Variation of Ventilation Practices With Center Volume After Pediatric Heart Surgery

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ABSTRACT

Background: This study was designed to evaluate the odds of mechanical ventilation and duration of mechanical ventilation after pediatric cardiac surgery across centers of varying center volume using the Virtual PICU Systems database.

Hypothesis: Children receiving cardiac surgery at high-volume centers will be associated with lower odds of mechanical ventilation and shorter duration of mechanical ventilation, compared with low-volume centers.

Methods: Patients age <18 years undergoing operations (with or without cardiopulmonary bypass) for congenital heart disease at one of the participating intensive care units in the Virtual PICU Systems database were included (2009–2013). Logistic regression models and Cox proportional hazards models were fitted for the probability of conventional mechanical ventilation and duration of mechanical ventilation, respectively, to investigate the difference in the outcomes between different center volume groups with/without adjustment for other risk factors.

Results: A total of 10 378 patients from 43 centers qualified for inclusion. Of these, 7648 (74%) patients received conventional mechanical ventilation after cardiac surgery. Higher center volume was significantly associated with lower odds of mechanical ventilation after cardiac surgery (odds ratio: 2.68, 95% confidence interval: 2.15–3.35). However, patients receiving mechanical ventilation in these centers were associated with longer duration of mechanical ventilation, compared with lower-volume centers (hazard ratio: 1.26, 95% confidence interval: 1.16–1.37). This association was most prominent in the lower surgical-risk categories.

Conclusions: Large clinical practice variations were demonstrated for mechanical ventilation following pediatric cardiac surgery among intensive care units of varied center volumes.

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Introduction

Postoperative management of children undergoing congenital heart surgery has improved over the years. Despite such improvement, many children frequently require both unwarranted and prolonged period of mechanical ventilation after cardiac surgery.[1,2] Recognition of children who can be successfully extubated after cardiac surgery is a complex decision-making process. Both patient-related and center-related factors may play a role in this decision. As both unwarranted and prolonged mechanical ventilation following pediatric cardiac surgery is associated with adverse outcomes, there is obvious appeal in any strategy that prevents these complications.[3–5]

Clinical practice variations are common in children undergoing congenital heart surgery.[6–10] It has been suggested that children with similar demographic patterns, comorbidities, and diagnoses undergoing congenital heart surgery receive different levels of care depending on when, where, or by whom they are treated. Some variability may be justified by uncertainty in knowledge, differences in case mix, and need for individualized patient care. Unexplained variability in practice could lead to heterogeneous quality and safety in care of patients.

Several studies have documented a relationship between center volume and mortality after pediatric cardiac surgery.[6–10] None of the existing literature to date has truly compared the volume-outcome relationship with mechanical ventilation after pediatric cardiac surgery as an outcome. To address these knowledge gaps, we undertook this project to evaluate the odds of mechanical ventilation and duration of mechanical ventilation after pediatric cardiac surgery across centers of varying center volume using the Virtual PICU Systems, LLC (VPS) database.

Methods

Data Source

The VPS database is an online pediatric critical-care network formed by NACHRI (National Association of Children's Hospitals and Related Institutions; now part of Children's Hospital Association), Children's Hospital Los Angeles, and Children's Hospital of Wisconsin to develop a Web-based database with prospective data collection using standardized clinical data definitions, data quality control, and data analysis. The VPS database is a prospective observational cohort of consecutive pediatric intensive care unit (ICU) admissions from a diverse set of hospitals caring for children in the United States. Data are collected and entered by trained individuals. Virtual PICU Systems performs initial and quarterly inter-rater reliability testing. The inter-rater reliability concordance in the VPS database is consistently >90%. There is extensive quality validation performed by VPS staff prior to release of the data for analysis, and thus the data have better reliability. The University of Arkansas for Medical Sciences institutional review board for the protection of human subjects reviewed the study protocol and determined that querying de-identified patient data does not fall under the jurisdiction of the institutional review board review process.

