



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 screening using digital breast tomosynthesis in addition to digital mammography vs. digital mammography alone be used in organised screening programmes for early detection of breast cancer in asymptomatic women?
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Abbreviations	CI: Confidence interval RR: Risk ratio

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Digital breast tomosynthesis in addition to digital mammography	Digital mammography	Relative (95% CI)	Absolute (95% CI)		
Breast cancer detection ^a												
24 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24	observational studies ^b	serious ^c	not serious	not serious	not serious	none	3733/650488 (0.6%)	4727/1076845 (0.4%) ^d	RR 1.26 (1.20 to 1.31) ^e	114 more per 100,000 (from 88 more to 136 more)	⊕⊕⊕○ MODERATE	CRITICAL
False positive recall for assessment ^f												
24 1,2,3,4,5,6,7,8,9,10,11,12,13,15,16,17,18,19,20,21,22,23,24	observational studies ^b	serious ^{c,g}	serious	not serious	not serious	none	49059/646550 (7.6%)	102519/1071751 (9.6%)	RR 0.81 (0.77 to 0.85)	1,817 fewer per 100,000 (from 2,200 fewer to 1,435 fewer)	⊕⊕○○ LOW	CRITICAL
Breast cancer stage (inferred from invasive cancer detection rate)												
15 2,3,5,7,9,12,13,14,15,18,19,20,23,24,25	observational studies ^b	serious ^{c,g}	serious	not serious ^h	not serious	none	1809/417722 (0.4%)	2043/657813 (0.3%) ^d	RR 1.34 (1.26 to 1.44)	106 more per 100,000 (from 81 more to 137 more)	⊕⊕○○ LOW	CRITICAL
Invasive cancers/total cancers												
15 2,3,5,7,9,12,13,14,15,18,19,20,23,24,25	observational studies	serious ^{c,g}	serious	not serious ^h	not serious	none	1809/2413 (75.0%)	2043/2884 (70.8%)	RR 1.03 (0.97 to 1.09)	2 more per 100 (from 2 fewer to 6 more)	⊕⊕○○ LOW	CRITICAL
Interval breast cancer ⁱ												
8 16,19,26,27,28,29,30,31,j,k	observational studies ^b	serious ^c	not serious	not serious	serious ^l	none	324/317913 (0.1%)	478/466253 (0.1%)	RR 1.04 (0.90 to 1.20)	4 more per 100,000 (from 10 fewer to 21 more)	⊕⊕○○ LOW	CRITICAL

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Digital breast tomosynthesis in addition to digital mammography	Digital mammography	Relative (95% CI)	Absolute (95% CI)		
Radiation exposure												
1 ²⁰	randomised trials	not serious	not serious	not serious ^m	not serious	none	The median dose per examination was 6.40 mGy (IQR, 5.68–7.36 mGy) and 4.84 mGy (IQR, 4.24–5.72 mGy) for DBT and DM, respectively, meaning that the dose for DBT in addition to DM was 11.24 mGy (2.3 times higher than DM alone).			⊕⊕⊕⊕ HIGH	CRITICAL	
Radiation exposure												
3 ^{32,33,34}	observational studies	not serious	not serious ^m	serious ⁿ	not serious	none	Radiation doses for digital mammography plus tomosynthesis were approximately twice that reported for digital mammography alone. ^o			⊕○○○ VERY LOW	CRITICAL	
Breast cancer mortality - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Quality of life - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Radiation induced cancers-related to radiation dose - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Overdiagnosis - not reported - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Other causes of mortality - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	

Explanations

- Calculated as the total number of women with positive screening/overall number of screening examinations
- Cohort studies provided partial diagnostic information. The risk of bias was assessed using an ad-hoc modified QUADAS-2 tool.
- Concerns for risk of bias due to reference standard was not blinded to the index tests. Additionally, there was variability in the number of readings, readers' experience and number of readers (i.e. single or double) across studies.
- Median or mean of the control group of the included studies as appropriate unless otherwise specified.
- Relative effect was adjusted for paired design.
- Calculated as the number of false positives/overall number of screening examinations - total number of cancers
- Despite only women with suggestive findings of malignancy being followed-up, the panel agreed that there was not an important risk of information bias, as the same strategy was implemented in both arms of the included studies, and the effects were consistent across them.
- Invasive cancer stage is a surrogate outcome of cumulative incidence of advance breast cancer.

- i. Calculates as the number of women with breast cancer after a negative screening/ overall number of screening examinations
- j. Data from one round (most recent 2008-2009) included in control arm (DM) (Skane 2018)
- k. Houssami 2018 gives data from women who did not participate in OTST study (external cohort) included as control arm (DM)
- l. Wide 95%CI and low number of events
- m. Results were consistent independently of the technology used (Hologic Selenia Dimension or Senographe Dimension).
- n. Radiation exposure is a surrogate outcome of "other cancer related to radiation".
- o. Doses are known to vary (diagnostic reference levels are typically country/region and technology specific).

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