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ABSTRACT & COMMENTARY

Antipsychotics Do Not Shorten the Duration of ICU Delirium

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

SYNOPSIS: In this randomized, placebo-controlled trial, neither haloperidol nor ziprasidone altered the duration of delirium when compared to placebo.

SOURCE: Girard TD, Exline MC, Carson SS, et al. Haloperidol and ziprasidone for treatment of delirium in critical illness. *N Engl J Med* 2018; Oct 22. doi: 10.1056/NEJMoa1808217. [Epub ahead of print].

This randomized, placebo-controlled trial was designed to test whether haloperidol or ziprasidone affected delirium in ICU patients with respiratory failure or shock. The study was carried out between 2011 and 2017 in 16 U.S. centers. In total, researchers screened 20,914 patients, resulting in 1,183 consenting patients, of whom 566 developed delirium and were studied. Delirium was identified using the Confusion Assessment Method for the ICU (CAM-ICU) assessment tool.[1] The Richmond Agitation-Sedation scale (RASS) was used to define hypoactive (RASS < 0) and hyperactive (RASS > 0) delirium.[2] Of the 566 patients randomized, 89% demonstrated hypoactive delirium. Approximately 190 patients were randomized to each treatment group (haloperidol, ziprasidone, or placebo). Once delirium was identified, treatments were initiated at small doses (e.g., 2.5 mg IV haloperidol every 12 hours for patients < 70 years of age) and were increased gradually until delirium was no longer present or maximum doses were achieved. The mean doses administered were modest (e.g., haloperidol 11 mg ± 5 mg), and investigators temporarily withheld the study drug at least once during the trial for approximately half the patients. The mean length of exposure to the drug was four days. The primary endpoint

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was days alive without delirium or coma during the 14-day intervention. Secondary endpoints included 30- and 90-day survival, days to liberation from ventilator, and length of stay in the ICU and the hospital. Patient characteristics were similar across the three treatment groups. No treatment effect was seen for any primary or secondary endpoint with all odds ratios (including unity). There was no difference in side effects between the treatment groups. The investigators concluded that haloperidol and ziprasidone did not affect duration of delirium among patients with shock or respiratory failure.

■ COMMENTARY

Girard et al are to be commended for tackling such an important project. The difficulty in completing this trial is evidenced by the screening of more than 20,000 individuals to consent 1,183 — only to enroll just 566 patients. This low percentage enrollment affects the generalizability of this result, particularly for the subgroup of patients (all 57 of them) defined as having hyperactive delirium. The trial design was good, with appropriate entry and exclusion criteria, safety screening, duration of treatment, and appropriateness of endpoints. There was surprisingly good adherence (88%) to the Awakening and Breathing Coordination, Delirium Monitoring and Management, and Early Mobility (ABCDE) bundle. The use of the CAM-ICU screening tool is standard of care for identification of delirium. While the RASS scale is used widely for assessment of agitation levels, it was not developed to differentiate subtypes of delirium.

The study results do not support using antipsychotics in nonagitated delirious patients routinely. Study limitations include the low percentage enrollment and the relatively low average dose of antipsychotics administered. Would a more rapid increase in dose have produced an effect? Intensivists are more likely to treat delirium with antipsychotics when the patient is agitated. The data from the 57 patients described as having hyperactive delirium are not robust enough to support any conclusions regarding the role of drugs in this subpopulation. Girard et al did not address the use of these drugs in the many subgroups excluded from the trial (e.g., preexisting cognitive impairment or high risk of medical complications from the drugs). The results support minimizing the use of haloperidol and ziprasidone in delirious patients who are not agitated. Current best practice is to adhere to the ABCDE bundle,[3] remove causative agents when possible, and continue antipsychotics (only if they appear effective and for the minimum time necessary). The jury is still out regarding how to manage agitated delirium. Hopefully, investigators can proceed to a trial of patients specifically with agitated delirium perhaps using a different study drug, such as quetiapine, that may be more effective.[4] ■

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ABSTRACT & COMMENTARY

A Combination of Commonly Measured Clinical Variables May Predict Prolonged Mechanical Ventilation

By Samuel Nadler, MD, PhD

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

SYNOPSIS: The presence of four or more of the I-TRACH criteria (Intubation in the ICU, Tachycardia [heart rate > 110], Renal failure [blood urea nitrogen > 25], Acidosis [pH < 7.25], Creatinine > 2, HCO_3 < 20) accurately predicted those patients who would require mechanical ventilation for seven or more days.

