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Research

The cost-effectiveness of adding tomosynthesis to mammography-based breast cancer screening: an economic analysis

Sonya Cressman PhD MBA, Colin Mar MD, Janette Sam MRT, Lisa Kan MSc, Caroline Lohrisch MD, John J. Spinelli PhD MSc

Abstract

Background: Observational studies show that digital breast tomosynthesis (DBT) combined with digital mammography (DM) can reduce recall rates and increases rates of breast cancer detection. The objective of this study was to examine the cost-effectiveness of DBT plus DM versus DM alone in British Columbia and to identify parameters that can improve the efficiency of breast cancer screening programs.

Methods: We conducted an economic analysis based on data from a cohort of screening participants in the BC Cancer Breast Screening Program. The decision model simulated lifetime costs and outcomes for participants in breast cancer screening who were aged 40–74 years between 2012 and 2017. We analyzed rates of health care resource utilization, health state costs and estimated incremental cost-effectiveness ratios (ICERs), to measure incremental cost differences per quality-adjusted life years (QALYs) gained from the addition of DBT to DM-based screening, from the government payer's perspective.

Results: The model simulated economic outcomes for 112 249 screening participants. We found that the ICER was highly sensitive to recall rate reductions and insensitive to parameters related to cancer detection. If DBT plus DM can reduce absolute recall rates by more than 2.1%, the base-case scenario had an ICER of $17 149 per QALY. At a willingness-to-pay threshold of $100 000 per QALY, more than 95% of the probabilistic simulations favoured the adoption of DBT plus DM versus DM alone. The ICER depended heavily on the ability of DBT plus DM to reduce recall rates.

Interpretation: The addition of DBT to DM would be considered cost-effective owing to the low positive predictive value of screening with DM alone. Reductions in false-positive recall rates should be monitored closely.

Digital breast tomosynthesis (DBT) is an imaging technique that may improve the specificity and positive predictive value of breast cancer screening.[1] The new technology provides multiple planar images per breast screened, thereby enhancing the ability to distinguish between malignant and benign characteristics on digital mammography (DM) screening exams. Observational studies have shown that using DBT as an adjunct to DM screening reduces the rate of recall exams[2–14] and increases rates of cancer detection.[1,3,6,7,13,15–17] Meta-analysis suggests that reductions in recall rates vary widely, with the highest reduction rates from North American trials.[18] The combined use of DBT plus DM for breast screening has been adopted in regions in the United States with greater socioeconomic resources.[19] The preventive services task forces in Canada and the US, however, do not recommend the use of adjunct DBT in normal-risk breast screening programs.[19–21]

The underlying hypothesis driving the adoption of adjunct DBT assumes that there would be a reduction in total screening costs associated with less diagnostic work-up for false positives. There are, however, concerns that the extra time required for radiologists to interpret the numerous additional images and the data-storage requirements may introduce costs that outweigh any potential savings.[22,23] As screening programs perform high volumes of breast exams, the decision to supplement DM-based screening with DBT requires data-driven analyses of the total costs and all downstream outcomes involved.

Population-based cohort models can rapidly account for long-term costs, outcomes and uncertainty in decision-making.[24]

Competing interests: None declared.

This article has been peer reviewed.

Correspondence to: Sonya Cressman, sonya_cressman@sfu.ca

***CMAJ Open* 2021. DOI:10.9778/cmajo.20200154**

Three studies have been published to estimate the cost-effectiveness of adjunct DBT for breast screening in the US.[25–27] These studies have offered information to support decisions about the population at risk, based on the natural history of breast cancer and how the cost-effectiveness varies with known risks such as age and breast density. The economic simulations to date suggest that, depending on the cost of DBT and the way cancer outcomes are simulated, the results generated can vary extensively, indicating a need for more economic evidence and definitive analysis of uncertainty. A recent review by the Canadian Agency for Drugs and Technologies in Health calls for economic evidence on the use of DBT in screening that is generalizable to the Canadian context.[19–21] The purpose of our study, therefore, is to provide Canadian evidence on the economics of breast cancer screening and insight into which aspects of screening may be optimized to improve program efficiency. Specifically, we aimed to examine the cost-effectiveness of DBT plus DM versus DM alone in British Columbia and to identify parameters that can improve the efficiency of breast cancer screening programs.

