Decision tree sensitivity analysis for cost-effectiveness of chest FDG-PET in patients with a pulmonary tumour (non-small cell carcinoma)

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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
Chest computed tomography (CT) and chest FDG-PET in patients with pulmonary tumours.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with a pulmonary tumour (non-small cell carcinoma, less than or equal to stage IIIB).

Setting
The setting was the National Defence Medical College Hospital, Japan.

Dates to which data relate
The effectiveness data came from a study conducted in the National Defence Medical College between April 1996 and March 1997 and from studies published between 1985 and 1997. Resource and cost data were from 1996 and 1997. No specific price year was given.

Source of effectiveness data
The effectiveness data were derived from a single study, a review of published studies conducted outside Japan, and estimates arrived at by the use of simulation techniques.

Link between effectiveness and cost data
The cost data were derived retrospectively from the same sample used in the clinical study.

Study sample
The study sample consisted of 56 patients who were suspected of having a pulmonary tumour and who were undergoing CT assessment. No power calculations were used to determine the sample size. The age range of patients who had a benign tumour was 23 to 71 years (mean 51.8 years). Patients with a malignant tumour had an age range of 34 to 85 years (mean 63.4 years).

Study design
The study was a cohort study conducted at a single centre. The results of the CT/biopsy/surgery of the sample were summarised in a decision tree.

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The outcomes assessed were the number of cases requiring other diagnostic and surgical procedures, and survival rate.

Effectiveness results
The results of the single study elements showed that 51 patients underwent bronchofiberscopy and 42 had their tumour status clarified (38 had a malignant tumour and 4 had a benign tumour). Nine patients failed to have their conditions clarified and five patients were found to be unsuitable for the bronchofiberscopy due to the size or the location of their tumour. The 14 patients who failed to have diagnosis at this stage underwent open chest surgery and 2 were found to have a pulmonary tumour and 12 were found to have a benign tumour. All of the 42 patients who had their condition verified through bronchofiberscopy had subsequent open chest surgery. Four who had a benign tumour chose to have surgery. The success rate of bronchofiberscopy was 75%.

Clinical conclusions
The reader is referred to the estimates of effectiveness results outlined below.

Modelling
Decision trees were used to assess the costs and outcomes of chest CT based on a single study of 56 pulmonary patients, and for the simulation of costs and outcomes of chest CT only and chest CT plus chest FDG-PET for a hypothetical patient population of 1,000 patients based on the results of the single study, augmented with data from published studies.

Outcomes assessed in the review
The outcomes assessed in the review were the sensitivity and specificity of CT and FDG-PET.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
18 primary studies were included.

Methods of combining primary studies
Meta-analysis was used to combine the results of primary studies.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
According to the published studies, CT has a 99.7% sensitivity for the diagnosis of pulmonary tumours. Specificity was found to be 57.9% but this figure was not used in the model, although this point is unclear from the descriptions in the paper. The sensitivity and specificity of FDG-PET were 96.3% and 78.6% respectively. The sensitivity and specificity of CT for diagnosing mediastinal lymph node metastasis were 67% and 73%, respectively compared to 90% and 91% for FDG-PET. These data were used in the construction of the decision trees, as described below in the estimates of effectiveness section.

**Methods used to derive estimates of effectiveness**
A simulation, using probabilities from the single study and the results of the literature review, was conducted with a hypothetical population of 1,000 patients to compare the effectiveness of CT only and CT plus FDG-PET.

**Estimates of effectiveness and key assumptions**
The cancer prevalence rate (derived from the single study described above) was 71.4%. The success rate for mediastinoscopy was estimated to be 100%. The simulation analyses showed that, while CT alone resulted in 1,000 bronchofiberoscopy procedures, CT plus FDG-PET resulted in 512. While CT did not lead to any mediastinoscopy procedures, CT plus FDG-PET did lead to mediastinoscopy procedures. 70 thoracotomy procedures for benign tumours and 433 thoracotomy procedures for cancer would be required by CT only, while 19 and 499 such procedures would be required by CT plus FDG-PET. CT only led to 347 cases of curable thoracotomy and 73 cases of non-curable thoracotomy, while CT plus FDG-PET gave 462 and 22 cases respectively. The number of surgical deaths would be 15 cases for both methods.

**Measure of benefits used in the economic analysis**
The outcome assessed was mean life expectancy per patient. This was determined from the decision analysis models described in the modelling field and estimates of effectiveness section, based on a hypothetical cohort of 1,000 patients. Life expectancy data were derived from published studies.