SOURCE: Clark PA, Inocencio RC, Lettieri CJ. I-TRACH: Validating a tool for predicting prolonged mechanical ventilation. *J Intensive Care Med* 2018;33:567-573.

The duration of mechanical ventilation carries significant implications for patient care. Many patients and their families report they do not wish to be on life support for a prolonged period and would opt not to be put on a ventilator if that were the expected outcome. However, it can be challenging to predict which patient likely will experience a lengthy course on a ventilator.

The I-TRACH trial was a prospective, observational study of 225 patients that sought to validate a prediction tool that identifies patients at greatest risk for prolonged mechanical ventilation (PMV). A previous study of 99 patients generated this prediction tool.[1] In a multivariate analysis, the variables statistically associated with PMV included: intubation in the ICU, heart rate > 110 beats per minute (bpm), blood urea nitrogen > 25 mg/dL, pH < 7.25, creatinine > 2 mg/dL, and serum bicarbonate < 20 mEq/L. For this study, PMV was defined as requiring > 7 or 14 days of mechanical support. Individually, none of these values were very predictive of PMV (odds ratios ranging from 1.26 for heart rate > 110 bpm to 1.91 for intubation in ICU). However, if four of more of these criteria were met, this tool demonstrated a receiver operator curve (ROC) of 0.824 for predicting PMV. This compared favorably with other screening tools such as Acute Physiology and Chronic Health Evaluation (APACHE) III (ROC = 0.634), APACHE II (ROC = 0.652), Sequential Organ Failure Assessment (ROC = 0.608), and Acute Physiology Score (ROC = 0.575).

■ COMMENTARY

The results of this study validate a clinical tool using common ICU variables for predicting prolonged mechanical ventilation. The ROC of 0.824 is better than other prediction models. However, one must consider both the implications and strength of any predictive model for clinical decision-making. For PMV defined as > 14 days, the positive predictive value was 45.7%. Fewer than half of patients who met four or more of these criteria required mechanical ventilation for more than two weeks. Meanwhile, the negative predictive value was 89.8%. This implies that not meeting four of these clinical criteria can give confidence that a patient will not need PMV, but meeting these criteria is not sufficiently predictive to direct discussion of forgoing intubation or the need for tracheostomy at the time of intubation.

Additionally, there was a large portion of this cohort with neurologic conditions, such as Guillain-Barré, syndrome that represent a very different population from most ICUs. In this study, 43.8% of patients intubated had underlying neurologic disease.

Another goal of this clinical tool was to identify patients who might benefit from early tracheostomy. Again, a positive predictive value of 45.7% does not seem strong enough to consider an invasive surgical procedure early in the course of mechanical ventilation. Furthermore, the benefit of early tracheostomy remains uncertain. The TRACHMAN trial did not show significant benefit in those patients who underwent tracheostomy within four days vs. those who received a tracheostomy after 10 days.[2] However, a limitation of this study was an inability to predict patients who ultimately required tracheostomy. Other researchers who use these criteria to randomize patients for early vs. late tracheostomy might be able to demonstrate benefit. ■

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ABSTRACT & COMMENTARY

Diagnosis Sepsis: Is Newer Better?

By Kathryn Radigan, MD, MSc

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

SYNOPSIS: In hospitalized patients who deteriorated from suspected infection, Sepsis-3 septic shock criteria predicted in-hospital mortality better than systemic inflammatory response syndrome-based criteria.

SOURCE: Fernando SM, Reardon PM, Rochwerg B, et al. Sepsis-3 septic shock criteria and associated mortality among infected hospitalized patients assessed by a rapid response team. *Chest* 2018;154:309-316.

Since sepsis remains the leading cause of in-hospital death, appropriate recognition, prognostication, and treatment are the most important components to improving survival. Rapid response teams (RRTs), groups trained specifically to respond to deteriorating patients, have been a major component in these efforts. Identification of sepsis patients has been based on the presence of the systemic inflammatory response syndrome (SIRS) since 1991. However, the authors of the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) criteria recently proposed using the Sequential Organ Failure Assessment (SOFA) score and the quick Sequential Organ Failure Assessment (qSOFA) score for detection, risk stratification, and prognostication of patients.

