



European Commission Initiative on Breast Cancer (ECIBC): European guidelines on breast cancer screening and diagnosis Evidence profile

Healthcare question	Should digital breast tomosynthesis vs. assessment mammography be used to diagnose breast cancer in recalled women due to suspicious lesions at mammography screening?
Date	April 2018

Digital breast tomosynthesis		Assessment mammography	
Sensitivity	0.96 (95% CI: 0.89 to 0.99)	Sensitivity	0.92 (95% CI: 0.86 to 0.96)
Specificity	0.76 (95% CI: 0.63 to 0.85)	Specificity	0.70 (95% CI: 0.57 to 0.81)

Prevalence	21%	9%
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Outcome	Nº of studies (Nº of participants)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested				Test accuracy CoE
								pre-test probability of 21%		pre-test probability of 9%		
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Digital breast tomosynthesis	Assessment mammography	Digital breast tomosynthesis	Assessment mammography	
True positives (TP) (patients with breast cancer)	10 studies 7958 participants	cross-sectional (cohort type accuracy study) 1,2,3,4,5,6,7,8,9,10,a	serious ^b	not serious	not serious ^{c,d}	not serious	none ^e	202 (187 to 208)	193 (181 to 202)	86 (80 to 89)	83 (77 to 86)	⊕⊕⊕○ MODERATE
9 more TP in Digital Breast Tomosynthesis								3 more TP in Digital Breast Tomosynthesis				
False negatives (FN)								8 (2 to 23)	17 (8 to 29)	4 (1 to 10)	7 (4 to 13)	
								9 fewer FN in Digital Breast Tomosynthesis		3 fewer FN in Digital Breast Tomosynthesis		

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								pre-test probability of 21%		pre-test probability of 9%		
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Digital breast tomosynthesis	Assessment mammography	Digital breast tomosynthesis	Assessment mammography	
True negatives (TN) (patients without breast cancer)	10 studies 7958 participants	cross-sectional (cohort type accuracy study) 1,2,3,4,5,6,7,8,9,10,a	serious b	not serious	not serious c,d,f	not serious	none e	600 (498 to 672)	553 (450 to 640)	692 (573 to 774)	637 (519 to 737)	⊕⊕⊕○ MODERATE
								47 more TN in Digital Breast Tomosynthesis		55 more TN in Digital Breast Tomosynthesis		
190 (118 to 292)								237 (150 to 340)	218 (136 to 337)	273 (173 to 391)		
47 fewer FP in Digital Breast Tomosynthesis								55 fewer FP in Digital Breast Tomosynthesis				
False positives (FP) (patients incorrectly classified as having breast cancer)												

Explanations

- The absolute differences are the additional cases identified or missed with digital breast tomosynthesis compared to additional mammographic views among those women recalled at the screening mammography assessment
- In some of the included studies there was a non-blinded reading of the index tests. There was variability in how the evaluations were performed, in some cases they included additional tests such as ultrasound or special mammographic views. Those additional exams might be requested at clinical discretion and therefore could be a source of differential misclassification in the tests accuracy estimates.
- One study (Gilbert 2015), performed a retrospective analysis comparing 2DM versus DBT plus synthesised two view mammography. The remaining studies compared DBT versus diagnostic two-view mammography.
- Observed heterogeneity is explained by the use of different thresholds to define positive results (i.e. different classification systems and cut-off points) and to a lesser extent to the use of diverse additional imaging tests or reference standards.
- There was no evidence of publication bias in the diagnostic forest plot, nor in the Deeks test (p value 0.34).
- There is large heterogeneity in the specificity estimates across studies.

References

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