Complications of Care in a Medical Intensive Care Unit

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Objective: *To determine the frequency and nature of complications of care in the medical intensive care unit (MICU).*
Design: *Prospective, observational study.*
Setting: *Seven-bed MICU in a teaching and referral VA hospital.*
Patients: *295 consecutive patients admitted to the MICU during a ten-month study period.*
Interventions: *None.*
Measurements and main results: *Forty-two patients (14%, 95% confidence interval 13%, 16%) experienced one or more complications during their MICU stays. Compared with other MICU patients, those experiencing complications tended to be older (mean age ± SD: 63.6 ± 10.1 years vs 59.3 ± 14.0 years, $p < 0.02$) and more acutely ill (mean Acute Physiology Score ± SD: 18.3 ± 8.0 vs 12.5 ± 8.0, $p = 0.0001$). These patients also had significantly longer MICU lengths of stay (mean ± SD: 12.3 ± 14.7 days vs 3.1 ± 4 days, $p < 0.0001$) and higher hospital mortality rates (67% vs 27%, $p < 0.001$). The 67% mortality rate among patients with complications significantly exceeded the expected mortality rate of 46% (calculated from the APACHE risk equation).*
Conclusion: *Complications of care in the MICU are not rare and may independently contribute to in-hospital mortality. The potential for complications must be recognized when considering ICU care.*
Key words: *critical care; iatrogenic disease; intensive care units.* J GEN INTERN MED 1990; 5:104–109.

THE PRICE WE PAY[1] for our sophisticated diagnostic and therapeutic capabilities is measured not only in dollars but also in occasional patient harm. The potential for harm is high in the intensive care unit (ICU), where very sick patients are subjected to intense management. Nevertheless, although complications of care have been studied in several settings,[2-5] there are no data[6] on the incidence and significance of such complications in the ICU. According to a National Institutes of Health Consensus Development Conference Statement, "This gap in our knowledge contributes substantially to our uncertainty about the effectiveness of ICU care."[7]

Intensive care is an expensive and limited resource. Patients, families, and physicians must often decide whether an individual is likely to benefit from such care. These decisions are best made when the particular circumstances of the clinical situation are considered in the context of objective information on the risks and benefits of ICU care.

The purpose of the present study was to document the frequency and nature of complications of care in a medical intensive care unit (MICU). It was not our intention to make a detailed study of the complications associated with any particular intervention, since most invasive procedures typically performed in ICUs have been studied extensively. Rather, we sought to provide an overview of the range of complications encountered in a MICU, their severity, and impact on outcome. These study questions and the study design and definitions outlined below were explicitly formulated prior to the study's inception.

METHODS

Data on 325 consecutive admissions to the MICU at the Boston Veterans Administration Medical Center (BVAMC) were collected between December 1984 and October 1985. The BVAMC is an acute care teaching hospital and a tertiary referral center within the VA system. The seven-bed MICU cares mostly for acute nonsurgical, noncardiac cases, with occasional overflow from the four other intensive care sites in the hospital. The MICU was staffed by a senior resident, a junior resident, and an intern under the supervision of a member of the full-time attending staff. The attending staff was composed of general internists and pulmonary, renal, and infectious disease subspecialists, each of whom attended in the MICU one to three months a year. During their month in the MICU, the attending physicians did not concurrently attend on the general wards. The nurse-to-patient ratio in the unit was maintained at no less than one to two.

Data Collection

All patients were followed until death or hospital discharge. Initial information on each patient was abstracted from the chart onto standardized forms within 48 hours of admission. Charts were then reviewed every one to two days during the patient's ICU stay for evidence of a complication and again, for outcome information, following death or hospital discharge. Only incidents documented in the medical record were included. All physician and nurse progress notes, order sheets, and consultant notes were routinely reviewed. Other data (e.g., flow sheets, laboratory data, medication sheets) were reviewed as necessary. The nature of the incident and the time of its occurrence (where applicable) were recorded.

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Definitions

Severity of illness was measured with the Acute Physiology Score of the APACHE II severity of illness index[8] using data obtained during the first 24 hours of the ICU stay. Patients were considered smokers if they had at least a ten-pack-year smoking history by self report. Alcohol abuse was considered present if any of the following was noted: history of delirium tremens or alcohol withdrawal seizures; alcohol consumption of at least 80 grams per day; alcohol abuse listed as a problem in the chart. The indication for ICU admission was defined as the single most important reason prompting ICU admission as recorded in the senior resident's admitting note. Indications for admission were categorized as active interventions (including, for example, mechanical ventilation, emergency dialysis) or observation (including ECG monitoring).

