A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation


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
Weaning patients from mechanical ventilation by nurses and respiratory therapists using protocol guidelines or by traditional physician-directed procedure.

Type of intervention
Rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was patients receiving mechanical ventilation. All patients aged over 18 years who were in the ICUs and who were receiving mechanical ventilation were eligible to be included in the study sample. The exclusion criteria were as follows: (a) head or facial burns or trauma, (b) transfer from other hospitals with prior mechanical ventilation and (c) a need for mechanical ventilation to allow organ retrieval following brain death.

Setting
The setting was a teaching hospital ICU. The economic study was carried out in Washington, USA.

Dates to which data relate
The effectiveness and resource use data were collected during a 4-month period (July 1995 to October 1995). The price dates were not reported.

Source of effectiveness data
The data related to final outcomes were derived from a single prospective study.

Link between effectiveness and cost data
The costing was conducted on the same patient sample as that used in the effectiveness study. It is not clear whether the costing was performed prospectively or retrospectively.

Study sample
Power calculations were used to determine the size of study sample. 377 subjects were included in the study sample. About 5% of the patients were excluded from the initial study sample. There were 179 patients in the intervention group (protocol-directed weaning) and 178 patients in the control group (physician-directed weaning).
Study design
The study was a randomised controlled trial, conducted in two hospitals and four ICUs. The patients were assigned randomly to the intervention and control groups. Stratified allocation according to ICU was used. The loss to follow up in the protocol-directed group was 12.3% and 13.5% in the physician-directed group. The staffing ratio of nurses to patients was 1:2. Physicians, nurses, and respiratory therapists were not blinded to the result of the randomisation process.

Analysis of effectiveness
The clinical study analysis was based on intention to treat. The primary outcome measure was the duration of mechanical ventilation. The secondary measures of study outcomes were need for reintubation, length of hospital stay, and hospital mortality rate. Statistical analysis showed that study groups were comparable in age, gender, ethnicity, presence of acute respiratory distress syndrome (ARDS), organ system failure index, hospital locations or type of ICU (i.e. medical vs. surgical), and indication for mechanical ventilation. Kaplan-Meier analysis was used to reveal the differences in the duration of ventilation between groups. Cox proportional-hazard regression was carried out to identify factors predicting the duration of mechanical ventilation.

For the intervention group (protocol-directed) the median duration of mechanical ventilation was 35 hours (first quartile 15 hours, third quartile 114 hours) and 44 hours (first quartile 21 hours, third quartile 209 hours) for the control groups (physician-directed). Kaplan-Meier analysis revealed that patients assigned to the intervention group had significantly shorter durations of mechanical ventilation compared with patients assigned to the control group (chi-square = 3.62, P = 0.057, log-rank test; chi-square = 5.12, P=.024, Wilcoxon test). Cox proportional-hazard regression analysis, showed, after adjustment for confounding variables, the rate of successful weaning as having a risk ratio of 1.31 (95% CI: 1.15 - 1.50; p=0.039) for the protocol directed weaning relative to the physician-directed weaning. In all the secondary outcome measures' differences between groups had p values above 0.05.

Measure of benefits used in the economic analysis
The main measure of benefit was the duration of mechanical ventilation, which was directly measured in the clinical study. By using the Kaplan Meier method, both the additional number (proportion) of successful weaning cases over time, and the duration of rate of successful weaning, were calculated to have a risk ratio of 1.31 (95% CI: 1.15 - 1.50; p=0.039) for the protocol-directed weaning relative to the physician-directed weaning.

Direct costs
Costs and resource quantities were not reported separately and in detail. It was not reported which, or whose, costs were included in the analysis. The Finance Offices of the clinical study hospitals were the source of cost data. The price data referred to the period from July 1995 to October 1995. The physician service costs were not included in the costing.

Statistical analysis of costs
Two-tailed Student t-test was carried out.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
For the intervention group (protocol-directed) the median duration of mechanical ventilation was 35 hours and 44 hours for the control group (physician-directed). The rate of successful weaning had a risk ratio of 1.31 (95% CI: 1.15 - 1.50;
p=0.039) for the protocol-directed weaning relative to the physician-directed weaning.

**Cost results**
The average total hospital costs were $27,680 (+/- 26,823) for the control group versus $27,439 (+/- 25,873) for the intervention group (p=0.932). During the 4-month study period the total hospital cost of the protocol-directed group was $42,960 less than the total hospital cost of the physician-directed group.

**Synthesis of costs and benefits**
Since the intervention was a dominated strategy, costs and benefits were not combined.

**Authors' conclusions**
Protocol-guided weaning of mechanical ventilation, as performed by nurses and respiratory therapists, was safe and led to extubation more rapidly than physician-directed weaning.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator is clear.

**Validity of estimate of measure of benefit**
The estimate of measure of benefit is likely to be internally valid, the only problem being that the members of the clinical team were not blinded to the result of the randomisation process. Also, it should be noted that the Kaplan-Meier analysis was performed by excluding all cases of death during the study period (n=82).

**Validity of estimate of costs**
Only broad resources use quantities (length of mechanical ventilation) were reported, and adequate details of costing methods used were not given. Moreover, the costs of physician services were not considered in the costing.

**Other issues**
The generalisability of the results to other settings or countries was not addressed.

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