTF, AAFP, and ACP recommend biennial intervals.

Arleo et al. used the NIH Cancer Intervention and Surveillance Modeling Network (CISNET) to compare projected benefits from screening 1,000 women according to three different screening strategies: annually ages 40-84 (ACR/SBI); annually ages 45-54 and biennially ages 55-79 (ACS); and biennially ages 50-74 (USPSTF) [52]. For...
greater detection sensitivity for younger
additional screening ultrasound will allow
Advances in mammography equipment and
ing, especially during the 40-50 year decade.
predictive values, cost per year of life saved
tially reduce breast cancer death rates for all
that screening mammography will substan-
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Practising in the Diagnostic Senology department of one of the largest hospitals in Florence, Italy, Dr. Jacopo Nori has a long experience with contrast-enhanced digital mammography (CEDM).

We caught up with Dr. Nori to discuss his experience with CEDM, the relatively new technology which he categorizes as representing a potential revolution in the field of breast imaging.

First of all you have to remember that the underlying principle behind CEDM is different from that of the purely morphological imaging modalities such as mammography, tomosynthesis or even ultrasound. Functional imaging, of which MRI and CEDM are examples, is based on the fact that newly-created blood vessels around a tumor (but also occasionally around a benign lesion) are of relatively poor quality in that they have endothelial damage so they leak. This gives rise to a passage of contrast medium — which is gadolinium-based in the case of contrast-enhanced MRI and standard iodine-based contrast media in the case of CEDM — into the extravascular space which results in image enhancement. In the context of breast imaging, MRI is the most widely used and familiar methodology since it has been used in breast imaging for approximately 20 years and has the highest sensitivity of all breast imaging modalities.

Compared to breast MRI, the literature on CEDM is relatively sparse, reflecting the relatively recent introduction of the technique. So far, combined reports of CEDM up to 2018 only totalled approximately 3000 patients although this number has undoubtedly grown since 2018. However there are enough data to be sure of CEDM’s high sensitivity of 95% with a range of 89% - 100%. Since, as I mentioned earlier, benign lesions can also enhance, specificity is slightly lower : 70% with a range of 41%- 95%)

In practice, CEDM first involves the acquisition of a normal low-energy image which is very similar to that of a normal mammography image. This is followed by the acquisition of a high

Figure 1. Pros and cons of CEDM vs. breast MRI
energy image which in its own right has no diagnostic value, but is used to subtract from the low energy image, so giving a recombined image. The CEDM procedure is very simple and takes between 2-8 minutes maximum. We use 1.5 mL per Kg of body weight of non-ionic CT contrast agent at a concentration of 370 mg/mL injected intravenously at 3mL per sec using a power injector. The breast is uncompressed during injection to allow maximum flow of the contrast in the vessels. We wait two minutes after injection before imaging, with a second image being taken after a further six minutes.

Our standard protocol involves 2D mammography 3D tomo and then CEDM

We started carrying out CEDM as far back as 2016 and so far we have examined more than 2000 patients with the technology. Out of these patients, the break-down of the various reasons for which we use CEDM is:

1) Pre-operative planning 67%
2) Problem solving 25%
3) MRI contraindication 4%
4) Scar assessment 3%
5) Post neo-adjuvant therapy 1%

CEDM compared to other modalities?

Since mammography/tomo are morphological imaging methods as opposed to the functional imaging of CEDM, it should be remembered that they provide different information. However one big difference is that, unlike mammography, CEDM is not affected by the density of the breasts. This means that the debate is not so much between CEDM and digital mammography or tomo, but between CEDM and MRI. As can be seen from Figure 1, CEDM has several advantages over breast MRI. These are:

- The possibility of detecting microcalcifications.
- Accessibility. In most hospitals in Europe, access to MRI is difficult and usually involves a long wait period.
- Costs. We estimate that in our institute, breast MRI costs are approximately four times those of CEDM.
- Patients appreciate the short time of the CEDM procedure, compared to the more lengthy MRI procedure.
- No use of Gadolinium-Based Contrast Agents (GBCA) as in MRI. Although no specific adverse effects have been identified so far, the recent observation of the deposition of gadolinium in the brain has given rise to some controversy regarding its significance. In Europe only macrocyclic GBCAs are approved.

The Diagnostic Senology unit carries out the CEDM procedures using Hologic’s Selenia Dimensions mammography system which is capable of performing full field 2D digital mammography, 3D tomosynthesis and CEDM (high and low energy images).

**BOOK REVIEW**

Contrast-Enhanced Digital Mammography (CEDM)
Edited by Jacopo Nori & Maninderpal Kaur

This book offers a comprehensive, practical resource entirely devoted to Contrast-Enhanced Digital Mammography (CEDM), a state-of-the-art technique that has emerged as a valuable addition to conventional imaging modalities in the detection of primary and recurrent breast cancer, and as an important preoperative staging tool for women with breast cancer. CEDM is a relatively new breast imaging technique based on dual energy acquisition, combining mammography with iodine-based contrast agents to display contrast uptake in breast lesions. It improves the sensitivity and specificity of breast cancer detection by providing higher foci to breast-gland contrast and better lesion delineation than digital mammography. Preliminary results suggest that CEDM is comparable to breast MRI for evaluating the extent and size of lesions and detecting multifocal lesions, and thus has the potential to become a readily available, fast and cost-effective examination. With a focus on the basic imaging principles of CEDM, this book takes a practical approach to breast imaging. Drawing on the editors’ and authors’ practical experience, it guides the reader through the basics of CEDM, making it especially accessible for beginners. By presenting the key aspects of CEDM in a straightforward manner and supported by clear images, the book represents a valuable guide for all practicing radiologists, in particular those who perform breast imaging and have recently incorporated or plan to incorporate CEDM into their diagnostic arsenal.
Low-dose Imaging Technique (LITE) MRI for breast imaging

By Dr. Federico Pineda, Dr. Deepa Sheth, and Dr. Gregory Karczmar

Breast MRI is the most sensitive imaging method for diagnosing breast cancer regardless of stage (pre-invasive or invasive) or type, and regardless of radiographic breast density [1]. Although it is presently only recommended for screening females at high risk of breast cancer, there is increasing evidence to suggest that it is equally useful for females at average risk [2]. One of the reservations against more widespread use of MRI use of a low-dose imaging technique (LITE) for breast DCE-MRI. In a recent article published in The British Journal of Radiology (BJR) we describe our initial experience with LITE MRI using 15% of the standard dose of GdBCA, 0.015mM/kg [6]. For this proof-of-principle study we imaged eight patients - a total of ten lesions - with imaging features most consistent with fibroadenoma on a 3T scanner. Fibroadenomas have rapid initial enhancement - similar to the initial kinetics seen in cancers – but are relatively homogeneous. Therefore, they provide a useful starting point for evaluating low-dose protocols that avoid confounding factors associated with the heterogeneity of cancers. We employed a dual-injection protocol, with an initial low dose, followed after 10 minutes by injection of the remaining 85% of a standard dose. The DCE protocol consisted of a combination of ‘ultrafast’ images [7](temporal resolution of 3.2-3.6 s) during the first 75 seconds after contrast injection, and high-spatial resolution images (temporal resolution of 61-79 s) interleaved with additional ultrafast imaging for the next 7 minutes. The same imaging protocol followed each administration of contrast media. Low and ‘(close to) standard’ dose sets of images were compared visually, and enhancement kinetics were compared quantitatively by measuring the mean signal enhancement in an ROI encompassing the entire enhancing lesion.

