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ABSTRACT & COMMENTARY

The Conundrum of Open Lung Biopsy in Critically Ill Patients

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

SYNOPSIS: Open lung biopsy in mechanically ventilated, adult patients with pulmonary infiltrates or acute respiratory distress syndrome of unclear etiology had a high histopathologic yield and resulted in a change in therapy in the majority of patients, but was associated with complication of persistent air leak in about one-third of patients and a significant hospital mortality of 54%.

SOURCE: Wong AK, Walkey AJ. Open lung biopsy among critically ill, mechanically ventilated patients: A meta-analysis. *Ann Am Thor Soc* 2015;12:1226-1230.

Open lung biopsy is used in critically ill patients with acute respiratory distress syndrome (ARDS) or other pulmonary infiltrates of uncertain etiology to establish a diagnosis, particularly when patients fail to respond to standard treatment strategies and when prior diagnostic efforts, such as imaging, bronchoscopy, and culture analysis, fail to reveal a diagnosis.

This meta-analysis included 14 case series studies through December 2014, representing 512 critically ill, mechanically ventilated patients undergoing open lung biopsy for diagnosis of pulmonary infiltrates of unclear etiology or ARDS. The purpose of the analysis was to determine the most likely diagnoses, frequency of changes to therapy, and the rate of complications after open lung biopsy. Studies with predominantly immunocompromised patients were excluded. The included studies were limited to adult patients on mechanical ventilation and those that provided histopathologic results of the biopsy. The authors reported pooled, weighted summary proportions across studies with 95% confidence intervals (CI).

The average age was 56 ± 5 years, with 56% male patients. Biopsies were performed an average of 7.8 ± 4.3 days after initiating mechanical ventila-

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tion. Diagnostic evaluation prior to open lung biopsy included bronchoscopy in all patients and chest CT scans in most patients.

The most common diagnosis obtained from open lung biopsy was "fibrosis/pneumonitis" (25%; 95% CI, 14-37%). The second most common diagnosis was infection (20%; 95% CI, 15-27%). Of infectious etiologies, viral pathogens were identified in 50% of samples, followed by bacterial (23%) and fungal (23%) pathogens. Diffuse alveolar damage (DAD) was the third most common diagnosis (16%, 95% CI, 8-25%). Other pathological diagnoses included cryptogenic organizing pneumonia (7%), malignancy (6%), and vasculitis/connective tissue disease (3%). In 4% of the samples, the biopsy was categorized as "non-specific."

A change in therapy or patient management occurred in 78% of patients after open lung biopsy (95% CI, 74-81%). In most patients, this involved either initiation of a new therapy or tailoring of existing therapy. In 10% of patients (95% CI, 7-13%), therapy ended after biopsy.

Complications occurred in 29% of patients (95% CI, 25-33%). The most commonly reported complication was persistent air leak (71%; 95% CI, 63-78%). Mortality (defined in the studies as hospital, ICU, or 28-30 days after lung biopsy) was 54%, but did not significantly differ based on histopathologic diagnosis.

In a sensitivity analysis including a subset of five case studies with patients meeting American-European Consensus Criteria for acute lung injury and ARDS, the resulting diagnoses were similarly distributed: fibrosis/pneumonitis (26%), infection (25%), and DAD (25%). In this subset, mortality was 49%.

■ COMMENTARY

The authors highlighted an interesting finding that DAD, the hallmark histopathologic finding in ARDS, presented in only a few patients (16%) with clinical ARDS. This may be due in part to the timing of open lung biopsy at 1 week following the initiation of mechanical ventilation on average. This may have represented patients transitioning from the acute exudative phase, when DAD would be an expected finding, into the fibroproliferative phase.

The strength of this analysis is the ability to review pooled data for more than 500 patients, whereas the individual case series reports were limited to between three and 100 patients. It is unlikely that a randomized, controlled trial would be feasible in this population, so the meta-analysis provides helpful information to guide clinical decision making in the complex subset of ARDS patients in whom etiology is unclear and clinical response to current therapy is limited.

