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Original Contributions

SEPSIS FLUID METRIC COMPLIANCE AND ITS IMPACT ON OUTCOMES OF PATIENTS WITH CONGESTIVE HEART FAILURE, END-STAGE RENAL DISEASE OR OBESITY

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□ **Abstract—Background: Emergency physicians express concern administering a 30-cc/kg fluid bolus to septic shock patients with pre-existing congestive heart failure (CHF), end-stage renal disease (ESRD), or obesity, due to the perceived risk of precipitating a fluid overload state. Objective: Our aim was to determine whether there is a difference in fluid administration to septic shock patients with these pre-existing conditions in the emergency department (ED). Secondary objectives focused on whether compliance impacts mortality, need for intubation, and length of stay. Methods: We conducted a retrospective chart review of 470,558 ED patient encounters at a single urban academic center during a 5-year period. Results: Of 847 patients with septic shock, 308 (36.36%) had no pre-existing condition and 199 (23.49%), 17 (2.01%), and 154 (18.18%) had the single pre-existing condition of CHF, ESRD, and obesity, respectively, and 169 (19.95%) had multiple pre-existing conditions. Weight-based fluid compliance was achieved in 460 patients (54.31%). There was a lower likelihood of compliance among patients with CHF (adjusted odds ratio [aOR] 0.35; 95% confidence interval [CI] 0.24–0.52; $p < 0.001$), ESRD (aOR 0.11, 95% CI 0.04–0.32; $p < 0.001$), and obesity (aOR 0.29, 95% CI 0.19–0.44; $p < 0.001$) compared with patients with no pre-existing conditions. Compliance decreased further in patients with multiple pre-existing conditions (aOR 0.49, 95% CI 0.33–0.72; $p < 0.001$). Compliance was not associated with mortality in patients with CHF and ESRD, but was protective in patients with obesity and those with no pre-existing conditions. Conclusions: Septic shock patients with pre-existing CHF, ESRD, or obesity are less likely to achieve compliance with a 30-cc/kg weight-based fluid goal compared with those without these pre-existing conditions.**

□ **Keywords—septic shock; fluid bundle metric; SEP-1**

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INTRODUCTION

Septic shock is a major cause of morbidity and mortality worldwide, as well as a leading cause of inpatient admissions associated with substantial cost and poor long-term outcomes in illness survivors (1). The Centers for Medicare and Medicaid Services (CMS) introduced Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1) as a national quality measure in October 2015 to standardize care and improve clinical outcomes of patients presenting along the spectrum of sepsis severity. SEP-1

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consists of a series of individual clinical elements to be applied to patients with severe sepsis and septic shock within 3 hours (h) and 6 h of emergency department (ED) arrival. Application and compliance with SEP-1 is mandated for all patients with severe sepsis and septic shock, except for those transferred from outside facilities or receiving comfort measures only, regardless of known comorbidities. Compliance with SEP-1 is all or none, meaning that compliance with the core measure requires satisfaction of all of its individual components and missing a single element equates to failure. Performance related to the SEP-1 core measure not only has an impact on hospital reimbursement and payment measures, but is ultimately disseminated to the public realm, in which potential patients can make informed decisions regarding where to seek future care.

On its release, SEP-1 core measure failure rates were as high as 67%, with considerably higher noncompliance among the septic shock group (2). Information gathered by the Emergency Quality Network Sepsis Initiative demonstrated a mean hospital SEP-1 compliance rate of 54%—with wide variation existing among each bundle component—and the bundle component delineating administration of a 30-cc/kg crystalloid fluid bolus to patients with septic shock within 3 h of ED arrival was associated with some of the widest practice variation (3). Despite this measure, rapid intravenous (i.v.) fluid infusion has become a staple of resuscitation efforts for patients with septic shock, despite a lack of strong evidence showing improved clinical outcomes (4,5). Knowledge of the effects of rapid fluid resuscitation on the septic shock patient populations at a theoretical risk for volume overload and flash pulmonary edema is lacking. In patients with severe sepsis and septic shock treated with aggressive fluid resuscitation in the medical intensive care unit (ICU) setting, 67% showed evidence of fluid overload defined by both clinical and radiographic data or requirement of fluid-related medical interventions, including thoracentesis or diuretic use (6). This might explain why some studies have suggested compliance with the fluid metric may be $< 50\%$, and certain subgroups of patients with pre-existing diagnoses of congestive heart failure (CHF), end-stage renal disease (ESRD), or obesity are at greater risk for noncompliance (7,8).

Based on its review of research related to Early Goal Directed Therapy, the Surviving Sepsis Campaign recommended patients with signs and symptoms of septic shock (i.e., hypotension or lactate ≥ 4 mmol/L) receive a 30-cc/kg bolus of crystalloid fluid within the first hour of presentation in the ED setting. In its attempt to standardize care, CMS has adapted this recommendation into one of its core measures to be applied to all patients with septic shock within 3 h of ED presentation, regardless of other pre-existing comorbidities. The recommendation is classified as strong, with low quality of evidence due to a lack of prospective randomized controlled studies according to the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) system (9). Several patient features, including pre-existing diagnoses of CHF, ESRD, or obesity, may be associated with decreased compliance with the fluid metric. It is currently unclear how the administration of a 30-cc/kg fluid bolus to septic shock patients with prior diagnoses of CHF, ESRD, or obesity impacts mortality, likelihood of precipitating a fluid overload state and pulmonary edema necessitating intubation, and ICU and inpatient length of stay (LOS).

The primary aim was to determine whether there is a significant difference in the volume of fluids administered during the ED resuscitation phase of septic shock patients with pre-existing diagnoses of CHF, ESRD, or obesity compared with the general population of septic shock patients without these pre-existing conditions. Secondary aims compare clinical outcomes between compliant and noncompliant CHF, ESRD, and obesity groups, based on a weight-based volume goal, focusing specifically on differences in all-cause mortality, need for intubation within 72 h of ED arrival, need for intubation during inpatient LOS, ICU LOS, and inpatient LOS.

METHODS

Study Design and Setting

The study was designed as a retrospective chart review and analysis of all patients presenting to the ED at a single urban academic institution in the northeast United States with an annual census of approximately 100,000 visits during a 5-year period between June 1, 2013 and May 30, 2018. The study protocol was submitted to and approved by the Human Subjects Research Committee under the affiliate Institutional Review Board (IRB 2000023422).

