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Breast Cancer Screening Among Medically Underserved Women in New Mexico: Potential for Lower Recall Rates with Digital Breast Tomosynthesis

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Abstract

Introduction: Digital breast tomosynthesis (DBT) may decrease recall rates (RRs) and improve positive predictive values (PPVs) and cancer detection rates (CDRs) versus full-field digital mammography (FFDM). The value of DBT has not been assessed in New Mexico's rural and minority population. Objectives of this study were to compare RRs, CDRs, and PPVs using FFDM+DBT versus FFDM in screening mammograms at the University of New Mexico between 2013 and 2016 and to qualitatively evaluate patient decision-making regarding DBT.

Materials and Methods: RRs, CDRs, and PPVs with 95% confidence intervals and relative risk were calculated from 35,147 mammograms. The association between relative risk and mammography approach was tested using Pearson's chi-square test. Twenty women undergoing screening were interviewed for qualitative evaluation of decision-making.

Results: From 2013 to 2016, RRs were 8.4% and 11.1% for FFDM+DBT and FFDM, respectively. The difference in RRs became more pronounced with time. No significant difference was observed in PPVs or CDRs. Qualitative interviews revealed that the majority had limited prior knowledge of DBT and relied on provider recommendations.

Conclusion: In New Mexico women undergoing screening mammography, a 30% relative risk reduction in RRs was observed with FFDM+DBT. Qualitative interviews suggest that women are aware of and receptive to DBT, assuming adequate educational support. Clinical Trials.gov ID: NCT03979729.

Keywords: medically underserved women, digital breast tomosynthesis, breast cancer screening, recall rate

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Introduction

Digital breast tomosynthesis (DBT), or three-dimensional (3D) mammography, involves the acquisition and reconstruction of multiple, thin-slice, tomographic projection images of the breast. It is performed in conjunction with a separate two-dimensional (2D) image or a synthetic reconstruction 2D image (denoted as FFDM+DBT hereafter). DBT has the potential to improve breast imaging when compared with 2D full-field digital mammography (FFDM) by providing a series of images through the breast. This reduces tissue overlap and assists in discrimination between normal tissue structures and malignancy detection. As a result, DBT may improve sensitivity and specificity of screening mammography and thereby reduce unnecessary recalls.[1] In addition to the cancer detection rate (CDR), recall rate (RR), which is defined as the percentage of screening mammogram studies that require further diagnostic evaluation,[2] is a metric of particular interest with regard to breast cancer screening. A concern related to DBT is the cost at a population level when its use is generalized to all women undergoing breast cancer screening. Despite increasing worldwide adoption of DBT, there is not yet a consensus regarding approved indications, management guidelines, and evidence-based application of the Breast Imaging Reporting and Data System.[3]

New Mexico has a large proportion of ethnic/racial minorities and widespread language barriers (a third of the population speaks a language other than English at home).[4] Nearly 25% of the population lives in a rural area.[5] Of the 2 million people living in New Mexico, according to the U.S. Census Bureau estimates, 48.5% self-identified as Hispanic, 37.8% self-identified as White, and 10.1% self-identified as American Indian.[5] The estimated percentages of women, aged 50–74 years, who had had a mammogram within the previous 2 years, by race/ethnicity, in New Mexico in 2016 were as follows: 75.3% Hispanic, 67.7% Black/African American, and 74.8% American Indian women compared with 70% non-Hispanic White women.[6] Overall, New Mexico ranked 50th in up-to-date mammography in women 45 years and older in 2018.[7] According to the 2017 U.S. Census Bureau, New Mexico was tied for second place with the highest percentage of people living below the poverty line at 19.7% (U.S. Census Bureau, 2017). Factors that have been associated with low mammography screening rates include low socioeconomic status, belonging to a racial/ethnic minority, and living in a rural area.[8,9]

RR compliance is also known to be affected by race and ethnicity, with delayed presentation common in Hispanic and African American women compared with non-Hispanic Whites.[10] The patient cost associated with recall after a false positive screening mammogram is a financial hardship that may disproportionally affect medically underserved women. This cost has been estimated at $138/recall, and although insurance covers part of the cost, there are other intangible costs involved, including travel, concerns regarding child care, and work absenteeism, as well as associated anxiety.[11]

The value of DBT as a method for breast cancer screening has not been assessed in unique patient populations such as ours. We hypothesize that DBT is associated with a reduction in RR compared with FFDM in the population of minority and medically underserved women who characterize our state. To evaluate this, we retrospectively analyzed 35,147 screening mammograms conducted at the University of New Mexico (UNM) between 2013 and 2016 for RRs. In addition, we analyzed two other key clinical outcomes of interest related to the screening mammogram, positive predictive value (PPV) and CDR. Additionally, we sought to characterize the general knowledge and perspectives of medically underinsured women toward DBT ± FFDM. We conducted a qualitative evaluation of patient perspectives on factors influencing uptake and decision-making regarding DBT to better understand the complexities of decision-making between FFDM+DBT and FFDM among Medicaid-eligible women in our breast cancer screening population.

