

Postoperative serious adverse events in a teaching hospital: a prospective study

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ADVERSE EVENTS (AEs) appear to be common among patients admitted to hospital and to have serious repercussions.¹ A review by Wilson et al² of 14 000 randomly selected medical records of Australian hospital patients revealed that 16.6% of admitted patients experienced an AE that contributed to longer hospital stays, disability or death. This Australian study created a great deal of lay attention³ and controversy, and was received with some scepticism.⁴ Much of the scepticism stemmed from methodological issues, especially the retrospective nature of the study.⁵

We performed a prospective study of the incidence and type of predefined serious AEs (SAEs) in inpatients having surgery in a teaching hospital and report our findings here. We also determined the number of SAEs in patients for whom postoperative intensive care unit (ICU) support was not requested (ie, SAEs were not anticipated).

METHODS

Subjects

All patients who had inpatient surgery at the Austin and Repatriation Medical Centre between December 1998 and March 1999, and remained in hospital for 48 hours or more after surgery, were included in our study. The 48-hour limit was used to exclude patients having day surgery or minor procedures, who were not expected to be at risk of SAEs.

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ABSTRACT

Objective: To assess the incidence and nature of postoperative serious adverse events (SAEs) among inpatients having surgery in a tertiary hospital, and to determine which subgroups of patients might be at greatest risk.

Design: Prospective observational study from 1 December 1998 – 31 March 1999.

Setting: Tertiary teaching hospital in Melbourne, Victoria.

Subjects: 1125 subjects having inpatient surgery during the study period.

Main outcome measures: Inhospital mortality, length of hospital stay, and SAEs (myocardial infarction, pulmonary embolism, acute pulmonary oedema, unscheduled tracheostomy, respiratory failure, cardiac arrest, stroke, severe sepsis, acute renal failure, and emergency admission to intensive care unit [ICU]).

Results: There were 414 SAEs in 190 of the 1125 patients (16.9%); 80 patients died (7.1%). The most common adverse events were emergency admission to ICU (95), respiratory failure (52) and readmission to ICU (37). In patients without SAEs, mean duration of hospital stay was 18.4 days (95% CI, 15.4–21.4), while in those with SAEs it was 38.5 days (95% CI, 35.3–41.7) ($P < 0.0001$). SAEs, including deaths, were more common after unscheduled surgery and in patients over 75 years of age. The combination of these two factors carried a 20% mortality. There were no differences in the incidence of SAEs among the major surgical specialties.

Conclusions: SAEs are common and result in high mortality, especially in older surgical inpatients and those having unscheduled surgery. These findings raise important issues of optimal perioperative management in tertiary hospitals.

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Design

Demographic and logistic data were collected for all patients at the time of inclusion in the study (age, sex, surgical specialty of admission, ward, scheduled or unscheduled status of surgery, planned ICU admission). After inclusion, all patients were followed up to either hospital discharge or in-hospital death. During follow-up, data were collected on type of surgery and outcome (length of hospital stay, survival and development of predefined postoperative SAEs).

Definition of serious adverse events

Specific criteria were used to define postoperative SAEs (Box 1). The criteria were developed after consultation with ICU specialist staff specifically for our study — these needed to reflect clinical practice, be reproducible, allow objective confirmation, and represent events that ICU clinicians would consider serious in nature. All events were recorded in an Excel database for subsequent statistical analysis.

Statistical analysis

Data were analysed using a commercially available statistical software package.^{6,7} Descriptive statistical analysis was performed and is reported as means with 95% CI. For comparisons of continuous variables Student's *t*-test was used, and for comparisons of ordinal data Fisher's exact test or the χ^2 test was used. Multivariate logistic regression analysis was also performed

1: Specific criteria used to define postoperative serious adverse events

Serious adverse event	Definition
Acute myocardial infarction	All of the following present within a 24-hour period: chest pain, either ST-segment elevation or ST-segment depression > 2 mm or new Q waves, and at least one measurement of serum creatine phosphokinase showing a raised level, in the absence of another cause
Pulmonary embolism	Clinical suspicion of pulmonary embolism and a ventilation-perfusion scan indicating a high probability of pulmonary embolism
Acute pulmonary oedema	Clinical suspicion of acute pulmonary oedema and formal radiological confirmation of this
Unscheduled tracheostomy	Tracheostomy which was not performed as a normal component of the initial surgery
Respiratory failure	The need to re-institute mechanical ventilation in the intensive care unit
Cardiac arrest	Documented pulseless cessation of cardiac output requiring cardiopulmonary resuscitation and advanced cardiac life support
Cerebrovascular accident	Clinical symptoms and neurological examination suggestive of a stroke, with formal radiological confirmation by computed tomography and/or magnetic resonance imaging
Severe sepsis	Clinical suspicion of infection <i>and</i> hypotension (systolic blood pressure < 90 mmHg) <i>and</i> at least one positive result of a blood culture
Acute renal failure	Acute need for continuous renal replacement therapy
Emergency admission to the intensive care unit	Unscheduled admission to the intensive care unit during the postoperative period due to a clinical complication
Death	Cessation of life indicated by the absence of heartbeat and respiration

to identify variables (age, type of surgery, scheduled or unscheduled operation) which might predict the occurrence of SAEs.

Ethical approval

Our study was approved by the Human Research Ethics Committee of the Austin and Repatriation Medical Centre.

