Human and financial costs of noninvasive mechanical ventilation in patients affected by COPD and acute respiratory failure

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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
Non-invasive mechanical ventilation (NIMV) using a full face mask was compared with invasive mechanical ventilation (InMV) achieved by endotracheal intubation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients affected by chronic obstructive pulmonary disease (COPD) and acute respiratory failure. The precipitating cause of respiratory failure was respiratory tract infection without radiologic evidence of pneumonia. All the patients were in a hemodynamically stable condition. The need for mechanical ventilation was based on 2 or more of the following:

(1) severe dyspnea at rest;
(2) PaCO2 greater than 70 mm Hg;
(3) pH less than 7.33;
(4) arterial oxygen saturation less than 88% despite oxygen addition.

Setting
Hospital respiratory intensive care unit. The economic study was performed at the Montescano Rehabilitation Centre, Montescano, Italy.

Dates to which data relate
The study was performed between June 1995 and March 1996, during which period clinical data and resource use data were collected. The price dates were not given.

Source of effectiveness data
Evidence was based on a single study.
Costing was undertaken on the same patient sample as the effectiveness study. Collection of resource data was prospective.

**Study sample**
Sixteen consecutive COPD patients requiring mechanical ventilation were studied. NIMV with a full face mask was tried on all patients. This was successful on 10 patients who became the treatment group A, the 6 for whom NIMV failed were ventilated invasively and became the control group B. The authors justified this method (and countered the argument that the control group might be more severely ill) by showing that there were no significant differences between groups on several parameters such as arterial blood gases, pulmonary function tests, neurologic status and the APACHE II score. Justification for the trial size was not given.

**Study design**
This study was a non-randomised trial with concurrent controls.

**Analysis of effectiveness**
It was not stated whether the analysis was based on intention to treat. The primary health outcomes considered were improvements in arterial blood gases, PaO2/FIO2, pH, and PaCO2, mmHg. Results were given as the mean and standard deviation of each measurement at admission, during the first 12 hours of mechanical ventilation and at discharge, but improvements were not calculated and differences between groups were not analysed in a stochastic way.

**Effectiveness results**
One patient died in each group, in group A from pneumonia and in group B from multiple organ failure.

Measurements for group A were as follows:

PaO2/FIO2: 1.64 (SD 0.32) on admission, 1.99 (SD 0.25) during first 12 hours and 2.04 (SD 0.15) on discharge;
pH: 7.21 (SD 0.08) on admission, 7.39 (SD 0.04) during first 12 hours and 7.36 (SD 0.03) on discharge;
PaCO2, mmHg: 88.16 (SD 9.8) on admission, 51.57 (SD 10.9) during first 12 hours and 55.26 (SD 13.00) on discharge.

Measurements for group B were as follows:

PaO2/FIO2: 1.58 (SD 0.37) on admission, 1.91 (SD 0.30) during first 12 hours and 1.95 (SD 0.19) on discharge;
pH: 7.20 (SD 0.08) on admission, 7.42 (SD 0.04) during first 12 hours and 7.38 (SD 0.04) on discharge;
PaCO2, mmHg: 90.51 (SD 12.8) on admission, 51.6 (SD 13.3) during first 12 hours and 53.6 (SD 12.1) on discharge.

**Clinical conclusions**
The institution of both NIMV and InMV improved the arterial blood gas values of the patients by hospital discharge.

**Modelling**
None.

**Measure of benefits used in the economic analysis**
The authors assumed no difference in clinical benefits and the analysis was based on costs only.
**Direct costs**
Particular emphasis was placed on staffing resources in this study and these were reported separately. Minutes and seconds spent at each patient's bedside were recorded by stopwatch and logged on a time sheet. Staff were categorised as nurses, medical doctors and respiratory therapists and the common activities undertaken were also categorised. This was done over the first 48 hours for all patients in the study. In group B the initial time consumption of personnel during the initial unsuccessful trial of NIMV was also calculated. For 5 patients treated non-invasively and 4 intubated patients, nurses and medical doctors continued to log time spent for the entire ventilatory period. Prices and costs of staffing were not given. The cost boundary was that of the RICU. A separate calculation was made based on hospital charges for each patient recorded by the hospital's computerised system, which also included distributed staffing costs. These calculations included variable costs such as diagnostic tests and studies and disposable supplies. They also included overhead costs to cover institutional services such as laundry, heating and non-disposable equipment. Costs of staffing were included in the overhead calculation as the daily rate of reimbursement for each full-time staff position assigned only to patients in the respiratory ICU. The cost boundary was not entirely clear. As the calculation was based on charges it may be that of the purchaser, but this was not specified. Prices were not given and the date of the costing was not given, although resources were measured between June 1995 and March 1996.

