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ABSTRACT & COMMENTARY

Screening for *C. difficile* Carriers at Hospital Admission Reduces Subsequent CDI

By Richard R. Watkins, MD, MS, FACP

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

SYNOPSIS: Patients admitted to a single hospital were screened for *C. difficile* carriage and those found to be positive were placed in contact isolation. This led to a significant decrease in hospital-acquired *C. difficile* infections.

SOURCE: Longtin Y, et al. Effect of detecting and isolating *Clostridium difficile* carriers at hospital admission on the incidence of *C. difficile* infections: A quasi-experimental controlled study. *JAMA Intern Med*. 2016;176:796-804.

Clostridium difficile infection (CDI) is now the leading nosocomial infection in the United States. Novel approaches are needed to decrease the CDI epidemic. Longtin and colleagues reported the results of one such strategy: identifying and isolating asymptomatic carriers of *C. difficile*.

The study was conducted at a single institution in Quebec City, Canada, that had been experiencing a high burden of hospital-acquired CDI (HA-CDI). Patients admitted through the emergency department underwent screening for *C. difficile* by rectal swabs that identified the tcdB gene by polymerase chain reaction. *C. difficile* carriers then were placed into modified isolation similar to what is done for cases of CDI but with some modifications, including not requiring healthcare workers to wear isolation gowns and allowing carriers to share a room with non-carriers. For logistical reasons, patients admitted directly to the wards and those who stayed less than 24 hours were excluded. The primary outcome was the change in incidence rate of HA-CDI per 10,000 patient-days after implementation of the intervention. Sec-

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ondary outcomes included changes in the proportion of HA-CDI cases with complications and changes in strain types causing CDI. The control used for the study was the HA-CDI incidence rates from other institutions in Quebec during the same time course.

The average incidence rate of HA-CDI before the intervention was 8.2 per 10,000 patient-days. After the intervention, the incidence rate decreased to 3.0 per 10,000 patient-days ($P < 0.001$). Out of 7,599 eligible patients who were screened, 368 (4.8%) were found to be asymptomatic carriers. There were no significant differences in complications (i.e., 10- and 30-day all-cause mortality, admission to the intensive care unit, need for colectomy, or readmission for recurrent CDI) between the pre-intervention and post-intervention periods ($P > 0.05$ for all).

Forecast modeling estimated that the intervention prevented 63 of 101 expected cases of HA-CDI, while there was no significant change detected in the control group. Furthermore, there was a significant decrease in the proportion of NAP1 strains after the intervention compared to beforehand (2 of 10 strains [20%] vs. 45 of 76 [59%], respectively; $P < 0.049$). No corresponding decrease in NAP1 strains was observed in the other hospitals in Quebec City during the intervention period (80% of *C. difficile* strains were NAP1). Notably, there also were outbreaks of influenza, viral gastroenteritis, and carbapenemase-producing *Enterobacteriaceae* during the intervention period at the study institution. Efforts to improve hand hygiene were introduced to mitigate the outbreaks. Consequently, the hand hygiene rate improved from 36.6% to 49.7%.

■ COMMENTARY

This study showed how a relatively simple intervention (i.e., rectal swabs that detect *C. difficile* followed by isolation of carriers) could have a significant impact on the burden of CDI in an inpatient setting. Before the intervention, the study institution had a high burden of HA-CDI. Afterward, it had the lowest incidence rate of HA-CDI among the 22 academic hospitals in Quebec. Experts believe that despite not having diarrhea, asymptomatic carriers of *C. difficile* still shed spores that contaminate the environment and get on caregivers' hands. This environmental contamination is particularly troublesome for institutions that do not have all private rooms.

Although the results were impressive, the study raises important economic questions. For example, do the cost savings from preventing HA-CDI exceed the cost of the intervention? The investigators attempted to address this issue by noting that each case costs $3,427 to $9,960 and since it was calculated that the intervention prevented 63 cases, the savings from averting HA-CDI ($216,000 to $627,000) exceeded the cost of the intervention ($130,000). However, further cost-analysis studies that include multiple sites are needed to determine if these savings can be replicated in other settings. Another issue to be elucidated is whether the intervention would have a significant impact at an institution that does not have a high incidence of HA-CDI. In this setting, the cost of the intervention might not be justified, although the public reporting of HA-CDI rates might nonetheless motivate hospital administrators to pay for it.

