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The need for triple assessment and predictors for diagnosis of breast cancer in patients <40 years of age[☆]

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AIM: To assess the safety of selective use of triple assessment with omission of radiological assessment proposed in patients <40-years old.

MATERIALS AND METHODS: Data were collected retrospectively for all patients seen in the one-stop breast clinic between January 2014 and August 2015. Demographics, symptoms, diagnostics, and treatment details were recorded. Subgroup and logistic regression analysis was performed to identify predictors for breast cancer.

RESULTS: Of the 3,305 patients included, 95.6% ($n=3,161$) were first-time referrals. 57.6% ($n=1,903$) had a breast lump, and 4% ($n=133$) had a high-risk family history; 75.6% ($n=2,499$) underwent imaging and 16.7% ($n=552$) underwent a biopsy. The median age was 29 years (interquartile range [IQR]=25–34). Breast cancer was diagnosed in 29 cases (0.88%) and 3.2% ($n=105$) had surgery. Median referral-to-diagnosis time was 13 days (IQR=9–14) and referral-to-surgery time was 44 days (IQR=34–95). Patients with breast cancer were significantly older (33 versus 28 years, $p=0.016$). All patients were first-time referrals. Most patients had a breast lump with low suspicion on clinical examination and breast cancer identified on imaging. Time-to-diagnosis (12 versus 14 days, $p=0.017$) and time-to-surgery (37 versus 67 days, $p=0.012$) was significantly shorter in the breast cancer group. Comparative older age (odds ratio [OR]=1.08, 95% confidence interval [CI]: 1.01–1.15) and breast lump (OR=11.43, 95% CI: 2.72–48.07) were the only significant predictors of cancer on uni/multivariate regression.

CONCLUSIONS: Triple assessment is also the best practice for all patients in the younger age group. This cohort should not be treated any differently regarding one-stop clinic infrastructure as the cancers detected were not clinically malignant. Missed cancers in this age group would have significant personal, clinical, and legal consequences.

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Introduction

Breast cancer is the most common cancer affecting women of all ages. The incidence of breast cancer in the UK and worldwide has been steadily increasing.¹ Moreover, the public awareness regarding the symptoms and signs of breast cancer has also increased over the years as a consequence of national campaigns, media coverage, and

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expansion of web based information.² This has led to a substantial increase in the number of new referrals to specialist breast care units. A large proportion of these new referrals are patients <40 years of age despite breast cancer being uncommon in this cohort. All new referrals undergo triple assessment with clinical examination, radiological imaging, and biopsy in accordance with the best practice guidelines and National Institute of Health and Care Excellence (NICE) quality standard.^{3–5} As all new referrals to breast care units have to be seen within 2 weeks, in accordance with the National Health Service (NHS) targets, this generates a considerable pressure on the resources of breast units as one-stop clinically allied immediate radiology slots are limited. This has led to suggestions for omission of radiological assessment in younger patients with low-risk symptoms⁶; however, there is a dearth of evidence to support such an approach. This study was designed to evaluate the use of triple assessment in this younger patient cohort and to assess if omission of radiological imaging is safe in this group, especially in patients with a low-risk history and examination findings.

Materials and methods

The study was carried out in the breast care unit of a tertiary care university hospital. It was designed as a retrospective review from the electronic patient record and case notes of all new referrals to the one-stop breast clinic between January 2014 and August 2015. Approval for the study was obtained from the institutional quality improvement review board. The study was approved as a retrospective audit against the NICE quality standard and did not require additional ethical approval.

All patients presenting to the one-stop breast clinic were initially reviewed by a clinician with interest and expertise in breast diseases (breast surgeon, breast physician, or advanced nurse practitioner). Patients were then referred for breast imaging by the consulting clinician, if deemed clinically appropriate. Imaging was performed by specialist breast radiologists or consultant radiographers. The Royal College of Radiologists Breast Imaging Group recommended five-point scoring system (1, normal; 2, benign findings; 3, indeterminate/probably benign findings; 4, findings suspicious of malignancy; 5, findings highly suspicious of malignancy) was used and similarly applied for each breast for the clinical (P1–P5), radiological (R1–R5), cytopathology (C1–C5), and histopathological components (B1–B5).^{7,8} This system recommends that all lesions that scored R3 warrant further investigations and all R2 abnormalities associated with a solid lesion often warrant a biopsy for confirmation of benignity.⁷ Therefore, further investigations including biopsy or fine-needle aspiration cytology (FNAC), were performed under radiological guidance in cases with concurrent clinical and radiological abnormality or in patients with normal clinical examination (P1), but with a radiological abnormality (R2–R5). The only exception to this rule were patients <25 years with a solid U2 lesion on imaging suggestive of a fibroadenoma with a concordant or

normal (P2/P1) clinical examination. This group of patients did not have a guided biopsy performed routinely. Elastography was not used in the unit to omit the need for biopsy and guided core biopsies were offered in all eligible cases. Freehand clinical biopsy or FNAC was performed in patients with a clinical abnormality (P2–P5) and normal radiological examination (R1) or with a more suspicious clinical abnormality (P3–P5) and discordant low-grade radiological findings (R1, R2). Results for all patients who had a histological or cytological investigation were discussed in the multidisciplinary team (MDT) meeting comprising breast surgeon, breast radiologist, pathologist, oncologist, breast care nurse, oncology nurse, and research nurse. Decisions regarding further investigations including additional imaging, repeat core, and vacuum assisted biopsies (VAB), diagnostic and definitive surgery, oncological treatment, and follow-up planning were made and approved by the MDT.

Data management and statistical analysis

Data were collected for patient demographics, presenting complaint, radiological investigations, and surgical and pathological outcomes. Referral-to-diagnosis time and referral-to-surgery time was calculated to assess compliance with the national standard (referral-to-diagnosis=31 days; referral-to-definitive treatment=62 days). Detailed review of the case notes was performed for all identified breast cancer cases to extract information regarding clinical examination at presentation and subsequent management. Data analysis was performed using SPSS 22.0 (IBM Corporation, Redmond, USA). Distribution testing was performed for all continuous variables. Continuous variables were represented as median with interquartile range (IQR) and hypothesis testing was performed using the Mann–Whitney *U*-test, where applicable. Categorical variables were represented as percentage (%) with actual number of patients (*n*) in each category and compared using the chi-square and Fisher's exact tests. Intergroup analysis was performed for patients with and without breast cancer. Focused logistic regression was performed to identify any potential predictors of breast cancer in this cohort and results were presented as odds ratio (OR) with 95% confidence interval (95% CI). Threshold for significance was set at the 0.05 level.

Results

Presentation

Over the 20-month study period, 13,146 new patients were reviewed in the one-stop breast clinic of which 25.1% (*n*=3,305) were patients <40 years utilising a total of 3,456 new referral slots; 95.6% (*n*=3,161/3,305) were first-time referrals to the breast unit while 4.4% (*n*=144/3,305) had more than one attendance recorded at the one-stop clinic during the study period. All patients <40 years (*n*=3,305) were included in the study. The median age of study participants was 29 years (IQR=25–34 years) and 2.6% (*n*=85/

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