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Complications of care in a pediatric intensive care unit: a prospective study

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Abstract *Objectives:* (a) To examine the frequency, type, and severity of complications occurring in a pediatric intensive care unit; (b) to identify populations at risk; and (c) to study the impact of complications on morbidity and mortality.
Design: Prospective survey.
Setting: Pediatric intensive care unit (PICU) of a university-affiliated hospital.
Patients: 1035 consecutive admissions over an 18-month period.
Results: 115 complications occurred during 83 (8.0%) admissions, for 2.7 complications per 100 PICU-days; 48 (42%) complications were major, 45 (39%) moderate, and 22 (19%) minor. Sixty complications (52%) were ventilator-related, 14 were drug-related, 13 procedure-related, 24 infectious, and 22 involved invasive devices (18 vascular catheters). Human error was involved in 41 (36%) cases, 21 of which were major (18%). Treatments included reintubation < 24 h (28), intravenous antimicrobials (24), and invasive bedside procedures (14). Cardiopulmonary resuscitation was required in 6 patients. Thirteen patients with complications died (15.7%); 2 deaths were directly due to complications.

Patients with complications were younger, had longer lengths of stay, and had a higher mortality. Length of stay was a positive risk factor for complication risk (odds ratio = 1.09, 95% confidence interval: 1.05 to 1.13; $p = 0.0001$); other patient characteristics had no predictive effect. Kaplan–Meier estimates showed that the most severe complications occurred early in the PICU stay. The best indicators of patient mortality were number of complications (odds ratio = 2.96, 95% confidence interval 1.72 to 5.08; $p = 0.0001$), and mortality risk derived from the Pediatric Risk of Mortality Score (odds ratio = 1.08, 95% confidence interval 1.06 to 1.10; $p = 0.0001$). Mortality was correlated with increasing severity of complications.
Conclusion: Complications have a significant impact on patient care. Patients may be at increased risk earlier in their PICU course, when the number of interventions may be greatest. Complications may increase patient mortality and predict patient death better than other patient variables.

Key words Pediatric critical care · Complications · Iatrogenic illness · Intensive care unit · Quality improvement

Introduction

First described by Barr [1] and Moser [2], complications of medical care have been shown to be an important cause of morbidity and mortality in hospitalized patients [3, 4]. This may be especially true in the intensive care unit (ICU). Abramson et al. [5] first reported complications occurring in ICU patients in 1980. Since then, investigators have shown increased mortality in ICU patients with complications, independent of age, acute illness, or chronic health [6, 7].

While complications as a cause for pediatric ICU admission have previously been evaluated [8], there have been no surveys of all complications occurring after PICU admission – their frequency, type, severity – nor their consequences, similar to those for adult ICUs. Can the adult experience be extrapolated to pediatric practice? Differences in the delivery of medical care between adult and pediatric ICUs [8, 9] may make any assumptions suspect. As the quality of medical care comes under greater scrutiny [10], the need for data specific to pediatrics becomes paramount.

The goals of this study were to examine the frequency, type, and severity of complications in PICU patients; the therapies needed to treat them; and their long-term effects, including mortality. We also sought to determine associations that might identify populations at risk.

Patients and methods

All patients admitted to the PICU of North Shore University Hospital between 1 January 1992 and 30 June 1993 were eligible for the study. The hospital is a pediatric tertiary care referral center on Long Island.

PICU description

The PICU is a multidisciplinary unit caring for patients from birth to 18 years of age. From 1 January 1992 to 15 December 1992 the PICU had a 10-bed capacity. After that time, PICU capacity was enlarged to 15 beds. Patients are referred from the emergency department, the operating suite, the general pediatric wards, and from other health care facilities in the region. In general, 40% of the patients are referred by the cardiology and cardiac surgery services, 20% by other surgical services, and 40% by other medical services. Patients not cared for at this center include those requiring solid organ transplantation, extracorporeal membrane oxygenation, and repair of hypoplastic left heart syndrome (Norwood procedure). Premature infants are routinely cared for in a separate neonatal ICU and were not included in this study.

