

Internal Medicine

Evidence-based summaries of the
latest research in internal medicine

[ALERT]

ABSTRACT & COMMENTARY

Perioperative Use of Aspirin in Patients Undergoing Noncardiac Surgery

By *Harold L. Karpman, MD, FACC, FACP*

Clinical Professor of Medicine, UCLA School of Medicine

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

SYNOPSIS: Administration of aspirin before surgery and throughout the early postsurgical period had no significant effect on the rate of composite of death or nonfatal myocardial infarction but did increase the risk of major bleeding.

SOURCE: Devereaux PJ, et al. Aspirin in patients undergoing noncardiac surgery. *N Eng J Med* 2014;370:1494-1503.

Since an acute myocardial infarction (MI) is the most common major vascular complication that occurs after noncardiac surgery¹⁻⁴ and acute coronary artery thrombosis is the likely mechanism of most perioperative MIs,^{5,6} the perioperative use of aspirin, which inhibits platelet aggregation,⁷ may decrease the frequency of major vascular complications by preventing thrombus formation.⁸ There is substantial variability in the perioperative administration of aspirin to patients undergoing cardiac surgery both for those patients who already are on an aspirin regimen and among those who are not. Uncertainty regarding the risks and benefits of aspirin administered perioperatively^{9,10} underscored the need for a large perioperative trial.

Devoreaux and his colleagues conducted the Perioperative Ischemic Evaluation 2 (POISE-2) trial to evaluate the effect of low-dose aspirin as compared with placebo on the 30-day risk of a composite of death or nonfatal MI among patients who were undergoing noncardiac surgery. The 4382 patients who were on an aspirin regimen prior to enrolling in the study discontinued aspirin intake 3 days prior to the surgery. A second group of 5628 patients who had not been on aspirin therapy preoperatively was also enrolled in the study. The total of 10,010 patients were randomly assigned to receive aspirin (200 mg daily) or placebo starting just before surgery. Aspirin was continued at a dose of 100 mg daily for 30 days after surgery or, if patients had been on aspirin preoperatively, they resumed their usual aspirin regimen 7 days after surgery.

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[INSIDE]

Obstructive Sleep
Apnea and Incident
Diabetes
page 98

For Seniors, Regular
Exercise Provides
Disability Benefits
page 99

Omega-3-Carboxylic
Acid Capsules
(Epanova®)
page 101

Clinical Briefs
page 102

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The primary outcome was a composite of death or nonfatal MI at 30 days. The primary outcome occurred in 351 patients (7%) in the aspirin group and in 355 patients (7.1%) in the placebo group. The authors concluded that administration of aspirin before surgery and throughout the early postsurgical period had no significant effect on the rate of a composite of death or nonfatal MI but did increase the risk of major bleeding.

COMMENTARY

Devereaux and colleagues conducted this major trial because of the uncertainties surrounding the risks and benefits of aspirin therapy in patients undergoing noncardiac surgery.¹¹ They concluded that aspirin therapy did not increase the risk of death or nonfatal MI, but did increase the risk of postoperative hemorrhage, which appears to be decreased significantly if aspirin therapy was stopped ≥ 3 days prior to the surgical procedure. If clinicians plan to use an anticoagulant agent for perioperative prevention of venous thromboembolism, the results of this study suggest that aspirin provides no additional benefit but increases the risk of major bleeding. It should be carefully noted that this study did not address the relative merits of aspirin vs other anticoagulant agents for perioperative thromboprophylaxis.¹² The authors suggested that aspirin should be discontinued ≥ 3 days prior to surgery and not be restarted until 8-10 days after surgery at which time the bleeding risks will have diminished

considerably.

In summary, it would appear that aspirin should not be continued or started in patients undergoing noncardiac surgery because it did not decrease the rate of thrombotic events and the risk of major bleeding was increased. If aspirin therapy is needed on a continuing basis in a patient, it should be discontinued prior to surgery and resumed postoperatively; other anticoagulants with a lesser bleeding risk such as Lovenox may be used to "bridge" the time period when aspirin therapy has to be discontinued. ■

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ABSTRACT & COMMENTARY

Obstructive Sleep Apnea and Incident Diabetes

By Barbara A. Phillips, MD, MSPH

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Dr. Phillips serves on the speakers bureau for PotomaCME.

