Prospective randomized comparison of thoracoscopic talc poudrage under local anesthesia versus bleomycin instillation for pleurodesis in malignant pleural effusions

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
Thoracoscopic talc poudrage under local anaesthesia versus bleomycin instillation for pleurodesis in malignant pleural effusions.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with malignant pleural effusions, expanded lungs after drainage and expected survival greater than one month.

Setting
Hospital. The economic study was set in Switzerland.

Dates to which data relate
Effectiveness, resource use, and cost data were collected between August 1996 and October 1998. The price year was not reported.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Sixteen patients were assigned to bleomycin instillation and 15 to talc poudrage. Inclusion in the study required documentation of malignant pleural disease, complete lung expansion on chest radiography at 12 to 24 hours after drainage, improvement of symptoms after drainage, and expected survival of more than 1 month. Patients with loculated effusions, those with previous drainages, and those with previous attempts at pleurodesis were not enrolled; nor were patients with known adverse reactions to the study medications or those with a severe coagulation disorder. Patients had to be judged as capable of undergoing medical thoracoscopy in order to be included. With a statistical power of 80%, at a significance level of 95%, a significant difference was expected after analysis of 100 treatments.
Study design
The study was a prospective, randomised, controlled trial carried out at a single centre. No patients were lost to follow-up. Follow-up continued after the analysis period of 180 days.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes included recurrence, fluid drainage, side effects, and well-being. General well-being was measured on a visual analogue scale. Survival was calculated with Kaplan-Meier estimates. At analysis, groups were shown to be comparable in terms of age, sex, dyspnea, cough, pain, and overall well-being.

Effectiveness results
The effectiveness results were as follows:

Three patients died of their malignancies at 7, 9, and 10 days, respectively, after bleomycin instillation, but none of these deaths were related to the procedure.

The authors observed a trend towards more frequent relapse at 30 days after bleomycin instillation, which reached significance after 90 days and achieved greater significance at 180 days.

Recurrences led to secondary treatments within 180 days after bleomycin in eight cases and after talc pleurodesis in two cases, (p=0.04).

After bleomycin pleurodesis, more fluid was drained than with talc poudrage, and the duration of chest tube drainage was longer by 1 day.

In the first three days after treatment, scores for dyspnea, cough, pain, and overall well-being were not significantly different in the talc poudrage and bleomycin groups. Bleomycin-treated patients, however, scored pain intensity, higher.

Side effects of both treatments were minor.

There was no major complication or death.

There were two recurrences of effusion in the thoracoscopic talc pleurodesis group.

Clinical conclusions
Thoracoscopic talc pleurodesis under local anaesthesia is highly effective and clearly superior to bleomycin instillation, especially in the long term. Both methods are safe, provide symptomatic relief, and have similar subjective tolerances.

Measure of benefits used in the economic analysis
Recurrence of pleural effusion was used as the measure of benefits.

Direct costs
Direct costs were not discounted due to the short time horizon of the study (less than 1 year). Quantities and costs were not reported separately. Direct costs related to professional costs, drainages and medications, intervention room time, pleurodesis substance, and hospitalisation. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs and quantities were collected from hospital records. The price year was not reported.

Statistical analysis of costs
No statistical analysis was reported.
Indirect Costs
Indirect costs were not included.

Currency
Swiss Francs (SFr).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
Total costs amounted to SFr 4,169 in the bleomycin group and to SFr 3,893 in the talc poudrage group.

Synthesis of costs and benefits
Taking into account the significant excess number of recurrences that were treated after bleomycin pleurodesis, thoracoscopic talc poudrage can be regarded as the dominant strategy in the long term.

Authors' conclusions
Thoracoscopic talc pleurodesis under local anaesthesia is superior to bleomycin instillation for pleurodesis in cases of malignant pleural effusion.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, which is a widely used treatment. You, as a user of the database, should decide if this health technology is relevant to your setting.

Validity of estimate of measure of benefit
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population and patient groups were shown to be comparable at analysis. Appropriate statistical analyses were undertaken to take account of potential biases and confounding factors. The analysis of effectiveness was handled credibly. Estimation of benefits was obtained directly from the effectiveness analysis. As such the validity of the benefit estimates is likely to be high.

Validity of estimate of costs
A good feature of the cost analysis was that all relevant direct cost categories were included. However, quantities and costs were not reported separately; no statistical or sensitivity analyses were reported on quantities or costs; the price year was not reported; and it was not clear if charges had been used to proxy prices. These features tend to limit the generalisability of the cost results.

Other issues
The authors did make appropriate comparisons of their findings with those from other studies and the issue of generalisability to other settings was addressed. The authors did not present their results selectively. The study enrolled patients with malignant pleural effusions and this was reflected in the authors’ conclusions. The authors noted that their
costs for pleurodesis might not be applicable to other countries.

**Implications of the study**
The results of the study suggest that general anaesthesia, as a major cost-driving factor, can be safely eliminated without impairing success rate, by the uses of talc pleurodesis.

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None stated.

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