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ABSTRACT & COMMENTARY

Effects of a Rapid Response System Driven by Real-time Automated Clinical Alerts

By Samuel Nadler, MD, PhD

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

SYNOPSIS: The addition of an automated real-time clinical deterioration alert system to a rapid response system had marginal effects.

SOURCE: Kollef MH, et al. Mortality and length of stay trends following implementation of a rapid response system and real-time automated clinical deterioration alerts. *Am J Med Qual* 2015 Nov 13 [Epub ahead of print].

Triage of medical admissions is imprecise, and patients on general medical wards may deteriorate, requiring higher levels of care. Early detection and treatment of these individuals should improve outcomes, but current staffing models preclude clinical staff from continuously monitoring every patient. Development of an automated, real-time system could assist in identifying those high-risk patients. Kollef et al previously published a prospective study over a 6-month period that demonstrated rapid response system (RRS) activations did not reduce ICU transfers, mortality, or the need for long-term placement, but did decrease hospital length of stay (LOS).[1] This study retrospectively examined trends in hospital mortality, rates of cardiopulmonary arrests (CPAs), hospital LOS, and RRS activations from 2003-2014, before, during, and after the implementation of automated real-time clinical deterioration alerts (RTCDAs). The RRS was implemented between 2006 and 2008 and RTCDAs started in 2009. The RTCDAs monitored 36 input variables with heaviest weighting of respiratory rates, oxygen (O_2) saturation, shock index, systolic and diastolic blood pressure, heart rate, and coagulation modifiers. During this period, researchers monitored 163,311 consecutive patients. Linear regressions identified study year as an independent determinant of hospital mortality (r = - 0.794, *P* = 0.002), CPAs (r = - 0.792,

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$P = 0.006$), and LOS (r = - 0.841, $P = 0.001$). Accordingly, RRS activations increased (r = 0.997, $P < 0.001$).

■ COMMENTARY

At first glance, this study seems to demonstrate improvements in important clinical outcomes with the implementation of an automated alert system. However, closer examination of the data calls this conclusion into question. The linear regression models examined the 11-year study period as a whole. During this period, there does appear to be a reduction in mortality and CPAs with an increase in RRS activations. This effect is most pronounced with the development of the RRS system from 2005-2008. After the automated RTCDAs started in 2009, although the rates of RRS activations increase dramatically (~170 to > 400), if anything, there is a mild increase in hospital mortality. The rates of CPAs increased from 2010-2011 before declining once again 2012-2014. The hospital LOS is lowest in 2009 and increased through 2011 before once again decreasing. If the linear regression were calculated during the period of time when the RTCDA system was active from 2009-2014, it is not clear that there would be a significant positive association.

How does this study alter our knowledge of RRSs and RTCDAs to improve clinical outcomes? It further supports the notion that RRSs improve clinical outcomes. The most recent meta-analysis demonstrated that RRSs reduce hospital mortality and rates of CPAs.[2] But the automated system in this study did not seem to improve outcomes beyond that observed with RRSs alone. An additional 200 RRS activations did not seem to affect outcomes. The RRS itself may have functioned well enough that most instances of real clinical deterioration were detected. It leaves open the question whether the automated system alone may have worked as well. Further, the automated system itself may not be sensitive enough to improve clinical outcomes. Bailey et al separately published the operating characteristics a real-time alert system within the same system.[3] That study reported good sensitivity for ICU transfers and mortality (89.6% and 89.2%, respectively), but the positive predictive values were poor (15.2% and 10.4%, respectively), as these events were relatively rare. Thus, many alerts occurred when a clinical deterioration may not have happened.

[If the linear regression were calculated during the period of time when the RTCDA system was active from 2009-2014, it is not clear that there would be a significant positive association.]

Increasing evidence shows RRSs improve outcomes. The addition of RTCDAs in this study did not seem to add to this pre-existing system. Considering the diversion of time and resources these additional alerts caused, they do not seem to confer an advantage. Only with an improved RTCDA would this system improve clinical outcomes. ■

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ABSTRACT & COMMENTARY

Does the Use of Saline vs Buffered Crystalloid Reduce Risk of Acute Kidney Injury in ICU?

