Early adopters of digital breast tomosynthesis in Spanish and Italian breast cancer screening programs are confident that potential organisational limitations can be overcome in order to maximise the benefits of increased cancer detection rate and reduced recall rates.

Key Implementation Factors

- Impact of organizational changes
- Technology feasibility in the screening program
- Costs/replacement cycle for mammographic units in the screening program
- Acceptance by the medical team
Acquisition time

Reading time

Results in sensitivity and specificity

Acceptance by the patient

The Spanish experience

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The Andalucía region of Spain set up its mammography screening program in 1995, achieving full coverage in 2005. Screening is offered to a population of 650,000 women between the ages of 50 and 69, every two years, and independent double reading is standard. The centre in Córdoba serves a population of 75,000 women.

The Córdoba centre recently installed a Hologic tomosynthesis unit in order to perform research and demonstrate that it is feasible screen with tomosynthesis with the same level of security and results, or probably better, than with mammography.

While the clinical benefit of tomosynthesis is clear, introducing the equipment was not without its barriers for our program. We made organisational changes, provided training for the radiographers and radiologists, and offered special information for the women coming for screening.

Results

Once we complete our research study, we will publish our results. The implementation has shown that radiographers have accepted the technique, radiologists have adapted, and 98% of women agreed to participate. Radiation doses are within the admissible limit and our results in sensitivity and specificity are promising.

The Italian experience

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The Screening with Tomosynthesis OR standard Mammography (STORM) trial compared two different screen reading modalities used sequentially: 2D mammography alone and integrated 2D/DBT mammography.

Using integrated 2D/3D mammography to screen 7294 women we detected 59 cancers, 20 more cancers compared to 2D mammography alone, an increase in cancer detection rate of 2.7 per thousand (Table 1).

Before introducing DBT to our screening program we needed to overcome the limitations, namely increased acquisition times, increased reading time and higher radiation dose to the breast.

<table>
<thead>
<tr>
<th></th>
<th>N. cancer</th>
<th>CDR %</th>
<th>p</th>
<th>% DCRP added to 2D/3D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>59</td>
<td>5.3</td>
<td>&lt;0.001</td>
<td>2.7</td>
</tr>
<tr>
<td>2D/3D</td>
<td>59</td>
<td>5.3</td>
<td>&lt;0.001</td>
<td>2.7</td>
</tr>
<tr>
<td>2D alone</td>
<td>39</td>
<td>5.3</td>
<td>0.78</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Results from the STORM trial
Source: Ciatto et al. 2013.

Acquisition Time

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We evaluated the impact of DBT on the radiographer’s activity and compared it to the time needed to acquire 2D mammography images (Table 2). We calculated that the time increases by 26%. However, this included the time for women to get undressed prior to the examination and dressed afterwards. Further calculations showed that the realistic impact is 10% more time to do a combo mammogram, which in the context of a screening program is not so significant.

**Reading Time**

We calculated that reading 2D + 3D images takes double the time compared to 2D mammography. Our results were similar to those reported in the Oslo trial (Skaane et al. 2013) (Table 3). This compares to the study by Dang et al (2014), which reported an increase in reading time of less than 50%. We consider 50% more time is realistic, because we radiologists experience a learning curve, and after gaining experience we are able to reduce the reading time for DBT. There were similar initial increases (+75%) in reading time when services moved from screen field mammography to digital mammography (eg. Ciatto 2006).

**Radiation Dose**

The dose administered during the DBT mammography projection is equal to the dose administered during 2D mammography in the same compression. So using integrated 2D/DBT mammography gives the patient double the dose.

<table>
<thead>
<tr>
<th>TSRM</th>
<th>Temp medi</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>3°13°</td>
</tr>
<tr>
<td>2D + 3D</td>
<td>4°03°</td>
</tr>
<tr>
<td>+ 3D vs 2D</td>
<td>+46°</td>
</tr>
<tr>
<td>+ % 2D + 3D vs 2D</td>
<td>+26%</td>
</tr>
</tbody>
</table>

Table 2.
Source: Bernardi et al. 2012

There are two possible solutions. The first is to acquire DBT Mammography alone, and the second, possibly more realistic, solution is to use reconstructed 2D images from the data acquired during the DBT exposure. Thus the first software gets a pseudo 3D reconstruction of the breast with the reconstruction of the different slices of the breast, and the second software gets the reconstruction of synthesized 2D mammography using C-view™ software. We are running the STORM 2 trial to compare the results of the different reading of 2D + DBT Mammography and synthesized 2D + DBT mammography, with double blind and sequential reading by four readers. The preliminary results showed an increase in the proportion of cancers detected of 22% (6/27), with no statistical significance.

**Screening Program Re-Organisation**

The Trento mammographic screening service started in October 2000. Women aged 50-69 are invited to one of seven screening centres. Initially the dedicated technicians travelled from the main centre in Trento to the peripheral sites. All readings were centralized in the Trento screening unit and performed by fully dedicated breast radiologists using double blind reading.

<table>
<thead>
<tr>
<th>Radiologist</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>41°28&quot;</td>
<td>46°32&quot;</td>
<td>76°10&quot;</td>
<td>54°23&quot;</td>
</tr>
<tr>
<td>2D + 3D</td>
<td>33°36&quot;</td>
<td>100°11&quot;</td>
<td>155°17&quot;</td>
<td>97°51&quot;</td>
</tr>
<tr>
<td>+ 3D vs 2D</td>
<td>91°38&quot;</td>
<td>54°39&quot;</td>
<td>74°06&quot;</td>
<td>73°28&quot;</td>
</tr>
<tr>
<td>+ % 2D + 3D vs 2D</td>
<td>-220%</td>
<td>+120%</td>
<td>-97%</td>
<td>-135%</td>
</tr>
</tbody>
</table>

Table 3.
Source: Bernadi et al. 2012

When our service started we installed analogue mammography units, and switched to full-screen digital mammography in Trento and indirect mammography using CR systems in the peripheral sites in 2005. In 2011 we installed our first DBT unit. By 2014 we needed to change the analogue mammography units, and we
decided to install DBT on the basis of our own interim results and the Oslo trial.

With the cost of installing DBT there was a risk of underutilisation of these hi-tech machines if we installed DBT units in all 7 screening centres. Therefore, we decided to adopt only 3 DBT units across the service. The radiographers no longer have to travel to all the peripheral sites, and the women are invited to the two main centres. The radiographers’ shifts were changed from one shift per day to two. Now we work from 7:30 in the morning to 7:30 in the evening. This optimised the use of the DBT units and extended the time for women to have their appointments.

Published on: Mon, 11 May 2015