Materials and Methods

This study was approved by the UNM Institutional Review Board and was compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Study population

Women undergoing screening mammography in the UNM Department of Radiology are referred predominantly from our primary care, gynecology, and cancer center clinics. Demographic data for the women undergoing screening mammography in this study were not available. However, as representative of our referral base, the University of New Mexico Comprehensive Cancer Center (UNM CCC) sees 1,884 new cancer diagnoses yearly. Hispanic patients account for 639 (33%) new cases per year, while American Indians account for an additional 127 cases (7%). Approximately 48% of the cancer patients seen at the UNM CCC reside outside Bernalillo County (where UNM CCC is located). Twenty percent of UNM CCC patients travel >100 miles to receive care compared with 9% of the national average for academic medical centers as per the Commission on Cancer.

Quantitative mammogram evaluation measurements

We retrospectively analyzed 35,147 screening mammograms conducted at the UNM between 2013 and 2016. The primary quantitative endpoints were RR, PPV, and CDR for DBT+FFDM and FFDM. RR is defined as the number of women recalled for additional imaging after the screening mammogram divided by the total number of women screened. PPV is defined as the percentage of all positive screening examinations that result in a tissue diagnosis of cancer within 1 year. CDR is defined as the number of cancer cases detected divided by 1,000 persons screened. Mammography data were collected from the UNM Hospital Mammography Tracking and Reporting System (PenRad Technologies, Inc., Buffalo, MN). Data were aggregated for FFDM and FFDM+DBT examinations performed between January 1, 2013, and December 31, 2016. The logic for the query and derivation of the resulting information was developed by PenRad from their pathology summary report. The selection logic for that query was modified to restrict the results to women whose age at the time of the examination was 40 years or older. Abstracted data elements are detailed in Table 1.

Table 1. Abstracted Data Elements

No. of screening cases or select mammogram type
No. of screening cases, BI-RADS categories 0, 4, or 5
No. of biopsy pathologies that were malignant
No. of biopsy pathologies that were benign
No. of cases from BI-RADS 4 and 5 lost, refused, *etc.*
No. of ductal carcinoma *in situ*
No. of true positives
No. of false positives
Positive predictive value
Cancer detection rate
% recall (recall rate)

BI-RADS, Breast Imaging-Reporting and Data System.

Qualitative evaluation of patient perspective measurement

We conducted qualitative interviews with women who had undergone recent mammographic screening. We purposefully sampled women who matched eligibility requirements for either Medicaid or the Breast and Cervical Cancer Early Detection Program. We sought to achieve sampling parity between women who had selected either FFDM or FFDM+DBT screening. The purpose of these interviews was to identify women's general experiences of barriers and/or facilitators to mammography, explore knowledge/awareness of DBT, assess decisional influences impacting receptivity to DBT, and identify concerns about DBT and preferred informational needs.

We developed a semistructured interview guide based on the domains above. Women were recruited using both clinic-based and telephone interview strategies. A research team member identified and approached women meeting eligibility requirements following completion of their mammogram. If interested, the interview was conducted at that time in a private setting at the clinic or scheduled for a subsequent phone interview. Additionally, we reviewed a list of completed mammograms and research staff contacted women by phone to confirm eligibility and assess interest in participation. All interviews were audio recorded for subsequent transcription and analysis. Women received a $50 merchandise card for their participation.

Interviews continued until we reached data saturation, a standard criterion used in qualitative research to determine the sample size.[12] Data saturation occurs when new data are redundant and the research team concludes that maximum variation has been reached with regard to relevant themes. Completed transcripts were reviewed by two members of the research team and a coding template was developed based on iterative readings and reaching consensus on major themes. Once the coding template was finalized, the interviews were imported into NVivo10, a qualitative data analysis software program that facilitates coding and analytic queries. The analysts generated coding reports and data summaries used to organize key findings.

