Iatrogenic Adverse Events in the Coronary Care Unit

Sherali A. Rahim, MD; Anita Mody, MD; Jennifer Pickering, BScPhm; P.J. Devereaux, MD, PhD; Salim Yusuf, MD, DPhil

Background—Although our understanding of medical adverse events has increased substantially over the last decade, little is known about iatrogenic adverse events (IAEs) in the coronary care unit (CCU). We sought to determine the frequency and potential preventability of IAEs in the CCU of a tertiary care center.

Methods and Results—We undertook a retrospective cohort study evaluating the hospital charts of consecutive patients admitted to the CCU at Hamilton General Hospital (Ontario, Canada) from November 1, 2005, to January 1, 2006. We used a priori developed definitions to determine whether patients suffered an IAE and whether it was potentially preventable. We included 194 patients, and 99 (51%; 95% CI, 44% to 58%) patients had at least 1 IAE, of which 45 (45%; 95% CI, 36% to 55%) were judged potentially preventable. Bleeding (14/51, 27%; 95% CI, 17% to 41%) was the most common potentially preventable IAE and was more common than recurrent ischemic events (4/51, 8%; 95% CI, 3% to 19%). Of the patients who died in the hospital, 9 of 17 (53%; 95% CI, 31% to 74%) had an IAE that was causally related to their death, of which 6 (67%; 95% CI, 35% to 88%) were judged potentially preventable.

Conclusions—The present study suggests that IAEs, especially bleeding, are common in the CCU setting and more frequent than recurrent ischemic events. These results suggest the need for large multicenter studies to evaluate in CCUs the rates of IAEs, their causes, and potential preventability. (Circ Cardiovasc Qual Outcomes. 2009;2:00-00.)

Key Words: iatrogenic disease ♦ outcome assessment

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R esearchers have defined an iatrogenic adverse event (IAE) as any unintended injury or complication that results from health care management rather than the underlying disease process.1 An IAE can have a devastating impact on the morbidity and mortality of a cardiac patient. It is estimated that adverse events cause between 9000 and 23 000 preventable deaths per year in Canada.1

Despite the overall potential magnitude of this problem little is known about adverse events specifically in the coronary care unit (CCU) setting. We undertook a study of CCU patients to determine the frequency of IAEs, the underlying causes, and whether these events were potentially preventable.

Methods

Study Design and Sample

A single physician retrospectively reviewed the charts of all consecutive patients admitted to the 10-bed CCU at Hamilton General Hospital from November 1, 2005, to January 1, 2006. This included a review of all paper and electronic physician notes, nursing notes, investigations, and medication records. Two reviewers independently reviewed the charts of patients who died in hospital to assess for interobserver agreement. The study was approved by the Hamilton Health Sciences Research Ethics Board.

Definitions

Based on definitions from the existing literature, we a priori defined terms associated with IAEs as follows.1,2,3

Health Care Management

Health care management refers to actions of individual hospital staff and broader systems and care processes. It encompasses acts of omission, acts of commission, or appropriate health care. An act of omission is the failure to make a diagnosis or failure to implement treatment. An act of commission is the generation of an incorrect diagnosis, or implementation of inappropriate treatment.1,2 Acts of omission or commission may lead to adverse events. There are 6 categories of health care management issues, as shown in Table 1.

IAE

IAE refers to any injury or complication that results from health care management rather than the underlying disease process. A complication related to the underlying disease process that occurs despite appropriate diagnosis and therapy is not considered an iatrogenic adverse event. A minor IAE does not result in disability at the time of discharge, the need for an additional procedure, prolonged hospital stay, hospital readmission within 1 week, or death.1 A major IAE is any injury or complication that results in disability at the time of discharge, the need for an additional procedure, prolonged hospital stay, hospital readmission, or death.1 IAE may be nonpreventable or potentially preventable.

Nonpreventable IAE

Nonpreventable IAE refers to an IAE that is attributable to inappropriate health care.2

Potentially Preventable IAE

Potentially preventable IAE refers to an IAE that is attributable to an act of omission or commission.1,2 Potentially preventable IAEs are not attributable to appropriate health care.

Major Life-Threatening Bleeding

Major life-threatening bleeding refers to one or more of the following: bleeding with hypotension requiring inotropes, reduction in hemoglobin of greater than or equal to 5 g per deciliter, requiring 4 or more units of blood, requiring surgical intervention, symptomatic intracranial hemorrhage, or a fatal bleed.3

Conclusions—The present study suggests that IAEs, especially bleeding, are common in the CCU setting and more frequent than recurrent ischemic events. These results suggest the need for large multicenter studies to evaluate in CCUs the rates of IAEs, their causes, and potential preventability. (Circ Cardiovasc Qual Outcomes. 2009;2:00-00.)