To optimize the timing of evaluation, the more simplified qSOFA criteria has been popularized. Two out of the three qSOFA criteria (low blood pressure [systolic ≤ 100 mmHg], higher respiratory rate [≥ 22 breaths/min], and altered mental status [Glasgow Coma Scale score < 15]) with suspicion for infection indicates an elevated risk of death. The authors of Sepsis-3 also identified septic shock as the initiation of vasopressors to maintain a mean arterial pressure of ≥ 65 mmHg with a serum lactate > 2.0 mmol/L after adequate fluid resuscitation.

On the other hand, SIRS-based sepsis criteria include two out of the four following criteria: fever > 38°C or < 36°C, heart rate > 90 beats/minute, respiratory rate > 20 breaths/minute or arterial $PaCO_2$ < 32 mmHg, or abnormal white blood cell count in patients with suspected infection. The authors of the SIRS-based septic shock criteria expanded the definition to include persistent hypotension (systolic blood pressure < 90 mmHg) requiring administration of vasopressors or evidence of perfusion abnormalities (including acidosis, lactic acid, altered mental state, or oliguria).

To compare the prognostic accuracy of the SIRS-based and Sepsis-3 criteria for predicting in-hospital mortality among hospitalized patients with suspected infection and who received an RRT call, Fernando et al prospectively collected registry data from two different academic hospitals within the Ottawa Hospital network system from 2012-2016. Patients who were administered antibiotics

with cultures were suspected of infection. If staff drew cultures first, it was necessary to administer antibiotics within 72 hours. If staff administered antibiotics first, it was necessary to send cultures to the lab within 24 hours. The authors excluded patients with incomplete demographic/outcome data or those already with scheduled RRT follow-up.

Results revealed that more of the hospitalized patients met the SIRS-based septic shock criteria (n = 545) compared to the Sepsis-3 septic shock criteria (n = 418). Compared to patients who met the SIRS-based septic shock criteria, patients meeting the Sepsis-3 septic shock criteria demonstrated higher in-hospital mortality (40.9% vs. 33.5%; $P < 0.001$), ICU admission (99.5% vs. 89.2%; $P < 0.001$), and discharge rates to long-term care (66.3% vs. 53.7%; $P < 0.001$).

As for the prediction of in-hospital mortality, the sensitivity was higher for the SIRS criteria compared to qSOFA (91.6% vs. 64.9%), but specificity was higher for qSOFA compared to the SIRS criteria (92.2% vs. 23.6%). For hospitalized patients with deterioration from suspected infection, those who met Sepsis-3 septic shock criteria were at a higher risk of in-hospital mortality compared to those who met the SIRS-based criteria. Therefore, Sepsis-3 may be the preferred method for prognostication, and the SIRS-based criteria may be the preferred method to screen patients for consideration of ICU admission.

■ COMMENTARY

Severe sepsis accounts for almost 10% of all deaths.[1] Interestingly, this study highlighted that although the Sepsis-3 criteria may predict in-hospital mortality more accurately, the SIRS-based criteria may be more helpful as a screening tool. This particular study and a recently published meta-analysis affirm that qSOFA has poor sensitivity, but a more reasonable specificity.[2] Since SIRS criteria has low specificity with higher sensitivity, it will lead to fewer missed patients but many more false positives. Meanwhile, qSOFA leads to more missed patients but significantly fewer false positives. Although neither qSOFA nor SIRS is an ideal screening tool, the data do not support abandoning the traditional SIRS criteria for the more novel qSOFA criteria. Ideally, it would be best to use these tools together to identify at-risk patients and those with a high likelihood for deterioration.

qSOFA was extrapolated from the full SOFA score to create a mnemonic that can help clinicians remember the components effectively: THAM (tachypnea, hypotension, altered mentation). However, application of these simplified criteria may not be as simple as the mnemonic.[3] Depending on the quality and dedication of nursing staff, the accuracy of the Glasgow Coma Scale may be compromised. Freund et al studied the applicability of qSOFA compared to the full SOFA score. Despite its reliance on only three parameters, 14% of recruited patients were excluded from the analysis due to missing values.[4] Furthermore, it is known that the Glasgow Coma Scale is used accurately by experienced and highly trained users. Still, inexperienced users make consistent errors, limiting the reliability and accuracy of this measurement.[5] Unfortunately, the error rates were highest at the intermediate levels of consciousness, for which the recognition of changes in mental status often is most critical. Although the Fernando et al findings support the continued use of the Glasgow Coma Scale by appropriately trained and seasoned personnel, the results raise doubts about the reliability of the scale when untrained or inexperienced staff use it.