[These results suggest that those patients with a finding of diffuse alveolar damage have potentially worse outcomes and may represent a subtype of acute respiratory distress syndrome patients who respond differently to treatment.]

The limitations of the study, as noted by the authors, include heterogeneity of preoperative diagnostic evaluation, surgical expertise, timing of open lung biopsy, comorbid conditions, severity of illness, and potential variability of pathologist interpretation. A selection bias also exists in that clinicians may have selected for open lung biopsy only those patients considered stable enough to undergo the procedure, thus potentially skewing the complication and mortality reports. Additionally, the meta-analysis did not include information on what standard therapies patients were receiving, including pharmacologic therapy for possible infection, making generalizability difficult in the current era of ARDS management, which includes lung-protective ventilation strategies, management of fluid balance, trials of neuromuscular blocking agent, and prone positioning.

A recent study by Kao et al, published after this meta-analysis, retrospectively

reviewed 101 patients with ARDS who underwent open lung biopsy.[1] These patients were screened using the Berlin definition of ARDS and categorized based on severity of ARDS: mild (17%), moderate (57%), and severe (27%). DAD was diagnosed in 56.4% of patients. The proportions of patients in each ARDS category with DAD identified on biopsy were mild (77%), moderate (56%), and severe (44%), respectively. The overall hospital mortality rate was 60.4%, and did not differ significantly between ARDS severity groups: mild (64.7%), moderate (61.4%), severe (55.6%); $P = 0.81$. Patients with ARDS and a diagnosis of DAD had a higher mortality rate than those without DAD (71.9% vs 45.5%, $P = 0.007$). In a multivariate logistic regression analysis, the finding of DAD on pathology and Sequential Organ Failure Assessment (SOFA) score on day of biopsy were significantly and independently associated with hospital mortality (odds ratio [OR], 3.554; 95% CI, 1.385-9.120; $P = 0.008$ and OR, 1.424; 95% CI, 1.187-1.701; $P < 0.001$, respectively.)

Although the findings by Kao et al show a higher proportion of patients diagnosed with DAD compared to the meta-analysis, they are consistent with the results of the meta-analysis with regard to high mortality in the population of patients with ARDS and undergoing open lung biopsy. These results suggest that those patients with a finding of DAD have potentially worse outcomes and may represent a subtype of ARDS patients who respond differently to treatment.

Overall, the yield of open lung biopsy in identifying a diagnosis is high and may inform treatment decisions, particularly if DAD is identified. However, the decision to perform open lung biopsy in these patients with ARDS receiving mechanical ventilation should receive careful consideration given the rate of complications of the procedure (particularly persistent air leak) and the associated hospital mortality (54-60%), based on these reports. ■

REFERENCE

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ABSTRACT & COMMENTARY

Initial Choice of Fluid for Sepsis Resuscitation May Affect Mortality

By Samuel Nadler, MD, PhD

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

SYNOPSIS: The use of balanced salt solutions rather than isotonic saline or colloids may improve in-hospital mortality in patients admitted with septic shock.

SOURCE: Raghunathan K, et al. Association between initial fluid choice and subsequent in-hospital mortality during the resuscitation of adults with septic shock. *Anesthesiology* 2015;123:1385-1393.

Appropriate fluid resuscitation is a foundation of appropriate sepsis care. Which fluid type is best remains unclear. There are studies comparing crystalloids and colloids, starch solutions, albumin, etc. In practice, however, combinations of these options are often employed. Previously, Raghunathan et al demonstrated a superiority of balanced salt solutions when compared with isotonic saline.[1] This study examined the effects of combinations of crystalloid and colloids on in-hospital mortality from sepsis.

