CLINICAL RESEARCH STUDY

Iatrogenic events resulting in intensive care admission: Frequency, cause, and disclosure to patients and institutions

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ABSTRACT

PURPOSE: To identify the frequency and type of iatrogenic medical events requiring admission to an intensive care unit. To assess the consequences of iatrogenic medical events for patients and institutions. To assess the prevalence of disclosure of iatrogenic medical events to patients, surrogates, and institutions.

METHODS: The project on Care Improvement for the Critically Ill enrolled 5727 patients to 8 intensive care units at 4 Boston teaching hospitals. To determine the nature, consequences, and disclosure of iatrogenic medical events, we did a retrospective chart review on all patients whose admission to an intensive care unit was precipitated by an iatrogenic event.

RESULTS: Sixty-six patients (1.2 %) were identified by an intensive care unit’s clinical team as having an iatrogenic medical event as the primary reason for admission to the unit. The majority (29, or 45%) of iatrogenic medical events were secondary to technical error, but a high percentage (21, or 33%) was due to iatrogenic drug events. Twenty-two (34%) cases were assessed by the investigators to have been preventable. In 60 (94%) cases there was no documentation in the patient’s chart of communication to the patient regarding the reason for admission to the intensive care unit. In 11 (17%) cases there was documentation of a discussion with the surrogate about the reason for admission to the unit. In only 3 (5%) cases was there documentation that the patient or surrogate was informed that an iatrogenic medical event was the reason for admission to the intensive care unit. Incident reports or malpractice claims were filed in only 4 (6 %) cases.

CONCLUSION: The frequency of iatrogenic medical events resulting in admission to intensive care units is lower than previous studies have reported. Iatrogenic drug events continue to be an important source of error. A considerable percentage of iatrogenic events may be preventable. Health care professionals rarely document disclosure of iatrogenic events to patients and surrogates.

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cern about errors in medicine remains at the forefront of public consciousness.

Although all medical errors should be a concern for our society, errors that either result in serious consequences for patients or that are preventable are of particular concern. We focused on errors that necessitated admission to an intensive care unit. Our goal was to better understand the errors that were most likely to have a negative impact on patient outcomes and to determine what type of communication with patients or surrogates occurs after an error that results in admission to an intensive care unit.

Methods

Background

This study was conducted as part of the project on Care Improvement for the Critically Ill, organized in 1997 by a consortium from the intensive care units at Harvard teaching hospitals in response to emerging controversies in critical care medicine. The complete methods for this project have been published elsewhere.8

Settings

The project on Care Improvement for the Critically Ill was a prospective observational study that examined decision making and satisfaction with care provided in 8 intensive care units at 4 teaching hospitals. This included 4 surgical intensive care units, 3 medical intensive care units, and 1 pediatric intensive care unit. The institutional review boards at participating hospitals approved the study.

Eligibility

All patients admitted to the intensive care unit during the study period were eligible for enrollment. Only a patient’s first admission was included to avoid counting 2 outcomes for the same individual. Any patient already admitted to the intensive care unit before the start of the study was excluded. Clinicians in the intensive care unit identified patients with an iatrogenic event. Each morning a trained research assistant attended rounds and queried the clinical team regarding whether a patient was admitted to the intensive care unit because of an iatrogenic event. If a member of the team questioned what was meant by the term “iatrogenic event,” the following definition was provided: “an injury or event induced inadvertently by a physician, other clinical staff or a medical treatment or diagnostic procedure resulting in a patient’s admission to the intensive care unit.”

Data collection

Data were collected between November 1998 and November 1999. Research nurses, who attended a training session and adhered to a detailed coding instruction manual, abstracted data from the medical record. Variables abstracted from the medical record included demographic information and measures of patient acuity, including the Simplified Acute Physiology Score II,9 a prognostic scoring system that estimates probability of outcome from physiologic measures.

Physicians reviewed the medical records using a structured abstraction instrument developed for this study to collect information on the details of iatrogenic medical events. The abstraction instrument included information on the etiology of the event requiring intensive care unit admission, a classification of iatrogenic drug events, an assessment of whether the event had been avoidable, and documentation of communication about the event. Physicians were instructed to select all the possible reasons for an iatrogenic event. The entire medical record was available to reviewers. Reviewers were instructed to carefully review the record for at least 2 days prior to the intensive care unit admission through discharge from the unit. To assess inter-rater reliability, 1 physician reviewed all patient charts and a second physician reviewed a random subset of 28 (44%) medical records.

