Safety of pediatric bedside tracheostomy in the intensive care unit

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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
Bedside paediatric tracheostomy (in an intensive care unit) was compared with the same procedure performed in the operating room.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised paediatric patients aged younger than 8 years with a diagnosis necessitating tracheostomy. A retrospective chart review identified the following inclusion criteria in those eligible for the bedside procedure:

- low ventilatory requirements;
- no anticipated need for additional diagnostic procedures;
- easily palpable laryngeal anatomy and the ability to be placed in flexion-extension position.

Those requiring tracheostomy on an emergent basis were excluded.

Setting
The setting was tertiary care (a referral centre in a university hospital). The economic study was carried out in the USA.

Dates to which data relate
The effectiveness evidence was collected between January 11, 1992 and November 25, 1998. The prices were calculated in 1999 US dollars.

Source of effectiveness data
The effectiveness data were derived 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. Given the study design used, it is likely that the cost data were derived retrospectively.
Study sample
There was no evidence of any sample size or power calculations. The sample was selected by medical chart review of all paediatric tracheostomies performed between 11 January 1992 and 25 November 1998. The number of, and reason for, any excluded patients was not stated. Fifty-seven patients were selected for analysis, 30 cases in the operating room group and 27 in the bedside group. The mean age was 20.5 months (range: 15 days - 8 years), with approximately 75% of each group under the age of 2 years. The most frequent diagnosis prior to tracheostomy was laryngotracheal disorder, followed by respiratory failure (bronchopulmonary dysplasia), neurological and other ‘solitary occurrence’ disorders.

Study design
This was a retrospective cohort study that was carried out in a single centre over a 6-year period.

Analysis of effectiveness
The primary outcome was the safety of the procedure. This was measured by complications occurring during the 48-hour postoperative period. It would appear that patients were not excluded on the basis of incomplete (or unclear) chart data. The patient groups were deemed comparable at baseline on demographic and diagnostic variables. It was unclear whether the groups were still comparable at analysis.

Effectiveness results
A total of five complications were reported within the 48-hour postoperative follow-up period.

Two complications (a rate of 7.4%) involving pneumothorax occurred in the bedside group.

Three complications (a rate of 10%) involving postoperative bleeding, site infection and bilateral pneumothorax occurred in the operating room group.

There was no significant difference in complication rates between the groups (chi-squared 0.12; p=0.73).

Clinical conclusions
The authors concluded that bedside paediatric tracheostomy performed in the intensive care unit was as safe as that performed in the operating room.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The authors demonstrated therapeutic equivalence (in terms of safety) and, as such, only the costs were considered in the economic analysis.

Direct costs
Hourly hospital charges relating to the operating room procedure comprised location and anaesthesia fees, along with charges (per case) for supplies or instruments. Charges related to the location included the rental of operating room space, lighting or energy, and personnel to run, stock and clean the space. For the bedside intensive care unit procedure, no additional facility or procedural charges were generally added to the basic level of care which included room charges, intravenous sedatives, pain management or paralytics. The exception was for one item of equipment and additional time from the physician who supervised the sedation and paralysation procedure. Physician fees and the costs of the tracheostomy tube were excluded from the analysis on the basis that they represented fixed costs in both bedside and operating room settings (differential costs).

It is assumed that the resource use data were obtained from the chart review, although total time for the operation was subsequently standardised across the two settings because of incomplete data. Charges were obtained from the paediatric intensive care unit, anaesthesia billing office and hospital financial accounting departments. The total charges for resource quantities (per hour or per case) were reported. The charges were calculated in 1999 dollar amounts.
Statistical analysis of costs
The data were treated deterministically.

Indirect Costs
In line with the chosen perspective, the indirect costs were not reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

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

Cost results
The total hospital charges (per hour) were $1,693 for the operating room group and $235 for the bedside group. The net saving was $1,458 (an 86% reduction).

Synthesis of costs and benefits
The charges and benefits were not combined.

Authors' conclusions
Bedside paediatric tracheostomies can be performed as safely as those carried out in the operating room, and at a reduced cost.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was justified on the basis of a need to identify the most efficient use of resources, to meet rising demands for paediatric tracheostomy. Bedside tracheostomy was being routinely performed in the authors' setting. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort design, which is associated with some threats to internal validity. For example, the comparability of study groups, and the potential effects of confounding upon the results in the absence of randomisation. Indeed, the data suggested substantial differences in median age, diagnosis of laryngotracheal disorders, and miscellaneous categories between the groups. With a mean age of 20.5 months (and 75% of each group aged under 2 years), it is unlikely that these patients were representative of the intended study population (children under 8 years), thus limiting the external generalisability of the results. Since no power calculations were reported and the sample size was small, it is not possible to ascertain whether the results obtained were due to chance.

Validity of estimate of measure of benefit
The effectiveness analysis demonstrated that the two intervention settings were equally effective in terms of the safety outcomes. No summary measure of benefit was used in the economic analysis. The comments in the 'Validity of estimate of measure of effectiveness' field (above) therefore apply.
Validity of estimate of costs
It appears that relevant charges (as a proxy for costs) relating to the hospital perspective have been included. The authors acknowledged that charges do not represent the reimbursement or true costs of the procedures and, therefore, potentially limit the external generalisability of the results. The exclusion of fixed costs (specifically, physician fees), together with the use of a standardised time estimate for the operation (in place of actual times) and no further charges (over and above standard care) added to the bedside setting, might have resulted in an overestimation in the interpretation of findings. Indeed, difficulties with incomplete data on operative times and (in 13 cases) at what stage in the patient's history a tracheostomy was decided upon present significant threats to the internal validity of this study. The resource quantities and charges were taken from the authors' setting. The absence of statistical or sensitivity analyses potentially limits the interpretation of findings. However, the reporting of the price year will aid any future reflation exercises.

Other issues
According to the authors, this was the first study to examine the efficacy and safety of bedside paediatric tracheostomy, so comparisons with other similar studies were not possible. Several limitations of the study were acknowledged. First, possible selection bias in favour of less complicated patients in the bedside group. Second, unclear or incomplete medical chart data. Third, the follow-up period was short, thus late procedural complications might have been missed. Fourth, the use of charges as a proxy for costs. Finally, the inability to determine actual operating time in each study group.

Implications of the study
The authors suggested that these preliminary findings are encouraging. They emphasised important practical considerations in terms of careful patient selection, and referred to a particular consistent technique in the safe performance of bedside tracheostomy. Future research should include larger, prospective, randomised controlled studies (incorporating rigorous cost-effectiveness analysis) that focus upon procedure-related complication rates according to strict age and weight categories of patients.

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