SYNOPSIS: Severe obstructive sleep apnea is associated with a 30% increase in risk of incident diabetes, controlling for multiple relevant confounders.

SOURCE: Kendzerska T, et al. Obstructive sleep apnea and incident diabetes: A historical cohort study. *Am J Respir Crit Care Med* 2014; Jun 4. [Epub ahead of print.]

These Canadian authors set out to undertake a rigorous study of the

relationship between obstructive sleep apnea (OSA) and incident diabetes. They collected

data from adults who did not have diabetes at baseline and who underwent a sleep study, then followed these people for a median time of about 5 years. The primary outcome was time from the diagnostic sleep study to the diagnosis of incident diabetes. During that time, 10,149 people had sleep studies. Of these, 8678 did not have diabetes at baseline. Over the follow-up of about 6 years, 11.7% (1017) of these people developed diabetes. After controlling for age, sex, body mass index (BMI), smoking, multiple medical comorbidities, and income, those people with a severe sleep apnea (defined as an apnea plus hypopnea index [AHI] > 30 events per hour of sleep) had a 30% higher risk of incident diabetes than those with AHIs < 5. In addition to AHI, time spent with oxygen saturations < 90%, heart rate, and neck circumference were associated with incident diabetes. The older and heavier the patients were, the less effect AHI had on risk of incident diabetes.

The authors also looked at the effect of continuous positive airway pressure (CPAP) (assessed by submission of CPAP insurance claims) on the risk of diabetes development. A claim for CPAP treatment did not have a significant effect on the risk of diabetes development.

■ COMMENTARY

The prevalence of both OSA and diabetes is increasing, at least partly because the prevalence of obesity is increasing. However, OSA is also associated with intermittent hypoxemia, arousals from sleep, and neurohumoral changes that may affect insulin sensitivity.¹ A few small studies have suggested an independent link between OSA and risk of diabetes, but those preliminary reports were not as large or as rigorously done as this one. Because these investigators were able to include health data for all residents of Ontario, they had a huge and rich source of data. (Indeed, legislation prohibits private delivery of services covered under the Ontario Health Insurance Plan, including laboratory testing!) The findings that degree and duration of hypoxemia and higher heart rate were associated with increased risk of diabetes in this study support the current hypothesis that

oxidative stress (resulting from sympathetic activation or hypoxemia) promotes glucose intolerance.

This study adds strong evidence to the notion that the relationship between sleep apnea and diabetes is not mediated by obesity alone. Stronger proof, of course, would be data demonstrating that CPAP treatment improves diabetic outcomes (which was not demonstrated in this study that was not designed to address this issue). A recent review² of 22 articles reported that CPAP use results in significant changes in glucose metabolism, including glycosylated hemoglobin (HbA1c), postprandial or nocturnal glucose, and insulin sensitivity. In addition, a recent report from the United Kingdom based on National Health Service (NHS) data, noted “Initiating treatment with CPAP in OSA patients with type 2 diabetes leads to significantly lower blood pressure and better controlled diabetes and affords a cost-effective use of NHS resources.”

An under-the-radar finding of the current study was that the time spent with oxygen saturation below 90% (that is, degree and duration of oxygen desaturation) predicted incident diabetes more strongly than did AHI, and that AHIs below 30% were not associated with statistically significant increases in incident diabetes after controlling for confounders. These and other findings (including the huge numbers of people at risk for OSA) are likely to further the migration of the diagnostic approach toward sleep apnea out of the sleep lab and into the home.

What does all of this mean for our patients? It is probably cost-effective to test for sleep apnea in patients who fit the profile (obese, sleepy, > 55 years of age, witnessed apneas, hypertension, big necks), particularly if the diagnosis can be done with an oximetry-based home study. ■

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ABSTRACT & COMMENTARY

For Seniors, Regular Exercise Provides Disability Benefits

By *Rahul Gupta, MD, MPH, FACP*

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

SYNOPSIS: In a study of vulnerable elderly population at risk for disability, a structured, moderate-intensity physical activity program compared with a health education program significantly reduced major mobility disability.