Selection of Participants

Patients with suspected septic shock qualified for study inclusion if all three of the following interventions were performed during their associated ED LOS: blood cultures ordered and collected, i.v. antibiotics ordered and administered, and vasopressors ordered and administered. The research site allows providers to use a standardized sepsis order set composed of elements including, but not limited to, two sets of blood cultures, empiric antibiotics recommended based on suspected source and the ED population's antibiogram, and an auto-calculated 30-cc/kg infusion of crystalloid fluid based on recorded body weight. Specific antibiotics and vasopressors were selected by the research team based on pharmacy formulary

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and standard of care at the study site to be used as parameters for the electronic query and selection of patients (Appendix A). If the patient did not satisfy all three criteria, they were not screened in during the electronic query and were therefore excluded from study enrollment. Patients who were younger than 18 years, transferred from an outside hospital, left against medical advice, received only push dose vasopressors, had multiple ED visits, or expired in the ED were also excluded.

Interventions

The electronic health records (EHRs) (Epic Systems, Verona, WI) for all ED patient encounters during the 5-year period were screened according to the specified inclusion criteria via electronic query by the Joint Data Analytics Team (JDAT). A list of all eligible medical record numbers (MRNs) was compiled and provided to the research team. Most metrics were electronically queried and abstracted by the JDAT, however, some clinical data required manual abstraction (Appendix B). After completing a training course on data abstraction with a glossary of defined terms and simulations of selected sample charts, each abstractor was assigned a subset of the total patient list. Each abstractor had significant clinical experience and familiarity navigating the EHR interface. Abstractors included three residents currently enrolled in an Accreditation Council for Graduate Medical Education–accredited emergency medicine residency program (E.B., A.H., V.J.) and a single American Board of Emergency Medicine–certified attending (J.B.). Once abstraction was complete, all data were reviewed for accuracy by two members of the research team (J.B., E.B.). All discrepancies regarding manually abstracted clinical data were presented to and discussed among the group of abstractors with rulings made by a majority consensus.

Measurements

A patient was classified as having CHF if the diagnosis of heart failure was included in the active medical problem list, described within a provider note, or if they met New York Heart Association functional classification objective assessment criteria; objective assessment was based on findings documented in an echocardiogram report filed prior to the selected ED encounter. A patient was considered to have systolic heart failure if the left ventricular ejection fraction was $< 50\%$. If diastolic dysfunction was indeterminate based on the echocardiogram report, the subsequent most recent prior echocardiogram was used to determine whether diastolic dysfunction was present. If no previous echocardiogram was available, the patient was classified as having no diastolic dysfunction. A patient was classified as having ESRD if the diagnosis was included in the active medical problem list or the patient was currently undergoing hemodialysis or peritoneal dialysis, as described within a provider note. Body mass index (BMI) categories were based on World Health Organization criteria, and a patient was classified as obese if the BMI calculated from the initial height and weight recorded during the ED or inpatient LOS was ≥ 30 kg/m^2. The total volume of fluids used to determine compliance was based on aggregate volume of fluids administered during the patient's ED LOS. These data were abstracted through an electronic query and then verified through chart abstraction by viewing the medication administration record (MAR), nursing and physician notes, and flowsheets. When electronic query differed from manual chart abstraction, the senior investigator (J.B.) adjudicated the final volume of fluid administered. Weight-based compliance was met if the total volume of fluids administered equaled or exceeded the calculated 30-cc/kg weight-based goal volume. Volume-based compliance was met if the total volume of fluids administered equaled or exceeded 2000 cc. The primary outcome of mortality was defined as all-cause mortality at any point during the inpatient LOS. Prehospital intubation referred to any case during which intubation was performed in the field prior to ED arrival and does not distinguish between patients requiring emergent intubation by emergency medical services or chronically intubated/ventilated patients. Time of intubation was defined by the time documented on the corresponding intubation procedure note written by the performing provider, and the calculated time to intubation references ED arrival time as time zero. ED LOS was calculated as the difference between electronic timestamps capturing ED arrival and ED disposition. ICU LOS was calculated as the difference between electronic timestamps capturing ED disposition to admit and request to transfer from the ICU or discharge as expired. Inpatient LOS was calculated as the difference between electronic timestamps capturing ED disposition to admit and discharge from hospital or discharge as expired.

Outcomes

The primary outcome was volume of fluids administered in the ED and corresponding metric compliance as defined by weight-based and total volume-based goals. Secondary outcomes were all-cause mortality, need for intubation within 72 h of ED arrival, need for intubation during inpatient LOS, ICU LOS, and inpatient LOS compared among CHF, ESRD, and obese patient groups compliant and noncompliant with the weight-based volume goal.

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Analysis

Patient characteristics were summarized using frequencies and percentages for categorical variables and medians and interquartile ranges for continuous variables, as the variables were skewed. All statistical analyses were performed using SAS/STAT software, version 9.4 (SAS Institute, Inc., Cary, NC). The significance level was set as $p < 0.05$, two-sided.

Primary analyses included linear models to investigate the relationship between the total volume of fluids administered and calculated weight-based (≥ 30 cc/kg) and total volume-based (≥ 2 L) goals based on disease. Logistic regression analysis was used to compare fluid metric compliance, defined by the calculated weight-based and total volume-based goals, between patients with a pre-existing condition and those without the pre-existing condition. Models were adjusted for age, gender, and race. Secondary analyses compared compliant patients with a given pre-existing condition with patients who were noncompliant while controlling for other disease types; specifically, linear mixed models compared LOS outcomes and logistic models compared intubation outcomes. Dummy variables were used to denote whether a patient had a given disease type or not. Dunnett's multiple comparison correction was used to compare each group to the reference group consisting of patients without a pre-existing condition.

RESULTS

Characteristics of Study Participants

There were 470,558 ED patient encounters during the 5-year period between June 1, 2013 and May 30, 2018. Nine hundred and sixty-five patient encounters (0.21%) were classified as septic shock, representing 898 unique MRNs. Of these MRNs, 847 (94.3%) had a single ED visit during the study period and 51 (5.7%) had multiple ED visits. Demographics and clinical characteristics for patients with a single ED visit are summarized in Table 1.

Main Results

Clinical outcome variables for the study sample and across disease groups are summarized in Table 2. The mean calculated weight-based fluid goal volume and total volume of fluid administered in the ED, as well as compliance with the weight-based and total volume-based fluid goals across all groups are described in Table 3. This information is further described and compared among patients with zero, a single, and multiple pre-existing conditions in Table 4.

