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Aspirin and Clopidogrel Dose in ACS

ABSTRACT & COMMENTARY

By Andrew J. Boyle, MBBS, PhD

*Assistant Professor of Medicine, Interventional Cardiology,
University of California, San Francisco*

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

This article originally appeared in the October 2010 issue of Clinical Cardiology Alert. It was edited by Michael H. Crawford, MD, and peer reviewed by Ethan Weiss, MD. Dr. Crawford is Professor of Medicine, Chief of Cardiology, University of California, San Francisco, and Dr. Weiss is Assistant Professor of Medicine, Division of Cardiology and CVRI, University of California, San Francisco. Dr. Crawford is on the speaker's bureau for Pfizer, and Dr. Weiss reports no financial relationships relevant to this field of study.

Source: The CURRENT – OASIS 7 Investigators. Dose comparisons of clopidogrel and aspirin in acute coronary syndromes. *N Engl J Med.* 2010;363:930-942.

FOR PATIENTS PRESENTING WITH ACUTE CORONARY SYNDROMES (ACS), the optimal doses of aspirin and clopidogrel remain unknown. There are significant geographical variations in the dose of antiplatelet agents in this clinical setting. Whether higher doses of aspirin or clopidogrel, or both, lead to better outcomes after ACS treated with an early invasive strategy has not been formally tested. Thus, the CURRENT — OASIS 7 investigators performed a prospective, randomized clinical trial to address this question.

Patients presenting with ACS, either non-ST elevation ACS (NSTEMI) or ST elevation myocardial infarction (STEMI), were randomly assigned in a 2 X 2 factorial design to high- or standard-dose clopidogrel and to high- or low-dose aspirin. Inclusion criteria included ischemic ECG changes and/or biomarkers of myocardial injury. High-dose clopidogrel was 600 mg loading dose followed by 150 mg daily for one week then 75 mg daily; standard-dose clopidogrel was a 300 mg loading dose followed by 75 mg daily. High-dose aspirin was 300-325 mg daily; low-dose aspirin was a loading dose of 300-325 mg daily and then 75-100 mg daily. The primary endpoint was a composite of cardiovascu-

EDITOR

Kenneth Steinberg, MD
Professor of Medicine,
Program Director, Internal
Medicine Residency Program,
University of Washington

MANAGING EDITOR

Leslie Hamlin

EXECUTIVE EDITOR

Russ Underwood

Financial Disclosure:

Hospital Medicine Alert's physician editor, Kenneth P. Steinberg, MD, has no relevant financial relationship related to the material presented in this issue.

VOLUME 5 • NUMBER 9 • NOVEMBER 2010 • PAGES 65-72

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lar death, myocardial infarction (MI), or stroke at 30 days.

Results: They enrolled 24,835 patients who underwent coronary angiography within 72 hours of presentation. Of these, 17,263 received PCI, 1,859 underwent coronary artery bypass graft (CABG) surgery, 3,520 had no significant coronary artery stenoses, and 2,444 were not candidates for any revascularization. The groups were well matched for all baseline clinical parameters, with a mean age of 61 years, 23% had diabetes, 71% presented with NSTEMI, and 29% presented with STEMI. There was a higher rate of proton-pump inhibitor (PPI) use in the high-dose aspirin group after cardiac catheterization.

There was no difference between high- and standard-dose clopidogrel (4.2% vs. 4.4%; $p = 0.30$), nor between high- and low-dose aspirin (4.2% vs. 4.4%; $p = 0.61$), in the primary endpoint of cardiovascular death, MI, or stroke.

