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Assessing the impact of organisational factors on patient outcome: Is a statistical approach appropriate?

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ABSTRACT

Does the manager of a department store need to carry out a case control study to establish that staff should be friendly, alert, supportive, well turned out and punctual? Some qualities of how organisations work transcend the realm of the purely scientific, particularly in relation to the many complex interactions between human and behavioural factors and technology.

The same issue has been considered when assessing the impact of organisational factors on outcome following a first time isolated coronary artery bypass graft (CABG). Patients reported as having died following a first time isolated CABG between 1st April 2004 and 31st March 2007 were matched with a sample of patients reported to have survived to discharge from hospital. No association was found between in-hospital death and whether the anaesthetist present at induction was a specialist in cardiothoracic anaesthesia, nor between in-hospital death and whether a written protocol for pre-operative investigations was followed. We discuss the limitations of formal statistical methods when applied to data representing patients cared for in a complex, dynamic and adaptive environment.

INTRODUCTION

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reviews the quality of care received by patients, in hospital. The methods used are founded on a detailed peer review of the circumstances surrounding cases where there has been a poor outcome to identify any common themes or patterns of failure where remediable actions can be taken. Recommendations are then made for changes in delivery of care.

There have been repeated questions about the 'statistical significance' of using peer review to assess the quality of care received by in-hospital patients. This has been a consideration since the earliest days of NCEPOD when it was recorded that over and over again the sickest emergency patients were being operated on by tired, on-call, often inexperienced surgical and anaesthetic teams, late into the night, when back up was at its least.[1] The recommendation that there should be consultant teams with a dedicated theatre available to do these operations in the working day (when appropriate) seemed like "the right thing to do". There was no control group or statistical proof but the story only had to be told and the answer appeared evident.

However, it was of interest to know whether case control methods could be used to supplement the peer-review data. To do this NCEPOD has used part of its data collection for a study into patients who died following an isolated first time coronary artery bypass graft[2] to see whether the application of such statistical techniques could be used to answer specific qualitative questions.

A considerable amount of research has been conducted to quantify the risk of peri-operative death attributable to patient -specific pre-operative factors in those having surgery for acquired heart disease. In addition, much attention has been given to the role of the individual surgeon in determining outcome and to identifying surgeons whose outcomes are less good than their colleagues. However, it is arguable that there are other components more amenable to change. These include: the organisation of care for cardiac surgery patients, the marshalling of the resources available, communication between the different clinical teams involved, the decision process preceding an operation, non-technical aspects of the operation itself and the care delivered to the patient before and after surgery.

In this paper we describe the case control analyses related to the following research questions:

- is in-hospital death associated with whether there was present at induction a consultant anaesthetist who devoted more than 3 clinical sessions "or programmed activities" per week to the practice of cardiothoracic anaesthesia?
- is in-hospital death associated with failure to follow a written protocol for pre-operative investigations?

METHODS

A consensus exercise was conducted with an expert group that identified a priority-ordered list of thirteen questions for the study to address [3].

At the outset it was recognised that it would not be possible to pursue case control analyses related to all the questions. Therefore half of the data collected over the first year of the study were used to select and refine the two questions given in the introduction of this paper.

Case identification

All sites in the UK that perform cardiothoracic surgery were asked to report all in-hospital deaths following a first time isolated CABG over the three year period, 1st April 2004 – 31st March 2007.

Identifying surviving controls matched for clinical risk factors

For each death reported to NCEPOD, it was our intention to identify a patient operated on during the same period who survived to be discharged from hospital and was matched to the patient that died in terms of patient-specific pre-operative factors known to be associated with the risk of peri-operative death. Patients were categorised according to the following criteria: age (<56 and then in ten year bands of increasing age), sex, left-ventricular function (classified as good/moderate **or** poor according to accepted definitions[4]), diabetic status (non-diabetic **or** diabetic) and priority of operation (classified as elective **or** urgent/emergency/salvage according to accepted definitions[4]).

After the end of each of the three years comprising the study period, the UK's Central Cardiac Audit Database (CCAD) provided NCEPOD with data concerning all patients who survived to discharge from hospital following a first time isolated coronary artery bypass graft performed during that year. The data provided by CCAD included the date of the procedure, the patient's date of birth and initials, the identity of the surgical unit and the data required for matching purposes as given above. The same data were requested directly from units that had not submitted data to CCAD.

Given the differing process by which cases and controls were identified, there was scope for there to be data available from a site concerning the deaths over a given period but not concerning the survivors at the same site, or vice-versa. To avoid potential bias due to this, data were only included in the matching process if they pertained to a period during which both case and control data were available from that site.

For each death identified to NCEPOD, the data pertaining to the matching criteria given above were extracted from a questionnaire completed by the surgeon or anaesthetist. In instances where ambiguity concerning the classification of a patient according to the matching scheme could not be resolved by reference to the case notes, the case was excluded from the case control analyses.

Computer software was written to identify all cases and controls. If a match could not be found for a case, then that case was excluded from the analyses. Hospitals were then notified of control patients included.

Analysis

For each case and each control included in the analysis, it was determined from the anaesthetic form whether the most senior anaesthetist present at induction was a consultant who devoted more than 3 clinical sessions "or programmed activities" per week to the practice of cardiothoracic anaesthesia. Each matched pair was categorised by whether just the case, just the control, both or neither met the criterion. We then calculated the odds-ratio for death associated with not meeting this criterion.

An identical analysis was carried out in relation to the second study question with the criterion of interest being the following of a written protocol for pre-operative investigations. To account for the effect of conducting two analyses with the same data, the analyses were "one-tailed" in that only the lower limits of the 95% confidence intervals were calculated as part of the primary analysis.