Weight-based volume goal compliance

The mean calculated 30-cc/kg weight-based goal volume for patients without a pre-existing condition was 1924 cc (95% confidence interval [CI] 1827–2020 cc) and further described by patient condition in Table 3. Mean calculated weight-based goal volumes were significantly higher in all groups that included patients with obesity. The weight-based volume goal was achieved in 460 patients (54.31%). As described in Table 4, patients with a single or multiple pre-existing conditions were less likely to achieve provider compliance with the weight-based volume goal compared with patients without a pre-existing condition. Weight-based volume goal compliance was the lowest in patients with all three pre-existing conditions (adjusted odds ratio [aOR] 0.05, 95% CI 0.01–0.21; $p < 0.001$), and compliance decreased as the number of pre-existing conditions increased.

Total volume-based goal compliance

The mean total volume of fluid administered for patients without a pre-existing condition was 2988 cc (95% CI 2717–3258 cc). Six hundred and twenty-six patients (73.91%) were administered at least 2000 cc of fluid in the ED. All disease groups except for obesity only and ESRD and obesity were less likely to receive a total volume of at least 2000 cc compared with the general population of patients with no pre-existing conditions (Table 3). Patients with a single pre-existing condition or combination of conditions were less likely to achieve provider compliance with the total volume-based fluid goal compared with patients without a pre-existing condition. Total volume-based goal compliance was lower in patients with multiple pre-existing conditions (aOR 0.08, 95% CI 0.03–0.26; $p < 0.001$), and compliance decreased as the number of pre-existing conditions increased (Table 4).

Secondary Results

Secondary results focus on differences in clinical outcomes between patients with any pre-existing condition who were compliant with the weight-based volume goal and those who were noncompliant, specifically targeting all-cause mortality, intubation within 72 h of ED arrival, intubation during inpatient LOS, ICU LOS, and inpatient LOS.

All-cause mortality and weight-based volume goal compliance

Overall, all-cause mortality was 27.63%. Figure 1 displays the effect of provider compliance with the 30-cc/kg bolus among septic shock patients with CHF, ESRD, obesity, and no conditions on mortality. Compliance is associated with lower mortality in the obesity (aOR 0.47, 95% CI 0.25–0.90; $p = 0.02$) and no pre-existing condition (aOR 0.44, 95% CI 0.27–0.74; $p < 0.01$) groups.

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Table 1. Demographic and Clinical Characteristics of Patients with Septic Shock Across Study Sample and Disease Subgroups

Characteristics	Overall (n = 847)	None (n = 308)	CHF Only (n = 199)	ESRD Only (n = 17)	Obesity Only (n = 154)	CHF and ESRD (n = 34)	CHF and Obesity (n = 115)	ESRD and Obesity (n = 5)	CHF, ESRD, and Obesity (n = 15)
Age, y, median (IQR)	70 (59–81)	69 (57–80)	80 (70–87)	61 (51–69)	63 (54–72)	67.5 (60–73)	70 (63–80)	56 (49–70)	64 (58–74)
Gender, male, n (%)	424 (50.06)	154 (50.00)	113 (56.78)	9 (52.94)	64 (41.56)	19 (55.88)	57 (49.57)	2 (40.00)	6 (40.00)
Race, n (%)									
White	632 (74.62)	238 (77.27)	150 (75.38)	7 (41.18)	120 (77.92)	17 (50.00)	89 (77.39)	2 (40.00)	9 (60.00)
Black	128 (15.11)	42 (13.64)	26 (13.07)	6 (35.29)	18 (11.69)	13 (38.24)	18 (15.65)	0 (0.00)	5 (33.33)
Asian	9 (1.06)	5 (01.62)	2 (1.01)	0 (0.00)	1 (0.65)	1 (2.94)	0 (0.00)	0 (0.00)	0 (0.00)
Other/unknown	78 (9.21)	23 (7.47)	21 (10.56)	4 (23.53)	15 (9.74)	3 (8.82)	8 (6.96)	3 (60.00)	1 (6.67)
Ethnicity, n (%)									
Non-Hispanic	769 (90.79)	287 (93.18)	179 (89.95)	13 (76.47)	133 (86.36)	31 (91.18)	109 (94.78)	3 (60.00)	14 (93.33)
Hispanic/Latino	73 (8.62)	17 (5.52)	20 (10.05)	4 (23.53)	20 (12.99)	3 (8.82)	6 (5.22)	2 (40.00)	1 (06.67)
Other/unknown	5 (0.59)	4 (1.29)	0 (0.00)	0 (0.00)	1(0.65)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
BMI (kg/m^2), median (IQR)	27.04 (22.80–32.72)	24.12 (21.08–26.92)	24.31 (21.82–26.90)	24.02 (18.65–27.77)	34.60 (32.36–38.74)	23.92 (20.44–26.84)	35.57 (32.72–40.03)	32.37 (31.49–34.47)	36.50 (32.53–44.43)
Insulin-dependent diabetes mellitus, yes, n (%)	144 (17.02)	33 (10.75)	29 (14.57)	7 (41.18)	22 (14.29)	13 (38.24)	33 (28.70)	2 (40.00)	5 (33.33)
Non–insulin-dependent diabetes mellitus, yes, n (%)	145 (17.14)	35 (11.40)	24 (12.06)	0 (0.00)	42 (27.27)	7 (20.59)	28 (24.35)	3 (60.00)	6 (40.00)
ED initial lactate (mmol/L), median (IQR)	2.80 (1.50–5.10)	2.80 (1.50–5.50)	2.50 (1.40–4.70)	5.15 (2.40–9.20)	2.90 (1.70–4.70)	2.60 (1.50–4.10)	3.00 (1.60–5.20)	5.10 (4.60–5.60)	2.00 (1.70–4.70)

BMI = body mass index; CHF = congestive heart failure; ED = emergency department; ESRD = end-stage renal disease; IQR = interquartile range.

