



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Directorate F - Health, Consumers & Reference Materials (Ispra)
Health in Society

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

Healthcare question	Should tailored screening with digital breast tomosynthesis in addition to digital mammography vs. digital mammography alone be used for early detection of breast cancer in asymptomatic women with high mammographic breast density in organised screening programmes?
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Abbreviations	CI: Confidence interval RR: Risk ratio

Certainty assessment							N° of patients		Effect		Certainty	Importance
N° of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tailored screening with digital breast tomosynthesis (DBT) in addition to digital mammography	Digital mammography alone	Relative (95% CI)	Absolute (95% CI)		
Breast cancer detection												
8 1,2,3,4,5,6,7,8,9	observational studies ^a	serious ^b	not serious	not serious	very serious ^c	none	1071/191834 (0.6%)	966/222452 (0.4%) ^d	RR 1.36 (1.25 to 1.48) ^e	156 more per 100,000 (from 109 more to 208 more)	⊕○○○ VERY LOW	CRITICAL
Breast cancer detection (invasive lesions)												
2 ^{7,9}	observational studies ^a	very serious ^f	not serious	not serious	serious ^g	none	24/5056 (0.5%)	12/3489 (0.3%)	RR 1.48 (1.28 to 1.70)	165 more per 100,000 (from 96 more to 241 more)	⊕○○○ VERY LOW	CRITICAL
Adverse effects (false positive)												
4 ^{1,2,5,10,11}	observational studies ^{a,h}	serious ^b	serious ⁱ	not serious	not serious ^j	none	1287/15251 (8.4%)	1325/15251 (8.7%)	RR 1.07 (0.86 to 1.34) ^k	608 more per 100,000 (from 1,216 fewer to 2,954 more)	⊕⊕○○ LOW	CRITICAL
Recall for assessment												
4 ^{1,3,4,5,12}	observational studies ^{a,l}	serious ^b	serious ⁱ	not serious	not serious ^m	none	1478/15422 (9.6%)	1463/15422 (9.5%)	RR 1.11 (0.89 to 1.39) ⁿ	1,044 more per 100,000 (from 1,044 fewer to 3,700 more)	⊕⊕○○ LOW	CRITICAL

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Tailored screening with digital breast tomosynthesis (DBT) in addition to digital mammography	Digital mammography alone	Relative (95% CI)	Absolute (95% CI)		
Interval breast cancer												
1 ⁸	observational studies ^a	very serious ^o	not serious	not serious	very serious ^g	none	10/8393 (0.1%)	23/30432 (0.1%)	RR 1.58 (0.75 to 3.31)	44 more per 100,000 (from 19 fewer to 175 more)	⊕○○○ VERY LOW	CRITICAL
Breast cancer mortality - not reported												
-	-	-	-	-	-	-				-	CRITICAL	
Breast cancer stage - not reported												
-	-	-	-	-	-	-				-	CRITICAL	
Rate of mastectomies - not reported												
-	-	-	-	-	-	-				-	CRITICAL	
Provision of chemotherapy - not reported												
-	-	-	-	-	-	-				-	CRITICAL	
Adverse effects - not reported												
-	-	-	-	-	-	-				-	CRITICAL	

Explanations

- Cohort studies provided partial diagnostic information from paired analysis. The risk of bias was assessed using an ad-hoc modified QUADAS-2 tool.
- There was variability in the number of readings, readers' experience and number of readers (i.e. single or double) across studies.
- The results shows imprecise estimates going from relevant decrease to increase on the breast cancer detection rate.
- Median or mean of the control group of the included studies as appropriate unless otherwise specified.
- STORM-2 additionally reports cancer detection rate of DBT + synthetic mammography, RR: 1.80 (95%CI: 1.04 to 3.10).
- The included study used an unpaired design. Participants might differ by relevant non-measured characteristics. The reader experience for DBT was not clearly reported.
- Imprecise estimates due to low number of events in both arms.

- h. A pooled analysis of the unpaired diagnostic studies (Alsheik 2018, Conant 2019, McCarthy 2014) showed an inconsistent result (RR 0.76; 95% CI 0.79 to 1.00). We presented here only the estimates from the lower RoB studies (paired design).
- i. There was important remaining heterogeneity on the effect size across studies among the paired studies.
- j. The results shows imprecise estimates going from relevant decrease to increase on the false positive rate.
- k. STORM-2 additionally reports false positive rate of DBT + synthetic mammography, RR: 1.53 (95%CI: 1.20 to 1.96).
- l. A pooled analysis of the unpaired diagnostic studies (Alsheik 2018, Conant 2019, McCarthy 2014) showed an inconsistent result (RR 0.78; 95% CI 0.72 to 0.85). We presented here only the estimates from the lower RoB studies (paired design).
- m. The results shows imprecise estimates going from relevant decrease to increase on the recall rate.
- n. STORM-2 additionally reports recall rate of DBT + synthetic mammography, RR: 1.50 (95%CI: 1.20 to 1.87).
- o. The included study used an unpaired design. Participants might differ by relevant non-measured characteristics. The minimum reader experience for DBT might be insufficient (50 previous screening exam).

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