Definitions of Complications

A complication was defined as an unintended, harmful occurrence or condition resulting from a diagnostic, prophylactic, or therapeutic intervention or an accidental injury occurring in the hospital setting. Excluded were the following: psychological reactions to hospitalization; functional deterioration resulting from hospitalization; hospital-acquired infections not directly related to an invasive procedure.

The probability that an observed adverse outcome was caused by a particular intervention or drug was graded definite or probable according to criteria modified from Karch and Lasagna.[9] *Non-drug-associated complications* were categorized as *definite* if 1) the reaction constituted a known response to the intervention; 2) the reaction occurred in appropriate temporal relation to the intervention; and 3) no other reasonable explanation for the reaction was apparent; and *probable* if 1 and 2 were present but a competing, although less likely, explanation for the complication was also present. *Drug-associated complications* were categorized as *definite* if 1) the reaction constituted a known response to the drug; 2) the reaction occurred in appropriate temporal relation to the drug administration; 3) no other reasonable explanation for the reaction was apparent; and 4) the reaction subsided with removal of the offending agent; and *probable* if 1, 2, and 4 were present but a competing, although less likely, explanation for the complication was also present. Other suspicious episodes not meeting these criteria were not included.

The frequently observed complications were defined as follows:

Intravascular catheter-associated sepsis was diagnosed if one or more blood cultures was positive; the catheter tip was culture-positive or local inflammation was evident at the insertion site; no other source for bacteremia was apparent; and the clinical picture was consistent with sepsis.

Intravascular catheter-associated local inflammation was diagnosed by any combination of erythema, induration, increased warmth, or pus at the insertion site without evidence of systemic sepsis (as defined above).

Catheter-associated urinary tract infection (UTI) was considered present if a patient with an indwelling urinary catheter developed new-onset bacteriuria (or funguria) associated with either clinical signs (fever, leukocytosis) or pyuria and received antibiotics for it.

Catheter-associated UTI with sepsis was defined as a UTI (as above) associated with blood cultures growing the same organism cultured from the urine with a clinical picture consistent with sepsis.

Drug-associated hypotension was diagnosed when the criteria for an adverse drug reaction were met and the systolic blood pressure fell by more than 20 points to below 100 mm Hg.

Heparin-associated thrombocytopenia was diagnosed when the criteria for an adverse drug reaction were met, the platelet count dropped from more than $150{,}000/mm^3$ to less than $100{,}000/mm^3$ on at least two occasions, and the platelet count returned to normal upon discontinuation of the heparin.

All events were classified as either serious (including fatal, life-threatening, resulting in substantial morbidity, resulting in disability prior to death or at discharge, or requiring ICU-level intervention) or minor (resulting in no substantial morbidity, or requiring routine or no therapy). All cases in which a complication was thought to have contributed to mortality ($n = 4$) were reviewed by a physician not connected with the study, who concurred with the initial assessments.

Statistical Methods

Statistical analyses were performed at the Boston University Computer Center with the Statistical Analysis System (SAS Institute, Inc., Cary, North Carolina). Nonpaired Student's t-tests were used for comparison of means and chi-square tests for association between categorical data. Nonparametric data (lengths of stay) were assessed with the Wilcoxon rank sum test. Multiple logistic regression was used to assess the effect of age on risk of complications independent of illness severity. Expected in-hospital mortality rates were calculated for each group (those with and without complications) using the APACHE II risk equation.[8] We then used a z statistic to compare the differences between the observed and the expected death rates under the hypothesis that each observation is an independent Bernoulli trial with known probability of success. All p values were two-tailed.

This project was approved by the Human Studies Subcommittee of the Research and Development Committee at the BVAMC.

TABLE 1

Complications of Care

	Complications* ($n = 58$)
Vascular catheter ($n = 18$)	
Local inflammation	7
Arrhythmia (pulmonary artery line)	6
Systemic sepsis	4
Thrombosis	1
Mechanical ventilation ($n = 12$)	
Intubation	
Local trauma	5
Selective bronchial intubation	1
Esophageal intubation	1
Aspiration pneumonitis	1
Barotrauma	3
Alarm failure	1
Medications ($n = 11$)	
Adverse drug reactions	
Heparin	5
Oxacillin	1
Phenytoin	1
Bretyllium	1
Digoxin	1
Excessive dose	2
Nasogastric intubation/UGI endoscopy ($n = 4$)	
Cardiopulmonary arrest	2
Atelectasis	1
Nasal trauma	1
Urinary catheter ($n = 4$)	
Simple urinary tract infection	3
Urosepsis	1
Other ($n = 9$)	
Febrile reaction to blood	2
Decubitus ulcers	2
Dye-induced acute renal failure	1
Flail chest following CPR	1
Fall	1
Bowel perforation associated with paracentesis	1
Cerebrovascular accident following carotid sinus massage	1

*Of the 58 events, 45 were graded definite and 13 probable. The probable events included: five central line arrhythmias; one barotrauma; two UGI endoscopy-associated cardiopulmonary arrests; oxacillin (1), bretyllium (1), and digoxin (1) reactions; one aspiration pneumonia; and one bowel perforation.