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Received December 25, 2008; accepted June 16, 2009.

From the Division of Cardiology, Department of Medicine (S.A.R., A.M., P.J.D., S.Y.), and the Cardiac and Vascular Program (J.P.), McMaster University and the Population Health Research Institute, Hamilton Health Sciences, Hamilton, Ontario, Canada.

Correspondence to Sherali Rahim, MD, McMaster University, 1200 Main St W, Room 2C8, Hamilton, Ontario, Canada, L8N 3Z5. E-mail sherali.rahim@utoronto.ca

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Circ Cardiovasc Qual Outcomes is available at http://circoutcomes.ahajournals.org

DOI: 10.1161/CIRCOUTCOMES.108.846493
WHAT IS KNOWN

- An iatrogenic adverse event is any unintended injury or complication that results from healthcare management rather than the underlying disease process, and it is estimated that these events cause between 9000 and 23,000 preventable deaths per year in Canada.
- Despite the overall potential magnitude of this problem, little is known about iatrogenic adverse events specifically in the coronary care unit where the rate of error is potentially high as care involves critically ill patients requiring high risk treatment decisions which are frequently made quickly and often with limited information available.

WHAT THE STUDY ADDS

- We found that 51% of patients admitted to the CCU at a major tertiary care center had one or more iatrogenic adverse events.
- Almost half of these events were potentially preventable, of which bleeding was the most common event. More than three quarters were attributable to treatments or procedures, and about one third of the deaths occurred after an adverse event that was potentially preventable.
- If our data are confirmed in larger studies, it suggests that in high-intensity units, substantial morbidity and mortality may be potentially reduced by having quality assurance systems in place to monitor and prevent serious adverse events.

Major Non–Life-Threatening Bleeding

Major non–life-threatening bleeding refers to one or more of the following: bleeding limiting mobility, required transfusion of at least 2 U of packed red blood cells, or intraocular bleeding resulting in vision loss.

Minor Bleeding

Minor bleeding refers to a drop in hemoglobin of at least 1 g per dL or visible documented bleeding and not classifiable as major or life threatening.

Data Collection

Demographic data were recorded in a standardized electronic database for all patients. If an adverse event was detected in the chart, a search for the causal health care management issue was conducted to determine whether it was iatrogenic. We further divided health care management issues into six categories as shown in Table 1. Causality between the health care management issue and the IAE was determined. Each IAE was assigned a preventability score out of 6 by one reviewer (S.R.). Potentially preventable IAEs had a score between 4 and 6. Nonpreventable IAEs had a score <4. Table 2 shows the scoring system for causality and preventability. Research ethics board approval was obtained for chart review. No individual consent from individual patients was obtained.

Statistics

We determined frequencies and 95% CIs for our various definitions listed above. We determined the \( \kappa \) statistic for interobserver agreement in patients who died in hospital with regards to the presence of an IAE, causality between the health care management issue and IAE, and preventability of the IAE.

Results

Study Population

A total of 194 consecutive patients admitted to the CCU were included in this study. The baseline characteristics of the study population are shown in Table 3.

IAEs

99 patients (51%; 95% CI, 44% to 58%) had at least 1 IAE. Over the course of the study a mean of 1.6 patients per day experienced an IAE. More patients experienced a major IAE (75 patients) than a minor IAE (24 patients).

Of the patients who experienced an IAE, 45 of 99 (45%; 95% CI, 36% to 55%) patients experienced one or more that were potentially preventable (preventability score 4 to 6). Of the patients with potentially preventable IAEs, 30 of 45 (67%; 95% CI, 52% to 79%) patients had a preventability score of 4, 6 of 45 (13%; 95% CI, 6 to 26) patients had a preventability score of 5, and 9 of 45 (20%; 95% CI, 11 to 34) patients had a preventability score of 6.

There were 50 health care management issues leading to 51 potentially preventable IAEs that occurred in 45 patients. The most frequent health care management issues were procedure (22/50, 44%; 95% CI, 31% to 58%), treatment (13/50, 26%; 95% CI, 16% to 40%), and diagnosis (9/50, 18%; 95% CI, 10% to 31%) related. Of the procedure related health care management issues, 13 of 22 (59%; 95% CI, 39% to 77%) were related to cardiac catheterization.