We interviewed a total of 20 women. The initial number sought was 40 women; however, data saturation was attained with 20. Of these, ten women received FFDM, 9 women received FFDM+DBT, and one woman was unsure of the mammogram type received. The average age was 57.6 years and all but two participants lived within 20 miles of the screening facility. Last, all participants were Medicaid recipients. To ensure that all participants had a similar baseline of knowledge from which to examine perceptions about test characteristics, including the RR, radiation exposure, and cost, we reviewed an informational brochure, developed by Department of Radiology clinicians, with all interviewees at the midpoint of the interview.

Statistical analysis

The 95% confidence interval (CI) for a rate was obtained under the exact binomial distribution using the Clopper–Pearson method. The relative risk, defined as the ratio of two RRs (*i.e.*, FFDM+DBT divided by FFDM), was used as the primary measure in our study to evaluate if FFDM+DBT reduces the RR compared with FFDM in our minority and medically underserved population. The 95% CI for relative risk for each year was calculated using the standard Wald asymptotic method. The association between relative risk and the mammography approach within each year was tested using Pearson's chi-square test. The Cochran–Mantel–Haenszel method was used to calculate a weighted average of the relative risk across the years and also to assess the significance of the association controlling the factor of the years.

Results

Quantitative mammogram evaluation

The percentage of DBT+FFDM mammograms performed increased over the study period from less than 10% (6.8% in 2013) DBT+FFDM examinations to 66.9% of total mammograms in 2016 (Table 2). Table 3 details RRs, PPVs, and CDRs over the study period.

Recall rate. RRs and relative risk of recall are summarized in Table 4. Over the 4-year period, RRs were 8.4% and 11.1% for FFDM+DBT and FFDM, respectively. The difference in RRs became more pronounced with time. This difference was statistically significant in the year 2016, at 8.1% versus 14% (RR: 0.58, 95% CI 0.51–0.66, $p < 0.001$). Across 4 years, the relative risk of a call back was 30% lower with FFDM+DBT (RR: 0.7, 95% CI 0.64–0.77).

Positive predictive value. The PPV for 2013–2016 was 6.1% versus 4.8% for FFDM+DBT and FFDM, respectively (RR 1.46, 95% CI 0.97–2.19, $p = 0.07$). PPVs are detailed by year and in total in Table 3.

Table 2. The Number (%) of Mammograms, by Type, Performed at the UNM CCC by Year

Year	*FFDM+DBT,* N *(%)*	*FFDM,* N *(%)*
2013	680 (6.8	9,387 (93.2)
2014	540 (6.5)	7,815 (93.5)
2015	837 (9.7)	7,771 (90.3)
2016	5431 (66.9)	2,686 (33.1)
Total	7,488 (21.3)	27,659 (78.7)

UNM CCC, University of New Mexico Comprehensive Cancer Center.

Table 3. The Recall Rate (%), PPV (%), and Cancer Detection Rate (%) with 95% CI for Mammograms, by Type, Performed at the UNM CCC by Year

	Recall rate % (95% CI)		*Positive predictive value % (95% CI)*		*Cancer detection rate % (95% CI)*	
Year	*FFDM+DBT*	*FFDM*	*FFDM+DBT*	*FFDM*	*FFDM+DBT*	*FFDM*
2013	10.15% (7.98%–12.67%)	10.90% (10.27%–11.55%)	10.14% (4.18%–19.79%)	4.99% (3.73%–6.5%)	1.03% (0.41%–2.11%)	0.54% (0.4%–0.71%)
2014	7.96% (5.82%–10.58%)	10.19% (9.52%–10.88%)	6.98% (1.46%–19.06%)	5.53% (4.04%–7.35%)	0.56% (0.11%–1.61%)	0.56% (0.41%–0.76%)
2015	9.08% (7.22%–11.23%)	11.14% (10.45%–11.86%)	5.26% (1.45%–12.93%)	4.27% (3.03%–5.84%)	0.48% (0.13%–1.22%)	0.48% (0.34%–0.66%)
2016	8.10% (7.39%–8.86%)	14.00% (12.71%–15.37%)	5.45% (3.53%–8.01%)	3.99% (2.25%–6.49%)	0.44% (0.28%–0.66%)	0.56% (0.31%–0.92%)
Total	8.39% (7.77%–9.04%)	11.07% (10.7%–11.44%)	6.05% (4.32%–8.21%)	4.80% (4.07%–5.62%)	0.51% (0.36%–0.7%)	0.53% (0.45%–0.62%)

CI, confidence interval; DBT, digital breast tomosynthesis; FFDM, full-field digital mammography; PPV, positive predictive value.

Cancer detection rate. The CDR for 2013–2016 was observed as 5.1 and 5.3 cases per 1,000 screening events for FFDM+DBT and FFDM, respectively, with no statistically significant difference observed. CDRs are detailed by year and in total in Table 3.