Nine of the ten lesions had measurable enhancement on both sets of DCE images (one lesion had no measurable enhancement for either dose). Figure 1 shows representative images for both low and standard dosage. As expected, signal enhancement was higher in the images acquired with a higher dose of contrast media, but the lesions were well visualized in the LITE images. Quantitative lesion conspicuity was higher in low doses than in the standard dose images – probably because the enhancement per micromole of contrast dose is higher at low doses than at higher doses; in other words, in lesions with high contrast uptake the effects of the contrast agent begin to ‘saturate’ so that contrast per unit dose decreases. The mean conspicuity (defined as signal increase in the lesion divided by signal increase in the surrounding uninvolved parenchyma) in the low-dose images was $1.48 \pm 0.15$ times higher than in the standard-dose images. Signal enhancement rates (how much relative enhancement increases in the lesion per unit time) were, on average, higher in the LITE images as well, although this difference was not significant (with a low-to-standard ratio of $1.22 \pm 0.4$). Post-contrast SNR, upper limit of enhancement,
and initial area under the uptake curve (iAUC), were all higher in the standard-dose images. However, the dose-normalized parameters (parameters for low dose images divided by the low dose; parameters for high dose images divided by the higher dose) are improved for the low dose relative to the high dose [Figure 2]. This suggests that lower doses may provide greater sensitivity to contrast media dynamics, this can be observed in the enhancement curves shown in Figure 3. In addition, quantitative analysis of low dose data is less subject to artifacts; at higher doses of GBCAs the effects of contrast media on T1* and exchange of water between the intracellular and extracellular spaces may change the measured enhancement kinetics. The results found in this study are consistent with a similar study performed in prostate imaging [8]. In that study He et al found that the signal enhancement rate from low-dose images better distinguished between prostate cancer and benign prostate tissue, and that the enhancement rates for both cancers and benign tissue were higher in the low-dose images.

While this preliminary study included only a small number of cases and one type of lesion, the results suggest that low GBCA dose breast imaging is clinically feasible and may offer some advantages over use of standard doses of contrast media. These encouraging results merit validation in a larger cohort that includes malignant lesions. If the trends observed in this study hold true, it is likely that the lower relative BPE in LITE MRI will translate to better visualization of malignant lesions (including less vascularized ones such as DCIS) than on routine MRI. All the images for this study were acquired on a 3T scanner, whereas most clinical breast MRI’s are performed at 1.5T. It is possible that the optimal dose may be greater for scans at lower magnetic field strengths, due to lower native T1’s; however contrast media relaxivity is higher at 1.5T than at 3T. The ideal dose of contrast media is one that delivers high image quality, allows accurate measurement of intrinsic lesion kinetic parameters, and maximizes patient safety and compliance with screening. This ideal dose will depend on several factors including magnetic field strength, type of breast coil used, imaging sequence parameters, and GBCA used. While it is not possible to exhaustively research the ideal dose for each scanner and site, the results of this pilot study show that imaging with low doses of GBCAs should be given serious consideration.

LITE MRI has the potential to be equivalent to standard-dose DCE-MRI in the detection of enhancing breast lesions, and may provide advantages for quantitative analysis. Growing concerns related to deposition of gadolinium in the brain may be addressed with low-dose contrast administration, increasing screening compliance and long-term patient safety.

REFERENCES

**Spiral Breast CT: an innovative technology for high resolution real 3D breast imaging without compression**

By E Bärnklau-Gooriah, V Ruth, Dr. C Steiding & Dr. D Kolditz.

Even when using images acquired by the latest high-tech breast imaging devices and read by experienced radiologists, the accurate diagnosis of early breast cancer remains challenging. The well-established conventional diagnostic breast imaging modalities all have well-known limitations. In contrast, 3D imaging of the breast at high isotropic resolution offers clear advantages. A dedicated breast CT system, nu:view developed by the German company AB-CT - Advanced Breast-CT, incorporates innovative technology that has the potential to take breast imaging to a new level. The new system provides high resolution 3D imaging of the breast at a very low radiation dose and without the need for any compression. To achieve this, nu:view uses state-of-the-art direct conversion photon-counting detector technology combined with a spiral CT acquisition concept. The CE-marked scanner is commercially available and is already in use with patients in Europe. This article gives an overview of the breakthrough technology as well as the clinical experience already obtained with the system in the University Hospital of Zurich, Switzerland.

**SPIRAL CT WITH PHOTON-COUNTING DETECTOR**
The design of the new nu:view scanner allows compression-free imaging of one breast at a time. To do this, the breast CT system uses a rotating gantry on which the X-ray tube and detector are mounted. During the image acquisition process, the gantry rotates around the breast in a downwards-oriented spiral trajectory. In the course of a single 360° rotation of the gantry around the breast, up to 2,000 projection images are acquired. A full spiral scan takes as little as 7 – 12 seconds. Exceptional image quality at a low radiation dose is possible, because the data acquisition is carried out by a dedicated, curved single photon-counting detector, which is the result of AB-CT's long-term technical collaboration with the Swedish company Direct Conversion. The nu:view scanner is the world's first CT in clinical use equipped with a direct converting detector. It features a pixel size of (100 µm)² and a frame rate of up to 1,000 Hz.

Unlike traditional scintillation methods used in conventional CTs which convert X-rays into scattered light, in the nu:view photon detector, every single photon is directly converted into electrical energy, thus avoiding scattering effects and resulting in a much higher image quality. The unique combination of the detector's highly sensitive cadmium telluride (CdTe) material with its dedicated shape allows for highest image quality and dose efficiency.

**HIGH PATIENT COMFORT**
The scanner is only 1.10m high which is easily accessible by the patient with the help of a step. The patient table is protected with lead foil sheeting, thus preventing any unintended radiation reaching the patient. For the examination procedure, the patient positions herself prone on the scanner table with the breast to be examined conveniently placed into the aperture. This non-compressive approach keeps the female breast in its natural shape – not only does this avoid the problem of superimposed tissue, but it also makes the examination procedure totally pain-free for the patients. Consequently the patients feel more reassured in a situation which, inevitably, is often highly stressful. A small supporting pillow and footrest may be used to help stabilize the position of the patient who can breathe normally during image acquisition.

The entire examination process only takes between 3 – 5 minutes, from patient positioning on the scanner table; double-checking of the breast positioning by the radiographer; selection and confirmation of the scan parameters; the scan itself; right through to the final dismounting of the patient from the scanner table. The overall examination time may be slightly extended if contrast media is administered. The actual data-acquiring scan itself takes only 7 – 12 seconds, depending on the length of the breast.

Scan parameters are adjustable to accommodate various clinical requirements and patient types.
There are no restrictions regarding age or gender of the patient; the system is also suitable for patients with small breasts, dense breasts, mastodynia or implants. Advanced visualization techniques such as 3D volume rendering make the 3D high isotropic spatial resolution images a highly useful option for surgery planning. Likewise, the gentle, pain-free examination procedure also makes it suitable for post-operative follow-ups. As the images are acquired with the breast in its natural shape and without any “squeezing” of tissue, the three-dimensional images provide precise information about the exact location of the depicted lesion.

**FLEXIBLE SUPPORT OF CLINICAL WORKFLOWS**

Following image acquisition, the image data are transferred to nu:view’s reconstruction workstation which is the platform where highly sophisticated algorithms operate on image reconstruction before sending the images in DICOM format to the Picture Archiving and Communication System (PACS). The nu:view system does not require any custom viewing software, so radiologists can continue working in their familiar reading environment. Radiologists used to reading 3D images (e.g. from standard clinical CT or MRI), have confirmed that they find the 3D multiplanar reconstructions of the female breast easy and intuitive to read.

