The PTL, Combitube, Laryngeal Mask, and Oral Airway: a randomized prehospital comparative study of ventilatory device effectiveness and cost-effectiveness in 470 cases of cardiorespiratory arrest

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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
Alternative airway devices (Pharyngeal Tracheal Lumen Airway - PTL, laryngeal mask - LM and esophageal tracheal Combitube - Combi) and the oral airway/bag-valve-mask (OA/BVM) in cases of cardiorespiratory arrest.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients in cardiac and respiratory arrest undergoing PTL, LM, Combi and OAM being attended by non-Advanced Life Support emergency medical assistants (EMAs)

Setting
Community. Emergency response stations in demographically similar communities without Advance Life Support (ALS) facilities. The economic study was conducted in Canada.

Dates to which data relate
The main effectiveness data were taken from a single study conducted between 1991 and 1995. Resource and cost data were obtained from 1991-1995 sources. The price year was 1995.

Source of effectiveness data
The estimates of success of insertion, ventilation, arterial blood gas (ABG) and spirometry measurements and complications were obtained from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study, although it was not stated whether it was undertaken prospectively or retrospectively.

Study sample
Four hundred and seventy patients in cardiac and/or respiratory arrest were included in the analysis: 142 (mean age: 63.7 years) received PTL, 147 (mean age: 64.5 years) received LM, 90 (mean age: 66.6 years) received Combi and 91 (mean age: 60.9 years) received OA/BVM. The causes of arrest were cardiac (90.9%), respiratory (4.04%), traumatic...
(3.6%) and unknown (1.5%). Power calculations to determine the sample size were not undertaken. Randomisation to device interventions was undertaken using a random numbers table and sealed instruction envelopes.

**Study design**
The study was a randomised trial with concurrent controls.

**Analysis of effectiveness**
The analysis of effectiveness was based on treatment completers only. The primary health outcomes were success of insertion, ventilation, arterial blood gas (ABG) and spirometry measurements and complications. The patient groups were shown to be comparable with respect to donor and recipient characteristics.

**Effectiveness results**
The successful insertion and ventilation rates were 86% (Combi), 82% (PTL), and 73% (LM), (p=0.048). The ABG scores were 55.6 mmHg and 153 mmHg in PTL for PCo2 and PO2, respectively (p=0.524). The corresponding figures for LM were 57.6 and 115 mmHg, for Combi were 43.3 and 214 mmHg, and for OA/BVM were 53.0 and 189 mmHg. The spirometry measurements were 596 (PTL), 547 (LM) and 720 mL (Combi). Overall, 137 patients (30.4%) had vomited prior to device insertion. A further 10% of patients vomited either during or after device insertion (PTL, 40%; LM 31%; Combi 42.5% and OA/BVM 42.5%). In patients in whom vomiting was not observed prior to or during device insertion, 3 cases of airway contamination with vomitus were observed at the time of intubation with LM, 2 with PTL and 1 with Combi.

**Clinical conclusions**
The PTL, LM and Combi appear to offer substantial advances over the OA/BVM system. In both areas of objective measurement of the adequacy of ventilation (ABGs and spirometry) Combi was associated with the least problems. LM had the lowest success of insertion.

**Measure of benefits used in the economic analysis**
The measure of benefits was lives saved.

**Direct costs**
Capital costs, training costs (not including instructor costs or facility fees) and operating expenses were included in the analysis. The quantities were reported separately from the prices. The quantity/cost boundary adopted was the hospital. The price year was 1995. Discounting was not undertaken due to the short period of analysis.

**Statistical analysis of costs**
Chi-squared test, student t test, paired t-test and analysis of variance were employed.

**Indirect Costs**
Not considered.

**Currency**
Canadian dollars (Can$) and US equivalent.

**Sensitivity analysis**
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
The number of lives saved for each device was not explicitly stated but the authors provided a synthesised cost/life saved as shown below in the "synthesis of costs and benefits".

Cost results
The total costs were:

PTL, Can$200.10 (capital cost: Can$55; training cost: Can$90.10; operating cost: Can$55);

LM with 5-day OR training, Can$1,053.25 (capital cost: Can$210; training cost: Can$632; operating cost: Can$211.25);

LM with mannequin training, Can$511.35 (capital cost: Can$210; training cost: Can$90.10; operating cost: Can$211.25);

Combi, Can$236.7 (capital cost: Can$73.35; training cost: Can$90; operating cost: Can$73.35);

LM with 1 day didactic and 1 day OR training, Can$647.25 (capital cost: Can$210; training cost: Can$253; operating cost: Can$211.25).

Synthesis of costs and benefits
The operational cost per life saved was $1,239.00 (PTL), $417.00 (LM with 5-day OR training), $441.47 (LM with mannequin training), $1,650.37 (Combi) and $417.00 (LM with didactic and OR training).

Authors' conclusions
The PTL, LM, and Combi appear to offer substantial advances over the OA/BVM system. Although the most costly alternative, the Combitube was associated with the least problems with ventilation.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear. The preferred method of ventilation and airway control in patients with cardiac arrest or upper airway compromise is endotracheal intubation. However, endotracheal intubation may not be feasible for many communities. A number of alternative airway devices have been developed in the past few decades. The OA/BVM system of ventilation is still the most common means of providing ventilatory support in non-advanced life support ambulance systems. PTL, LM, and Combitube have been introduced as alternatives to OA/BVM. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
The methods used to determine the clinical outcomes of each device appear to be sound although, as noted by the authors, the accuracy of measurements made with manually ventilated airway flow may be suspect. The authors also produced a summary measure of cost per life saved although it is not clear how the number of life years was derived.

Validity of estimate of costs
Resource quantities were analysed separately from the prices. Adequate details of methods of quantity/cost estimation were given. Important cost items do not appear to have been omitted.

Other issues
The authors' conclusions are likely to be justified given the uncertainties in the data. The issue of generalisability to other setting or countries was not addressed. However, appropriate comparisons were made with other studies as a
systematic review of relevant literature was conducted which included studies which addressed the rate of successful pre-hospital insertion and ventilation and complications. Results do not appear to have been presented selectively. However, as the authors noted, the study suffers from limitations due to the study design of pre-hospital-system-based research such as complex interrelated questions, multiple data points, a large number of participants and data collectors and variable outcome parameters.

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**Other publications of related interest**

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