Although there is apprehension with the accuracy of the Glasgow Coma Scale for qSOFA, there remains concern about using respiratory rate as a major criterion for both the SIRS-based and Sepsis-3 criteria. Unlike other vital signs, this is a significant concern, as respiratory rate is the only vital sign that is not measured by a machine and tends to be the most neglected. Although measuring respiratory

rate is a simple task, it is rarely completed with this standard in mind. In a different study, Mukkamala et al asked medical students to evaluate patients' respiratory rates within an hour of nursing staff recording those rates. For respiratory rates > 23 breaths/min, nurses were correct only 15% of the time.[6] As the respiratory rate is used for both the SIRS-based and Sepsis-3 criteria, this may be one of the issues that make both criteria less than ideal.

Sepsis-3 criteria may be the favored method for prognostication, whereas SIRS-based criteria may be the preferred method to screen patients for consideration of ICU admission. Future studies are necessary to continue to explore the benefits of qSOFA and potentially reveal a more precise and reliable screening tool. Most importantly, it is paramount to remember that neither set of criteria is diagnostic. Using clinical judgment along with these guides remains the ideal approach. ■

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ABSTRACT & COMMENTARY

Early Rehospitalization Among ICU Survivors: How Can We Do Better?

By Betty Tran, MD, MSc, Editor

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

SYNOPSIS: In this mostly qualitative study focused on patient and caregiver experiences after ICU discharge, researchers identified two major readmission contexts — medically unavoidable and complex health and psychosocial needs — as well as 10 patient-level and system-level themes that contributed to readmission primarily in the latter context.

SOURCE: Donaghy E, Salisbury L, Lone NI, et al. Unplanned early hospital readmission among critical care survivors: A mixed methods study of patients and carers. *BMJ Qual Saf* 2018;27:915-927.

In an era that has seen improvement in hospital mortality for ICU patients,[1] there is a growing population of ICU survivors with post-intensive care syndrome (PICS). This syndrome includes disabilities in cognition, psychological health, and physical function. Additionally, family members of critically ill patients may experience symptoms of anxiety, depression, post-traumatic stress disorder, and lower quality of life (known as post-intensive care syndrome-family, or PICS-F).[2] Given these issues, readmission to the acute hospital setting is common,[3] although the exact determinants of readmission, especially from a patient and caregiver perspective, are poorly understood.

Donaghy et al chose a mixed methods approach to clarify contributors to unplanned hospital readmissions among ICU survivors across Scotland. Inclusion criteria included mechanical ventilation for > 48 hours and age > 18 years. The authors excluded organ transplant recipients, primary neurologic admissions, patients enrolled in palliative care, non-English speakers, and those lacking capacity or those who were too ill to participate. Investigators recruited 58 individuals (29 patients, 29 caregivers) to participate in semistructured interviews and to complete questionnaires (Functional Comorbidity Index for patients; Modified Caregiver Strain Index for caregivers) and a rating scale of the importance of nine previously identified factors important to readmission based on an *a priori* literature review. Separately, the investigators also conducted five focus groups comprised of a different set of 42 participants

(20 patients, 22 caregivers) that aimed to provide independent validation for and refinement of their interview findings.

Based on their data, the researchers identified two major readmission contexts: "complex health and psychosocial needs" and "medically unavoidable." In the former context, patients and caregivers believed several patient-level and system-level issues accumulated and interacted with pre-existing health and social issues to contribute to readmission. The five major patient-level themes that emerged included: multimorbidity and polypharmacy, problems with specialist equipment, psychological problems and alcohol/drug dependency, poor mobility, and fragile social support. The five major system-level themes included: poor preparation for hospital discharge (i.e., uncertain expectations for recovery, how to deal with common post-ICU problems), poor communication between acute and community-based care, inadequate psychological care, inadequate medication support (i.e., changes to treatment, inadequate explanation, poor communication with community services, delays in receiving new medications, and/or continuation of medications that should have been stopped), and lack of goal setting (i.e., lack of and/or unrealistic recovery goals, uncertainty in relation to participating in previously important activities).