Nu:view offers two out-of-the-box protocols for acquisition and reconstruction: a Standard mode with a voxel size of (300 µm)³ and a HighRes mode with (150 µm)³ voxel size. Although the choice of these protocols always depends on individual circumstances, with the ultimate decision being made by the radiologist, the Standard mode is typically the preferred method for scrolling through soft tissue, before switching to HighRes mode e.g. for a more granular analysis of microcalcifications.

**CLINICAL RESULTS - INCREASED DETECTION OF EARLY CANCERS**

Clinical experience from the University Hospital Zurich (USZ), where the nu:view was first installed, confirms that breast CT provides high quality images and is a viable alternative to mammography or tomosynthesis, especially in those patients reluctant to undergo mammography because of the issue of breast compression. In the absence of an organized national screening programme in the canton of Zurich, breast CT is now being offered to women as an alternative to screening mammography at the USZ. Since the availability of the new system, breast cancer detection rates have notably increased. The senior consultant responsible for breast imaging at USZ, Prof. Andreas Boss has expressed himself to be very pleased with nu:view’s image quality. He attributes the increase in detected lesions primarily to the fact that women who had previously refused routine check-ups are now much more willing to undergo the potentially life-saving examination of their breasts.

In a recently published study [1] of the first 300 consecutive women who were examined using spiral breast CT at the University Hospital of Zurich (August 2018 to March 2019, age range: 35 to 84 years (mean age, 56.8 +/- 9.9 years)), a total of 591 acquisitions were performed. The main reason cited by the women for their preference of the breast CT system over mammography was the lack of breast compression. Out of the 300 women in the trial, 254 (84.7%) explained that they preferred the breast CT for personal reasons or

The nu:view dedicated breast CT scanner is highly appreciated by the patients because no breast compression is needed.
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mammary glands, while 10 patients (0.3%) had implants hampering conventional mammography.

The scans were performed with an initial tube current of 25 mA which later was routinely increased to 32 mA for better image quality (at a fixed X-ray tube voltage: 60 kV).

The breast CT system detected 102 possible lesions, including 4 cases of breast cancer (1.3% of all patients). Additional ultrasound was performed in 226 patients (102 due to detected lesions and 124 due to dense breast tissue).

Three malignant lesions were detected in an additional ultrasound (1% of all patients). None of the examinations showed any movement artifacts. In 99% of all women, the examination was carried out without any problems, demonstrating the “already high degree of technical maturity of this new breast imaging modality” [1]. Out of the 300 patients, nine suspicious lesions were biopsied, resulting in seven confirmed malignancies (2.3% of the examined patients). Four of the lesions were seen in breast CT (1.3%), 36 lesions were rated BI-RADS 3 (12%). Those numbers are much higher than the number of malignant lesions typically found in breast screening mammography programs, which detect about three to four cancers in 1000 patients (0.3%-0.4%) [4, 1].

These findings are in line with Prof. Boss’ personal observation who noted that the modality proved to be particularly beneficial for women who did not want to undergo breast compression, for reasons ranging from inconvenience or personal dislike to deep-rooted fear: “I cannot emphasize enough the importance of this method being completely compression-free. Some women had missed their breast checks for years because they feared compression. Breast CT really solves their dilemma…”

Prof. A Boss

Combining high resolution images with high dose efficiency, the nu:view system was developed to support radiologists to reliably diagnose breast cancer at the earliest possible stage. With high resolution, non-superimposing isotropic 3D images and excellent soft tissue differentiation, the innovative spiral breast CT integrates the strengths of mammography/tomosynthesis and MRI technologies in one system, providing a valuable tool for diagnostic breast imaging.

REFERENCES


FURTHER READING

Mammography has been proven to reduce deaths due to breast cancer in women aged 40-74; however, there is growing understanding that screening with mammography alone may not be enough in women with higher risk and/or dense breasts. While the European Society of Breast Imaging (EUSOBI) attributes a 40% reduction in breast cancer mortality to population-based screening [1], breast cancer remains the most prevalent cancer among women across Europe with more than 523,000 new cases each year (after excluding non-melanoma skin cancers), and the third most common cause of cancer death in Europe (after lung and colorectal cancers) [2].

Breast density is the most common factor that may prompt women to seek additional screening beyond mammography to increase the likelihood of early cancer detection. Recently published results from a number of large-scale studies have demonstrated improved breast cancer detection and decreased interval (symptomatic) cancer rates associated with supplemental screening of women with dense breasts. This includes the DENSE trial, recently published in the New England Journal of Medicine [3]. The study, “Supplemental MRI Screening for Women with Extremely Dense Breast Tissue” spanning an eight-year period, is the first randomized controlled study on the clinical utility of breast MRI supplemental screening for women with extremely dense breasts. Results showed that the interval cancer rate was reduced from 4.9/1000, in the control group with mammography alone, to 0.8/1000 among women having supplemental MRI every other year, with MRI identifying another 16.5 cancers per 1000 women screened after negative mammography.

In our recent article, “Screening Breast Ultrasound Using Handheld or Automatic Technique in Women with Dense Breasts” [4], we reviewed outcomes from the literature on more than 400,000 screening ultrasound exams in women with dense breasts. Both handheld and automated techniques consistently reveal an additional 2-3 cancers per 1000 women screened, that are not seen on mammography. Nearly 90% of cancers found on screening ultrasound are invasive and node negative, i.e. those with the most favorable prognosis.

Despite a growing body of evidence that demonstrates the beneficial effect of supplemental screening in dense breasts, the widespread adoption of supplemental screening has been hampered, in large part, by the lack of consistent guidelines. Moving forward, education may be one of the most important tools in advancing the importance of supplemental screening and understanding that mammography does not perform equally well in all women.

ADDRESSING THE NEED FOR MEDICALLY SOURCED DENSITY INFORMATION

Most women in Europe do not have a choice to pursue supplemental screening independent of their healthcare providers or government-sponsored screening. DenseBreast-info.org (DB-I), and subsequently DB-I/Europe (https://eu.densebreast-info.org/), was launched to provide education to healthcare professionals about the screening and risk implications of dense breast tissue and value of supplemental screening. This educational goal is supported by availability of our CME opportunity, Breast Density: Why it Matters through the European Accreditation Council for CME. Other educational features on the European website include:

- Dense Breast Primer for health care providers
- An interactive map featuring screening guidelines for each specific country
- A comprehensive list of FAQs with literature citations
- An easy-to-follow screening flowchart
- An illustrated explanation of screening technologies

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Healthcare professionals need to know that having dense breasts is a normal condition that is found in 40% of European women age 40-74 years old. Compared to women with predominantly fatty breasts, women with heterogeneously dense and extremely dense breasts (BI-RADS category C or D respectively) have a 2-fold and 4-fold relative risk of developing invasive breast carcinomas respectively [5]. More importantly, breast density hampers the detectability of breast cancer on mammography due to its “masking effect.” This significantly decreases both the sensitivity and specificity of mammography. Cancers are more likely to present due to symptoms after a normal mammogram in women with dense breasts (“interval cancers”) and may be detected later with worse prognosis. Mammography alone may not be adequate screening in such women. Due to its clinical importance, breast density has been incorporated into the Tyrer-Cuzick (IBIS v.8) and Breast Cancer Surveillance Consortium risk models that are used to determine which women are at high risk and should have MRI or consider risk-reducing medications, respectively.

