



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 conventional staging exams vs. no staging exams be used for patients with clinical stage I breast cancer without symptoms suggestive of metastases?
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Abbreviations	CI: Confidence interval

Certainty assessment							Impact	Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Detection rate: Combined tests (prevalence)									
5 ^{1,2,3,4,5}	randomised trials	serious _{a,b,c}	not serious	serious ^d	not serious	none	Pooled detection rate: 8 per 1,000 examinations (95% CI: 0 - 30); n/N = 15/1,958	⊕⊕○○ LOW	CRITICAL
False Positive: Combined tests									
3 ^{3,4,5}	randomised trials	serious _{a,b,c}	not serious	serious ^d	not serious	none	Pooled false positive: 49 per 1,000 examinations (95% CI: 4 - 131); n/N = 29/1,220	⊕⊕○○ LOW	CRITICAL

Certainty assessment							Impact	Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Detection rate: Bone Scan									
5 ^{1,2,4,6,7}	randomised trials	serious _{a,b,e}	not serious	serious ^d	not serious	none	Pooled detection rate: 5 per 1,000 examinations (95% CI 0 - 21) n/N = 17/2,397	⊕⊕○○ LOW	CRITICAL
False positive: Bone Scan									
1 ⁴	randomised trials	serious _{a,b,e}	serious ^f	not serious	not serious	none	False positive: 164 per 1,000 examinations (95% CI: 91.6 - 276.1); n/N = 10/61	⊕⊕○○ LOW	CRITICAL
Detection rate: TC chest									
2 ^{1,8}	randomised trials	serious _{a,b,e}	not serious	serious ^d	not serious	none	Pooled detection rate: 0 per 1,000 examinations (95% CI: 0 - 5) n/N = 2/485	⊕⊕○○ LOW	CRITICAL
False positive: TC chest									
1 ⁸	randomised trials	serious _{a,b,e}	serious ^f	not serious	not serious	none	False positive: 134 per 1,000 examinations (95% CI: 106 - 169); n/N = 60/448	⊕⊕○○ LOW	CRITICAL
Detection rate: CT Pelvic									
1 ¹	randomised trials	serious _{a,b,e}	not serious	serious ^d	serious ^g	none	Detection rate: 31 per 1,000 examinations (95% CI: 7.3 - 92.1); n/N = 1/32	⊕○○○ VERY LOW	CRÍTICO
False positive: CT Pelvic - not reported									
-	-	-	-	-	-	-		-	CRITICAL
Detection rate: TC abdominal									
1 ¹	randomised trials	serious _{a,b,e}	not serious	serious ^d	serious ^g	none	Detection rate: 23 per 1,000 examinations (95% CI: 7.3 - 92.1); n/N = 1/43	⊕○○○ VERY LOW	CRITICAL
False positive: TC abdominal - not reported									
-	-	-	-	-	-	-		-	CRITICAL
Detection rate: Chest X-Ray									
3 ^{1,2,5}	randomised trials	serious _{a,b,e}	not serious	serious ^d	not serious	none	Pooled detection rate: 0 per 1,000 examinations (95% CI: 0 - 2); n/N = 0/1,049	⊕⊕○○ LOW	CRITICAL
False positive: Chest X-Ray - not reported									
-	-	-	-	-	-	-		-	CRITICAL
Detection rate: US									
3 ^{1,2,4}	randomised trials	serious _{a,b,e}	not serious	not serious	not serious	none	Pooled detection rate: 0 per 1000 examinations (95% CI: 0 - 11); n/N = 1/407	⊕⊕⊕○ MODERATE	CRITICAL
False positive: US									
1 ⁴	randomised trials	serious _{a,b,e}	not serious	not serious	serious ^g	none	False positive: 16 per 1,000 examinations (95% CI: 3 - 87); n/N = 1/61	⊕⊕○○ LOW	CRITICAL

Explanations

- a. Different reference standards were used, some included another imaging test without histological confirmation which is likely to incorrectly classify the condition
- b. Some studies included retrospective case records where inclusion criteria cannot be properly assessed, in some cases the distribution of stages at diagnosis is not that expected in the population, in particular stage I and stage II are under-represented; this suggest that only a subpopulation of these cases entered in the study and that they could be those with higher suspicious of having distal metastases.
- c. The proportion of patients actually staging investigated with more than one imaging tests was variable, which could underestimated the exams ' performance. All studies reported to include follow-up of patients although with different time frame.
- d. Some or most of the studies recruited consecutive patients from medical records (or prospectively) which could or could not have symptoms suggestive of metastases.
- e. The assessment of each individual tests is based in the number of patients that were examined who are a subpopulation of all those subject at this stage which could overestimate its performance measurements.
- f. Judgement about inconsistency was considered serious given that the reported detected rate was inconsistent with other studies performed in the same stage and applying similar procedures to identify distant metastases.
- g. Judgement of imprecision was considered serious as one or both of the confidence interval limits reached detection rates threshold, which could potentially change the decision about requesting staging tests.

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