Methods

Study design and setting

We conducted an economic analysis of the additional costs and quality-adjusted life years (QALYs) from adding DBT to breast cancer screening programs. We used data from a provincially funded breast cancer screening program for participants aged 40–74 years in BC.

Model overview

We developed a cost-effectiveness model to simulate the long-term economic impact of supplementing DM with DBT. Policy-makers in BC are considering the adoption of DBT as an adjunct to the provincial DM-based breast cancer screening program. The model was co-developed with stakeholders from BC Cancer Breast Screening and clinical staff, who participated in the design of the model (Figure 1).

We used data from the BC Cancer Breast Screening Program and the BC Cancer Registry for all new screening participants, aged 40–74 years, with an initial, "index," screening exam received between Jan. 1, 2012, and Dec. 31, 2017. We assumed 100% return rates for biennial exams over 23 years (i.e., the period of screening eligibility) to estimate the maximum possible increase in costs from the addition of DBT. Long-term cancer outcomes were simulated with data from former screening participants who developed breast cancer between Jan. 1, 2007, and Dec. 31, 2016. Further details about the modelling approach and permitted transitions are provided in Appendix 1, available at www.cmajopen.ca/content/9/2/E443/suppl/DC1.

The total costs and benefits were simulated from the government payer's perspective over a 40-year time horizon, encompassing years of screening eligibility and mortality from breast cancer and other causes. The isolated and combined parameter uncertainty was assessed with deterministic and probabilistic sensitivity analyses, respectively.

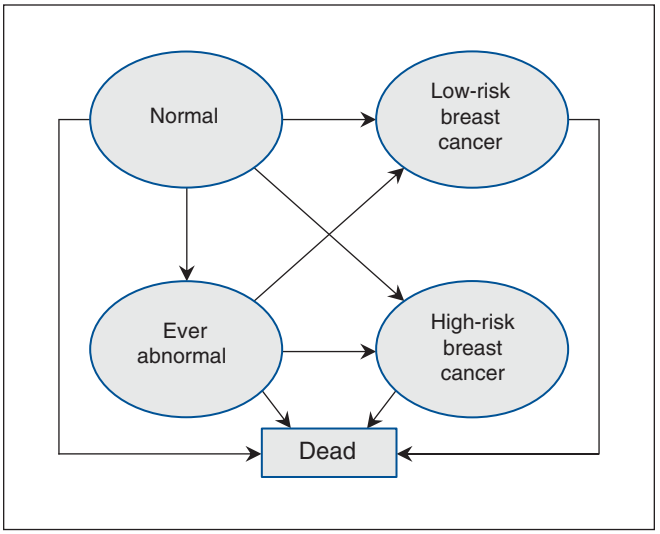

Figure 1: Health states and permitted transitions in the model. Any abnormal exam resulted in movement through the "ever abnormal" health state. High- and low-risk breast cancer were based on stage and histology fields. All in situ and stage I breast cancer, excluding triple-negative breast cancer, were subgrouped as "low risk." All other breast cancer was assigned to the "high risk" subgroup.

Screening outcomes

The screening outcomes were defined as follows. Recall rate was the proportion of mammograms classified as abnormal according to the radiologist's interpretation. The cancer rate was the number of participants with cancer diagnosed within 1 year of a mammogram, per 1000 screens. The cancer detection rate was the number of participants with a cancer diagnosis within 12 months of an abnormal screen, per 1000 abnormal screening exams. The interval cancer rate was the number of participants with a confirmed incident cancer within 0–12 months of their last screening exam that was negative, per 1000 normal screening exams.

The screening outcome measures were defined for screening participants who had their baseline exam before Dec. 31, 2015, allowing for at least a year of follow-up, to enable comparison with the measures reported in other published screening studies. Linkage between the BC Cancer Breast Screening database and the BC Cancer Registry was performed using each participant's unique personal health number.

Cost-effectiveness modelling

The cumulative sum of all additional costs and benefits attributed to the adoption of DBT plus DM versus DM alone was determined with the baseline assumptions that DBT plus DM screening exams cost an additional $44 over DM and offer an absolute 2.2% recall rate reduction, and that the cancer detection rate increased by 1.6 per 1000 scans.[18] For time-dependent transitions, we used the shape and slope parameters from Weibull regression to determine the transition probabilities. Outcomes from ever-screened patients who developed breast cancer were used to estimate long-term mortality and treatment costs that could be expected for screening with DBT plus DM versus DM alone. In the cost analysis, we used data

from 809 patients in the screening cohort who developed breast cancer within the observation period. The modelling parameters and assumptions are provided in Table 1.