Table 2. Clinical Outcomes of Patients with Septic Shock Across Study Sample and Disease Subgroups

Characteristic	Overall (n = 847)	None (n = 308)	CHF Only (n = 199)	ESRD Only (n = 17)	Obesity Only (n = 154)	CHF and ESRD (n = 34)	CHF and Obesity (n = 115)	ESRD and Obesity (n = 5)	CHF, ESRD, and Obesity (n = 15)
Weight-based volume goal met (30 cc/kg), yes, n (%)	460 (54.31)	231 (75.00)	94 (47.24)	5 (29.41)	77 (50.00)	9 (26.47)	41 (35.65)	1 (20.00)	2 (13.33)
Total volume goal met (≥ 2000 cc), yes, n (%)	626 (73.91)	261 (84.74)	129 (64.82)	8 (47.06)	132 (85.71)	16 (47.06)	72 (62.61)	3 (60.00)	5 (33.33)
All-cause mortality. Yes, n (%)	234 (27.63)	76 (24.68)	62 (31.16)	5 (29.41)	30 (19.48)	17 (50.00)	36 (31.30)	1 (20.00)	7 (46.67)
Intubated within 72 h of ED arrival, n (%)									
No	537 (63.40)	194 (62.99)	138 (69.35)	9 (52.94)	102 (66.23)	19 (55.88)	64 (55.65)	3 (60.00)	8 (53.33)
Yes	294 (34.71)	106 (34.42)	60 (30.15)	8 (47.06)	48 (31.17)	15 (44.12)	48 (41.74)	2 (40.00)	7 (46.67)
Prehospital	16 (1.89)	8 (02.60)	1 (00.50)	0 (0.00)	4 (2.60)	0 (0.00)	3 (2.61)	0 (0.00)	0 (0.00)
Intubated during hospitalization, n (%)									
No	520 (61.39)	187 (60.71)	134 (67.34)	9 (52.94)	99 (64.29)	18 (52.94)	61 (53.04)	4 (80.00)	8 (53.33)
Yes	311 (36.72)	113 (36.69)	64 (32.16)	8 (47.06)	51 (33.12)	16 (47.06)	51 (44.35)	1 (20.00)	7 (46.67)
ED LOS, min, median (IQR)	381 (267–515)	388.5 (281.5–531)	375.9 (264–493)	387 (295–444)	398 (262.9–537)	376.5 (302–540.9)	348 (241–454.9)	350 (201–439)	342 (273–486)
ICU LOS, h, median (IQR)	61 (32–122)	58 (31.5–121)	61 (34–115)	79 (33–124)	56.5 (27–114)	56 (38–106)	66 (38–131)	188 (20–222)	85 (41–222)
Hospital LOS, days, median (IQR)	7 (4–13)	7 (4–12)	8 (4–13)	9 (4–15)	7 (4–12)	5.5 (2–11)	7 (3–14)	31 (6–38)	10 (4–14)

CHF = congestive heart failure; ED = emergency department; ESRD = end-stage renal disease; ICU = intensive care unit; IQR = interquartile range; LOS = length of stay.

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Table 3. Compliance with Calculated Weight-Based and Total Volume-Based Goals of Patients with Septic Shock Across Study Sample and Disease Groups

Variable	Mean Calculated Weight-Based Fluid Goal Volume for Each Disease Group Compared with "None"			Mean Total Fluid Volume Administered in ED for Each Disease Group Compared with "None"		
	Mean Calculated Goal Volume (cc)	95% CI (cc)	*P* Value*	Mean Total Fluid Volume in ED (cc)	95% CI (cc)	*P* Value*
None	1924	1827–2020	Ref	2988	2717–3258	Ref
CHF only	1936	1830–2043	1.00	2303	2005–2601	< 0.001
ESRD only	1846	1601–2090	0.99	1772	1089–2455	0.003
Obesity only	2951	2837–3065	< 0.001	2979	2660–3298	1.00
CHF and ESRD	1844	1665–2023	0.95	1490	991–1990	< 0.001
CHF and obesity	2990	2868–3113	< 0.001	2311	1969–2654	< 0.001
ESRD and obesity	2718	2283–3153	0.002	1659	443–2875	0.19
CHF, ESRD, and obesity	3010	2751–3270	< 0.001	1306	581–2031	< 0.001
Variable	Compliance With Weight-Based Volume Goal for Each Disease Group Compared with "None"			Compliance with Total Volume-Based Volume Goal for Each Disease Group Compared with "None"		
	aOR†	95% CI	*P* Value	aOR†	95% CI	*P* Value
None (references	—	—	—	—	—	—
CHF only	0.35	0.24–0.52	< 0.001	0.39	0.25–0.61	< 0.001
ESRD only	0.11	0.04–0.32	< 0.001	0.12	0.04–0.35	< 0.001
Obesity only	0.29	0.19–0.44	< 0.001	0.97	0.56–1.70	0.92
CHF and ESRD	0.11	0.05–0.25	< 0.001	0.15	0.07–0.32	< 0.001
CHF and obesity	0.19	0.12–0.30	< 0.001	0.32	0.19–0.52	< 0.001
ESRD and obesity	0.05	0.01–0.48	0.01	0.15	0.02–0.98	0.04
CHF, ESRD, and obesity	0.05	0.01–0.21	< 0.001	0.08	0.03–0.26	< 0.001

aOR = adjusted odds ratio; CHF = congestive heart failure; CI = confidence interval; ED = emergency department; ESRD = end-stage renal disease.

* Dunnett-adjusted *p* value.

† Models adjusted for age, race, and gender.

Table 4. Compliance with Calculated Weight-Based and Total Volume-Based Goals of Patients with Septic Shock Across Disease Groups

Variable	Mean Calculated Weight-Based Fluid Goal Volume for Single and Multiple Condition Groups Compared with "None"			Mean Total Fluid Volume Administered in ED for Single and Multiple Condition Groups Compared with "None"		
	Mean Calculated Goal Volume (cc)	95% CI	*p* Value*	Mean Total Fluid Volume in ED (cc)	95% CI	*p* Value*
None	1845	1723–1967	Ref	2930	2655–3205	Ref
Single	2302	2182–2422	< 0.001	2517	2247–2788	< 0.001
Multiple	2698	2559–2836	< 0.001	1996	1685–2308	< 0.001
Variable	Compliance With Weight-Based Volume Goal for Single and Multiple Condition Groups Compared with "None"			Compliance With Total Volume-Based Volume Goal for Single and Multiple Condition Groups Compared with "None"		
	aOR†	95% CI	*p* Value	aOR†	95% CI	*p* Value
Single vs None	0.31	0.22–0.43	< 0.001	0.50	0.34–0.74	< 0.001
Multiple vs None	0.15	0.01–0.23	< 0.001	0.24	0.15–0.37	< 0.001
Multiple vs Single	0.49	0.33–0.72	< 0.001	0.47	0.32–0.70	< 0.001

aOR = adjusted odds ratio; CI = confidence interval; ED = emergency department.

