



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 followed by 18F-FDG PET-CT staging vs. conventional staging exams be used for patients with clinical stage III breast cancer without symptoms suggestive of metastases?
Date	July 2018
Authors	ECIBC Guidelines Development Group (GDG): Mariangela Autelitano, Bettina Borisch, Mireille Broeders, Xavier Castells, Edoardo Colzani, Jan Daneš, Stephen Duffy, Patricia Fitzpatrick, Markus Follmann, Livia Giordano, Paolo Giorgi Rossi, Axel Gräwingholt, Solveig Hofvind, Lydia Ioannidou-Mouzaka, Susan Knox, Miranda Langendam, Annette Lebeau, Helen McGarrigle, Lennarth Nyström, Elsa Pérez Gómez, Cecily Quinn, Holger Schünemann, Alberto Torresin, Ruben Van Engen, Cary Van Landsveld-Verhoeven, Sue Warman, Kenneth Young. Systematic Review team: Carlos Canelo-Aybar, David Rigau, Margarita Posso, Ivan Solá, Pablo Alonso Coello. JRC Healthcare Quality team: Asli Uluturk, Zuleika Saz-Parkinson
Abbreviations	CI: Confidence interval

Certainty assessment							Impact	Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Additional Detection rate (negative to conventional staging exams)									
7 ^{1,2,3,4,5,6,7}	randomised trials	serious _{ab}	not serious	not serious	not serious	none	Pooled additional detection rate: 205 per 1,000 examinations (95% CI 154 - 261) n/N = 19/382	⊕⊕⊕○ MODERATE	CRITICAL
Detection rate									
8 ^{4,8,9,10,11,12,13,14,c}	randomised trials	serious _{ab}	not serious	very serious _d	not serious	none	*18F-FDG PET/CT: 301 per 1,000 examinations (95% CI: 225 - 382); n/N = 180/627. *Combined conventional test: 157 per 1,000 examinations (95% CI 125 -192); n/N = 74/465.	⊕○○○ VERY LOW	CRITICAL

Certainty assessment							Impact	Certainty	Importance
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
False positive									
4 ^{9,10,12,13,e}	randomised trials	serious ^{ab}	not serious	very serious ^d	serious ^{f,g}	none	*18F-FDG PET/CT (pooled FP): 7 per 1,000 examinations (95% CI: 0 - 24); n/N = 3/328. *Combined conventional tests: 68 per 1,000 examinations (95%CI 13 – 156) n/N= 88/792. ^h	⊕○○○ VERY LOW	CRITICAL

Explanations

- Different reference standards were used across studies, some included another imaging test without histological confirmation which is likely to incorrectly classify the condition. Additional follow up were not implemented in all cases.
- Some studies collected its data from medical registries on a retrospective design which preclude them from implementing standard procedures and quality of data.
- Seven studies included in the pooled analysis for 18F-FDG PET/CT, and 5 studies for conventional tests (see ref in the technical report for conventional tests).
- Event rates to assess 18F-FDG PET/CT and conventional tests were indirectly compared. Studies differ in the number of patients, level of health care and time of follow-up.
- Four studies included in the pooled analysis for 18F-FDG PET/CT, and 4 studies for conventional tests (see ref in the technical report for conventional tests).
- Judgement of imprecision depends on the panel decision about the detection rate threshold which lead to change decision.
- Overall studies included small sample sizes, therefore confidence interval are wider.
- Two studies reported false positives rates for patients in stage II/III as overall, from 7.6 (Groheux 2012) to 11.8 (Groheux 2011) per 1000 examined women.

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