This retrospective cohort study between January 2006 and December 2010 evaluated 60,734 patients admitted with sepsis who had received at least 2 L of volume resuscitation, required vasopressors, had not undergone any major surgical procedure, and remained in the ICU for at least 2 days. Four categories of exposures were defined: isotonic saline alone (Sal); isotonic saline and balanced salt solutions (Sal + Bal); isotonic saline and colloids (Sal + Col); and all three (Sal + Bal + Col). The primary outcome was in-hospital mortality with secondary analyses looking at length of stay and cost per day among survivors. As there were significant differences in baseline characteristics in each group, risk adjustments for 27 known comorbidities were used, including inverse probability weighting, propensity score matching, and hierarchical logistic regression methods.

In the study cohort, most patients (n = 44,347) received Sal, while 3651 patients received Sal + Bal, 11,038 received Sal + Col, and 1698 received Sal +

Bal + Col. Using various risk adjustment methods, patients in the Sal + Bal cohort had the lowest absolute mortality (17.64-18.83%) as compared with Sal (20.19-21.35%), Sal + Col (24.16-29.94%), or Sal + Bal + Col (19.23-25.15%). In pairwise comparisons, Sal + Bal was associated with the lowest mortality whether Col were used (relative risk [RR], 0.84; 95% confidence interval [CI], 0.76-0.92; $P < 0.001$) or not (RR, 0.76; 95% CI, 0.70-0.89; $P < 0.001$). Conversely, administration of Col was not associated with an increased risk when Bal were used but did have an increased mortality rate when in combination with Sal (RR, 1.14; 95% CI, 1.08-1.19; $P < 0.001$). This effect persisted when the Col were restricted to albumin and hetastarch was excluded in the analysis. Additional sensitivity analysis demonstrated that the difference in mortality with Col administration could be due to an unidentified confounder but that the difference in mortality between Sal and Sal + Bal was robust. Secondary outcomes such as hospital length of stay and costs per day were comparable in the Sal vs Sal + Bal group, but were higher in the cohorts receiving colloids (Sal + Col and Sal + Bal + Col).

■ COMMENTARY

This study extends the conclusions of a previous analysis of similar data with respect to the choice of fluid for sepsis resuscitation. The baseline differences encountered included a lower rate of congestive heart failure in the Sal + Bal and Sal + Bal + Col cohorts and a higher rate of liver disease in the Sal + Col cohort. With inverse probability weighting and propensity score matching adjustments, these differences can be eliminated but other confounders may still bias results. When evaluating the outcomes in these cohorts at day 2, there are a few striking results. The Col-containing groups had the highest rates of mechanical ventilation, vasopressor use, bicarbonate infusions, total parenteral nutrition, and diuretic needs. Also telling is that the rate of tracheostomy at day 2 in the Sal + Bal+ Col group was 7.07% as compared with 3.12%, 4.74%, and 3.86% in the Sal, Sal + Bal, and Sal + Col groups, respectively, implying that clinicians saw this cohort as having the greatest likelihood of prolonged mechanical ventilation early in the course of the hospital stay.

While this is a retrospective analysis, some confidence can be gained that Bal seem to improve patient outcomes, regardless of Col co-administration. Looking at mortality at the hospital level, with an increasing proportion of balanced salt solution use, there is decreasing mortality. In general, one would not expect clinicians to adjust the proportion of Bal vs Sal based on perceptions of severity of illness. But this may belie that hospital-level interventions and protocols may have an effect on sepsis mortality.

Overall, this study adds to the evidence that Bal improve patient outcomes with sepsis. There has yet to be shown a significant risk or cost associated with their use, and lactated ringers is as prevalent in most ICUs as isotonic saline. It may be time to start using Bal routinely as part of sepsis resuscitation. ■

REFERENCE

1. Raghunathan K, et al. Association between the choice of IV crystalloid and in-hospital mortality among critically ill adults with sepsis. *Crit Care Med* 2014;42:1585-1591.

ABSTRACT & COMMENTARY

Bedside Ultrasound: Is It a Reliable Tool for Guiding Resuscitation in Patients with Undifferentiated Hypotension?