There were a couple of limitations to the study worth mentioning. The authors did not assess how many of the asymptomatic carriers had a previous history of CDI. Also, the institutional hand hygiene compliance improved during the study, which may have falsely inflated the benefit of the intervention. On the other hand, the improvement was quite modest, going from 37% to a rather dismal 50%. Institutional antibiotic stewardship also might have played a confounding role by limiting antibiotics that are most associated with HA-CDI, such as clindamycin and quinolones. Despite these limitations, isolating asymptomatic carriers of *C. difficile* seems like a promising strategy that should be investigated with larger clinical trials. ■

STROKE ALERT

In Patients with Intracerebral Hemorrhage, Intensive Lowering of Blood Pressure Does Not Improve Outcome

By Matthew E. Fink, MD

Professor and Chairman, Department of Neurology, Weill Cornell Medical College; Neurologist-in-Chief, New York Presbyterian Hospital

Dr. Fink reports he is a retained consultant for Procter & Gamble and Pfizer.

SOURCE: Qureshi AI, Palesch YY, Barsan WG, et al for the ATTACH-2 Trial Investigators. Intensive blood-pressure lowering in patients with acute cerebral hemorrhage. *N Engl J Med* 2016; DOI: 10.1056/NEJMoa1603460 [Epub ahead of print].

After spontaneous intracerebral hemorrhage, there is a severe hypertensive response that may be associated with hematoma expansion and increased mortality. The INERACT-2 study (*N Engl J Med* 2013;368:2355-2365) looked at the effectiveness of blood pressure reduction within six hours after symptom onset, to a target systolic blood pressure of < 140 mmHg. There was no significant difference in neurological outcome or mortality, compared to patients who were treated with a target systolic blood pressure of < 180 mmHg. The ATTACH-2 trial was designed to determine if even more rapid lowering of blood pressure, within 4.5 hours of onset of symptoms, and a target blood pressure of < 120 mmHg, would result in an improved rate of death or disability at three months.

Of 1,000 participants with a mean systolic blood pressure of 200 ± 27 mmHg at baseline, 500 were assigned to intensive treatment and 500 to standard treatment. Enrollment was stopped because of futility after an interim analysis. The primary outcome of death or disability was observed in 38.7% of the participants in the intensive treatment group and 37.7% of participants in the standard treatment group, after adjustment for age, initial Glasgow Coma Scale score, presence or absence of intraventricular hemorrhage, and other premorbid factors. The rate of renal adverse events, within seven days after randomization, were significantly higher in the intensive treatment group than in the standard treatment group. In conclusion, intensive treatment of patients with intracerebral hemorrhage to achieve a target systolic blood pressure < 120 mmHg did not result in a lower rate of death or disability, but did result in an increased rate of renal adverse events. ■

ABSTRACT & COMMENTARY

How Good Is Passive Leg Raise at Predicting Fluid Responsiveness?

By Eric Walter, MD, MSc

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

SYNOPSIS: In a meta-analysis of 23 clinical trials, passive leg raise was shown to be an excellent predictor of fluid responsiveness.

SOURCE: Cherpanath TG, Hirsch A, Geerts BF, et al. Predicting fluid responsiveness by passive leg raising: A systematic review and meta-analysis of 23 clinical trials. *Crit Care Med* 2016:44:981-991.

Fluid resuscitation is a fundamental procedure in critical care medicine. At first, this appears easy: If blood pressure is low, give more fluids. Time has taught clinicians that this is not such a simple decision. In some patients, more fluids are lifesaving. For others, fluid resuscitation increases morbidity and mortality. Determining who will respond to fluids is now one of the principle questions in criti-

cal care. Passive leg raise (PLR) is a simple bedside test used to assess fluid responsiveness. The patient raises both straightened legs 45 degrees and holds the pose for approximately one minute. PLR acts as a reversible fluid bolus, rapidly, yet transiently increasing preload and cardiac output.