By Kathryn Radigan, MD

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

SYNOPSIS: The use of a buffered crystalloid compared with saline did not reduce the risk of acute kidney injury (AKI) in patients receiving crystalloid fluid therapy in the ICU.

SOURCE: Young P et al. Effect of a buffered crystalloid solution vs saline on acute kidney injury among patients in the intensive care unit. *JAMA* 2015;314:1701-1710.

The use of saline (0.9% sodium chloride) in critically ill patients is a common intervention to increase intravascular volume or maintain hydration. Although the use of saline in the critically ill is widespread, there is concern that the high chloride content of saline contributes to the development of acute kidney injury (AKI), and its use may be associated with an increased risk of mortality. It is unclear whether a buffered crystalloid solution with an electrolyte composition that more closely resembles plasma would lead to better outcomes.

Since the relationship between the use of saline in critically ill patients and renal failure is unclear, Young et al pursued a double-blind, cluster randomized, double-crossover trial from April 2014 through October 2014 to determine the effect of a buffered crystalloid compared with saline on renal complications in ICU patients. The trial took place in four New Zealand ICUs and included all patients admitted to the ICU who required crystalloid fluid therapy. The trial excluded patients with established AKI requiring renal replacement therapy (RRT) or expected to require RRT within 6 hours. Most patients were admitted to the ICU following elective surgery, most commonly cardiovascular surgery, and few had comorbidities. Of the 2278 eligible patients enrolled in the study, researchers analyzed 1152 of the 1162 patients (99.1%) receiving buffered crystalloid and 1110 of the 1116 patients (99.5%) receiving saline. Researchers randomized two of four ICUs to saline intervention and the other two to buffered crystalloid for alternating treatment blocks of 7 weeks. Two crossovers occurred so that each ICU used one of two study fluids twice over the 28-week period. The treating physician determined the rate and frequency of fluid administration. The primary outcome was proportion of patients with AKI (defined as a rise in serum creatinine level of at least two-fold or a serum creatinine level of ≥ 3.96 mg/dL with an increase of ≥ 0.5 mg/dL). The incidence of RRT and in-hospital mortality were the main secondary outcomes.

For the patients who received buffered crystalloid, 102 developed AKI compared with 94 in the saline group (absolute difference [AD], 0.4%; 95% confidence interval [CI], -2.1% to 2.9%; relative risk [RR], 1.04; 95% CI, 0.80-1.36; $P = 0.77$). Similarly, for patients who received buffered crystalloid, RRT was required in 38 (3.3%) compared with 38 (3.4%) in the saline group (AD, -0.1%; 95% CI, -1.6% to 1.4%; RR, 0.96; 95% CI, 0.62-1.50; $P = 0.91$). Additionally, there was no difference in mortality between the buffered crystalloid and saline groups (7.6% vs 8.6%; AD, -1.0%; 95% CI, -3.3% to 1.2%; RR, 0.88; 95% CI, 0.67-1.17; $P = 0.40$). In summary, for patients who received crystalloid fluid therapy in the ICU, the use of a buffered crystalloid compared with saline did not reduce the risk of AKI, RRT, or in-hospital mortality.

■ COMMENTARY

The administration of IV fluids for hydration and resuscitation is common in critically ill patients. Many different types of IV fluid, including normal saline, contain supraphysiological concentrations of chloride. Excessive chloride administration is associated with hyperchloremic metabolic acidosis and may lead to renal vasoconstriction along with a reduced GFR.[1]

Since renal failure in the ICU is associated with increased hospital mortality,[2] there has been substantial interest in examining the relationship between the high chloride content of saline and the development of AKI. In a single-center, open-label study of chloride-rich (n = 760) vs chloride-restrictive (n = 773) fluids in the ICU, Yunos et al found that implementation of a chloride-restrictive strategy in a tertiary ICU was associated with a significant decrease in the incidence of AKI and use of RRT. Unfortunately, physicians should inter-

pret cautiously the outcomes of this trial, as one of the alternative IV fluids used was a synthetic gelatin-based colloid that has been associated with increased risk of AKI in patients with sepsis.[1] Other recently conducted studies, including a retrospective study and a meta-analysis, favored balanced fluids, but results were tempered in light of the innate design of the trials.[3,4] In light of the remaining question, it was expected that this double-blind, cluster randomized, double-crossover trial might finally achieve some clarity on the subject.