The proportion of senior citizens is increasing faster than any other age group, and by the year 2050, it is expected that more than 80 million people in the United States will be over age 65. The number of Americans over age 85 will also reach record levels. From a public health perspective, the central challenge would be to balance the goal of maximizing quantity of life with the goal of maximizing quality of life. Fundamental to the quality of life is the ability for elderly individuals to preserve the capacity to remain functionally independent and thus prevent disability. With the aging process, maintaining the ability to be physically active is crucial since research demonstrates that individuals who are regularly physically active report better overall health, lower health care expenditures, and fewer mobility limitations than their peers who are sedentary.^{1,2} On the other hand, older adults who lose their mobility have higher rates of disease, disability, and death. However, when it comes to identifying proven specific interventions aimed at preventing or delaying the onset of mobility disability over an extended period of time, the research is surprisingly limited.

In their study, Pahor et al conducted a multicenter, randomized trial consisting of 1635 sedentary men and women aged 70-89 years from communities at eight centers throughout the United States. The average age of the participants was 78.9 years, more than half (about 67%) were women, and nearly 18% were African American. Participants were randomly divided into two groups. In the physical activity group, 818 men and women participated in a moderate-intensity physical activity program that included aerobic, resistance, and flexibility training activities. In the health education group, 817 adults attended workshops on topics relevant to their age group and performed upper extremity stretching exercises. The physical activity group gradually worked up to the goal of 150 minutes of weekly activity, including 30 minutes of brisk walking, 10 minutes of lower extremity strength training, 10 minutes of balance training, and large muscle flexibility exercises. The comparison group participated in weekly health education workshops for the first 26 weeks, followed by monthly sessions thereafter and performed 5-10 minutes of upper body stretching and flexibility exercises in each session. Participants remained with their assigned programs for an average of 2.6 years.

Researchers found that compared with the health education group, physical activity programs reduced the risk of major mobility disability by 18% (hazard ratio [HR], 0.82; $P = 0.03$) in an elderly, vulnerable

population. Similar benefits were also demonstrated for persistent mobility disability (HR, 0.72; $P = 0.006$) and the combined outcome of major mobility disability or death (HR, 0.82; $P = 0.02$). However, physical activity did not decrease the death rate, although the sample size for this event did not reach statistical significance. The participants receiving the physical activity intervention were better able to maintain their ability to walk without assistance for 400 meters, or about a quarter of a mile.

■ COMMENTARY

It is well-known that the benefits of recommended moderate-intensity physical activity in the elderly may be multifold and include improved strength, conditioning, flexibility, mobility, physiological benefits in several chronic conditions as well as reduced likelihood of falls and several mental health disorders.³ Regular physical activity has also been shown to reduce the risk of developing certain cancers (colon, breast) and other medical conditions such as cardiovascular disease, hypertension, stroke, type 2 diabetes, osteoporosis, and obesity. With aging, aerobic capacity, muscle mass, and strength all decline, which may have a significant negative impact on the elderly individuals' ability to perform daily activities. Moderate-intensity physical activity programs, including muscle strengthening activities, may allow the maintenance of adequate functional status resulting in lesser disability. While previous studies have demonstrated decreased mortality along with a greater likelihood of healthy aging as a result of regular physical activity, the study was not able to replicate this particular finding and perhaps more research is needed in this area.⁴ However, it is abundantly clear that each older adult patient can benefit from physical activity and that participation in any amount of physical activity will result in some health benefit, especially in those with existing chronic conditions. These study findings indicate that a structured, moderate-intensity physical activity program compared with a health education program has the potential to reduce major mobility disability over an extended period of time among older adults at risk for disability. Perhaps it is time to not just educate but ensure that our senior population of patients is receiving this benefit in their community setting. ■

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Omega-3-Carboxylic Acid Capsules (Epanova®)

By William T. Elliott, MD, FACP, and James Chan, PharmD, PhD

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Drs. Elliott and Chan report no financial relationships relevant to this field of study.

The FDA has approved the first free fatty acid form of omega-3. Previous formulations have been ethyl esters of omega-3-acids. The omega-3-carboxylic acid is a fish oil-derived mixture of 50-60% eicosapentaenoic acid (EPA) and 15-25% docosahexaenoic acid (DHA) along with other potentially active omega-3 fatty acids. It is marketed by AstraZeneca as Epanova.

