

Title:	Sentinel Lymph Node Biopsy in Breast Cancer
Agency:	Medical Services Advisory Committee (MSAC) Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia
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Aim

To determine whether sentinel lymph node biopsy (SLNB) for breast cancer can identify patients for whom axillary clearance (AC) is not indicated (i.e. who are lymph node negative), without increasing axillary recurrence rates or decreasing long-term survival.

Conclusions and results

Diagnostic accuracy of SLNB

A random effects Bayesian meta-analysis found the pooled localisation rate to be 94.1% (95% posterior interval 93.3% to 95.0%; 192 studies) and the pooled false negative rate (calculated as false negatives over all negatives) to be 4.7% (95% posterior interval 4.0% to 5.4%; 130 studies). Calculated as false negatives over all positives, the false negative rate is 7.4% (95% posterior interval 6.5% to 8.5%).

Safety

In one non-randomised study, the SLNB complication rate was significantly lower than for AC and for SLNB followed by AC. There were statistically significantly fewer wound infections for SLNB than for AC in one out of two non-randomised studies. Fourteen case series studies reported whether women reacted to the blue dye, ranging from 0% to 1.6% (median 0%).

Effectiveness

Significantly more AC patients experienced lymphoedema than did SLNB only patients; the median across six studies was 3.25% for SLNB and 27.05% for AC, a risk difference of 23.8%. However, this reduction in morbidity will only apply to 70% to 80% of patients undergoing SLNB, since the remaining 20% to 30% (with positive nodes) will subsequently need AC.

In one randomised controlled trial there were no axillary recurrences in either the SLNB group or the SLNB+AC group after a median follow-up of 46 months. In 29 case series of SLNB, the axillary recurrence rate did not exceed 1% in patients who were node negative at the time of SLNB (follow-up ranged from 8 months to 47 months). There was insufficient evidence to assess the relative effect on survival of SLNB. In twelve SLNB case series studies, survival after at least 24 months was greater than 98% in all but two of these studies.

Cost-effectiveness and cost impact

In a cost-minimisation analysis using recurrence and survival as effectiveness outcomes (SLNB and AC assumed to be of similar effectiveness) the cost per 100 procedures for SLNB (plus AC in the same surgery when required) ranged from \$251,942 to \$514,277 compared to a range of \$325,185 to \$499,600 for AC alone. The cost per 100 procedures for SLNB (plus AC in a subsequent surgery when required) ranged from \$280,203 to \$590,097 compared to a range of \$325,185 to \$499,600 for AC alone.

Using lymphoedema as the measure of effectiveness, in a cost-effectiveness analysis, SLNB costs less and is more effective in the lower end of the costing range. At the high end of the costing range, SLNB (with AC in the same surgery when required) costs \$8.63 for one case of lymphoedema avoided and \$53.20 when AC (if required) is performed in a subsequent surgery.

Recommendation

Sentinel node biopsy appears to be safe and effective in identifying sentinel lymph nodes resulting in the reduction of complications due to axillary lymph node dissection, in particular lymphoedema. Long term outcomes are uncertain. MSAC recommends that interim funding for sentinel node biopsy should be provided pending the outcome of trials already in progress and should be reviewed in five years.

Methods

MSAC conducted a system review of medical literature via electronic databases and health technology websites published between 1966 and 2003. Those citations that met predefined inclusion criteria were included in the review of evidence.