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SPECIAL FEATURE

What's in a Name: Should Protocols for Sepsis Treatment Be So Complete?

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Dr. Nadler reports no relationships relevant to this field of study.

Sepsis is a systemic inflammatory response to a variety of infectious processes. Often seen in modern hospitals, this phenomenon was described more than two millennia ago by Hippocrates as the process through "which flesh is made rotten."[1] Despite this long awareness of sepsis, it remains challenging to properly diagnose and treat today, leading to high mortality despite protocolized care.[2,3] One of the first sepsis protocols was implemented by Ignaz Semmelweis in the 19th century when he insisted on hand washing with chlorinated lime solution prior to exams of pregnant women, significantly reducing the mortality rate from puerperal fever. Although it was not widely accepted in his time, other researchers, such as Lister, Koch, and Schottmuller, further extended this insight and developed methods for preventing sepsis.

In 2001, Rivers et al published a landmark study describing the efficacy of a comprehensive protocol driven by specific goals of treatment in 263 patients with sepsis.[4] This became known as early goal-directed therapy (EGDT). The fundamental principle underlying this protocol was to match oxygen delivery to oxygen

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demand, thereby limiting organ damage and subsequent mortality. Patients with sepsis in the EGDT arm received a central venous catheter (CVC) with continuous central venous O_2 saturation ($ScvO_2$) monitoring, fluid until the central venous pressure (CVP) measured > 8-12 mmHg, vasopressors to achieve a mean arterial pressure (MAP) > 65 mmHg, and transfusions of packed red cells and inotropes to maintain $ScvO_2$ > 70%. The standard care arm targeted a CVP > 8-12, MAP > 65, and urine output > 0.5 mL/kg/hr. In-hospital mortality was significantly lower in the EGDT group (38/130, 38%) than in the standard therapy group (59/133, 46.5%; relative risk = 0.58, $P < 0.009$). A benefit was also observed with 28- and 60-day mortality.

With these results, the EGDT protocol was disseminated as part of the Surviving Sepsis Campaign. A subsequent meta-analysis composed largely of before and after trials demonstrated that adoption of sepsis protocols improved mortality.[5] However, questions arose regarding the necessity of every step within this complicated protocol.[6] Recently, several large, randomized, controlled trials examined whether all components of EGDT are important for improving survival.[7-9] Additional studies specifically addressed the utility of CVP monitoring, the goal of $ScvO_2$ for resuscitation, and appropriate transfusion thresholds.[10-12]

SEPSIS PROTOCOL TRIALS

In May 2014, the Protocolized Care for Early Septic Shock (ProCESS) trial was published.[7] This multicenter, randomized, controlled trial of 1341 patients compared three approaches to early sepsis care. The first approach was EGDT as described by Rivers in 2001. The second arm used a "protocol-based standard of care" that did not mandate central line placement, $ScvO_2$ monitoring, inotropes, or blood transfusions, but contained other components of EGDT. The third arm was "usual care" in which there were no prompts or educational materials given to staff managing these patients. Remarkably, the primary outcome of 60-day mortality was similar in all three arms (21%, 18.2%, and 18.9%, respectively). The major difference was an increased admission rate to the ICU in the EGDT arm (91.3% vs 85.4% and 86.2%). When compared with EGDT, the protocol-based and usual care arms led to significantly lower rates of central line placement, use of inotropes, and blood transfusions (*see Table 1*). Reports of serious adverse effects were similar in each group. In a post-hoc analysis, there was no effect when adjusting for APACHE II scores, lactate levels, or randomization times. This cohort had similar demographics to the Rivers study, although these patients were slightly younger and had fewer comorbidities.

The Australian Resuscitation in Sepsis Evaluation (ARISE) trial followed the ProCESS trial.[8] This was another multicenter trial that included 1600 patients, mostly in Australia and New Zealand, and compared EGDT with "usual care." Similar to the ProCESS trial, usual care meant all investigations, monitoring, and treatment were only instituted if the primary team considered it clinically indicated. The primary endpoint was 90-day mortality with secondary endpoints evaluating duration of stay and necessity for organ support, such as mechanical ventilation, renal-replacement therapy, and vasopressors. As with the ProCESS trial, there was no significant difference in 90-day mortality between the EGDT and usual care groups (18.6% vs 18.8%; *see Table 1*). Furthermore, a prespecified subgroup analysis failed to demonstrate a benefit from EGDT when stratified by age, APACHE II score, use of invasive mechanical ventilation, refractory hypotension, or hypoperfusion. There were fewer central venous catheters overall as well as fewer arterial lines placed in the usual care group (91.4% vs 76.3%) (*see Table 1*). The total amount of intravenous fluid was similar in the two groups (1964 mL vs 1714 mL, $P = 0.51$). Similar to the ProCESS trial, the usual care group used less inotropes and red cell transfusions than

the EGDT group (*see Table 1*). No differences in rates of adverse outcomes were observed between the two groups.