Indications

Omega-3-carboxylic acid is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults with severe hypertriglyceridemia (≥ 500 mg/dL).¹

Dosage

The recommended dose is 2 grams or 4 grams once daily based on response and tolerability.¹ It may be taken without regard to meals. Omega-3-carboxylic acid is available as 1 gram capsules. Each capsule contains at least 850 mg of polyunsaturated fatty acids, including multiple omega-3 fatty acids.

Potential Advantages

Omega-3-carboxylic acid (Epanova) provides an alternative to the two marketed omega-3-acid ethyl esters (Lovaza® and Vascepa®).

Potential Disadvantages

In some patients, omega-3-carboxylic acid may increase LDL-C levels.¹ Adverse events reported with omega-3-carboxylic acid include diarrhea (7-15%), nausea (4-6%), and abdominal pain or discomfort (3-5%) compared to 1-2% for placebo (olive oil).¹ Omega-3-fatty acids may increase bleeding time.¹

Comment

Omega-3-carboxylic acid was evaluated in a randomized, double-blind, placebo-controlled, parallel-group, 12-week study.¹ Subjects with TG levels between 500 and 2000 mg/dL (median 694 mg/dL) were randomized to omega-3-carboxylic acid, 2, 3, or 4 grams per day or olive oil placebo. Other median lipid levels at baseline were: non-HDL-C 217 mg/dL, LDL-C 81 mg/dL, and HDL-C 28 mg/dL. Statins and ezetimibe were permitted during the study. Thirty-five percent were on a

statin and/or ezetimibe. The treatment differences for TG between placebo and omega-3-carboxylic acid were -16% and -21% for the 2 g dose and 4 g dose, respectively. For non-HDL-C, reductions were 7% and 10%, respectively. These reductions were statistically significant. LDL-C was increased by 13% and 15%. Statistical significance tests were not performed for LDL-C.¹ The effect of the 3 g dose was not meaningfully different than the 2 g dose.¹ Omega-3 fatty acids have not been shown to affect the risk of pancreatitis or cardiovascular mortality or morbidity.¹

Clinical Implications

Epanova is the fatty acid form of EPA and DHA along with other fatty acids. The previously marketed products are ethyl esters. Since esterified products are de-esterified during absorption, it is not certain if the new fatty acid form offers any clinical advantage. Similar to Lovaza, which contains EPA and DHA, Epanova increased LDL-C while icosapent ethyl, which contains only EPA, showed no significant change.² AstraZeneca plans to evaluate the safety and efficacy on cardiovascular outcomes in combination with a statin in subjects with hypertriglyceridemia and high cardiovascular risk at a dose of 4 gm per day (estimated completion date 2019).³ A similar study with icosapent ethyl (4 g) is expected to be completed in 2016.⁴ Generally, omega-3 fatty acid supplementation has not been shown to reduce cardiovascular mortality and morbidity, cancer incidence, non-vascular death, or total mortality.^{5,6} The wholesale cost for Epanova was not available at the time of this review. ■

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Pain and Fall Risk Assessment in Cognitively Impaired Nursing Home Residents

Source: Burfield AH, Cooper JW. *Ann Long-Term Care: Clin Care Aging* 2014;22:36-41.

In senior citizens, there may be an underrecognized link between pain and falls, and even if this link is not as strong as suspected, assessments for both need to be enhanced since in the nursing home, pain and falls are key quality measures.

More than half of nursing home residents fall each year, comprising 20% of all fall-related deaths. Cognitively impaired nursing home residents are 4-5 times more likely to fall than age-matched cognitively intact individuals.

Overall, the prevalence of pain syndromes in nursing home residents is approximately 30%. The impact of cognitive impairment upon pain reporting is clear when it is recognized that reporting of pain is essentially half as frequent among persons with severe cognitive impairment as compared to the nursing home resident population as a whole. Despite cognitive impairment, clinical trial data indicate that almost two-thirds of severe dementia patients can meaningfully utilize at least one pain scale.