Qualitative interview results

Overall, participants in both FFDM and FFDM+DBT groups believed that breast cancer screening is a high priority and they strongly endorsed the general merits of the test. The vast majority of women ($N = 18$) indicated that they seek to obtain an annual mammogram, although lapses or variations in insurance coverage may impact screening follow-through. In terms of decisional influences for routine annual screening recommendations, women identified the importance of their primary care provider's recommendation as the most salient factor.

The majority of women ($N = 14$) had some degree of awareness with respect to FFDM+DBT through advertisements, friends/family, or a health care provider. Despite the lack of definitive clinical evidence for FFDM+DBT, women commonly reported a perspective that this screening test is superior, mostly attributable to the belief that the images are clearer. When asked whether they would be willing to pay an additional amount out of pocket for FFDM+DBT, all participants indicated this would be a financial hardship. However, consistent with the predominant view that FFDM+DBT is superior, over half of the women ($N = 11$) noted that they would defer to the strength of their provider's recommendation. If this recommendation was strong, they would be willing to sacrifice other necessities to secure additional funds to cover the cost. Among the remaining women ($N = 9$), financial hardship was cited as the primary reason for not undergoing FFDM+DBT if an additional copay is required (see Appendix Table 1 for individual interview quotes).

In terms of the potential for DBT to reduce the RR, virtually all participants supported the benefits of minimizing return visits. With regard to radiation, there were mixed views about the slight increase in radiation exposure with FFDM+DBT. Half of the women ($N = 10$) indicated that they would like to have more specific information about the implications of this increased radiation, although all believed that the superior accuracy of the test warranted this slight risk.

Discussion

In our New Mexico population, women undergoing screening mammography between 2013 and 2016 had a significant 30% relative risk reduction in the RR with the use of FFDM+DBT compared with conventional FFDM. This difference was most pronounced in the last year of the study. Our finding of reduced RRs in the FFDM+DBT arm is in line with findings of the Italian Screening with Tomosynthesis Or standard Mammography (STORM) trial and the Oslo Tomosynthesis Screening Trial (OTST).[13,14] Our study did not show an increase in CDR, contrary to findings of the STORM trial and Malmo and Oslo trials.

Similar to our findings, DiPrete et al. observed an increased RR for FFDM as years of experience with FFDM+DBT increased. This increase in RR approached statistical significance in their study. This is thought to be due to a decrease in confidence by the radiologist when interpreting FFDM after seeing improved visualization of cancers on FFDM+DBT. Simultaneous viewing of DBT

Table 4. Recall Rate, Digital Breast Tomosynthesis (FFDM+DBT) Versus FFDM, 2013–2016

Year	*FFDM+DBT vs. FFDM*	*Relative risk*[a] *(95% CI)*	p-*Value for relative risk = 1*
2013	10.15% vs. 10.90%	0.931 (0.739–1.173)	0.5431
2014	7.96% vs. 10.19%	0.782 (0.583–1.049)	0.0965
2015	9.08% vs. 11.14%	0.815 (0.652–1.019)	0.0692
2016	8.10% vs. 14.00%	0.579 (0.508–0.659)	<0.0001
2013–2016	8.39% vs. 11.07%	0.699[a] (0.635–0.768)	<0.0001

[a]Relative risk adjusted by the CMH method.
CMH, Cochran–Mantel–Haenszel.

and FFDM images could simply demonstrate the lack of visualization of cancer findings on FFDM alone and increase diagnostic uncertainty. The increased RR with FFDM (2016) in our study seems to be explained by this effect, but the exact reason is unknown.

Our qualitative interview data found that the majority of women had prior knowledge of FFDM+DBT, although they were not aware of the specific differences between the tests other than a general sense of advanced technology being utilized. We purposefully sampled Medicaid-eligible participants to better understand the complexities of decision-making between FFDM+DBT and FFDM among underserved women. Not surprisingly, all women noted that cost was a major consideration if FFDM+DBT was not covered through Medicaid. However, given that most of the participants viewed this as a superior test, they anticipated basing a final decision on the strength of their provider's recommendation. If their health care provider strongly encouraged the test, most women agreed that they would find the resources to pay even if it meant sacrificing another necessity. Last, despite awareness of the slight increase in radiation exposure for FFDM+DBT, all participants indicated receptivity to this screening test in the future; however, most indicated a desire to obtain further information about this risk.

