Safety and efficacy of median sternotomy versus video-assisted thoracic surgery for lung volume reduction surgery

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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
Two approaches for lung-volume reduction surgery (LVRS) for advanced bilateral emphysema were examined. The approaches were median sternotomy (MS) and video-assisted thoracoscopy (VATS).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with advanced bilateral emphysema. Patients with a high risk of mortality after LVRS were excluded. These were defined as patients with a forced expiratory volume in 1 second (FEV1) of, at most, 20% of predicted, and either a homogeneous pattern of emphysema or a diffusing capacity of the lung for carbon monoxide of less than or equal to 20% of predicted.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered between January 1998 and July 2002. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the sub-group of patients that was included in the effectiveness trial.

Study sample
There was limited information on the methods and design of the study since the study had already been published (see Other Publications of Related Interest). Power calculations, if performed, were not reported. An initial group of 1,218 patients was identified, of which 610 received medical treatment and 608 underwent LVRS. After excluding patients who could not benefit from the surgical approach, 538 patients were to receive LVRS, but 20 refused the operation and 7 were unsuitable. Thus, there were 511 patients in the final sample, 359 in the MS group and 152 in the VATS group.
The mean age was 67.3 (+/- 6) years in the MS group and 66.3 (+/- 6.7) years in the VATS group. The proportion of men was 57% in both groups.

**Study design**
Two main comparisons were made. These corresponded to two different study designs, a randomised, clinical trial and a prospective cohort study. Eight centres performed LVRS by MS only and 3 centres by VARS only. Six centres performed both VATS and MS. In the non-randomised comparison, the pooled MS group (data from 14 centres) was compared with the pooled VATS group (data from 9 centres). In the randomised comparison, the MS and VATS groups at the 6 centres were compared; there were 77 patients in the MS group and 71 patients in the VATS group. The method of randomisation was not described. It was not stated whether blinding was performed. The average length of follow-up was 31.9 months. Details of the loss to follow-up were not reported.

**Analysis of effectiveness**
The effectiveness results were based on all patients included in the initial study sample. The outcome measures used were:

- the mortality rates;
- intra-operative outcomes, including blood loss, need for transfusion, operating time, and complications;
- days in intensive care unit (ICU) and days on mechanical ventilation;
- the length of stay (LOS);
- the proportion of patients living independently after the operation; and
- functional outcomes, including exercise capacity, FEV1, 6-minute walk distance, St George's Respiratory questionnaire, and Quality of Well-Being Scale after 12 and 24 months of follow-up.

The study groups were comparable in terms of the demographic and disease characteristics. However, there was a larger proportion of patients with heterogeneous emphysema in the MS group compared with the VATS group (61% versus 51%, p=0.04). When the analysis was restricted to the randomised group, the patients were comparable on all aspects.

**Effectiveness results**
Data were presented for the non-randomised comparison, while p-values were reported for the whole study (both non-randomised and randomised patients).

There were no intra-operative deaths in either treatment group. The 30-day mortality rate was 2.8% for MS and 2% for VATS, (p=0.76). The 90-day mortality rate was 5.9% for MS and 4.6% for VATS, (p=0.67). The overall mortality rate over the follow-up period was 0.08 deaths per person-year for MS patients and 0.10 deaths per person-year for VATS patients (risk ratio for death in the VATS group, 1.18; p=0.42). Similar results were observed in the randomised comparison.

There were no statistically significant differences in blood loss, (p=0.55), and the need for transfusion, (p=0.99). However, the operating time was 105 minutes with MS and 126.7 minutes with VATS, (p<0.001).

Ninety-three per cent of MS patients and 86.2% of VATS patients had no intra-operative complications, (p=0.02). However, hypoxemia was the only intra-operative complication significantly less frequent with MS than with VATS (0.8% versus 5.3%; p=0.004).

During the 30 days after operation, the only statistically significant different complication was the need to reoperate for air leak (2.2% with MS versus 5.9% with VATS; p=0.05). However, in the randomised comparison, only the failure to wean differed significantly (7.8% with MS versus 0% with VATS; p=0.03).
There was no difference in the number of days with air leak in the two groups.

In general, patients in the MS group required more ICU days than those in the VATS group, \(p<0.001\). The difference did not reach statistical significance in the randomised comparison. The need for mechanical ventilation was comparable.

