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Title **Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI) for the Assessment of Axillary Lymph Node Metastases in Early Breast Cancer: Systematic Review and Economic Evaluation**

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Aim

To evaluate the diagnostic accuracy, cost effectiveness, and effect on patient outcomes of positron emission tomography (PET), with or without computed tomography (CT), and magnetic resonance imaging (MRI) in evaluating axillary lymph node metastases in patients with newly diagnosed early-stage breast cancer.

Conclusions and results

The clinical effectiveness review included 45 citations relating to 35 studies: 26 studies of PET and 9 studies of MRI. Of the 7 studies evaluating PET/CT (n=862), mean sensitivity was 56% (95% confidence interval [CI] 44%-67%) and mean specificity 96% (95% CI 90%-99%). Of the 19 studies evaluating PET only (n=1729), mean sensitivity was 66% (95% CI 50%-79%) and mean specificity 93% (95% CI 89%-96%). PET performed less well for small metastases; mean sensitivity was 11% (95% CI 5%-22%) for micrometastases (≤2 mm; 5 studies; n=63), and 57% (95% CI 47%-66%) for macrometastases (>2 mm; 4 studies; n=111). The smallest metastatic nodes detected by PET measured 3 mm, while PET failed to detect some nodes >15 mm. Studies in which all patients were clinically node negative showed a trend toward lower sensitivity of PET compared to studies with a mixed population. Across 5 studies evaluating ultrasmall super-paramagnetic iron oxide (USPIO)-enhanced MRI (n=93), mean sensitivity was 98% (95% CI 61%-100%) and mean specificity 96% (95% CI 72%-100%). Across 3 studies of gadolinium-enhanced MRI (n=187), mean sensitivity was 88% (95% CI 78%-94%) and mean specificity 73% (95% CI 63%-81%). In the single study of in vivo proton magnetic resonance spectroscopy (n=27), sensitivity was 65% (95% CI 38%-86%) and specificity 100% (95% CI 69%-100%). USPIO-enhanced MRI showed a trend toward higher sensitivity and specificity than gadolinium-enhanced MRI. Studies demonstrated that PET and MRI have lower sensitivity and specificity than SLNB and 4-NS, but are associated with fewer adverse events. Included studies indicated a significantly higher mean sensitivity for MRI than for PET, with USPIO-enhanced MRI providing the highest sensitivity. However, sensitivity and specificity of PET and MRI varied widely between studies, and MRI studies were relatively small. Hence, results should be interpreted with caution. Decision modeling based on these results suggests that the most cost-effective strategy is to replace SLNB or 4-NS with MRI. This strategy reduces costs and increases quality-adjusted life-years (QALYs) because adverse events are fewer for the majority of patients. However, this strategy leads to more false-negative cases at higher risk of cancer recurrence and more false-positive cases that would undergo unnecessary axillary lymph node dissection.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1848.asp.

Methods

See Executive Summary link www.hta.ac.uk/project/1848.asp.

Further research/reviews required

If MRI is deemed clinically acceptable (either to replace SLNB or 4-NS or as an additional test), then further large, well-conducted studies of MRI, particularly using USPIO, would be useful to obtain more robust data on sensitivity and specificity, adverse effects, and the optimum criteria for defining a node as metastatic. Further data on the long-term impact of lymphoedema on cost and patient utility would be valuable, as would studies that compare effectiveness and cost-effectiveness of SLNB and 4-NS. More robust UK cost data is needed for 4-NS, SLNB, MRI, and PET.

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