The base-case scenario assumed that the intervention offered a 2.2% absolute reduction in recall rates, as reported in a recent meta-analysis of observational screening studies on DBT in North America.[18] The model predicted the additional costs and QALYs gained from adding DBT to DM, compared with DM, following a participant's index screening exam. The ratio of the additional costs to QALYs gained was reported as the incremental cost-effectiveness ratio (ICER). A series of screening scenarios was evaluated deterministically

Table 1: Model parameters and assumptions

Parameter	Description	Source data and assumptions
Breast cancer screening and diagnosis		
Screening utilization rates	Biennial screening exams for new screening participants, assuming 100% return rates over 25 years	Maximum additional costs and the average age of new mammography screening participants
Abnormal index exam rate	Percentage of index mammograms identified as abnormal; 19.5% of all index exams	Screening cohort, index exam
Subsequent abnormal exam rate	Probability of a subsequent abnormal exam; 9.0%	Screening cohort, subsequent exams
Detection after an abnormal exam	Time-dependent rate of developing breast cancer following history of any abnormal exam result	Screening cohort linked with breast cancer cohort
Incremental cancer detection rate	Additional incidences of low-risk breast cancer applied to the intervention arm attributed to increased cancer detection rates from DBT plus DM over DM alone (an additional 1.6 per 1000), applied biennially over 25 years	Parameter assumption based on meta-analysis[18]
Undetected breast cancer	Time-dependent rate of developing breast cancer in the absence of any abnormal exam result, by high- or low-risk breast cancer	Screening cohort linked with breast cancer cohort
Absolute recall rate reduction	Absolute recall rate reduction from meta-analysis of observational trials for the use of DBT versus DM (2.2%), applied biennially over 25 years	Parameter assumption based on meta-analysis[18]
Mortality		
Survival	Long-term survival for ever-screened participants, after diagnosis, by high- or low-risk breast cancer	Breast cancer cohort
Background mortality	Age- and sex-specific mortality adjustments by 5-year age groupings	Statistics Canada data for female mortality by age, in BC
Costs		
Screening	$125 for DM; $169 for combined DM and DBT, applied biennially, over 25 years	Established billing fees for Alberta Health Services*
Diagnostic evaluation	$550 following the first abnormal exam	Mean cost for investigation in BC*
Treatment costs	Health state–specific costs, in 2019 Canadian dollars	Resource utilization rates and unit costs for screening participants who had breast cancer
Utilities		
Screening with normal exam results	Quality of life expected for screening with normal exam results, 0.006 decrease in utility score for 1 week after having a mammogram (0.994)	Matched CISNET assumption†
Screening with an abnormal exam result	Quality of life following an abnormal exam result. Year 1, utility = 0.990 (5 wk of disutility); years 2–40 returns to 1.000	CISNET assumptions for false positive exams†
Low-risk breast cancer	Utility weight of 0.900 for 2 years, then returns to 1.000	CISNET assumptions for localized breast cancer and expert opinion†
High-risk breast cancer	Utility weight of 0.750 for the first 13 years, then 0.600 for years 14–40.	CISNET assumptions for advanced breast cancer and expert opinion†

Note: CISNET = National Cancer Institute's Cancer Intervention and Surveillance Modeling Network, DBT = digital breast tomosynthesis, DM = digital mammography.
*Unit costing described in full detail in Appendix 1, available at www.cmajopen.ca/content/9/2/E443/suppl/DC1.
†Common model inputs used by the CISNET modelling group and consensus with the breast cancer experts on this study team (C.L. and C.M.).[28]

to define isolated parameter uncertainty attributable to variation in absolute reductions in recall rates, variation in screening costs, cancer detection rates that might be expected in different population subgroups (i.e., participants aged < 50 yr) or different regional outcomes and potential reductions in mortality from breast cancer. We also explored impacts from uncertainty around the disutility parameter to evaluate the quality-of-life assumptions for participants with abnormal exam results or overdiagnosis of breast cancer that is not life-threatening.

Cost-effectiveness was directly calculated from the modelled cohort. All future costs and benefits were discounted to net present value at a rate of 3% per year. We performed a probabilistic sensitivity analysis to simulate a range of possible ICER estimates by sampling from parameter distributions (Appendix 1). A standard threshold for acceptability of $100 000 per QALY was selected for comparison with commonly cited thresholds of acceptability for breast screening in the published literature.