Secondary endpoint analysis revealed similar outcomes for high- and standard-dose clopidogrel in total mortality, as well as each component of the primary endpoint. However, higher-dose clopidogrel resulted in higher rates of major bleeding (2.5% vs. 2.0%; $p = 0.01$), blood transfusion (2.2% vs. 1.7%; $p = 0.01$), and minor bleeding (5.1% vs. 4.3%; $p = 0.01$). High- and low-dose aspirin showed similar outcomes in all components of the primary endpoint, as well as total mortality. However, high-dose aspirin resulted in less recurrent ischemia (0.3% vs. 0.5%; $p = 0.02$), although the absolute reduction is modest. There was no difference in major bleeding between aspirin doses, but there was a slight increase in minor bleeding (5.0%

vs. 4.4%; $p = 0.04$) and major gastrointestinal bleeding with high-dose aspirin (0.4% vs. 0.2%; $p = 0.04$). There was no excess in CABG-related bleeding in any group.

Interestingly, there was an unexpected interaction between the aspirin and clopidogrel dose groups. Among patients receiving high-dose aspirin, those assigned to high-dose clopidogrel had a lower primary outcome rate than those in the standard-dose group (3.8% vs. 4.6%; $p = 0.03$). However, in patients receiving low-dose aspirin, this difference was not seen. The cause of this interaction is not clear and is somewhat counter-intuitive.

Subgroup analysis showed no differences between groups based on age, gender, race, diabetes, weight, presentation with STEMI or NSTEMI, use of glycoprotein IIb/IIIa inhibitors, or use of PPI. In patients who underwent PCI, double-dose clopidogrel was associated with a reduction in stent thrombosis (1.6% vs. 2.3%; $p < 0.001$). The authors conclude that in patients with ACS referred for early invasive strategy, there was no difference between high- and standard-dose clopidogrel, nor between high- and low-dose aspirin, in the primary outcome of cardiovascular death, MI, or stroke.

■ COMMENTARY

The authors are to be congratulated on this very large trial enrolling high-risk patients (elevated cardiac biomarkers or ECG changes), the population who would be most likely to benefit from more aggressive anti-platelet therapy. The lack of any difference in mortality, in the composite primary endpoint, or in any of its components is very reassuring that the current standard of care in dual anti-platelet therapy has a wide therapeutic index. This allows physicians some flexibility in individually tailoring anti-platelet therapy doses based on an individual patient's risk of ischemic vs. bleeding outcomes, within this range of doses. Despite the large number of patients and the rigorous follow-up (99.9% of patients completed follow-up), several issues should be addressed. Firstly, the follow-up was only 30 days, so whether there is a long-term impact of the early anti-platelet dosing strategy remains unknown. Secondly, the majority of patients underwent PCI, but 58% received bare-metal stents and only 42% received drug-eluting stents. This reflects the heterogeneous nature of this international study performed in 37 countries. We are not told if there are any differences based on the choice of bare-metal vs. drug-eluting stents. Thirdly, all patients received aspirin and clopidogrel loading doses before cardiac catheterization. The results of the study may not be applicable when used after cardiac catheterization, as the full effects of the medications may not be evident for some time after PCI. Finally, we are not told which anti-thrombins were used (heparin, bivalirudin, low molecular-weight heparin, fondaparinux) and

Hospital Medicine Alert, ISSN 1931-9037, is published monthly by AHC Media LLC, 3325 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

MANAGING EDITOR: Leslie Hamlin.
EXECUTIVE EDITOR: Russ Underwood.
GST Registration Number: R129870672.

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to **Hospital Medicine Alert**, P.O. Box 740059, Atlanta, GA 30374.

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there may be an interaction between anti-platelet agents and the type of anti-thrombins used. These issues will likely be the subject of future manuscripts. ■

Preoperative Consultations

ABSTRACT & COMMENTARY

By Michael H. Crawford, MD

*Professor of Medicine, Chief of Cardiology,
University of California, San Francisco*

Dr. Crawford is on the speaker's bureau for Pfizer.

*This article originally appeared in the October 2010 issue of
Clinical Cardiology Alert. It was peer reviewed by Ethan Weiss, MD.*

Source: Wijeyesundera DN, et al. Outcomes and processes of care related to preoperative medical consultation. *Arch Intern Med.* 2010;170:1365-1374.