Falls in nursing home residents are often attributed to psychoactive medications such as sedatives, antiparkinsonian agents, anticonvulsants, opioid analgesics, and antihistamines. There are several lines of evidence to suggest that review and potential revision of psychotropic agents can have a positive effect. In one study, daily administration of acetaminophen 3 g allowed reduction of psychotropics by 75%. Similarly, a trial of psychotropic substitution with buspirone as a preferred anxiolytic resulted in reduced falls and was even

associated with improved cognition. The authors provide a one page (two-sided) *Checklist of Nonverbal Indicators of Chronic Pain/Fall Risk Assessment Guideline* with permission for free use by clinicians. ■

PSA Screening: Maybe You Saw the Movie 'NeverEnding Story'?

Source: Carroll PR, Vickers AJ. *J Natl Compr Canc Netw* 2014;12:768-771.

The most recent lecture presentation I gave to an audience of clinicians about prostate cancer in May was titled: "Prostate Cancer: Game Over." And yet it seems that this controversy may be far from over. Presentations at the American Urological Association in Orlando in 2014 confirm the continued ambivalence about whether/how/when we should be addressing prostate cancer screening.

No one disagrees that routine prostate-specific antigen (PSA) screening can lead to overdiagnosis: that is, identification of disease destined to have no ultimate impact on the life span or well-being of the patient. New 2014 guidelines from the National Comprehensive Cancer Network (NCCN) include a more restricted PSA level indication for biopsy (> 3.0 ng/mL), less frequent testing, and restriction of biopsy to palpable abnormalities that are "highly suspicious" rather than "minor abnormalities." Use of PSA velocity, particularly at very low PSA levels, is now recognized to also lead to overdetection. Finally, active surveillance for low-risk disease is advocated by the NCCN.

Despite the availability of data representing more than 230,000 men from two recent randomized, controlled trials (PLCO and ERSC) that does not support the ability of PSA screening to reduce mortality, the issue continues to stimulate debate. ■

Screening for Lung Cancer in Asbestos Workers

Source: Ollier MD, et al. *Chest* 2014;145:1339-1346.

The United States Preventive Services Task Force (USPSTF) has endorsed screening for lung cancer in selected smokers by means of a series of three low-dose CT scans. This Level B endorsement has met with some resistance. The Medicare Advisory Panel has reviewed the evidence (2014), including a 20% reduction in lung cancer mortality and a 7% reduction in total mortality seen in the National Lung Screening Trial (n = 53,454), and has not advocated paying for screening. A similar position has been taken by the American Academy of Family Physicians, whose position statement expresses doubt about the achievable benefits in typical clinical settings. Asbestos workers, even when non-smokers, are recognized to be at increased risk of lung cancer. Ollier et al reviewed data from seven clinical trials in which chest CT scans were used to screen former asbestos workers (n = 5074). Within this population, 49 cases of asymptomatic lung cancer were found, of which about one-third were stage 1, indicative of high potential for cure.

The prevalence of lung cancer detected among asbestos workers (1.1%) was quite similar to that found in the National Lung Screening Trial (1.0%). This would lead to the conclusion that specifically screening asbestos workers might be at least as beneficial as screening the recommended population of smokers suggested by the USPSTF guidance. ■

What is the ‘Culprit’ Artery?

By Ken Grauer, MD

Professor Emeritus in Family Medicine, College of Medicine, University of Florida

Dr. Grauer is the sole proprietor of KG-EKG Press, and publisher of an ECG pocket brain book.

