



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 automated breast ultrasound system (ABUS) based on high mammographic breast density, in addition to mammography, compared to mammography alone for early detection of breast cancer in asymptomatic women?
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Abbreviations	CI: Confidence interval OR: Odds 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 automated breast ultrasound system based on high mammographic breast density, in addition to mammography	Mammography alone	Relative (95% CI)	Absolute (95% CI)		
Breast cancer detection rate												
3 ^{1,2,3}	observational studies	not serious ^a	not serious ^b	serious ^c	not serious	none	176/23,083 (0.8%)	108/23,741 (0.5%) ^d	OR 1.83 (1.15 to 2.92) ^{e,f}	374 more per 100,000 (from 68 more to 862 more)	⊕○○○ VERY LOW	CRITICAL
Recall rate												
2 ^{2,3}	observational studies	not serious ^a	not serious ^g	not serious ^c	serious ^h	none	4,350/21,743 (20.0%)	2,339/20,309 (11.5%) ⁱ	OR 2.17 (0.75 to 6.25) ^e	10,507 more per 100,000 (from 2,623 fewer to 33,341 more)	⊕○○○ VERY LOW	CRITICAL
Interval cancer rate (one-year)												
1 ²	observational studies	not serious	not serious	not serious ^j	not serious	none	Interval cancer rate of 1.7 per 1,000 exams (11/6425 exams)				⊕⊕○○ LOW	CRITICAL
Breast cancer mortality - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Rate of mastectomies - not measured												
-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Provision of chemotherapy - not measured												
-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Adverse effects - not measured												

-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
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Explanations

- a. Potential aspects related with risk of bias (selection and misclassification bias) were considered not important given the consistency of results across studies.
- b. High statistical heterogeneity ($I^2 = 86\%$, $P = 0,001$) were considered not important given the consistency of results across studies.
- c. Two studies included women with personal or family history of breast cancer (Brem 2015, Kelly 2010).
- d. Median or mean of the control group of the included studies as appropriate unless otherwise specified.
- e. Relative effect was adjusted for paired design.
- f. Incremental cancer detection rate was 174 cancers per 100 000 (from 119 more to 238 more) (Brem 2015, Kelly 2010). Incremental cancer detection rate was 1 053 more cancers per 100 000 (from 738 more to 1 455 more) (Giuliano 2013)
- g. High statistical heterogeneity ($I^2 = 100\%$, $P = 0,000$) were considered not important given the consistency of results across studies.
- h. 95% CI includes both benefits and harms.
- i. Median or mean of the control group of the included studies may vary based on baseline risk.
- j. One study included women with personal or family history of breast in a population cancer (Kelly 2010).

References

1. Giuliano V, Giuliano C. Improved breast cancer detection in asymptomatic women using 3D-automated breast ultrasound in mammographically dense breasts. Clin Imaging ; 2013.
2. Kelly KM, Dean J, Comulada WS, Lee SJ. Breast cancer detection using automated whole breast ultrasound and mammography in radiographically dense breasts. Eur Radiol; 2010.
3. Brem RF, Tabár L, Duffy SW, Inciardi MF, Guingrich JA, Hashimoto BE, et al. Assessing improvement in detection of breast cancer with three dimensional automated breast US in women with dense breast tissue: the Somolnsight Study. Radiology; 2015.