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Mammographic image reject rate analysis and cause – A National Maltese Study

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ABSTRACT

Mammography is used as a first-line investigation in the detection of breast cancer and imaging is required to be of optimal quality and achieved without adverse effects on the health of individuals. Repeated images come at a cost in terms of radiation dose, discomfort to clients and unnecessary financial burdens. No studies investigating mammography quality in Malta had been previously undertaken. Hence, this research aimed to investigate whether mammography is being performed at an acceptable level, through the investigation of reject rates.

Quantitative methodology was used to collect data from eight participating mammography units, which were utilising screen film (SFM), computed radiography (CR) and direct digital mammography (DDM). Data relating to the total number of images performed, rejects and causes was prospectively collected over two weeks, resulting in a sample of 2291 images. All units were also asked to answer a questionnaire which provided other data that could be used for analysis.

The national mammography reject rate was found to be 2.62%; within the 3% acceptable range. Individual rates' analysis revealed unacceptably high or low reject rates in some units. Positioning was the main reject cause. No significant difference in rejection was found between different types of mammography units or radiographers' experience. Alternatively, radiographers' qualifications, employment conditions and use of rejection criteria were proven to affect reject rates.

Whilst on a national level, images are being rejected at an acceptable rate, individual units revealed suboptimal rates; at the cost of extra radiation, added discomfort and financial burden.

Introduction

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death in women worldwide, accounting to 23% of all cancer cases and to 14% of cancer deaths.[1] In 2009, Malta was ranked as having one of the highest breast cancer mortality rates in Europe, with 34.4 deaths per 100, 000 women.[2] Mammography is used as a first-line investigation in the detection of breast cancer, as it has the potential to identify this disease at an early stage, equating into improved survival rates.[3] However, mammography is required to be of optimal quality and achieved without adverse effects on the health of individuals.[4] Mammography is known to be a sensitive area of radiology due to the difficulty associated with positioning and the nature of the examination itself.[5] Rigorous Quality Assurance (QA) and Quality Control (QC) are essential to achieve high quality images, whilst controlling associated risks.[4,6–8] One of the advised QC tests is reject analysis (RA) as this is an inexpensive method of gaining information related to image quality (IQ), revealing deficits in service and consequently bringing about a reduction in rejected images, doses and financial burden.

The Malta National Breast Screening Programme (MNBSP) was launched in 2009 and invites women aged 50–60 for free breast screening every 3 years.[9] The state general hospital offers free mammography to women being followed up after breast cancer and to those presenting with symptoms. Several private clinics offer mammography, both to symptomatic and screening clients.

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Recently, local mammography has been undergoing the transition from SFM to DDM. In some units, QC Guidelines are drawn up by the medical physicist according to guidelines.[4,6] However, as previously documented[10] the researcher was aware that QC programs were only implemented in some of the units.

The aim of this research was to identify the national mammography reject rate in Malta. Several objectives were formulated including critical appraisal of reasons that led to image rejection, comparison between different mammography technologies and assessing factors which affected rejected rates. Analysis of IQ, through RA, at a time when mammography is undergoing changes was crucial as it provided insight to whether an adequate service in terms of IQ, dose and cost-effectiveness was being offered. Recommendations to improve IQ would then serve to reduce rates.

Literature review

Image quality

Adequate IQ is essential for successful detection of breast cancer, which consecutively contributes to improved prognosis and mortality reduction.[11] Previous research investigating IQ revealed several deficiencies, including inadequate labelling and compression.[5] Positioning was also suboptimal due to improper visualization of pectoral muscle on mediolateral oblique views and missing pectoral muscle and medial borders on craniocaudal views. Another study[12] conducted across Africa, Asia and Europe (including Malta), also revealed suboptimal IQ, due to artefacts, poor visualization of structures and incorrect exposures. Technologist-related IQ variability has also been documented, this being associated with the time spent in mammography and with their experience working amid breast specialists.[13]