The Protocolized Management in Sepsis (ProMISe) trial continued the investigation of protocolized care for early sepsis.[9] This multicenter trial randomized 1260 patients from 56 centers in England to EGDT vs usual care. The primary outcome was 90-day mortality with secondary outcomes, including Sequential Organ Failure Assessment (SOFA) scores at 6 and 72 hours, advanced organ support, and length of stay in the ED and ICU, among others. Although this study demonstrated overall higher mortality than ProCESS and ARISE, there was no statistically significant difference in mortality between the EGDT and usual care groups (29.5% vs 29.2%; *see Table 1*). Again, the two groups had similar intravenous fluid administration but fewer use of inotropes, central lines, and red cell transfusions in the usual care group (*see Table 1*). Interestingly, average SOFA scores were higher in the EGDT group than the usual care group at 6 and 72 hours (6.4 vs 5.6 and 4.0 vs 3.7, respectively) while their baseline values were similar (4.2 and 4.3). There were no differences between the EGDT and usual care groups with respect to advanced respiratory support (28.9% vs 28.5%, $P = 0.90$) or renal support (14.2% vs 13.2%, $P = 0.97$). There were more patients requiring advanced cardiovascular support in the EGDT group (37.0% vs 30.9%, $P = 0.026$), and this group had a longer median ICU length of stay (2.6 vs 2.2 days, $P = 0.005$). The ProMISe study further evaluated cost-effectiveness and demonstrated no significant difference in health-related quality of life, quality-adjusted life-years up to 90 days, costs to 90 days, or incremental net benefit up to 90 days of EGDT compared with usual care. As before, there was no difference in adverse effects between the groups.

■ COMMENTARY

How do we reconcile the early success of EGDT with more recent trials that demonstrate similar efficacy of EGDT with "usual care"? It is clear that mortality due to sepsis has steadily decreased since 2000.[2,13] Using the Healthcare Costs and Utilization Project's Nationwide Inpatient sample, Kumar et al demonstrated that between 2000 and 2007 while the number of hospitalizations for sepsis increased from 143 to 243 per 100,000 and the number of organ systems affected increased from 1.6 to 1.9, the mortality rate from sepsis decreased from 39% to 27%.[2] Similar trends are evident overseas.[13] Clinicians have become better at treating sepsis. In the Rivers study, patients receiving EGDT had significantly more fluid given than standard therapy (4981 vs 3499 mL, $P < 0.001$).[4] In the ProCESS, ARISE, and ProMISe trials, the treatment and usual care arms generally had similar fluid administration, source control measures, and early antibiotics.[7-9] With the publication by Rivers of EGDT in 2001, early and aggressive treatment of sepsis has become "usual care."

Furthermore, there is a better understanding of the important physiologic goals for treatment. Crucial for EGDT was the placement of $ScvO_2$ catheters that not only allowed for infusion of vasopressor agents, but also measurements of CVP for fluid management and $ScvO_2$ measurements to direct transfusion and inotropic support. However, it has become clear that CVP is not the best determinant of fluid-responsiveness in hypotension. In a systematic review of 24 studies including 803 patients, Marik et al demonstrated a very poor relationship between CVP, intravascular volume, and the ability of CVP to predict the hemodynamic response to fluid challenges.[10] The likelihood of CVP predicting fluid responsiveness was 56%, "no better than flipping a coin." $ScvO_2$ is an imperfect surrogate for tissue perfusion, and the goal of $ScvO_2 > 70\%$ may not optimize tissue perfusion. Jones et al studied a protocol directed at improving lactate instead of optimizing $ScvO_2$ and demonstrated no difference in mortality.[11] There may not be a need for $ScvO_2$ monitoring. Finally, EGDT protocols targeted a hematocrit > 30% when $ScvO_2$ was low. Recently, Holst et al reported no difference in 90-day mortality in patients with septic shock randomized to a conservative transfusion threshold (hematocrit < 21%) vs a more liberal threshold (hematocrit < 28%).[12]