By Kathryn Radigan, MD

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

SYNOPSIS: The use of bedside ultrasound for patients with undifferentiated hypotension in the emergency department substantially changed the plan of care and reduced physician diagnostic uncertainty.

SOURCE: Shokoohi H, et al. Bedside ultrasound reduces diagnostic uncertainty and guides resuscitation in patients with undifferentiated hypotension. *Crit Care Med* 2015;43:2562-2569.

The use of bedside ultrasound has expanded tremendously over the last few decades. As it is readily available and relatively inexpensive, ultrasound provides the opportunity to examine hypotensive, critically ill patients, potentially leading to a faster, more accurate diagnosis.

Shokoohi et al used bedside ultrasound in an emergency department (ED) to help determine the etiology of undifferentiated hypotension. In this prospective, observational trial conducted at a single, academic, tertiary care hospital within a 32-month period, 118 patients with a systolic blood pressure < 90 mmHg after initial fluid resuscitation without an obvious source of hypotension were examined with an ultrasound using a standardized hypotension protocol. Although the duration of ultrasound exam was not recorded, a formally trained attending physician with extensive experience in emergency and critical care ultrasound performed the ultrasound protocol and included a focused cardiac scan to assess cardiac contractility, right ventricle size, and the presence of pericardial effusion/tamponade. It also included an inferior vena cava, abdominal, and transthoracic scan. Primary outcome measures included change in treating physician's diagnostic certainty before and after ultrasound and concordance of post-ultrasound ED diagnosis with chart review final diagnosis. Secondary outcomes were changes in treatment plan, use of resources, and changes in disposition after performing ultrasound protocol.

Results of the study revealed a 28% decrease in mean aggregate complexity of diagnostic uncertainty before and after ultrasound protocol (1.85-1.34; -0.51; 95% confidence interval, -0.41 to -0.62) along with a significant increase in the proportion of patients with a definitive diagnosis from 0.8% to 12.7%. There was exceptional concordance with the blinded consensus final diagnosis (Cohen kappa = 0.80). Furthermore, 24.6% of patients experienced a significant change in the use of IV fluids, vasoactive agents, and blood products, and there were significant changes in plans for further diagnostic imaging (30.5%) and ED disposition (11.9%). Early use of bedside ultrasound for critically ill patients with undifferentiated hypotension had a clinically significant effect on physicians' differential diagnosis with subsequent changes in patients' ED management.

■ COMMENTARY

Performance of bedside ultrasound has become an invaluable tool for immediate assessment of the critically ill patient, especially for evaluation of goal-directed therapy in the setting of a hemodynamically unstable patient. Shokoohi et al were able to show that early use of bedside ultrasound by a formally trained, experienced attending physician resulted in a statistically significant reduction in physicians' diagnostic uncertainty, with the leading diagnoses after ultrasound highly concordant with the final diagnosis. It also guided management decisions with significant changes in resuscitation efforts, diagnostic imaging, and ED disposition. Additionally, echo in the critically ill patient is known to be portable, quick, easy to use, and cost-effective.[1] It can also be used serially in patients to assess response to interventions in "real-time."

[Shokoohi et al were able to show that early use of bedside ultrasound by a formally trained, experienced attending physician resulted in a statistically significant reduction in physicians' diagnostic uncertainty, with the leading diagnoses after ultrasound highly concordant with the final diagnosis.]

Proper training is the main challenge of utilizing ultrasound for the diagnostic assessment and treatment of the ICU patient. The recent International consensus statement on training standards for advanced critical care echocardiography states that training programs should be rigorous and include competence-based testing.[2] The American College of Emergency Physicians suggests that didactic training, extensive hands-on experience, and expert review, along with formal certification, be included in every case.[3] This is particularly important, as proper training for intensivists requires competence in patients who are the most technically difficult in the most challenging situations. Unfortunately, this particular study did not address proper training, as the ultrasonographers were only described as formally trained attending physicians with "extensive experience" in emergency and critical care ultrasound but without specific reference to the methods of training and/or certification. Fortunately, other recent studies have suggested that training internists and residents with minimal ultrasound skills is feasible and effective.[1,4] Regardless of whether the ultrasonographer is a new resident early in training or a well-seasoned attending, it is most critical for the physician to appreciate when necessary images are not acquired or are insufficient for diagnosis. At that point, the timely

acquisition of a formal, comprehensive, confirmatory 2-D echocardiogram is essential, which was only performed in a limited number of patients in this study.