UNEQUAL ACCESS TO SUPPLEMENTAL SCREENING

Nearly all European countries offer national breast cancer screening programs to comply with the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis [6]. However, there is variation in both the reporting of breast density to medical providers and the implementation of risk-stratified screening. This lack of consistent European-wide guidelines results in unequal access to supplemental screening — with the potential for sub-standard care. Two countries that stratify screening based on

### Comparative Analysis Sample - National Breast Screening Guidelines in Europe

<table>
<thead>
<tr>
<th>Country</th>
<th>Age to Start/Stop</th>
<th>Recommended Screening Interval</th>
<th>Breast Density in Medical Mammography Reports (BI-RADS categories used)</th>
<th>Screening Guidelines on Dense Breasts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>45ª / 59ª</td>
<td>Every 2 years</td>
<td>Yes</td>
<td>Screening ultrasound is standard in addition to mammography in women with heterogeneously dense or extremely dense breasts.</td>
</tr>
<tr>
<td>Cyprus</td>
<td>50 / 59</td>
<td>Every 2 years</td>
<td>Yes</td>
<td>If breasts are heterogeneously or extremely dense, ultrasound beginning 6 months after the screening mammogram and continuing annually.</td>
</tr>
<tr>
<td>France</td>
<td>50 / 74</td>
<td>Every 2 years</td>
<td>Yes</td>
<td>Supplemental ultrasound is recommended in women with heterogeneously and extremely dense breasts.</td>
</tr>
<tr>
<td>Germany</td>
<td>50 / 86</td>
<td>Every 2 years</td>
<td>No</td>
<td>No national guidelines.</td>
</tr>
<tr>
<td>Greece³</td>
<td>40 / 72</td>
<td>Annual</td>
<td>Yes</td>
<td>Opportunistic screening; Most centers offer supplemental ultrasound to women with dense breasts.</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>50 / 70°</td>
<td>Every 3 years</td>
<td>No</td>
<td>No national guidelines.</td>
</tr>
</tbody>
</table>

* Opt-in possible to begin at age 40; opt-in also possible to continue after age 69
* No national screening program; opportunistic screening only
* Women over age 70 may self-refer

For additional information about screening guidelines by country, please visit the European interactive map at DenseBreast-info.org

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Table 1. DB-I/Europe’s Screening Guidelines’ chart and interactive map (excerpted above) provide information on five key data points: Screening Process, Screening Technologies, Breast Density Notification, Payment/Reimbursement and High-Risk Screening. https://eu.densebreast-info.org/, Table ©2020 DenseBreast-info.org
breast density are France and Austria where women with heterogeneously or extremely dense breasts are routinely offered supplemental physician-performed US screening.

“REQUEST FOR DENSITY” TEMPLATE

However, in the UK, breast density is not part of data collection in the UK national screening programme; therefore it is neither recorded, nor reported. Cheryl Cruwys, DB-I’s European Education Coordinator, is English but currently lives in France where breast density composition is included in mammography screening reports. As she was frequently contacted by UK women concerned about their breast health and breast density, Cheryl developed the ‘Request for Density’ template (clickable here) to provide an educational, communication tool between patients and radiologists to encourage informed conversations. [Figure 1, overleaf]. Following a small trial, feedback was positive; breast radiologists responded, providing women’s breast density compositions and offering to answer any further questions. Some women who were informed that their breasts were BI-RADS category C/D pursued discussions with their imaging experts to discuss their screening options.

Opportunist mammography exists in some countries either as the sole screening system or in addition to the national breast screening program. In opportunistic screening, women are advised by their physician or they decide on their own to have a screening mammogram, and programmatic results are not officially monitored. In these countries, access and implementation of breast density reporting and supplemental screening is ad hoc – left to the discretion of individual physicians or imaging practices.

Dr Vourtsis comments: “While there is no national screening program in Greece, I believe it is important for women to have ongoing screening, which is why I have always performed an individualized approach to breast evaluation in my practice. Throughout the years, I have informed my patients about their breast composition and the potential benefits of supplemental screening”.

BEYOND MAMMOGRAPHY: WHERE DO WE GO FROM HERE?

Mammography remains the primary screening method for breast cancer as it is proven to reduce breast cancer mortality. However, we also know that not all women benefit equally and women with high breast density are at high risk for interval cancers due to the reduced sensitivity of screening mammography. As breast imaging professionals, we have a responsibility to investigate any and all methods of improving screening and reducing interval cancers.

Launched in October 2018 in conjunction with publication of the European Radiology article, *Breast Density Implications and Supplemental Screening*, [7] DB-I/Europe (https://eu.densebreast-info.org) is the only breast density educational website developed specifically for European medical healthcare professionals. We continue to focus on raising awareness through coalition building and social media support from European Federation of Radiographer’s Societies, Society/College of Radiographers, European Society of Radiology, eCancer and various patient breast-cancer groups.

At the time of launch, 14 Education Ambassadors represented 11 countries, including Austria, Croatia, Cyprus, France, Germany, Greece, Italy, Serbia, Spain, and United Kingdom. We have since expanded to include Iceland, Lithuania, Norway, Portugal, and Turkey. We will continue to add country-specific screening information and advance education to the medical community in order to set a standard of care for screening women with dense breasts.

Working with the European Education Ambassadors and other thought leaders throughout Europe, we are creating a European Coalition for breast density working to establish clear and consistent guidelines that ensure high quality breast cancer screening. Such screening should be consistently and equitably accessible across Europe.

REFERENCES

1. Sardanelli F, Aase HS, Álvarez M et al. Position paper on screening for breast cancer by the European Society of Breast Imaging (EUSOBI) and 30 national breast radiology bodies from Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Israel, Lithuania, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland and Turkey, Eur Radiol (2016). doi:10.1007/s00330-016-4612-z


Dear Sir/Madam,

I am writing with regards to my mammogram (information below).

It is my understanding that information about the category of my breast density would have been determined by the radiologist who read my mammogram.

I am aware of the two-fold issue of breast density, firstly that mammograms are not as effective for dense breasts as dense tissue can ‘mask’ cancer and secondly, that the denser the breast, the greater the risk of developing breast cancer.

Therefore, I write to request the category the radiologist assessed my breast density to be. (A: Fatty; B: Scattered areas of Density; C: Heterogeneously Dense or D: Extremely Dense).

I would like this information because I believe awareness of my breast density is important information for me to have to participate in my own breast health surveillance.

My information can be sent to me by email or mail (below). Thank you, in advance, for your assistance.

Signature: __________________________________________________

Name (in capitals): _____________________________________________

Date: __________________________

Address: _____________________________________________________

______________________________________________________________

Email: _______________________________________________________

For a comprehensive, medically-sourced resource, visit DenseBreast-info.org

**Figure 1.** Letter used in UK for patient to request breast density category
A recently published article [1] described the results of a clinical trial to assess the effect of a patient-assisted breast compression system on image quality, radiation dose and patients’ perception pain and discomfort during the mammography procedure. The results showed that patients preferred to participate actively in the breast compression procedure as compared to the standard system controlled by the breast technologist.

We wanted to know more about the trial and the implications of the results, so we spoke to Morgane Cousin, senior radiographer at the Gustave Roussy Institute, the renowned cancer hospital located in the suburbs of Paris.

**Q** How many examinations for breast cancer do you carry out in the Breast Unit of Institut Gustave Roussy?

We see more that 12000 women each year in our breast care department, of which the vast majority are symptomatic/diagnostic cases or examinations of women at high-risk of breast cancer. However since October 2018 our department has also accepted asymptomatic women for screening. We have all the breast imaging modalities: we have three mammography systems, capable of tomosynthesis and angiomammography (CESM); three ultrasound systems, and two MRIs. Of our mammography systems, only one — the Pristina model from GE — is currently equipped with the patient-assisted compression device but we are expecting a second Pristina to be installed soon.

