Tracheostomy in cardiosurgical patients: surgical tracheostomy versus Ciaglia and Fantoni methods


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
Minimally invasive percutaneous dilatational tracheostomy (PDT)(the technique of Ciaglia and colleagues), or translaryngeal tracheostomy (TLT)(the technique of Fantoni and Ripamonte), in patients in the cardiosurgical intensive care unit (ICU) who required elective tracheostomy because of the necessity of long-term mechanical ventilation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of cardiosurgical ICU patients who required elective tracheostomy because of the necessity of long-term mechanical ventilation.

Setting
Hospital. The economic study was carried out in Germany.

Dates to which data relate
Effectiveness and resource use data corresponded to ICU patients treated between January 1996 and July 1998. The price year was not explicitly reported.

Source of effectiveness data
The evidence for the final clinical outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken on the same patient sample as that used in the effectiveness analysis, however, it was not clear whether it was performed prospectively or retrospectively.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 120 patients (out of 2,909 who were admitted to the cardiosurgical ICU in the study hospital) who required elective tracheostomy. There were 40 patients in each study group; the mean age was 59.7 years (range: 23-75) in the OT group, 69 years (range: 39-85) in the PDT group, and 70.9 years (range: 60-79) in the TLT group.
Study design
This was a non-randomised controlled trial with concurrent controls, carried out in a single centre. The duration of the follow-up was 6 months after final decannulation. Loss to follow-up was not reported. OT was conducted in the operating room, while PDT and TLT were carried out at the patient's bedside.

Analysis of effectiveness
The principle used in the analysis of effectiveness (intention to treat or treatment completers only) was not explicitly specified. The main health outcomes were oxygenation index (partial pressure of arterial oxygen divided by fraction of inspired oxygen), complication rate, bacterial contamination of the tracheostomy site, survival rate, and operating time. The patient groups were different in terms of age, coagulation factors, and time intervals between endotracheal intubation and tracheostomy.

Effectiveness results
The effectiveness results were as follows:

The percentage of reduction in oxygenation index compared with the state before tracheostomy was 16.4% in the OT group, 10.8% in the PDT group, and 9.4% in the TLT group, significantly lower in both minimally invasive techniques versus the OT method.

The OT and PDT groups had an overall complication rate of 12.5% versus 0% in the TLT group. However, advancing the guide wire retrograde into the oropharynx was often difficult.

Bacterial contamination of the tracheostomy site was found in 35% of the OTs, with no infection observed in the PDTs or TLTs.

Survival rates were 50% for OT, 65% for PDT, and 45% for TLT (NS); no deaths could be attributed to the procedures involved.

The corresponding values in terms of procedure time were 35 minutes (range: 20-60) for OT, 10 minutes (range: 5-25) for PDT, and 10 minutes (range: 6-27) for TLT (p<0.05).

Clinical conclusions
The authors conclude that OT results in a contamination of the wound with the patient's own tracheal and bronchial bacteria. Patients who had minimally invasive tracheostomy were also checked routinely for bacterial colonisation. However, there was not a single case of wound infection or irritation of the wound tissue.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs only in terms of procedure time. Cost items were reported separately. Cost analysis covered the costs of anaesthesia, surgeon, tracheostomy set, and transportation. The perspective adopted in the cost analysis was not explicitly specified. Tracheostomy-related patient charges were used to estimate costs. The price year was not explicitly reported. It appears that no adjustments were made for inflation.

Indirect Costs
Not included.
Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total charge for the OT procedure was $698.53 versus $506.47 for PDT and $361.77 for TLT. The main differences between minimally invasive procedures and OT procedure lay in rental costs of the operating room and transportation of the patient. Equipment charges were the main cause of differences between the PDT and TLT procedures.

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

Authors' conclusions
The authors conclude that percutaneous dilatational and translaryngeal tracheostomies are safe and cost-effective procedures that can be done easily at the patient's bedside and thus are attractive alternatives to conventional surgical tracheostomy in long-term airway access in a cardiosurgical intensive care unit.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (OT) which was the conventional method used in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results can not be guaranteed given the non-randomised design of the study. The study groups were found to be different in terms of demographic and prognostic features. The patient sample appears to be representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The economic analysis may therefore be regarded as a cost-consequences analysis.

Validity of estimate of costs
Some quantities were reported separately from the costs. Insufficient details of methods of cost estimation were provided; it is not clear whether all relevant cost components (such as the costs associated with complications and bacterial contamination) were included in the analysis. Using charge data rather than true costs may have adversely affected the external validity of the cost results. Statistical analysis was not performed on all components of the resource use or cost data. The price year was not specified and no adjustment appears to have been made for inflation. The effects of different procedures on indirect costs were not discussed. The conversion rate from German currency to US dollars was not reported.
Other issues
In view of the non-randomised nature of the study design and the lack of sensitivity analysis, some degree of caution may need to be exercised in the interpretation of the study results. The issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with other studies. The study sample consisted of cardiosurgical ICU patients and the authors’ general comments appear to reflect this.

Implications of the study
It should be emphasised that an experienced physician should perform these minimally invasive procedures under bronchoscopic control. Only then can they be considered safe and unlikely to result in major complications. Conventional tracheostomy should still be considered for patients whose neck anatomy would make a minimally invasive procedure difficult, when it is impossible to identify the trachea clearly enough, or when there are large vessels at the tracheostomy site.

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