FIASCO II failure to achieve a satisfactory cardiac outcome study: the elimination of system errors

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Abstract

OBJECTIVES: Death in low-risk cardiac surgical patients provides a simple and accessible method by which modifiable causes of death can be identified. In the first FIASCO study published in 2009, local potentially modifiable causes of preventable death in low-risk patients with a logistic EuroSCORE of 0–2 undergoing cardiac surgery were inadequate myocardial protection and lack of clarity in the chain of responsibility. As a result, myocardial protection was improved, and a formalized system introduced to ensure clarity of the chain of responsibility in the care of all cardiac surgical patients. The purpose of the current study was to re-audit outcomes in low-risk patients to see if improvements have been achieved.

METHODS: Patients with a logistic EuroSCORE of 0–2 who had cardiac surgery from January 2006 to August 2012 were included. Data were prospectively collected and retrospectively analysed. The case notes of patients who died in hospital were subject to internal and external review and classified according to preventability.

RESULTS: Two thousand five hundred and forty-nine patients with a logistic EuroSCORE of 0–2 underwent cardiac surgery during the study period. Seven deaths occurred in truly low-risk patients, giving a mortality of 0.27%. Of the seven, three were considered preventable and four non-preventable. Mortality was marginally lower than in our previous study (0.37%), and no death occurred as a result of inadequate myocardial protection or communication failures.

CONCLUSION: We postulate that the regular study of such events in all institutions may unmask systemic errors that can be remedied to prevent or reduce future occurrences. We encourage all units to use this methodology to detect any similarly modifiable factors in their practice.

Keywords: Statistics • Risk analysis/modelling • Perioperative care • Surgical complications

INTRODUCTION

There is much reporting on the mortality of high-risk cardiac surgery, and much less emphasis on low-risk outcomes. Deaths do, however, occur in very low-risk patients, albeit very rarely. The identification and correction of systemic problems in a cardiac surgical unit can be facilitated by examining such events, as these are more likely to occur because of failure in achieving a satisfactory cardiac outcome (FIASCO) than because of comorbidity or other confounding variables.

In 2009, we published the results of the first FIASCO study [1] and identified local potentially modifiable causes of preventable death, including inadequate myocardial protection and the lack of clarity in the chain of command regarding the senior surgeon responsible for the patient. Janiec et al. [2] applied our methodology in Stockholm and also confirmed that suboptimal communication between senior and junior doctors led to potentially preventable deaths in low-risk cardiac surgery in their institution. In our unit, the FIASCO study resulted in the enhancement of myocardial protection strategies and a formalized system to ensure clarity of the chain of responsibility in the care of all cardiac surgical patients. We have therefore re-audited outcomes in low-risk patients to see if improvements have been achieved.

MATERIALS AND METHODS

Papworth Hospital is the largest-volume cardiac surgical centre in the United Kingdom, currently performing more than 2000 standard major cardiac procedures per year. Standard practice includes intraoperative transoesophageal echocardiography (TOE) in valve surgery and in selected coronary surgery cases. Measurements of graft flow and TOE are not routinely used for straightforward coronary artery bypass grafting (CABG).
The study followed the methods established in the original FIASCO article [1]. Briefly, all consecutive patients with a logistic EuroSCORE [3] of 0–2 who underwent cardiac surgery between January 2006 and August 2012 were retrospectively analysed. Information was obtained from the operating department computer database into which all data on procedures, risk stratification and outcomes are prospectively entered.

All patients with a logistic EuroSCORE of 0–2 who died after cardiac surgery were identified. We studied the notes for each identified patient, including post-mortem records where available, in order to classify the deaths. To eliminate bias, expert surgeons (two internal and one external) also reviewed the cases. These were the same reviewers for the original FIASCO study [1] and had considerable experience providing expert reviews for the National Confidential Enquiry into Postoperative Deaths (NCEPOD) since 1988.

Case review was used first to exclude any patients who had serious risk factors unrecognized by the risk model (not truly low risk). The remaining deaths were then classified into three categories:

(1) Preventable (system error)
(2) Preventable (technical error)
(3) Non-preventable

Preventable technical errors were included regardless of the professional responsible.

RESULTS

During the study period from January 2006 to August 2012, 12,966 patients underwent cardiac surgery at Papworth hospital including elective, urgent and emergency cases. Among them, there were 2,549 patients with a logistic EuroSCORE of 0–2, of whom 8 died in hospital. One patient had a pericardectomy for pericardial constriction due to malignant mesothelioma. EuroSCORE is not a suitable risk model to predict the outcome in such a patient, and this case was therefore excluded. Seven deaths occurred in truly low-risk cardiac surgery patients, giving an overall mortality of 0.27%. Of the seven deaths, three were considered to be preventable and four were considered non-preventable. The results are summarized in Table 1.

