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Abstract & Commentary

Dual Antibiotic Therapy Is Not Routinely Necessary for Uncomplicated Cellulitis

By Richard R. Watkins, MD, MS, FACP, FIDSA

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Dr. Watkins reports that he has received research support from Allergan.

SYNOPSIS: A randomized, multicenter, placebo-controlled clinical trial that enrolled patients presenting to emergency departments with uncomplicated cellulitis found the addition of trimethoprim-sulfamethoxazole to cephalexin did not lead to better outcomes.

SOURCE: Moran GJ, Krishnadasan A, Mower WR, et al. Effect of cephalexin plus trimethoprim-sulfamethoxazole vs cephalexin alone on clinical cure of uncomplicated cellulitis: A randomized clinical trial. *JAMA* 2017;317:2088-2096.

The increase in skin infections caused by community-associated methicillin-resistant *Staphylococcus aureus* (MRSA) over the last 10 to 15 years has led many clinicians to prescribe antibiotics with anti-MRSA activity to treat cellulitis. However, guidelines from the Infectious Diseases Society of America recommend that in cases without systemic illness, penetrating trauma, intravenous drug use, or evidence of MRSA elsewhere, therapy should be directed only against streptococci.[1] Therefore, Moran et al sought to determine whether covering for MRSA improves outcomes in cellulitis.

The study was a randomized, double-blind, placebo-controlled clinical trial that enrolled patients aged 12 years and older who presented to five U.S. emergency departments with uncomplicated cellulitis, defined as erythema without an abscess, purulent drainage, or wound. All patients had an ultrasound to rule out an underlying abscess at enrollment. They were assigned in a 1:1 ratio to receive either a seven-day course of cephalexin plus placebo

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or cephalexin plus trimethoprim-sulfamethoxazole (TMP-SMX). The primary outcome was clinical cure of cellulitis at the test-of-cure visit, 14 to 21 days after enrollment in the study. Failure was defined at day 3 or 4 as fever, an increase in erythema by 25% from baseline, or worsening of swelling and tenderness by the visit. Failure at days 8 to 10 was defined by fever, no decrease in erythema, or no decrease in swelling or tenderness. Failure at days 14 to 21 was defined as fever or more than minimal erythema, swelling, or tenderness. For patients who met failure criteria, assigned antibiotics were stopped and another non-study antibiotic was given along with assessment for possible surgical drainage. The study was designed as a superiority trial. The modified intention-to-treat analysis was defined as patients who took at least one dose of study medication and had an interview through the test-of-cure visit or withdrew from the study and/or were lost to follow-up. The per-protocol population was defined as those patients who took at least 75% of the total doses of study medicines during the first five days and had an in-person test-of-clinical-cure visit.

In the per-protocol population, clinical cure was achieved at 14 to 21 days in 182 (83.5%) of 218 patients enrolled in the cephalexin/TMP-SMX group and in 165 (85.5%) of 193 in the cephalexin/placebo group ($P = 0.50$). However, in the modified intention-to-treat analysis, the cephalexin/TMP-SMX group showed a numerically (but not statistically significant) higher clinical cure rate (189/248, 76.2%) compared to those who received cephalexin/placebo (171/248, 69.0%) ($P = 0.09$). Of the 36 who experienced treatment failure with cephalexin/TMP-SMX, 10 (27.8%) had an abscess at the time of clinical failure and nine (25%) developed purulent drainage. Of the 28 patients with clinical failure in the cephalexin/placebo group, 10 (35.7%) had an abscess at the time of clinical failure and 10 also developed purulent drainage. Among the 60 patients with clinical failure who had culture data available, MRSA was isolated from 41 (68.3%), methicillin-susceptible *S. aureus* (MSSA) from eight (13.3%), and streptococci from two (3.3%). Regarding adverse events, there were no significant differences between the groups, and 90% of the reactions were considered mild. The most common adverse event was gastrointestinal upset, which occurred in 46% of the cephalexin/TMP-SMX group and in 38.7% of the cephalexin/placebo group. One case of *Clostridium difficile* infection occurred, which was attributed to clindamycin given after a treatment failure with cephalexin/TMP-SMX. One patient who received cephalexin/TMP-SMX developed acute-on-chronic kidney injury that subsequently resolved.

