The utility of routine frozen section examination for intraoperative diagnosis of thyroid cancer

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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
Routine frozen section examination for intraoperative diagnosis of thyroid cancer.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients operated on for nodular thyroid disease and having an adequate preoperative FNAB.

Setting
One hospital in the United States. The economic study was carried out in the United States.

Dates to which data relate
Effectiveness and resource use data were based on patients operated on during the periods 1990 to 1993 and 1995 to 1996. The 2-year hiatus occurred because the study was initially halted in 1993 but was restarted because it was felt that the conclusions needed to be verified using a larger number of patients. The price year was not stated.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing (based on charges) was undertaken retrospectively on the same patient group as that used in the effectiveness study.

Study sample
A total of 76 patients with nodular thyroid disease, an adequate preoperative FNAB and who underwent thyroidectomy with one or more routine intraoperative frozen section examinations. No power calculations were presented.

Study design
The study was a case series in a single centre. The duration of follow-up was not clearly reported.
Analysis of effectiveness

Although the analysis of diagnostic value (sensitivity, specificity, and accuracy) was based on the treatment completers principle, the analysis of the impact of diagnostic test results on intraoperative management was based on the intention to treat principle. The reference test was 'permanent pathological examination'.

Effectiveness results

The sensitivity, specificity and accuracy of frozen section examination were 93%, 100% and 97%, respectively compared with 88%, 89% and 91% for FNAB (p>0.05). Frozen section examination affected intraoperative decision making regarding the extent of thyroidectomy in only 2 patients (3%), one of whom had lymphocytic thyroiditis and a false-positive FNAB, whilst the other had papillary thyroid cancer that was diagnosed on frozen section examination but which a FNAB interpreted as follicular neoplasm. There was one false-negative frozen section examination compared with two false-negative FNABs and no false-positive frozen section examinations compared with two false-positive FNABs.

Clinical conclusions

The data demonstrated that there was no statistically significant difference in the sensitivity, specificity, or accuracy of frozen section examination and FNAB.

Measure of benefits used in the economic analysis

Cases with an alteration in the extent of thyroidectomy (impact on intraoperative patient management) was used as the measure of benefits in the economic analysis.

Direct costs

The average number of frozen section examinations per patient were analysed separately from the costs. Hospital charges to patients were used in the economic analysis: $246 for a single frozen section examination (comprising a hospital fee of $53 and an interpretation fee of $193; there was an additional $72 fee for each additional frozen section examination). The price year was not clearly reported. The costs associated with the comparator (preoperative FNAB without frozen section examination) were implicitly assumed to be common to both strategies.

Currency

US dollars ($).

Sensitivity analysis

No sensitivity analysis was performed.

Estimated benefits used in the economic analysis

Frozen section examination affected intraoperative decision making regarding the extent of thyroidectomy in only 2 patients (3%), one of whom had lymphocytic thyroiditis and a false-positive FNAB, whilst the other had papillary thyroid cancer that was diagnosed on frozen section examination but which a FNAB interpreted as follicular neoplasm.

Cost results

The total charge for all frozen section examinations performed in 76 patients was $26,040.

Synthesis of costs and benefits

Although the estimated benefits and costs were not explicitly combined, it can easily be seen from the above results that the cost per case of alteration in the extent of thyroidectomy was $13,020 (price year not given) for the routine use
of frozen section examination relative to the FNAB-clinical evaluation preoperative combination.

**Authors' conclusions**
The routine use of frozen section examinations is not indicated. The authors no longer advocate the use of routine frozen section examinations in patients who have an adequate preoperative FNAB. They thus recommend that frozen section examination be reserved for patients with a persistently nondiagnostic FNAB or an incidental thyroid nodule discovered at operation that has not been biopsied and for confirmation of lymph node metastases and parathyroid tissue prior to autotransplantation.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator is clear. FNAB was chosen as the comparator because of its widespread application and reported high sensitivity, specificity and accuracy, and the documented limitations of frozen section examination. You, as a user of this database, should consider whether these are appropriate comparators in your own setting.

**Validity of estimate of measure of benefit**
The measure of benefit used in the economic analysis may not capture adequately the health related benefits associated with the intervention. The consequences of the change in the intraoperative management of the 2 patients were not fully discussed. The authors noted that the 97% accuracy of frozen section examination was somewhat misleading due to the principle used in the analysis (treatment completers). Such an estimate reflects the exclusion of 50% of the patients in the series in whom definitive diagnosis was deferred because frozen section examination revealed a follicular neoplasm.

**Validity of estimate of costs**
Cost information was based solely on hospital charges and resource use quantities were not analysed separately from costs with adequate detail. Moreover, the price year used in the calculations was not stated.

**Other issues**
The cost data, based on charges in one US hospital, may not be generalisable to other countries. The uncertainty in key costs parameters was not addressed.

**Source of funding**
None stated.

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