It is also important to highlight that the ultrasonographers within this study were blinded to patient's history and physical exam. It makes one consider the limitations of a trial that would randomize patients to standard care vs bedside echocardiography while blinded to details related to the clinical presentation. However, while these ultrasonographers were blinded to the clinical presentation, there was still a statistically significant change in diagnostic certainty, thus supporting application of ultrasound assessment despite the operator. In our practice, it is important to interpret information in the context of the available clinical presentation with the available hemodynamic information and respiratory data (i.e., central venous pressure, response to fluids, urine output, chest X-ray, venous oxygenation, etc.).

The role of bedside ultrasound in critically ill patients is extremely valuable and continually evolving. As this manuscript supports, bedside ultrasound has become a beneficial modality in the treatment, care, and monitoring of critically ill patients. Establishing optimal bedside echo protocols with the assurance of exceptional training and maintenance of skills remains a critical concern. We should continue to develop high quality and accuracy for echocardiography skills while applying this information to the clinical context of the patient to achieve the optimal benefit for each individual. ■

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ABSTRACT & COMMENTARY

Clinicians Are Skeptical of Early Warning Systems for Sepsis

By Elaine Chen, MD

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

SYNOPSIS: While early warning systems for sepsis lead to clinical action, clinicians are skeptical and do not perceive them to be beneficial.

SOURCE: Guidi JL, et al. Clinician perception of the effectiveness of an automated early warning and response system for sepsis in an academic medical center. *Ann Am Thorac Soc* 2015;12:1514-1519.

Severe sepsis is very common, with high morbidity and mortality. Early recognition and intervention improves mortality. However, the diagnosis may often be missed in early sepsis. An academic health system developed an electronic early warning and response system (EWRS) for sepsis in 2012, monitoring real time vital signs and laboratory data for hospitalized, non-ICU, acute care patients and notifying clinicians when specific criteria were met. This EWRS accurately identified patients at increased risk for deterioration and death, resulting in more timely sepsis care and ICU transfer, and possibly reducing sepsis mortality.[1]

All non-ICU medical and surgical inpatients were screened continuously for systemic inflammatory response syndrome (SIRS) criteria as well as criteria suggesting organ dysfunction. Whenever a patient fulfilled four or more criteria, a text page was sent to the covering provider (physician or advanced practice provider) and rapid response coordinator, and the bedside nurse received a pop-up notification in the electronic health record (EHR). Clinicians were instructed to meet at the bedside within 30 minutes to evaluate the patient and make any management changes. A patient could only trigger the alert once during hospitalization.

Successful implementation of new clinical systems includes clinician acceptance. The authors hypoth-

esized that clinicians would perceive the EWRS as useful and effective. They tested their hypothesis by surveying clinicians immediately after receiving the EWRS alert to evaluate their perception of the value of the alert. A 16-item questionnaire examined the utility of implementation of the EWRS. The rapid response coordinator distributed paper surveys within 2 hours of an EWRS alert for 6 weeks. Subjects included providers and bedside nurses in a single academic medical center. Anonymously completed surveys were returned to a designated envelope.

The EWRS generated 247 alerts; 494 surveys were distributed, and 232 were returned (127 from providers and 105 from nurses) for an overall response rate of 47%. Both providers and nurses reported that patients were medically stable both before and after the alert in approximately 80% of cases and did not commonly perceive the presence of a new critical illness. Sepsis was the suspected trigger in one-third of cases and volume depletion in one-fifth. In one-third of cases, clinicians perceived the values to be erroneous at baseline or inconsequential.