We perform around thirty mammograms and ultrasounds per day in addition to breast interventions involving approximately ten biopsies per day.

**Q** Now let’s get on to the patient controllable breast compression system itself

The auto compression system from GE is composed of a remote control unit known as Dueta which is connected to the Pristina mammography unit via a wifi connection. The Dueta is fitted with 2 buttons, a + button to increase compression, with a maximum of 20 decaNewtons (daN), and a - button for decompression, which is decreased by 1daN for each push of the button to a minimum of 3daN decompression. It’s always important that the technologist/radiographer first explains to the patient the general importance of having good compression in mammography before giving the patient the compression control device.

In practice, the technologist always begins the examination by first positioning the patient’s breast on the paddles and initiating minimal compression to ensure proper positioning of the breast and its immobilization. Then, through use of the remote control, the patient can play an active role in her own breast examination by applying compression herself. Throughout the examination, the technologist directs, controls and remains responsible for the successful completion of the mammogram. The technologist stays with the patient to accompany her during the compression process and can intervene at any time.

The self-compression system can be used for both standard mammograms and tomosynthesis (tomosynthesis is a key part of our work protocols, except for women aged under 30 or high-risk women).

One practical point is that when the patient holds the remote control during the examination, she often wants to look at the buttons she will be...
pressing, even though the buttons are distinguishable by touch. When looking at the compression controller, the patient often involuntarily raises the device to get a better view, so moving her arm, which can then induce a movement of her breast. To avoid this, it is therefore important that the patient holds the remote control unit in the contralateral hand.

**Q** What was the design of the study that you carried out to evaluate the breast compression system?

The study [1] was carried out on 100 patients, over a period of six months, from October 2016 to March 2017. The average age of the patients was 59 years with a minimum age of 34 years and a maximum age of 89 years. The essence of the study involved comparison of the performance of the Patient-Assisted Compression (PAC) procedure on one breast with the standard Technologist Compression (TC) on the other breast, so in our study we only included women who needed bilateral mammograms, with or without tomosynthesis.

The technologist positions one breast and carries out the complete compression process and cranio-caudal (CC) image acquisition on this breast. Then the technologist initially positions and starts the compression on the contralateral breast before handing the Dueta control unit to the patient so that she can control the whole compression process. The same procedure is used for the MedioLateral Oblique (MLO) acquisition. Data on the procedure were collected during the mammogram via a questionnaire filled out by the operator. This form was used also to record the patient's comments about the procedure.

The radiologists interpreting the images were blinded to which images were acquired either by the standard technologist-imposed compression or by the patient-assisted compression.

**Q** And the results?

See Table 1.

**Compression levels.**

Compression was significantly higher with the patient-assisted compression (PAC) than with technologist compression (TC) for both CC (median difference 2.0 daN, \( p < 0.0001 \)) and MLO views (median difference 1.5 daN, \( p < 0.0001 \)).

**Breast Thickness on compression.**

The average breast thickness under compression in the CC view was 52.6 mm (range 23-84) and 54.1 mm (range 24-82) for PAC and TC respectively. For the MLO view the average breast thickness and 55.7 mm (range 22-97) and 58.2 mm (range 24-104) for PAC and TC, respectively. The median difference was significant for CC view.

**Radiation dose.**

In CC view, the Average Glandular Dose (AGD) was 1.35 mGy with the use of patient-assisted compression and 1.36 mGy with the technologist compression. In MLO view, the AGD average was 1.38 mGy with self-compression and 1.45 mGy with technologist compression.

**Image quality.**

In 85% of cases, the image quality between the two techniques was judged by the blinded radiologists to be equivalent. In 10% of the cases the radiologists considered the image derived from the patient-assisted compression to be superior to the technologist compression and in 5% of the cases inferior.

**Effect on the work flow, the time that the patients remain under compression.**

In our study we found little impact of the Patient-Assisted Compression on the work flow. In our department, the usual examination time for a mammogram is between 12 and 15 minutes, which can be explained by the complex nature of the cases we care for. When using the new system, 4% of the technologists found that the procedure was faster using patient-assisted compression, 16% found the time longer with auto-compression but the vast majority of technologists found that the examination time was the same for the two techniques.

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**Table 1.** Comparative results of patient-assisted compression (PAC) and Technologist compression (TC) for compression force, breast thickness and average glandular dose

<table>
<thead>
<tr>
<th>Technical Parameters</th>
<th>Patient-Assisted Compression (PAC)</th>
<th>Technologist Compression (TC)</th>
<th>Difference PAC-TC</th>
<th>( p )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compression force (daN)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC view</td>
<td>10 (3 ; 18)</td>
<td>8 (3 ; 17)</td>
<td>2 (7 ; 8)</td>
<td>( &lt;0.0001 )</td>
</tr>
<tr>
<td>MLO view</td>
<td>9.5 (4 ; 19)</td>
<td>8 (3 ; 15)</td>
<td>1.5 (9 ; 10)</td>
<td>( &lt;0.0001 )</td>
</tr>
<tr>
<td><strong>Thickness (mm)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC view</td>
<td>52.2 (23.3 ; 84.3)</td>
<td>54.1 (24.1 ; 62.3)</td>
<td>-1.90 (-19.6 ; 25.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>MLO view</td>
<td>55.7 (21.8 ; 97.2)</td>
<td>58.2 (4.1 ; 1.04)</td>
<td>-0.20 (-29.0 ; 39.9)</td>
<td>0.76</td>
</tr>
<tr>
<td><strong>Average Glandular Dose (mGy)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC view</td>
<td>1.35 (0.76 ; 2.66)</td>
<td>1.36 (0.84 ; 2.90)</td>
<td>-0.03 (-1.15 ; 1.22)</td>
<td>0.02</td>
</tr>
<tr>
<td>MLO view</td>
<td>1.38 (0.58 ; 2.65)</td>
<td>1.45 (0.96 ; 4.33)</td>
<td>-0.02 (2.5 ; 8.7)</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Abbreviations: CC cranio-caudal view; MLO mediolateral oblique view; PAC patient-assisted compression; TC technologist compression.

Table adapted with permission from Ref 1 Balleyguier et al, courtesy of Eur J Cancer.
Many women who participated in the trial said that the use of the Dueta device made them feel that they were actively participating in the imaging process, and specifically requested the device for follow-up imaging appointments.

90% of the technologists found that the explanations that had to be given to the patient did not take much time and did not affect the total duration of the exam.

**Patient perception of pain/discomfort**

Of the patients in our study, 92% of them had not used the self-compression system before.

After they had their mammogram with the new system, 90% of them reported that they found the system useful and 74% stated that they would be more reassured for their next examination.

The patient assessed pain using a visual analog scale (VAS), classifying the feeling of pain as follows:

- 0 to 3: Not painful examination
- 3 to 5: Exam considered as bothersome
- Greater than 5: Painful

Of the entire group studied, 70% of the patients reported that their mammography was not painful; 17% considered it as bothersome and 13% reported it as painful. The difference between the level of discomfort and pain experienced in the two compression systems as measured by the VAS was not significant (p value = 0.60).

The pain reported by the patients was predominantly associated with the breast in which a lesion had previously been detected, no matter which compression regime was used. (66% of the patients in our study were symptomatic or had been treated or operated on whereas the remaining 34% of the patients were undergoing screening mammography or were high-risk patients but symptom-free).

**And what are the implications of the results of the study?**

Well, one implication is that we definitely intend to continue using the self-compression device with our patients. In fact, patients who have already used the system frequently specifically request the system on their follow-up visits. Since currently not all of our mammography systems are fitted with the Dueta system, we can’t schedule this automatically for all our patients but with the arrival of our new Pristina mammography system we will be able to offer the possibility of self-compression to more patients.