RESULTS

We studied 1125 patients having 1319 procedures. There were 661 males (58.8%) and 464 females (41.2%), with a mean age of 61.3 years (median, 65.5; range, 6–99 years); 309 (27.5%) were over 75 years of age. Of these patients, 699 (62.1%) had scheduled surgery and 426 (37.9%) had unscheduled surgery.

In only 201 of these patients was immediate postoperative ICU support requested. In the remaining 924 patients, the age and sex profile and

proportion having scheduled and unscheduled surgery were similar to the total group of patients.

Serious adverse events

There were 414 SAEs, which affected 190 patients (16.9%). Eighty patients (7.1%) died. The incidence of SAEs did not change significantly with the type of surgery performed (Box 2). The type of SAEs is summarised in Box 3. Of the 924 patients in whom postoperative ICU support was not requested, 138 experienced 309 SAEs (14.9%), with 62 deaths (mortality rate, 6.7%).

Variables associated with SAEs

Multivariate logistic regression analysis confirmed that the patient's sex and the surgical unit had no effect on the incidence of SAEs, but that age did (odds ratio [OR], 1.02; 95% CI, 1.01–1.03), as did the occurrence of unscheduled surgery (OR, 2.28; 95% CI, 1.63–3.19).

The incidence of SAEs (including deaths) was particularly high in patients over 75 years of age. Among 262 such patients, in the absence of planned postoperative ICU admission, 59 (22.5%) experienced an SAE, and 37 (14.1%) died. Furthermore, of 135 patients over 75 years of age having unscheduled surgery, 27 (20%) died. Six of nine patients over 92 years of age having hip surgery died.

Unscheduled surgery was independently associated with a high incidence of SAEs (22.5% v 13.4%; $P < 0.0001$). One hundred and twenty-eight patients had unscheduled surgery, no planned ICU admission, and were over 75 years of age. Of these, 24 (18.8%) died.

Hospital stay

Mean duration of hospital stay was 21.8 days (95% CI, 18.7–24.9). Duration of hospital stay among patients who experienced SAEs was 38.5 days (95% CI, 35.3–41.7), compared with 18.4 days (95% CI, 15.4–21.4) for those who did not experience SAEs ($P < 0.0001$).

DISCUSSION

Our prospective study of postoperative SAEs in an Australian teaching hospital found that one in six surgical patients experienced one or more SAEs during their hospital stay. Both unscheduled surgery and age over 75 years were associated with a higher incidence of SAEs, including mortality. Mortality reached 20% when these two risk factors were combined, and 14.1% when such older patients had no

2: Serious adverse events (SAEs) according to surgical unit

Type of surgery	Number (%) of patients with SAEs	Number of SAEs
General	49/271 (18.1%)	126
Orthopaedic	31/206 (15.0%)	51
Cardiac	26/150 (17.3%)	63
Vascular	24/118 (20.3%)	49
Neurosurgery	14/106 (13.2%)	27
Thoracic	18/106 (17.0%)	35
Other	23/116 (19.8%)	57
Plastic	5/52 (9.6%)	6
Total	190/1125 (16.9%)	414

3: Type and incidence of serious adverse events (SAEs)

Serious adverse event	Number (%)
Emergency admission to intensive care unit	95 (22.9%)
Death	80 (19.3%)
Respiratory failure	52 (12.6%)
Readmission to intensive care unit	37 (8.9%)
Sepsis	27 (6.5%)
Cardiac arrest	27 (6.5%)
Unscheduled tracheostomy	26 (6.3%)
Acute pulmonary oedema	19 (4.6%)
Continuous haemofiltration	16 (3.8%)
Stroke	16 (3.8%)
Acute myocardial infarction	15 (3.6%)
Pulmonary embolism	4 (1.2%)
Total	414

planned postoperative ICU support. Our findings suggest that there is much scope for improving perioperative care in our tertiary hospitals.

As far as we are aware, there have been no other prospective studies in surgical patients in which criteria for SAEs have been predefined. However, a large retrospective chart review of the incidence and nature of surgical AEs in Colorado and Utah⁸ found incidences of 14.1% (lower extremity bypass grafting), 18.9% (abdominal aortic aneurysm repair), and 12.3% (cardiac surgery). These incidences are similar to those we found. Specific SAEs, such as pulmonary embolism (2.3%), acute myocardial infarction (2.1%) and stroke (1.2%), were also similar (Box 3). This concordance supports the view that our findings are accurate and representative not just of our own institution but of the larger population of patients undergoing inpatient surgery in Australia, and perhaps in other developed countries. Further support comes from a recent retrospective study of AEs in British hospitals⁹ (15.3% incidence of AEs among patients undergoing orthopaedic and general surgery) and from other, smaller surgical cohort studies.^{10,11}

Our study could not address the cause of the SAEs, which is likely to be extremely complex. Furthermore, we did not seek to establish whether the detected SAEs were "preventable". We consider that determining "preventabil-

ity" has been shown to be a highly speculative activity, even when using optimal methodology.^{12,13} In our view, the correct test of preventability is intervention (ie, a change in the system followed by evaluation of its effects on SAEs, or a randomised controlled study of one approach to postoperative care versus another). No such studies exist for broad surgical populations.

In summary, SAEs are common among patients having inpatient surgery in a teaching hospital. They are particularly common in the elderly and in those having unscheduled surgery. They occur in patients from all major specialties. In our view, this is a "silent" epidemic which requires urgent and systematic attention.

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