Validation of continuous thermodilution cardiac output in critically ill patients with analysis of systematic errors

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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
Two methods were compared for the measurement of cardiac output in the intensive care unit. These were a continuous automated thermal technique (CCO) and bolus thermodilution cardiac output (BCO).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised critically ill patients in an intensive care unit with low, normal and high cardiac output states.

Setting
The setting was secondary care. The economic study was carried out in the intensive care unit of the Warren G Magnuson Clinical Centre in the USA.

Dates to which data relate
The effectiveness and resource data were collected between December 1995 and May 1996. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data were collected prospectively, alongside the effectiveness data, using the same patient sample.

Study sample
No power calculations were reported. The study sample consisted of a prospective convenience sample of 20 patients who underwent both BCO and CCO measurements of cardiac output.

Study design
The study was a prospective non-randomised trial carried out in a single centre. The duration of follow-up was not
Analysis of effectiveness
All 20 patients were included in the final analysis. The primary outcomes were: CCO and BCO measurements (L/minute), the absolute differences between CCO and BCO, and the correlation between systematic sources of error for CCO and BCO measurements.

Effectiveness results
CCO measurements ranged from 2.5 to 14.4 L/minute, whilst BCO measurements ranged from 2.4 to 13.3 L/minute. The correlation of CCO to BCO was 0.87, (p<0.0001), with a slope of 1.06 and a mean absolute error of 0.70 L/minute.

The absolute differences between CCO and BCO increased with increasing cardiac output, whereas the percentage difference remained constant across the entire cardiac output range. Of the paired values, 77% were within 1 L/minute of one another, 96 sets were in the high range (cardiac output greater than 8 L/minute) and 20 sets were in the low range (cardiac output less than 4 L/minute).

Only weak correlations were found when comparing the potential sources of error for CCO and BCO measurements. The authors reported that the fluctuation of body temperature, defined as the change in core body temperature from the first to the second CCO recording, correlated weakly with the absolute percentage difference between the two methods. Likewise, the signal-to-noise ratio correlated weakly, but significantly, with the absolute percentage difference.

Clinical conclusions
The authors concluded that CCO was a reliable alternative to BCO for critically ill patients in low, normal, and high cardiac output states.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. The outcomes were subsequently left disaggregated, and the study should, therefore, be considered as a cost-consequence analysis.

Direct costs
The costs and quantities were reported separately. The authors included the following direct costs for the hospital in the analysis.

BCO supplies: the number of units of aqueous 5% dextrose; the number of thermodilution catheters used; and labour, which was valued as operator time.

CCO supplies: the number of CCO catheters. The number of units used was based on the total number of cardiac output determinations during the study period.

The salary figure for the operator's time was an average of the per-hour salaries of all the operators employed during the study period (December 1995 to May 1996). Discounting was not performed because of the short timeframe of the study. The price year was not reported.

Statistical analysis of costs
No statistical analysis of costs was conducted.

Indirect Costs
No indirect costs were included in the analysis.
Currency
US dollars ($). No currency conversions were reported.

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The authors reported that total cost of the CCO system during the study period was $13,853.

The total cost of the conventional BCO method during the study period was $10,690.

The CCO system was $3,163 more expensive than the BCO method during the study period.

Synthesis of costs and benefits
No synthesis of costs and benefits was carried out, and no incremental analysis was reported.

Authors' conclusions
The continuous automated thermal technique (CCO) was a reliable and cost-effective alternative to bolus thermodilution cardiac output (BCO) for critically ill patients in low, normal, and high CO states.

CRD COMMENTARY - Selection of comparators
The comparator was justified on the grounds that it represented the clinical standard for the measurement of cardiac output. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a single-centred non-randomised trial, which was inappropriate for the study question. It was not possible to validate CCO against BCO using a non-randomised trial design. The statistical power of the study was not reported.

The study sample was representative of the study population. Appropriate statistical analyses were undertaken in order to take account of potential biases.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The perspective and timeframe of the study were not reported explicitly. It was unclear if all the categories of cost relevant to the implicit study perspective adopted were included in the analysis. The exclusion of certain costs from the analysis, such as those due to adverse events, may have affected the authors' conclusions. The costs and quantities were reported separately. The authors performed a statistical analysis of outcomes but not costs. The authors did not acknowledge the uncertain reliability of their conclusions. They also did not conduct any sensitivity analysis, which may limit the interpretation of the findings of the study. Discounting was not carried out because of the short timeframe of
the study (6 months).

**Other issues**
The authors did not make appropriate comparisons of their findings with those from other studies. In addition, they did not fully address the issue of generalisability to other settings. The study enrolled critically ill patients in low, normal, and high cardiac output states, and this was reflected in the authors’ conclusions. The authors did not report any limitations to their study.

**Implications of the study**
The authors concluded that CCO was a reliable and cost-effective alternative to BCO for critically ill patients in low, normal, and high cardiac output states. Moreover, the authors also stated that continuous measurement of cardiac output may aid the early detection of significant haemodynamic changes, and provide a prompt mechanism for therapeutic interventions.

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