As mentioned above, another effect is that with the explanation that the technologist gives to the patient about the reason for and importance of compression, she feels more involved in the whole procedure and has a greater desire to participate in order to achieve a positive result in image quality and to reduce the required radiation dose by optimal compression.

**And the future?**

The future I see is a continuation of the effort to make mammography/tomography more acceptable to women by minimizing the discomfort they experience during the procedure. In my opinion and based on our experience self compression is definitely part of this future and means that the “dreaded” compression may no longer be so daunting for women in the future.

In addition to the technical aspects of image quality and reduced radiation dose provided by the self-compression system as shown in our study, there is also the additional psychological benefit for the patient, who feels, correctly, that she is taking an active role in her mammography examination.

The combined effect of all this could be less resistance by women to be screened and be followed by mammography.

**REFERENCE.**

How do I measure mammographic breast density? Let me count the ways

By Dr. Jennifer Stone

Mammographic breast density is both one of the strongest predictors of breast cancer risk [1-3] and substantially reduces the sensitivity of mammography to detect the disease [4-6]. However, the clinical use of mammographic breast density to help identify and target women at increased risk is limited, largely due to issues regarding its measurement.

Historically, Wolfe first described an association between four ordinal parenchymal patterns (visually assessed from mammograms) and increased breast cancer risk [7, 8]. Development of the Cumulus software [9, 10] provided a semi-automated continuous measurement of mammographic breast density. Led by Boyd [10-16], Cumulus facilitated over 3 decades of epidemiological and clinical study of the etiology of mammographic breast density and its association with breast cancer risk and screening outcomes. Clinically, the most common measure is BIRADS (Breast Imaging Reporting and Data System), developed to alert radiologists about reduced sensitivity of mammography in women with dense breasts. Like Wolfe’s parenchymal patterns, BIRADS is a visual categorical measurement (A—almost entirely fat; B—scattered density; C—heterogeneously dense; D—extremely dense) that is often subject to low inter- and intra-observer reliability [17]. Cumulus measures are also prone to observer subjectivity and the software is not suited for large scale clinical use. However, all of these robust measures are both associated with the risk of breast cancer [1, 3] and the risk of a cancer going undetected [12, 18], also referred to as “masking”. More recently, there are dozens of other measurement techniques that provide automated and continuous measures of mammographic breast density that are also associated with breast cancer risk and/or risk of masking [19, 20].

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First, to determine the optimal measures in terms of predictive power to discriminate between women who will or will not become diagnosed with breast cancer, an equal playing field is required. The literature is littered with reports of the latest and greatest ways to measure mammographic breast density. A common set of images enables a platform to apply and compare different measurement techniques. Sufficient sample sizes of case-control FFDM image sets in which to estimate odds ratios and/or OPERAs (odds per adjusted standard deviation) [2] with adequate estimates of precision (95% confidence intervals) are also needed. The Measurement Challenge includes 1650 cases and 1929 controls from 5 countries, providing robust assessment of which measurement technique “best”
predicts breast cancer risk within different screening settings. However, stratification of analyses by sub-groups significantly reduces power and precision of estimates. For example, different vendors of mammography machines apply different processing algorithms to FFDM images to improve cancer detection for radiologists. Processing of the mammogram alters the appearance of density. Some measurement techniques should only be applied to non-processed images to avoid measurement error [23, 24, 26-28]. Others have adapted their techniques to accommodate processing since non-processed images are not typically available/stored within screening programs, but are limited to certain vendors [29, 30]. These different techniques can only be compared within case-control sets that have both image types (non-processed and processed) available.

Within the Measurement Challenge, over 1000 cases and nearly 1300 controls have both processed and non-processed FFDM images available for measurement and comparison however, these images are from only two vendors, GE and Hologic.

Second, the predictive power of the measures should be robust across different populations. In particular, while there are ethnic differences in mammographic breast density measures which are consistent with the corresponding breast cancer incidence rates [31, 32], an exception occurs with comparison of East Asian and Caucasian populations [33, 34]. On average, East Asian women tend to have smaller, denser breasts (at least in percentage area) compared with European women despite their breast cancer incidence being lower. This is thought to be related to breast size, body mass index (BMI) and whether the density measure is a volume or an area.

The case-control image sets included within The Measurement Challenge are largely from European/Caucasian populations with only a small image set from Chinese Malaysian women.

Third, the mammographic measure should be readily usable within a clinical setting. Many practical issues are related to the infrastructure of the screening program. As mentioned previously, processed images are not typically stored within screening programs. Issues of double (processed and non-processed) image transmission and storage require consideration and suitable infrastructure. Questions of cost, ease of use and implementation also impact the uptake of available software, particularly in public screening settings. Also, widespread implementation of tomosynthesis for screening, particular in the US, requires adaptation of measurement techniques to suit 3D mammography.

Even in the absence of evidence-based screening recommendations for women with dense breasts, consumer advocacy for mammographic screening programs to measure and report mammographic breast density is increasing. In the US, the FDA is currently developing language for a national minimum standard for ‘breast density’ notification, where all screened women are to be informed of their mammographic density. Screening programs in Canada have also introduced ‘breast density’ notification protocols. The literature describing the impact of ‘breast density’ notification on screening populations is largely American [35] and more research is needed to investigate ways to educate both women and health professionals about mammographic breast density and breast cancer risk.

In the future it is hoped that the Measurement Challenge or similar initiatives will inform screening programs about the measure(s) that best predict breast cancer for their population and across different vendors and image types. There is considerable literature supporting the role of mammographic breast density measurement in breast cancer screening [17, 36, 37]. The implementation of optimal automated mammographic measures will support the development and standardization of mammogram-based risk measures that can reliably determine groups of women at substantially different levels of risk. There is increasing evidence to support tailored screening programs whereby risk factor information collected at the time of mammography is used to identify different risk groups who could potentially benefit from either modified screening intervals and/or supplemental screening using alternative modalities [38-40]. Risk prediction tools, validated within the targeted screening population, can be modified/improved to incorporate one or more mammographic measures into the models to stratify women into these different risk groups [41-43]. Ultimately, the implementation of mammogram-based risk measures could lead to more effective and efficient screening programs.

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BIRADS is a visual categorical measurement (A-almost entirely fat; B-scattered density; C-heterogenously dense; D-extremely dense) that is often subject to low inter- and intra-observer reliability.

"... the Measurement Challenge facilitates access to mammographic images from breast cancer case/control sets by as many measures as possible for comparison of their abilities to predict breast cancer risk..."
SUMMARY

There is a clear and present need to identify the optimal and automated mammographic measures of breast cancer risk for standard use by screening programs. To help achieve this, the Measurement Challenge facilitates access to mammographic images from breast cancer case/control sets by as many measures as possible for comparison of their abilities to predict breast cancer risk. The Measurement Challenge is an ongoing collaboration and we are continuing to expand the resource to include additional image sets across different populations.

MORE INFORMATION AND CONTRIBUTING CASE-CONTROL SETS

Anyone interested in receiving more information and/or contributing case-control sets of FFDM images or participating as a challenger, please contact jennifer.stone@uwa.edu.au.

REFERENCES:

39. https://www.athenacarenetwork.org/wisdom-study 2017 [ ]
Range of mammography products

The 3Dimensions Mammography System from Hologic is the industry’s fastest and highest resolution breast tomosynthesis system on the market. The system offers a variety of features designed to provide higher quality 3D images for radiologists, and enhanced workflow for technologists, with low-dose options, for patients. For example, the system includes Intelligent 2D imaging technology, which works with the system’s Clarity HD high-resolution 3D imaging to deliver unprecedented clarity, contrast and detail at a lower dose.

