The clinical utility of endoscopic ultrasound-guided fine-needle aspiration in the diagnosis and staging of pancreatic carcinoma


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
Endoscopic ultrasound (EUS) guided fine-needle aspiration (FNA).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with pancreatic masses with or without associated lymph nodes (43% seen on ERCP, 18.5% on EUS and 38.5% on CT).

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

Dates to which data relate
Effectiveness and resource use data were collected during the period April 1993 - November 1995. The price year was not clearly reported.

Source of effectiveness data
Evidence for final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively. It was not clear whether the costing was undertaken on the same patient sample as that used in the effectiveness study.

Study sample
A total of 44 consecutive patients (24 men, 20 women) with a mean age of 61 years (range 28 to 88 years) who underwent EUS-guided FNA procedures was included in the study. The inclusion criteria established that patients with a clinical suspicion of pancreatic cancer who were referred for a diagnosis as well as those who had an established diagnosis of pancreatic cancer who were referred for further staging were included in the study.

Study design
Analysis of effectiveness
The principle used in the analysis of the clinical study was not stated and the outcomes used in the analysis were 'avoided surgery' (if the pre-procedure plan for going to surgery was established by the referring physician), 'may have avoided surgery' (if the referring physician did not commit to a pre-procedure plan and surgery was subsequently avoided) and 'expedited therapy' (EUS-guided FNA established a tissue diagnosis and no further diagnostic imaging tests were performed). The final diagnosis was based on results of surgery, autopsy or clinical follow-up of at least 6 months duration.

Effectiveness results
EUS-guided FNA made the correct diagnosis in 43 out of 46 lesions for which the specimen was adequate (accuracy of 93%). EUS-guided FNA avoided surgery in 12 out of 44 (27%) patients and may have avoided surgery in an additional 6 out of 44 (14%). In 25 out of 44 (57%) patients, EUS-guided FNA made a tissue diagnosis of malignancy, which avoided the need for subsequent imaging tests. For all lesions (pancreatic lesions and lymph nodes) and all specimens, the sensitivity of EUS-guided FNA was 83%, the specificity 82%, the diagnostic accuracy 88%, the negative predictive value 82% and the positive predictive value 100%. There was one complication (2%): a patient with a pancreatic mass and an adjacent pancreatic cyst had EUS-guided FNA of both lesions and developed a fever of 102 degrees Fahrenheit 3 days after the procedure. The patient was treated with intravenous antibiotics and was discharged after 2 days.

Clinical conclusions
EUS-guided FNA of pancreatic lesions appears to be a safe and effective method for establishing a tissue diagnosis of pancreatic carcinoma, especially in cases where CT does not show a focal lesion. In addition, the tissue diagnosis of metastatic lymph nodes increases the specificity, and hence the overall diagnostic accuracy, of nodal staging by EUS.

Measure of benefits used in the economic analysis
Cases of avoided surgery, relative to the pre-procedure plan or indication (number of definitive diagnoses) made by the referring physician. The side-effects of treatment (2% rate) were not considered in the economic analysis.

Direct costs
While the main quantities of resource use were reported separately from the costs, the costs included were based on an independent audit of the hospital's costs and the professional fees associated with exploratory laparotomy compared to EUS-guided FNA during the period of the study. The price year was not clearly reported. The analysis omitted the costs associated with avoided repeat imaging studies and included only the number of “avoided surgery” cases without “may have avoided” cases.

Currency
US dollars ($).

Sensitivity analysis
Not performed.

Estimated benefits used in the economic analysis
By using EUS in combination with EUS-guided FNA, 12 out of 44 patients avoided surgery.
The total "approximate" cost savings of EUS-guided FNA was $145,192 thereby attaining a $3,300 cost saving per patient.

**Synthesis of costs and benefits**
As the EUS-guided FNA was found to be the dominant strategy, the costs and benefits were not combined.

**Authors' conclusions**
The avoidance of surgery by EUS-guided FNA results in a substantial cost saving.

**CRD COMMENTARY - Selection of comparators**
A reasonable justification was given for the comparators used. You should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of benefit**
The estimate of the benefit was based on a relatively small case-series of patients in one hospital in the US and makes assumptions about the likely impact on patient outcomes of additional diagnostic information due to the lack of a proper control group in the clinical study. Such assumptions may not be valid in other institutions.

**Validity of estimate of costs**
Although broad resource quantities were reported separately from the prices, it is likely that important cost items may have been omitted, as was the case for repeat imaging studies avoided. The authors did not provide adequate detail of materials and methods for estimating unit costs. The price year was not clearly stated.

**Other issues**
The cost data may not be generalisable to countries beyond the USA (the authors did not address this issue). The conclusions were not justified given the uncertainties in the data.

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