Several large population-based studies have been conducted internationally regarding the role of DBT in comparison with FFDM as a method for breast cancer screening. These include the Italian STORM trial, which demonstrated an increase in CDR with DBT of 2.7 cancers per 1,000 screens over FFDM and resulted in fewer false positive recalls at 1.0% versus 2.0% ($p < 0.0001$).[13] The Swedish Malmo Breast Tomosynthesis Screening Trial compared one-view DBT with two-view digital mammography in 14,851 women and demonstrated that sensitivity with regard to breast cancer detection was higher for DBT at 81% versus 60.4%, with a slightly lower specificity than digital mammography (97.2% vs. 98.1%). Cancer detection was higher in the DBT arm by 2.2/1,000 women screened over the digital mammography arm. Interestingly, the RR was higher among women undergoing DBT versus digital mammography with a 1.1% increase (95% CI 0.8–1.4; $p < 0.0001$).[15] The UK-based TOMosynthesis with digital MammographY (TOMMY) trial also showed significantly increased specificity for FFDM+DBT and DBT+synthetic FFDM compared with FFDM, with increases observed in all subgroups of breast density and across all age groups.[16] In the recently published OTST, there was a significant increase in specificity (97.5% vs. 96.4%) and CDRs per 1,000 women screened (9.3 vs. 6.3) in women who underwent FFDM+DBT screening compared with FFDM alone ($p < 0.001$). The number of recalls per screen-detected cancer decreased from 6.7 to 3.6 with the addition of DBT ($p < 0.001$).[14] A meta-analysis of cancer detection and recall comparing DBT and FFDM found that the pooled incremental increase in CDR for tomosynthesis from all studies ($n = 17$) was 1.6 cancers per 1,000 screens (95% CI 1.1–2.0, $p < 0.001$, $I^2 = 36.9\%$).[17] The ongoing US-led Tomosynthesis Mammographic Imaging Screening Trial, with an expected enrollment of 164,946 participants and study completion in 2030, is designed to compare the number of advanced cancers detected with DBT and FFDM.

Strengths of this study include a robust number of subject examinations, 35,147 in total, which compares favorably with the range of study populations reported in other 3D mammography trials, ranging from 524 to 173,663, with a median number of $\sim$8,000.[18] Additionally, this is the first study to investigate and report qualitative patient perspective data regarding DBT.

Limitations of this study include the small number of 3D examinations in the initial transition period, a circumstance that likely explains the absence of statistically meaningful reduction in RRs for the first 3 years. Additionally, we were unable to exclude a potential bias toward unequal cancer prevalence rates in the two groups given the unavailability of individualized cancer risk factors. Furthermore, inclusion of individual demographics associated with our study population as a whole may have provided additional insight with regard to which subgroup gained the most benefit from recall reduction. Future study directions should assess a more robust view of the true financial impact of DBT on underserved populations.

The findings of this study are pertinent to centers that similarly serve large numbers of women from minority, rural, financially constrained, and medically underserved patient populations. The value of FFDM+DBT as a screening method for breast cancer continues to be evaluated in multiple large population-based studies. However, the results of this study provide novel and previously unpublished insights regarding the unique value of incorporating DBT into cancer care delivery for medically underserved women.

Author Disclosure Statement

No competing financial interests exist.

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Appendix

Appendix Table A1. Patient Exemplary Quotes

General views of DBT	''I'm under the assumption that the 3D is a lot better. I always go with the 3D, just because of the advanced technology.''
	''I think it's marvelous technology. And I think that in the effort to fight breast cancer, 3D mammography should be mandatory at least every couple years or every third year just to make sure certain things are ok.''
DBT decision as contingent on provider recommendation	''My health care provider usually does tell me what is necessary…now had my provider felt that it was something that needed to be addressed immediately (getting a 3D mammogram), absolutely. I would figure out how to pay for it. I don't really have a lot for extras. It would probably end up being one of the bills being put off.''
Inability to undergo DBT if additional payment is required	''Yeah that's something I would not be able to do so I wouldn't be willing to do it. I wouldn't be able to cut into my budget because like I said I'm on a fixed income, so for people like myself, we're living paycheck to paycheck so there's no extra money. I would probably be willing to let all of that go undiagnosed because of my income.''
Recall rate	''It eliminates that question mark where people have to come back. I think it means a great deal to any woman…it takes the concern out.''
Concerns about radiation	''I just want to know if it's ok or not. And that was my first one (3D mammogram) so I thought, you know what, it's ok that this has to be done because it's more important to find whatever is wrong…that I need to take it and suck up the radiation to make sure.''

DBT, digital breast tomosynthesis.