PLR has been well studied in small clinical trials. Cherpanath et al summarized the predictive value of PLR in various clinical situations. They presented a meta-analysis of 23 studies that compared PLR to a true fluid challenge (the gold standard). Studies defined a positive response to a fluid challenge differently, but in general an increase of more than 15% in blood flow was defined as a positive response. Techniques used to measure blood flow included esophageal doppler, transthoracic echocardiography, calibrated pulse contour analysis, and bioreactance. The meta-analysis included 1,013 patients, although individual studies were small (17-102 patients). The majority of patients were septic (57%) and required vasopressor support (56%).

The pooled sensitivity for PLR was 86% (95% confidence interval [CI], 79-92%) with a specificity of 92% (95% CI, 88-96%). The area under the receiver operating curve was 0.95. PLR diagnostic performance did not differ between spontaneously and mechanically ventilated patients. Using changes in pulse pressure as a measure of fluid responsiveness was less predictive (sensitivity 58% [95% CI, 44-71%]; specificity 83% [95% CI, 68-92%]) than the use of flow variables such as cardiac output, stroke volume, or aortic blood flow. Researchers could not assess the utility of PLR in patients in atrial fibrillation because most patients were in normal sinus rhythm.

■ COMMENTARY

PLR works by creating an "auto transfusion" that reversibly moves an estimated 250-350 mL of blood into the chest cavity. Cardiac preload increases, and if patients are fluid responsive, an increase in cardiac output occurs. Clinicians observe the maximal effect in about one minute and it disappears when the legs are lowered. The reported sensitivity of 86% and specificity of 92% is remarkable (almost too good to be true). Furthermore, PLR is easy, requires minimal training, and has few complications. This sounds like the perfect test. So should medical professionals use PLR as part of a routine clinical exam?

Maybe, but several questions remain. First, for most of these studies the assessment of whether a patient responded to PLR required measurements of cardiac output was not easily available to many ICU clinicians. Although echocardiography is used more commonly in the ICU, few clinicians will have the expertise to measure cardiac output, let alone differentiate between a change in cardiac output of 15%. Esophageal doppler and bioreactance are not commonly available. Pulse contour analysis is more widely available but requires equipment and arterial access.

Second, what does fluid responsive really mean? This was defined as an increase in cardiac output of ≥ 15%. Is this a clinically relevant definition? The goal of fluid resuscitation is not just to improve cardiac output but to improve perfusion and ultimately patient outcomes. The lessons learned from the pulmonary artery catheter remind one that simply knowing how to measure physiologic variables does not automatically translate into better care. Researchers must conduct more studies showing that a PLR-informed fluid strategy leads to better outcomes compared to other approaches. ■

Individualized Integrative Medicine Treatment for Preoperative Anxiety

By Ellen Feldman, MD

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

SYNOPSIS: In a randomized, clinical trial investigating the treatment of preoperative anxiety, standard sedating medication with a specified add-on individualized integrative technique is the most effective intervention.

SOURCE: Attias S, Keinan B. Effectiveness of integrating individualized and generic complementary medicine treatments with standard care versus standard care alone for reducing preoperative anxiety. *J Clin Anesth* 2016;29:54-64.

Anxiety prior to surgery is common and can be a significant factor in postoperative morbidity and mortality.[1] Multiple studies demonstrate that preoperative anxiety may negatively affect the course of surgery and the postoperative period (via increased use of anxiolytics and/or via direct physiological changes, including increases in blood pressure and pulse), but there are few controlled studies regarding reducing

anxiety in this setting. Attias et al conducted a randomized, controlled trial investigating the relative effect of specific treatments on preoperative anxiety. Each arm of the study includes conventional or standard anxiolytic medication (ST) with or without a specified add-on integrative medicine treatment (IMT).

The aim of the investigation is to examine reduction of preoperative anxiety with ST alone compared with ST plus a generic IMT or ST plus an individualized IMT.