**Statistical analysis of costs**
Costs were treated stochastically. Results were expressed as the mean +/- SD. Comparisons between groups were performed with a 2-sample t-test and short term (48 hour) and long term (until discharge) comparisons were analysed using 2-way analysis of variance for repeated measurements. Statistical significance was defined as a 2-tailed p value less than 0.05.

**Indirect Costs**
These were not considered.

**Currency**
US dollars ($) after conversion from Italian lira (L) (rate: $1 = L1,590).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
The authors assumed no difference in clinical benefits and the analysis was based on costs only.

**Cost results**
In the first 6 hours the total time spent at the bedside was: for group A, nurses spent 178.8 minutes, MDs spent 72.3 minutes and respiratory therapists 87.2 minutes. For group B, nurses spent 197.6 minutes, MDs spent 98.8 minutes and therapists 12.5 minutes. These differences were not significant. In the first 48 hours the total time of nursing assistance for group A was 540.1 (+/- 76.4) minutes and for group B was 527.5 (+/- 51.1) minutes, (not significant). The total medical doctors' workload for this time was 415 (+/- 110) minutes for group A and 524 (+/- 156) minutes for group B, (not significant). The total time spent by respiratory therapists was 250.8 (+/- 66.5) minutes for group A and 72.7 (+/- 38.5) minutes for group B, (significance not stated). The amount of time spent on both groups by nurses differed significantly between the first 6 and the following 42 hours, (p<0.001). After 40% of the total ventilation-time, time spent by nurses on group A was significantly less (p<0.05) and after 60% of total ventilation-time, time spent by MDs on group A patients was very significantly less, (p<0.01). Total daily costs of the first 48 hours for group A were $806.17 (+/-73.60) and for group B were $864.53 (+/- 51.36). The difference was not significant.

The breakdown of costs was expressed in percentages:
Personnel (group A = 36%, group B = 36%);
Radiograph (group A = 8.5%, group B = 6.5%);
Drugs (group A = 8.5%, group B = 9%);
Supplies (group A = 8%, group B = 10%);
Laboratory (group A = 7%, group B = 9%);
Indirect costs (group A = 21%, group B = 21%);
Others (group A = 11%, group B = 8.5%).

Synthesis of costs and benefits
Costs and benefits were not combined since the authors assumed no difference in clinical benefits.

Authors' conclusions
In the first 48 hours of ventilation daily NIMV is neither more expensive nor more time consuming than InMv. After the first few days of ventilation NIMV was significantly less time consuming for medical doctors and nurses than InMV.

CRD COMMENTARY - Selection of comparators
It was clear why the comparator was chosen but a more valid comparison would have been to have randomised some patients to InMV and included those who could not tolerate NIMV in the treatment group on an intention to treat basis.

Validity of estimate of measure of benefit
The implication of the study is that NIMV has clinical advantages but no real attempt was made to measure benefit. The authors mention some minor side effects of NIMV, but not of InMV where side effects may conceivably be more serious. The timescale and numbers involved in the study are not sufficient for clinical conclusions to be valid.

Validity of estimate of costs
The measurement of time in minutes could have been translated into costs as a bottom up measurement and this would have been valid and useful. The costing taken from the hospital records is a top down accounting procedure that also includes staff time. A more detailed explanation of this, which included quantities and prices rather than percentages of total costs, would have been useful. The double counting of staff time is presented without adequate explanation and is confusing although it is reasonable to attempt both procedures.

Other issues
Since the authors assumed no difference in clinical benefits, the economic study performed was a cost-minimisation analysis, which is a sub-type of cost-effectiveness analysis. The authors mention the higher costs of staff in the USA and the separating out of staffing from other costs is useful for generalisability. However the very short follow-up (48 hours for the main part of the study) renders the findings inconclusive.

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