Figure 1 shows the relative frequency of potentially preventable IAEs that were causally linked to a health care management issue. The most frequent potentially preventable IAE was bleeding (14/51, 27%; 95% CI, 17% to 41%). 6/14 potentially preventable bleeding events were life threatening of which 2 were intracranial hemorrhages. Potentially preventable recurrent ischemic events (4/51, 8%; 95% CI, 3% to 19%) were less common than bleeding.

The frequency and nature of health care management issues and adverse events for patients with \( \geq 1 \) potentially preventable IAE are summarized in Table 4.

Bleeding

Of all the patients with an IAE (both preventable and nonpreventable), 20 of 99 (20%; 95% CI, 13% to 29%) were bleeding events. Fourteen of 20 (70%; 95% CI, 48% to 85%) were potentially preventable, 9 (45%; 95% CI, 26% to 66%) of which were life-threatening. Six of 20 (30%; 95% CI, 15% to 52%) were major bleeding events but were not life-threatening. The remaining 5 of 20 (25%; 95% CI, 11% to 47%) were minor bleeding events.

Location of Healthcare Management Issues

Patients experienced health care management issues at the following locations: at the Hamilton General Hospital (67/99, 68%), at the referring hospital (28/99, 28%), and at the patient’s home (4/99, 4%). Of the patients who experienced health care management issues at the Hamilton General
Within the subset of patients who died in hospital, the interobserver agreement for the presence or absence of an IAE was substantial (κ=0.76). In these patients where both reviewers documented an IAE, interobserver agreement for causality between the health care management issue and the IAE was perfect (κ=1.00) and for potential preventability of the event was moderate (κ=0.5). Disagreements were resolved by discussion between the 2 reviewers. An independent third party would have been consulted if agreement could not be achieved.

### Discussion

#### Summary of Main Findings

Our retrospective study of patients admitted to the CCU demonstrates that more than one-half (99/194, 51%) of patients admitted to the coronary care unit had at least 1 IAE, of which just less than one-half (45/99, 45%) of the patients...
Management causation more strongly evidenced than diagnostic errors. Our data shows a much higher proportion of bleeding and a low proportion of recurrent ischemic events. This study emphasizes the need for systematic data collection in a larger number of individuals across many types of hospitals in Canada.

Results in Relation to Other Studies

Based on prospective observational data collected in 2002 to 2003 from a combination of ICU and CCU patients, 20% of admitted patients had 1 or more adverse events. Of these events, 55% were preventable, 45% were not, and 13% of adverse events were life-threatening or fatal. Considering the proportion of IAEs with a high proportion of bleeding and a low proportion of recurrent ischemic events. This study emphasizes the need for systematic data collection in a larger number of individuals across many types of hospitals in Canada.

Table 2. Causality and Preventability Scoring System

<table>
<thead>
<tr>
<th>Score</th>
<th>Causality</th>
<th>Preventability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Virtually no evidence of management causation</td>
<td>Virtually no evidence of preventability</td>
</tr>
<tr>
<td>2</td>
<td>Slight to modest evidence of management causation</td>
<td>Slight to modest evidence of preventability</td>
</tr>
<tr>
<td>3</td>
<td>Management causation not quite likely (less than 50/50)</td>
<td>Preventability not quite likely (less than 50/50)</td>
</tr>
<tr>
<td>4</td>
<td>Management causation more than likely (more than 50/50)</td>
<td>Preventability more than likely (more than 50/50)</td>
</tr>
<tr>
<td>5</td>
<td>Strong evidence of management causation</td>
<td>Strong evidence of preventability</td>
</tr>
<tr>
<td>6</td>
<td>Virtually certain evidence of management causation</td>
<td>Virtually certain evidence of preventability</td>
</tr>
</tbody>
</table>

The scoring system used to determine causality between a health care management issue and an iatrogenic adverse event. The analogous scoring system used to determine preventability of a health care management issue and the corresponding iatrogenic adverse event is also shown.1

had an IAE which was potentially preventable. The most common preventable IAEs were related to procedural (22/50, 44%), treatment (13/50, 26%), or diagnostic (9/50, 18%) issues. Bleeding (14/51, 27%) was the most common preventable IAE. Of the patients who died in hospital, 9 of 17 (53%) had an IAE that was causally related to their death, and 6 of 17 (35%) were judged potentially preventable.

Strengths and Weaknesses of Study
To our knowledge, this is the first study reporting and classifying IAEs and their underlying causes focused solely on the CCU setting. The data from this observational study are from a single tertiary care hospital, are based on modest numbers, and include a high proportion of referred patients with serious complications and comorbidities; however, these factors do not undermine the major findings of a high proportion of IAEs with a high proportion of bleeding and a low proportion of recurrent ischemic events. This study emphasizes the need for systematic data collection in a larger number of individuals across many types of hospitals in Canada.

