Analytical decision model for the cost-effective management of solitary pulmonary nodules


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
Strategies for the diagnostic management of patients presenting with solitary pulmonary nodules.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Hypothetical patients presenting with solitary pulmonary nodules less than 3cm in diameter in whom nodule growth rate had not been established, with no calcium visible on a standard chest x-ray, no evidence of metastasis and no recent history of primary malignancy outside of the chest. The base case analysis focused upon a 64 year old white male smoker presenting with a 2.5 cm nodule.

Setting
Hospital and community. The economic study was carried out in Los Angeles, USA.

Dates to which data relate
The effectiveness data were taken from studies and models previously published between 1980-1996. Cost data were derived from published schedules from 1995. The price year was not explicitly stated and is assumed to be 1995.

Source of effectiveness data
The effectiveness data utilised within the model were derived from previously published sources.

Modelling
A decision tree was used to model the costs and consequences of the various management strategies generating a total cost and life expectancy value for each strategy.

Outcomes assessed in the review
The following parameters, used within the model, were assessed from the literature: the sensitivity and specificity of CT, PET and biopsy; the morbidity and mortality associated with surgery and biopsy; the probability of malignancy; the probability of resectable solitary pulmonary nodules; the probability of pneumothorax as a result of biopsy and the probability of an indeterminate biopsy.
Study designs and other criteria for inclusion in the review
No specific design criteria were identified by the authors for inclusion but the date range was 1980-1996.

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
Numerous studies were included.

Methods of combining primary studies
The sensitivity and specificity of PET and biopsy were determined by pooling data from 4 studies and 6 studies respectively. The remaining parameters used within the model were determined by selecting from the range identified within the review.

Investigation of differences between primary studies
Not stated.

Results of the review
The sensitivity and specificity of CT was 0.999 and 0.610, of PET was 0.925 and 0.83 and of biopsy was 0.895 and 0.959. The morbidity associated with surgery and biopsy was assessed to be 0.08 and 0.0008 years respectively. The mortality rate associated with exploratory surgery was 0.5% and that associated with curative surgery was 4%. The mortality rate associated with biopsy was either 0.2% or 2.5% depending upon the method used. The probability of malignancy was 0.83; the probability of resectable solitary pulmonary nodules was 0.8; the probability of pneumothorax as a result of biopsy was either 0.24 or 1 and the probability of an indeterminate biopsy was either 0.02 or 0.06 depending upon the method used.

Measure of benefits used in the economic analysis
The measure of benefits was life years gained derived from the decision model.

Direct costs
The costs associated with the diagnostic and subsequent clinical procedures were included within the analysis, including chest radiograph, thoracic computed tomography, thoracic positron emission tomography, transthoracic needle aspiration biopsy, video-assisted thoracoscopy, surgery and chest tubes. The costs were given per item and the resource use was determined by the model, although not specifically detailed within the paper. The quantity/cost boundary adopted was that of the health care provider. The costs are assumed to refer to 1995 (although this was not explicitly stated within the paper) and were not discounted.

Statistical analysis of costs
Not stated.
Indirect Costs
Not assessed.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analysis was undertaken for various key variables to identify the impact of uncertainty upon the results. The sensitivity and specificity of PET and CT, the cost of surgery and the cost of PET were among the variables subjected to sensitivity analysis across the identified range of values. Thresholds where the cost-effectiveness of strategies were equal were identified. In addition, worst case analysis was undertaken to determine the cost-effectiveness of the CT + PET strategy when, firstly, all the variables which favour the strategy were penalised by 15% and secondly, all the variables which were unfavourable to the strategy were inflated by 15% in addition to penalising the favourable variables. In addition, the model was used to provide estimates of cost-effectiveness for a variety of patient groups and across the full range of prior probabilities of disease.

Estimated benefits used in the economic analysis
For the base case patient the wait and watch strategy provided an average 6.35 life years, whilst the CT strategy provided 6.86 and the CT + PET strategy provided 6.83. The results were not discounted.

Cost results
For the base case patient the wait and watch strategy cost $11,886 on average, whilst the CT strategy cost $13,541 and the CT + PET strategy cost $13,928. The results were not discounted.