■ COMMENTARY

This study supports the notion that routine antibiotic coverage for MRSA is not necessary when treating uncomplicated cellulitis. As an accompanying editorial notes, the different findings between the modified intention-to-treat analysis and the per-protocol population likely can be explained by the large number of patients in the analysis who did not complete the recommended course of therapy and, thus, were excluded.[2] Indeed, adherence actually was lower in the cephalexin/placebo group, making it unlikely that drug intolerance led to post-randomization bias. The most common reason for clinical failure was the development of an abscess, for which the primary management is incision and drainage. Thus, it should not come as a surprise that many cases of treatment failure occurred when only antibiotics (including those that treat MRSA) were prescribed and an abscess was present.

The study has some limitations worth mentioning. First, despite enrolling nearly 500 patients, the power was limited such that it is possible the effect of TMP-SMX therapy could have improved outcomes in some of the subgroups. Second, bedside ultrasound may not be available in some settings and using physical examination alone

is not reliable to detect abscesses. Third, there are many cases of uncomplicated cellulitis that resolve without antibiotics, which could have biased the results toward the null hypothesis.

Despite some uncertainty in the different findings between the per-protocol group and the modified intention-to-treat analysis, the present study suggests the addition of a second antibiotic to cover for MRSA in cases of uncomplicated cellulitis is unnecessary. One caveat is that patients with clinically undetectable abscesses or with abscesses in evolution likely will experience treatment failure, although it can be argued that in these cases incision and drainage is more important than the antibiotic chosen. Finally, the dangers of unnecessary and excessive antibiotics are well-described, and Moran et al should be commended for helping advance antibiotic stewardship from an ambulatory standpoint. ■

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Abstract & Commentary

Sepsis Management: What We Think We Know

By Dean L. Winslow, MD, FACP, FIDSA

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

SYNOPSIS: In the Protocolized Resuscitation in Sepsis Meta-Analysis (PRISM), 3,723 patients' outcomes from the ProCESS, ARISE, and ProMISe randomized, controlled trials of early goal-directed therapy (EGDT) were evaluated. EGDT did not result in better outcomes than usual care and was associated with higher costs. The authors of a second study looked at outcomes of 49,331 patients with sepsis treated in New York from April 2014 to June 2016. More rapid completion of the three-hour sepsis bundle and antibiotic administration (but not rapid bolus administration of IV fluids) was associated with reduced in-hospital mortality.

SOURCES: The PRISM Investigators, Rowan KM, Angus DC, et al. Early, goal-directed therapy for septic shock — A patient-level meta-analysis. *N Engl J Med* 2017;376:2223-2234.

Seymour CW, Gesten F, Prescott HC, et al. Time to treatment and mortality during mandated emergency care for sepsis. *N Engl J Med* 2017;376:2235-2244.

In the PRISM meta-analysis, data were pooled across the three large prospective randomized, controlled trials (ProCESS, ARISE, and ProMISe) of early goal-directed therapy (EGDT) vs. usual care. The primary outcome was 90-day mortality. Secondary outcomes included one-year survival, organ support, and hospitalization costs. Included in the analysis were 3,723 patients from 138 hospitals in seven countries. Mortality at 90 days was 24.9% in the EGDT arm and 25.4% in the usual care arm. The EGDT arm was associated with greater use of intensive care unit

(ICU) and cardiovascular support and higher costs, but resulted in no benefit in any of the secondary outcomes. Subgroup analysis showed no benefit of EGDT even in patients with more severe septic shock (higher lactate levels and other factors predicting higher risk of death).