**Direct costs**
Discounting was not applied but may not have been relevant due to the short period of analysis. Costs and quantities were not reported separately. Based on the receipts from 40 patients with a malignant tumour at the hospital, mean test costs were calculated to be:

- Y74, 150 for bronchofiberoscopy,
- Y120, 450 for mediastinoscopy (including three days hospitalization)
- Y53, 003 for outpatient testing costs (costs for such examinations as tumour marker measurements, lung function examination, bone scanning, brain CT, brain MRI, chest CT, ultrasonic examination).

Mean surgery costs were Y1, 165,284 (hospitalisation 25.2 days, n=16) for benign tumours and Y2, 292,768 (hospitalisation 46.8 days, n=40) for the removal of malignant tumours. Hospitalisation costs included testing costs during the periods. Irradiation costs were Y300, 000 (30 fractionations). The price year was not stated.
Statistical analysis of costs
No statistical analysis was undertaken.

Indirect Costs
Indirect costs were not included.

Currency
Japanese Yen (Y).

Sensitivity analysis
In order to investigate the variability in the FDG-PET price a one-way sensitivity analysis was undertaken by changing the costs between Y30,000 and Y200,000 per test. The effect on mean life expectancy was also assessed. Additionally, the costs necessary to extend life expectancy for one year were examined.

Estimated benefits used in the economic analysis
The mean life expectancy of patients with a malignant tumour after a lung cancer operation was set at 7 years. Without operation or treatment because of misdiagnosis of having a benign tumour, life expectancy was 1 year, and for malignant tumour with irradiation, life expectancy was 2 years. In N3 tumour cases with irradiation treatment life expectancy was 1 year. Patients with a benign tumour would be expected to achieve their full life expectancy. Life expectancy with the CT alone strategy was 10.33 years/patient while for CT plus FDG-PET the figure was 10.94 years/patient. Incremental life expectancy was therefore 0.607 years.

Cost results
Total costs for the CT only group for 1,000 patients were Y1,262,145,009. Costs for the CT plus FDG-PET strategy were Y1,294,520,753 plus the FDG-PET testing fee. Diagnostic and treatment costs increased with the introduction of FDG-PET by Y32,375,744 plus the FDG-PET testing fee. If the testing fee was set at Y100,000 per test, the FDG-PET strategy would cost 10.5% more than the CT only strategy.

Synthesis of costs and benefits
Costs and benefits were not combined although this would have been feasible and can be calculated from the paper.

Authors’ conclusions
The authors concluded that the chest CT plus FDG-PET strategy might not be cost-effective in Japan. The authors speculated that use of all body FDG-PET rather than chest FDG-PET would lead to better cost-effectiveness results as patients would be spared tests which were required in the CT or chest FDG-PET strategy.

CRD COMMENTARY - Selection of comparators
The chest CT only strategy and chest CT plus chest FDG-PET strategy were chosen as the comparators because chest CT was the current testing method for patients with a pulmonary tumour and the authors speculated that the introduction of FDG-PET in the testing procedure would increase the cost-effectiveness of cancer treatment.

Validity of estimate of measure of effectiveness
Effectiveness measures were appropriately derived from a single study, augmented by a review of the literature to derive sensitivity and specificity data relevant to each test. These were applied within the simulation analysis. As it was not clear whether a systematic search of the literature was undertaken to identify all relevant studies, and the single study was based on a cohort design, the results may need to be treated with a degree of caution.
Validity of estimate of measure of benefit
The benefit measure of life expectancy was derived by modelling and was appropriate for the analysis.

Validity of estimate of costs
The cost analysis appears to have included all relevant items for the chosen perspective. However, given the population studied, indirect costs would have been relevant and future analyses should include these if a societal perspective is to be of primary concern. The authors included in their sensitivity analysis the cost of the FDG-PET test, which was the major area of uncertainty in their analyses.

Other issues
The authors made good and appropriate comparisons with other similar studies and identified how their analysis addressed the limitations of other studies for a Japanese setting, such as differences in lung cancer diagnosis protocols between America and Japan, and assumptions included in previous simulations of this nature. In this sense the authors did address the issue of the generalisability of their results, although this was not specifically addressed as an issue in its own right. The study sample appears to have been representative of the study population to which the results apply.

Implications of the study
A strategy of chest CT plus FDG-PET is probably not a cost-effective strategy in Japan. The use of all body FDG-PET rather than chest FDG-PET may be associated with better cost-effectiveness results as patients would be spared tests which are required in the CT or chest FDG-PET strategy.

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