Endobronchial ultrasound-guided transbronchial needle aspiration prevents mediastinoscopies in the diagnosis of isolated mediastinal lymphadenopathy: a prospective trial


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.

CRD summary
The study assessed the cost-effectiveness of using endobronchial ultrasound-guided transbronchial needle aspiration (endoscopic biopsy) versus cervical mediastinoscopy (surgical biopsy) for initial diagnosis of patients with isolated mediastinal lymphadenopathy (swollen lymph nodes in the chest cavity). There were a few limitations to the study, which were discussed by the authors. The results should be considered with these limitations in mind.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The study assessed the cost-effectiveness of using endobronchial ultrasound-guided transbronchial needle aspiration (endoscopic biopsy) versus mediastinoscopy (surgical biopsy) for the initial diagnostic investigation of patients with isolated mediastinal lymphadenopathy

Interventions
Endobronchial ultrasound-guided transbronchial needle aspiration (needle biopsy) used of a linear endoscope with a 21 or 22 gauge needle to systematically assess hilar and mediastinal lymph nodes by puncture and suction; patients received intravenous midazolam and fentanyl sedation, with additional topical lidocaine. This procedure was compared with cervical mediastinoscopy via an incision above the suprasternal notch and lymph node stations 2, 4 and 7; patients received general anaesthetic.

Location/setting
UK/secondary care.

Methods
Analytical approach:
The analysis was based on data from a single study used to populate a decision tree. The authors stated that the perspective of the study was that of the UK NHS. An assumption of equal effectiveness was made. A cost-minimisation approach adopted.

Effectiveness data:
The clinical evidence came from a diagnostic study in which all patients were initially investigated using needle biopsy. In the lack of a definitive diagnosis, mediastinoscopy (surgical biopsy) was used, if a diagnosis was not achieved clinical and radiological follow-up over a period of six months was undertaken. The study included 77 patients; retrospective comparison with 68 previous patients who had undergone mediastinoscopy was undertaken to assess the representativeness of the prospective sample. Patients were followed for a minimum of six months. The main clinical estimates were: the proportion of mediastinoscopy procedures saved; and the diagnostic sensitivity, negative predictive value, and diagnostic accuracy of the needle biopsy.

Monetary benefit and utility valuations:
Not relevant.
Measure of benefit:
A summary measure of benefit was not derived.

Cost data:
The costs included those of diagnosis using needle or endoscope biopsy, clinical follow-up following diagnosis, and any additional in-patient stay. The source of resource use was the clinical study. Prices were based on manufacturer's prices, local hospital costs and NHS tariffs (UK Department of Health) for procedures from 2010 to 2011 (where available). Costs were reported in UK £.

Analysis of uncertainty:
The sensitivity of the diagnostic procedures costs was assessed by varying costs from the NHS tariff across extremes of values.

Results
Endobronchial ultrasound-guided needle biopsy precluded the need for surgical biopsy in 87% of cases; it failed to provide a diagnosis in 13% of isolated mediastinal lymphadenopathy cases. The diagnostic sensitivity of needle biopsy was estimated to be 92%, the negative predictive value was 40%, and the diagnostic accuracy was 92%.

The mean cost of the needle biopsy strategy per patient was estimated to be £1,892 compared with £3,228 per patient for surgical biopsy, which was a cost saving of £1,336.

If the cost of the needle biopsy remained below £2,718, the strategy remained cost-saving.

Authors' conclusions
The authors concluded that endobronchial ultrasound-guided needle biopsy was a safe, sensitive, and cost-saving method of diagnosing patients with isolated mediastinal lymphadenopathy.

CRD commentary
Interventions:
The level of reporting of the interventions was good. The relevance of the interventions included appeared to be appropriate as both were recommended strategies in the UK NHS setting.

Effectiveness/benefits:
The sources of effectiveness data were well reported. The study setting appeared to be generalisable to the wider UK setting. It is important to note that, as highlighted in by the authors the assumption of 100% accuracy for mediastinoscopy would not hold in clinical practice. The clinical characteristics of both the prospective and historical cohort were presented; there were some differences in baseline characteristics for age: historical cohort had three patients <30 years (4%); prospective cohort had 15 patients <30 years (19%); historical cohort median age was 53 years (range 25 to 85); prospective cohort median age was 42 years (range 17 to 79). The impact of these differences is unknown, but likely to be negligible given that the model focused on diagnosis and did not include treatment or health related quality-of-life outcomes.

Costs:
The cost data were adequately reported. Costs relevant to the UK NHS perspective were included; justification for excluded costs was discussed. The authors made an assumption that treatment and treatment costs were unaffected by the method of diagnosis; embedded within that was an assumption that there were no complications associated with surgical biopsy. This was unlikely to hold true in clinical practice, and the costs and health disutility of any adverse effects may impact on the results. However, this assumption was conservative for endoscopic biopsy and the inclusion of adverse events would make the intervention more cost-effective. The price year was not stated explicitly, but the authors conducted the study from 2009 to 2011 and used NHS tariffs for 2010 to 2011.

Analysis and results:
The cost-minimisation approach stated by the authors appeared appropriate, regardless of diagnosis method, treatment for the condition would remain the same. The level of reporting of results was good. The authors discussed some key limitations of their analysis, which included some of the underlying assumptions around equality of tests, conduct of the
study in a tertiary centre, potential generalisability issues outside of the UK. The impact of uncertainty was addressed, but more comprehensive methods of assessing parameter uncertainty could have been used.

Concluding remarks:
There were a few limitations to the study, which were discussed by the authors. The results should be considered with these limitations in mind.

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