In the large 49,331 patient analysis of New York sepsis data from 149 hospitals, 82.5% of patients had the three-hour sepsis bundle (consisting of blood cultures, administration of antibiotics, and lactate measurements) completed within three hours. Among patients who had the three-hour bundle completed within 12 hours, a longer time to the completion of the bundle was associated with higher risk-adjusted in-hospital mortality, as was a longer time to the administration of antibiotics, but not a longer time to the completion of a bolus of intravenous fluids.

COMMENTARY

The famous Rivers trial,[1] in which the term "early goal-directed therapy" of sepsis was coined, has influenced the management of sepsis positively throughout the world. The small, single-center Rivers trial emphasized, and the results of subsequent larger and better-quality randomized, controlled trials made clear, that patients who have sepsis recognized earlier and receive appropriate antibiotics and appropriate fluid resuscitation in a timely fashion experience better outcomes than patients who have diagnosis and appropriate treatment delayed.

Unfortunately, since the Rivers trial was published in the *New England Journal of Medicine* in 2001, many of the specific interventions in the EGDT arm (including measurement of CVP, central venous O_2 saturation, use of serum lactate to guide fluid resuscitation, the mandated "one-size-fits-all" 30 mL/kg IV saline bolus) have not been shown to be helpful in subsequent trials. Despite this, many of these interventions now have been codified into "sepsis bundles" mandated by the Centers for Medicare & Medicaid Services (CMS). Compliance with these bundles is tracked by hospitals' QI committees, is publicly reportable, and soon reimbursement will be tied to adherence to these bundles, with little room given for thoughtful deviation.

Another unwanted side effect is that the wide net that is cast to define sepsis ends up catching many patients who are not really septic. An extreme example I saw recently was a patient with a bad asthma attack, who, despite being normotensive, was labeled as having "sepsis" since the patient had HR > 90, high respiratory rate, and leukocytosis (from stress or glucocorticoid administration). This then triggered the drawing of a serum lactate (which is often elevated due to the inhaled β-agonists patients with wheezing are generally receiving in the ED). This then triggers the 30 mL/kg fluid challenge. In a young, healthy person, this generally is tolerated but could easily put an older patient with diastolic dysfunction into pulmonary edema. I also recently saw a 90-year-old lady from a skilled nursing facility receive 2.1 liters of IV saline because she was tachycardic, had leukocytosis, and had a minimally elevated lactate in the setting of PCR+ influenza (and no evidence of sepsis, but had received an albuterol treatment) despite a blood pressure of 150/100. She ended up in the ICU and needed BiPAP as well as 40 mg of IV furosemide as a result of the pulmonary edema that developed.

Similarly, I have seen residents order IV saline boluses in patients with atrial flutter with 2:1 conduction, multifocal atrial tachycardia, and supraventricular tachycardia (rather than treating the underlying arrhythmia). Just recently Kalil et al2 also published a wonderful meta-analysis of 19,998 patients from 31 observational studies and six randomized trials. As in the two studies discussed above, he also showed that survival was not correlated with sepsis bundle compliance but rather that survival was associated with more rapid administration of appropriate antibiotics that occurred in the EGDT arms of the studies he examined.

As I was writing this piece, it occurred to me that the effect of EGDT on survival in sepsis may be analogous to the improvement that we saw in survival of acute myocardial infarction and unstable angina after critical care units (CCUs) became common beginning in the 1960s. When I did my Medicine residency in the 1970s, the "CCU bundle" (although we didn't call it that) consisted of: admission to a dedicated CCU where the patient had continuous cardiac monitoring; care generally provided by internists or cardiologists rather than general practitioners; nursing care from experienced nurses trained in ACLS who could defibrillate patients rapidly if necessary; O_2 administered by nasal cannula at 2 L/min; prophylactic heparin SQ; and at the sight of the first VPC, the patient was given a lidocaine bolus and drip. Over the years, it was shown that supplemental O_2 wasn't helpful unless the O_2 saturation was low, and prophylactic lidocaine was actually harmful, but the survival advantages afforded by CCU-level care were real, and we eventually eliminated the interventions that were found to be unhelpful or harmful.

