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Clinical performance of Siemens digital breast tomosynthesis versus standard supplementary mammography for the assessment of screen-detected soft-tissue abnormalities: a multi-reader study

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AIM: To compare the diagnostic accuracy of standard screening images plus single-view digital breast tomosynthesis (DBT), using Siemens DBT equipment, with standard screening images plus supplementary mammographic views in non-calcific, screen-detected mammographic abnormalities.

MATERIALS AND METHODS: Participants were unselected women aged 50–69 years recalled within a population-based European breast screening programme for assessment of soft-tissue mammographic abnormalities. Supplementary mammographic views (SMVs) and DBT were performed in all cases. A range of equipment was used for screening and supplementary mammography, but all DBT examinations were performed using the Siemens Mammomat Inspiration. A retrospective multi-reader study including 238 cases for whom either histology or at least 2 years' follow-up was available was performed with eight suitably accredited UK breast screening personnel reading all cases under both conditions, with temporal separation. Readers were blinded to case outcomes and findings from other examinations. Diagnostic accuracy using receiver operating characteristic (ROC) analysis was compared between screening plus SMV images and screening plus DBT images. The study was powered to detect a 3% inferiority margin in diagnostic accuracy between methods.

RESULTS: The final sample with complete data available for analysis included 195 benign cases (1,560 reads) and 35 malignant cases (280 reads). The DBT method yielded a slightly

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higher area under the curve (AUC) value than the SMV method (0.870 versus 0.857), but the difference was not statistically significant (p=0.4890), indicating that the methods have equivalent accuracy.

CONCLUSION: Siemens DBT demonstrates equivalent diagnostic accuracy according to ROC curve analysis when used in place of SMVs in screen-detected soft-tissue mammographic abnormalities.

Introduction

Supplementary mammography, such as spot compression views, has traditionally been performed when standard screening mammography has detected masses, distortions and asymmetric densities that do not display definitively benign appearances. Although spot compression views can accurately characterise the borders of masses and confirm the presence or absence of distortion, they are sometimes wrongly interpreted as benign or normal.[1,2] Some of the errors arise from the lesion being displaced out of the field by the compression paddle.[2] The limitations of spot compression views have led to the recommendation in UK assessment guidelines that ultrasound examinations should always be performed in cases of recall for asymmetric density.[3]

Digital breast tomosynthesis (DBT) is a recent development of full-field digital mammography (FFDM). By acquiring multiple low-radiation-dose images across a range of angles and reconstructing the data to present a series of thin "slice" images, DBT ameliorates the problem of feature obscuration by overlying tissues. It has been shown that clinical accuracy can be improved as a result,[4] with DBT being particularly effective at detecting mammographic spiculation.[5] As DBT images the whole breast, displacement of the lesion out of the imaging field is not an issue and DBT also has the potential to enable the detection of additional ipsilateral lesions not apparent on the original FFDM images. These potential advantages have led to a number of studies comparing supplementary mammographic views (SMVs) and DBT in women recalled from mammographic screening for non-calcific abnormalities. These studies have tended to show that DBT is not inferior to SMVs or, in some cases, slightly superior.[6–11] One of the larger studies, from the UK, demonstrated that for standard FFDM plus SMVs, the area under the receiver operating characteristic (ROC) curve (the AUC) was 0.87, while for FFDM plus single-view DBT, the AUC was 0.93 (p=0.0014)[8]. Such studies have, until recently, been performed using equipment from a single vendor, Hologic.

DBT equipment from other vendors is now commercially available in the UK, but the technical specifications vary to such an extent that the National Health Service Breast Screening Programme (NHSBSP) in the UK requires vendor-specific data before approving the replacement of SMVs with DBT for the assessment of non-calcific screen-detected abnormalities. The specifications of the three systems that have received NHSBSP technical evaluations to date are described in a series of reports.[12–14] Tomosynthesis-specific variations between these systems include whether a grid is used: no in Siemens and Hologic, yes in GE; the height of the centre of rotation of the tube in relation to the detector surface; whether the projection images are obtained while the tube is in motion (Hologic and Siemens), or with a step-and-shoot process (GE); the reconstruction algorithm (filtered back projection in Siemens, filtered back projection with iterative optimisation in Hologic, iterative in GE); the pixel size of the reconstructed images (85 μm in Siemens, 100 μm in Hologic and GE); and the number of projection images and the angular range over which they are obtained. In the Siemens equipment, 25 projection images are obtained across 50°,[14] in the Hologic, 15 are obtained across 15°,[12] and in the GE, nine are obtained across 25°.[13] In general, variations in such parameters not only interact but, in themselves, yield gains and losses in image quality and, in some cases, radiation dose. Therefore, the design details always involve a trade-off. For example, a wider angular range is expected to enhance in-depth resolution, which might aid radiological interpretation, but this comes at the cost of lower in-plane resolution.[15]

In a recent study using GE equipment, retrospective analysis with blinding to the opposite condition demonstrated that the performance of two-view screening FFDM plus two-view DBT performed at assessment was non-inferior to the performance of two-view FFDM plus SMVs – AUC = 0.873 (95% CI: 0.834–0.906) and 0.900 (95% CI: 0.864–0.929), respectively (p=0.17).[16]

The aim of the present study was to compare the diagnostic accuracy of standard screening images plus single-view assessment DBT, using Siemens DBT equipment, with standard screening images plus supplementary mammographic views in non-calcific, screen-detected mammographic abnormalities.

Materials and methods

This study was a collaboration between a breast screening programme in Germany and a research group in the UK. This approach was used to avoid unnecessarily repeating a prospective interventional study while at the same time providing data applicable to the UK breast screening programmes.

The study cases were acquired prospectively in a population-based screening programme in Germany, in

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