A prospective, randomized study comparing percutaneous with surgical tracheostomy in critically ill patients


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
The use of percutaneous dilational tracheostomy (PDT), a technique first described in 1985, for the treatment of critically ill patients. The technique is generally conducted at the bedside, thus reducing the risk of transporting patients to operating room facilities.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised critically ill patients requiring elective tracheostomy, who were eligible for both PDT and SP. The inclusion criteria for the patients were as follows:

- age over 18 years;
- the necessity of mechanical ventilation for more than 1 week;
- haemodynamic stability, for example, not requiring vasopressor support;
- ventilatory support of no greater than FiO2 of 0.40 and positive end-expiratory pressure of 5 cm H2O; and
- no signs of active infection.

Patients were excluded if they had a distorted neck anatomy that precluded operating surgeon from identifying surface landmarks necessary for safely performing PDT. In addition, if they had refractory coagulopathy, or were considered to have a difficult airway for translaryngeal intubation in the event that airway control was inadvertently lost. Patients transported to the operating room for another purpose were also excluded.

Setting
The setting was a hospital. The economic study was carried out at the Barnes-Jewish Hospital, a 1,200-bed tertiary care medical centre, in the USA.

Dates to which data relate
Both the effectiveness evidence and resource use data were gathered from July 1997 to April 1999. The price year was not reported.
**Source of effectiveness data**
The effectiveness evidence was 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**
Power calculations were not performed to determine the sample size. Eighty patients admitted at the medical, surgical, and coronary intensive care units (ICUs) of the Barnes-Jewish Hospital for tracheostomy were enrolled in the study and assigned to PDT or SP. Two patients (one in the PDT group and one in the ST group) clinically deteriorated after enrolment and died before the performance of the procedures. The baseline characteristics were given in terms of demographics and clinical status.

**Study design**
The study was a randomised clinical trial carried out in a single centre. After enrolment, the patients were randomly allocated to the treatment by sealed envelopes. The length of follow-up and the method for assessing the outcomes were not reported.

**Analysis of effectiveness**
The effectiveness was analysed on an intention to treat basis. The two patients who died after randomisation were accounted for in the analysis. The primary health outcomes were procedure time, days intubated, length of stay in the ICU, hospital stay, mortality rate, and adverse events. Statistical analyses were conducted to show the comparability of the PDT and ST groups in terms of the following:

- age, 65.44 (+/- 2.82) years in the PDT group versus 61.4 (+/-2.89) years in the ST group;
- gender, 45% male in the PDT group versus 45.5% male in the ST group; and
- severity of illness (Acute Physiology and Chronic Health Evaluation II score), 16.85 (+/-0.84) in the PDT group versus 17.88 (+/- 0.92) in the ST group.

**Effectiveness results**
The procedure time was 20.1 (+/-2) minutes in the PDT group and 41.7 (+/-4) minutes in the ST group, (p<0.0001).

The number of days intubated were 12.7 (+/-1.2) in the PDT group and 15.6 (+/-1.9) in the ST group, (p=0.20).

The length of stay in the ICU was 24.5 (+/-2.5) days in the PDT group and 28.4 (+/-3.1) days in the ST group, (p=0.33).

The length of stay in the hospital was 46.7 (+/-4.2) days in the PDT group and 43.8 (+/-3.5) days in the ST group, (p=0.16).

The mortality rate was 22.5% in the PDT group and 45% in the ST group, (p=0.06).

One ST patient was reported to have had bleeding from the airway, which required removal of the tracheostomy. The bleeding was stated to have resolved spontaneously. Another ST patient also had bleeding and later died. The authors stated that this was the only death possibly attributable to the procedure.

**Clinical conclusions**
PDT and ST were similar in many respects. Only procedure time was statistically significantly lower in the PDT group relative to the ST group, although mortality rate was higher for the ST group with p=0.06.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was not carried out, due to the short time horizon of the study. The costs and the quantities were not reported separately, except that procedure time and length of stay were given. The economic analysis included the patient charges for professional services and supplies (equipment and drugs). The source of the unit cost data was not reported. The data on resource use were collected between July 1997 and April 1999. The price year was not reported.

Statistical analysis of costs
Statistical analyses were conducted for durations (see 'Effectiveness Results' section), and for supply, professional and total charges.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results section'.

Cost results
The results were presented as the mean (+/- SE). The supply charges were $688 (+/- 103) in the PDT group and $1,526 (+/- 87) in the ST group, (p<0.001). The professional charges were $880 (+/- 54) in the PDT group and $1,647 (+/- 50) in the ST group, (p<0.001).

The total charges were $1,569 (+/- 156) in the PDT group and $3,172 (+/- 114) in the ST group, (p<0.001).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Percutaneous dilational tracheostomy (PDT) was a cost-effective alternative to surgical tracheostomy (ST). Most of the cost-savings associated with PDT in the study patients resulted from it being performed in the intensive care unit (ICU), thus eliminating the need for operating room facilities and personnel.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparator was clear. ST represented the routine treatment before the introduction of PDT. You should consider whether it represents a widely used technology in your own setting.
Validity of estimate of measure of effectiveness
The internal validity of the study was likely to be high due to the randomised design, and the fact that statistical analyses of the baseline characteristics were performed. The study design appears to have been appropriate for the study question. However, the length of follow-up was not reported and the authors showed little attention to the health outcomes. In fact, mortality rate was only borderline statistically significantly lower for ST, which would lead to it being dominated by PDT, in other words lower effectiveness and higher cost.

Validity of estimate of measure of benefit
No summary benefit measure was used.

Validity of estimate of costs
Patient charges were used as a proxy for the actual treatment costs. The authors acknowledged that it represented an approximation of the real savings associated with the choice of PDT. The costs associated with respiratory therapy, patient transport, and nursing efforts were not included. It was unclear whether these omissions would have affected the authors' conclusions. Finally, the source of the cost data and the price year were not reported.

Other issues
The authors made several, appropriate comparisons of their findings with those from other studies. Their results generally confirmed previous analyses. Also, the results were not reported selectively apart from incomplete resource use and unit cost data, which might have been unavailable. The issue of generalisability of the results to other settings was not explicitly addressed and sensitivity analyses were not conducted. These limited the external validity of the study. The authors reported two main limitations of the study. First, the rate of long-term complications of PDT was not included, as it was not well defined in the literature. Second, there could have been some difficulties in patient selection, because PDT was not appropriate for patients with significant distortion of neck anatomy, maxillofacial trauma, and refractory coagulopathy. Further, the presence of a learning curve with PDT was observed in the study: four of the patients enrolled in the first half of the study, when the operator was less experienced with the technique, required conversion to ST.

Implications of the study
The authors recommend the adoption of PDT only as an elective, not an emergency, procedure. This conclusion should be viewed in the light of the caveats reported.

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