A Before and After Trial of The Effect of a High-Dependency Unit on Post-Operative Morbidity and Mortality

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ABSTRACT

Objective: *It has been suggested that the availability of a high-dependency unit (HDU), to facilitate graded admission to, and discharge from, an intensive care unit (ICU), might decrease post-operative morbidity. We wished to determine whether the addition of a 4-bed HDU to a tertiary 17-bed ICU facility at a University-affiliated hospital would decrease post-operative morbidity and mortality.*

Patients and Methods: *A prospective controlled before-and-after trial was performed with the opening of a 4-bed HDU. Consecutive patients admitted to hospital for major surgery during a 4-month control (pre-HDU) phase and during a 4-month intervention (HDU) phase were studied for the incidence of serious adverse events (SAEs), mortality after major surgery and mean duration of hospital stay.*

Results: *There were 1319 operations performed in 1125 patients during the pre-HDU period and 1369 operations performed in 1127 patients during the HDU period. During the HDU period there was an excess in unscheduled surgery cases (674 during HDU vs. 531 during the pre-HDU period; $p < 0.0001$). In the pre-HDU period, there were 414 SAEs in 190 patients compared with 456 SAEs in 209 patients during the HDU period (NS). There were no significant changes in any of the individual SAEs measured except for the incidence of post-operative acute pulmonary edema, which increased from 19 cases to 46 during the HDU period ($p = 0.028$). This increase was associated with a greater number of patients requiring re-intubation (52 vs. 75 cases; $p = 0.044$). The introduction of an HDU had no effect on mortality (80 deaths vs. 76; NS) and failed to reduce mean hospital length of stay (21.8 vs. 24 days; NS).*

Conclusions: *The introduction of a 4-bed HDU in a teaching hospital was associated with a marked increase in unscheduled surgery and failed to reduce the incidence of post-operative SAEs, post-operative mortality, and mean duration of hospital stay.* (**Critical Care and Resuscitation 2005; 7: 16-21**)

Key words: High dependency unit, intensive care unit, postoperative morbidity, postoperative mortality

Adverse events appear to be common among patients admitted to hospital and may stem from poor adherence to recommended processes.[1] A review of 30,121 medical records in New York State showed that adverse events affected up to 4% of all hospital admissions. Of these events, 13.6% led to death.[2] A similar review of 14,000 randomly selected Australian medical records by Wilson *et al*,[3] revealed similar findings showing that problems identified within the United States of America health care system are likely to occur worldwide.

The findings by Wilson *et al*, were criticised because of the retrospective nature of the studies.[4] Nonetheless, although the true prevalence remains unknown, serious adverse events (SAEs) might be particularly common after major surgery.[4-9] A large retrospective chart review of the incidence and nature of surgical adverse events in Colorado and Utah found an incidence of adverse events of 14.1% among patients undergoing lower extremity bypass grafting, 18.9%

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among those undergoing abdominal aortic aneurysm repair and 12.3% among those undergoing cardiac surgery. It remains unclear, however, whether these SAEs are the inevitable consequence of performing major surgery in patients of older age and with serious co-morbidities or whether some of these SAEs are preventable.[10-18]

We hypothesised that some SAEs might be preventable and that the addition of a high-dependency unit to standard intensive care unit (ICU) facilities would facilitate graded ICU admission and discharge, intensify patient monitoring and thereby increase patient safety and decrease surgery-associated morbidity. We tested our hypotheses by conducting a prospective controlled trial comparing the above outcome measures before and after the opening of a 4-bed HDU in our hospital.

PATIENTS and METHODS

We obtained Institutional Review Board (IRB) approval for the implementation of the High Dependency Unit (HDU) and for the collection of data related to the study. The need for informed consent was waived by the IRB. The study was conducted from January 1999 to August 1999. To understand the study design, we review the Hospital, its pre-intervention structure and the structure of the HDU.

The hospital. The Austin Health is one of three major teaching hospitals affiliated to the medical school of the University of Melbourne. It performs all types of surgery including liver transplantation, for which it is the exclusive state center, and open-heart surgery. The hospital is also a state referral center for spinal trauma and neurosurgery for epilepsy. It does not perform heart and lung transplantation. The medical center has two campuses located in the North-East of Melbourne, a city with a population of approximately 4 million. One campus (400 beds) receives all acute admissions and the other more chronic, less severely ill admissions. The acute care campus admits approximately 60,000 patients per year and is the campus where this study was conducted. The acute care campus has 17 ICU beds, which admit approximately 1,700 patients per year. The Medical Center has a strong academic tradition with two research institutes (immunology and oncology) located within its campus.

