A retrospective audit of the first screening round of the Maltese breast screening programme

D. Mizzi [a, *], F. Zarb [b], A. Dennis [c]

[a] Medical Imaging Department, Mater Dei Hospital, Msida, MSD 2090, Malta
[b] Department of Radiography, Faculty of Health Sciences, University of Malta, Msida, MSD 2080, Malta
[c] School of Radiography, Faculty of Health, Social Care and Education (HSCE), Kingston University and St George's, University of London, Tower Block 4004, Penrhyn Road, Kingston Upon Thames, Surrey, KT1 2EE, United Kingdom

ARTICLE INFO

ABSTRACT

Purpose: To analyse whether the screening performance parameters of the Maltese National Breast Screening Programme first screening round met requirements set by European standards. The association between screening age and results of screening performance parameters was also investigated.
Method: Quantitative methodology was used to review examinations of women who were recalled for a technical recall or further assessment rates. All accessible members of the population recalled during the first round were retrospectively reviewed resulting in a sample of 2300 recalled examinations.
Results: Malta's first screening round met the European Guidelines recommendations for technical repeat rate (0.26%), early recall rate (0.45%), breast cancer detection rate (13.77 per 1000 women) and Positive Predictive Value of screening test (7.58%). However, local recall rate (18.53%) and further assessment rate (18.27%) were higher than recommended.
The Chi square test showed a statistically significant difference ($p \leq 0.05$) in recall rates between the compared age groups, as younger women (51—55 years) were more likely to have a negative diagnosis after the initial mammogram whereas older women (56—60 years) were more likely to be recalled. There was no age discrepancy ($p \geq 0.05$) in local breast cancer detection rate and positive predictive value of screening test.
Conclusion: Although the Maltese first screening round performed well, this study found deficiencies in recall and further assessment rates, which according to literature may result in psychological morbidity and inefficient use of screening resources. This study also concluded that when a cohort is analysed, age is not as significant as the screening round itself (first/subsequent).

© 2016 The College of Radiographers. Published by Elsevier Ltd. All rights reserved.

Introduction

Breast cancer is the most common cancer among Maltese women and accounts for a third of all female cancer deaths. Every one in twelve Maltese women will get breast cancer in her lifetime; a significantly higher proportion than the European average.[1] In October 2009, Malta's Department for Health agreed to implement a National Breast Screening Programme (MNBSP).[2] The aim of screening was to reduce morbidity and mortality from the disease without adversely affecting the health of participants.[3,4] Key to achieving this aim were high levels of quality within the entire screening process.[4] The MNBSP strives to protect the dignity and privacy of women, while offering an effective service at the highest levels of quality to diagnose and treat breast cancers at the earliest possible stage, and also meeting the European clinical standards.[4]

The first MNBSP round commenced in October 2009 and ended in February 2013. The local screening programme provided free screening, every three years for all women aged 50—60, resident in the Maltese Islands. This age range was selected for the first screening round since this age group was deemed to be the 'most at risk' of developing breast cancer.[1] Malta's Department for Health additionally states that as soon as more human resources became available, the programme will be extended even to older women.[1]

Double reading of mammograms was performed locally, as recommended for programmes in their first round of screening.[4]

* Corresponding author.
E-mail addresses: mizzideborahi@gmail.com (D. Mizzi), francis.zarb@um.edu.mt (F. Zarb), a.dennis@sgul.kingston.ac.uk (A. Dennis).

When comparing dual to single reading, studies have shown that sensitivity increased by 5–10% without a significant effect on recall rates.[5] Consensus arbitration of discordant double read cases also improved reading performance since it decreased recall rates and increased Positive Predictive Value (PPV).[4,6,7] Since consensus arbitration was not practised locally, as per radiologists' choice, women who were recalled by one radiologist experienced additional examinations during further assessment clinics. This could have resulted in higher recall rates and lower PPV.

A high quality screening service can be achieved through the use of targets, performance parameters and audits.[4] Although audits of performance parameters were undertaken in European screening units, this research was the first of its kind in Malta. The findings offer valuable contribution for future advancement of the local screening unit as they helped to identify areas of strength, as well as areas needing improvement.

