Quality care outcomes in cardiac surgery: the role of evidence-based practice

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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
This study considered the treatment of cardiac surgical patients with clopidogrel prior to coronary artery bypass graft (CABG) surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing non emergency CABG surgery who had not undergone cardiac surgery before. The study population excluded patients who had been exposed to coumadin or intravenous antiplatelet agents preoperatively, or who underwent an additional procedure (e.g. valve repair or replacement or aneurysctomy) at the same time as the CABG.

Setting
The setting was secondary care. The economic study was undertaken in the California Pacific Medical Center, San Francisco, USA.

Dates to which data relate
The clinical effectiveness and resource use data referred to the period between January 1999 and March 2000. 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 resource use data were collected retrospectively from a sub-sample of the main patient sample that provided the clinical effectiveness data (those with a Diagnosis Related Group 107).

Study sample
The patients were selected from a clinical database. All of the patients that met the inclusion criteria were included in the study. An initial look at the clinical database identified 325 potential study participants. After the exclusion of patients who underwent concurrent procedures, had preoperative exposure to coumadin or intravenous antiplatelet agents, or were emergent cases, the study sample consisted of 165 patients. Of these, 48 patients (mean age 67.4 years;
75% males) had been exposed to clopidogrel in the 7 days prior to surgery and 117 (mean age 66.8 years; 73.5% males) had not. No sample size or power calculations were reported.

**Study design**
The study was of a single-centre retrospective cohort design. The patients were followed up for the duration of their hospital stay. The nature of the study meant that there was no loss to follow-up and it was not possible to blind to treatment group.

**Analysis of effectiveness**
The following health outcomes were assessed:

- chest tube output;
- the number of patients who had transfused blood products;
- blood use;
- reoperation for bleeding;
- non surgical bleeding;
- severe low cardiac output;
- atrial fibrillation;
- the length of time intubated;
- the length of stay (LOS) in intensive care; and
- the postoperative LOS.

The two patient groups were comparable in terms of age, gender, body surface area, haematocrit, creatinine and whether or not they had congestive heart failure. Patients who had been exposed to clopidogrel in the 7 days prior to surgery were more likely to have angina than those not exposed (56.2% versus 40.2%; p=0.058), and to have been operated on urgently (within 24 hours) (33.3% versus 14.5%; p=0.0095). No adjustment for these differences appears to have been made in the analysis. In addition, patients exposed to clopidogrel were significantly more likely to have preoperative aspirin exposure than patients not exposed to clopidogrel (87.5% versus 43%; p<0.0001). There was no significant difference between control patients with and without recent aspirin exposure.

**Effectiveness results**
The following health outcomes were statistically different between the two patient groups:

- the mean chest tube output at 8 hours, 864 mL in the clopidogrel group versus 492 mL in the control group, (p=0.001);
- the mean chest tube output at 24 hours, 1,384 mL in the clopidogrel group versus 801 mL in the control group, (p=0.001);
- the percentage of patients transfused any blood product, 89.6% of the clopidogrel group versus 53.8% of the control group, (p<0.0001);
- the percentage of patients transfused red blood cells, 85.4% of the clopidogrel group versus 50.4% of the control group, (p<0.0001);
- the percentage of patients transfused platelets, 50% of the clopidogrel group versus 14.5% of the control group,
(p<0.0001);

the mean number of fresh frozen plasma units transfused, 0.79 in the clopidogrel group versus 0.20 in the control group, (p=0.001);

the mean number of single-donor platelet units transfused, 0.94 in the clopidogrel group versus 0.19 in the control group, (p=0.001);

the mean number of red blood cell units transfused, 2.79 in the clopidogrel group versus 1.42 in the control group, (p=0.001);

the mean time intubated, 15.5 hours in the clopidogrel group versus 8.3 hours in the control group, (p=0.006);

the percentage of patients with a postoperative stay of 5 days or less, 25% in the clopidogrel group versus 55.1% in the control group, (p=0.0005); and

reoperation rates for bleeding, which were 10-fold higher in the clopidogrel group (8.3%) than in the control group (0.85%), (p=0.027).