Statistical analysis

We used χ^2 tests to detect differences in rates of histologic subgroups between high- and low-risk breast cancer to characterize the cohort members entering either of these breast cancer health states in the model and for comparison between the breast cancer costing and outcomes data sets. Mann–Whitney rank-sum tests were used to distinguish differences in mean costs for breast cancer treatment across low- and high-risk subgroups, differences between means in the cohort data and differences in mean follow-up time for low- versus high-risk breast cancer cost data. We estimated the odds ratio of a cancer diagnosis or subsequent abnormal exam using multivariable logistic regression models that adjusted for age and the baseline exam result. All tests of statistical significance report a p value from 2-sided tests, with a 5% threshold. The model was programmed with TreeAge Pro, version 2020.

Ethics approval

The study was approved by the University of British Columbia's Research Ethics Board (H17-03064).

Results

A total of 112 249 participants were in the screening cohort with index mammograms recorded over the observation period. Their baseline demographic characteristics are provided in Table 2. The mean age for the onset of screening with the index exam was 49.3 years, and most people in the cohort (61.2%) had their first exam between age 40 and 49 years. The average recall rate was higher for index exams versus all subsequent exams (19.5% v. 9.0%), and the chances of having a subsequent abnormal exam was higher after an abnormal versus normal index exam (odds ratio 1.24, 95% confidence interval 1.14–1.35).

Of the 88 975 screening participants with at least 1 year of follow-up, 592 had breast cancer detected within 1 year of

Table 2: Baseline demographic characteristics and screening exam results for new screening participants with an index screening exam from 2012 to 2017

Characteristic	No. (%) of participants* n = 112 249
Age at index exam, yr	
Mean (range)	49.3 (40–74)
40–49	68 703 (61.2)
50–59	27 976 (24.9)
60–69	13 688 (12.2)
70–75	1902 (1.7)
Ethnicity†	
European or British ancestry	56 706 (50.5)
East or Southeast Asian	27 614 (24.6)
South Asian	7783 (6.9)
Aboriginal	2867 (2.5)
West Asian	2130 (1.9)
All others (including multiple ethnicities)	10 848 (9.7)
Not reported or unknown	7319 (6.5)
Breast density (at index exam)‡	
A	10 057 (9.0)
B	24 547 (21.9)
C	27 977 (24.9)
D	9000 (8.0)
Missing	40 668 (36.2)
Index exam year	
2012	9279 (8.3)
2013	13 558 (12.1)
2014	19 473 (17.4)
2015	21 869 (19.5)
2016	23 979 (21.4)
2017	24 091 (21.5)
Recall rate	
Index exam abnormal/total index exams (% total index exams)	21 894/112 249 (19.5)
Subsequent abnormal exams/total subsequent exams (% of all subsequent)	4965/55 304 (9.0)
Completion rate (% total)	
Index exam	112 249 (100.0)
First subsequent	40 019 (35.7)
Second subsequent	11 508 (10.3)
Third subsequent	3037 (2.7)
Fourth subsequent	632 (0.6)
Fifth subsequent	108 (0.1)

*Unless stated otherwise.
†All self-reported responses to questions about race or ethnicity on registration with BC Cancer Breast Screening totalling more than 1.0% for any subgroup were included.
‡Breast Imaging Reporting and Data System (BI-RADS; www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads).

an abnormal index exam. The cancer detection rate was 6.7 per 1000 for abnormal index exams and 1.7 per 1000 for all subsequent abnormal exams. There were 50 interval cancers that developed after a normal index screen, and the 1-year interval cancer rate was 0.57 per 1000 for index exams and 0.12 per 1000 for subsequent exams. Of the cancers detected within 1 year of an abnormal exam, 373 (63.0%) were low risk, and 15 of the 50 interval cancers (30.0%) were low risk.

Resource utilization and cost analysis

The costing cohort had lower proportions of hormone receptor–positive breast cancer and younger age at diagnosis than the breast cancer cohort, but similar histology and stage characteristics (Appendix 1). The difference was attributed to risks from age or menopausal status that distinguish new screening participants from all other patients with breast cancer who have screening exposure. The resource utilization rates and cost inputs shown in Table 3 indicate similar follow-up for patients in high-risk versus low-risk groups, over each of the 5 years analyzed for costs (all $p > 0.1$).