There was complete agreement among the internal and external reviewers regarding the cause and preventability of death. The primary causes of the three preventable deaths were haemorrhage, perioperative myocardial infarction and multi-organ failure. All the preventable causes of death were due to technical errors that first manifested with excessive bleeding.

The first patient had septal myomectomy by a senior surgeon with extensive experience in this procedure. During the operation, the myomectomy incision spontaneously extended into the anterolateral wall of the left ventricle with free wall rupture that was refractory to multiple repair attempts, leading to death on the operating table.

The second patient was re-explored for excessive bleeding following CABG, and had repairs to coronary anastomoses. This patient had bilateral mammary arteries used for bypass grafting. On re-exploration, the right internal mammary artery graft to the obtuse marginal was bleeding and required additional sutures, followed by a further vein graft to the same vessel distally. The patient eventually developed severe myocardial dysfunction and had a biventricular assist device followed by continued deterioration and death.

The third patient was also re-explored after CABG for bleeding from multiple sites including a proximal anastomosis. The proximal anastomosis of the right coronary graft was bleeding, had multiple additional sutures and was subsequently ligated. The patient died a few days later from multiorgan failure.

In the four non-preventable deaths, the primary causes of death were septicaemia with multiorgan failure, bowel ischaemia with multiorgan failure, perioperative myocardial infarction and bronchopneumonia.

All of these patients received adequate, multidose and frequent administration of cold blood cardioplegia. There were no suggestions of technical anastomotic problem either at surgery or at post-mortem examination.

No death occurred due to inadequate myocardial protection. No death occurred due to communication failure or due to lack of clarity in the chain of responsibility.

DISCUSSION

The operative mortality rates for cardiac surgery continue to fall despite an older and sicker patient population, indicating better quality of in-hospital care. Deaths in low-risk cardiac surgery are now very rare, and at 0.27% in the present study, the risk of death is <1 in 300. Nevertheless, such deaths do occur. When they do, there are three possible reasons. The first is that the

<p>| Table 1: Causes of death in low-risk patients undergoing cardiac surgery between January 2006 and August 2012 at Papworth Hospital, UK |
|-----------------|------------|-----------------|------------------|------------------|</p>
<table>
<thead>
<tr>
<th>Operation</th>
<th>Age (years)</th>
<th>Cause of death</th>
<th>Preventable</th>
<th>Problem identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Septal myomectomy</td>
<td>69</td>
<td>Haemorrhage</td>
<td>YES technical</td>
<td>LV rupture due to extension of septal dissection</td>
</tr>
<tr>
<td>2 CABG</td>
<td>48</td>
<td>Myocardial infarction</td>
<td>YES technical</td>
<td>Bleeding from the distal anastomosis to the obtuse marginal artery</td>
</tr>
<tr>
<td>3 CABG</td>
<td>65</td>
<td>Multiorgan failure</td>
<td>YES technical</td>
<td>Bleeding from the top end of the right coronary artery graft</td>
</tr>
<tr>
<td>4 CABG</td>
<td>63</td>
<td>Perioperative myocardial infarction</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>5 CABG</td>
<td>59</td>
<td>Septicaemia and multiorgan failure</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>6 CABG</td>
<td>60</td>
<td>Small bowel ischaemia and multiorgan failure</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>7 CABG</td>
<td>71</td>
<td>Bronchopneumonia</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>8 Pericardiectomy</td>
<td>44</td>
<td>Pericardial malignant mesothelioma</td>
<td>NO</td>
<td>Excluded (not truly low risk)</td>
</tr>
</tbody>
</table>
patient is not truly low risk, in that there may be undiagnosed comorbidity or a serious condition that is not recognized or appropriately weighted in the risk model. In the first FIASCO study, there were no such cases, but there was one in this study. The second reason is that an unforeseen event may happen, such as a stroke or pneumonia, which could not have been predicted or prevented and which leads to death despite corrective effort. Such deaths are presumed to be non-preventable. The third is that a technical or clinical error may have led to the death, most often by FIASCO. Having identified such errors in our institution in the first FIASCO study and introduced measures to correct them, we embarked on FIASCO II to see if our measures have been effective.