Patient Population

This analysis focused on the most recent 5 years (2009–2013) of de-identified data available in the VPS database. Patients age <18 years undergoing operations (with or without cardiopulmonary bypass) for congenital heart disease at one of the participating ICUs in the VPS database were included. Cases were classified on the basis of the first cardiovascular operation of each hospital admission (the index operation). To ensure data integrity, centers with >10% missing data were excluded. We also excluded patients whose operation was not classified into one of the Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery (STS-EACTS) mortality categories (category 1, lowest mortality risk; category 5, highest mortality risk).[11] Patients with "altered code status" were also excluded. Patients receiving high-frequency oscillatory ventilation or jet ventilation were also excluded.

Center volume was defined as average number of cardiac surgery cases per year for each center during the study period. The average annual program volume was calculated by dividing the number of patients receiving cardiac surgery by the number of months that the program participated in the database during the study period and then multiplying by 12. Study centers were grouped into in 3 categories using the center-volume tertiles: low-volume centers (<175 cases/year), medium-volume centers (≥175 to <275 cases/year), and high-volume centers (≥275 cases/year). The categories for center volume were designed to keep similar number of patients in each group. However, as each center is discrete, it was not possible to have exactly equal number of patients in each category. Finally, to explore the nonlinear volume effects, volume was analyzed using restricted cubic splines. Knots for the spline function were placed at 42, 229, and 436 cases per year.

Data on demographics, patient diagnoses, mechanical ventilation (conventional and noninvasive), severity of illness, and outcomes were collected. Specific data collected for demographics and severity of illness included age, sex, developmental disorder, failure to thrive, genetic disorder, low birth weight, pediatric index of morality-2 (PIM-2) score, and pediatric risk of mortality-3 (PRISM-3) score. Data were also collected on the use of extracorporeal membrane oxygenation (ECMO), use of cardiopulmonary bypass for cardiac surgery, heart transplantation, and use of conventional mechanical ventilation (CMV) prior to cardiac surgery. Center characteristics were also collected, including presence of dedicated cardiovascular ICU, annual discharges per center, and annual cardiac surgery cases per year. The unadjusted outcomes evaluated included need for CMV after cardiac surgery, need for noninvasive ventilation after cardiac surgery, duration of CMV, ICU length of stay, and ICU mortality. The specific adjusted outcomes evaluated included variation in odds of mechanical ventilation across centers of varying center volume, and duration of mechanical ventilation.

Statistical Analysis

Descriptive statistics were expressed as median (first quartile, third quartile) for continuous variables, and

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frequency (%) for categorical variables. The distributions of continuous variables were compared among center-volume groups (<175, 175–275, and ≥275) using the Kruskal-Wallis tests, whereas the proportions of categorical variables were compared using the χ^2 tests. Logistic regression models and Cox proportional hazards models were fitted for the probability of conventional mechanical ventilation (binary outcome) and duration of mechanical ventilation (survival outcome), respectively, to investigate the difference in the outcomes between different center-volume groups with/without adjustment for other risk factors.

Variables with a univariate $P < 0.2$ and clinically important a priori variables were selected for multivariable models. Patient-specific variables selected for multivariable models included age at surgery (months), sex, weight for age z-score, PIM-2 score, PRISM-3 score, STS-EACTS mortality risk category, use of cardiopulmonary bypass, heart transplant, use of ECMO, arrhythmias, brain hemorrhage, cardiac arrest, chronic lung disease, chylothorax, development disorder, failure to thrive, heart failure, low birth weight, other cerebrovascular diseases, pulmonary hypertension, renal failure, seizures, and genetic syndromes. Center-specific variables selected for multivariable models included presence of dedicated cardiac ICU, average annual discharges per center, and average annual cardiac surgery cases per center.

Subgroup analysis was performed to evaluate whether the relationship of center volume with outcome differed across varying levels of surgical risk. For this analysis, patients were grouped on the basis of STS-EACTS risk categories (categories 1, 2, and 3 representing low risk and 4 to 5 representing high risk). Both unadjusted and adjusted estimates and 95% confidence intervals are reported. The model's goodness-of-fit was evaluated using the Hosmer-Lemeshow test, and the discrimination of the model was assessed using the area under the receiver operating characteristic curve. The statistical software programs used for analysis were R 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria) and SAS version 9.4 (SAS Institute Inc., Cary, NC). All tests were 2-sided tests at a significance level of 5%. P values < 0.05 were considered to indicate statistical significance.