Unfortunately, the trial revealed that there was no difference in AKI and mortality between patients who received 0.9% saline vs buffered crystalloid. Although results of the trial appeared to be definitive, there were aspects of the trial design worth noting. First, 90% of patients received fluids prior to admission to the ICU; the majority of this IV fluid was buffered crystalloid with 1.2 L administered to the buffered crystalloid group and 1 L of buffered crystalloid administered to the saline group. Although 1 L of fluid does not appear to be significant, the average fluid administration between groups over the entire study period was only 2 L. This low volume of fluid may be insufficient to demonstrate a hazard, especially in study groups that are lower risk and may not be representative of a typical ICU patient population since the majority of patients were surgical. Second, the design of the trial may require more consideration. Although this trial anticipated examining the effect of IV fluids on AKI, RRT, and mortality, the design of the study was not based on this particular intervention. For instance, the treating physician determined the rate and frequency of fluid administration, but the reason for the fluid administration was unknown. Therefore, the effectiveness of the fluid provided for each indication could not be measured, and researchers measured the overall adverse events instead.

Although this study fails to reveal an ideal fluid management strategy for our high-risk, severely septic patients who will need aggressive fluid administration, it does emphasize that neither 0.9% saline nor a low-chloride electrolyte IV fluid is particularly hazardous in a lower-risk patient population receiving on average 2 L of fluid. Until further studies examine a higher-risk patient population, there is insufficient evidence to support the use of one type of IV crystalloid fluid vs another. Therefore, it is our responsibility to continue to be thoughtful regarding the administration of fluids in our patients on a case-by-case basis. ■

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ABSTRACT & COMMENTARY

Does Finding the Portal of Entry of Bacteria in Infective Endocarditis Matter?

By Michael Crawford, MD, Editor

SYNOPSIS: A comprehensive, systematic search for the portal of bacterial entry in infective endocarditis is frequently successful and affords an opportunity to prevent recurrent episodes.

SOURCES: Delahaye F, et al. Systematic search for present and potential portals of entry for infective endocarditis. *Am Coll Cardiol* 2016;67:151-158.

Chu VH. When the cat's out of the bag: Searching for portals of entry in infective endocarditis. *J Am Coll Cardiol* 2016;67:159-161.

It would seem that the portal of entry (POE) of the microorganisms responsible for infective endocarditis (IE) is important to prevent further episodes, which occur in up to 30% of patients with IE. However, little data on this topic exist. Thus, investigators from Lyon, France, prospectively and systematically sought the POE in all cases of IE admitted between 2005 and 2011. A dentist, an ENT physician, and a urologist examined all patients. A gynecologist also examined all female patients. If skin lesions were present, a dermatologist saw them. Patients also underwent dental, cerebral, and thoracic-abdominal-pelvic X-rays. If the organism identified originated in the gastrointestinal (GI) tract, if the patient was > 50 years of age, or if there was a family history of colon polyposis, patients received a colonoscopy. For each case, the most probable POE was inferred from the results of these tests and the natural habitat of the identified causative microorganism. Researchers

performed treatment of the POE where feasible. From 444 IE admissions, 82 were excluded because they died in hospital and 44 were excluded for incomplete data, leaving 318 patients with 320 episodes of IE. In 74% of patients, researchers identified a POE; of these, 40% were cutaneous, 29% oral or dental, and 23% were GI. The majority of cutaneous sources were related to healthcare or IV drug use. Dental infections were the source for the majority with oral/dental POEs, rather than dental procedures (59% vs 12%). Half those with GI POEs had colonic polyps. The authors concluded that the search for a POE in patients with IE is frequently successful, and they advise a systematic oral examination in all and colonoscopy in selected patients with IE.