Definitions

An iatrogenic event was defined as an unintended injury or harm to a patient resulting from health care management rather than a disease process. An iatrogenic event was considered preventable if it was avoidable using any means currently available, unless those means were not considered standard of care.2 Iatrogenic events were categorized as either technical, diagnostic, or medication errors. Technical error was defined as medical procedure events such as injury occurring during an operation or bleeding.10 Diagnostic error was defined as delayed or incorrect diagnosis or therapy.11 In order to place our results within the context of previous data in this field, the relationship between a medication error and an iatrogenic event was categorized as definite, probable, possible, conditional, or doubtful.12

Statistical analysis

The characteristics of patients are expressed as means ± standard deviation or as the frequency of patients or events. Kappa statistics were performed to determine inter-rater reliability for judgments concerning preventability of iatrogenic medical events. All statistical calculations were performed using SAS version 8 statistical software (SAS Institute; Cary, NC).

Results

Characteristics of patients

A total of 5727 patients were admitted to the intensive care units during the period of November 1998 to March
Among these, 873 (15%) patients were enrolled in the project on Care Improvement for the Critically Ill based on a positive response to 1 of 4 screening questions. Sixty-six patients (1.2%) were identified as having an iatrogenic medical event that was the primary reason for admission to the intensive care unit. A retrospective review of patient charts was performed for 64 (97%) of the 66 patients. Two charts were unavailable for review. Table 1 describes the characteristics of patients admitted to the intensive care unit secondary to an iatrogenic medical event and the etiology of the iatrogenic events. Approximately half of all patients admitted to the intensive care units as a result of an iatrogenic event were men, greater than three quarters were white, and the mean age was 59 (±21) years. The median length of stay was 3 days. The Simplified Acute Physiology Score II was 33. Eight patients admitted to an intensive care unit secondary to an iatrogenic event died while in the intensive care unit. This represented 4% of the 185 deaths among the 873 patients enrolled in the project on Care Improvement for the Critically Ill.

**Etiology of iatrogenic medical events resulting in intensive care unit admission**

For 20 patients (31%), the primary reason for intensive care unit admission was respiratory decompensation. The majority of iatrogenic medical events (29, or 45%) were secondary to technical error, but a high percentage (21, or 33%) were also due to adverse drug events (Table 1). Adverse drug events were further categorized into dosage error for 9 (43%) events, idiosyncratic reaction for 7 (33%), frequency error for 2 (10%), errors that did not fit any general classification for 2 (10%), and wrong drug to patient for 1 (5%). Narcotic analgesics were the most common type of drug (9 events, or 43%) resulting in an iatrogenic event, with sedative hypnotics being responsible for 5 (24%) of adverse events.

Invasive procedures were related to the iatrogenic event in 51 (80%) cases. The types of procedures involved were surgical 28 (44%), gastrointestinal 9 (14%), line placement 4 (6%), renal 3 (5%), cardiac catheterization 3 (5%), obstetrical and gynecological 2 (3%), and pulmonary 2 (3%). When procedures were involved, perforation (12, or 19%) and hypotension (12, or 19%) were the most common iatrogenic outcomes resulting from the procedure.

Reviewers were asked to evaluate whether the iatrogenic medical event was preventable. The inter-rater reliability for determining preventability was only fair. In 22 (34%) cases, reviewers thought the event was preventable; in 9 (14%) cases, the iatrogenic medical event was thought not to be preventable; and in 33 (52%) cases, the preventability of the iatrogenic medical event could not be evaluated with certainty (kappa=0.5).

**Documentation of disclosure of iatrogenic medical event**

In only 1 (2%) case did we find the use of the term “iatrogenic” in the chart to describe the event that resulted in admission to the intensive care unit. In 60 (94%) cases, there was no documentation in the chart of communication to the patient regarding the reason for admission to the unit. Because 768 (88%) patients enrolled in the Care Improvement for Critically Ill study did not have the capacity to make decisions for themselves, we assessed disclosure of iatrogenic events to patient surrogates. In 11 (17%) cases, there was documentation of a discussion with the surrogate about the reason for admission to the intensive care unit (Table 2).

**Discussion**

Over 20 years ago, Trunet et al found that 41 (12.6%) intensive care unit admissions during a 1-year period were linked to iatrogenic medical events and, of those, 19 (46%) were preventable. In 1999 Darchy et al. did a retrospective review of admissions during a 1-year period to a French general hospital and found a similar percentage of admissions (68 or 10.9%) to the intensive care unit resulted from iatrogenic medical events. Because many errors may not be documented in the medical record and implicit review
Similarly, explicit nonphysician review is also limited. Explicit nonphysician review is as likely as retrospective review to underestimate error frequency. Indeed, O’Neil et al showed that physician review is as likely as retrospective review to understate error frequency. Non-disclosure of error also undermines efforts to improve the safety of medical practice. Institutions that are unaware of errors cannot make efforts to improve the systems that resulted in the development of the error. Previous studies have indicated that patients have a clear preference for disclosure of errors even when the error was minor. The Joint Commission on Hospital Accreditation recently introduced patient safety and medical/health care error reduction standards for hospital practitioners. These stipulate that “patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.”