Although patients in the clopidogrel group experienced a trend toward increased atrial fibrillation, this did not reach statistical significance.

**Clinical conclusions**
The author concluded that improvements in blood use and clinical outcomes were documented within 3 months after the evidence-based clinical practice guideline for Clopidogrel Exposure in Cardiac Surgery Patients had been implemented.

**Measure of benefits used in the economic analysis**
No measure of benefits was used in the economic analysis. In effect, the author carried out a cost-consequences analysis.

**Direct costs**
Hospital costs were included in this study. The cost data represented actual data and were collected from the hospital's central costing database. The cost components combined to derive a total cost were the laboratory/blood, critical care, medical/surgical, respiratory therapy/physiotherapy, supplies, pharmacy, operating room and anaesthesia, physical therapy, radiology and other costs. The resources used and the unit costs were not reported separately. The cost data referred to the period between January 1999 and 2000, but no price year was reported. Discounting was not undertaken as the costs were incurred during less than two years.

**Statistical analysis of costs**
The difference between the costs was tested using the t-test. The mean total costs were reported.

**Indirect Costs**
No indirect costs were included in the study.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was undertaken.

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

**Cost results**
The mean total costs were $20,304 for the group exposed to clopidogrel in the 7 days prior to surgery and $17,624 for those in the comparator group, (p=0.1936). The only cost component that was statistically different between the two groups was laboratory and blood costs, $1,699 for the clopidogrel group versus $1,018 for the comparator group, (p=0.0135).

The acute care costs averaged $2,680 more for patients who received clopidogrel, (p=0.1936).

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

**Authors' conclusions**
Exposure to clopidogrel prior to coronary artery bypass graft (CABG) surgery had a negative affect on postoperative bleeding and length of stay (LOS). Reduced use of clopidogrel prior to surgery might be cost-saving, given the intensity of resource use with acute haemorrhage and the expense of blood products.

**CRD COMMENTARY - Selection of comparators**
The author did not provide an explicit justification for her choice of the comparator. However, it did represent a do-nothing approach. You should consider how this relates to current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The measure of the clinical implications of using clopidogrel prior to CABG surgery was taken from a retrospective cohort study. This was appropriate to the study question, although it provides a potentially biased assessment. The retrospective nature of the study meant that patient allocation to the clopidogrel group or the non clopidogrel group will have been subject to a number of factors that can no longer be assessed. The two patient groups were shown to not be comparable in terms of the prevalence of angina and whether or not they were operated on urgently. The analysis did not adjust for these factors, thus it was not possible to assess their impact on the study findings. A randomised controlled trial would have provided a more robust assessment of the true impact of clopidogrel on postoperative bleeding and recovery. The author did not compare the characteristics of her study sample with the characteristics of the study population. This means that it was not possible to assess the extent to which the study sample represents the study population.

**Validity of estimate of measure of benefit**
No measure of benefit was used in the economic evaluation since, in effect, a cost-consequences analysis was undertaken.

**Validity of estimate of costs**
The author did not report the economic perspective used, but it appears to have been that of a hospital. All appropriate costs appear to have been included in the analysis. Resource use and the unit costs were not reported separately. This, along with that fact that costs were taken from the author's own setting rather than a nationally applicable cost framework, reduces the generalisability of the study findings. The lack of a clear price year further limits the study and prevents any future reflation exercises. No statistical analysis of the resource use data was performed, although the cost
data were tested for statistically significant differences using an appropriate test. The costs were not discounted, which was appropriate as they were incurred during less than two years.

**Other issues**
The author presented her results comprehensively. Her conclusions accurately represented the data presented, and the uncertainty over the conclusion that reducing the use of clopidogrel preoperatively may be cost-saving is acknowledged. The author did not compare her findings with those of other studies, as the only other similar study was published by colleagues at the same institution.

**Implications of the study**
The author did not make any specific recommendations for further research or changes in clinical practice.

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None stated.

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