Results

A total of 10 378 patients from 43 centers were included. Of these, 7648 (74%) patients received CMV after cardiac surgery and 1008 (10%) received noninvasive ventilation after cardiac surgery. The median center volume was 229 cases per year (interquartile range, 96–297 cases per year). There were 36 centers (56%) with <175 cases per year, 4 centers (9%) with 175 to 275 cases per year, and 3 centers (7%) with ≥275 cases per year. Among the study patients, 3657 patients (35%) received treatment in centers with <175 cases per year, 3176 patients (31%) received treatment in centers with 175 to 275 cases per year, and 3545 patients (34%) received treatment in centers with ≥275 cases per year.

Patient characteristics, overall and stratified by volume category, are displayed in Table 1. The majority of the patient characteristics, diagnoses categories, and procedures performed differed among patients in different volume categories. PIM-2 scores were highest among centers with 175 to 275 cases per year. PRISM-3 scores were highest among centers with ≥275 cases per year. Although proportions of patients receiving high-complexity operations (STS-EACTS categories 4–5) were highest in centers with ≥275 cases per year, use of ECMO after heart operation was lowest in this category. Use of CMV prior to cardiac surgery was highest in centers with <175 cases per year.

Center characteristics and unadjusted patient outcomes are depicted in Table 2. The presence of a dedicated cardiac ICU increased with increasing center volume. Annual discharges per center and annual number of cardiac surgery cases also followed similar trends. The overall in-hospital mortality was 3% (Table 2), with lowest mortality noted in centers with ≥275 cases per year. Although the proportion of patients receiving CMV and noninvasive ventilation after heart operation were lowest in centers with ≥275 cases per year, the duration of CMV and ICU length of stay were longest in this category. Overall reintubation rate was 3%, with highest reintubation rate noted in centers with ≥275 cases per year (5%).

Unadjusted and adjusted results regarding the relationship between center volume and odds of mechanical ventilation after cardiac surgery are presented in Table 3. In multivariable analysis, higher center volume was associated with lower odds of mechanical ventilation after cardiac surgery (odds ratio [OR] in centers with <175 vs >275 cases per year = 2.68 [95% CI: 2.15–3.35], $P < 0.001$). We subsequently restricted the analysis by surgical risk group. In the lower-risk patients (STS-EACTS categories 1–3), higher-volume centers were associated with lower odds of mechanical ventilation (OR in centers with <175 vs >275 cases per year = 3.12 [95% CI: 2.40–4.06], $P < 0.001$). In contrast, there was no significant relationship between center volume and odds of mechanical ventilation in the higher-risk patients (STS-EACTS categories 4–5; OR in centers with <175 vs >275 cases per year = 1.35 [95% CI: 0.86–2.14], $P = 0.19$).

We further evaluated the relationship of center volume and length of mechanical ventilation after cardiac surgery in unadjusted and adjusted models (Table 4). In multivariable analysis, higher center volume was associated with longer duration of mechanical ventilation (hazard ratio [HR] in centers with <175 vs >275 cases per year = 1.26 [95% CI: 1.16–1.37], $P < 0.001$). In the lower-risk patients (STS-EACTS categories 1–3), higher-volume centers were associated with longer duration of mechanical ventilation (HR in centers with <175 vs >275 cases per year = 1.25 [95% CI: 1.13–1.38], $P < 0.001$). Similar results were demonstrated in the higher-risk patients (STS-EACTS categories 4–5; HR in centers with <175 vs >275 cases per year = 1.46 [95% CI: 1.25–1.70], $P < 0.001$).