■ COMMENTARY

Prevention of IE has revolved around antibiotic prophylaxis for procedures likely to result in significant bacteremia in individuals at high risk of IE. One of those high-risk features is previous IE. So efforts to identify the likely POE and treat or eliminate it would make sense. However, not only is there little literature on this topic, but physicians pay scant attention to it in patients with IE. This study is remarkable in its comprehensive approach to finding the POE. Researchers were able to identify a likely POE in about three-quarters of their patients. In about one-third, researchers discovered additional potential POEs for new episodes of IE. Although not assessed in this study, it is hard to argue that treating these POEs and potential POEs would not have a beneficial effect.

Based on the results of this study, a more streamlined and cost-effective approach to finding the POE emerged. Routine ENT or GU evaluations were low yield and should be reserved for those with evidence of infections in these areas. On the other hand, a comprehensive oral exam was high yield (53%). It constituted a dental exam and panoramic X-rays of the teeth. Of the oral POEs, 59% were tooth infections, some only detected by X-ray, and 28% were periodontal. Only 12% were related to dental procedures. Colonoscopy was also high yield (40%) in a high-risk subgroup, age > 50 years, or a family history of colonic polyposis. In addition, a dermatologist examined those with suspicious skin lesions. Healthcare-associated skin issues were identified in 41% and 34% had community-acquired lesions. The former included vascular access (44%), EP devices (28%), and operative wounds (28%). The latter included IV drug use (22%) and insect bites or cat scratches (3%). The rest had ulcers and other wounds.

The study's major weakness is that the role of organism identification (performed in all but 9 cases) in determining the POE is not spelled out clearly. Not all POEs were cultured and those that were did not undergo genetic analysis to see if they were the same organism identified in the blood cultures. However, the likely POE correlated well with the known body habitat of the organisms identified by blood culture. Also, in 25% with no POE discovered, the distribution of the organisms was similar to that found in those with a POE identified. In addition, the authors did not discuss the possibility of multiple POEs.

In summary, patients with high-risk cardiac conditions for IE, such as prosthetic valves or other material, EP devices, and certain types of congenital heart disease, not only need antibiotic prophylaxis for IE, but should have any infections treated expeditiously. Those with IE should have reasonable efforts to find the POE and treat it if feasible. The type of exams performed could be guided by the organisms found: a careful skin exam in those with *Staph* species, an oral exam and X-rays in those with oral *Strep* species, and colonoscopy in those with GI organisms detected. ■

ABSTRACT & COMMENTARY

Nitrate Therapy Shows Possible Harm in Heart Failure with Preserved Ejection Fraction

By Van Selby, MD

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

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

SYNOPSIS: In heart failure with preserved ejection fraction, the use of isosorbide mononitrate was associated with a nonsignificant decrease in physical activity level, and no improvement in symptoms or quality of life.

SOURCE: Redfield MM, et al. Isosorbide mononitrate in heart failure with preserved ejection fraction. *N Engl J Med* 2015;373:2314-2324.

No pharmacologic therapy has been proven to improve survival in heart failure with preserved ejection fraction (HFpEF). Long-acting nitrates are used frequently to improve

symptoms, but the effectiveness of this practice has not been studied in a clinical trial.

The Nitrate's Effect on Activity Tolerance in Heart Failure with Preserved Ejection Fraction (NEAT-HFpEF) trial tested the hypothesis that isosorbide mononitrate would increase patient activity level in HFpEF. One hundred and ten patients were randomized to isosorbide mononitrate vs placebo, using a crossover design. Inclusion criteria included age ≥ 50 years, New York Heart Association (NYHA) functional class II-IV symptoms, and at least one of the following criteria: history of heart failure (HF) hospitalization, elevated B-type natriuretic peptide (BNP) level, elevated pulmonary artery wedge pressure, or evidence of diastolic dysfunction on echocardiography. Additionally, all patients reported dyspnea, chest pain, or fatigue as the cause of their exercise limitation. Researchers administered isosorbide mononitrate at 30 mg and doubled the dose every week to a target dose of 120 mg daily. The primary outcome was daily activity level, measured using a patient-worn accelerometer.