RESULTS

There were 325 admissions to the MICU among 295 patients during the ten-month study period. Forty-two of these patients (14%, 95% confidence interval 13%, 16%) experienced one or more complications in the MICU. A total of 58 complications were documented in these 42 patients. Thirty-four of the complications (59%) were considered minor and 24 (41%) serious. Forty-five events (78%) were judged definite and 13 (22%) probable. Overall, 22 of 295 patients (8%) suffered a serious complication in the MICU. There was no appreciable clustering of incidents either by time of day, day of week, or month of year. The complications are listed in Table 1 and described below.

Vascular Catheters

Complications associated with vascular catheters were the most frequent. In addition to local inflammation at the insertion site (seven), there were six episodes of pulmonary artery catheter-associated arrhythmias (one supraventricular tachycardia requiring electrical cardioversion and five ventricular tachycardias), four episodes of systemic sepsis, and one episode of arterial line-associated thrombosis. Overall, eight of 84 pulmonary artery catheterizations (10%) resulted in complications (six arrhythmias and two sepsis), and three of 238 arterial lines (2%) resulted in complications (single occurrences of thrombosis, local inflammation, and sepsis).

Of the six episodes of pulmonary artery catheter-associated arrhythmia, five occurred in persons with other risk factors for ectopy (e.g., dilated congestive cardiomyopathy, aminophylline toxicity). Four of the six episodes required intravenous antiarrhythmic therapy or electrical cardioversion but none resulted in any clinically significant sequela.

Of the four episodes of systemic sepsis, two were considered to have contributed to mortality. One patient, in whom fever developed five days after placement of a Swan-Ganz catheter, eventually died from sepsis after *Staphylococcus aureus* was grown both in blood culture and in material from the catheter tip. The findings were confirmed at autopsy. A second patient became febrile and hypotensive four days after placement of a Swan-Ganz catheter. He died of refractory hypotension that was thought to be secondary to either sepsis or end-stage congestive heart failure. Catheter tip and blood cultures subsequently grew *Serratia marcescens.*

Mechanical Ventilation

Among 122 courses of mechanical ventilation, there were 12 documented complications (10%), including eight related to intubation, three secondary to barotrauma, and one due to equipment failure. Four of these 12 episodes were considered serious. One patient suffered a pneumothorax that occurred with high levels of positive end-expiratory pressure and necessitated emergency chest tube insertion. A traumatic intubation resulted in aspiration of gastric contents with subsequent pneumonia. An accidental disconnection from the ventilator resulted in hypoxia with subsequent temporary mental status changes. Finally, an unrecognized esophageal intubation in a ventilator-dependent patient resulted in respiratory arrest and eventual death.

Medication

There were 11 complications attributable to medication. Heparin was the most frequent offender, causing four episodes of thrombocytopenia (only one of

which was complicated by overt bleeding) and one episode of bleeding from multiple sites without associated thrombocytopenia. In neither patient was heparin-associated bleeding severe. Other adverse effects from medications included single episodes of hypotension from intravenous phenytoin and bretyllium, ventricular ectopy from digoxin, and oxacillin-associated rash. In addition there were two patients who received excessive doses of drugs. In one, dobutamine resulted in transitory hypotension, and in the other, insulin led to symptomatic hypoglycemia (blood glucose of 43 mg/dl associated with diaphoresis and lightheadedness). None of these incidents resulted in serious morbidity.

Other

An additional 17 incidents, seven of which were considered serious, are listed in Table 1. Of note were two episodes of cardiorespiratory arrest associated with emergency upper gastrointestinal endoscopy. In both cases aspiration during the procedure was thought to have been the precipitating event. One patient could not be resuscitated and the other died several days later of massive gastrointestinal bleeding. This represents a complication rate of 6% (2/31) for emergency upper gastrointestinal endoscopies performed in the MICU.

The two episodes of febrile reactions to blood transfusions (in one case a temperature of 105°F with shaking chills and in the other a temperature of 102.6°F with a drop in blood pressure to 90/60 mm Hg) represent a 0.3% incidence of such reactions (2/750 units transfused).