For the complex health and psychosocial needs group, patients believed that timely anticipatory care, preparing them for what to expect at home, and early responses to address post-discharge needs could have prevented their readmissions. In contrast, the medically unavoidable group believed that few of the themes were present or contributed to their readmission. These patients tended to have better pre-existing health, stronger caregiver support, and lower reliance on health/social care services.

■ COMMENTARY

Other investigators have reported that pre-ICU health status is a significant driver for hospital readmission after an ICU stay.[4-5] Researchers interested in this area find it difficult to determine whether these hospitalizations are avoidable. Although a pre-ICU health trajectory may not be entirely modifiable, Donaghy et al neatly identified and organized common themes from a patient and caregiver perspective that can serve as constructs for interventions aimed to improve quality of care and patient outcomes.

The patient-level and system-level themes presented could be used in multiple ways. Clinicians could use the themes to screen ICU patients prior to discharge who are at high risk for readmission. Further, these themes could help clinicians develop multifaceted anticipatory care plans to address the diverse needs of ICU patients. Care plans and pathways after discharge have been developed for other patient populations after admission for diagnoses such as myocardial infarction, stroke, or cancer; however, ICU follow-up poses a bigger challenge in its heterogeneity of patient diagnoses, PICS dysfunction, and complex care needs compared to "disease-focused" groups.

[Based on an inductive analysis of a large sample of patients and caregivers, this study provides an organizational framework on which to focus efforts to develop complex healthcare interventions aimed at reducing readmissions after critical illness.]

There may be more concrete solutions for some issues, such as problems with specialist equipment or medication support, compared to other issues, such as fragile social support and goal setting. Based on this study alone, we are unable to determine the relative importance of each factor and how patient and caregiver resilience or coping interacts with the issues presented. In addition, these themes may manifest differently depending on the patient population or healthcare system. Based on inductive analysis of a large sample of patients and caregivers, this study provides an organizational framework on which to focus efforts to develop complex healthcare interventions aimed at reducing readmission after critical illness. ■

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CME/CE QUESTIONS

1. **In the trial by Girard et al, of the 1,163 patients consented, how many patients eventually developed agitated delirium?**
   a. 16
   b. 57
   c. 243
   d. 12

2. **In the trial by Girard et al, which antipsychotic was studied?**
   a. Olanzapine
   b. Risperidone
   c. Ziprasidone
   d. Quetiapine

3. **The I-TRACH trial demonstrated a clinical prediction tool to identify patients most likely to have prolonged mechanical ventilation with:**
   a. high negative predictive value.
   b. high positive predictive value.
   c. low positive predictive value.
   d. None of the above

4. **I-TRACH criteria associated with prolonged mechanical ventilation include:**
   a. intubation in the ICU.
   b. heart rate > 110 beats per minute.
   c. acidosis.
   d. All of the above

5. **Which of the following may be the preferred method to screen patients for consideration of ICU admission for sepsis?**
   a. SIRS-based septic shock criteria
   b. Sepsis-3 septic shock criteria
   c. Respiratory rate criteria
   d. None of the above

6. **In the study by Donaghy et al, which of the following was not a patient-level theme that was important to readmission after an ICU stay?**
   a. Poor mobility
   b. Prior ICU hospitalization within one year
   c. Fragile social support
   d. Problems with specialist equipment

7. **Based on the study by Donaghy et al, which of the following statements is true about patients who believed their hospital readmission was "medically unavoidable?"**
   a. Many believed system-level themes still were present.
   b. They had less robust caregiver support.
   c. They relied less on social care services.
   d. They had worse pre-existing health.

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Upon completion of this educational activity, participants should be able to:

- identify relevant topics in the practice of critical care medicine;
- utilize recommendations from current clinical guidelines; and
- manage common critically ill patient and ICU administration scenarios.