Discussion

Data from this large, multicenter national database establish that approximately 74% of children receive CMV after

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Table 1. Study Characteristics

	Overall N = 10 378	<175 N = 3657	175–275 N = 3176	≥275 N = 3545	*P* Value
Age, mo	9.1 (2.5, 53.5)	9.7 (2.8, 58.7)	7.9 (1.7, 46.5)	10.1 (2.6, 54.2)	<0.001
Male sex	5661 (55)	1957 (54)	1777 (56))	1927 (54)	0.12
Weight, kg	7.6 (4.3, 16.2)	7.9 (4.5, 17.2)	7.1 (4.0, 15.2)	7.9 (4.4, 16.5)	<0.001
Weight for age z-score	−0.95 (−1.93, −0.00)	−0.93 (−1.95, 0.08)	−0.99 (−1.96, −0.11)	−0.93 (−1.90, 0.01)	0.02
Developmental disorder	219 (2)	75 (2)	83 (3)	61 (2)	0.03
Failure to thrive	1166 (11	337 (9)	248 (8)	581 (16)	<0.001
Genetic disorder	844 (8)	270 (7)	256 (8)	318 (9))	0.04
Low birth weight	588 (6)	230 (6)	156 (5)	202 (6)	0.04
PIM-2 score	−3.9 (−4.6, −3.1)	−3.9 (−4.9, −3.1)	−3.6 (−4.3, −2.9)	−3.9 (−4.9, −3.1)	<0.001
PRISM-3 score	6 (3, 10)	6 (3, 9)	6 (3, 10)	7 (4, 11)	<0.001
Use of CMV prior to cardiac surgery	335 (3)	131 (4)	100 (3)	104 (3)	0.28
Operation details					
CPB case	7035 (68)	2308 (63)	2251 (71)	2476 (70)	<0.001
High-complexity operation	2730 (29)	811 (25)	886 (30)	1033 (31)	<0.001
>1 cardiothoracic surgery	1651 (15)	522 (14)	611 (19)	518 (14)	<0.001
Use of ECMO	362 (32)	132 (4)	136 (4)	94 (3)	0.001
Heart transplantation	197 (2)	42 (1)	80 (3)	75 (2)	<0.001
Diagnoses					
Arrhythmias	1014 (10)	401 (11)	299 (9)	314 (9)	0.008
Chronic lung disease	273 (3)	66 (2)	27 (1)	180 (5)	<0.001
Pulmonary hypertension	506 (5)	213 (6)	144 (5)	149 (4)	0.003
Cardiac arrest	460 (4)	169 (5)	207 (7)	84 (2)	<0.001
Chylothorax	64 (1)	47 (1)	6 (0)	11 (0)	<0.001
Diaphragm disorders	206 (2)	93 (3)	56 (2)	57 (2)	0.01
Renal failure	780 (8)	253 (7)	179 (6)	348 (10)	<0.001
Seizures	275 (3)	100 (3)	84 (3)	91 (3)	0.91
Sepsis	60 (1)	38 (1)	11 (0)	11 (0)	<0.001
Brain hemorrhage	440 (4)	131 (4)	187 (6)	122 (3)	<0.001

Abbreviations: CPB, cardiopulmonary bypass; CMV, conventional mechanical ventilation; ECMO, extracorporeal membrane oxygenation; NIV, noninvasive ventilation; PIM-2, Pediatric Index of Mortality; PRISM, Pediatric Risk of Mortality.
Continuous variables are summarized by the triplet of quartiles 50th (25th and 75th). Categorical variables are presented as n (%).

surgery for congenital heart disease. There was significant variation in mechanical ventilation practices with center volume. Higher center volume was significantly associated with lower odds of mechanical ventilation after cardiac surgery. However, patients receiving mechanical ventilation in these centers were associated with longer duration of mechanical ventilation, compared with lower-volume centers. This association was most prominent in the lower surgical-risk categories. These data suggest that both odds of mechanical ventilation and duration of mechanical ventilation are a function of patient characteristics, surgical-risk category, and center volume.

Though certain hospital characteristics have been studied related to mechanical ventilation in children after congenital heart surgery, relationship of center volume with rate of mechanical ventilation and duration of mechanical ventilation following heart surgery has not been previously evaluated in the pediatric population. In a recent study, the

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Table 2. Patient Outcomes and Center Characteristics