TABLE 2

Characteristics on Admission to the MICU of Patients with and without Complications

	Group with Complications ($n = 42$)	Group without Complications ($n = 253$)
Age (mean ± SD)*	63.6 ± 10.1 years	59.3 ± 14.0 years
Sex (male)	42 (100%)	247 (98%)
Race		
White	30 (71%)	205 (81%)
Black	12 (29%)	41 (16%)
Other	0	7 (3%)
Pre-hospital residence†		
Home	35 (83%)	190 (76%)
Nursing home	1 (2%)	15 (6%)
Other	6 (15%)	44 (18%)
Smoking history	28 (76%)	174 (76%)
Excessive alcohol use	27 (68%)	134 (56%)
Indication for admission‡		
Observation only	12 (29%)	137 (54%)
Active intervention	30 (71%)	116 (46%)
Acute Physiology Score§ (mean ± SD)	18.3 ± 8.0	12.5 ± 8.0

*$p < 0.02$.
†Data missing on four patients in group without complications.
‡$p = 0.002$.
§$p = 0.001$; other differences not significant.

TABLE 3

MICU Admission Diagnoses for Patients with and without Complications*

	Group with Complications ($n = 42$)	Group without Complications ($n = 253$)
Respiratory insufficiency	14 (33%)	59 (23%)
Acute cardiac disease	8 (19%)	45 (18%)
Upper gastrointestinal bleeding	7 (17%)	23 (9%)
Sepsis	5 (12%)	19 (8%)
Drug overdose	1 (2%)	30 (12%)
Chest pain to rule out myocardial infarction	0	28 (11%)
Other	7 (17%)	49 (19%)
Total	42 (100%)	253 (100%)

*Chi-square = 12.2, $p = 0.06$.

TABLE 4

MICU and Hospital Lengths of Stay for Patients with and without Complications

	Group with Complications ($n = 42$) (Days)	Group without Complications ($n = 253$) (Days)
In MICU		
Mean ± SD*	12.3 ± 14.7	3.1 ± 4
Range	1–63	1–30
In hospital†		
Mean ± SD‡	41 ± 35.7	31.2 ± 43.9
Range	7–149	1–391

*$p < 0.0001$ by the Wilcoxon rank sum test.
†Based on 41 patients in the group with complications and 251 patients in the group without complications.
‡$p < 0.002$ by the Wilcoxon rank sum test.

Comparative Data

MICU patients who experienced complications are compared with the group of MICU patients without such complications in Tables 2 through 4. On admission to the MICU, the two groups were comparable with respect to sex, race, pre-hospital residence, and smoking and alcohol history (Table 2). The group with complications was significantly older (63.6 ± 10.1 years vs 59.3 ± 14.0 years, $p < 0.02$), more acutely ill (Acute Physiology Score: 18.3 ± 8 vs 12.5 ± 8, $p < 0.0001$), and more likely to have been admitted to the unit for active intervention (71% vs 46%, $p < 0.002$). When we controlled for severity of illness with logistic regression, however, age was not independently associated with risk of complications.

There was a higher percentage of patients with upper gastrointestinal bleeding in the group with complications (17% vs 9%) (Table 3). No patient with chest pain admitted for exclusion of myocardial infarction

and only one patient with a drug overdose experienced a complication of care in the unit.

Mean MICU length of stay was nearly four times longer in the group with complications, (12.3 days) than in the group without complications (3.1 days) (Table 4). Mean MICU length of stay prior to the event was 3.3 days, indicating that the excess MICU length of stay occurred after the event. Although this suggests that the complication may have led to the longer MICU length of stay, our record review indicated that this was the case for only five patients.

The in-hospital mortality was strikingly higher in the group with complications (28/42, 67%, 95% confidence interval 60%, 73%) compared with that of the group without (68/253, 27%, 95% confidence interval 25%, 29%) ($\chi^2 = 24.2$, $p<0.001$). The expected in-hospital mortality rate for the group without complications based on the APACHE risk equation, which takes into account age, chronic health status, severity of acute illness, and diagnosis, was 27%, identical to the observed rate. In the group with complications, on the other hand, the calculated expected mortality rate was 46%, significantly ($p<0.001$) lower than the observed rate of 67%. This suggests that the high in-hospital mortality in patients with complications cannot be fully explained by age, chronic health status, severity of acute illness, and diagnosis. On the basis of chart review, complications were thought probably to have contributed to death in four cases.

