Rationale for glycemic control in cardiac surgical patients: the Portland Diabetic Project

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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 author investigated the administration of continuous intravenous insulin (CII) in surgical patients with diabetes mellitus. This intervention was compared with subcutaneous (SC) insulin administration.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with diabetes mellitus (including non-insulin and insulin-dependent diabetes mellitus) who were undergoing open-heart surgical procedures such as coronary artery bypass grafting (CABG) and isolated valve procedures.

Setting
The study setting was tertiary care. The economic study was undertaken in Portland, USA.

Dates to which data relate
The effectiveness and resource data were derived from patients enrolled in the study between 1987 and 2004. The price year was not stated.

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

Link between effectiveness and cost data
The costing study was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Between 1987 and 2004, the Portland Diabetic Project enrolled 5,099 patients undergoing open cardiac surgery from a total population of 21,278 patients with diabetes mellitus. Between 1987 and 1991, a total of 986 perioperative patients were not permitted to receive intravenous insulin, and underwent perioperative blood glucose control with SC insulin. Between 1987 and 2004, a total of 4,041 patients received CII. The author did not provide the demographic or baseline characteristics of these two groups.
Study design
This was a prospective, non-randomised study that compared two interventions, whereby SC was administered mainly between 1987 and 1991 and CII mainly between 1992 and 2004. The study was undertaken in a single centre (the Providence St. Vincent Medical Centre in Portland, USA). The patients appear to have been followed up for 3 days after the operation, although this was not explicitly reported in the study.

Analysis of effectiveness
The analysis was conducted on the basis of treatment completers only. The primary health outcomes used were the postoperative mortality rate and the risk of postoperative deep sternal wound infection (DSWI). The author did not report whether the SC and CII groups were comparable at analysis as no details of the age, gender, or other baseline characteristics of the patients were provided. However, multivariate regression analyses were undertaken to assess whether treatment was statistically associated with outcomes after controlling for other factors.

Effectiveness results
Postoperative mortality was significantly reduced by the administration of preoperative CII in patients with diabetes who underwent CABG surgery, from 5.3% with SC insulin to 2.5% with CII, (p<0.001). The results of the multivariate analysis also showed that mortality in patients after CABG was significantly reduced by treatment with CII (odds ratio 0.4, p=0.001).

The author also reported that mortality was significantly lower in CII patients after cardiac surgery of any type.

The incidence of DSWI was 2.0% with SC insulin and 0.7% with CII, (p=0.01).

When controlling for other factors, the CII protocol was associated with a relative risk reduction of 66%, (p=0.005).

Clinical conclusions
The CII protocol was more effective than SC insulin administration in reducing postoperative mortality and DSWI.

Measure of benefits used in the economic analysis
The author did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences analysis.

Direct costs
The costs included in the analysis were for intravenous insulin (insulin, intravenous bags, tubing and pumps), SC insulin (insulin, syringes and strings), nursing, pharmacy time and hospital length of stay. Discounting was not relevant, as the costs were incurred during a short time, and was appropriately not performed. The study reported the average costs. The price year was not reported.

Statistical analysis of costs
The costs were treated as point estimates (i.e. the data were deterministic).

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The cost of administering 3 days of SC insulin therapy was $32 per patient, compared with $138 for CII patients.

The savings associated with reductions in DSWI rates when administering CII as opposed to SC insulin were $2,631 per patient.

The savings associated with reductions in length of stay when administering CII as opposed to SC insulin were $4,500 per patient.

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

Authors' conclusions
The continuous intravenous insulin (CII) protocol was more expensive to administer than subcutaneous (SC) insulin. However, the author also concluded that, when cost-savings associated with reduced rates of serious infection and reduced hospital stay were considered, CII resulted in total savings of over $6,500 per patient.

CRD COMMENTARY - Selection of comparators
SC insulin administration was used as the comparator as it used to represent current practice in the author's settings. You should decide if this intervention represents current practice in your own setting.

Validity of estimate of measure of effectiveness
This was a prospective, non-randomised study in which the two interventions being compared were administered over two time periods. A randomised controlled trial would have been a better study design in terms of comparing the efficacy of CII over SC insulin administration, as the design used in this study may have led to bias or confounding. For example, factors external to the study, such as improving medical standards, hospital administration and hygiene over time, could have biased the results in favour of CII administration. Further, the author did not provide details of the baseline characteristics of each patient group, making it difficult to judge whether the groups were comparable at analysis. However, the author did report that multivariate analyses were undertaken in order to control for other clinical and non-clinical factors on outcomes.

Validity of estimate of measure of benefit
The author did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences analysis. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The author did not report the perspective adopted in the economic analysis, but it appears to have been that of the health care provider. If this was indeed the perspective, then all appropriate cost categories appear to have been included and no relevant cost appear to have been omitted. The costs and resource use were reported separately, which will increase the generalisability and transferability of the author's results. Resource use was derived directly from the
effectiveness study. The author reported incremental resource use (e.g. additional hospital stay). However, no statistical analyses were reported, which makes it difficult to assess whether differences in resource use were statistically significant. The unit costs appear to have been obtained from the literature. As with resource use, differences in costs were not analysed to determine whether they were statistically significant, and no sensitivity analyses were performed. Discounting was not relevant, as the costs were incurred during a short time, and was appropriately not performed. The price year was not reported, which will limit any future inflation exercises.

**Other issues**
Comparisons with other studies and the issue of generalisability to other settings were not addressed. The results do not appear to have been reported selectively. However, it would have been more informative had the results of statistical or sensitivity analyses been reported to show that differences in resource use and costs were statistically significant and robust. The author reported no further limitations to his study.

**Implications of the study**
The findings of this study suggest that the nationwide adoption of the Portland CII protocol would result in annual expected savings of 3,825 external infections, 3,545 lives, and 278,000 hospital days, all of which would save the US health care system $470 million per year.

**Source of funding**
None stated.

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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Acute Kidney Injury /chemically induced /metabolism; Adenosine Triphosphate /metabolism; Anemia, Iron-Deficiency /drug therapy /etiology /metabolism; Animals; Endothelial Cells /drug effects /metabolism; Ferric Compounds /toxicity; Glucaric Acid; Hematinics /administration & dosage /toxicity; Humans; Inflammation /chemically induced