CVP monitoring, $ScvO_2$ goals, and transfusions are unlikely to significantly affect outcomes in sepsis. In fact, a thorough evaluation of the effect of each component of sepsis bundles individually did not demonstrate large treatment effects for many variables.[14] While overall mortality improved with the adoption of sepsis protocols, risk-adjusted odds ratios of mortality due to achieving CVP > 8 and $ScvO_2 > 70$ were 1.00 and 0.98 respectively ($P = 0.98$ and 0.69). In contrast, within this same study significant effects were seen in obtaining blood cultures prior to antibiotics (odds ratio [OR], 0.76; $P < 0.0001$), commencing broad spectrum antibiotics (OR, 0.86; $P < 0.0001$), and plateau pressure control with mechanical ventilation (OR, 0.70; $P < 0.0001$). Many interventions within EGDT protocols were not shown to affect outcomes.

Table 1. Comparison of Sepsis Trials

Trial/Arm	CVCs (%)[a]	Intravenous Fluid (mL)[b]	Inotropes (%)[c]	Transfusion (%)[c]	Pressors (%)[c]	Mortality (%)[d]
Rivers Trial[4] (n = 263)						
EGDT	100	4981	13.7	64.1	27.4	44.3
Usual Care	100	3499	0.8	18.5	30.3	56.9
ProCESS[7] (n = 1341)						
EGDT	93.6	2805	8	63	54.9	21.0
Protocol-based	56.5	3285	1.1	37	52.2	18.2
Usual Care	57.9	2279	0.9	34	44.1	18.0
ARISE[8] (n = 1600)						
EGDT	90	1964	15.4	13.6	66.6	18.6
Usual Care	~61.9	1713	2.6	7	57.8	18.8
ProMISe[9] (n = 1260)						
EGDT	92.1	2000	18.1	8.8	53.3	29.5
Usual Care	50.9	1784	3.8	3.8	46.6	29.2

[a]6-hour time. In the ARISE trial, usual care CVC use is approximate.
[b]6-hour time point. In the ProMISe trial, intravenous fluid use represents median values, while the others are averages.
[c]6-hour time point.
[d]Rivers and ProCESS trials' mortality is assessed at 60 days, while ARISE and ProMISe trials report 90-day mortality.

With these studies in mind, where do we stand on protocols for the identification and treatment of sepsis? It may be the legacy of Rivers et al that the key interventions are early and aggressive management of sepsis with fluids, antibiotics, and source control. The protocolized approach originally proposed and studied served to direct needed attention and resources to the early recognition and treatment of sepsis. It is the repeated assessment, management of fluids, and attention to organ dysfunction that are the critical pieces of the protocol. CVP measurement, $ScvO_2$ monitoring, and transfusions, while part of EGDT, are not driving the improvements in mortality. That is not to say protocols are unimportant for sepsis management. As we learn which parameters are most predictive of fluid responsiveness and which are the best indications of poor tissue perfusion, we can refine these protocols further and continue to drive sepsis mortality downward. And of course, don't forget to wash your hands. ■

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ABSTRACT & COMMENTARY

Is Peripheral Intravenous Administration of Vasopressors Really Safe?

By Kathryn Radigan, MD, MSc

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Dr. Radigan reports no financial relationships relevant to this field of study.

SYNOPSIS: Administration of vasoactive medications by peripheral intravenous access is safe and feasible in critically ill, hypotensive patients.

SOURCE: Cardenas-Garcia J, et al. Safety of peripheral intravenous administration of vasoactive medication. *J Hosp Med* 2015 May 26 [Epub ahead of print].

Vasoactive medications (VMs) are most commonly administered through central venous catheters (CVCs). Cardenas-Garcia et al sought to evaluate the safety of administering VM through peripheral intravenous (PIV) access. In this single-center, single-arm, consecutive-patient study conducted between September 2012 and June 2014, 734 patients received norepinephrine, dopamine, or phenylephrine through PIV access 783 times. The duration of administration through the PIV was 49 ± 22 hours. Prior to study enrollment, there was an established protocol summarizing the safety requirements for the use of VMs through a PIV. These requirements included: a vein diameter > 4 mm, confirming placement of the PIV within the vein by ultrasound, appropriate PIV size (18 or 20 gauge), appropriate access positioning (no hand, wrist, or antecubital fossa sites), and blood return from the PIV access site prior to VM administration. According to the nursing protocol, the PIV site was assessed every 2 hours, and the medical team was alerted immediately if there was evidence of line extravasation. PIVs were limited to 72 hours maximum duration.