The high dependency unit. The HDU is a 4-bed unit located adjacent to the ICU. It takes the form of a large square room with 4 monitored beds making all forms of cardiovascular and oximetry monitoring possible. Nursing care is provided at a 1 nurse: 2 patient ratio by acute care trained nurses, which are part of the ICU nursing staff complement. Medical care is provided by the same team of ICU specialists, advanced trainees and residents responsible for patient care in the ICU.

By hospital policy, HDU patients can not receive a) invasive mechanical ventilation, b) monitoring with pulmonary artery catheters, c) high dose vasopressor therapy (defined as a norepinephrine dose > 10 μg/min), d) continuous renal replacement therapy or e) intra-aortic balloon counterpulsation. They can, however, receive any form of non-invasive mechanical ventilation. Admission to the HDU can occur from the wards, operating rooms, emergency department and ICU. Discharge from the HDU can be to the ICU (in case of a worsening in the patient's condition) or the wards (in case of clinical stability) and therefore functions as a step-up and/or step down unit.

Intensivists determine the need for HDU admission on the basis of clinical judgement after referral from the emergency department physicians, anaesthetists, or ward clinicians. Admission can occur as an acute referral or as a planned post-operative admission. Intensivists also determine HDU discharge to the ward on the basis of clinical judgement. Similarly, they determine if a patient requires escalation of care and admission to ICU. The ICU and HDU of our hospital operate within a "closed" ICU model, meaning that all treatment prescription is exclusively by ICU doctors.

Study Design

The study design was that of a prospective controlled before-and-after intervention trial. All patients admitted to hospital who had major surgery were considered as participants. Major surgery was defined as any operation associated with a hospital stay greater than 48 hours.

The "before" study period was a 4-month period (control period) during which the outcome measures were studied under the normal operating conditions of the hospital. The "after" study period was the following 4-month period (intervention period) during which the outcome measures were studied under the new operating conditions (i.e. availability of a 4-bed HDU) of the hospital.

Analysis included all subjects who had inpatient surgery during the study period and who remained in hospital for 48 hours or more after surgery. The 48-hour limit was used to exclude patients having day surgery or minor procedures who were not expected to be at risk of serious adverse events.

Demographic and logistic data were collected at inclusion (i.e. age, gender, surgical specialty of admission, ward, scheduled or unscheduled status of surgery, planned ICU admission). Following inclusion, all patients were followed up to either death or hospital discharge. During follow up, outcome data (i.e. length of hospital stay, survival and development of predefined postoperative SAEs) were obtained.

Specific criteria were used to define post-operative SAEs (Table 1) as previously described.[11] The primary outcome measure for the trial was the incidence of SAEs

The secondary outcome measures were:

1) percentage of patients affected by SAEs,
2) incidence of in-hospital deaths,
3) incidence of individual SAEs and,
4) mean duration of hospital stay.

Statistical analysis

A computerised statistical package was used for data analysis (Statview, Abacus Inc., Berkeley, CA) and descriptive statistics. Comparisons of nominal data between the two study periods were performed using Fisher's exact test. For non-normally distributed continuous data, such as length of stay, the Mann-Whitney was used. A $p < 0.05$ was considered statistically significant.

RESULTS

During the control period, there were 1,125 patients who received 1,319 operations compared with 1,127 patients who received 1,369 operations in the pre-HDU period. The demographic features and surgical specialty distribution of these patients are presented in Table 2. They showed a similar distribution of surgical subgroups and a similar age but a non significant excess of patients of > 75 years of age (382 vs. 351). However, during the HDU period there was a marked excess in unscheduled surgery cases (674 during HDU vs. 531 during the control period; $p < 0.0001$).

During the pre-HDU period there were 414 SAEs which affected 190 patients. During the HDU period, there were 456 SAEs, which affected 209 patients.

Table 2. Demographic features and surgical specialty of study patients

	Control (n=1125)	*HDU (n=1127)*	*P*
Gender	M = 661, F = 464	M = 660 F = 467	ns
Age	61.4 ± 18.6	60.7 ± 19.8	ns
Scheduled post-operative ICU admission	201	247	0.0175
Unscheduled surgery	426	529	< 0.0001
> 75 years old	309	315	ns
Cardiac	150	169	ns
Thoracic	106	116	ns
General	271	240	ns
Orthopedic	206	216	ns
Vascular	118	119	ns
Neurosurgical	106	122	ns
Plastic	52	52	ns
Other	116	93	ns

ICU = Intensive care unit, HDU = High dependency unit, Unscheduled surgery = surgery started between 5 p.m. and 8 a.m.