* Dunnett-adjusted *p* value.

† Models adjusted for age, race, and gender.

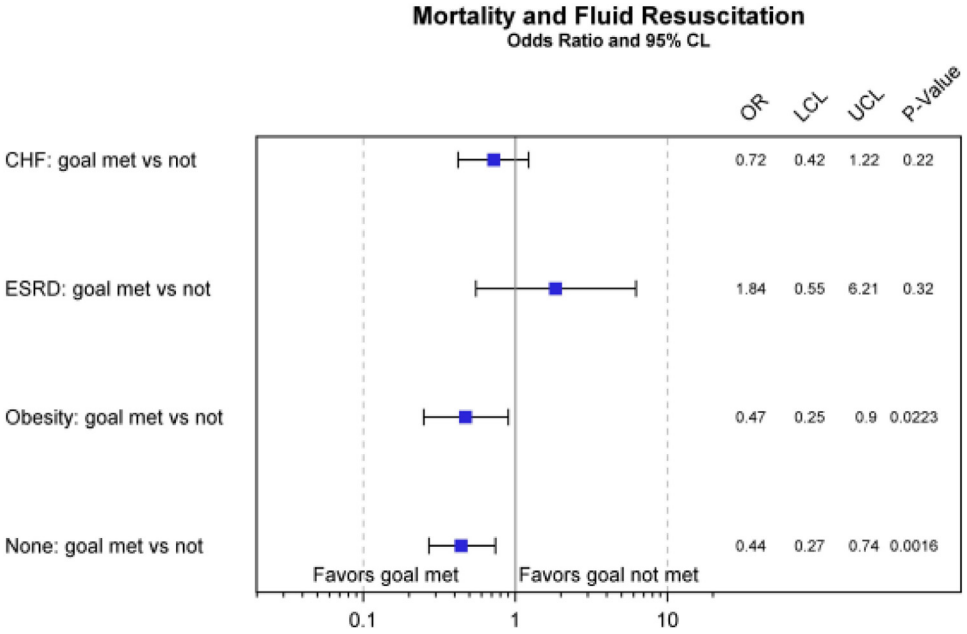

Figure 1. Likelihood of mortality in patients with septic shock given compliance with weight-based fluid volume goal, adjusted for age, race, and gender. CHF = congestive heart failure; ESRD = end-stage renal disease; LCL = lower confidence limit; OR = odds ratio; UCL = upper confidence limit.

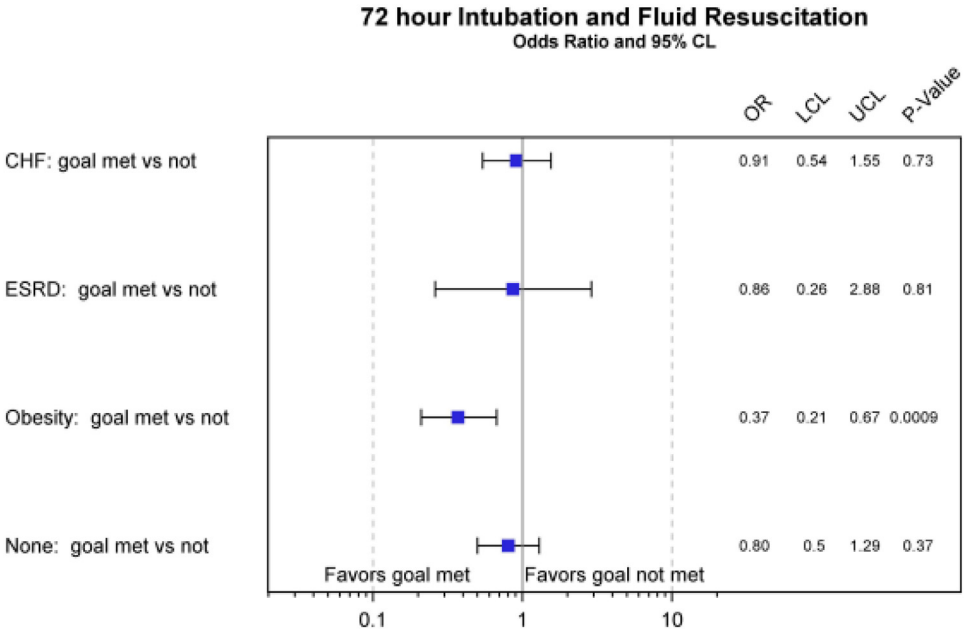

Figure 2. Likelihood of intubation within 72 h in patients with septic shock given compliance with weight-based fluid volume goal, adjusted for age, race, and gender. CHF = congestive heart failure; ESRD = end-stage renal disease; LCL = lower confidence limit; OR = odds ratio; UCL = upper confidence limit.

Intubation within 72 h of ED arrival and weight-based volume goal compliance

Overall, 34.71% patients were intubated within 72 h of ED arrival. Figure 2 displays the effect of provider compliance with the 30-cc/kg bolus among septic shock patients with CHF, ESRD, obesity, and no conditions on likelihood of intubation within 72 h of ED arrival. Compliance is associated with a lower likelihood of intubation within 72 h of ED arrival in the obesity group (aOR 0.37, 95% CI 0.21–0.67; $p < 0.01$).

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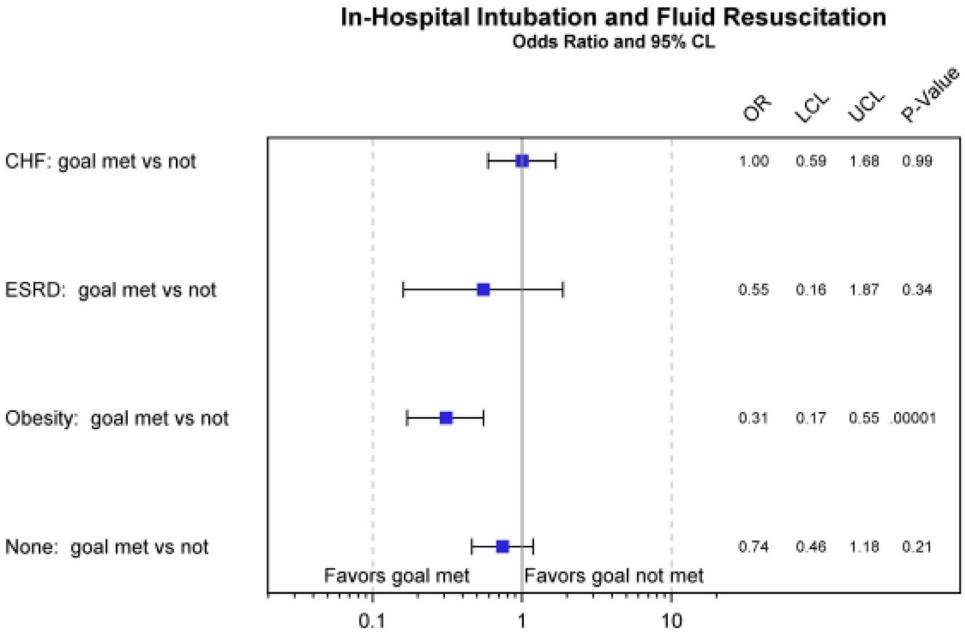

