

Breast tomosynthesis for screening – A comparison of USA and European experiences.

In the US Breast Tomosynthesis (BT) has been in wide use for diagnostic and screening applications since 2011 and in Europe since 2008, primarily for diagnostic mammography with emerging use for screening. The recent European Congress of Radiology (ECR) in Vienna addressed the question of whether tomosynthesis will become as important for screening in Europe as it has in the United States.



Prof. Emeritus Skaane, Norway; Dr. Bernardi, Italy; Dr. Friedewald, USA; Dr. Romero and Dr. Alvarez, Spain at the 2015 ECR Symposium

The packed Hologic-supported Symposium was addressed by five speakers from four countries – the U.S., Norway, Spain, and Italy. They presented their findings on screening with the Hologic 3D mammography™ system and explained the benefits of using breast tomosynthesis over traditional 2D digital mammography in screening.

Prof. Emeritus Per Skaane from Oslo University Hospital in Ullevaal, Norway, who wrote a paper on the Use of Hologic 3D mammography, chaired the session and gave a presentation in which he said the move from 2D to 3D mammography was far less challenging than the move from analogue to digital approximately 15 years ago. “Put bluntly”, he said, “3D is just a better mammogram”. He added that his team’s research prior to implementation clearly showed higher specificity and higher sensitivity and the ability to keep doses at low levels using generated 2D imaging (i.e. from Hologic C-View™ software, which is part of the Hologic 3D mammography solution). Generated 2D is a 2D image digitally produced from a

3D data set and presented as a 2D image thanks to sophisticated algorithms. There is no additional examination required, and the results enable 3D imaging to be undertaken cost effectively and more quickly than the traditional approach of combo imaging (3D and 2D simultaneous acquisition) with a significant reduction in dose.

Prof. Skaane predicted that 3D will become the screening technique of choice in Norway within the next two to four years.

The main themes of better cancer detection, reduction in the number of false positives (recall rates) and the ability to keep dose down were cited by all five presenters as the principle reasons why, in their opinion, 3D is the way that mammography screening will progress.

Dr Sarah Friedewald from Chicago presented the findings of a U.S. study she led covering over 450,000 patients across 13 sites. She said “Although the actual reading of 3D mammograms takes

longer, these benefits plus the ability to reduce some needless examinations and save on other modality examinations has meant that our workforce in those areas has been reduced and the clear patient benefit of less recalls puts a much better slant on patient outcomes”.

Dr Daniela Bernardi from Trentino Health Authority, Italy, stated “After four years of activity since our research studies and the move to screening, we have found no need to increase our work force as additional reading has been compensated by both a reduced need for additional modality examinations and less need for additional diagnostic mammography – both real benefits to the ladies being screened. Plus the use of synthetic 2D has enabled us to reap the benefits of 3D without the recourse of any dose increase”, she added from her study that covered 60,000 cases over a two-year period.

In Spain the breast screening programme is managed by epidemiologists, not radiologists, but Dr Marina Alvarez and Dr Romero from Reina Sofia Hospital, Cordoba, Spain believe that the research and initial screening with the Hologic 3D mammography systems at their facility have been so conclusive that within a few years, 3D screening will be the gold standard for breast imaging.

Findings in Breast Tomosynthesis Screening

All the research studies play out similar themes, and all relate to trials that have taken place over extended periods with their authors involved with mammography research and screening over a number of years. They may hence be summarised in the following way:

- Detection of significantly more cancers and at an earlier stage means better patient outcomes.

- Reduction in overlapping structures is not only seen in dense breasts.
- Reduction in false positives – partly from the above.
- No increase in overall patient dose rates from the 3D examination.
- Benefits of 2D images from a generated 3D data set.
- Confidence of all radiological staff is enhanced.
- Physician referral confidence is also enhanced.
- Enhanced patient outcomes through better detection and greater accuracy.

All the study authors are convinced that 3D enables them to do better mammography, and on that basis there is consensus that the move to a complete 3D screening service is merely a matter of time.

There is a recognition from all the studies about costs associated with the equipment needs. But there is also the uncomfortable knowledge that **the inability to undertake all breast imaging in 3D today is leaving patients with missed cancers from a screening perspective. That remains unacceptable** given that diagnostic recognition at a later stage may not be good enough, nor is it acceptable to the patient who could have been treated at a much earlier stage and given a greater chance of a full recovery.

Of great concern is the statement made by the presenters that going back to just 2D imaging without 3D information, Dr Friedewald, Prof Skaane and Dr Bernardi specifically refer to this, stated that this is not an option, nor is it at all easy for them because they have become dependent on the generated 2D images to give them the 3D information with which to make a better mammography diagnosis.



A packed lecture theatre at ECR 2015 where the 3D Breast Symposium took place, Dr Marina, Alvarez from Cordoba, Spain is presenting.

Next Steps

A recently published research paper in *ClinicoEconomics and Outcomes Research* in the U.S. – ‘Value analysis of DBT for breast cancer screening in a commercially insured U.S. population’ concluded that “..... clinical and economical favourability of DBT for breast cancer screening amongst commercially insured U.S. women”. In broad terms, the comprehensive model shows overall savings in the region of \$2.4 million per annum for a hypothetical 1-million-women-member health plan with \$5.5 million from avoiding follow-up services and \$1.2 million from earlier detection of breast cancer set against the \$4.2 million incremental cost of adding BT to screening. This would equate to \$8 billion savings per year, clearly making a strong economic case.

In Europe, where there are the economic considerations of government-funded screening programmes, many of which are cash strapped (e.g. NHS in the UK), it is far more difficult for the economic benefits to be realised often within the lifetime of a government. There is also the matter of funding upgrades to equipment, most of which is still relatively new from the analogue to digital screening conversion, as well as the more recent replacement of first-generation CR units with 2D digital equipment for national breast screening services.

It is most likely that the human aspects associated with the use of breast tomosynthesis – the psychological benefits from reducing false positives, the improvement to patient outcomes of earlier and more accurate detection of breast cancer – will play a much greater role in the transition to 3D. In fact, in her presentation, Dr Bernardi said, “Reduced false positives and better quality diagnosis will actually encourage women to return to each and every screening session as they will have greater confidence. And if we can increase the rate of attendance, which will enhance the quality of patient care and would enable many more patients to benefit from the screening process itself”.

The move to 3D breast screening is seen by the presenters as a natural progression that will take place at a fast pace as society recognises that mere 2D imaging is not sufficient to provide the most accurate diagnosis of breast cancer and that 3D requires no increase in dose rates. Additionally, with no increase in overall resources required to undertake the examination – (yes, there is the need for redeployment of resources) – that should not on its own cause issues other than the delay of DBT screening introduction country by country. The message is clear: **there are no issues of efficacy or economics standing in the way, just a lack of inertia that public opinion will surely address.**

Breast Health Solutions

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