Table 1. Specific criteria used to define post-operative serious adverse events

Serious adverse event	*Definition*
Acute myocardial infarction	All of the following: chest pain, characteristic ECG changes and at least one elevated plasma creatine kinase concentration
Pulmonary embolism	Clinical suspicion of a pulmonary embolism and a high probability V/Q scan
Acute pulmonary oedema	Clinical suspicion and a formal radiological confirmation of acute pulmonary oedema
Respiratory failure	The need to re-institute mechanical ventilation in the intensive care unit
Stroke	Clinical symptoms and neurological examination suggestive of a stroke with formal radiological confirmation by CT and/or MR scanning
Severe sepsis	Clinical suspicion of infection and hypotension (systolic blood pressure < 90 mmHg) and at least one positive blood culture
Acute renal failure	Acute need for continuous renal replacement therapy
Tracheostomy	Unplanned tracheostomy
Cardiac arrest	Unconsciousness with lack of a palpable pulse
Emergency admission to the intensive care unit	Unscheduled admission to the intensive care unit during the post-operative period due to a clinical complication
Death	Cessation of life indicated by the absence of heartbeat and respiration

Table 3. Incidence of serious adverse events in the two study groups

Serious adverse event	*Control period*	*HDU period*	*P*
Respiratory failure	52	75	0.044
Stroke	16	19	0.73
Severe sepsis	27	18	0.17
Emergency ICU admission	95	88	0.59
ICU readmission	37	32	0.62
Acute RRT	16	28	0.092
AMI	15	22	0.32
Cardiac arrest	27	29	0.89
Tracheostomy	26	21	0.46
PE	4	5	0.99
Deaths	80	76	0.8

ICU = Intensive care unit, HDU = High dependency unit, AMI = acute myocardial infarction, PE = pulmonary embolism, RRT = renal replacement therapy

There were no beneficial changes in any of the SAEs measured during the study (Table 3), on the contrary, there was a significant increase in the incidence of acute pulmonary oedema and respiratory failure requiring re-intubation (Table 3).

Because the excess in respiratory failure seemed attributable to the greater incidence of acute pulmonary oedema (APO), we investigated whether the HDU contributed directly to its occurrence. We found that, of the 43 cases of APO, 14 cases had no ICU or HDU involvement during their admission and were treated in the ward, 5 were admitted to ICU or HDU because of the APO, 12 were admitted to ICU or HDU because of acute respiratory failure which was diagnosed to be due to APO on ICU admission and 13 cases developed APO who had been in HDU/ICU. In all cases this occurred at least > 48 hours after ICU or HDU discharge.

There were 80 in-patient deaths during the control (pre-HDU) period compared with 76 deaths during the intervention (HDU) period (NS). Duration of hospital stay was a mean of 21.8 ± 53 days pre-HDU and 24 ± 56.5 days during the HDU period (NS).

DISCUSSION

Our study showed that the introduction of a 4-bed HDU was associated with a marked excess in unscheduled surgery cases (674 during HDU vs. 531 during the pre-HDU period; $p < 0.0001$) and no decrease in the over-all incidence of serious adverse events, mortality and mean duration of hospital stay among surgical patients. Furthermore, it showed that the introduction of an HDU was linked with a significant increase in the incidence of acute pulmonary oedema and respiratory failure requiring re-intubation. These findings require careful consideration.

The introduction of an HDU failed to decrease the incidence of SAEs in surgical patients and was associated with an increased incidence of pulmonary oedema and respiratory failure. Previous studies of the effect of introducing an HDU in large hospitals[19,20,21] have reported some benefits in association with the introduction of a HDU. However, these studies have been of poor methodology, uncontrolled, retrospective and without clear clinical prospectively defined outcome measures. In addition, similar studies have shown that the introduction of a HDU increased inpatient mortality and emergency out-of-hours operating[22] and the use of critical care resources.[23] It was also noted that more elderly patients were admitted for longer and more frequently during midweek elective surgery.[23] A recent review of issues related to the planning of HDUs also highlighted the lack of convincing data that HDUs lead to improved clinical outcomes.[24] In their aggregate, these observations support the notion that the clinical effects and usefulness of HDUs are undefined.