PATIENTS UNDERGOING MAJOR SURGERY TEND TO BE OLDER individuals with more comorbidities than the general non-surgical population. Thus, preoperative consultations by internal-medicine specialists are often requested by the surgeon or anesthesiologist. Such consultations clearly have a role in defining the risk-benefit ratio of surgery, but their value for altering the outcome of surgery is less well known. Thus, this group from Ontario, Canada, performed a population-based cohort study of patients over age 40 years undergoing major elective non-cardiac surgery, comparing outcomes in those who had preoperative consultations to those who did not. Since it would be expected that consultation patients would have more comorbidities and be at higher risk, a propensity score-matched pairs-cohort was constructed to account for these differences. The association between mortality and hospital stay was evaluated in this matched cohort of 191,852 patients.

Results: In the entire cohort (269,866), 39% underwent consultation, 94% of which were in the outpatient setting. As expected, there were differences between all measured characteristics, between those having a consultation and those not. In the matched cohort, these differences were markedly reduced. Consultation in the matched cohort was associated with higher rates of preoperative testing, use of beta-blockers or statins, and preoperative cardiac interventions. Also, consultation increased 30-day mortality (RR 1.16, 95% CI 1.07-1.25, NNH 516), one-year mortality (RR 1.08, NNH 227), and mean hospital stay (mean difference 0.67 days). As a control, consultation did not affect the incidence of postoperative wound infections. The authors concluded that medical consultation prior to major non-cardiac surgery increases pharmacologic therapy, testing, hospital stay, and mortality.

■ COMMENTARY

To those of us who spend a considerable amount of time doing preoperative consultations, this study is sobering. First, let me emphasize that this study does not say that preoperative consultations are worthless. At a minimum, they help define the risks of surgery and, therefore, may prevent some patients from having surgery in which the risk clearly outweighs the potential benefits. This study did not take this into account since the authors only studied patients who had surgery. However, in my experience, the number of patients not cleared for surgery is small (2%). Also, the propensity matching could not be done for about 8% of the patients in this study because their risk was so high, and few did not have consultations. Management of these patients may have been enhanced. However, in total, these two exceptions represent 10% of those undergoing surgery. In addition, propensity matching did not eliminate all the differences between the two groups, so there clearly was some residual confounding. The investigators admit this, but claim their sensitivity analyses suggest this residual confounding is small. Therefore, for the vast majority of preoperative patients, their results are likely to be valid; preoperative consultation increases costs and does not seem to change outcomes.

Why would mortality worsen with consultation? The authors suggest that this could be due to the increase in tests and therapy observed after consultations. The investigators noted that there was an increase in strokes related to beta-blocker use, which was increased in the consult group. This is consistent with recent data suggesting that perioperative beta-blockers can be harmful, especially if inappropriate hypotension and bradycardia occur. Also, consultation was associated with less epidural anesthesia use, which could increase complications. In addition, consultation was associated with less warfarin and low-molecular-weight heparin use in the first 30 days post-op — all factors that could influence mortality.

On the other hand, although statistically significant, the changes in mortality and hospital stay were small and could be accounted for partially by inadequate matching of patients. Also, this is an administrative database study, so details like how many patients had myocardial infarction are not available. This renders the data less useful for analyzing the problem. Finally, once a patient is deemed at higher risk, short of cancelling surgery, there are not a lot of things to do to improve his/her risk that are proven effective. Variations in anesthesia technique and beta-blockers are frequently employed, but have little supporting data. Other approaches have even less supporting evidence. It may be that the best we can do is to do no harm. Resist the temptation to test and do procedures of dubious value in the perioperative setting. The best rule of thumb is to not do anything that the patient does not need anyway, regardless of surgery. ■

SVT and Ischemia

ABSTRACT & COMMENTARY

By Michael H. Crawford, MD

This article originally appeared in the October 2010 issue of Clinical Cardiology Alert. It was peer reviewed by Ethan Weiss, MD.