Patient care was managed by the PICU care team. The team included two senior pediatric house officers, supervised by an attending pediatric intensivist. Night coverage was provided by rotating housestaff, so that dedicated physician coverage was available in the PICU 24 h/day. Nurse:patient staffing ratios varied from 1:1 to 1:2.

Patient data

Consecutive admissions to the PICU were evaluated. Descriptive data recorded included age, sex, diagnosis, operative status, emergency/elective admission status, and admission Pediatric Risk of Mortality (PRISM) score [11], which was used to calculate mortality risk. Data recorded while patients were in the PICU included length of stay, the occurrence of a complication, its severity and therapy required, and patient survival to PICU discharge.

Data were recorded by the authors on a daily basis, and the PICU care team and nursing staff were questioned about the occurrence of complications, which were then reviewed.

Complications of care

A complication of care was defined as an unexpected, adverse condition that occurred as a result of medical therapy and was independent of the patient's underlying disease or condition [8]. This may be secondary to either drugs or a medical–surgical act. Chronic complications were defined as those that required treatment for > 30 days after the precipitating event [8].

A drug-induced complication (a) followed an appropriate temporal sequence for a known complication of that drug and (b) was inconsistent with other clinical conditions of the patient at that time. A complication of a medical or surgical action (a) followed an appropriate temporal sequence for a known but unexpected complication of the action and (b) was inconsistent with the patient's clinical state just before the action. Sequelae of drugs or medical–surgical actions that routinely occur in a well-established clinical sequence (such as hypokalemia after diuretic use or respiratory failure after open-heart surgery) were excluded [8].

Infectious complications of invasive devices were considered to have occurred if medical management was altered. Criteria considered by the PICU care team in making the clinical diagnoses included: 1. Catheter-related infection: temperature $> 38°$, leukocytosis, one or more positive body-fluid cultures, culture-positive catheter tip, local inflammation at the insertion site, and/or no other apparent source of infection. 2. Ventilator-related infection: new radiologic infiltrate on chest radiograph, purulent endotracheal secretions with organisms and leukocytes seen on Gram stain, temperature $> 38°$, potential pathogenic organisms cultured from tracheal aspirate, and/or deterioration in patient's respiratory status. 3. Wound infection: temperature $> 38°$, local inflammation, and/or positive culture of the site.

If a patient's clinical condition changed in a manner consistent with a complication, based on the criteria above, a complication of care was considered to have occurred. This approach emphasized clinical decision making. All patient management decisions were made by the PICU care team, independent of this study.

Complication severity was classified as major, moderate, or minor. A major complication was defined as life-threatening and/or requiring therapy specific to the PICU [12]; a moderate complication required routine therapy, available outside the PICU; and a minor complication resolved spontaneously.

Human errors were defined according Cooper et al. [13] and included technical errors, judgmental errors, and monitoring or vigilance failures. Classification of a patient's condition or an event as a complication of care should not be taken as an indication that there was negligence, or a deviation from an acceptable standard of medical care [4, 8, 14].

Statistical methods

Comparisons of proportions of complications (presence vs absence, or none vs minor vs moderate vs major) and survival (yes vs no) with other categorical variables – for example, iatrogenic admissions or operative status – were made using the chi-square test for proportions or Fisher's Exact test, where appropriate. Comparisons based on the complications groupings and survival status for continuous variables, such as length of stay, probability of mortality, and age, were made using Mann–Whitney tests (for two groups) or Kruskal–Wallis tests (for the four-group complications grouping). In cases where the Kruskal–Wallis test was significant, pairwise Mann–Whitney tests were used for post hoc comparisons. Multiple logistic regression models were used to examine the risk of complication or death based on the admission variables and PICU length of stay. Kaplan–Meier estimates were used to estimate the time until first (or subsequent) complication. Comparisons of the distributions of time until complications for the degree of complication groupings were made using the log rank test.

Results

Data were collected on 1035 consecutive PICU admissions and 4266 days of PICU care (range 1–356). Mechanical ventilation was used on 398 patients, for 2044 ventilator-days (range 1–87).

PICU complications

We recorded 115 complications of care in 83 (8.0%) patient admissions, an incidence of 2.7 complications per 100 PICU-days. Sixty-two admissions had one complication, 14 had two complications, 4 had three complications, 2 had four complications, and 1 had five recorded complications.