Another feature available with the 3Dimensions system is the Quantra 2.2 breast density assessment software, which enables standardization in patient protocols, providing reproducible and consistent breast density assessment. Furthermore, thanks to the addition of the SmartCurve breast stabilization system, the 3Dimensions system is also clinically proven to deliver a more comfortable mammogram compared to standard compression, without compromising on speed, dose or accuracy.

Hologic also offers other products for interventional breast operations: The Brevera Breast Biopsy System with CorLumina Imaging Technology is a real-time breast biopsy and verification system that improves the patient experience and streamlines the biopsy process from start to finish. Before the Brevera system, radiologists performing stereotactic breast biopsy procedures were often required to leave the patient under compression while they moved to another room to image and verify tissue samples. With the Brevera system, radiologists are able to obtain and image tissue samples in the procedure room in just a few seconds, potentially saving up to 10 minutes per patient and cutting the procedure time by up to 25 percent.

The Affirm Prone Breast Biopsy System is the only dedicated prone biopsy system offering superior 2D or tomosynthesis imaging. Thanks to this high-quality 2D or tomosynthesis imaging and a field of view that’s more than 6.5 times larger than older generations of prone biopsy systems, clinicians can visualize more tissue and pinpoint subtle lesions and faint calcifications that may not be visible on older systems. Of note, more than 95 percent of patients reported their Affirm prone biopsy procedure was faster, more comfortable and less painful than expected. The system is designed with patients’ physical and emotional comfort in mind.

Hologic,
MALVERN, MA, USA
www.hologic.com

12 Megapixel Color Monitor for Multi-Modality Medical Applications

EIZO have announced the release of their RadiForce RX1270 monitor, a 30.9-inch, super-high-resolution 12-megapixel color monitor ideal for multi-modality medical applications.

The monitor was developed in response to the persisting need for radiologists to read and interpret a wide variety of medical image types. The RX1270 is EIZO’s highest resolution monitor at 12-megapixels (horizontal 4200 x vertical 2800 pixels). The resolution is approximately 1.3 times larger than EIZO’s former highest 8-megapixel (horizontal 4096 x vertical 2160 pixels) monitor. This allows an even wider range of medical images to be viewed at once, including high volume images displayed in full, for increased reading efficiency. Consistent with EIZO’s line of multi-modality monitors, the RX1270 automatically distinguishes between monochrome and color, ensuring faithfully reproduced images for any modality.

The stark contrast of the low-light in reading rooms and a bright screen are often a cause of eye fatigue. To combat this, the RX1270 features a built-in comfort light that gently illuminates the wall behind the monitor without interfering with the visibility of the image. An adjustable spotlight is also attached to make reading documents easier.

To facilitate more efficient diagnostic image viewing, EIZO’s unique Work-and-Flow functions are also included with the RX1270. The Point-and-Focus function allows users to highlight specific areas of the screen for deeper interpretation. The Hide-and-Seek function allows a secondary input to be displayed in the corner of the screen for quick referencing without needing an additional monitor. The Switch-and-Go function allows two PCs to be controlled with a single mouse and keyboard via a simple mouseover movement.

EIZO
HAKUSAN, ISHIKAWA, JAPAN
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Siemens Healthineers has introduced its new Somatom X.cite single-source CT scanner, together with the totally new myExam Companion user guiding system, based on algorithms developed through artificial intelligence (AI). The intelligent user guidance system pilots the med-tech through the workflow using specific questions. This intuitive user interface and the latest scanner hardware all work together to open up vast new possibilities. myExam Companion makes use of available patient data, such as sex, height, and age, and combines these with additional patient-specific information gathered by asking the user specific questions, for example about the presence of metal implants or the ability of patients to hold their breath. The scanner then optimizes the scan parameters accordingly to ensure the best possible scan conditions. In combination, these innovations help structure workflow more efficiently, smooth out differences in experience between the technicians, and achieve extremely high-quality results even in difficult diagnostic situations. The first CT scanner with myExam Companion incorporated is the new Somatom X.cite, featuring a Vectron x-ray tube that has previously only been used in Siemens’ Somatom Force dual-source CT scanner. In combination with its 82 cm gantry, Somatom X.cite can offer unprecedented image quality in the single-source segment, in addition to maximum patient comfort.

“We have been testing Somatom X.cite with the new software platform for the past two months with successful results. We have been impressed not only by the excellent images but also by the way the new user guidance system made the workflows faster. Also The large gantry width facilitates the examination of seriously ill patients”, commented Professor Christoph Stippich, Chairman and director, Department of Neuroradiology, University Hospital Zurich.

The very large 82 cm gantry of Somatom X.cite and its pleasant lighting offer a high level of comfort for the patients. The medical technologists can prepare and perform the scan using removable tablets that are connected to the scanner via wi-fi and stored magnetically at the scanner. That means the technologists can remain alongside the patients until immediately before the scan and ensure the patients are better prepared. While the scan is in progress, the patients are instructed not only via the speaker on how to breathe, but also visually, using an easy-to-follow display. The med-techs keep their patients in view via a 2D camera integrated in the housing of the gantry. This all helps the patients’ sense of well-being and enables them to cooperate as much as possible during the scan. An optional 3D camera gathers additional information on the patients’ anatomy and automatically positions them in the isocenter.

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“Staff shortages, insufficient time, the development of standards for high quality diagnostics and decision support, and patient well-being are the major challenges in the day-to-day business of radiology,” says Dr. Philipp Fischer, Head of Computed Tomography at Siemens Healthineers. “With Somatom X.cite and myExam Companion, we’re equipping our customers with unique tools to effectively overcome these hurdles.”

The high-end Vectron-x-ray tube and the Stellar Infinity Detector form a combination of technologies for clinical imaging that is unique in this segment. The image data thus generated are very well suited for processing using artificial intelligence, for example with the AI-Rad Companion Chest-CT from Siemens Healthineers. The tube voltage can be set between 70 kV to 150 kV in 10 kV increments, which enables even more individual adaptation to the patient’s anatomy.

Follow-up scan for coronary heart disease patient with multiple bypass: Coronary CME CTA spiral scan. Copyright: Image courtesy of University Hospital Erlangen, Germany

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Please continue with question #2 below

**MEDICAL DOCTORS** (respond below)

1. What is your occupation? (check only one)
   50. Diagnostic Radiologist
   51. Other Physician (please specify)

1a. What is your radiology sub-specialty? (check only one)
   52. General Radiology
   04. Nuclear Medicine
   53. Nuclear Radiology
   54. Pediatric Radiology

1b. I am a Head of my department
   58. Yes
   59. No

Please continue with question #2 below

**NON-PHYSICIAN PROFESSIONALS** (respond below)

1c. What is your occupation? (check only one)
   Administrator/Manager: 60. Radiology Administrator
   61. Radiology Business Manager
   62. PACS Administrator

Executive: 63. Chief Information Officer/IT Manager
   64. Chairman/Managing Director/Executive Director

65. Chief Financial Officer/Other executive titles

Please continue with question #2 below

**ALL RESPONDENTS** reply to the questions below

2. In what type of facility do you work? (check only one)
   20. Private Clinic
   21. Hospital (check number of beds):
      a. More than 500 beds
      b. 200-299 beds
      c. 100-199 beds
      d. 300-399 beds
      e. 0-99 beds