Table 3. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sample (N=194)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>65±35</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>56 (29)</td>
</tr>
<tr>
<td>Diagnosis on admission, n (%)</td>
<td></td>
</tr>
<tr>
<td>ACS/UA</td>
<td>145 (75)</td>
</tr>
<tr>
<td>Tachyarrhythmia</td>
<td>23 (12)</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>13 (7)</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>12 (6)</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>9 (5)</td>
</tr>
<tr>
<td>In hospital cardiac arrest</td>
<td>7 (4)</td>
</tr>
<tr>
<td>Valvular disease</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Gastrointestinal bleed</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Aortic dissection</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Out of hospital cardiac arrest</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>18 (9)</td>
</tr>
</tbody>
</table>

More than 1 diagnosis may apply to a particular patient. ACS/UA indicates acute coronary syndrome/unstable angina.
ICU population because of variations in the use of specific therapies and interventions that predispose patients to bleeding.

A recent analysis of more than 30,000 patients demonstrated that a major bleed in a patient with an acute coronary syndrome increased the risk of death 5-fold. With the increasing use of combined antiplatelet, anticoagulant, and thrombolytic agents in cardiac patients the risk of ischemic events has decreased, but the risk of bleeding has almost certainly increased. Despite the decrease in ischemic events, the overall risk of death may paradoxically have remained unchanged or even increase because of the increased risk of bleeding. This is especially true given the narrow therapeutic dosing range of many of these medications with a fine balance between benefit and harm. Once bleeding occurs, the clinician is forced to choose between withdrawing anticoagulant therapy, which can potentially increase the risk of ischemic events and in-stent thrombosis, or continuing anticoagulant therapy, which exacerbates bleeding and potentially predisposes to cardiac ischemia. Procedures that may induce mechanical causes of bleeding further compound this problem. Thus, it follows that preventing bleeding from occurring in the first place through judicious and careful use of antithrombotic agents and invasive procedures might lead to the most optimal outcome. This hypothesis needs evaluation in prospective studies.

**Future Research**

There is a need for a large CCU study to classify IAEs into the categories in Figure 3. Using this classification scheme that we developed, IAEs can arise by 2 major pathways. In the first pathway, a clear case of medical error leads to an IAE. When such a pathway is identified, a multidisciplinary group should undertake root cause analysis to determine the underlying cause and to propose recommendations for change. The categories of change usually include: education, policy change, practice change, or equipment change.

In the second pathway, an IAE occurs where no medical error is made and then it is necessary to determine whether the IAE is judged as unacceptable or acceptable. To establish what is acceptable and what is unacceptable is a value judgment. Various quantitative methods (ie, decision analytic modeling, probability trade-off) exist for eliciting and incorporating values into decision making. Research suggests that the results of the probability trade-off as opposed to the decision analysis may better reflect an individual’s values. Probability trade-off technique presents individuals with the probabilities for the various interventions being considered and then asks the individuals to make a decision based on this information. This allows a direct and quantitative incorporation of the individual’s preferences. There is a need for a CCU study assessing the values of a large group of individuals within the relevant stakeholder group (ie, physicians, nurses, pharmacists, patients, and administrators). By presenting a list of specific interventions and corresponding clinical scenarios, it is possible to determine which interventions the stakeholders consider reasonable in terms of benefit when weighed against the risk. Subsequently, when analyzing data collected regarding IAEs and their corresponding health care management issues, well-validated models can be used.
to determine the potential benefit and the potential risk for the therapy in question. Comparing the benefit and risk, therapy can be deemed acceptable or unacceptable based on the stakeholders thresholds established during the prior interview process.

**Interpretation of Study and Conclusion**

In our retrospective review of patients admitted to the CCU at a major tertiary care center, there was a high rate of adverse events. Almost half of these adverse events were potentially preventable, and more than three quarters were attributable to treatments or procedures. About one third of the deaths occurred after an adverse event that was potentially preventable. If our data are confirmed in larger studies, it suggests that in high-intensity units, substantial morbidity and mortality may be potentially reduced by having quality assurance systems in place to monitor and prevent serious adverse events.

**Disclosures**

None.

**References**


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Circ Cardiovasc Qual Outcomes. published online August 18, 2009;
Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/early/2009/08/18/CIRCOUTCOMES.108.846493

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