Source: Bukkapatnam RN, et al. Relationship of myocardial ischemia and injury to coronary artery disease in patients with supraventricular tachycardia. *Am J Cardiol.* 2010;106:374-377.

SUPRAVENTRICULAR TACHYCARDIA (SVT) IS KNOWN TO BE ASSOCIATED with troponin leaks and ST-wave depression on ECG, both potential markers of ischemia. However, the exact significance of these findings is unclear. Thus, these investigators from UC Davis did a retrospective review of 104 subjects admitted for SVT over five years. Patients with specific atrial arrhythmias, such as atrial fibrillation, flutter, and sinus tachycardia were excluded. During SVT, at a mean rate of 174 beats/min, one-third of patients had chest pain, 57% had ST depression, and 48% had an increased Troponin I. Among 35 patients who had stress testing or coronary angiography, 11 had CAD, and were compared to the rest of the sample. ST depression was present in 100% of these 11 patients, but also in 60% of the patients without known CAD. After adjustment for covariates, ST depression was not a predictor of CAD. Troponin I was elevated in 55% of the CAD patients and 46% of the rest ($p = \text{NS}$). Chest pain occurred during tachycardia in 45% with CAD and 34% without ($p = \text{NS}$). The presence of these three clinical variables during SVT (chest pain, ST depression, troponin elevation) was more prevalent in those with CAD (2.4 v. 0.9 risk factors, $p = 0.03$). The authors concluded that ECG ST depression and Troponin I elevation are not accurate markers for acute coronary syndromes in SVT patients.

■ COMMENTARY

This observational study highlights a clinical dilemma of SVT: Which patients have ischemic heart disease? It is well known that ischemic-appearing ST depression can occur with SVT and persist for up to 24 hours after conversion to sinus rhythm. Yet most of the patients who exhibit these ECG findings do not have underlying CAD. This study contributes to our knowledge by adding information on troponin, which shows the same phenomena: frequent elevations, but not diagnostic of the presence of CAD. In fact, over two-thirds of their patients had some evidence suggesting ischemic heart disease, yet less than one-third were shown to have CAD. Hence the authors' conclusion that these signs of ischemia do not accurately

predict acute coronary syndromes. However, they probably represent so-called demand ischemia, where the oxygen demands of the tachycardia exceed the coronary artery supply.

Their results are consistent with other smaller studies, but studies of younger patients have shown a lower prevalence of troponin leakage, suggesting that older age may impair coronary vasoreactivity during tachycardia or represent a higher incidence of CAD at older ages. Their population was heterogeneous, with a mean age of 58, more than 50% women, and some with a history of CAD. Since everyone was admitted in their study, the population was probably biased toward more CAD. The real clinical issue in SVT patients is who to evaluate for CAD and how? Since classic clinical signs of ischemia are inaccurate, other clinical features, such as traditional risk factors, should be used. In most cases, non-invasive testing would make sense initially. Since about one-third of those evaluated had CAD; those with evidence of ischemia and other risk factors for CAD should probably be admitted. Those with no risk factors for CAD can probably be evaluated as outpatients. ■

Your Patients Live Longer When Discharged with Home Care After Hemiarthroplasty

ABSTRACT & COMMENTARY

By Rahul Gupta, MD, MPH, FACP

Clinical Assistant Professor,

West Virginia University School of Medicine, Charleston, WV,

Dr. Gupta reports no financial relationship relevant to this field of study.

This article originally appeared in the October 15, 2010 issue of

Internal Medicine Alert. It was edited by Stephen A. Brunton, MD, and peer reviewed

by Gerald Roberts, MD. Dr. Brunton is Adjunct Clinical Professor, University of North

Carolina, Chapel Hill, and Dr. Roberts is Assistant Clinical Professor of Medicine, Al-

bert Einstein College of Medicine, New York, NY. Dr. Brunton is a consultant for Novo

Nordisk, Shionogi Pharma, and Takeda, receives grant/research support and serves

on the speaker's bureau for Novo Nordisk. Dr. Roberts reports no financial relation-

ships relevant to this field of study.