I am hoping that some of our professional societies and both ID and critical care experts will be able to persuade CMS to allow thoughtful deviation from these mandated sepsis bundles and also to modify them by eliminating some elements (like serum lactate levels and "one-size-fits-all" 30 mL/kg fluid bolus) that actually drive inappropriate care. ■

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Abstract & Commentary

B-type Natriuretic Peptide Is Less Useful in Elderly Patients with Dyspnea

By Van Selby, MD

Assistant Professor of Medicine, University of California, San Francisco Cardiology Division, Advanced Heart Failure Section

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

SYNOPSIS: Among patients ≥ 80 years of age presenting with acute dyspnea, B-type natriuretic peptide level was not useful for differentiating cardiac vs. respiratory etiologies when added to a model of clinical predictors.

SOURCE: Plichart M, Orvoën G, Jourdain P, et al. Brain natriuretic peptide usefulness in very elderly dyspnoeic patients: The BED study. *Eur J Heart Fail* 2017;19:540-548.

B-type natriuretic peptide (BNP) is used frequently to identify cardiac vs. respiratory etiologies in patients presenting with dyspnea. However, many factors influence BNP level, limiting its usefulness in certain populations. The diagnostic accuracy of BNP concentration in the assessment of dyspnea in very elderly (> 80 years of age) patients has not been studied adequately. The authors of the BNP Usefulness in Elderly Dyspneic Patients (BED) study enrolled 383 patients ≥ 80 years of age who were evaluated for acute dyspnea. All patients had BNP levels measured in addition to other clinical testing, including echocardiography. Independent cardiologists blinded to the BNP result evaluated each case according to standard guidelines to determine whether the cause of dyspnea was cardiac vs. respiratory.

Sixty-two percent of patients had cardiac dyspnea, and 38% had respiratory dyspnea. BNP levels were significantly higher among patients with cardiac vs. respiratory etiologies (median level 385.5 vs. 172.0 ng/L; $P < 0.001$). However, BNP was not a good test for discriminating cardiac vs. respiratory etiologies (area under the curve [AUC] = 0.68). The authors created a multivariate model of clinical predictors that discriminated cardiac vs. respiratory dyspnea with high accuracy (AUC = 0.915). When added to this model, BNP was independently associated with cardiac etiology but did not improve the AUC significantly ($P = 0.16$). No single BNP cutoff value was found that diagnosed or excluded cardiac etiologies with adequate reliability. Clinical predictors associated with a cardiac etiology included higher body mass index, history of heart failure (HF), X-ray findings consistent with pulmonary edema, and lower ejection fraction. History of chronic respiratory disease, rhonchi, and higher white blood cell count all were associated with a respiratory etiology. The authors concluded that BNP is not a useful diagnostic tool among very elderly patients with acute dyspnea, but noted that it may be of interest for prognosis in heart failure.

■ COMMENTARY

Both American and European guidelines give a class IA recommendation for the use of natriuretic peptide biomarkers such as BNP to support or exclude heart failure in patients presenting with dyspnea. A cutoff level of 100 ng/L is recommended often to rule out cardiac dyspnea, regardless of

age. However, guidelines also acknowledge that comorbidities can influence BNP levels and recommend they be taken into account when interpreting a given patient's BNP. Elderly patients are more likely to present with comorbidities, and age alone can influence BNP level. Therefore, it is important to understand how this changes the utility of BNP as a diagnostic test.