Mammography hazards

Contradictory opinions regarding the use of mammography as a screening tool have been debated for years[14] due to hazards which are inevitably heightened with image rejection and repeats.[15] Potential harms include anxiety, radiation and costs; due to the time spent re-taking images, wear and tear of equipment and use of extra material.[16]

Implementation of DDM

Whilst the implementation of DDM has led to significant advantages including higher cancer detection rates and decreased radiation doses[17,18] it has been associated with an increased number of repeat images, particularly initially[19] due to the bulkier breast support.[7] In SFM having a film to dispose of, equating to tangible evidence of repeats might deter radiographers from rejection, whereas the invisibility of DDM images might contribute to an increase in rejects. Conversely, due to the associated increased dynamic range, exposure-related rejects are drastically decreased.[7]

Reject analysis

Following a comprehensive literature search, limited research was found dealing with RA in DDM. A single study analysing both SFM and DDM reject rates monitored rejects in seven units, two weeks before and after the implementation of corrective action.[20] When compared to the suggested acceptable rate,[4] high rates were discovered in some units ranging from 3 to 8.5%, which were reduced to 1–3% after implementation of corrective action. Rejected images were mainly attributed to incorrect exposures and poor positioning.

Reject rates had been previously investigated but only dealt with SFM.[21–23] High rates ranging up to 18% were documented in centres lacking QC protocols.[7] Reasons for rejection included incorrect exposures, unsatisfactory positioning[7,21] and improper collimation.[23]

Methods

Following ethical approval through the Faculty Research Ethics Committee (Kingston University) and the University Research Ethics Committee (Malta), all twelve mammography units in Malta were invited to participate, with eight of these being available for participation. These included both state-owned facilities in Malta and Gozo and four private units. Only one participating unit was still using SFM, whilst two were utilising CR. The remaining units had already converted to DDM at the time of data collection.

The study was divided into two main phases; the initial phase encompassed the completion of a questionnaire, by the heads of units (Appendix A). The questionnaire looked into variables which the researcher aimed to investigate, i.e. radiographers' experience, condition of employment, qualifications and the mammography device used.

The second phase involved the actual RA which was dependent on the mammography technology utilised. Sample size was calculated utilising a power calculation, providing a measure of the statistical significance of results.[24] The recommended sample size was 1548. Having a large sample size led to high statistical significance.[25] Numbers of a typical week at the two centres with the largest workloads were analysed. Consequently, it was estimated that a two-week period (avoiding holidays and promotions) would be sufficient to collect the required data, coinciding with the IAEA recommendations.[26] All the images taken were collected, excluding tissue samples, wire-guided localisations and stereotactic biopsies since these were specific to some units. Exclusion rendered data more comparable. Radiographers were informed of the research study before it initiated. Although this was deemed necessary for ethical purposes, the Hawthorne effect was another possible limitation of this research. This limitation is brought about when persons aware of being under scrutiny act in a different way than normal. In this case radiographers could have refrained from rejecting images they would normally consider inappropriate in order to keep rejects to a minimum.

In **film and CR mammography**, a data collection sheet was used to monitor all the projections performed (Appendix B). Rejects were documented on a sheet titled '*Mammography Reject– Repeat*', developed by ACR[27] (Appendix C). This served to obtain both the number of rejected images and rejection causes. A 'waste box' was allocated in the SFM unit for reject disposal. With CR systems, rejects were retrieved from the computer system.

In **digital mammography**, a '*Reject Analysis*' report, including reject rates, rejected projections, rejection causes and the total number of images was retrieved from the machine itself. Radiographers then exported anonymised, rejected images, which were analysed by the researcher as a means of moderation.

Results

Reject rates and causes

A total of 2291 images were collected, with 60 rejected images being recorded; accounting to a national reject rate of 2.62%. This sample size was deemed to be sufficient as for the repeat rates to be