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Editorial

EDITORIAL

Time to Consider a Personalized Approach to Incorporate Tomosynthesis Into Routine Breast Cancer Screening

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Tomosynthesis, also known as 3D mammography, is a new screening technology approved by the US Food and Drug Administration in 2011 that has been shown to increase cancer detection rates, decrease recall rates, and improve the performance characteristics of screening, especially among women with dense breasts (1,2). The diffusion of digital breast tomosynthesis (DBT) into clinical practices has been swift, and it appeared to have accelerated with the increasing number of states that passed breast density notification legislation (3). In addition, this new technology has been quickly gaining support in the clinical community. For example, in the breast cancer screening guidelines released by the American Society of Breast Surgeons in May 2019, DBT was designated as the preferred screening modality, regardless of women's risk classification and breast density (4).

The Centers for Medicare and Medicaid Services (CMS) approved reimbursement for DBT performed in conjunction with conventional digital mammography (DM) in October of 2014 (5), with the reimbursement rate for DBT at $50–$60 higher than for DM alone. However, the coverage policy from the CMS only applies to Medicare and Medicaid beneficiaries, not to women with private insurance. Furthermore, states that require providers to notify women of their breast density after a mammogram exam do not necessarily mandate private insurance to cover DBT. A patient survey conducted at an academic center in 2017 reported that additional out-of-pocket payment was the most important reason for patients to decline DBT when offered in the screening setting (6). A study that reviewed national Medicare Part B Physician/Supplier Procedure Summary master files reported that of the 5 730 635 screening full-field DM billed to Medicare Part B fee-for-service plans in 2015, 1 084 256 (18.9%) had also billed DBT as an add-on procedure (7). Using the CMS reimbursement rate of $56.16 for add-on bilateral screening DBT (Current Procedural Terminology code 77063), DBT alone would have cost Medicare over $60 million dollars in 2015. As DBT becomes more prevalent, the cost of add-on DBT is expected to be higher in more recent years. Given the financial implications of DBT for payers and some patients, it is important to assess the additional value DBT (over DM alone) contributes to breast cancer control and prevention. Cost-effectiveness analysis offers a well-accepted analytical framework for such value assessment (8).

In this issue of the Journal, Lowry et al. present the results of three simulation models from the Cancer Intervention and Surveillance Modeling Network breast cancer group to compare the cost-effectiveness of DBT in conjunction with DM vs DM alone among women at average risk of breast cancer (9). The authors conclude that although DBT + DM was associated with a noticeable reduction in false-positive exams, this new screening modality, at its current reimbursement rate, is not a cost-effective routine breast screening strategy in the general screening eligible population, which includes a mixture of women with dense and nondense breasts. It is worth noting that an earlier study from investigators in the Cancer Intervention and Surveillance Modeling Network breast cancer group found DBT + DM to be cost-effective compared with DM alone among women with dense breasts (10). Although Lowry et al. did not perform separate cost-effectiveness analyses for women with dense and those with nondense breasts, collective evidence from these two modeling studies suggests that DBT in conjunction with DM is unlikely to be a cost-effective strategy for routine screening among women with nondense breasts. This raises a concern that any breast cancer screening strategy not differentiated by breast density status will likely only be cost-effective for either the subgroup of women with dense breasts or those with nondense breasts, but not both. Thus, the design of an optimal screening strategy at the population level should employ a more personalized approach. A screening strategy worth exploring in future modeling studies is one that begins with a baseline screening with DM alone at a younger

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age (eg, age 40 years) to determine breast density classification, followed by screening strategies consisting of different screening modalities and/or screening intervals based on breast density classification. This personalized screening strategy should also be dynamic to allow for the flexibility to modify the best path forward by taking into consideration changes in breast density with aging.

From a methodological perspective, more can be done to better address uncertainty. Two common sources of uncertainty in modeling studies are parameter uncertainty and structural uncertainty. Lowry et al. address structural uncertainty by reporting a range of results from three independently developed models. They did not address parameter uncertainty, citing "prohibitively large number of parameters" as the reason. While computationally intense, addressing parameter uncertainty is technically doable and is especially important for this study, given the somewhat preliminary nature of clinical parameters and the small magnitude of improvement in quality-adjusted life years from DM to DBT+DM at the population level (range = 1.97–3.27 quality-adjusted life years per 1000 women) relative to a rather large increase in cost ($395 553–$445 722 per 1000 women), resulting in a small denominator for the incremental cost-effectiveness ratio. In such case, the estimated incremental cost-effectiveness ratio could have wide variations, which makes it critical for policy makers to better understand the impact of modeling parameters.

Prior research has found that the diffusion of new medical devices for cancer treatment tends to move ahead of trial-based evidence. In oncology practice, it is not uncommon to find that before the results of trials for the treatment associated with a new technology become available, the new treatment has begun to replace the conventional treatment (11). The same pattern is also observed in new technologies for cancer screening and is happening with the embrace of DBT in breast cancer screening practice. By documenting that the addition of DBT to DM is not a cost-effective routine screening strategy for screening eligible women, the study by Lowry et al. cautions technenthused practitioners to reassess the value of DBT, especially for women with nondense breasts for whom the clinical benefits of DBT seem unlikely to outweigh the additional costs.

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