In the first FIASCO study, the two predominant causes of preventable death were inadequate myocardial protection and communication failures. It is gratifying to note that these were absent from the current series.

There are several risk models for predicting mortality after cardiac surgery ranging from simple additive models such as Parsonnet [4] and EuroSCORE [5] to complex Bayesian and logistic models, such as logistic EuroSCORE [3], the Society of Thoracic Surgeons risk models [6–8] and EuroSCORE II [9]. Artificial neural network models have also been developed [10]. All such models provide a standard, corrected for case mix, against which the performance of hospitals, units and surgeons can be measured. No risk model is perfect, and none can take account of all the potential risk factors, but all can serve to identify a low-risk population for the purposes of studies such as this. Outcomes of surgery in very high-risk patients have been addressed [11, 12], but little is known about the causes of death after low-risk cardiac surgery. Apart from our own previous study, only one study from Sweden [2] examined the causes of death in this low-risk group. The findings of different studies looking at death of low-risk patients undergoing cardiac surgery are summarized in Table 2.

In our previous study, we had shown that about one-third of deaths in the low-risk group were potentially preventable [1]. These were subdivided into technical errors and system errors. Surgeons are human, and occasionally technical errors will occur despite all attempts to prevent them. In fact, to eliminate technical errors in their entirety may not be an achievable aim. It should be possible to eliminate system errors, however, by making appropriate alterations to the protocols and methodology used.

In the previous study, inadequate myocardial protection strategies and lack of clarity in the chain of responsibility stood out as potentially modifiable causes of death. As a result of the first FIASCO study, surgeons who in the past had used a single dose of crystalloid cardioplegia regardless of the duration of ischaemic time have altered their practice to use repeated doses of cold blood cardioplegia. In the previous study, severe perioperative myocardial infarctions were ascribed to poor myocardial protection only when they occurred for no technical reasons, when the cross-clamp times were prolonged, and the only form of myocardial protection was a single dose of 500 ml of crystalloid antegrade cardioplegia.

A rule has been introduced mandating a requirement for clarity regarding the identity of the senior surgeon responsible for a patient, especially when more than one senior surgeon is involved in a patient’s care, and for that identity to be communicated and documented so that junior staff and nurses are all aware of which surgeon is finally responsible. Having introduced the modifications required to prevent such alterable causes, we are gratified to see that they appear to have been completely abolished as causes of death in this follow-up study.

Previous studies [13] have shown resternotomy for bleeding to be associated with increased mortality and morbidity. In our series, all of the preventable deaths happened due to either intraoperative or postoperative bleeding or as a consequence of that. Postoperative bleeding continues to be a challenge in cardiac surgery. The incidence of postoperative bleeding is regularly audited in our institution, with a significant reduction in the rate of resternotomy for bleeding. However, there is still room for improvement.

Our hypothesis is that examining deaths in low-risk groups gives an exclusive insight into any system weaknesses. We have shown that by identifying system weaknesses in our previous study, we have been successful in eliminating them in the current series. Further information about system errors can be obtained from near-miss analysis, but this is not the subject of this article. The systematic review of low-risk death sets the platform for looking into near-miss events in cardiac surgery, which will reduce mortality and morbidity further.

Heart surgery is entering its sixth decade and continues to be the most extensively studied and scrutinized therapeutic modality in the history of medicine. Mortality has dropped significantly over the last 10 years. To reduce it even further, we believe that it is essential to search actively for modifiable causes and to modify them. Death in low-risk cardiac surgical patients provides a simple and accessible means by which its modifiable causes can be identified. We postulate that the regular study of such events in any institution may unmask systemic errors that can be remedied to prevent or reduce future occurrences. Such errors are likely to vary between institutions, and we encourage all units to use the methodology of this study to detect any similarly modifiable factors in their practice.

### Table 2: Studies looking at death of low-risk patients undergoing cardiac surgery

<table>
<thead>
<tr>
<th>Year of publication</th>
<th>Period of study</th>
<th>Number of patients</th>
<th>Number of deaths (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current series</td>
<td>2006–2012</td>
<td>2549</td>
<td>7 (0.27)</td>
</tr>
</tbody>
</table>

### LIMITATIONS

This is a retrospective study of prospectively collected data. The study population is necessarily small, as mortality in low-risk cardiac surgery is very rare. The classification of the causes of death may be affected by a degree of subjectivity. As this is a follow-up study, we did not change the classification system and used the same reviewers. The reviewers were not blinded to the identity of the operators.

**Conflict of interest:** none declared.
REFERENCES


