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Assessing Performance in Digital Mammography Technology

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Review of Current Digital Mammography Systems and Clinical Studies

There are many ways in which digital mammography can make a difference not only in detecting breast cancers, but also preventing unnecessary biopsies and changing surgical management, by providing better opportunities for the clinician or technologist to manipulate the resulting images, enhancing image quality and ensuring that nothing is missed on the scan.

In this article, I will provide an overview of the latest FDA-approved digital systems, as well as results from important clinical studies about digital mammography, which will perhaps highlight for service providers in greater detail the issues that have arisen in attempts to quantify standards for judging quality.

Assessing a Digital Mammography System: Image Qual ity

The digital mammography systems that are currently licensed by the US Food and Drug Administration (FDA) achieve a resolution of up to 5-12.5 lp/mm. The quality of resolution and its importance in assessing a digital mammography system have been the centre of technical discussions for a long time. At a European level, work is being done on an addendum to the section covering “digital mammography” in the European Protocol for Quality Control (EPOQ), of the physical and technical aspects of mammography screening to determine the upper limits of contrast visibility, which would act as a crucial measure of image quality.

The lower requirements of local contrast visibility for digital mammography systems are being justified by the fact that lesions are detected

because of their contrast to their background and that contrast visibility or other functions of transmission that use contrast are a more appropriate measure than the modulation transfer function used by film screen systems or the threshold frequency of visual perception that is derived from it.

Quality Control for Digital Mammography

The European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening states that 'A prerequisite for a successful screening project is that mammograms contain sufficient diagnostic information to be able to detect breast cancer, using as low a radiation dose as is reasonably achievable (ALARA).' This quality demand holds for every single mammogram. Quality Control (QC) therefore must ascertain that the equipment performs at a constant high quality level.

As QC of the physical and technical aspects in mammography screening starts with specification and purchase of the appropriate equipment, meeting accepted standards of performance. Before the system is put into clinical use, it must undergo acceptance testing to ensure that the performance meets these standards. This holds for the mammography X-ray equipment, image receptor, film processor and QC test equipment. After acceptance, the performance of all equipment must be maintained at the highest level possible.

The QC of the physical and technical aspects must guarantee that the radiologist is provided with images that have the best possible diagnostic information obtainable, and images should at least contain the defined level of information necessary to detect the smaller lesions (see CEC Document EUR 16260). Image quality should be stable with respect to information content and optical density and consistent with that obtained by other participating screening centres, and breast dose must be 'As Low As Reasonably Achievable' (ALARA) for the diagnostic information required.

Further information is available from the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) at www.euref.org.

FDA-approved Digital Mammography Systems

With this in mind, it is useful to examine the current range of digital mammography systems that hold an FDA licence, in order to provide an overview of how digital mammography technologies are shaping up to improve the quality of their function. These include the Senographe 2000D (GE Medical Systems), which uses a flat panel digital detector of 19 x 23 cm2. The detector is based on a semiconductor layer from amorphous silicium. Also, Fischer Imaging's Senoscan, uses a "slot scan" detector measuring 1 x 22 cm2 and consisting of four charge coupled devices (CCDs), using a default pixel size of 54 µm. CCD technology converts incoming light photons into mobile charge carriers. The Lorad Digital Breast Imager (LDBI) works with a digital image acquisition system, which consists of 12 CCDs that are arranged in the form of a mosaic, and that are coupled with a large scintillator plate that is thallium doped caesium iodide. This receptor covers an area of 18,6 x 24,8 cm2. Hologic is, however, not planning further marketing of the CCD-based units but is concentrating its activities on the flat panel digital detector consisting of amorphous selenium.

The last two I will mention here, include a system consisting of Hologic's Selenia, Siemens Novation, and digital mammography systems Instrumentarium and Giotto, from AGFA. The digital mammography system uses a 24 x 29 cm2 flat panel detector, which, instead of a scintillator, has a semiconductor layer of amorphous selenium. Selenium enables the direct conversion of X-rays into electrical charge. Finally, Fujifilm's FCR 5000MA full-field mammography system includes an image-plate reader with a resolution of 50 µm for all mammography formats, with dual-sided reading technology.