Figure 3. Likelihood of inpatient intubation in patients with septic shock given compliance with weight-based fluid volume goal, adjusted for age, race, and gender. CHF = congestive heart failure; ESRD = end-stage renal disease; LCL = lower confidence limit; OR = odds ratio; UCL = upper confidence limit.

Intubation during inpatient LOS and weight-based volume goal compliance

Overall, 36.72% patients were intubated during their inpatient LOS. Figure 3 displays the effect of provider compliance with the 30-cc/kg bolus among septic shock patients with CHF, ESRD, obesity, and no conditions on likelihood of intubation during inpatient LOS. Compliance is associated with a lower likelihood of intubation in the obesity group (aOR 0.31, 95% CI 0.17–0.55; $p < 0.01$).

ICU LOS and weight-based volume goal compliance

Figure 4 displays the effect of provider compliance with the 30-cc/kg bolus among septic shock patients with CHF, ESRD, obesity, and no conditions on mean ICU LOS. Compliance is associated with a lower mean ICU LOS for patients with CHF (66.7 vs. 93.6 h; $p = 0.02$).

Inpatient LOS and weight-based volume goal compliance

There were no statistically significant differences in the mean inpatient LOS for patients whose provider met the weight-based volume goal compared with those who were noncompliant within each disease subgroup, controlling for other diseases (Figure 5).

DISCUSSION

Included within the SEP-1 bundle is administration of a 30-cc/kg i.v. crystalloid bolus to all septic shock patients within 3 h of ED presentation, which raises concern about the management of patients at risk for fluid overload, such as those with pre-existing CHF, ESRD, or obesity. Our results suggest that ED providers are less likely to achieve compliance with the weight-based and total volume-based fluid goals in patients with at least one pre-existing condition, and compliance decreases further as the number of pre-existing conditions increases. In patients with multiple pre-existing conditions, the mean total i.v. fluid volume was approximately an entire liter of fluids less than the general population of patients without a pre-existing condition. Our results are consistent with similar studies evaluating these subgroups, however, our study is unique in that it also demonstrates the additive effects of multiple pre-existing conditions on further decreasing fluid administration and metric compliance.

Fluid resuscitation in septic shock patients with CHF

Our results demonstrate that CHF patients received significantly less fluids and were less likely to be compliant with weight-based and total volume-based fluid goals compared with the general population of patients without a pre-existing condition. The only statistically significant difference between compliant and noncompliant CHF patients was a shorter ICU LOS in the compliant group. Despite the fear of precipitating a fluid overload state, no statistically significant differences in mortality, likelihood of intubation, or inpatient LOS were elucidated between compliant and noncompliant patients with CHF. Patients with CHF are at an increased risk of fluid

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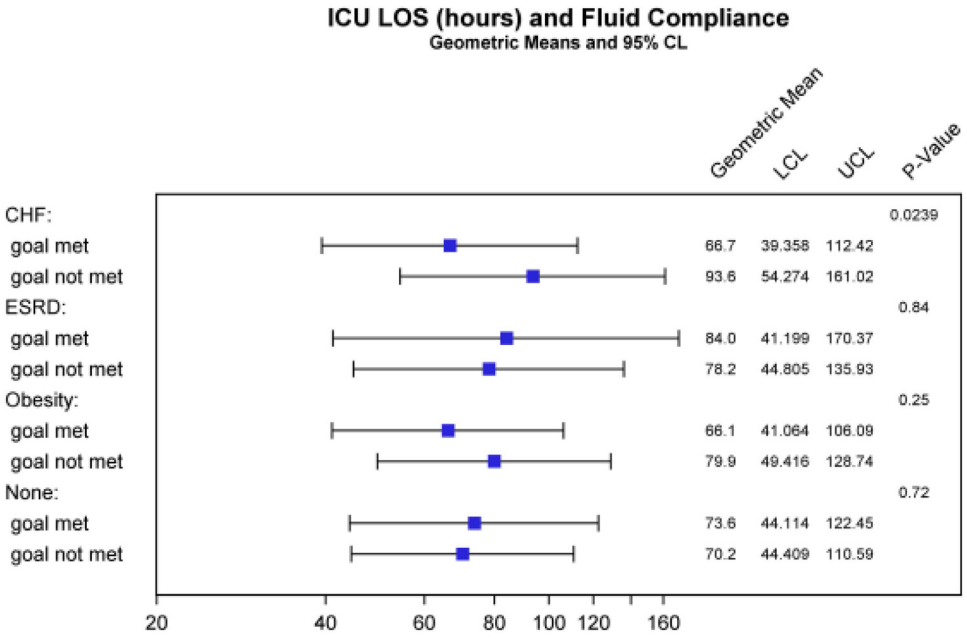

Figure 4. Mean intensive care unit (ICU) length of stay (LOS) (h) in patients with septic shock based on compliance with weight-based fluid volume goal, adjusted for age, race, and gender. CHF = congestive heart failure; ESRD = end-stage renal disease; LCL = lower confidence limit; OR = odds ratio; UCL = upper confidence limit.