The possible effect of opening an HDU on the amount of unscheduled surgery had been previously noted.[22] Our findings are in keeping with such observations. They suggest that the surgical population treated by the hospital during the HDU period might have been more acutely ill. They also suggest that increased availability of acute care beds might invite a less conservative approach to out-of-hours surgery among surgeons and anaesthetists who are aware that a "fall back option" exists for the more intensive monitoring of their patients. Whether this practice shift is clinically or financially beneficial is unknown.

We found that the opening of an HDU was associated with an increased incidence of re-intubation. This effect on the incidence of respiratory failure was mostly accounted for by the number of patients who developed acute pulmonary oedema. This phenomenon might have been secondary to increased patient acuity associated with out-of-hours surgery. The introduction of an HDU, however, might, have led to other changes in hospital care, which accounted for this condition. One such change might have been an increased administration of post-operative fluids. Patients admitted to the HDU might have been resuscitated more vigorously in the early post-operative phases than would normally have been the case in the wards. We reviewed the fluid balance charts of all the patients who developed pulmonary oedema during the HDU period and found that a positive fluid balance during post-operative HDU stay might have contributed to the condition in 3 cases. All other cases had either a neutral or negative fluid balance while in the ICU/HDU or were never admitted

to ICU/HDU before the development of pulmonary oedema. It is possible that the patients treated during the HDU period were more seriously ill than during the pre-HDU period. This view is supported by the observation that there were more unscheduled cases and more planned ICU admissions during the HDU period. Unfortunately, as no validated illness severity scores exist for broad groups of surgical patients, we could not quantify and scientifically compare illness severity during the two study periods.

The introduction of the HDU was associated with no change in post-operative hospital mortality. To our knowledge this is the first controlled study of the effect of introducing an HDU on mortality. These findings do not support a major beneficial impact of HDU care on the prevention of post-operative mortality. By improveing the intensity of post-operative monitoring in some patients, it was hoped that the HDU would reduce mean duration of hospital stay for surgical patients. However, this was not observed.

The limitations of this study should be carefully considered. First, it was neither double-blinded, nor placebo-controlled, nor randomised. However, it is not possible to double-blind the introduction of an HDU. We consider a traditional patient randomisation-based study of HDUs ethically, scientifically and logistically impossible in a single hospital. It might be possible to perform a cluster randomisation-based study where hospitals rather than individuals would be randomised to have, or not to have, the addition of an HDU. Such a study, however, would pose extraordinary organisational challenges.

We studied the HDU within a single institution and our findings might not apply to other hospitals. Institution specific heuristics and unique administrative features may have lent themselves to making the impact of the introduction of an HDU much smaller in our institution than in others. However, our institution has all the organisational, structural, logistic and clinical performance features of a typical tertiary referral hospital in a developed country. Furthermore, the HDU represented an increase of > 20% in bed-availability thus offering reasonable scope for improved resource allocation and patient monitoring. It is possible that our doctors and nurses had particular characteristics in that they did not recognise signs of imminent SAEs that would be easily identified by other physicians or nurses in other hospitals and, when they did, failed to refer patients for HDU care. We cannot confirm or deny this possibility.

It is possible that the change in SAEs was secondary to seasonal fluctuations or some other changes in post-operative care during the period that separated the pre-HDU from the HDU period. The changes in the incidence of unscheduled surgery and planned ICU admissions support this view. These changes in practice, however, may have also reflected a less conservative approach to out-of-hours surgery induced by the presence of the HDU itself. The impact of such changes on SAEs, however, is unclear.

The incidence of SAEs during the control and HDU periods may appear high. However, a large (i.e. 15,000 patients) retrospective chart review of the incidence and nature of surgical adverse events in Colorado and Utah shows similar problems.[6] This study identified an incidence of adverse events of 14.1% among patients undergoing lower extremity bypass grafting, 18.9% among those undergoing abdominal aortic aneurysm repair and 12.3% among those undergoing cardiac surgery. These values are similar to those seen in our pre-HDU group. For specific SAEs reported in the above study,[6] such as pulmonary embolism (2.3%), acute myocardial infarction (2.1%) and stroke (1.2%) the similarities are striking. These observations support the view that our findings might be representative of the larger population of patients undergoing in-patient surgery in developed countries.

In conclusion, the introduction of a 4-bed HDU was not associated with a beneficial effect on the number of SAEs and deaths among patients receiving major surgery in our hospital. It also appeared to be linked with an increase in the incidence of acute pulmonary oedema and acute respiratory failure.

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