Compared to patients receiving placebo, those taking isosorbide mononitrate 120 mg daily showed a nonsignificant trend toward lower daily activity (difference of -381 accelerometer units, 95% confidence interval [CI], -780 to 31; $P = 0.06$), with a significant decrease in the total hours of activity per day ($P = 0.02$). Activity levels decreased with increasing doses of isosorbide mononitrate in a stepwise manner. There were no statistically significant differences in 6-minute-walk distance, BNP, or quality of life scores.

Both adverse events and discontinuation of study drug were more common among the isosorbide mononitrate group. The authors concluded that in HFpEF, treatment with isosorbide mononitrate as compared to placebo is associated with decreased daily activity levels and no significant improvement in submaximal exercise capacity or quality of life.

■ COMMENTARY

Nitrates have been shown to improve symptoms in both heart failure with reduced ejection fraction (HFrEF) and ischemic heart disease. Based on these studies and our hemodynamic understanding of HF, long-acting nitrates are used frequently in the management of HFpEF as well. However, this strategy has never been evaluated rigorously in HFpEF. The authors of NEAT-HFpEF demonstrated that empiric use of long-acting nitrates is not beneficial and may actually be detrimental in this population.

These findings are somewhat surprising, and the authors offered several potential explanations. The pathophysiology of HFpEF is different from that of HFrEF or ischemic heart disease. Patients with HFpEF have more comorbidities as well as autonomic dysfunction, chronotropic incompetence, and vascular stiffness. All these comorbidities contribute to symptoms in HFpEF. Additionally, nitrates do not improve these conditions.

The observed difference in reported side effects between isosorbide mononitrate and placebo was insufficient to explain the decline in physical activity, but nitrates may cause subtle, unreported side effects that led patients to be less active. The dose of isosorbide increased at a faster rate than what is common in clinical practice. Patients may have better tolerated a slower dose escalation.

Another possible explanation is patient selection. As has been seen in other clinical trials, identifying patients who truly have HFpEF rather than dyspnea due to other etiologies can be challenging. Nitrates are particularly effective for relieving elevated left-sided filling pressures. Perhaps if the trial had been limited to patients with documented elevation in left-sided pressures, or at least symptoms of elevated pressure such as orthopnea, the authors could have identified a subset of HFpEF patients more likely to benefit from nitrate therapy. Alternatively, it is also possible the increased vascular stiffness in HFpEF makes the left-sided pressures less responsive to the hemodynamic effects of nitrates.

One particularly interesting aspect of this study is the use of patient-worn accelerometers for measuring the primary outcome. This provides continuous assessment of physical activity in a real-world setting, and may be a better measure of functional status than traditional measures such as NYHA class or 6-minute-walk distance. It would not be surprising to see increased use of mobile technology in future HF clinical trials.

Based on the findings of NEAT-HFpEF, nitrate therapy should not be used indiscriminately in HFpEF. That said, selected patients may still benefit, and a brief trial of long-acting nitrates in patients with clear evidence of elevated left-sided filling pressures, either by catheterization or symptoms, still seems reasonable. Patients with HFpEF and co-existing coronary artery disease may also benefit. Given the lack of mortality benefit and potential for harm, it would be reasonable to discontinue nitrate therapy in those who do not experience clear symptomatic improvement. ■

Why We Can't Allow Physical Exam Skills to Languish

SOURCE: Verghese A, et al. *Am J Med* 2015;128:1322-1324.