Synthesis of costs and benefits
The base case results were combined to give the additional cost per life year gained for CT and CT + PET compared with wait and watch strategy. The costs and life years associated with the strategy of immediate surgery were not provided. The additional cost per life year gained for the CT strategy was $3,266 compared with the wait and watch strategy. The additional cost per life year gained for the CT + PET strategy was $4,273 compared with the wait and watch strategy.

Authors’ conclusions
The results illustrate that a combined diagnostic strategy employing CT and PET scanning is cost-effective over a wide range of pretest likelihoods of malignancy. In addition, the use of PET scanning to supplement CT scanning may potentially save thousands of unnecessary surgical procedures with consequent health benefits for patients and financial benefits for health care providers.

CRD COMMENTARY - Selection of comparators
The reason for the comparators are clear. You, as a user of this database, should consider whether these health technologies apply to your setting.

Validity of estimate of measure of benefit
The authors identified a wide range of studies from which they have determined parameter values for the model. There was no apparent selective use of data, however few details were provided concerning how the studies were identified and how the selection process was undertaken; it is therefore difficult to determine the internal validity of the model.
Validity of estimate of costs
Prices were derived from published reimbursement schedules in the USA, which whilst internally valid are not generalisable to the UK. The analysis focused upon the costs of the procedures from the perspective of the health care provider and ignored any patient or societal costs. Resource quantities were derived from the model but were not reported separately from prices.

Other issues
The authors relied on published data from the literature which has inherent biases. The data are often from specialised medical settings and are not externally valid a limitation acknowledged by the authors. The issue of generalisability to other settings and countries has not been addressed. The authors undertook an external check on the results of the model through comparison with a previously published model, although no other studies were identified for comparison. The authors correctly undertook the modelling at a population level and for mathematical simplicity split the population according to disease status (benign or malignant). Given that disease status is initially unobserved these patient groups must be treated identically within the decision tree until such time as the status is observed. Within the wait and watch strategy the observation period over which growth is determined is different for the two groups. It might have been better to use a Markov process to model the dynamic nature of the growth process.

The authors presented a simplified version of the decision tree within the paper which, whilst aiding comprehension, does suggest some structural problems within the model. Embedded decision nodes (those that occur downstream of the initial decision) are valid within clinical decision analysis where the aim is to maximise or minimise a value. However, the cost-effectiveness ratio employed within economic evaluation and the lack of a simple maximise or minimise decision rule means that embedded decision nodes can cause difficulties within models for economic evaluation. The authors stated a decision rule ($50,000 per life year saved) but it is unclear if this has been used to evaluate options at this embedded decision node. The results would have been clearer if the embedded decision nodes had been removed by incorporating separate strategies for each of the options (e.g. CT + PET with biopsy if the PET is negative and a separate strategy for CT + PET with wait and watch if the PET is negative).

The model also employs chance nodes where decision nodes are more appropriate and hence separate strategies should have been employed (e.g. after a positive CT there is a 20% chance of biopsy and a 80% chance of surgery). When a model is to be used to provide policy and practice guidance it is inappropriate to employ chance nodes in this manner with probabilities determined according to current practice. Whilst this type of analysis provides an estimate of the cost-effectiveness of current practice it fails to provide an estimate of the cost-effectiveness of optimal practice which would involve either biopsy or surgery but not a mixture of both. More specifically the decision tree suggests that the biopsy strategy is not associated with death if undertaken after a negative PET whilst there is a possibility of death when biopsy is used after a positive PET or straight after a positive CT. Some of these issues perhaps arise from the presentation of a simplified version of the decision tree within the paper.

Finally, the authors have not calculated the incremental cost-effectiveness ratios (ICERs) correctly. They have compared the costs and effects of each strategy with a base strategy as opposed to comparing each consecutively more expensive strategy to the next cheapest non-dominated strategy. The authors have not correctly identified dominated strategies that provide fewer life year gains at higher cost than other strategies. As such the ICERs presented within table 3 are misleading, although the graphs appear to provide an appropriate assessment of cost-effectiveness, and care should be taken when using the results of this analysis. For example within the base case the cost per life year for CT + PET is given as $4,273 compared with wait and watch. The correct approach would be to compare CT + PET with CT alone and to identify that the CT + PET strategy is dominated by CT only for the base case patient group.

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