Utility of rapid on-site evaluation of transbronchial needle aspirates

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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
The study assessed the use of rapid on-site evaluation (ROSE) of transbronchial aspirates by a cytologist during transbronchial needle aspiration (TBNA) via flexible bronchoscopy (FB).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients scheduled for routine bronchoscopy in whom computed tomography had revealed a lesion that appeared accessible with TBNA.

Setting
The setting was secondary care. The economic study was carried out in South Africa.

Dates to which data relate
The effectiveness data were collected between September 2001 and February 2003. The resource use data were based on the same period. The price year was 2002.

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

Link between effectiveness and cost data
The cost data were collected prospectively (for the intervention group) on the same patient sample as that used in the effectiveness study.

Study sample
The authors performed a sample size calculation based on detecting a significant reduction in the need for forceps biopsy as a result of ROSE-TBNA. The calculation assumed that 75% of patients would exhibit malignant disease, of which 40% would be detected by TBNA with a 75% success rate of ROSE. At a 5% significance level and 80% power for a two-tailed test, it was estimated that 85 patients would be required. The authors recruited consecutive patients to the study. Seventy (78%) of the 90 patients recruited to the study had malignant disease. The authors stated that the study sample was representative of routine practice. The authors did not report any refusals to participate or any patients excluded from the study sample.
Study design
The study was a single-centred prospective cohort study. The patients were followed up for the duration of the diagnostic procedures. The authors did not report any loss to follow-up. In evaluating ROSE, the cytopathologists who provided the definitive TBNA diagnosis were blind to the results of the rapid on-site diagnosis.

Analysis of effectiveness
The analysis of effectiveness included all patients recruited to the study. The primary health outcomes were the diagnostic yield and accuracy of ROSE.

Effectiveness results
TBNA was diagnostic in 60 (67%) out of 90 FB procedures, while ROSE was positive for diagnostic material in 59 (66%).

The sensitivity and specificity of ROSE were both 96.7% in patients with positive TBNA.

The negative predictive value was 93.5% and the positive predictive value was 98.3%.

Clinical conclusions
The authors concluded that ROSE improves the yield and accuracy of TBNA.

Measure of benefits used in the economic analysis
No summary measure of health benefits was used in the economic analysis. In effect, a cost-consequences analysis was performed.

Direct costs
The study included the direct hospital costs. These covered salary and hardware costs for the whole sequence of specimen collection from bronchoscopy to generation of a final report, and included the costs of the procedure, transport, preparation, analysis and reporting. Salary costs were based on the 2002 local salaries. The costs of diagnostic tools were based on local distributors’ pricing lists. Discounting was not relevant. The study reported the average costs and the quantities were reported separately. The authors ignored any time and hardware costs that did not differ between strategies.

Statistical analysis of costs
The majority of the costs and resource use were treated as point estimates. This approach may be justified given that the comparator costs for TBNA without ROSE were based on assumption and not measured directly. The study was powered to detect a reduction in the need for forceps biopsy. The difference in the proportions requiring forceps biopsy was assessed using a chi-squared test.

Indirect Costs
The indirect costs were not included in the analysis. This was appropriate for the study question.

Currency
South African rand (ZAR).

Sensitivity analysis
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The use of ROSE was estimated to significantly reduce the need for forceps biopsy from 65% to 18%, (p<0.01).

With the exception of the cytopathologist, the use of ROSE reduced the number of minutes’ participation and, therefore, the salary costs of health care workers and administrators.

Overall, the use of ROSE increased salary costs by ZAR 17.2 per patient and reduced the cost of consumables by ZAR 24.8.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Rapid on-site evaluation (ROSE) increased the value of transbronchial needle aspiration (TBNA) as a diagnostic modality.

CRD COMMENTARY - Selection of comparators
The authors stated that there were a number of practical innovations for improving the usefulness of TBNA, but they did not explicitly state why they elected to focus on ROSE. The use of ROSE was compared with TBNA without ROSE, although comparative data on the costs and outcomes were estimated rather than measured directly. You must decide whether TBNA with or without ROSE is widely used in your own setting.

Validity of estimate of measure of effectiveness
The estimate of effectiveness was based on a single study. The study did not have a comparator group and the estimates of resource use without ROSE were based on hypothetical situations. The study sample was representative of the study population, but the lack of an observed comparator group limits the validity of the study findings.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The authors did not specify a perspective for their analysis. However, the study appears to have been conducted from a hospital perspective and cost categories relevant to this perspective were included in the analysis. The authors omitted any costs that were estimated to be the same with and without ROSE. This should not affect the incremental analysis and, as the results were treated deterministically, it cannot affect the estimated uncertainty. The costs were reported separately from the quantities to improve the generalisability of the study results. The authors only statistically analysed the numbers of forceps biopsies required. The remaining resource use estimates were treated deterministically. This may be appropriate given that the estimates for the comparator group were based on hypothetical situations rather than being directly observed. The unit costs were taken from the authors' setting. A statistical analysis of the prices was not conducted. The unit costs used reflect the costs in the local setting and referred to the price year 2002. An experimental study design would be needed to validate the cost findings from this study.
Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was addressed well. The authors acknowledged that factors such as hospital geography, the local health care system and available expertise may affect the cost-effectiveness of ROSE-TBNA in different settings. The authors do not appear to have presented their results selectively. They acknowledged that the cost-effectiveness of ROSE must be compared with other methods for improving TBNA, such as endobronchial ultrasound.

Implications of the study
The authors suggested that further studies should assess the cost-effectiveness of ROSE and other methods for improving TBNA.

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