Forty-eight complications (42%) were classified as major, 45 (39%) as moderate, and 22 (19%) as minor. Characteristics of these patient groups are shown in Table 1. There were no differences between groups with respect to sex, operative status, or emergency/elective admission status. However, patients with complications were younger and had longer lengths of stay in the PICU than patients without complications. The distribution of predicted mortality, derived from the admission PRISM score, was higher for each subgroup of patients with complications than for the group without complications ("None") ($p = 0.0001$). Similarly, the observed mortality was significantly different between these same groups ($p = 0.0001$).

The types of complications are shown in Table 2. Over half were ventilator-related (60 of 115). Accidental extubations occurred a total of 29 times, in 26 patients, for a frequency of 1.4 accidental extubations per 100 ventilator-days. Other complications occurred as outlined.

Forty-one (36%) complications involved human error (Table 3). Among these, accidental extubations were by far the most common, accounting for 19 of 21 major, or life-threatening, events.

Table 1 Characteristics of patients admitted during the study. The patients are divided into groups based on the most severe complication that occurred (*PRISM* Pediatric Risk of Mortality)

Category	All	Complication severity				All complications
		None	Major	Moderate	Minor	
No. of admissions	1035	952	43	27	13	83
Age (years) (median and interquartile range)	2.7 (0.7–9.1)	2.8 (0.8–9.3)	1.1 (0.3–5.7)	0.7 (0.1–5.9)*	2.3 (0.7–8.4)*	0.9 (0.3–6.8)*
Sex						
Male (%)	600 (58)	549 (58)	29 (67)	15 (56)	7 (54)	51 (61)
Female (%)	435 (42)	403 (42)	14 (33)	12 (44)	6 (46)	32 (29)
Operative status						
Postoperative (%)	398 (38)	366 (38)	15 (35)	11 (41)	6 (46)	32 (39)
Nonoperative (%)	637 (62)	586 (62)	28 (65)	16 (59)	7 (54)	51 (61)
Admission status						
Emergency (%)	685 (66)	630 (66)	30 (70)	16 (59)	9 (69)	55 (66)
Elective (%)	350 (34)	322 (34)	13 (30)	11 (41)	4 (31)	28 (34)
PICU days (median and interquartile range)	2 (1–5)	2 (1–4)	13 (7–28)**	13 (5–22)**	5 (4–13)**	12 (5–22)**
Mortality risk (derived from PRISM) (median and interquartile range)	0.010 (0.006–0.025)	0.009 (0.005–0.023)	0.018** (0.008–0.061)	0.020** (0.008–0.090)	0.034** (0.022–0.109)	0.022** (0.008–0.075)
Deaths (%)	39 (3.8)	26 (2.7)	8 (19)**	3 (11)**	2 (18)**	13 (16)**

*$p = 0.005$, compared to "none"; **$p = 0.0001$, compared to "none"

Table 2 Types of complications

	No.[a]
Ventilator-related	60
Accidental extubations	29
Barotrauma[b]	10
Postextubation stridor[c]	8
Infections	7
Failed extubations (< 24 h)	4
Mucus plugging/atelectasis	2
Infections	24
Invasive devices	22
Vascular catheters	18
Drug-related	14
Procedure-related (medical–surgical)	13

[a] The sum is greater than the total number of complications because some complications fall into more than one category, e.g., infection of a vascular catheter
[b] Air-leak syndrome, e.g., pneumothorax, pneumomediastinum, etc.
[c] Requiring therapy

Table 3 Human errors

	No.	Major	Moderate/ minor
Accidental extubations	29	19	10
Medication error	4	0	4
Intravenous fluid error	3	1	2
Invasive device dislodged from patient	4	0	4
Procedure-related	1	1	–
Total	41	21	20

Seasonal variations in the frequency of complications were assessed on a quarterly basis, and compared to PICU mortality. No differences were seen. There were no instances of equipment failure causing a complication of care.

Risk factors for PICU complications

We studied the effect that admission variables and PICU length of stay had on placing patients at risk for complications by performing stepwise multiple logistic regression analysis (Table 4). The only significant finding was that complication risk was positively correlated with PICU day-number (odds ratio 1.09, 95% confidence interval 1.05 to 1.13; $p = 0.0001$).