Nineteen patients (2%) experienced extravasation of the PIV access during the administration of the VM. These patients were treated with local phentolamine injection and application of local nitroglycerin paste without any evidence of tissue injury following treatment. Ninety-five (13%) of the patients who received VM through PIV access eventually required central intravenous access. The investigators concluded the administration of VM by PIV access was feasible and safe in this single-center medical ICU. They further concluded that clinicians should not regard the use of vasoactive medication as an automatic indication for central venous access.

■ COMMENTARY

VMs are necessary to improve hypotension in many critically ill patients. Traditionally, it has been standard of care to place a CVC prior to the administration of VM. Most intensivists have based this decision on the concern for local tissue injury due to the vasoconstrictive effect of the vasopressors. Although this study appears promising, a 2015 review that included 270 patients (from 85 primary studies or case reports) reported 325 separate local tissue injuries and extravasation events (318 events resulting from peripheral vasopressor administration and 7 events resulting from central administration).[1] Local tissue injury was defined as an adverse event attributed to vasopressor administration occurring within close proximity to the infusion site, while extravasation of vasopressor was considered an escape of vasopressor medication from the vessel. There were 204 local tissue injury events (179 skin necrosis, 5 tissue necrosis, and 20 gangrene) from peripheral administration of vasopressors, with an average duration of infusion of 55.9 hours (± 68.1 hours). There were also 114 events of extravasation of vasopressor solution, with 24.6%

of the events leading to tissue injury. Interestingly, this review highlights that tissue injury may occur without extravasation as a result of the profound effects of vasoconstriction local to the site of administration, leading to local tissue hypoperfusion.

Since the 2015 review was derived mainly from case reports, it is important to note that it may not be representative of general clinical practice outcomes, especially with the concern for publication bias. Regardless, it is apparent the 2015 review of the literature and the current study have disparate results. As already mentioned, this investigation maintained a strict protocol for IV placement and VM administration. Furthermore, the program also incorporated a multidisciplinary team that included training and education of the nursing staff and MICU house staff teams. If a patient experienced tissue extravasation, there was a standard treatment protocol, including treatment with phentolamine and nitroglycerin paste, implemented immediately. Given the disparate results found in the review and the current article, caution should be exercised in adhering to the recommendations made by the authors; PIVs *may* be safe *only* with a strict protocol that addresses training, education, and treatment. Without complete adherence to these protocols, the administration of VM through a PIV can be very risky. As intensivists, we also have to reflect on the potential consequences of such complications, which may include skin grafting with plastic surgery as well as how patients and families may react to this complication. The risks of PIVs must be weighed carefully with the known risks of CVCs, which may include infection, clot, bleeding, or pneumothorax. Regardless, the conclusion that "clinicians should no longer consider administration of norepinephrine, dopamine, or phenylephrine to be an automatic indication for CVC access" is dangerous. One cannot appropriately make this conclusion without a randomized, controlled trial comparing outcomes of VM use in critically ill, hypotensive patients with PIVs vs CVC. ■

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ABSTRACT & COMMENTARY

Emergent Vascular Access: Is Intraosseous Better Than Central Venous Catheter Placement?

By Betty Tran, MD, MSc

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Dr. Tran reports no financial relationships relevant to this field of study.

SYNOPSIS: In this single-center, prospective, observational study, intraosseous access outperformed central venous catheter placement in terms of first-pass success rates, mean placement times, and complication rates.

SOURCE: Lee PMJ, et al. Intraosseous versus central venous catheter utilization and performance during inpatient medical emergencies. *Crit Care Med* 2015;43:1233-8.

During inpatient medical emergencies, response teams are charged with obtaining quick vascular access for the delivery of life-saving medications and fluid therapy. Traditionally, the easiest vascular access has been placement of a triple lumen catheter in the femoral vein, as anatomic landmarks here are often easier to identify than other areas, minimizing the need for ultrasound assistance. Choice of this site over others also allows for easier compression of blood vessels in the event bleeding occurs, avoids unwanted central line complications such as pneumothorax, and avoids multiple personnel working in the same area (e.g., provider at head of bed performing intubation, provider doing chest compressions, etc). In pre-hospital and emergency

department settings, however, intraosseous (IO) catheter placement has provided a fast and safe alternative for vascular access, although data on their use in the inpatient setting are limited.