Management changed in approximately half of patients, most commonly by way of closer monitoring, basic diagnostic testing, or therapies such as intravenous fluids and antibiotics. Less than half of providers or nurses found the alert helpful and less than one-third thought it improved patient care. Nurses thought more favorably about the EWRS than providers.

Overall, clinicians were lukewarm in their support of the EWRS. The authors noted that users received no formal education regarding the importance of early sepsis recognition and treatment. The authors suggested that the alert may have resulted in behavioral modifications that improved clinical outcomes, but that clinicians may not have appreciated that the tool was a catalyst to better patient care. Alternatively, the alert may have caused pressure to order tests or escalate care in patients who did not truly require it. That most patients were perceived to be stable both before and after the alert may be a sign of low signal-to-noise ratio, which has a risk of leading to alert fatigue. Further investigation can focus on acceptability, resource allocation, and system improvement.

■ COMMENTARY

Previously, the article by Umscheid et al described with great enthusiasm some potential benefits of the EWRS.[1] In contrast, this article tempers that enthusiasm, with only moderate clinician support. While clinicians are often initially skeptical of any changes that disrupt their usual work flow, the benefits may be borne out over a longer time period before clinicians recognize them. Thus, I would be hesitant to discount the results of lukewarm clinician support to a potentially beneficial early warning system.

[This alert is highly personnel-intensive. Electronic health records have the potential to (and do) provide alerts at many points of contact ... I would be hesitant to warmly welcome a system that identifies stable patients 80%of the time because it has the potential to overburden busy clinicians with low-yield clinical data.]

However, as three clinicians were required to evaluate and communicate about each alert, this alert is highly personnel-intensive. EHRs have the potential to (and do) provide alerts at many points of contact. I have watched clinicians ignore myriad alerts in order to proceed with their work. Additionally, I would be hesitant to warmly welcome a system that identifies stable patients 80%of the time because it has the potential to overburden busy clinicians with low-yield clinical data. While I am optimistic about the EWRS and its potential to improve outcomes in sepsis, this system needs some improvements prior to widespread adoption. ■

REFERENCE

1. Umscheid JA, et al. Development, implementation, and impact of an automated early warning and response system for sepsis. *J Hosp Med* 2015;10:26-31.

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CME/CE QUESTIONS

1. In the meta-analysis reviewing open lung biopsy for determining the etiology of pulmonary infiltrates/acute respiratory distress syndrome, the most common histopathologic diagnosis was:
a. diffuse alveolar damage.
b. infection.
c. cryptogenic organizing pneumonia.
d. fibrosis/pneumonitis.
e. malignancy.

2. In this retrospective cohort study of fluid choice in sepsis resuscitation, which cohort had the lowest risk-adjusted in-hospital mortality?
a. Saline
b. Saline with balanced salt solutions
c. Saline with colloids
d. Saline with balanced salt solutions and colloids
e. None of the above

3. Sensitivity analyses in this paper showed which of the following conclusions to be robust and unlikely due to unaccounted confounding factors?
a. Saline was better than balanced salt solutions
b. Colloid was better than crystalloid alone
c. Balanced salt solutions were superior to isotonic saline
d. Crystalloids were better than mixed crystalloid/colloid combinations
e. Both b and c

4. To facilitate determining the etiology of undifferentiated hypotension in emergency department patients, bedside ultrasound evaluation may include:
a. cardiac contractility, right ventricle size, and the presence of pericardial effusion/tamponade.
b. inferior vena cava scan.
c. abdominal scan.
d. transthoracic scan.
e. All of the above

5. Which of the following statements is true regarding early warning response systems for sepsis?
a. Physicians are more enthusiastic about their potential than nurses.
b. Less than one-third of clinicians perceive that they improve patient care.
c. Approximately 50% of patients identified were perceived to be medically stable both before and after the alert.
d. They have been shown to decrease mortality in sepsis by more than 10%.
e. A majority of clinicians perceive them to be helpful.

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

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