The Breathing Not Properly Multinational Study was one of the first and largest to evaluate the utility of BNP measurement in patients presenting with dyspnea. A post-hoc subanalysis of this study found that BNP was a weaker predictor in subjects > 70 years of age. BNP levels tended to be higher in elderly subjects, and this decreased the specificity for any given cutpoint. Several smaller studies subsequently found that BNP remained useful in elderly patients, though higher cut-points were needed.

Plichard et al now add the largest study to date specifically evaluating the utility of BNP in elderly patients. Their primary finding is that a clinical model consisting of age, body mass index, gender, and other covariates discriminated cardiac vs. respiratory etiologies with high accuracy. Although BNP levels were higher in patients with cardiac dyspnea, adding BNP levels to their clinical model did not improve the discriminative ability of their model significantly.

Although the findings of this study weaken enthusiasm for BNP use in elderly patients, there are a few important aspects to keep in mind. The baseline multivariable model already had an impressive ability to discriminate cardiac vs. respiratory dyspnea, and it would be difficult for the addition of BNP to improve on this model significantly. The model these authors used involved many variables and was not practical for routine use in clinical settings. BNP levels were clearly higher in patients with cardiac etiologies, and perhaps if a simpler, more realistic baseline model were used, then adding BNP would improve the diagnostic accuracy. Another limitation is the lack of a "gold standard" for the diagnosis of cardiac (as opposed to respiratory) dyspnea. Instead of abandoning BNP testing in elderly patients, it may be better to continue using it to differentiate cardiac vs. respiratory causes of dyspnea while taking into consideration its limitations. Elderly patients have higher BNP levels than younger patients, and a higher BNP level cannot "rule in" cardiac dyspnea with the same accuracy as it can in younger patients. BNP levels should be used along with all other available clinical data when determining the etiology of acute dyspnea in elderly patients. ■

Abstract & Commentary

Distinguishing Ischemic from Non-ischemic Cardiomyopathy Clinically

By Michael H. Crawford, MD, Editor

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

SYNOPSIS: This cardiac catheterization-based study of patients with newly diagnosed reduced left ventricular ejection fraction of unknown etiology showed that 15% had ischemic cardiomyopathy and they could be identified by clinical characteristics and an ECG-based risk score.

SOURCE: Smilowitz NR, Devanabanda AR, Zakhem G, et al. Comparison of clinical and electrocardiographic predictors of ischemic and nonischemic cardiomyopathy during the initial evaluation of patients with reduced (≤ 40%) left ventricular ejection fraction. *Am J Cardiol* 2017;119:1650-1655.

In newly discovered reduced left ventricular ejection fraction (LVEF), it is considered appropriate to perform invasive coronary angiography to identify ischemic cardiomyopathy (ICM), which is potentially treatable by revascularization. However, are angiograms always necessary? Investigators from New York University retrospectively identified patients referred for left heart catheterization with a new diagnosis of LVEF < 40% by echocardiography between 2010 and 2014 to see if they could develop a clinical risk score to predict the likelihood of obstructive (> 70% diameter

reduction) coronary artery disease (CAD). Patients were excluded if the etiologic diagnosis was obvious, such as those admitted with acute coronary syndrome, previous revascularization or myocardial infarction, severe left heart valve disease, right ventricular pacing for conduction disease, or had an established non-ischemic cardiomyopathy diagnosis.

Inclusion criteria were met in 273 of the 5,030 patients referred for coronary angiography, and ischemic cardiomyopathy (ICM) was found in 41 patients (15%). Patients with ICM were older, more likely to have diabetes, peripheral arterial disease, and use tobacco. Also, ICM patients were more likely to have ECG evidence of Q wave infarction (34% vs. 13%; $P < 0.001$) and ischemic ST-T changes (22% vs. 9%; $P = 0.02$), but left bundle branch block was less likely (2% vs. 15%; $P = 0.03$). A risk model including all clinical and ECG data was highly predictive of ICM (C statistic = 0.81). A simplified model that only included age, hypertension, diabetes, tobacco, Q wave infarction, and ST-T changes on ECG also was highly predictive (C = 0.80). When the risk score (range -1 to 9 points) was dichotomized at 3.5, the negative predictive value was 95%. The authors concluded that specific clinical and ECG abnormalities could be used to estimate which patients with reduced LVEF were at low risk of having ICM.