In a single urban teaching hospital over a period of 17 months, Lee et al collected data on emergent central access placement in 79 adult patients, 31 of whom received IO catheters and 48 received central venous catheters (CVC) during medical emergency team (MET) calls. The primary CVC site was the femoral vein (access was obtained without the use of ultrasound guidance), and the primary IO site was the medial proximal tibia, with the proximal humeral head being the secondary target if the first site attempt failed or if there was a contraindication. In their protocol, IO catheters were the first-line access for patients in cardiac arrest and were to be used if a CVC could not be placed after two attempts or within 5 minutes. Rotating house staff on METs were provided monthly simulation instruction in CVC and IO insertion. Most of the CVCs and IOs were placed by postgraduate year 2 and 3 residents, and a more senior resident, critical care fellow, or attending took over the procedure after failed attempts at the discretion of the MET leader. The primary outcome was first-pass success rates for CVC and IO placement. Secondary outcomes included time to successful placement, number of attempts, BMI, anatomical location, number of kits used, and complications of both catheters.

First-pass success rates were significantly higher during IO attempts compared to CVC passes (90.3% [95% CI, 80-100%] vs 37.5% [95% CI, 24-51%]; $P < 0.001$). Overall success rates were also significantly higher for IO vs CVC placement (96.8% vs 81.3%; $P = 0.04$). Procedure times were longer for CVC vs IO placement (10.7 vs 1.2 minutes; $P < 0.001$). Compared to IO placement, mean attempts per patient were higher for CVC (2.8 vs 1.1; $P < 0.001$), with more CVC kits used per patient (1.3 vs 1.1; $P = 0.03$). Complication rates were higher in the CVC group compared to the IO group (45.8% vs 9.1%) and were mostly due to arterial puncture or bleeding from the site; the three complications seen in patients receiving IOs were misplacement of the catheter, resulting in extravasation of vasopressors, resultant tissue necrosis, significant pain with infusion, and dislodgement.

■ COMMENTARY

Although this study was limited by a single center experience, smaller sample size, protocol design limiting IO attempts, and missing data due to lack of collection at night and on weekends, it highlights an intervention that could potentially alter clinical practice for many institutions. IO catheters allow for quick vascular access for fluids, vasopressors, and blood draws. Placement time is consistently faster compared to CVCs. Similar to other procedures, such as CVC placement, which could be considered high acuity/low opportunity situations, simulation training in IO will be helpful to gain practice and avoid complications, although there are no data to suggest learning this skill is more time-intensive or difficult than any other procedure. Although they are not meant to (and should not) replace the use of CVCs in the ICU, they provide an attractive option for vascular access in patients during emergent situations, such as in-hospital cardiac arrests, especially those with compromised vascular access (e.g., end-stage renal disease) without increased complication rates. Further prospective, randomized trials comparing IO to CVC placement in cardiac arrest and other emergent situations would help solidify the role of IO vascular access in these settings. ■

[Although they are not meant to (and should not replace the use of central venous catheters in the ICU, IO catheters provide an attractive option for vascular access in emergent situations.]

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CME/CNE QUESTIONS

1. In contrast to the original early goal-directed therapy (EGDT) trial, the ProCESS, ARISE, and ProMISe trials demonstrated:

a. improvement in mortality with EGDT vs usual care.

b. no difference in mortality with EGDT vs usual care.

c. EGDT led to fewer red cell transfusions.

d. EGDT led to significantly greater fluid resuscitation.

e. EGDT led to less inotrope use.

2. Which of the following statements regarding sepsis management is correct?

a. A central venous pressure < 8 mmHg accurately predicts mean arterial pressure will increase with a fluid challenge.

b. Transfusing to a hematocrit of > 30% improves outcomes in individuals with sepsis compared with lower transfusion thresholds.

c. A central venous oxygen saturation of > 70% guarantees adequate tissue perfusion.

d. Early administration of antibiotics is important for improving mortality in sepsis

e. All of the above.

3. When compared to the ProCESS, ARISE and ProMISe trials, the Rivers study of EGDT:

a. had the highest overall mortality.

b. had the largest patient population.

c. was the only multicenter study.

d. was the only multinational study.

e. was the only randomized, controlled trial of sepsis.

4. Local tissue injury from the infusion of vasoactive medications through a peripheral IV can be caused by:

a. the profound effects of vasoconstriction local to the site of administration, leading to local tissue hypoperfusion.

b. the extravasation of vasopressor outside of the vessel causing local injury.

c. both a and b.

d. neither a or b.

5. In the study by Lee et al comparing intraosseous (IO) catheters to central venous catheters (CVC):

a. CVC placement was more comfortable for the patient.

b. there were more complications during IO placement.

c. first-pass success rates were higher for IO placement.

d. mean placement times were shorter for CVC placement.

e. more IO kits were used per patient.

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