Cost-effectiveness

The model predicted that the addition of DBT to DM screening would result in an additional 0.027 QALY, with an average incremental cost difference of $470 per person. The estimated ICER was $17 149 per QALY. The deterministic analysis showed that absolute reductions in recall rates had a major impact on cost-effectiveness; when this parameter was varied over the range of results reported in observational studies, either the intervention or the comparator would appear cost-effective (Figure 2). Increasing the costs to treat high-risk breast cancer and increasing cancer detection rate had only marginal impacts on the overall cost-effectiveness, owing to the low number of individuals who receive a breast cancer diagnosis relative to the high number that are screened.

The probabilistic sensitivity analysis showed that 95% of 100 000 iterations simulated fell below the commonly referenced willingness to pay threshold of $100 000 per QALY. Full details for both sensitivity analyses are provided in Appendix 1. If DBT plus DM reduces absolute recall rates by at least 2.1%, and the additional cost of providing DBT exams is not higher than the established reimbursement fees, the technology would be considered a cost-effective addition to DM screening.

Interpretation

The cost-effectiveness of adding DBT to DM screening depends critically on the ability of DBT to improve the specificity of DM — a screening intervention with low positive predictive values and potential for overdiagnosis. Our analysis was most sensitive to parameters related to screening exam results and relatively insensitive to parameters related to cancer detection; specifically, there was negligible impact from varying rates of breast cancer deaths, higher treatment costs or disutility from overdiagnosis of low-risk breast cancer on their own. Using assumptions from meta-analysis, we find that the average incremental benefits provided by DBT plus DM are small (0.027 QALY per person), driven by DBT plus DM enabling a lower probability of transitions to the ever-abnormal health state, and this benefit is achieved with an incremental cost of $470 per person.

Our findings add to the existing knowledge offered by published microsimulation models by identifying recall rates as the parameter with the most impact. The main difference with our modelling approach is the distinction of an "ever-abnormal" health state. The strong economic effects of recall rate reductions may be washed out if the history of an abnormal exam is not accounted for as an independent risk factor. Most breast cancer screening participants can expect to receive an abnormal screen if they participate long enough with the current DM technology.[29] Parameterizing recall rates independently aligns with knowledge of a higher risk of developing breast cancer after having had an abnormal exam.[30] There may also be subtle differences attributed to our use of data from patients with breast cancer who had prior screening exposure, rather than using whole registry data for all patients with breast cancer, regardless of screening history. Members of our research group have found that breast cancer outcomes are better for participants of screening mammography than for those not exposed to screening, and the treatment was less intensive.[31]

Recall rate reductions vary widely in observational DBT studies. An early population-based study in the US suggests that DBT plus DM will be able to replicate observational findings.[32] Definitive outcomes from the ongoing randomized Tomosynthesis Mammographic Imaging Screening Trial (NCT02616432) will, however, clarify the diagnostic accuracy of DBT screening and its ability to improve the stage distribution of screen-detected breast cancer. Central to these results will be the ability of DBT plus DM to reduce interval cancer rates, which are more likely to be diagnosed as high-risk breast cancer. Recall rate reductions are also a function of breast cancer–specific risk factors. Age and family history, for example, are important predictors of aggressive forms of breast cancer that occur with overall low incidence rates before age 50. The evidence on individual risk factors and tailored screening strategies is emerging, and widespread mammography screening below age 50 is not recommended at this time.[19,21]

Improving the positive predictive value of breast cancer screening has the potential to improve program efficiency and there are several tools on the technology development horizon that aim to do so.[28] Population-based risk prediction and predictive imaging models could improve the efficiency of breast screening.

Limitations

Our study used data available for screening participants aged 40–74 who used either a fixed-location mammography clinic or mobile breast screening vans that service BC.

