Indwelling small pleural catheter needle thoracentesis in the management of large pleural effusions  

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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
Small indwelling pleural catheter (7F, Turkel Safety Thoracentesis System) in the management of large-volume pleural effusions.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Inpatients with large pleural effusions.

Setting
The setting was a tertiary care teaching hospital in Chicago, USA.

Dates to which data relate
Patients participating in the study were enrolled between 1 July 1994 and 30 June 1995. Dates for data were not stated.

Source of effectiveness data
The clinical effectiveness data were taken from a single study and a review of the literature.

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
23 patients with a mean age of 57.7 years (range, 40 to 96 years) were studied. 8 patients had transudative effusion and 15 had an exudative effusion. Comorbidities included: renal failure; congestive heart failure; respiratory failure; hypertension; end-stage liver disease; diabetes mellitus; sepsis; cancer; inflammatory processes; AIDS; Budd-Chiari syndrome; chest trauma and anaemia. Inclusion criteria were: aged over 18 years and large free-flowing pleural effusion identified by opacification of at least one third of the hemithorax on chest radiography. Exclusion criteria were: documented loculations; structural chest abnormalities; severe uncontrolled coagulopathy and refusal of informed consent. Power calculations to determine the sample size were not reported.
Study design
The study was a cohort study with historical controls.

Analysis of effectiveness
The study did not state what the analysis of the clinical study was based upon. Primary health outcomes considered were: average number of aspirations required to drain the pleural space; total complication rate; incidence of major complications (pneumothorax, tube thoracostomy required, splenic laceration and haemopneumothorax); incidence of minor complications (pain, dry tap, haematoma).

Effectiveness results
The average number of aspirations was 2.5. The total complication rate was 12%. The incidence of major complications was 3.5% (pneumothorax: 3.5%, tube thoracostomy required: 1.75%, splenic laceration and haemopneumothorax: 0%). The incidence of minor complications was 8.7% (pain: 1.75%, dry tap: 1.75%, haematoma: 0%). Effectiveness results for the controls were indicated in the review of previous studies.

Clinical conclusions
The total complication rate and the incidence of major and minor complications was lower for the intervention evaluated in this study.

Outcomes assessed in the review
The outcomes assessed were the total complication rate, the incidence of major complications (pneumothorax, tube thoracostomy required, splenic laceration and haemopneumothorax) and the incidence of minor complications (pain, dry tap, haematoma).

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Total complications, and the incidence of major and minor complications were obtained from 2 studies. Incidence of a major complication (pneumothorax) was derived from 8 different studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Results of the review
The total complication rate was 46% in both of the two studies considered. In the first study, major primary complications included: pneumothorax (11%); tube thoracostomy required (2.4%); splenic laceration (0.8%) and haemopneumothorax (0.8%). Minor complications included: pain (22%) dry tap (13%) and haematoma (0.8%). In the second study major primary complications using a needle-catheter system included pneumothorax (39%) and tube thoracostomy (11%). Minor complications were 61% and included: pain (38%) dry tap (11%) and haematoma (5.5%). Complications using a traditional needle procedure included pneumothorax (20%) but no need for tube thoracostomy. Minor complications occurred in 27% of cases and included pain (13%), and dry tap (13.5%). Pneumothorax ranged from 5.2% to 19.2% in the 8 studies considered for this complication.

Measure of benefits used in the economic analysis
The authors did not combine the primary health outcomes into a single benefit measure. As such the benefits are assumed to be equal to the effectiveness results.

Direct costs
The direct costs were estimated from a provider perspective. Discounting was not applied due to the study duration. Costs and quantities were reported separately. The costs for catheter and insertion kit, thoracentesis, closed tube thoracostomy and daily chest radiograph were derived from the institution's own records.

Statistical analysis of costs
The costs were not treated in a stochastic way.

Indirect Costs
Not stated.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was not performed.

Estimated benefits used in the economic analysis
The clinical study using small pleural catheter needle thoracentesis provided a total complication rate of 12%. The incidence of major complications was 3.5% (pneumothorax: 3.5%, tube thoracostomy required: 1.75%, splenic laceration and haemopneumothorax: 0%). The incidence of minor complications was 8.7% (pain: 1.75%, dry tap: 1.75%, hematoma: 0%). The review of previous studies using alternative thoracentesis procedures provided a total complication rate of 46%. In the first study, major primary complications included: pneumothorax (11%); tube thoracostomy required (2.4%); splenic laceration (0.8%) and haemopneumothorax (0.8%). Minor complications included: pain (22%); dry tap (13%) and haematoma (0.8%). In the second study major primary complications using a needle-catheter system included pneumothorax (39%) and tube thoracostomy (11%). Minor complications were 61% and included: pain (38%); dry tap (11%) and haematoma (5.5%). Complications using a traditional needle procedure included pneumothorax (20%) but no need for tube thoracostomy. Minor complications occurred in 27% of cases and included pain (13%) and dry tap (13.5%). Pneumothorax ranged from 5.2% to 19.2% in the 8 studies considered for this complication.
Cost results
The Turkel Safety needle-catheter system was cost saving in comparison with a single-use thoracentesis kit for each aspiration and a closed tube thoracostomy (incremental costs were -$2,400 and -$284, respectively).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Small indwelling catheter needle thoracentesis in the management of large-volume pleural effusion reduces morbidity, is safer and cost saving compared with more traditional methods. Since the practice of medicine is becoming more outpatient-based, the method can contribute to cost reductions and to increasing patients' comfort.

CRD COMMENTARY - Selection of comparators
The comparators were correctly identified as the current traditional methods of practice.

Validity of estimate of benefit:
The primary benefits for comparison were extrapolated from only two previous studies. A complete review of the literature does not seem to have been undertaken. The benefits of small pleural catheter needle thoracentesis were based on a clinical study and controls were historical, which places some limitations on validity.

Validity of estimate of costs
The direct costs only were calculated from a specific provider perspective. Cost dates were not stated.

Other issues
The principal weakness of this study is that results from previous studies were not combined in order to provide a more precise comparison with the intervention.

Implications of the study
The findings need to be validated by a large clinical trial from both a provider and a patient perspective. The intervention may then be shown to be preferred to traditional methods in inpatient and outpatient practice.

Source of funding
None stated.

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