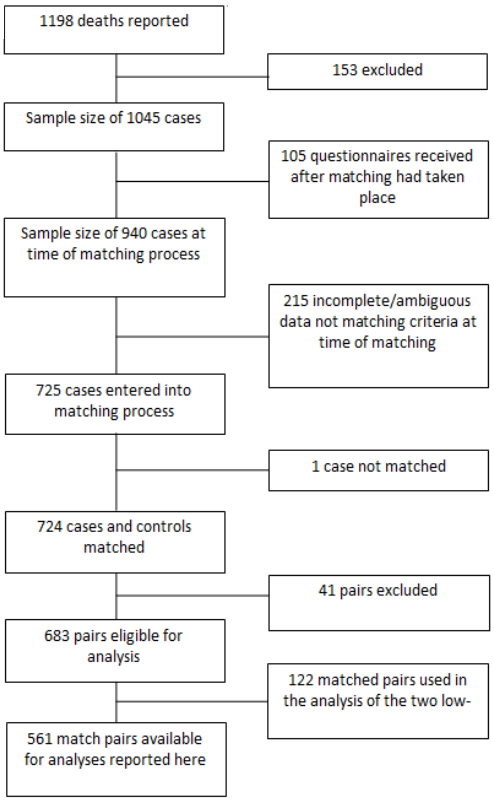
Errors in the matching process

The above analyses were conducted on an "intention to match" basis. The identification of control patients was, of necessity, conducted in the absence of case notes or information from the relevant surgeon and anaesthetist. For this reason, we counted the number of instances where it became apparent, on receipt of clinical information, that the data used in the matching process was erroneous to the extent that the match of control to case was incorrect.

RESULTS

Figure 1 shows the number of deaths reported, the number of patients excluded and the number of matched case control pairs available for analysis.

Figure 1. Number of included patients (cases and controls)



Over the three year period 724 patients who died following first time isolated CABG were matched to a patient who survived to discharge.

In 112 instances, a discrepancy between the electronic data provided by the units for use by NCEPOD in the matching process and data contained within the case notes and questionnaires later submitted to NCEPOD rendered the match of case to control suspect.

There were 131 such discrepancies across these 112 pairs, 46 concerning priority, 37 diabetic status, 34 left ventricular function, eight age, and six concerning sex. That is to say that in six instances, the sex recorded in the electronic data used to identify control patients was different from the sex recorded in the case notes and/or questionnaires subsequently inspected by NCEPOD staff.

In 294 pairs the criterion related to the anaesthetist present at induction was met for both case and control. In 45 pairs the criterion was not met for the patient that died but was met for the control. The reverse was found in 43 pairs giving an odds-ratio of 45/43 = 1.05 (lower 95% CL 0.7). In 15 pairs the criterion was met for neither, with 164 pairs excluded because of insufficient data.

In 260 pairs the criterion related to the protocol for re-operative investigations was met for both case and control. In 36 pairs the criterion was not met for the patient that died but was met for the control. The reverse was found in 45 pairs giving an odds-ratio of 36/45 = 0.8 (lower 95% CL 0.5). In 5 pairs the criterion was met for neither, with 215 pairs excluded because of insufficient data.

DISCUSSION

A major strength of this study is that every unit performing this surgery, both in the state and private sector, was involved in the study, which gives us confidence that our data are representative of UK practice. For the study as a whole[2] we received data for over 85% of patients.

It was of concern that there were many discrepancies between the patient specific data provided to NCEPOD which were used to identify cases and controls in the first instance and those data later extracted by NCEPOD from the case notes and the questionnaires supplied by surgeons and anaesthetists. Many databases are used to audit and monitor patient activity; both locally and nationally. The resulting output can only be as good as the data input. For example data supplied to CCAD are used in national audit to calculate risk adjusted mortality rates for units and for individual surgeons. Recent work[5] demonstrates that even small miscoding rates with respect to outcome can have serious consequences for the measurement of mortality rates in low risk procedures. The discrepancies in data between different sources undoubtedly undermined the validity of the matching process employed in the case control analysis.

Our analysis did not show an association between in-hospital death following first time isolated coronary artery surgery and the number of sessions provided by the most senior anaesthetist present at induction; nor did our analysis show an association between the failure to follow a written protocol for pre-operative investigations and in-hospital death following first time isolated coronary artery surgery.

A consultant anaesthetist who devotes more than three sessions per week to cardiothoracic anaesthesia was present at induction in 85% of patients in this study, for whom data were available. The lack of an association between this provision and outcome cannot be and should not be interpreted as suggesting the involvement of specialist cardiothoracic anaesthetists in the care of these patients is in any way redundant.

This single yes/no criterion of the presence of a specialist anaesthetist at one point in time fails to capture anything else of the constantly moving dynamic in the care of patients. Observers of cardiac surgery (and other health care interventions) note the interaction of team skills, checks and balances, and the sheer complexity and subtlety of a lot of what is going on, often unspoken and unrecorded. Responsible and r esponsive clinical practice includes many subtle judgements. The typical cardiac surgical unit has a complex interplay between surgeons, anaesthetists, perfusionists, nurses, and operating department technical staff who are “watching each other’s backs” in the interests of the patient.

With respect to the lack of association between the failure to follow a written protocol for pre-operative investigations and death, it may be that overall standards of following implicit protocols are so high that the method adopted was simply too insensitive to detect differences attributable to protocol provision and adherence.

This confirms our concerns regarding the use of case control analysis, or indeed any similar formal inductive scientific method, for identifying remediable deficiencies in health care processes and organisation. Certainly, such scientific methods have a pivotal role in evaluating purely technical issues such as which of two medications is more effective, but is it sensible to adopt such a purist view when dealing with complex health care processes and procedures?

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