This study aimed to retrospectively audit results of the first screening round of the MNBSP and to assess whether the service fulfilled the European standard requirements. Thus the study objectives were to measure screening performance parameters (Recall Rate, Technical Recall (TR) Rate, Further Assessment Rate, Early Recall (ER) Rate, Breast Cancer Detection Rate, PPV of Screening Test) of the local first screening round; calculate the different types of clinical examinations performed during further assessment clinics; compare the rates of the screening performance parameters to the levels set by European and United Kingdom (UK) guidelines and investigate any association between screening age and results of screening performance parameters.

Literature review

Several online databases such as Medline, Cumulative Index Nursing and Allied Health Literature, and Science Direct were utilised to access e-journals. Although most of the identified literature was undertaken after the inception of screening programmes, around 10–20 years ago, it was seminal to the study and was therefore included in this review. Only peer-reviewed, European studies written in the English language were included due to the similarity of breast screening programmes.

Quality assurance (QA)

Ensuring the quality of a screening service is vital. This could be achieved by early monitoring of screening performance parameters of the unit, potentially optimising the use of resources and ultimately producing an observable reduction in mortality.[4] Strict adherence to quality assurance and quality control guidelines must be practised in all mammography facilities to ensure accurate diagnosis, thus minimising false positive mammograms.[8,9] False-positive rate refers to recalls for further assessment which turn out to be normal or benign.[10] This is one of the reasons for the ongoing screening debate, since it gives rise to negative effects, namely: financial costs to the health service and psychological strain on the women.[10,11] Since the majority of screening mammograms are normal, radiologists' record of reporting should demonstrate high specificity avoiding false-positive mammograms.[12]

In addition to false positive rates, several other performance parameters were identified by 'The European Guidelines for QA in Breast Cancer Screening and Diagnosis'. Recommended acceptable levels for each parameter were also set.[4] Table 1 defines the screening performance parameters audited in this study and indicates the acceptable EU and UK levels for programmes in their first screening round.[1,4,13–15]

Several research studies investigated these screening performance parameters.

Recall rate

No increase in cancer detection rates and in screening sensitivity beyond a recall rate of 4.8% were recorded.[16] High recall rates were found to signify that resources are used inefficiently in women undergoing unnecessary follow-up procedures.[17,18] Conversely, rates lower than 1% were associated with reduced cancer detection and increased interval cancers.[4] Previous research states that recall rates were influenced by several factors including training and experience of radiologists, image quality, the volume of mammograms interpreted and the age of screened women.[19–21]

Early recall rate

ER was found to be associated with a low predictive value for malignancy and thus every effort should be made to obtain a definitive diagnosis at initial assessment.[4,22–24] Additionally, a study analysing 110 women who were recalled early, revealed that 3.6% had invasive cancer, 0.9% had DCIS, while 84% had benign findings.[25]

PPV of screening tests

The European guidelines did not define an acceptable PPV of Screening Test, whilst the UK National Health Service Breast Screening Programme (NHSBSP) defined the minimum standard PPV as 2.7% or more at first screenings.[26] Due to the similarity between the UK NHSBSP and the MNBSP, this value was taken and accepted as the recommended level.[27] Although recall rates of first screening rounds are generally high, the PPVs are usually low. In subsequent screenings the previous investigations could be referred to without the need for recall. Therefore only new findings would be fully investigated, thus lowering recall rates and further increasing PPV.[20,28]

Performance in European breast screening programmes

Performance indicators for mammography screening in 17 European countries showed some discrepancies, with recall rates ranging from 1.3% to 18.4%.[29] First screening rounds resulted in detection rates varying from 10.7 per 1000 women screened in Copenhagen to 3.6 per 1000 in Finland.[29,30] This difference between countries should be interpreted with caution due to variations in screening and interpretation methods used within the various programmes. For instance the UK NHSBSP and the Netherlands followed very different recall policies; the latter deliberately aiming at a very low recall rate. Other differences included the use of one versus two-view mammography, screening interval, double-reading and methods for arriving at a resolution when double-reading led to different conclusions.[29,30]

Effect of age

Age is another independent factor predicting the accuracy of screening mammography.[31,32] As screening age increased, recall rates decreased. Sensitivity, specificity and PPV increased with age thus increasing the accuracy of screening.[31,32]

A study that analysed 215,665 mammograms revealed that the PPV was inversely related to the recall rates for age.[31] Recall rates decreased from 7.3% for the youngest women to 4.9% for the oldest women, whilst the PPV rose from 1.9% to 12.7%. This outcome was supported by an extensive study of 1.5 million examinations reporting an increase in PPV by age.[33] This was reasonable given the relatively higher breast density and lower incidence of disease in younger women.[20,34]