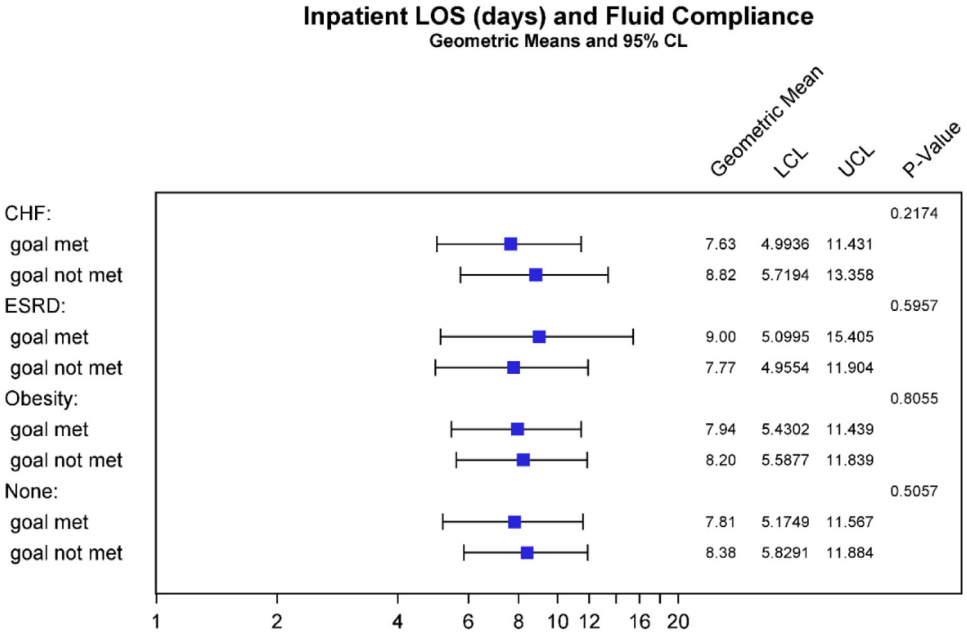

Figure 5. Mean inpatient length of stay (LOS) (days) in patients with septic shock based on compliance with weight-based fluid volume goal, adjusted for age, race, and gender. CHF = congestive heart failure; ESRD = end-stage renal disease; LCL = lower confidence limit; OR = odds ratio; UCL = upper confidence limit.

overload when receiving rapid infusions and theoretically may have worse clinical outcomes when subject to aggressive fluid resuscitation (10). A single study estimates that septic shock patients with pre-existing CHF receive approximately 1000 cc less fluid during the initial 24-h period, and independent measures of cardiac function and structure, including left ventricular ejection fraction, diastolic dysfunction, and left ventricular hypertrophy, may not be independently associated with fluid compliance (11,12).

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Fluid resuscitation in septic shock patients with ESRD

Our results demonstrate that ESRD patients received significantly less fluid and were less likely to achieve provider compliance with weight-based and total volume-based goals compared with the general population of patients without a pre-existing condition. Despite the fear of precipitating a fluid overload state in patients with ESRD, there were no statistically significant differences in all-cause mortality, need for intubation, and ICU and inpatient LOS between ESRD patients who were compliant and noncompliant with the weight-based volume goal. Previous studies have demonstrated that approximately 4% of patients with septic shock presenting to the ED may have a previous diagnosis of ESRD and, despite representing a small percentage of the septic shock population as a whole, these ESRD patients have presentation characteristics similar to non-ESRD patients (13). In spite of these similarities, it has been shown that ESRD patients are less likely to receive a 30-cc/kg fluid bolus within 3 h and 6 h of ED arrival (14,15). Although a positive fluid balance is associated with increased 60-day mortality in sepsis patients with renal failure, ESRD patients who receive the 30-cc/kg bolus have not been found to have an increased risk of inpatient mortality, need for urgent dialysis, need for intubation, or prolonged ICU or inpatient LOS (15,16).

Fluid resuscitation in septic shock patients with obesity

Our results show that all groups containing obese patients had significantly higher calculated weight-based volume goals than the general population of patients without a pre-existing condition. Although the obesity-only group was as likely to receive at least 2000 cc of i.v. fluids compared with the general population of patients without a pre-existing condition, all of the groups containing obese patients were significantly less likely to achieve provider compliance with the weight-based volume goal. Obese patients who were compliant with the weight-based volume goal had significantly lower all-cause mortality and were less likely to require intubation at 72 h and during hospitalization compared with obese patients who were noncompliant with no significant differences seen in ICU and inpatient LOS. Obese patients and those without a pre-existing condition were the only subgroups that had statistically improved mortality when achieving compliance with a 30-cc/kg weight-based volume goal in the ED. Approximately one-third of patients presenting with septic shock in the United States are also obese (17). Despite being a significant mortality risk factor and contributor to a multitude of medical comorbidities, including cardiovascular disease, diabetes, cancer, liver disease, chronic kidney disease, and sleep apnea, outcome data have shown that, during critical illness, obesity is not associated with increased mortality compared with patients of normal weight (18,19). Although obese patients may receive significantly less fluid per kilogram within 3 h of ED arrival compared with patients with lower BMIs, a systematic review on the association between obesity and mortality among patients admitted with septic shock demonstrated mixed results with all but a single study demonstrating either no difference or lower mortality among obese patients (20). Findings suggestive of lower mortality in the obese have collectively been labeled the obesity paradox, and this phenomenon in which increasing BMI seems to serve as a protective factor has been identified in other disease states as well (21). An international multicenter study investigating sepsis bundle interventions on clinical outcomes in obese patients found that despite receiving significantly lower weight-based volumes of crystalloid or colloid fluids, obese and very obese patients with septic shock had lower ICU mortality outcomes (22). Further analysis has found that focusing on adjusted body weight vs. actual body weight goals is associated with decreased mortality and improved clinical outcomes (17).

Along with early recognition, source control and administration of antibiotics, and support of the cardiopulmonary system, the administration of i.v. fluids is central to the management of patients presenting with septic shock. Current evidence and opinion suggest that a "one size fits all" approach regarding administration of a 30-cc/kg i.v. fluid bolus within 3 h of ED arrival is suboptimal for certain patient subgroups, especially those with ESRD and CHF. Use of alternative means of determining fluid status, such as history, physical examination findings, inferior vena cava diameter and collapsibility, central venous pressure, and other markers, may be best to direct individualized care. The authors believe that a CMS requirement that encourages emergency physicians to administer a 30-cc/kg bolus to patients with pre-existing CHF, ESRD, or obesity should be further evaluated for proof of concept and lack of harm, and the recommendation influencing the SEP-1 fluid metric may be strengthened with a prospective, multicenter, and randomized controlled trial that stratifies at-risk patient subgroups.