With more highly evolved and readily available technology at our fingertips, it is sometimes tempting to let the echocardiogram sort out the abnormal heart sounds we detected, or allow the pelvic ultrasound to inform whether the uterus is enlarged, or short-cut parts of the physical exam we anticipate to be unlikely sources of pertinent information. At the same time, there may not be large-scale clinician awareness that a textbook of *Evidence-based Physical Diagnosis* even exists. (McGee, S. *Evidence-based Physical Diagnosis*, 3rd Edition. Philadelphia: Elsevier Saunders Publishers; 2012.) Could over-reliance on technology lead to meaningful errors? Verghese et al reported on 208 vignettes that were volitionally reported to them in response to a survey soliciting instances of oversights related to the physical exam. The most common consequence of an inadequate physical exam was missed/delayed diagnosis. However, unnecessary treatment, delay in treatment, unnecessary exposure to radiation or contrast, and complications related to treatment were also reported. Commonly missed items included abdominal masses, pregnancy, neurologic findings, murmurs, adenopathy, breast masses, heart failure, and herpes zoster. The authors reported that most of the cases in which inadequate physical examination led to consequences were the result of simply not performing the appropriate physical exam (rather than, for example, misinterpretation of an appropriately performed exam). The authors made a case for reminding clinicians that appropriate physical examination skills need to be taught and maintained. Inadequate performance of the physical exam, as documented here, can lead to important consequences. ■

SHORT REPORT

Potatoes Increase Risk of Type 2 Diabetes Mellitus

By William C. Haas III, MD, MBA

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

SOURCE: Muraki I, et al. Potato consumption and risk of type 2 diabetes: Results from three prospective cohort studies. *Diabetes Care* 2015; pii: dc150547.

Few would question the recommendation to increase daily vegetable intake. Yet, an important question arises — are all vegetables created equal?

A group of researchers recently evaluated the effect of potato consumption on the risk of developing type 2 diabetes mellitus (T2DM). Potatoes were selected because of high consumption patterns in the United States in addition to their ability to rapidly raise blood sugar levels based on their high glycemic index. Researchers retrospectively evaluated potato consumption from three major prospective cohort studies: the Nurses' Health Study (NHS), NHS-II, and the Health Professionals Follow-up Study (HPFS). In addition to overall consumption levels, the form of consumption was evaluated, i.e. baked, boiled, mashed, or fried.

Higher total potato consumption was significantly associated with an elevated risk for developing T2DM. Compared to consuming < 1 serving/week, the pooled hazard ratio (HR) was 1.07 (95% confidence interval [CI], 0.97-1.18) for 2-4 servings/week and 1.33 (95% CI, 1.17-1.52) for ≥ 7 servings/week. With regard to the form consumed, French fries were associated with a higher HR compared to baked/boiled/mashed forms; 1.19 (95% CI, 1.13-1.25) and 1.04 (95% CI, 1.01 to -1.08), respectively. Interestingly, the HR for T2DM dropped to 0.88 (95% CI, 0.84-0.91) when replacing three total servings/week of potatoes with the same amount of whole grains.

When providing nutritional counseling to your patients, keep in mind that all vegetables may not be created equal. If the thought of replacing potatoes with kale or collard greens is off-putting, consider swapping out French fries for baked or boiled potatoes at the very least. ■

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CME QUESTIONS

1. Based on the study by Kollef and colleagues, the use of an automated alert system in addition to the use a rapid response system led to:

A. a decrease in the number of cardiopulmonary arrests.

B. improved survival from cardiopulmonary arrests.

C. no improvments in outcomes over a rapid response system alone.

D. faster transfers to the ICU.

2. According to the randomized, controlled trial by Young et al, the use of buffered crystalloid versus 0.9% saline in patients requiring fluid resuscitation in the ICU led to which of the following outcomes?

A. No difference in the incidence of acute kidney injury.

B. No difference in in-hospital mortality.

C. No difference in the use of renal replacement therapy.

D. All of the above.

3. The study by Delahaye and colleagues identified which of the following as high-yield examinations for a portal of entry in patients with infective endocarditis?

A. GU exams

B. Comprehensive oral exams

C. Colonoscopy

D. B and C only

CME OBJECTIVES

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

- discuss pertinent safety, infection control and quality improvement practices;
- explain diagnosis and treatment of acute illness in the hospital setting; and;
- discuss current data on diagnostic and therapeutic modalities for common inpatient problems.

[IN FUTURE ISSUES]

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