Results from Clinical Studies

Is the latest in digital mammography technology, so superior to conventional film-screen mammography systems, that it makes it an imperative acquisition when equipping a modern imaging department? Current results on detection rates for malignancies from important clinical studies are not so sure. In fact it is perhaps the difference in outcome from these studies that throws the most confusion over what the advantages in new technologies really are. Can digital technology definitively quantify how exactly it is superior to its non-digital predecessor?

For example, when Obenauer et al. and Fischer et al. Compared digital mammography and conventional screen film mammography in clinical and control investigations, they found comparable results or only slight superiority of the digital technique. In a comparative study of 692 female patients, Venta, Hendrick et al. found that results were in agreement between conventional film screen mammography and digital mammography in 82%, part-agreement in 14%, and no agreement in 4% of results, which they explained by the variability of interobserver agreement. Interobserver reliability is an important factor here, as it measures agreement between two or more subjects rating the same target.

Yet another comparative study of conventional versus digital mammography carried out by Lewin, Hendrick et al., including 4,945 female patients, found that out of 35 cases of breast cancer, the conventional system detected 22 cases and the digital system 21 cases. Authors found no significant difference in detection rate, but a lower recall rate in digital than in conventional mammography (11.5% versus 13.8%, respectively). They did not find a significant difference in the rate of positive biopsies (19% versus 30%). Lewin and Hendrick, in a study in 2002 with 6,736 patients whose condition was generally diagnosed through both imaging modalities, found 42 malignancies in 181 biopsies, of which 15 were detected exclusively though conventional mammography and only 9 through digital mammography. They did not find a significant difference in the detection rate for malignancy, but a lower recall rate for digital mammography.

A study by Skaane et al. (Oslo I) included 1,832 women who were examined with both techniques, where although authors found no significant differences in the detection rate, a higher rate of air ingress and average parenchymal

dosis for the digital system than for the conventional system was noted. This study has met with substantial criticism with regard to different variables, and in addition the results are diametrically opposed to those of Hermann et al., who found a dose reduction of 25% for digital mammography compared with conventional mammography. In 2004 Skaane et al. published a further study (Oslo II) with 10,303 patients examined with conventional and 3,985 patients with digital technology. The results in terms of detection rates for digital mammography were significant better. As Skaane later verified this through observations of investigators by working every day with the digital mammography, he concluded that there is an essential need for at least two to three months training with digital mammography in order to improve accuracy, in contrast to conventional screen film mammography.

Another interesting study which I would like to highlight, published of the Digital Mammography Imaging Screening Trial (DMIST) Investigators Group, the only prospective, randomised clinical trial including a total of 49,000 women, all of whom were examined with both techniques, evaluated separately in 11 institutions found that despite the same detection rate of cancer for all patients, there were significant improvements in results for digital mammography systems in women under 50 years, those with radiological dense breasts and peri-menopausal women.

Conclusion

On the basis of phantom and clinical studies, luminescence radiography with high resolution imaging plates, digital full-field mammography using a digital amorphous silicium detector, digital full-field mammography using digital CCD-detectors and the digital full-field mammography digital amorphous selenium detector has been found to be of equal value or slightly superior to conventional film screen system, information that continues to be of value to healthcare providers concerned with improving both breast cancer detection rates and image quality in their facilities.

Overview

In digital mammography, an electronic detector absorbs incoming X-rays and produces an electronic signal that is digitalised in an analogue-to-digital converter and can be therefore be processed, exposed, and stored on a computer. In digital radiography, actual imaging is split into three steps: recording, processing, and reproduction. This means that each individual step can be optimised, and in addition an opportunity arises for electronic imagine transfer via teleradiography.

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