Synopsis: *A Canadian study reveals that while a majority of elderly patients undergoing hemiarthroplasty did not receive home care upon discharge, those that did had longer short-term survival.*

Source: Rahme E, et al. Short-term mortality associated with failure to receive home care after hemiarthroplasty. *CMAJ.* 2010 Aug 16; Epub ahead of print.

HEMIARTHROPLASTY OF THE HIP IS GENERALLY RECOMMENDED for patients with displaced hip fracture who are elderly and in poor general health, or those who may previously have had a debilitating degenerative joint disease or avascular necrosis, or rheumatoid arthritis of the hip. There is a high short-term mortality rate in patients undergoing this procedure.¹ Often, the patients are already at risk of complications and death due to pre-existing comorbid conditions. Due to the comorbid conditions, such patients may have a high rate of readmission during the postoperative period as well. It is widely anticipated that in the near future, hospitals will face fierce resistance from third-party payers in the reimbursement for such readmission services connected with the initial surgery itself. As a result, more of such elderly and frail patients may be denied services resulting in unanticipated widening of a disparity gap in the geriatric population. It is vital that we explore all methods that would not only lower hospital re-admission rates, but also improve postoperative short-term mortality rates and avoid some of the unintended consequences from the upcoming health care reform law.

While the study mentioned here is from Canada, there are lessons to be learned for us in the United States. In Quebec, post-discharge care rendered to patients who undergo elective hip replacement is quite dissimilar to those undergoing hemiarthroplasty for a hip fracture. People undergoing planned elective surgery also have a planned discharge with home care, which includes nursing, physiotherapy, occupational therapy, nutrition, psychosocial care, and daily housekeeping. This is not always possible for those undergoing unplanned or emergency procedures such as repair of a hip fracture.

Rahme et al conducted a retrospective cohort study using provincial hospital discharge records data. They obtained the administrative data for 11,326 patients (all 65 years and older) who were discharged from hospital after hemiarthroplasty in the province of Quebec during the period 1997-2004. Of 11,326 study patients, 5.6% were discharged home with home care, 29.9% were discharged home without home care, 2.0% were sent to a rehabilitation center, 24.2% were sent to a nursing home, and 38.3% were sent to another hospital. Among patients who were discharged home, those who were less likely to receive home care were older, had osteoarthritis, had an emergent admission, and were admitted to a high-volume hospital. Discharge with home care was most likely among patients admitted to teaching hospitals, those in hospital for more than 7 days, those with atrial fibrillation, and those with acute renal failure. In those discharged home, the rate of death per 100 patient-months was lowest among patients who were discharged with home care.

Another way to interpret the findings may be that the study revealed that in the province of Quebec, more than 84% of the elderly patients discharged home from hospital after hemiarthroplasty did not receive home care after discharge. Patients who did receive home care were at 43% lower risk of death in the first three months post-discharge than those sent home without it.

■ COMMENTARY

While it has been previously established that patients receiving hemiarthroplasty after a hip fracture have higher mortality rate than those receiving elective arthroplasty, Rahme et al evaluated the impact of post-discharge home care (inclusive of comprehensive services as mentioned above) on short-term mortality in such patients.² In the context of clinical practice in the United States, a comprehensive post-discharge care model for identified high-risk admissions, such as those undergoing hemiarthroplasty, should become defining criteria for high-rated, superior performing hospitals. It is widely accepted that bending the long-term cost curve will be the cornerstone of reforming our health care system, which will lead to improved quality of care at an affordable price. To control long-term costs, the current health care reform law attempts to utilize a hybrid approach that not only depends upon results of comparative effectiveness research, but also utilizes a system of taxes and penalties to address individual behavior.³ However, it is incumbent upon every health care provider, as a community, to understand that if we are to have a modernized health care system, it must be anchored in good science. The results of studies such as the one above mandate that we continue to advocate for comprehensive patient care models that do not discontinue once the patient leaves the hospital or the physician offices and that such care models are not limited to large metropolitan areas in the nation. The results of this study should be taken as another piece of that puzzle, which has the potential to ultimately lead us in the right direction. ■

