Cost reduction of perioperative coagulation management in cardiac surgery: value of 'bedside' thrombelastography (ROTEM)

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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
The study examined a bedside coagulation management system for the early identification and targeting of particular coagulation disorders in patients undergoing cardiac surgery. The system, ROTEM, consisted of a simple bedside-analysis utilising whole-blood viscoelastic measurement of clot-formation and clot dissolution to indicate changes in coagulation, platelet function, platelet-fibrinogen interaction and fibrinolysis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing cardiac surgery.

Setting
The setting was a hospital. The economic study was carried out in Germany.

Dates to which data relate
The period during which the effectiveness and resource use data were gathered was not reported, but all data were obtained over a 1-year time-period. The price year was not given.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that included in the analysis of effectiveness.

Study sample
A sample of 729 patients (mean age 67 +/- 9 years; 70.6% male) was identified in the pre-intervention period and a sample of 693 patients (mean age 67 +/- 8 years; 74.5% male) in the post-intervention period. All cardiosurgical patients who entered the hospital 6 months before and 6 months after the implementation of the ROTEM system were enrolled in the study. Specific inclusion and exclusion criteria were not reported. The majority of the patients (71% in the pre-intervention period and 72% in the post-intervention period) received isolated coronary artery revascularisation (CABG).

Study design
This was a retrospective comparative study with historical control that was carried out at a single institution, the Department of Cardiovascular Surgery of the Heart Center Brandenburg in Bernau/Berlin, Germany. The length of follow-up was not explicitly stated, but patients are likely to have been followed up to hospital discharge. No patient appears to have been lost to the final assessment. Blinding was not performed.

Analysis of effectiveness
The clinical end points used in the analysis were early mortality and the number of early re-sternotomies for bleeding. The EuroSCORE was also used as a measure of patient outcome, although it was not described. All patients in the initial study sample appear to have been included in the final analysis. At baseline, the study groups were comparable in terms of demographic and clinical factors.

Effectiveness results
The rate of early mortality did not change significantly over the study period. It was 5.9% in the pre-intervention period and 6.0% in the post-intervention period.

The rate of early re-sternotomies did not differ statistically between the groups. It was 6.6% in the pre-intervention period and 5.5% in the post-intervention period, (p=0.384).

The EuroSCORE exhibited a significant increase, from 5.0 (+/- 3.3) in the pre-intervention period to 5.4 (+/- 3.1) in the post-intervention period, (p=0.006). The authors stated that this might indicate an increase in morbidity.

Clinical conclusions
The effectiveness analysis showed that clinical end points were stable after the implementation of the bedside coagulation management system.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and were not combined with the costs. In effect, a cost-consequences analysis was carried out.

Direct costs
The perspective of the analysis was unclear, but it might have been that of the hospital. The categories of costs included in the study were those associated with red blood cells, platelet concentrate, fresh frozen plasma, pooled coagulation concentrate, fibrinogen, rfactor VIIa, factor XIII, aprotinin, antithrombin III and desmopressin. The cost of the ROTEM device (rental cost and cost per analysis) was included only in the post-intervention group. The unit costs were presented separately from the quantities of resources used. The source of the costs was not reported although it might have been the authors’ institution. The resource use data were derived retrospectively from the sample of patients included in the analysis of effectiveness. Discounting was not relevant as short-term costs were evaluated. The price year was not reported.

Statistical analysis of costs
Conventional statistical tests of the costs and quantities were performed.

Indirect Costs
Productivity costs were not considered.

Currency
Euros (EUR).
Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The use of ROTEM led to a statistically significant reduction in the use of platelet concentrate, pooled coagulation concentrate, rfactor VIIa, factor XIII, aprotinin, antithrombin III and desmopressin.

The cost analysis therefore showed that, over the study period, the cumulative average monthly costs fell from EUR 125,828 in the pre-intervention period to EUR 55,925 in the post-intervention period.

The costs of all blood products decreased from EUR 66,000 to EUR 45,000 (-32%). Coagulation factor average monthly costs decreased from EUR 60,000 to EUR 30,000 (-50%) yielding combined savings of 44%. In contrast, the average monthly cost for the bedside coagulation management system amounted to EUR 1,580.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was performed.

Authors’ conclusions
The implementation of a bedside coagulation management system in patients undergoing cardiac surgery led to a significant reduction in the total costs of care and to a non significant reduction in the number of re-sternotomies, without affecting early mortality.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear in that the new intervention was compared with the pattern of care delivered before its implementation. A detailed description of ROTEM was given. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The clinical data were derived from a retrospective study, which is usually associated with a limited internal validity. Further, the two groups of patients were not studied concurrently, which means that the impact of factors other than the study intervention might have had an impact on the clinical end points. The authors did not take the potential impact of time- and organisation-related confounding factors into consideration. However, the two patients groups were similar at baseline in terms of their demographic and clinical characteristics. Although a large sample of patients was considered, no formal justification for the size of the sample was provided and power calculations were not performed. Another drawback of the analysis was the fact that patients were identified at a single institution, which may not have been representative of other medical centres. This casts some doubt on the degree to which the study sample was representative of the patient population. These issues should be considered when judging the internal validity of the analysis.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of the costs was restricted to the resources strictly involved in the assessment of the coagulation status of the patients. A breakdown of the cost items, together with their unit costs, was provided. Extensive details of resource use were given, but the price year was not reported, thus limiting the possibility of replicating the analysis in other time periods. The sources of the costs were not explicitly stated. Typical statistical analyses were carried out to test the statistical significance of cost-differences. However, the impact of using alternative cost estimates was not investigated.

Other issues
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. It was noted that the cost analysis in the current study might not reflect the situation in other settings, given the differences among health care systems. Sensitivity analyses were not performed, which further limits the external validity of the study.

Implications of the study
The study results suggest that adequate differential coagulation management can be cost-effective. The authors stated that further studies, on a larger scale, should be performed to verify the potential effects on the quality of coagulation management.

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