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Sensitivity of a Direct Computer-aided Detection System in Full-field Digital Mammography for Detection of Microcalcifications Not Associated with Mass or Architectural Distortion

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Abstract

Purpose: The purpose of this study was to evaluate the sensitivity of a direct computer-aided detection (CAD) system (d-CAD) in full-field digital mammography (FFDM) for the detection of microcalcifications not associated with mass or architectural distortion.
Materials and Methods: A database search of 1063 consecutive stereotactic core biopsies performed between 2002 and 2005 identified 196 patients with Breast Imaging-Reporting and Data System (BI-RADS) 4 and 5 microcalcifications not associated with mass or distortion detected exclusively by bilateral FFDM. A commercially available CAD system (Second Look, version 7.2) was retrospectively applied to the cranio-caudal and mediolateral oblique views in these patients (mean age, 59 years; range, 35−84 years). Breast density, location and mammographic size of the lesion, distribution, and tumour histology were recorded and analysed by using χ^2, Fisher exact, or McNemar tests, when applicable.
Results: When using d-CAD, 71 of 74 malignant microcalcification cases (96%) and 101 of 122 benign microcalcifications (83%) were identified. There was a significant difference ($P < .05$) between CAD sensitivity on the craniocaudal view, 91% (68 of 75), vs CAD sensitivity on the mediolateral oblique view, 80% (60 of 75). The d-CAD sensitivity for dense breast tissue (American College of Radiology [ACR] density 3 and 4) was higher (97%) than d-CAD sensitivity (95%) for nondense tissue (ACR density 1 and 2), but the difference was not statically significant. All 28 malignant calcifications larger than 10 mm were detected by CAD, whereas the sensitivity for lesions small than or equal to 10 mm was 94%.
Conclusions: D-CAD had a high sensitivity in the depiction of asymptomatic breast cancers, which were seen as microcalcifications on FFDM screening, with a sensitivity of d-CAD on the craniocaudal view being significantly better. All malignant microcalcifications larger than 10 mm were detected by d-CAD.

Résumé

Objet: Cette étude avait pour objet d'évaluer la sensibilité d'un système direct de détection assistée par ordinateur utilisé en mammographie numérique plein champ pour détecter les microcalcifications non associées à la présence de masses ou à une distorsion architecturale.
Matériel et méthodes: Une recherche dans une base de données répertoriant 1 063 microbiopsies stéréotaxiques consécutives pratiquées entre 2002 et 2005 a permis d'identifier 196 patientes présentant des microcalcifications de type BI-RADS 4 et 5 non associées à la présence de masses ou à une distorsion architecturale détectées exclusivement au moyen de la mammographie numérique plein champ bilatérale. Un système de détection assistée par ordinateur offert sur le marché (Second Look, version 7.2) a été appliqué rétrospectivement aux incidences cranio-caudales et médio-latérales obliques de ces patientes (âge moyen de 59 ans; fourchette de 35 à 84 ans). La densité mammaire, l'emplacement et la taille mammographique de la lésion, la répartition et l'histologie de la tumeur ont été consignés et analysés au moyen du χ^2, de la méthode exacte de Fisher ou du test McNemar, selon le cas.
Résultats: L'utilisation du système direct de détection assistée par ordinateur a permis de détecter 71 cas de microcalcifications malignes sur 74 (96 %) et 101 cas de microcalcifications bénignes sur 122 (83 %). Il y avait une différence significative ($P < 0{,}05$) entre la sensibilité de la détection assistée par ordinateur par l'analyse des incidences cranio-caudales, soit 91 % (68 sur 75), par opposition à sa sensibilité par l'analyse des incidences médio-latérales obliques, soit 80 % (60 sur 75). La sensibilité du système direct de détection assistée par ordinateur

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était plus élevée (97 %) par l'analyse de tissus mammaires denses (densité de 3 et 4 selon l'ACR) que par l'analyse de tissus mammaires non denses (densité de 1 et 2 selon l'ACR) (95 %), mais cette différence n'était pas statistiquement significative. Le système de détection assistée par ordinateur a détecté les 28 calcifications malignes d'une taille supérieure à 10 mm et a affiché un taux de sensibilité de 94 % à l'égard des lésions d'une taille inférieure ou égale à 10 mm.

