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Digital tomosynthesis in breast cancer: A systematic review☆

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KEYWORDS
Breast cancer;
Screening;
Tomosynthesis;
Three-dimensional imaging;
Mammography;
Sensitivity and specificity

Abstract
Objective: To estimate and compare the diagnostic validity of tomosynthesis and digital mammography for screening and diagnosing breast cancer.
Material and methods: We systematically searched MedLine, EMBASE, and Web of Science for the terms breast cancer, screening, tomosynthesis, mammography, sensitivity, and specificity in publications in the period comprising June 2010 through February 2013. We included studies on diagnostic tests and systematic reviews. Two reviewers selected and evaluated the articles. We used QUADAS 2 to evaluate the risk of bias and the NICE criteria to determine the level of evidence. We compiled a narrative synthesis.
Results: Of the 151 original studies identified, we selected 11 that included a total of 2475 women. The overall quality was low, with a risk of bias and follow-up and limitations regarding the applicability of the results. The level of evidence was not greater than level II. The sensitivity of tomosynthesis ranged from 69% to 100% and the specificity ranged from 54% to 100%. The negative likelihood ratio was good, and this makes tomosynthesis useful as a test to confirm a diagnosis. One-view tomosynthesis was no better than two-view digital mammography, and the evidence for the superiority of two-view tomosynthesis was inconclusive.
Conclusions: The results for the diagnostic validity of tomosynthesis in the diagnosis of breast cancer were inconclusive and there were no results for its use in screening.

PALABRAS CLAVE
Cáncer de mama;
Cribado;
Tomosíntesis;

Tomosíntesis digital en el cáncer de mama. Revisión sistemática

Resumen
Objetivo: Estimar y comparar la validez diagnóstica de la tomosíntesis y la mamografía digital para cribar y diagnosticar el cáncer de mama.

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Imagen tridimensional;
Mamografía;
Sensibilidad y especificidad

Material y métodos: Realizamos una revisión sistemática consultando MedLine, EMBASE y *Web of Science* en el periodo de junio de 2010 a febrero de 2013. Los términos de búsqueda fueron: cáncer de mama, cribado, tomosíntesis, mamografía, sensibilidad y especificidad. Se incluyeron estudios de pruebas diagnósticas y revisiones sistemáticas. Dos investigadores hicieron la selección y evaluación. Usamos QUADAS 2 para valorar el riesgo de sesgo y los criterios NICE para el nivel de evidencia. Se hizo una síntesis narrativa.
Resultados: De los 151 estudios originales identificados se seleccionaron 11 que incluyeron 2.475 mujeres. Su calidad fue baja, con riesgo de sesgo de selección y seguimiento, y limitaciones para aplicar sus resultados. Su nivel de evidencia no fue superior a II. La sensibilidad de la tomosíntesis osciló entre el 69 y el 100% y la especificidad entre el 54 y el 100%. El cociente de probabilidad negativo fue bueno, lo que la convertiría en una prueba de confirmación diagnóstica. La tomosíntesis con una proyección no fue superior a la mamografía digital con 2, y con 2 proyecciones los resultados no fueron concluyentes.
Conclusiones: Los resultados de la validez diagnóstica de la tomosíntesis en el diagnóstico del cáncer de mama no fueron concluyentes, y no los hubo para usarla en el cribado.

Introduction

Mammogram is the basic modality for breast cancer clinical diagnosis and screening. Screening continues to be the main preventive measure to reduce mortality though its effect is subject to discussion.[1] In Spain, it is recommended for 50–69-year-old women, though some autonomous communities also include 45–49 year-old women. In spite of its high sensitivity (between 85 and 95%) and specificity (>90%)[2] mammograms also give false negatives and positives that bring about anxiety, unnecessary procedures and overdiagnoses. To this we have to add the effects of radiation and the discomfort caused by breast compression. Diagnostic limitations are greater in dense breasts which are in turn the ones with the highest risk for developing cancer.[1,3]

Digital mammographies have operational advantages and possibilities for technological evolution. With them, cancer detection rate is slightly higher than that of conventional mammographs yet recall rates or the characteristics of the tumors found do not usually vary.[4] Digital breast tomosynthesis has developed from digital mammographs as an alternative or complement.[5,6] It was approved by European Commission (EC) in 2008 and by the U.S. Food and Drug Administration (FDA) in 2011 and it is installed in 12 health care centers in Spain. It differs from digital mammographies in that for each projection the X-ray tube describes a rotation arch on a plane around the breast ranging from 11 to 50°, taking between 9 and 25 images.[5–7] The images are computed processed for a digital breast reconstruction in 3 dimensions. There is a great variety of machines for tomosynthesis. With a single breast compression some machines successively obtain two-dimensional digital mammographic images and three-dimensional tomosynthesis images, while others obtain the 3D images directly from tomosynthesis from which they reconstruct a 2D image (synthesized image). Applications for the analysis of texture, to make numerical quantifications and detect and help to diagnose masses and microcalcifications[5] have been developed to analyze the images.

A systematic review was conducted in the year 2010 to evaluate the diagnostic validity of tomosynthesis, which demonstrated its possible utility for the diagnosis of breast cancer but without evidence about its utility in screening.[8] Due to the increase of medical literature on this regard and the growing interest among professionals we thought it was a good idea to repeat it in order to update the evidence available to establish its effectiveness, in terms of diagnostic validity and accuracy, in screening and breast cancer diagnosis.

Material and methods

This systematic literature review was conducted following the PRISMA[9] statement recommendations and devising an internal work protocol. The results were synthesized in a narrative manner because it was not possible to achieve statistic combination due to the heterogeneity of the studies.

Sources of information

The MedLine, EMBASE, Web of Science and PubMed (Annex 1) databases were reviewed (from June 2010 to February 2013). Research was also conducted at the Center for Reviews and Dissemination (CRD), the International Information Network on New and Emerging Health Technologies (EuroScan) and the Cochrane Library. The websites of agencies not included in INAHTA were reviewed, the Spanish Ministry of Health, Social Services and Equality, the platform of Agencies and Units of Evaluation of Health Technologies (AUnETS), the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), The Emergency Care Research Institute (ECRI), The National Institute for Health and Clinical Excellence (NICE) and the American Cancer Society (http://www.cancer.org). Also a manual review of the bibliography of the studies included was implemented.