■ COMMENTARY

The issue of performing an invasive evaluation of the coronary arteries in patients with newly diagnosed LV systolic dysfunction of unclear etiology is important because myocardial ischemia is potentially treatable. Many centers, such as the one where this study was performed, have had a policy that all such patients undergo a left heart catheterization. This study hypothesized that clinical and ECG features of the patient may be able to identify a low-risk group in which catheterization is not mandatory. They found that four clinical factors (age, hypertension, diabetes, and tobacco use) and two ECG abnormalities (Q waves and ischemic ST-T changes) could be used to calculate a point score that would identify a low risk of ICM group. The feature with the highest points assigned was age > 65 years (3 points). Age 55-64, diabetes, and Q waves all were assigned 2 points each. All the rest were 1 point, except for hypertension, which was scored as a -1. The maximum score was 9, but any score < 3.5 was considered a low risk for ICM. The up to 3.5-point cutoff for the low risk of ICM group had a negative predictive value of 95%. From a qualitative approach, if a patient is < 65 years of age and does not have diabetes or Q waves, their score will not be > 3.5, even if they have all the other factors in the score, so invasive angiography could be avoided in such patients. Since the false-negative rate is not zero perhaps in those with low scores, a non-invasive test for coronary disease should be used, such as stress testing or CT angiography. Other interesting findings were that 12% of non-ICM patients had ECG Q waves and only 2% of ICM patients had left bundle branch block. Both these findings have been found in other studies, and the paucity of left bundle in ICM is well-known.

There are several weaknesses to this study. It is a single-center retrospective study and suffers from the selection bias of catheterization-referred patients. However, at this center the policy was to perform invasive coronary angiography in this type of patient. CAD was defined as significant obstructive disease, but this is the disease most likely to be amenable to revascularization. Right ventricular dysfunction on echocardiography also is known to be associated with non-ICM, but wasn't considered in this study. Also, the authors didn't look at segmental left ventricular wall motion abnormalities either, perhaps because previous studies have not shown this to be a useful discriminator.

I believe many clinicians are using clinical judgment based on the characteristics of the patient, the ECG, and the echocardiogram to cull the low likelihood group and not performing invasive angiography on them. However, this paper provides a more systematic approach, which would promote more uniformity in decision-making. ■

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CME QUESTIONS

1. Based on the randomized, double-blinded, controlled trial by Moran and colleagues of treatment for uncomplicated cellulitis, which of the following is true?

a. Cephalexin alone was inadequate treatment.

b. MRSA was the most common cause of cellulitis.

c. The addition of TMP-SMX to cephalexin did not improve outcomes compared to cephalexin alone.

d. TMP-SMX was inferior to cephalexin.

2. According to the study conducted by Plichart, et al., when evaluating elderly patients with dyspnea which of the following statements is true:

a. A cut-off of 200 ng/L should be used to rule out cardiac dyspnea instead of the usual value of 100 ng/L.

b. The same cut-off value of 100 ng/L should be used in patients regardless of age

c. BNP was not a good test for discriminating cardiac vs. respiratory etiologies in patients over the age of 80 years.

d. BNP values were lower in elderly patients with cardiac disease than patients with respiratory disease.

3. In the retrospective study by Smilowitz and co-investigators, patients with a newly identified LV ejection fraction of <40% and who underwent coronary angiography were studied. In that group of patients, what percentage was diagnosed with ischemic cardiomyopathy?

a. < 5%

b. 15%

c. 45%

d. 75%

CME OBJECTIVES

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

- discuss pertinent safety, infection control and quality improvement practices;
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