Table 3: Resource utilization rates and costs for breast cancer treatment

Health state	Year	Resource	Resource utilization rate (per person)	Mean cost (95% CI), $
Low-risk breast cancer	1	Surgery	1.00	7312 (7111 to 7512)
		Genetic testing*	0.51	2719 (2480 to 2957)
		Systemic therapy	0.59	3008 (2085 to 3931)
		Radiotherapy	0.51	4283 (3893 to 4667)
		End-of-life breast cancer care	NR	0
	2	Surgery	NR	85 (17 to 153)
		Systemic therapy	0.53	1577 (999 to 2156)
		Radiotherapy	0	54 (–22 to 131)
		End-of-life breast cancer care	NR	0
	3	Surgery	0.06	40 (–16 to 96)
		Systemic therapy	0.48	450 (123 to 776)
		Radiotherapy	NR	90 (–50 to 231)
		End-of-life breast cancer care	NR	0
	4	Surgery	0	213 (–206 to 634)
		Systemic therapy	0.50	241 (137 to 346)
		Radiotherapy	0.01	120 (–50 to 288)
		End-of-life breast cancer care	NR	214 (–106 to 634)
	5	Surgery	0	79 (–77 to 235)
		Systemic therapy	0.48	516 (–251 to 1285)
		Radiotherapy	0	0
		End-of-life breast cancer care	NR	0
	6–40	Continue year 5		
High-risk breast cancer	1	Surgery	0.96	7881 (7547 to 8216)
		Systemic therapy	0.98	19 664 (17 496 to 21 832)
		Radiotherapy	0.79	9019 (8457 to 9581)
		End-of-life breast cancer care	NR	274 (–106 to 655)
	2	Surgery	0.02	111 (10 to 213)
		Systemic therapy	0.83	7718 (5736 to 9699)
		Radiotherapy	NR	285 (102 to 468)
		End-of-life breast cancer care	NR	277 (–107 to 621)
	3	Surgery	0	0
		Systemic therapy	0.76	4004 (1967 to 6312)
		Radiotherapy	NR	106 (0 to 212)
		End-of-life breast cancer care	NR	960 (124 to 1795)
	4	Surgery	0	0
		Systemic therapy	0.70	1574 (404 to 2743)
		Radiotherapy	0.01	112 (–14 to 237)
		End-of-life breast cancer care	NR	984 (–124 to 2095)
	5	Surgery	0	0
		Systemic therapy	0.70	1619 (–76 to 3314)
		Radiotherapy	0	0
		End-of-life breast cancer care	NR	647 (–630 to 1925)
	6–40	Continue year 5		

Note: CI = confidence interval, NR = not reportable (results for fewer than 10 individuals are not reported).
*Score based on genetic testing that predicts 10-year recurrence rate for breast cancer and patient response to chemotherapy.