Nine of the 42 patients (22%) in the group with complications had "do not resuscitate" (DNR) orders written in their charts, and in all cases, this decision was made at some point after the event. In other words, no patient with a DNR order subsequently experienced a complication in the MICU. Only 23 of 253 patients in the group without complications (9%) had a DNR order written at any time during their hospitalization.

DISCUSSION

This study documents a 14% frequency of complications of care in patients hospitalized in a MICU. The proportion of serious complications in this population was 8%. Our estimate is undoubtedly a conservative one. We specifically excluded certain categories of complications (e.g., psychological and functional deterioration, non-procedure-related nosocomial infections). In addition, our criteria for inclusion were strict. Many suggestive occurrences were noted but not included because they failed to meet the predetermined criteria. Finally, it is likely that some events were not documented in the chart and thus were not included in this study.

The generalizability of this study's results might be questioned because it was performed in a VA hospital. However, as we have noted before,[10] our ICU appears to fall within the spectrum of ICUs described in the literature with respect to average length of unit stay, severity of illness on admission to the unit, proportion of patients requiring active treatment, unit and hospital mortality, and readmission rates.

The only other study we were able to find that specifically looked at adverse occurrences in the adult ICU was a retrospective survey of incident reports filed in a medical-surgical ICU.[6] In that study, 1.5% of patients experienced harmful events. A retrospective study based on formal incident reports is likely to underestimate the true incidence of untoward events. Others have found rates of complications from 20% to 45% in general hospital populations, with the higher figures coming from studies focusing on older patients.[2-4, 11, 12] Most of the adverse events in these series, as in the present study, were minor.

Vascular catheters, mechanical ventilation, and medications were responsible for 41 of the 58 episodes (71%). Specific complication rates (e.g., complications associated with pulmonary artery catheters,[13-17] intubation and mechanical ventilation,[18-20] and arterial lines[14, 15, 21]) were similar to those reported in the literature. Thus, although no comparable data on the overall incidence of complications in the ICU are available, the comparability of our specific complication rates with other series suggests that our ICU is not atypical. It also suggests that our methodology, consisting of periodic, concurrent chart review, reliably identified most complications.

The patients who experienced complications in this series were older and more acutely ill than were the other ICU patients. The greater vulnerability of elderly patients to such complications has been noted by others.[3, 4, 11, 12] It is not clear whether age itself is a risk factor or merely a marker for illness severity. Steel et al.[3] found that age was not an independent risk factor when illness severity and source of admission (i.e., home versus other hospital or nursing home) were taken into account. Jahnigen et al.,[4] on the other hand, reported that among medical service patients, age was positively associated with complications independent of disease severity. In the present study, we were unable to show an independent contribution of age to risk of complications when severity of illness was adjusted for in the analysis.

Mortality, ICU length of stay, and total hospital length of stay were all greater in the patients who experienced complications, as has been noted by others.[2, 3] By comparing observed with expected mortality rates (the latter calculated by the APACHE risk equation), we were able to show that the increased mortality in the group with complications was independent of age, chronic health status, severity of acute illness, and diagnosis. It seems likely, therefore, that complications occurring in the MICU contributed independently to increased mortality.

Efforts to minimize complications of care should be vigorously pursued. These may include monitoring and review activities, educational programs, provision

of adequate staffing, and institution of practical guidelines for specific procedures. Nevertheless, even with such efforts, it must be recognized that complications of care will continue to occur. Certain complications are not preventable (e.g., idiosyncratic drug reactions). Others that are at least theoretically preventable (e.g., catheter-associated sepsis) will never be completely eliminated given the complexity of the hospital environment, the severity of disease seen in the ICU, the unpredictability of machine function, and the human fallibility of the staff.

The benefits of ICU care are difficult to quantify and have been the subject of considerable interest,[22] particularly in relation to cost saving. The data presented here do not provide any insight into the relative risks and benefits of an ICU stay since benefit was not assessed. They do make clear, however, that complications of care in this setting are not rare. Patients, families, and attending physicians must recognize that when a patient is admitted to an ICU, the "technological imperative" becomes operative. Because the ICU is designed to monitor exhaustively and respond aggressively, patients are often subjected to invasive interventions, and these are often more extensive than originally anticipated. That such interventions carry an appreciable risk of complications is documented in this study and should be borne in mind by all involved in decisions about ICU care.

The authors acknowledge the excellent suggestions made by Drs. B. Graeme Fincke, Jeffrey B. Rubins, and Gordon L. Snider, and thank Drs. Fincke and Stephan A. Gaehde for record review assistance and Dr. Arlene Ash, for statistical advice.

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