Is intraoperative touch imprint cytology of sentinel lymph nodes in patients with breast cancer cost effective?

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The technology considered was intraoperative touch imprint cytology (TIC) compared with postoperative standard sentinel lymph (SLN) node assessment in patients with invasive breast cancer.

Type of intervention
Diagnosis.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with invasive breast cancer who were undergoing SLN biopsy. No further details of the study population were provided.

Setting
The setting was secondary care. The economic analysis was carried out in the USA.

Dates to which data relate
The baseline effectiveness data used to populate the model came from patient-level data obtained from the authors' institution; the year to which the data referred was not reported. The effectiveness ranges used in the sensitivity analysis came from studies published between 2000 and 2005. The price year was 2005. The dates to which the resource use referred were not reported.

Source of effectiveness data
The clinical parameters associated with the model included:
the sensitivity and specificity of TIC;
the prevalence of SLN metastases for Stage one, Stage two, Stage three and Stage four tumours; and complications.

Modelling
A decision tree with a time horizon of 6 months was used to model disease progression. The model was evaluated for eight different clinical pathways. The cumulative costs and utility outcomes were reported for each pathway. Model parameters, base-case and ranges were reported in full.
Sources searched to identify primary studies
The clinical effectiveness data were derived from a study conducted at the authors' institute. A total of 342 patients were enrolled in the study and patient-level data were used to estimate the baseline model inputs. The ranges used in the sensitivity analysis were taken from published studies; details of the study designs were not provided.

Methods used to judge relevance and validity, and for extracting data
The authors selected data from their own institution. In order to facilitate sensitivity analyses, ranges were derived from the literature. No details of the methods used to identify or select the estimates included were reported.

Measure of benefits used in the economic analysis
The measure of benefit used was the quality-adjusted life-years (QALYs). Utility weights were derived for each of the clinical scenarios by surveying four surgical oncologists using the EuroQol-5D.

Direct costs
The study reported the direct costs to the hospital. These were professional fees (including surgery and anaesthesia fees), pathology costs, costs associated with medications, anaesthesia supplies, immediate pathologic assessment, operating room time and postoperative observation time, and treatment for complications associated with auxiliary lymph node dissection. Resource use was calculated using microcosting methodology: detailed resource use for 5 patients undergoing treatment in accordance with each scenario was extracted from Anderson Cancer Centre cost databases with the assistance of institutional financial analysts. The costs were reported as the average cost per patient. The price year was identified. Discounting was not performed, which was appropriate given the short time horizon considered for the cost estimation.

Statistical analysis of costs
The quantities and costs were treated deterministically.

Indirect Costs
In line with the perspective adopted, no productivity losses were considered.

Currency
US dollars ($).

Sensitivity analysis
The authors investigated uncertainty related to variability in the data. Sensitivity analyses to investigate the effects of changes in model parameters, including estimated costs and utilities, were performed. The parameters in this analysis included the sensitivity and specificity of TIC, the prevalence of SLN metastases, the probability of complications, the utility for standard SLN assessment and delayed axillary lymph node dissection (ALND), and all direct costs.

Estimated benefits used in the economic analysis
The mean QALYs for the SLN assessment strategy were 0.4 for patients with T1 tumour stage, 0.39 for T2, 0.38 for T3 and 0.38 for T4.

The mean QALYs for the TIC strategy were 0.43 for patients with T1 tumour stage, 0.42 for T2, 0.41 for T3 and 0.4 for T4.
Cost results
The average costs of the SLN assessment strategy were $5,831 for patients with T1 tumour stage, $6,484 for T2, $7,356 for T3 and $7,534 for T4.

The average costs of the TIC strategy were $6,160 for patients with T1 tumour stage, $6,652 for T2, $7,311 for T3 and $7,445 for T4.

Synthesis of costs and benefits
An incremental analysis was performed. The results of this showed that, for those patients with smaller tumours (T1 and T2), the incremental cost-effectiveness ratio (ICER) of the TIC strategy was $13,731 for T1 and $7,103 for T2.

For those patients with larger tumours (T3 and T4), the TIC strategy was dominant (more effective and less costly).

The sensitivity analysis showed that as the sensitivity of TIC approached 60%, the intraoperative TIC became dominant. Costs were also examined as a parameter in the sensitivity analysis. The TIC strategy dominated if the cost of TIC or TIC with immediate ALND fell to 50% below the base-case estimate, or if the cost associated with SLN assessment or ALND increased to 150% above the base-case estimate. However, if the cost associated with TIC and immediate ALND were increased to 200% above the base-case estimate, this strategy was no longer cost-effective.

The ICER of TIC was affected by the utility score assigned to the health state associated with waiting for SLN evaluation results (utility threshold=0.8). For patients in whom the utility of waiting for SLN results did not significantly impact their well-being, the selection of the preferred treatment strategy was reversed.

Authors’ conclusions
Overall, intraoperative assessment using touch imprint cytology (TIC) is cost-effective, but it is more so for those patients with larger tumours as they are more likely to have metastases in the sentinel lymph nodes (SLN), thus necessitating completion node dissection.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. It represented standard practice in breast cancer treatment in the USA. You should decide whether this represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The authors used data from a study conducted within their institution in order to obtain baseline estimates. The ranges used for the sensitivity analysis were derived from published studies. The authors did not report any search methods or inclusion criteria, nor did they provide any justification for their selection of the estimates. The details of the clinical trial were sparsely reported as the focus of the paper was the modelling. It was also unclear whether the study had been published elsewhere.

Validity of estimate of measure of benefit
The estimation of health benefits (QALYs) was modelled. QALYs were an appropriate measure because they capture the impact of the intervention on quality of care and survival, which are the most relevant dimensions of health. The utility weights were derived using the EuroQol-5D which was administered to four oncologists. The use of QALYs permits comparisons with the benefits of other health care interventions.

Validity of estimate of costs
The analysis of the costs was consistent with the perspective adopted in the study, but a more detailed breakdown of the costs might have been more informative. The price year and the source of the data were provided. Resource consumption reflected actual patterns of treatment at Anderson Cancer Center. Moreover, the cost estimates are likely to have been specific to the institution, although this might have been overcome to some degree by the sensitivity
analyses performed. Despite the use of patient-level data, the costs were treated deterministically. Discounting was not relevant and was not applied.

**Other issues**
The authors made extensive comparisons of their findings with those of other studies. They stated that although this piece of research does not conform to a previous trend of an overall TIC sensitivity in the range of 50 to 70%, this could be due to the standard practice in the institution of obtaining routine axillary ultrasonography as a component of preoperative staging, as well as the frequent use of preoperative chemotherapy. A more detailed costing exercise would have been more informative to the decision-maker, whilst detailed description of resource use would have helped transferability to other settings. The authors also acknowledged that data for the decision analysis model were taken from a single institution with inherent biases, and the unique characteristics of patients treated in the institution. They also pointed out that the utilities were not patient derived. The results of the study do not appear to have been presented selectively and the authors' conclusions would appear to be an adequate reflection of the scope of the analysis.

**Implications of the study**
The study suggests that TIC may be particularly useful for patients who experience significant anxiety whilst awaiting the results of standard SLN assessment.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
17039501

**DOI**
10.1002/cncr.22275

**Other publications of related interest**
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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**