3. With what technologies or disciplines do you work? (check all that apply)
   01. Diagnostic X-ray
   02. Nuclear Imaging
   03. Interventional Radiology
   04. CT
   05. Ultrasound
   06. MRI
   10. Mammography
   11. Bone Densitometry
   12. PACS/Teleradiology
   70. Cardiac Imaging
   71. PET
   72. Angio
   73. Radiation Therapy
   74. Oncology
   75. Women’s Imaging
   76. Molecular Imaging
   77. None of the above

4. If you currently receive Diagnostic Imaging Europe, how many other people read your copy?
   a. 0
   b. 1
   c. 2
   d. 3
   e. 4
   f. 5
   g. 6 or more

5. Please describe your involvement in the decision to purchase medical imaging equipment/products for your department.
   (Check all that apply)
   33. Approve purchase of product
   35. Recommend purchase of product
   34. Specify type of product to purchase
   36. None of the above
MR technology accelerates scan time by up to four times for improved patient experience

Physicians can now scan faster while maintaining MR image resolution with the Compressed SPEEDER technology from Canon Medical Systems. Scan times in MRIs have historically been a challenge in clinical practices, where shorter scan times are typically associated with lower resolution or a lower signal to noise ratio (SNR). To reduce acquisition time while maintaining image quality, Canon Medical’s innovative Compressed SPEEDER supports high acceleration and can be used to avoid artifacts, while maintaining resolution and SNR.

Available on the Vantage Galan 3T (pictured above) and the Vantage Vantage Oria 1.5T, the new technology speeds up MRI scan times by up to four times by reconstructing full resolution images from highly under-sampled data and shorter scans. The technology provides exceptional image quality and has great potential to help clinicians improve productivity. Reduced scan times also enhance patient comfort, which in turn produces higher quality images by mitigating patient movement caused by patient discomfort during long scans.

“In advanced imaging, generating high quality images and shortening scan times are paramount to success for both the patient and physician,” said Jonathan Furuyama, managing director, MR Business Unit, Canon Medical Systems USA “With the help of this new advanced imaging technology and Canon Medical’s innovative MR systems, health care experience for their patients, we can achieve this aim.”

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https://eu.medical.canon/

First Glass-Free Digital Radiography Detector

Forward-thinking design eliminates traditional glass substrate from the capture layer, the most fragile layer inside.

Fujifilm Healthcare have announced the introduction of the new FDR D-EVO III DR detector. Recently 510k cleared by the FDA, the FDR D-EVO III is Fujifilm’s third generation digital X-ray detector and features a sleek, thin design and enjoys the status of being the world’s first glass-free DR detector with patented Irradiated Side Sampling (ISS)1 – also making it the world’s lightest 14x17” detector weighing approximately 1.9 Kg. The innovative design removes the traditional glass substrate from the capture layer, eliminating the most fragile layer inside, allowing for a much lighter weight compared to previous models. The FDR D-EVO III will initially be available in 14x17” and 17x17” sizes to fit a wide range of diagnostic needs.

“As imaging departments navigate their future, the need to advance technology while containing costs will continue to be a focus,” said Robert Fabrizio, Director of Strategic Marketing, Modality Solutions, FUJIFILM Medical Systems U.S.A., Inc. “Fujifilm is focused on the future - with the new FDR D-EVO III detector, imaging departments will be able to invest in a smart solution, providing cutting edge technology to their patients and which is built to last well into the future.”

The next generation 14x17” detector incorporates all of the groundbreaking features of the earlier model in the range, the FDR D-EVO II including its sleek design with smooth and tapered edges for easier positioning, antibacterial nano-coating to help fight against HAIs and a long-lasting battery life.

Fujifilm, TOKYO, JAPAN.
www.fujiimed.com
Safety profile of Philips low-dose drug-coated balloon reaffirmed

Philips has announced the four-year results of the randomized controlled ILLUMENATE Pivotal trial in the U.S. With an excellent follow-up compliance rate of over 95% in a highly complex disease patient cohort, the data show similar mortality rates through four years for patients treated with Stellarex compared to those treated with the current standard of care (plain balloon angioplasty). The results were presented at the recent Leipzig Interventional Course in January by Dr. Sean Lyden, co-Primary Investigator for the ILLUMENATE Pivotal trial.

The four-year ILLUMENATE Pivotal trial data are the latest data from a series of trials evaluating the safety and efficacy of the Philips Stellarex .035" low-dose DCB in restoring and maintaining blood flow in the superficial femoral artery and popliteal arteries of patients with peripheral arterial disease. The results were evaluated compared to percutaneous transluminal angioplasty (PTA) treatment with uncoated balloons, the current standard of care.

“The four-year data from the ILLUMENATE Pivotal trial further substantiates the three-year results that were presented at LINC 2019 and published in Circulation in 2019,” said Sean Lyden, MD. “The high compliance follow-up rate further affirms the findings of these data in a complex patient population.”

The study’s patient population is complex with a high proportion suffering from severely calcified lesions. The mortality rate at four years was virtually identical between the two patient groups, at 15.6% for the Stellarex patient group and 15.2% for the control group. Secondary safety outcomes were also similar across the two groups. The four-year data also show a clinically relevant lower rate of clinically-driven target lesion revascularization (CD-TLR) in the Stellarex DCB patient group of 28.2%, vs 34.1% in the control group. CD-TLR is a commonly used indicator of treatment efficacy durability.

“The ILLUMENATE Pivotal four-year data builds on the robust, consistent long-term data of the Stellarex clinical evaluation program,” said Chris Landon, general manager, Image Guided Therapy Devices at Philips. “We continue to make relevant data available to healthcare providers in order to help them make an informed decision on the optimal treatment for often complex disease patients with peripheral arterial disease.”

Featuring Philips EnduraCoat technology, a unique coating consisting of a polyethylene glycol excipient with amorphous and crystalline paclitaxel particles dispersed in it, the Stellarex .035" DCB is unlike any other drug-coated balloon for the treatment of peripheral artery disease. EnduraCoat technology provides efficient drug transfer and effective drug residency coupled with high coating durability and minimal particulate loss, thereby enabling a low therapeutic drug dose.

Deep Learning-Based CT Image Reconstruction Technology

GE Healthcare has announced its Deep Learning Image Reconstruction engine on its new Revolution Apex CT device and as an upgrade to its Revolution CT system in the United States. Mike Barber of GE Healthcare said “Our Deep Learning Image Reconstruction engine combines the ground truth image quality of filtered back projection (FBP) with the low dose capabilities of iterative reconstruction to produce TrueFidelity CT Images. These images offer outstanding image quality and restore noise texture to improve radiologists’ confidence in diagnosing a wide range of clinical cases.”

Deep Learning Image Reconstruction (DLIR) is the next generation image reconstruction option that uses a dedicated Deep Neural Network (DNN) to generate TrueFidelity CT Images, which have the potential to improve reading confidence in a wide range of clinical applications such as head, whole body and cardiovascular, for patients of all ages.

Compared to current iterative reconstruction technology, TrueFidelity CT Images can elevate every image to a powerful first impression with outstanding image quality performance, and preferred image sharpness and noise texture, without compromising dose performance.

“Physicians who have reviewed our new TrueFidelity CT Images consistently say they are among the best CT images they have ever seen, and our 510(k)-reader study also demonstrated this improvement,” said Scott Schubert, General Manager of Global Premium CT, GE Healthcare. “Revolution Apex delivers CT technology innovations including the Quantix 160 x-ray tube and Deep Learning Image Reconstruction, and so we are pleased to bring these innovations as optional upgrades to our Revolution CT users as well.”

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Dr. Constantino S. Peña, Medical director of Vascular Imaging, Baptist Hospital, Miami, FL, USA

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\(^1\) Compared to Philips scans without Compressed SENSE.