To further examine the relationship between PICU-days and complications, in those patients who developed a complication, we studied the severity of a complication and the time until it developed. Kaplan–Meier estimates of time until first complication demonstrated that they occurred relatively early in the patients' PICU course. The median time from PICU admission until first complication was 3.5 days for a major complication, 7 days for a moderate complication, and 2 days for a minor complication. There were no significant differences in times between any of the severity groups.

Table 4 Predictors for the occurrence of a complication

Predictor	Odds ratio	95% confidence interval	*p*-value
Age	0.97	0.92 to 1.01	0.17
Sex	0.91	0.55 to 1.46	0.71
Mortality risk	1.01	0.996 to 1.02	0.16
PICU days[a]	1.09	1.05 to 1.13	0.0001
Emergency/elective admission	0.94	0.49 to 1.80	0.85
Operative status	1.08	0.57 to 2.02	0.82

[a] Time until first complication, or PICU discharge for patients without complications

Therapy and outcome

Airway management and respiratory support were frequently required. Reintubation in less than 24 h was required in 28 cases (including 19 patients who self-extubated), and emergent nebulizer treatments and pulmonary toilet was required in 14. Other treatments included intravenous antimicrobials (24), invasive procedures (14), other intravenous therapy (10), surgery (6), mechanical ventilation (4), inotropic support (2), and hemodialysis (1). Cardiopulmonary resuscitation was required in 6 patients – in 2 during emergency reintubation following accidental extubation, in 2 with severe lung disease and barotrauma during chest tube placement, in 1 following an inadvertent intravenous potassium bolus, and in 1 after cardiac catheterization, involving balloon valvuloplasty of the main pulmonary artery (this child died).

Chronic therapy was required by 5 patients. Treatments included pacemaker insertion (3), chronic rehabilitation therapy (1), and tracheostomy (1).

Thirteen patients who suffered a complication in the PICU died, 2 as a direct consequence of it. One child was status-post cardiac catheterization (described above). The other was an infant with congenital heart disease who had cardiopulmonary arrest, developed severe pneumonitis postresuscitation, and subsequent ventilator-related barotrauma with pneumothoraces.

Table 5 Indicators of patient mortality

Predictor	Odds ratio	95% confidence interval	*p*-value
Mortality risk[a]	1.08	1.06 to 1.10	0.0001
PICU days	0.995	0.98 to 1.01	0.581
No. of complications	2.96	1.72 to 5.08	0.0001
Age	1.05	0.97 to 1.12	0.221
Operative status	0.73	0.27 to 1.95	0.535
Sex	1.73	0.74 to 4.09	0.210

[a] Derived from PRISM

We examined the impact of explanatory variables, especially complications, on mortality probability. The results of multiple logistic regression analysis are shown in Table 5. While the PRISM-derived mortality risk was a significant indicator, the risk of PICU death was about threefold higher for patients who had complications than for those who did not (odds-ratio 2.96, 95% confidence interval 1.72 to 5.08, $p = 0.0001$). Mortality was also associated with increasing severity, and not merely number, of complications ($p = 0.0001$; data not shown).

Discussion

We found that complications of care afflicted 8% of patients admitted to our PICU and occurred with a frequency of 2.7 complications per 100 PICU-days. This contrasts with previously reported complication rates of 14% for Rubins and Moskowitz [6] and 31% for Giraud et al. [7]. Neither group reported complication frequency; however, one may calculate it from their data: 4.5 [6] and 10.0 [7] per 100 ICU-days. While this may reflect differences in care between pediatric and adult medicine, another explanation may lie in the difference between the two populations. It has been suggested that pediatricians require less physiologic dysfunction to admit their patients to an ICU than is the case with adults [9]. PICUs might then contain a greater proportion of low-risk, monitored patients, requiring fewer interventions, who would be at less risk for complications compared to adult patients.