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Is a Central Venous Blood Gas a Useful Surrogate for an Arterial Blood Gas?

ABSTRACT & COMMENTARY

By Saadia R. Akhtar, MD, MSc

St. Luke's Idaho Pulmonary Associates, Boise

Dr. Akhtar reports no financial relationship to this field of study.

This article originally appeared in the October 2010 issue of Critical Care Alert.

It was edited by David J. Pierson, MD, and peer reviewed by William Thompson, MD. Dr. Pierson is Professor, Pulmonary and Critical Care Medicine, Harborview Medical Center, University of Washington, Seattle, and Dr. Thompson is Associate Professor of Medicine, University of Washington. Drs. Pierson and Thompson report no financial relationships relevant to this field of study.

Synopsis: *This observational study compared simultaneous arterial and central venous blood gases in a mixed patient population and found high agreement between normal gases after the application of a predefined adjustment algorithm.*

Source: Walkey AJ, et al. The accuracy of the central venous blood gas for acid-base monitoring. *J Intensive Care Med.* 2010;25:104-110.

THE AUTHORS SET OUT TO COMPARE ARTERIAL AND CENTRAL venous blood gases (ABG and VBG, respectively), to evaluate the utility and accuracy of a predefined algorithm for adjusting VBG pH and pCO₂ to approximate that of ABG, and to define clinical scenarios where a VBG may not be a useful substitute for an ABG. The study took place over 2 months at a tertiary care academic medical center in the United States.

Patients older than age 18 years admitted to any adult ICU or the cardiac catheterization laboratory with a central venous line in place and a need for a blood gas were eligible. Simultaneous ABG (radial or femoral) and VBG (tip of line in distal superior vena cava or right atrium) were drawn and analyzed by a standard point-of-care system. A predefined algorithm (based on prior literature on arteriovenous pH and pCO₂ differences) was used to derive an adjusted VBG (aVBG) by adding 0.05 to the VBG pH and subtracting 5 cm H₂O from the VBG pCO₂. A clinical acid-base diagnosis (e.g., "metabolic acidosis") was

given to each blood gas result. Standard statistical methods were used to measure agreement between ABG and VBG or aVBG results (detailed below). Multiple logistic regression modeling was applied to define patient characteristics most highly associated with ABG-aVBG agreement in clinical acid-base diagnosis.

Of 202 consecutive patients, 187 were enrolled in the study. The majority (56%) of patients were admitted to the cardiac catheterization laboratory and more than half (54%) of patients in the study had normal blood gases. Only 32% of the patients were intubated, 8% required vasopressors, and small percentages had admitting diagnoses such as sepsis (8.4%) or the acute respiratory distress syndrome (ARDS; 2.6%). Venous O₂ saturation was < 65% in 30% of subjects. As expected, ABG and VBG pH and pCO₂ showed fairly high gross correlation (using scatterplots and Pearson's correlation coefficient). The agreement between the values was more robustly evaluated using Bland-Altman plots, which revealed 95% limits of agreement of 0.025 to -0.057 for pH and 7.5 to -6.5 for pCO₂. Agreement between clinical acid-base diagnosis based on ABG and VBG values was low at 45%, but increased to 74% between ABG and aVBG (κ 0.61); it was 90% when the aVBG was normal. Finally, presence of an abnormal aVBG had the highest association with discrepancy with ABG-based clinical acid-base diagnosis; other factors such as presence of sepsis or ARDS or venous O₂ saturation < 65% showed no association.

