

## Summary

**Title:** Effectiveness and safety of Positron Emission Tomography in breast cancer

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**Objetives:** Within breast cancer diagnostic techniques we can find the Positron Emission Tomography (PET). It is an imaging diagnostic technique that requires the previous injection of an emitting radioactive positron tracer. The objective of this review is to assess the effectiveness and safety of 18-FDG-PET in evaluating breast cancer in the main indications comparing the outcomes with other imaging techniques.

**Methodology:** A systematic review of the available literature was performed. Comprehensive electronic search strategy was developed to find health technology assessment reports, systematic reviews and primary studies in a range of databases (Cancerlit, Cinahl, Embase, Medline, Cochrane Database, HTA Database) and in the web pages of health technology assessment agencies. It was also made a manual search from the references of the studies included. It has been carried out a critical appraisal of all selected literature and an extraction of the relevant data as well as a synthesis of the evidence.

**Outcomes:** 75 retrospective or prospective cases series studies were included, with variable sample size. In relation to detection of primary tumors, FDG-PET does not provide enough accuracy as isolated technique to rule out the presence of primary tumor. Inferior sensitivity of the FDG-PET and superior presence of false negatives was obtained in minor size tumor, as well as a high histological grade implies superior sensitivity of the FDG-PET. Higher values of sensitivity have been obtained with FDG-PET by comparison with mammography or physical examination, similar values of sensitivity by comparison with SPECT and lower values of sensitivity with respect to MRI. In some studies the combination of FDG-PET with Magnetic Resonance Mammography (MRM) allows to delimit better the exact diameter of the tumors by comparison with the conventional diagnostic procedures. In relation with axillary lymph nodes, the accuracy of FDG-PET is directly related with metastases size and with the number of implied nodes, with some limitations for the detection of single nodes.

The FDG-PET is not an accurate technique for detecting occult axillary metastases or micrometastases in comparison with the sentinel lymph node biopsy, mainly in initial stages of the tumor. The biopsy it could be avoided in patients with positive axillary FDG-PET, using in these cases the axillary dissection directly. In relation with the detection of metastases or recurrences, there is not enough evidence to use the FDG-PET as isolated technique in the assessment of bone metastases due its limitation in the detection of osteoblastic metastases, so the FDG-PET could be complemented with other techniques like bone scintigraphy or

SPECT. In some cases FDG-PET is able to detect unsuspected metastatic disease producing a change in the patient management. Another indication of FDG-PET is breast cancer treatment response evaluation, normally chemotherapy or tamoxifen treatment. There are studies with few patients, heterogenous, without enough follow up to assure an absence of disease with complete pathological response. There is not an uniform criteria for establishing a value of SUV threshold to differentiate between treatment responders patients from nonresponders.

It have not been found studies in relation with the safety of FDG-PET.

**Conclusions:** FDG-PET does not have enough sensitivity to rule out primary tumors of small size. FDG-PET does not replace the confirmation obtained with axillary dissection due to their elevated rate of false negatives. Nevertheless, sentinel lymph node biopsy could be avoided in patients with positive axillary FDG-PET, since its values of specificity and positive predictive value are elevated. FDG-PET is more sensible and specific than the conventional imaging techniques in the detection of metastases, it is comparable to other noninvasive techniques and its sensitivity increases in combination with other techniques. In relation with the treatment evaluation, we cannot assure that a complete pathological response observed with FDG-PET is accompanied for a disease absence. It is necessary to standardize in the studies some aspects of the technology like technical characteristics of the FDG-PET and the use of a gold standard. Comparative studies of higher quality and follow up are needed comparing FDG-PET with the alternative techniques that today are considered of reference to assess the breast cancer in all its indications.

**Peer review process:** Yes