There are many reasons why physicians may not disclose errors to patients. Lack of knowledge about reporting rules, uncertainty about how to disclose errors, concerns about upsetting patients, and a fear of the consequences of disclosure may influence physicians’ response to an iatrogenic event. If we are to succeed in improving the quality of care, physicians must be educated about the importance of disclosure as a catalyst for system change, as a protection against malpractice, and as information that patients prefer to receive. Most importantly, we need to be certain that physicians have the communication skills to sensitively disclose iatrogenic events.

Our results are limited by our inclusion of only major academic teaching institutions. Our reliance on implicit physician review to make judgments concerning the preventability of iatrogenic events is another limitation. Our data about disclosure of error is limited by medical record review. It is possible that health care providers had more frequent discussions with patients or surrogates regarding iatrogenic events and the reason for admission to the intensive care units and did not document these discussions in the medical record. The low rate of incidence report filing, however, suggests that, even when health care providers do discuss errors with patients, they do not disclose those conversations to the institution. Patients were also enrolled in our study prior to the Institute of Medicine report To Err Is Human. It is possible that this report may have led to an increase in the frequency of disclosure of iatrogenic events to patients and families.

Iatrogenic medical events have negative consequences for patients, population health, and the cost of medical care. Our study suggests that iatrogenic events continue to be an important cause of admission to intensive care units and in many cases may be preventable. The challenge that remains is for health care institutions to develop systems to better identify errors, reduce the incidence of preventable iatrogenic events, and ultimately provide better quality care.

to identify error may result in underestimations, we sought to screen for medical errors at the time of admission to the intensive care unit. In this study, clinicians who admitted patients to intensive care units identified patients who had an iatrogenic event as the cause of intensive care unit admission. In contrast to previous retrospective studies, however, our study revealed a low frequency of intensive care unit admissions resulting from iatrogenic medical events (66 or 1.2 %).

Determining the true frequency of iatrogenic events resulting in admission to intensive care units is an unattainable goal. Health care professionals may not acknowledge all errors that occur. The Harvard Medical Practice Study, the Utah and Colorado Medical Practice Study, and the Quality in Australian Health Care Study all relied on retrospective chart review. Implicit chart review by physicians is fraught with inconsistency among reviewers. Similarly, explicit nonphysician review is also limited. Our study suggests that the frequency of errors at the institutions studied is lower than at institutions previously studied, errors have been decreasing over time, or prospective review is as likely as retrospective review to underestimate error frequency. Indeed, O’Neil et al showed that physician reporting and retrospective record review uncover similar frequencies of iatrogenic events. Our study only captured patients who were in the intensive care unit on morning rounds. It is possible that some patients with an iatrogenic event were admitted to the intensive care unit after morning rounds and died or were discharged prior to the next morning rounds. Thomas et al. also showed that patients in major teaching hospitals are less likely to suffer preventable iatrogenic drug events. It is therefore possible that the inclusion of major academic teaching institutions within our study is part of the reason for our finding a lower frequency of iatrogenic events.

Most surprising among our data was the low rate of documented discussions concerning the reason for admission to the intensive care unit with patients or surrogates. It is possible that health care professionals discussed iatrogenic events with patients without documenting their discussions. The extremely low rate of documentation of disclosure, however, raises questions about health care professionals’ understanding that disclosure is vital to changing systems and the resultant improvement in health care.

Disclosure of error should be encouraged from both an ethical and legal perspective. Failing to disclose errors undermines patients’ trust in physicians and the public’s trust in medicine as a profession. Furthermore, failure to disclose known errors is a manifestation of disrespect for patients because it entails deception. Nondisclosure of error also undermines efforts to improve the safety of medical practice. Institutions that are unaware of errors cannot make efforts to improve the systems that resulted in the development of the error. Previous studies have indicated that patients have a clear preference for disclosure of errors even when the error was minor. The Joint Commission on Hospital Accreditation recently introduced patient safety and medical/health care error reduction standards for hospital practitioners. These stipulate that “patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.”

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Iatrogenic” present in chart</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Reason for intensive care unit admission discussed with patient</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Reason for intensive care unit admission discussed with surrogate</td>
<td>11 (17)</td>
</tr>
<tr>
<td>Iatrogenic nature of intensive care unit admission discussed with patient or surrogate</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Incident report filed with hospital</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Medical record suggests litigation</td>
<td>3 (5)</td>
</tr>
</tbody>
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Table 2 Documentation of disclosure of iatrogenic medical event
to our patients. Developing a system of anonymous physician self-reporting of errors might come closest to capturing the true rate of iatrogenic events within an institution. Improving the systems by which drugs are ordered and administered could prevent some iatrogenic drug events.3,4

Further data is needed on the disclosure of iatrogenic medical events. Are physicians having conversations with patients or surrogates about iatrogenic events and, if so, what is the content and process of that communication? Future research should also be directed at assessing patients’ perspectives on the ideal way to respond to iatrogenic medical events.

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References