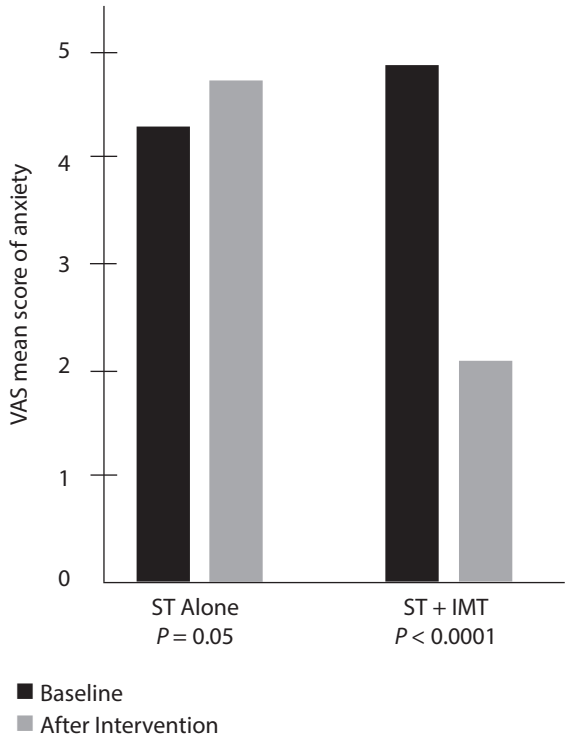
Conducted over a period of three years, Israeli researchers recruited patients on a general surgical ward. Out of 519 patients eligible for participation, 360 completed the investigation, including both baseline and post-intervention assessment of anxiety.

Randomization was accomplished by assigning patients to groups via sealed envelopes. Patients were assigned to either ST alone (premedication with a benzodiazepine); ST plus a commercially available compact disc recording of guided imagery recording (CDRGI); or ST plus one of the following individualized treatments randomized according to the day of the week: individualized acupuncture, reflexology, guided imagery or reflexology plus guided imagery, specific to the patient as per below.

Summary Points

- This study randomized 360 preoperative patients into six groups to receive: 1) standard anxiolytic treatment (ST), 2) ST plus a compact disk recording of guided imagery (CDRGI), 3) ST plus acupuncture, 4) ST plus individualized guided imagery, 5) ST plus reflexology, or 6) ST plus reflexology plus individualized guided imagery.
- The group receiving ST alone showed no significant difference in measurement of level of anxiety pre- or post-treatment.
- All groups receiving add-on integrative interventions showed a statistically significant reduction in preoperative anxiety; the groups receiving ST plus individualized interventions showed statistically significant greater reduction in anxiety than the group receiving ST plus CDRGI.
- When looking at the four groups receiving an individualized treatment (plus ST), there is no statistical evidence pointing to superiority of any one treatment in reduction of preoperative anxiety.