Patients with complications had greater lengths of stay, in agreement with the reports of others [3, 4, 6, 7]. However, we found that the more severe complications occurred early in patients' PICU stay. While the cumulative risk for certain incidents may increase over time – for example, catheter-related sepsis, or minor types of complications – we suggest that it is the greater frequency of therapeutic interventions and diagnostic testing that patients undergo at earlier points in their PICU course that determines their risk of serious mishap. Length of stay would then be a consequence of new, PICU-acquired morbidities, rather than an independent factor. Consistent with this hypothesis is the inability of PRISM, which does not measure interventions or PICU resource utilization, to predict complication risk. The Therapeutic Intervention Scoring System [15] may prove to be a more useful tool in this regard.

Many complications involved the airways and respiratory tract management, particularly in younger patients. This should not be surprising considering the vital role that respiratory care plays in pediatrics. Previous authors have documented various respiratory complications in pediatric critical care, including barotrauma, mucus plugging, infections, postextubation stridor, and accidental extubations [16–19]. Our rate of 1.4 accidental extubations per 100 ventilator-days compares favorably with published series [18, 19].

As a group, patients who suffered complications required aggressive treatment. Beyond the acute setting is the effect that complications have on long-term outcome. Five patients required chronic therapy, including surgery, and 13 others died. Our analysis showed that the number and severity of complications were significant risk factors for mortality. Previously, Giraud et al. [7] found the severity-adjusted mortality risk to be twice as great for patients with complications than for those without, though they were unable to show any effect of increasing complication number. Ferraris and Propp [20] have even suggested that patient outcome may be most dependent on ICU complications, rather than admission variables or severity of illness.

It is important to realize that the occurrence of a complication does not in itself imply negligence or a deviation from an acceptable standard of care [4, 8, 14, 21]. Studies documenting the known risks of drug therapy [22–25] and medical procedures [26–29] abound. Kane [14] has classified iatrogenic illness into four categories: conscious risk, unexpected complications, inept care, and overzealous care. A complication that occurs after a drug is correctly prescribed and monitored, or after an indicated procedure has been correctly performed, would be an example of conscious risk, or unexpected complication, but not negligence. Brennan et al. [21] have shown that the occurrence of adverse events does not correlate with the quality of care and that certain medical specialties may be expected to have higher risks for complications.

Human error was involved in one-third of our complications. This compares with the findings of Abramson et al. [5], who reported that 63% of their "adverse occurrences" were due to human error, and Giraud et al. [7], who found they accounted for half of their

complications. We described our complications according to the method of Cooper et al. [13], who divided them into three categories: technical errors, judgmental errors, and monitoring or vigilance failures. Some events, such as accidental extubations, may involve multiple factors. Of concern are suggestions that inexperienced personnel contribute to complications [5, 30]. This did not appear to be an issue in our PICU, as we did not see any increased risk of complications during the summer, that early portion of the academic year when resident inexperience is greatest. This may reflect the "hands-on" style of attending coverage employed in our unit.

While complications should not be regarded as acceptable, they may never be completely eliminated. Therefore, efforts should be directed at decreasing morbidity, as well as prevention. The best strategy may be a heightened sense of awareness, especially during procedures or interventions. Monitoring and preparations to treat problems promptly should be emphasized. Our data specifically point to airway support, and to the dangers of invasive devices. The greatest care should be taken with the young. We recommend that medical interventions be viewed not merely in isolation but as significant events in the lives of our patients.

There are limitations to our study. Although this is a multidisciplinary unit, and data were collected on a large number of patients, we may be describing a unique population. However, our PICU's characteristics appear similar to those of other PICUs that have been described [31]. The similarity between our rate of accidental extubations and those of other PICUs [17, 18] also speaks for the generalizability of our data. Another potential limitation involves reporting. The authors surveyed the PICU staff for complications on a regular basis and included incidents only if all clinical authors agreed. While minor complications may have been overlooked, we doubt that this happened for major complications, due to the memorability they tend to provoke.

Complications of care are a serious problem in the PICU. The patient morbidity that results is clearly linked to increased length of stay and greater resource utilization. Some patients die because of complications. The monetary charges that accrue, though difficult to calculate, are substantial [32]. As medicine enters an era marked by quality controls and cost containment [10], the challenge to intensivists will be to maintain that quality, while minimizing the cost to the patient, both financially and medically.

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