



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 additional magnetic resonance imaging vs. no additional magnetic resonance imaging be used in women with histologically confirmed ductal carcinoma in situ for preoperative planning?
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Abbreviations	CI: Confidence interval RR: Risk ratio OR: Odds ratio

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Additional magnetic resonance imaging (MRI)	No additional magnetic resonance imaging	Relative (95% CI)	Absolute (95% CI)		
Initial BCS - RCT												
1 ¹	randomised trials	serious ^a	not serious	serious ^b	very serious ^c	none	27/39 (69.2%)	27/41 (65.9%)	RR 1.05 (0.77 to 1.42)	33 more per 1,000 (from 151 fewer to 277 more)	⊕○○○ VERY LOW	CRITICAL
Initial BCS - Cohorts												
7 ^{2,3,4,5,6,7,8}	observational studies	serious ^{d,e}	serious ^f	not serious	not serious	none	361/1033 (34.9%)	2245/2958 (75.9%)	OR 0.45 (0.27 to 0.76)	173 fewer per 1,000 (from 299 fewer to 54 fewer)	⊕○○○ VERY LOW	CRITICAL
Proportion of positive margins after BCS - RCT												
1 ⁹	randomised trials	serious ^{a,g}	not serious	not serious	very serious ^c	none	17/43 (39.5%)	12/48 (25.0%)	RR 1.58 (0.85 to 2.92)	145 more per 1,000 (from 38 fewer to 480 more)	⊕○○○ VERY LOW	CRITICAL
Proportion of positive margins after BCS - Cohorts												
6 ^{2,5,8,10,11}	observational studies	serious ^{d,e}	serious ^f	not serious	not serious	none	138/836 (16.5%)	439/2376 (18.5%)	OR 0.95 (0.67 to 1.35)	8 fewer per 1,000 (from 53 fewer to 50 more)	⊕○○○ VERY LOW	CRITICAL
Proportion of re-operation after BCS (Re-operation rate) - RCT												
1 ¹	randomised trials	serious ^a	not serious	not serious	very serious ^c	none	15/28 (53.6%)	10/27 (37.0%)	RR 1.44 (0.79 to 2.64)	163 more per 1,000 (from 78 fewer to 607 more)	⊕○○○ VERY LOW	CRITICAL
Proportion of re-operation after BCS (Re-operation rate) - Cohorts												
10 ^{2,3,6,7,8,11,12}	observational studies	serious ^{d,e}	serious ^f	not serious	not serious	none	192/698 (27.5%)	227/956 (23.7%)	OR 0.97 (0.63 to 1.48)	5 fewer per 1,000 (from 73 fewer to 78 more)	⊕○○○ VERY LOW	CRITICAL

Certainty assessment							Nº of patients		Effect		Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Additional magnetic resonance imaging (MRI)	No additional magnetic resonance imaging	Relative (95% CI)	Absolute (95% CI)		
Mastectomy (total mastectomy rate) - RCT												
1 ¹	randomised trials	serious ^a	not serious	not serious	very serious ^c	none	15/39 (38.5%)	20/41 (48.8%)	RR 0.79 (0.48 to 1.31)	102 fewer per 1,000 (from 254 fewer to 151 more)	⊕○○○ VERY LOW	CRITICAL
Mastectomy (total mastectomy rate) - Cohorts												
4 ^{2,3,7,8,11}	observational studies	serious ^{d,e}	serious ^f	not serious	not serious	none	203/571 (35.6%)	167/712 (23.5%)	OR 1.59 (0.90 to 2.81)	93 more per 1,000 (from 18 fewer to 228 more)	⊕○○○ VERY LOW	CRITICAL
Disease free survival (inferred from locoregional recurrence) - Cohorts												
2 ^{10,13}	observational studies	not serious	not serious	serious ^{h,i}	serious ^j	none	38/612 (6.2%)	143/1735 (8.2%)	OR 1.17 (0.79 to 1.73)	13 more per 1,000 (from 16 fewer to 52 more)	⊕○○○ VERY LOW	CRITICAL
MRI triggered treatment change - Cohort												
6 ^{3,14,15,16,17,18}	observational studies	not serious	not serious	not serious	not serious	none	The pooled proportion of treatment change was 19% (95% CI 13% to 24%; I ² 67%). (n/N= 127/750).			⊕⊕○○ LOW	CRITICAL	
Quality of Life - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	
Direct adverse events - not reported												
-	-	-	-	-	-	-	-	-	-	-	-	

Explanations

- The intervention (preoperative MRI) was not feasible to be blinded which originated a performance high risk of bias which might have impacted on the surgeon initial planning decision.
- Downgraded due that initial BCS is not an end outcome, as later women might have received re-excision or a mastectomy depending on the status of operative margins.
- The number of events from the patients recruited in each arm is much lower than the minimum required to have adequate power.

- d. In some cohort studies, the comparison was between arms over different periods of time (no overlapping), and thus potentially introducing a high risk of secular bias.
- e. The majority of studies reported measurement of association as crude estimates or it had to be calculated from crude numbers.
- f. There is a high heterogeneity in the estimated effect across the included studies ranging from significant benefit to harm.
- g. The definition of positive margins was variable across the different clinical centres included (distance from operative margins) this might have introduced a misclassification bias.
- h. Downgraded due to be a surrogate outcome of disease-free survival.
- i. A proportion of patients had breast MRI performed after lumpectomy or at re-excision stage which does not directly apply to the clinical pathway of interest.
- j. The confidence interval of the effect size ranged from significant benefit to harm.

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