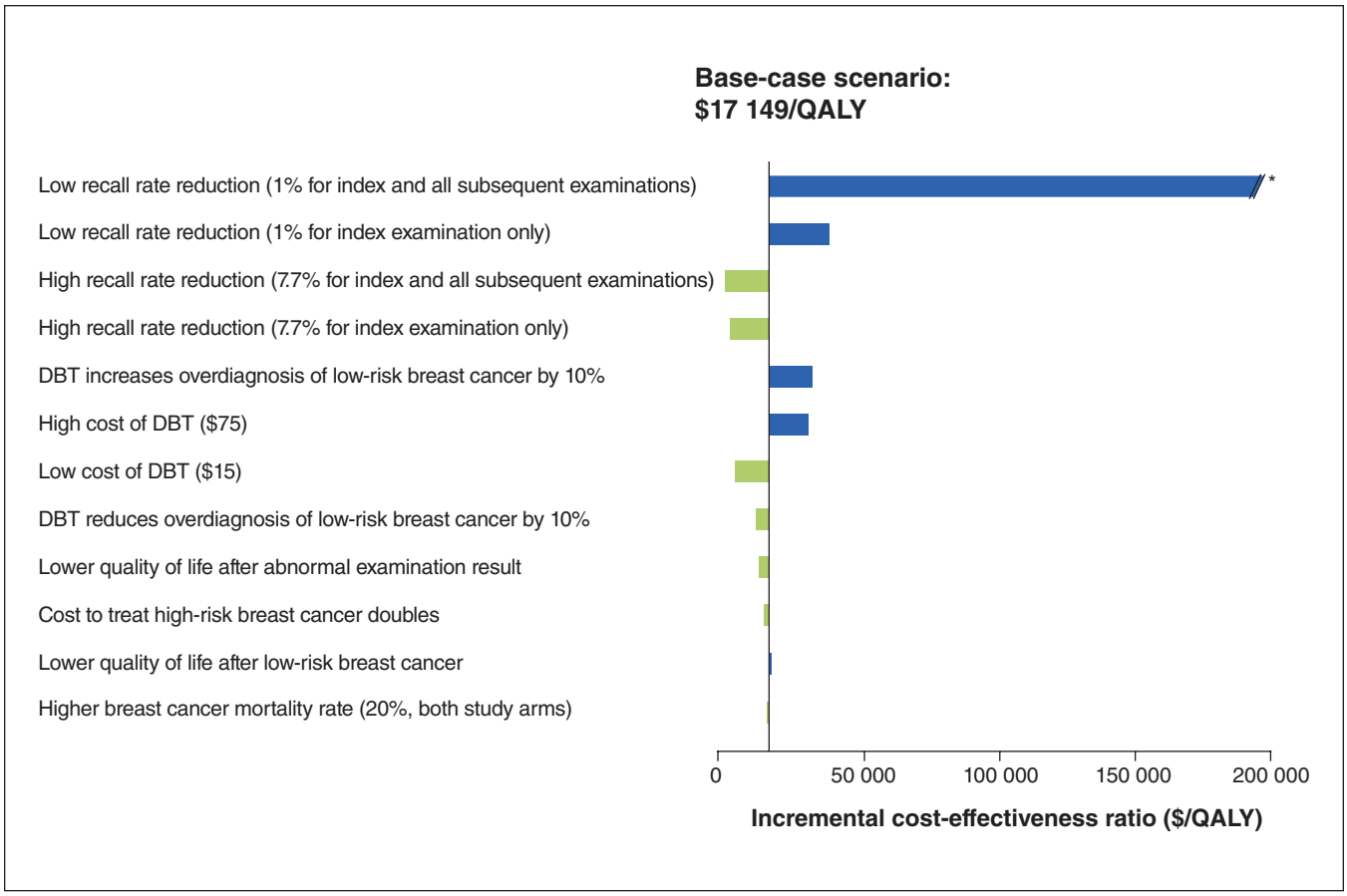

Figure 2: Variability in cost-effectiveness of scenarios simulated in the deterministic sensitivity analysis. Note: DBT = digital breast tomosynthesis, QALY = quality-adjusted life year. In the scenario marked with an asterisk (*), the incremental cost-effectiveness ratio is truncated at a maximum of $200 000 per QALY in this figure.

Breast density assessment was not adopted as routine screening practice in BC until 2017; therefore, our analysis did not adjust for this variable. If DBT can reduce recall rates in some screening participants with high breast density but increase recall in others, then cost-effectiveness results need to be stratified to account for heterogeneity in breast density.

Our study is limited by the amount of follow-up data available for simulating long-term breast cancer outcomes for screening participants. The screening literature in general is limited by the absence of patient-level data on disutility from abnormal exam results or low-risk breast cancer that may not have affected mortality if left untreated. There is emerging literature on disutility for cancer screening that cites methodological challenges related to obtaining this information from screening participants accurately.[33] These data therefore may not be visible in standard economic evaluations that rely on standard health utility instruments.

Conclusion

If DBT can reduce recall rates and does not introduce additional screening costs, it is likely to be considered cost-effective. Canadian evidence showing recall rate reductions with DBT is required.

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Affiliations: Department of Integrative Oncology (Cressman), BC Cancer Research Centre, Vancouver, BC; Faculty of Health Sciences (Cressman), Simon Fraser University, Burnaby, BC; Cancer Screening (Mar, Sam, Kan), BC Cancer; Department of Radiology (Mar), Division of Medical Oncology (Lohrisch) and School of Population and Public Health (Spinelli), Faculty of Medicine, University of British Columbia; Department of Medical Oncology (Lohrisch), BC Cancer; Division of Population Oncology (Spinelli), BC Cancer, Vancouver, BC

Contributors: Sonya Cressman, Lisa Kan, Janette Sam, John Spinelli, Caroline Lohrisch and Colin Mar contributed to the conceptualization of the work, acquisition of the data, its analysis and/or the interpretation of the data. All authors have contributed to the drafting and revision of the manuscript and approved the final version to be published. All authors agree to be accountable for aspects of the work.

Funding: This study received funding from BC Cancer Breast Screening. The funder manages the provincial breast screening budget in BC.

Data sharing: Data for this study are available as aggregated modelling parameters on request.

Supplemental information: For reviewer comments and the original submission of this manuscript, please see www.cmajopen.ca/content/9/2/E443/suppl/DC1.