Limitations

As a retrospective review, the accuracy of our results is limited by source information as recorded by providers in patient charts. Patients were selected from a single urban academic center with approximately 100,000 ED visits per year serving a diverse patient community, and results may not be generalizable across other academic and community sites with significantly lower or higher patient volume or acuity. In addition, our inclusion criteria consisted of those patients requiring vasopressors and may not be generalizable to those patients with severe

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sepsis or those less critically ill who may be less likely to benefit from fluid resuscitation. Patient encounters between June 1, 2013 and May 30, 2018 were screened for study inclusion, and the CMS bundle metrics were published and disseminated in 2015. These recommendations may have affected provider awareness of septic shock and therefore influenced practice standards. Patients presenting before and after the dissemination of the SEP-1 guidelines may not be directly comparable. Our sample included patients with suspected septic shock, and final International Statistical Classification of Diseases and Related Health Problems, 10th Revision, codes were not cross-referenced, making it plausible that some patients had an alternate type or combination of shock states, however, given provider practice styles at the research site, if all inclusion criteria were met, there was likely to be a high clinical suspicion for septic shock. It is plausible that some patients may have had undiagnosed CHF or only clinical symptoms with normal features on echocardiogram, and were inappropriately excluded from the CHF groups. Bedside point-of-care echocardiograms, if performed during the ED encounter, were not evaluated. Regarding the primary outcome, total volume of fluid administered in the ED was measured as documented in the MAR during the patient's ED LOS and then verified through manual chart abstraction for confirmation. It is possible that fluid was administered and not recorded, or recorded and not administered, however, this should be consistent among all groups. Only MRNs with a single ED encounter during the 5-year period were used in final data analyses as more complex analytic models would be required to perform same-subject correlation of patients with multiple visits, and the sample size of patients with multiple visits was relatively small. Compliance with the sepsis fluid bundle metric was assessed and compliance with other bundle metrics was not analyzed; as such, their impact on secondary clinical outcomes is unknown. In addition, the small sample size of ESRD patients may have led to an underpowered analysis of the multiple condition groups, which included ESRD.

CONCLUSIONS

In summary, patients with septic shock and pre-existing conditions, including CHF, ESRD, or obesity, are at an increased risk of provider noncompliance with the SEP-1 weight-based fluid metric, and the likelihood of noncompliance increases as the number of pre-existing conditions increases. Although our results do not demonstrate that provider compliance leads to a significant decrease in all-cause mortality for CHF and ESRD patients, they also do not show an increase in the risk of intubation for these groups. Our results indicate that obese patients benefit from provider compliance with the weight-based volume goal as demonstrated by lower likelihoods of mortality and intubation. Compliance does not appear to have a clinically significant impact on ICU and inpatient LOS across subgroups with at least one pre-existing condition, although a shorter ICU LOS for CHF patients compliant with the weight-based volume goal was found to be statistically significant. Further studies to determine optimal initial fluid resuscitation strategies in these subgroups are warranted.

APPENDIX A ANTIBIOTICS AND VASOPRESSORS USED DURING ELECTRONIC QUERY OF STUDY PARTICIPANTS

Intravenous Antibiotics

Amikacin, ampicillin, ampicillin/sulbactam, azithromycin, cefazolin, cefmetazole, cefotaxime, ceftazidime, ceftazidime/avibactam, ceftolozane/tazobactam, ceftriaxone, cefuroxime, chloramphenicol, ciprofloxacin, clindamycin, cloxacillin, colistin, daptomycin, doripenem, doxycycline, gatifloxacin, gentamicin, levofloxacin, linezolid, meropenem, metronidazole, minocycline, moxifloxacin, nafcillin, oxacillin, penicillin, piperacillin, piperacillin/tazobactam, polymyxin B, ticarcillin/clavulanate, tobramycin, trimethoprim/sulfamethoxazole, vancomycin

Intravenous Vasopressors

Norepinephrine, epinephrine, dopamine, vasopressin, phenylephrine

APPENDIX B UNIQUE METRICS ELECTRONICALLY AND MANUALLY ABSTRACTED FROM INDIVIDUAL ELECTRONIC HEALTH RECORDS

List of Electronically Abstracted Metrics

1. Medical record number
2. Date of emergency department visit
3. Gender
4. Admit date
5. Discharge date
6. Inpatient length of stay, in hours
7. Age, in years
8. Discharge disposition
9. Recorded height, in meters
10. Recorded weight, in kilograms
11. Calculated body mass index
12. Calculated weight-based goal fluid volume

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13. Total volume of fluid ordered in emergency department, in cubic centimeters
14. Race
15. Ethnicity

List of Manually Abstracted Metrics

1. Transfer from outside hospital
2. Emergency department death
3. Intubated in prehospital setting
4. Intubated within 72 h of emergency department arrival
5. Intubated during inpatient length of stay
6. Pre-existing diagnosis of non–insulin-dependent diabetes mellitus
7. Pre-existing diagnosis of insulin-dependent diabetes mellitus
8. Prior echocardiogram documented
9. Left ventricular ejection fraction measured on most recent echocardiogram, as percent
10. Grade diastolic dysfunction
11. Pre-existing diagnosis of congestive heart failure
12. Pre-existing diagnosis of end-stage renal disease
13. Documentation that patient is actively undergoing dialysis treatment
14. Emergency department length of stay, in minutes
15. Intensive care unit length of stay, in hours
16. Initial lactate, in mmol/L

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ARTICLE SUMMARY

1. Why is this topic important?

Emergency physicians express concern administering a 30-cc/kg fluid bolus to patients with septic shock with pre-existing congestive heart failure (CHF), end-stage renal disease (ESRD), or obesity, due to the perceived risk of precipitating a fluid overload state.

2. What does this study attempt to show?

This study attempts to determine whether there is a difference in fluid administration to patients with septic shock with these pre-existing conditions in the emergency department. Secondary objectives focus on whether compliance impacts mortality, need for intubation, and length of stay (LOS).

3. What are the key findings?

Patients with septic shock with pre-existing comorbidities, such as CHF, ESRD, or obesity, are less likely to achieve provider compliance with a 30-cc/kg weight-based fluid bolus in the emergency department. As the number of pre-existing conditions increases, compliance decreases further. Although compliance is not associated with mortality, need for intubation, or ICU LOS in CHF and ESRD patients, it does seem to be protective in patients with obesity or no pre-existing conditions with no significant increase in need for intubation or LOS.

4. How is patient care impacted?

Management of patients exhibiting features of septic shock should be individualized, and objective measures of fluid status should be used to guide fluid resuscitation. Further studies investigating the potential benefits and harm of a 30-cc/kg bolus in subgroups of patients with septic shock are warranted.

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