Conclusions: Le système direct de détection assistée par ordinateur était très sensible lorsqu'il s'agissait de démontrer les cancers du sein asymptomatiques, qui apparaissaient sous la forme de microcalcifications lors du dépistage par mammographie numérique plein champ. Sa sensibilité était plus élevée par l'analyse des incidences cranio-caudales. Le système de détection assistée par ordinateur a détecté toutes les microcalcifications malignes d'une taille supérieure à 10 mm.

Key Words: Breast cancer; Computer-aided detection; Computer-aided diagnosis; Digital images; Full-field digital mammography; Microcalcifications

New technologies in medical imaging often herald great promise for clinical advancement. Since its approval by the U.S. Food and Drug Administration (FDA) in June 1998 for the first commercial use, computer-aided detection (CAD) software in mammography has become increasingly available worldwide. CAD is designed to provide visual prompts in specific areas on the image. The image needs to be in digital media presentation for the interpreting radiologist, either by digitizing analog mammograms or by using digital mammography systems (direct radiography [DR] or computed radiography [CR]).

Much of the clinical research that evaluated CAD in mammography was based on digitized film-screen mammograms, which is also called indirect CAD [1−16]. For indirect CAD, the reported sensitivity is 76% for masses (49%−90%) and 90% for calcifications (40%−100%). Little has been published [17−23] about the accuracy of CAD applied to digital mammography, called direct CAD (d-CAD). One of the FDA's approved devices (ImageChecker; R2 Technology, Los Altos, CA) has a reported sensitivity of 79% for masses and 90% for calcifications [1−4,9,10,17−22] and the other major FDA-approved device (Second Look System, iCAD, Nashua, NH) has a reported sensitivity of 92% for masses and 93% for calcifications [23]. The purpose of our study was to retrospectively evaluate the sensitivity of a d-CAD system in depicting pure microcalcification or areas of microcalcifications without associated density, mass, or architectural distortion depicted on bilateral full-field digital mammography (FFDM) that proved to be malignant at subsequent surgery.

Materials and Methods

Patients

Institutional research ethics board approval was obtained. The study was compliant with the Health Insurance Portability and Accountability Act. Chart review was performed for all patients who underwent stereotactic core biopsy between 2002 and 2005 at a tertiary hospital. Patients referred for biopsy with Breast Imaging-Reporting and Data System (BI-RADS) 4 and 5 calcifications detected by routine screening FFDM were included in the study population. Patients ranged in age from 35–84 years (mean age, 59 years), and those younger than 40 years had screening mammography because they were high-risk patients. A total of 1063 patients underwent stereotactic biopsies; of these, 243 had screening mammogram performed on a FFDM (Senographe 2000D; GE Medical Systems, Milwaukee, WI). Of 243 cases, 39 had to be excluded because of technical factors (in 35 patients, the most recent d-CAD version could not be retrospectively applied, and 4 cases had only magnification views done on FFDM). Eight cases were excluded because of the association with a mass. Of the remaining 196 patients, 193 had excision biopsy. Three patients refused surgical excision and opted out for mammographic follow-up. Our study population was made up diagnosis of 74 cases of breast cancer (21 invasive and 53 in situ carcinomas) and 122 benign calcifications on surgical excision or with a mean 4.17 years imaging follow-up. The mean (standard deviation) age of the 196 women was 57.23 $\pm$ 8.47 years.

Digital Mammography and d-CAD

All digital mammograms were obtained by using a FFDM unit (Senographe 2000D). All mammograms (craniocaudal [CC] and mediolateral oblique [MLO] views) were reviewed by using a dedicated workstation (Advantage GE Workstation; GE Medical Systems), which runs with a d-CAD system (Second Look System, version 7.2; iCAD, Nashua, NH). The d-CAD system marks areas of concern, such as calcifications, masses, and architectural distortion.

Images Review

A soft-copy review was performed in a dedicated darkened room for digital mammography by a single radiologist (A.M.S., with 13 years of post−breast imaging fellowship experience and 5 years of experience with soft-copy reading) who used the Advantage GE Workstation, which included 2 high-resolution 2,000 $\times$ 2,500-pixel monitors and a dedicated keypad. This single radiologist recorded the location (quadrant and subareolar), distribution (clustered, segmental, linear, and regional), and the density of the breast (American College of Radiology [ACR] density 3 or heterogeneously dense, and ACR density 4 or extremely dense were