LOS data were available for 343 MS patients and 146 VATS patients. The mean LOS was 17 (+/- 19) days for MS patients and 14 (+/- 9) days for VATS patients, \(p=0.06\). The median LOS was 10 days for MS patients and 9 days for VATS patients, \(p=0.01\). The LOS was significantly shorter for VATS patients in the randomised comparison.

The proportions of patients living independently were 70.5\% with MS and 80.9\% with VATS after 30 days, \(p=0.02\), and 87.5\% (MS) versus 90.8\% (VATS) after 4 months, \(p=0.36\). Similar results were obtained in the randomised comparison.

Functional outcomes were comparable between the two groups in both the non-randomised and the randomised comparisons.

**Clinical conclusions**
The effectiveness analysis showed that functional outcomes and mortality data were comparable between the groups. A shorter LOS was observed with VATS. With respect to the frequency of complications, hypoxemia was significantly less frequent with MS, while significantly more VATS patients required reoperation for air leak.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

**Direct costs**
Discounting was not relevant since the costs were incurred during a 6-month period. The unit costs were not presented separately from the quantities of resources used, and a breakdown of the cost items was not provided. The economic evaluation included hospital and physician costs, as well as all medical and non-medical costs incurred over the 6-month postoperative period. The cost/resource boundary of the third-party payer appears to have been adopted. Resource use and costs were estimated using Medicare data that were available for 343 MS patients and 146 VATS patients. The price year was not reported.

**Statistical analysis of costs**
The mean costs were estimated using the non-parametric Kaplan-Meier sample average estimator, then compared using 2-sample t-tests. The median costs were compared using the Wilcoxon rank sum test.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean initial costs (hospital and physician costs) were $38,557 (+/- 40,519) (median $23,418) with MS and $30,350 (+/- 37,219) (median $19,947) with VATS, (p=0.03). The difference in mean initial costs was $8,207 (95% confidence interval, CI: 917 - 16,035).

The mean total costs were $61,481 (+/- 3,189) with MS and $51,053 (+/- 4,502) with VATS, (p=0.005). The difference in mean total costs was $10,428 (95% CI: 9,786 - 109,062).

When only randomised patients were considered, the mean initial costs for the VATS group were $7,138 lower than those for the MS group (95% CI: 5,900 - 20,177; p=0.28). The mean total costs were also lower for the VATS group, by $6,500 (95% CI: 4,295 - 8,705; p<0.001).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

Authors' conclusions
The median sternotomy (MS) and video-assisted thoracoscopy (VATS) approaches for the treatment of advanced bilateral emphysema led, in general, to comparable mortality, complications and functional outcomes. However, longer length of stay (LOS) and higher costs were observed with MS relative to VATS.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was based on the two most commonly used LVRS approaches for the treatment of patients with advanced bilateral emphysema. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
Two different analyses were carried out because both a randomised and a non-randomised comparison were made. The main focus was on the cohort study, probably because of the larger sample size. Details of the design of the study were generally not reported as they had been published elsewhere. Therefore, it was not possible to examine the validity of the analysis. The length of follow-up appears to have been appropriately long. The method of sample selection was described and the study groups were quite comparable at baseline. Moreover, the patients were enrolled in multiple centres. This enhances the robustness of the comparison.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted in the study was not explicitly stated, but appears to have been that of the third-party payer because Medicare reimbursement rates were used to assess the treatment costs. A detailed breakdown of the cost items was not provided since the costs were presented as macro-categories. This reduces the possibility of replicating the analysis. Statistical analyses of the costs were carried out in both the randomised and non-randomised groups. The price year was not reported, which makes reflation exercises in other settings difficult. The cost estimates were specific to the study setting.
Other issues
The authors compared mortality and complication data with those reported in the literature and found similar estimates. However, the issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were carried out. This limits the external validity of the analysis. The study referred to patients with advanced bilateral emphysema and this was reflected in the authors’ conclusions.

Implications of the study
The authors noted that caution is required when interpreting the results of the study. This is because the randomised comparison took place only for a small fraction (29%) of the sample, as most of the surgeons preferred to perform only one surgical approach. The choice of the surgical approach should be left to the surgeon’s preference and experience.

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Other publications of related interest

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