Figure 1: ST Alone vs. ST + IMT: Preoperative Anxiety

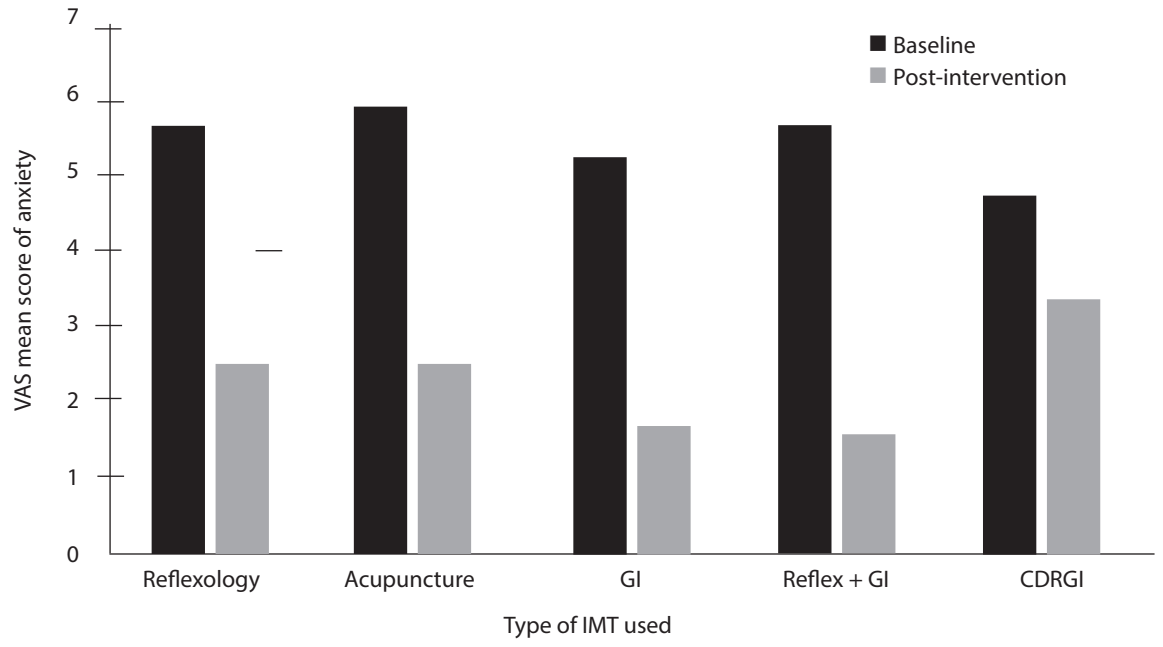


Each group completed the study with 60 patients. Acupuncture treatment was individualized in accordance with the traditional Chinese medicine diagnoses. Reflexology points were selected "according to the patients' mental and physical condition." Guided imagery was specific to the surgical procedure. Anxiety was measured using a validated anxiety questionnaire, a Visual Analog Scale (VAS), with possible scores between 0 (no anxiety) and 10 (maximum anxiety). Participants were asked to complete the scale twice: once after entering the study and then again after intervention, but before surgery. Thus, both measurements were taken preoperatively within a 30-60 minute period. It is worth noting again that every patient received ST; dose and type of medication was left to the judgment of the anesthesiologist (either PO oxazepam 10 mg or diazepam 5-10 mg.)

Baseline scores of anxiety were elevated, with more than 70% of participants in all groups scoring higher than 4 (3 is generally the cutoff for moderate anxiety.) Figure 1 shows anxiety scores pre- and post-intervention when comparing all groups receiving IMT + ST (n = 300) with ST alone (n = 60.) The consolidated group of 300 patients included the group receiving generic IMT (CDRGI) plus ST, as well as the four groups receiving individualized IMT plus ST.

All anxiety scores dropped post-intervention in

Figure 2: Effect on Mean Anxiety Scores: IMT + ST



the groups receiving IMT and ST, demonstrating a reduction of anxiety, although to different degrees *(see Figure 2)*. The group receiving ST alone showed a mean increase in anxiety scores; this increase was not shown to be statistically significant.

Figure 2 compares results from each group receiving any form of IMT (in combination with ST.) Statistical analysis (as explained by the authors) shows no significant difference in results when comparing the individualized IMT head-to-head. However, there was a statistically significant effect ($P < 0.0001$ for each) when comparing each individualized treatment to CDRGI.

■ COMMENTARY

Why all the worry about preoperative anxiety? Although there has been some historical thought that preoperative anxiety actually may be protective in the postoperative period,[2] recent studies have found that high levels of preoperative anxiety are not desirable.[1,3,4] These studies noted that preoperative anxiety levels correlate with longer hospital stays, adverse perioperative outcomes, and poorer patient satisfaction scores.[3,4] Increased use of anxiolytic medication may lead to secondary problems such as excessive sedation, confusion, and interactions with anesthesia.[5] Investigations looking at cardiovascular procedures have linked preoperative anxiety with increased mortality.6 Given the risks, many interventions to reduce anxiety in the preoperative period actively are being explored.

Preoperative education7 and music,8 as well as the interventions used in this study, all have been studied as alternatives or add-ons to conventional anxiolytic medication in a preoperative setting. All seem to have potential use in this arena, although well-controlled and well-designed studies are still needed.

However, there are few studies that look at the manner of administration of an integrative medical technique to determine if the modality itself affects outcome. There are few studies that look at relative efficacy of integrative techniques.[1] These are the unique factors incorporated into the design and purpose of this investigation.

This study looked at adding IMT to a conventional benzodiazepine regimen and then, even more specifically, at the manner of administration of IMT — generic (in this case prerecorded on a CD) vs. customized. There is a mention that the relatively more robust effect of the individualized treatments may be due to the "human factor" — future studies looking at individualized treatments without hands-on involvement could be helpful in sorting this out.