■ COMMENTARY

An ABG is the simplest and most accurate method for assessment of acid-base status and ventilation that is available to the clinician at the bedside. Unfortunately, there are always occasional patients in whom arterial lines are unable to be placed or ABGs are not able to be obtained (or only with great difficulty). Severe peripheral vascular disease, marked soft-tissue edema, or hematomas related to a prior arterial line are some potential reasons for these difficulties. It would be attractive to have an alternative test or surrogate measure for serum pH and pCO₂ in these situations. Patients could also then be spared the risks and discomfort of arterial punctures and arterial lines.

The current study is an interesting one. The authors should be commended for trying to go a step beyond what other investigators have done; they are the first to use an adjustment algorithm for the VBG and the first to consider comparing not just the ABG and VBG results but the associated clinical acid-base diagnoses. The decision to obtain central as opposed to peripheral venous blood gases was prudent as the former are not directly impacted by variations in distal tissue perfusion and thus may be

more likely to demonstrate a consistent relationship with ABGs. Unfortunately, this study has a number of limitations and inconclusive results.

The majority of the study population consists of patients coming in for cardiac catheterization; "usual" ICU diagnoses and scenarios are underrepresented, thus the results cannot be generalized to most of our patients. The limits of agreement found between ABG and VBG mean, in simplistic terms, that a venous pH of 7.35 could represent an arterial pH of 7.375-7.293; similarly, a venous pCO₂ of 50 could represent an arterial pCO₂ of 43.5-57.5. Clinical decision-making and response to the results at the extremes of these ranges could differ considerably; therefore, the study results suggest that a single VBG may not be a very useful surrogate for an ABG. The authors describe similarly disappointing findings when comparing the clinical acid-base diagnoses derived from venous vs. arterial blood gases in their study; even using adjusted VBGs, the κ coefficient of 0.61 (where 0 is no agreement and 1 is perfect agreement) shows only fair-to-moderate agreement. The discussion rightly notes that there were only a small number of blood gases in each "abnormal" diagnostic category so that no clear conclusions can be drawn from the relatively low diagnostic agreement; these data at least do not support a VBG being a good surrogate for an ABG. Finally, this work attempts to evaluate the relationship between some clinical characteristics and the likelihood of discrepancy between an ABG and the aVBG; however, these characteristics are not defined a priori and the numbers of patients with each characteristic are relatively small, putting the validity of this analysis into question as well.

The clearest findings seem to be that the authors' adjustment algorithm is reasonable under normal circumstances and that a normal aVBG (and its diagnosis of normal acid-base status) accurately predicts a normal ABG. This information may be valuable in certain specific clinical scenarios when an ABG is unable to be obtained.

It is important to remember that the results of a single abnormal VBG or aVBG must be considered with caution and should not be the primary data guiding significant clinical decision-making. I suggest that trends in these gases may prove more helpful but, again, only in combination with other clinical data. ■

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CME Questions

7. All but which one are frequent findings in SVT?

- a. Chest pain
- b. ECG ST depression
- c. ECG ST elevation
- d. Troponin leak

8. In the study by Rahme et al for patients undergoing hemiarthroplasty, rate of death per 100 patient-months was lowest among patients who were discharged to:

- a. home with home care.
- b. home without home care.
- c. nursing home.
- d. rehabilitation center.
- e. another hospital.

9. Walkey et al's study of VBGs compared to ABGs:

- a. used peripheral IV sampling for VBGs.
- b. required APACHE II scores ≥ 25 for enrollment.
- c. enrolled a mixed population including patients being admitted for cardiac catheterization.
- d. excluded patients on vasopressors.
- e. is the first study to ever consider VBGs in the ICU setting.

Answers: 7. (c); 8. (a); 9. (c)

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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Tria Kreutzer

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Fax: (800) 284-3291

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