Digital Breast Tomosynthesis and the Challenges of Implementing an Emerging Breast Cancer Screening Technology Into Clinical Practice

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Abstract

Emerging imaging technologies, including digital breast tomosynthesis, have the potential to transform breast cancer screening. However, the rapid adoption of these new technologies outpaces the evidence of their clinical and cost-effectiveness. The authors describe the forces driving the rapid diffusion of tomosynthesis into clinical practice, comparing it with the rapid diffusion of digital mammography shortly after its introduction. They outline the potential positive and negative effects that adoption can have on imaging workflow and describe the practice management challenges when incorporating tomosynthesis. The authors also provide recommendations for collecting evidence supporting the development of policies and best practices.

Key Words: Digital breast tomosynthesis, technology adoption, adjunct screening

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INTRODUCTION

According to the American Cancer Society, 130,000 US lives have been saved in the past 20 years through early detection and treatment of breast cancer, with substantial credit given to screening [1]. However, mammography remains an imperfect modality, with concerns for potential harms outweighing benefits among certain subgroups of women, including those aged 40 to 49 years [2]. An estimated 10% of screening women with no cancer undergo unnecessary diagnostic imaging and/or biopsy [3]. The potential harms from false-positive screening results provided the impetus for the US Preventive Service Task Force to revise its guidelines in 2009 to no longer recommend routine screening for women 40 to 50 years of age.

Over the past decade, screen-film mammography (SFM) has been rapidly replaced by digital mammography (DM), which has comparable accuracy but greater workflow efficiency compared with SFM. In 2011, the FDA approved digital breast tomosynthesis (DBT) for all mammographic clinical indications. With FDA endorsement, DBT is diffusing into routine clinical practice with the promise of decreasing false-positives and increasing cancer detection by eliminating DM's interpretive limitations caused by superimposed breast tissue. Yet, the adoption of DBT is outpacing the collection of clinical effectiveness data and reimbursement policies, leaving individual radiology groups with little guidance regarding whether and how to implement this emerging technology into their practices.

In this article, we review the drivers for rapid DBT adoption, compared with the drivers of DM; evaluate the potential impact of DBT on breast imaging workflow and practice management; and provide recommendations for evidence gathering to guide DBT policy and best practices.

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INITIAL EVIDENCE AND PROMISE

DBT garnered great enthusiasm on the basis of early observer performance studies that showed its equal or better accuracy compared with standard DM [4-6]. Single-institution studies showed adjunct DBT in addition to standard DM to improve diagnostic accuracy, largely because of a reduction in false-positives [7-9]. More recently, two population-based screening studies demonstrated substantial, statistically significant gains in screening performance when DBT is added to DM. Both an interim analysis from the Oslo screening study (n = 12,631 women) and final results from the Italian Screening With Tomosynthesis or Standard Mammography trial (n = 7,292 women) confirmed significant reductions in recall rates (15%–17%) and improvements in cancer detection rates (33%–53%) with adjunct DBT in national screening populations [10,11].

As an adjunct tool, DBT has many workflow advantages compared with screening ultrasound and MRI. Because it is built into newer generation mammographic units and is obtained during the same breast compression as standard digital mammographic projections, DBT is associated with little extra time investment for patients and technologists. The addition of screening ultrasound or MRI, in contrast, requires the transfer of patients between examination rooms and both patient and technologist time for image acquisition. Thus, compared with ultrasound and MRI, DBT has the advantage of increased patient throughput, streamlined equipment needs (including purchasing, maintenance, certification, and quality assurance), reduced physical space needs, and reduced training of technical staff members and physicians across modalities. These advantages have led many practices to adopt DBT at an early stage, before the acquisition of sufficient clinical effectiveness data.

DRIVERS OF EARLY ADOPTION

To identify the key drivers of DBT's early adoption, comparison with DM's adoption over the past decade may be helpful. DM received FDA approval in 2000 for the same screening and diagnostic indications as traditional SFM. However, the major clinical trial (ACRIN®'s Digital Mammographic Imaging Screening Trial) demonstrating that DM had similar overall accuracy to SFM was conducted from 2001 to 2003, with results published in 2005 [3]. The study found no statistically significant difference in overall diagnostic accuracy between SFM and DM but did find improved accuracy with DM in premenopausal women and in those with dense breasts. Regardless, DM had already diffused into general radiology practices at the time of reporting. Moreover, a cost-effectiveness analysis comparing DM with SFM for screening was not published until 2008 and demonstrated that using DM for all screening was not more cost-effective than using SFM [12]. However, by that time, DM had firmly supplanted SFM in the majority of US radiology practices.

FDA approval is only one step in allowing technology adoption. The main purpose of FDA approval is to determine that new imaging technologies are safe and effective. However, the threshold level of evidence required for FDA approval of new or modified imaging modalities does not necessarily require demonstration of improved patient outcomes [13]. Moreover, this subtlety of FDA approval is not clear to most patients or many health care providers.

After FDA approval, rapid diffusion of DM coincided with reimbursement, in accordance with the Benefits Improvement and Protection Act of 2000 [14]. Congress enacted DM reimbursement for Medicare beneficiaries, with private insurers following suit shortly thereafter. Similar to DM, adjunct computer-aided detection (CAD) programs (which received FDA approval in 1998) obtained Medicare coverage in 2000 to assist radiologists in mammographic interpretation, despite limited evidence that CAD improved accuracy compared with routine mammography alone [15,16]. Subsequently, a 2007 study of > 400,000 mammograms from > 40 US facilities found overall reduced screening accuracy with CAD versus without CAD [17]. Other recent analyses suggest uncertainty regarding whether CAD has made any positive impact on patient outcomes [18,19]. Similar to DM, rapid diffusion of CAD was highly associated with Medicare coverage, with prevalence of CAD increasing from 4.8% in 2001 to 26.9% in 2003 [20].

In contrast to DM and CAD, DBT is currently not reimbursed by Medicare, and yet the technology continues to diffuse into community settings [21]. Therefore, financial remuneration from third-party payers, although critical for technological adoption, is not the sole driving force. Instead, device manufacturers are using direct-to-consumer marketing to target women who may be interested in paying out of pocket for potentially improved screening outcomes. DBT is being touted as "3-D mammography" in community settings, and practices are adopting the new technology to differentiate themselves from their regional competitors and gain a higher proportion of the available imaging market share.