	Overall N = 10 378	<175 N = 3657	175–275 N = 3176	≥275 N = 3545	*P* Value
Outcomes					
Mortality	301 (3)	127 (3)	102 (3)	72 (2)	<0.001
ICU length of stay, d	3.7 (1.9, 8.8)	3.7 (1.9, 8.8)	3.1 (1.8, 8.4)	3.9 (2.1, 9.0)	<0.001
CMV after cardiac surgery	7648 (74)	2675 (73)	2576 (81)	2397 (68)	<0.001
NIV after cardiac surgery	1008 (10)	326 (9)	431 (14)	251 (7)	<0.001
Duration of CMV, h	28.7 (11.4, 104.9)	24.4 (8.2, 95.7)	26.9 (7.7, 99.5)	44.9 (19.0, 118.9)	<0.001
Reintubation within 96 h	353 (3)	112 (3)	76 (2)	165 (5)	<0.001
Center data					
Dedicated cardiac ICU	6255 (60)	1130 (31)	1580 (50)	3545 (100)	<0.001
Annual discharges per center	812 (568, 1064)	808 (568, 812)	882 (631, 1077)	1787 (411, 1787)	<0.001
Annual cardiac surgery per center	229 (96, 297)	78 (42, 123)	238 (229, 240)	310 (297, 436)	<0.001

Abbreviations: CMV, conventional mechanical ventilation; ICU, intensive care unit; NIV, noninvasive ventilation.
Continuous variables are summarized by the triplet of quartiles 50th (25th and 75th). Categorical variables are summarized as n (%).

Table 3. Relationship Between Center Volume and Odds of Mechanical Ventilation After Cardiac Surgery

	Unadjusted		Adjusted	
Center Volume	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
Volume as a continuous variable[a]	1.20 (1.12–1.29)	<0.001	0.68 (0.59–0.80)	<0.001
Volume as a categorical variable				
<175	1.26 (1.14–1.39)	<0.001	2.68 (2.15–3.35)	<0.001
175–275	1.78 (1.60–1.98)	<0.001	1.31 (1.12–1.52)	<0.001
≥275	Ref		Ref	
STS-EACTS risk categories 1–3				
Volume as a continuous variable[a]	1.08 (0.99–1.18)	0.067	0.65 (0.54–0.78)	<0.001
Volume as a categorical variable				
<175	1.57 (1.40–1.76)	<0.001	3.12 (2.40–4.06)	<0.001
175–275	2.18 (1.92–2.47)	<0.001	1.43 (1.19–1.71)	<0.001
≥275	Ref		Ref	
STS-EACTS risk categories 4–5				
Volume as a continuous variable[a]	1.32 (1.09–1.61)	0.005	0.93 (0.68–1.28)	0.66
Volume as a categorical variable				
<175	0.90 (0.70–1.15)	0.41	1.35 (0.86–2.14)	0.19
175–275	1.16 (0.90–1.49)	0.26	0.89 (0.65–1.22)	0.46
≥275	Ref		Ref	

Abbreviations: CI, confidence interval; OR, odds ratio; Ref, reference; STS-EACTS, Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery.
[a]Volume as a continuous variable depicts comparison of high center volume vs low center volume.

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Table 4. Relationship Between Center Volume and Length of Mechanical Ventilation After Cardiac Surgery

	Unadjusted		Adjusted	
Center Volume	HR (95% CI)	*P* Value	HR (95% CI)	*P* Value
Volume as a continuous variable[a]	0.93 (0.89–0.97)	0.001	0.99 (0.93–1.06)	0.81
Volume as a categorical variable				
<175	1.16 (1.10–1.23)	<0.001	1.26 (1.16–1.37)	<0.001
175–275	1.14 (1.08–1.21)	<0.001	1.19 (1.11–1.28)	<0.001
≥275	Ref		Ref	
STS-EACTS risk categories 1–3				
Volume as a continuous variable[a]	0.96 (0.91–1.01)	0.15	1.02 (0.94–1.10)	0.64
Volume as a categorical variable				
<175	1.17 (1.09–1.26)	<0.001	1.25 (1.13–1.38)	<0.001
175–275	1.21 (1.13–1.31)	<0.001	1.21 (1.11–1.32)	<0.001
≥275	Ref		Ref	
STS-EACTS risk categories 4–5				
Volume as a continuous variable[a]	1.00 (0.92–1.08)	0.95	0.86 (0.76–0.97)	0.011
Volume as a categorical variable				
<175	1.00 (0.91–1.10)	0.99	1.46 (1.25–1.70)	<0.001
175–275	0.98 (0.89–1.08)	0.73	1.16 (1.03–1.30)	0.018
≥275	Ref		Ref	