Another aspect of the IMTs chosen for this study is that each has been studied in treatment of anxiety disorders.[8,9] However, it is important to differentiate between a disorder of anxiety and an anxious mood or state occurring in the context of impending surgery. This study strictly looked into treatment of an anxious state (known as "state anxiety") measured by self-assessment on a validated scale; there are no claims or implications for the treatment of anxiety disorder on the basis of this work. In this case, validation means that a measurement on the VAS

correlates with other known measurements of state anxiety.[10] Unfortunately, there is very little published information linking changes in physiologic parameters directly with measurements of state anxiety.

This may explain why the benzodiazepines used as ST in the study failed to show an effect on levels of anxiety. Previous studies have demonstrated moderate effectiveness of these agents in treatment of preoperative anxiety,[11] so it is puzzling why they showed no effect here. It may be a factor of timing (determined by when the second measurement of anxiety was taken), but also may have to do with the subjective nature of the scale used to measure anxiety and the absence of any objective determinants of relief of anxiety. That is, there is no information from this study regarding objective measurements of any parameters related to an anxious state and so no way to know if measurements in addition to the VAS would have reflected an effect of these agents or been more sensitive to distinguishing effects from the various IMTs.

Relevant literature fails to fully explain if the perioperative risks related to preoperative anxiety are due to self-awareness of anxiety or expected physiological changes due to state anxiety, or a combination of the two factors. This is another area ripe for future exploration.

The authors made clear that theirs is an exploratory study and that there were no investigations into any positive or negative implications of the IMTs after the second measure of anxiety just prior to surgery. To definitively link IMTs to clinically significant preoperative anxiety relief and to reduction in perioperative complications linked with preoperative anxiety, it will be important for future studies to explore not only subjective measures of anxiety but also some objective measures as well (blood pressure, heart rate, or even length of time in surgery, postoperative complications, hospitalization length, etc.).

There is little doubt (as noted by studies mentioned above) that addressing anxiety in a preoperative setting is helpful in reducing perioperative complications. This study reinforces the idea that IMTs reduce the experience of anxious feelings during the preoperative period, and introduces the concept that the method of administration of the IMT may be as important as the type of IMT used.

Understanding how and why individualizing an IMT leads to increased efficacy will be important in advancing the field of integrative medicine. The relative ease of individualization makes this an area ripe for exploration. Of course, the flip side is that this study and others of a similar design rely heavily on expertise of a particular practitioner. This can add to difficulties identifying direct causal relationships as standardization challenging.

Essential elements in future studies include understanding the relationship between self-reporting an anxious state and exhibiting cardiovascular and other objective measures of this state. Changes in cardiovascular parameters with decline of self-assessed anxiety would be useful to explore as well. With this link clearly established, more definitive conclusions can be drawn.

The medical field appears to be rapidly moving toward adopting many integrative therapies as mainstream. Understanding specific efficacies and mechanism of action of each intervention will help cement legitimacy and propel this movement forward. Understanding how much individualized therapy contributes to their effect also will be an important consideration. ■

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CME QUESTIONS

1. The randomized clinical trial by Attias, et al., of preoperative anxiety demonstrated which of the following outcomes:

a. Benzodiazepines alone were the best method for reducing preoperative anxiety

b. The addition of a compact disk recording of guided imagery plus benzodiazepines was the most effective way of reducing preoperative anxiety

c. The addition of an individualized integrative intervention to benzodiazepines was the most effective way of reducing preoperative anxiety

d. Of the individualized integrative interventions, individualized acupuncture was the most effective way of reducing preoperative anxiety

2. In the study from Longtin and colleagues, screening for *Clostridium difficile* carriage at the time of admission to the hospital led to what observable outsome?

a. Decreased need for colectomy

b. Decreased 30-day mortality

c. Decreased need for ICU admission

d. Decreased incidence of hospital-acquired *C. difficile* infections

e. All of the above

3. The clinical trial by Qureshi AI and collaborators demonstrated that lowering the target blood pressure in patients with an acute intracerebral bleed to < 120 mmHg within 4.5 hours led to what outcomes:

a. No difference in the rate of death or disability

b. Increased rate of renal adverse events

c. Decreased size of the intracerebral bleed

d. A and B only

e. All of the above

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.

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