Abbreviations: CI, confidence interval; OR, odds ratio; Ref, reference; STS-EACTS, Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery.
[a]Volume as a continuous variable depicts comparison of high center volume vs low center volume.

impact of staffing strategy (presence or absence of a 24/7 in-house attending physician) on rates of nighttime extubation and duration of mechanical ventilation was evaluated.[12] It was demonstrated that the utilization of nighttime in-house attending coverage does not appear to have significant benefits on the rate of nighttime extubation and may not reduce the duration of mechanical ventilation in units that already use in-house residents, fellows, or other midlevel providers.[12]

Traditionally, case volume has been considered a key factor with regard to good outcomes. In both adult and pediatric populations, higher hospital volume has been associated with improved outcomes for certain complex surgical procedures.[13–15] As a result of these studies, third-party payers and health care policymakers have come together to develop volume-based referral initiatives. In our study, higher center volume was significantly associated with lower odds of mechanical ventilation after cardiac surgery. It is possible that higher-volume centers may have greater resources, permitting higher staffing levels, higher nurse-to-patient ratios, larger multidisciplinary teams, and/or intensivist-led staffing models that may have led to lower odds of mechanical ventilation. However, it should be noted that the prevalence of reintubation was highest among the higher-volume centers. Moreover, the duration of mechanical ventilation was longer in higher-volume centers. This may have been because higher-volume centers were taking care of sicker and more complex patients (as demonstrated by higher PRISM-3 scores and increasing numbers of high-complexity operations).

Study Limitations

Our study has several potential limitations. This study is subject to the limitations of all observational analyses, including selection bias, residual confounding, and measurement error. Our methodology for constructing center-volume categories is somewhat arbitrary; however, we treated center volume as both a continuous and categorical variable in an attempt to increase our ability to detect volume-based differences in children with cardiac arrest. Although we attempted to adjust for important patient confounders, it is possible that there could be other unmeasured confounders present impacting our analysis. Other limitations of the present study are related to the nature of the VPS dataset. Not all US centers participate in the VPS database. Nonetheless, the present report represents the most inclusive evaluation, with data from 43 US pediatric heart centers.

We were also limited to consideration of variables collected in the VPS database. As such, we could not

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evaluate or account for the potential impact of variables such as hospital structure and process measures, training or availability of ICU personnel, or nursing factors, in our evaluation of odds for mechanical ventilation, for example. Our study also lacks data on the 24/7 in-hospital coverage by attending intensivists for the study hospitals, which could potentially be another study confounder. Our goal was to focus on hospital volume, the major component of quality initiatives, rather than other characteristics that could be associated with volume. Our study lacked data on certain key variables such as partial pressure of oxygen in arterial blood (PaO_2), partial pressure of carbon dioxide in arterial blood ($PaCO_2$), fraction of inspired oxygen (FiO_2), PaO_2/FiO_2 ratio, presence of focal vs diffuse lung disease, use of nitric oxide, and presence of air leak that could have been used in the multivariable modeling. Our study also lacked data on mechanical ventilation, such as plateau, mean, and end-expiratory pressures; and data on inotropes, sedatives, and neuromuscular blocking agents that could have potentially affected outcomes. Due to the large sample size, some differences that are not clinically significant may appear to be statistically significant in univariable analysis. However, the effect of these variables was accounted for in the multivariable analysis.

Conclusions

Large clinical-practice variations were demonstrated for mechanical ventilation following pediatric cardiac surgery among ICUs of varied center volumes. Both odds of mechanical ventilation and duration of mechanical ventilation following cardiac surgery vary substantially across hospitals. Although higher-volume hospitals are associated with lower odds of mechanical ventilation following cardiac surgery, these centers are associated with longer duration of mechanical ventilation, compared with lower-volume centers. Additional efforts are required to determine which patient and center characteristics might account for this variability. Using databases such as the VPS for clinical-outcomes research may in the future decrease the cost of discovery and guide us in improving outcomes for critically ill patients.

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