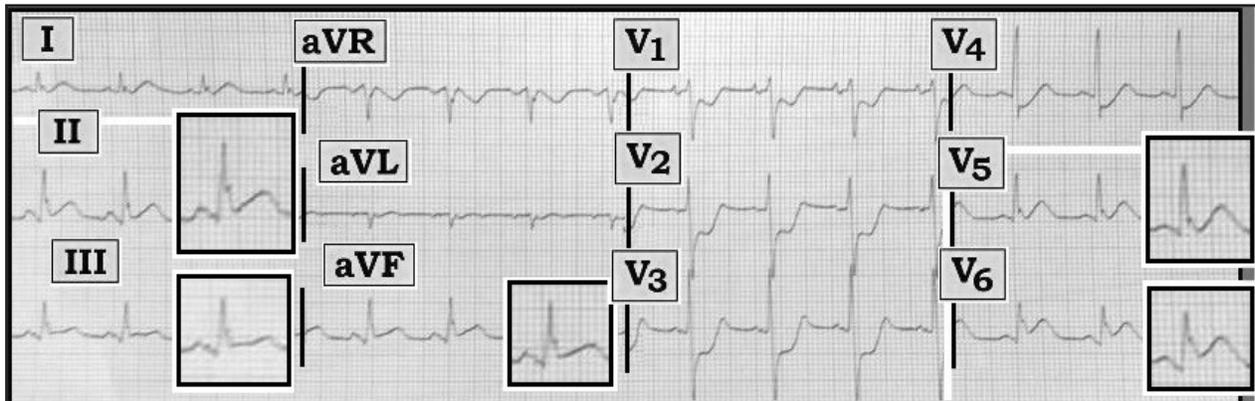


Figure — ECG obtained from a patient with new-onset chest pain.

Scenario: Interpret the ECG in the Figure — obtained from a patient with *new-onset* chest pain. Localize the area(s) of acute infarction. Which coronary artery is likely to be acutely occluded?

Interpretation: The rhythm is sinus. Intervals and axis are normal. No chamber enlargement. Regarding Q-R-S-T Changes:

- Small q waves are seen in leads II, III, aVF; and in leads V5, V6.
- Transition is normal (occurs between lead V2-to-V3) — albeit the R wave is *taller-than-expected* in leads V2, V3.
- There is *subtle-but-real* ST elevation in each of the inferior leads (II, III, aVF) — with suggestion of hyperacute T waves (especially in lead II). A similar pattern of slight J-point ST elevation is seen in leads V5, V6 — with suggestion of hyperacute T waves in these leads.
- There is marked ST depression in leads V1 through V4.

Impression: Sinus rhythm with acute *infero-postero-lateral* ST elevation myocardial infarction (STEMI). The cardiologist on call should be notified of the need for immediate cardiac catheterization and reperfusion. We suspect acute LCx (Left Circumflex Artery) occlusion.

- The ECG picture in leads V1, V2, V3 strongly suggests associated acute posterior infarction. Although none of the standard 12 leads directly visualize the posterior wall of the left ventricle,

the anterior leads provide a mirror-image of ongoing posterior events. Turning the tracing over and holding it up to the light (performing a “mirror test”) suggests that rather than taller-than-expected R waves and marked ST depression in anterior leads, there are deepening Q waves and increasing ST elevation in posterior leads. Alternatively — one could apply posterior leads (V7, V8, V9) directly.

In most patients (~85%), the right coronary artery (RCA) is a dominant vessel that supplies the right ventricle before continuing as the posterior descending artery (PDA) that runs along the undersurface of the heart to supply the inferior and posterior walls of the left ventricle. Acute occlusion of the RCA therefore may result in acute infero-postero infarction. RCA involvement is suggested on ECG by the finding of ST elevation that is more marked in lead III than in lead II and by marked reciprocal ST depression in lead aVL. Neither of these signs is seen in the Figure. Instead we see inferior, posterior, and lateral precordial involvement with ST elevation in leads V5, V6. This distribution of changes (with minimal ST elevation in lead III, and significant ST elevation in lead V6) is much more suggestive of acute LCx occlusion. In ~15% of patients, rather than the RCA, it is the LCx that is dominant and gives rise to the PDA to supply the posterior and inferior walls of the left ventricle. Acute occlusion of a dominant LCx is the situation we suspect in this case. ■

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5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.



CME QUESTIONS

- 1. Administration of aspirin before surgery and throughout the early postsurgical period in patients undergoing noncardiac surgery:**
 - a. decreased the rate of death or nonfatal myocardial infarction.
 - b. increased the rate of major bleeding.
 - c. had no significant effect on the rate of deaths, nonfatal myocardial infarction, or major bleeding.
 - d. should be continued.
- 2. The relationship between obstructive sleep apnea and type 2 diabetes:**
 - a. is most likely incidental to the fact that both conditions are associated with obesity.
 - b. is strongly linked to the degree and duration of hypoxemia.
 - c. includes improvement in sleep apnea control when diabetes is effectively managed with hypoglycemic agents.
 - d. is strongest in older individuals.
- 3. In the study by Pahon et al, compared with providing health education, a moderate-intensity physical activity program was found to reduce all of the following *except*:**
 - a. Major mobility disability
 - b. Major mobility disability or death combined
 - c. Persistent mobility disability
 - d. Death

CME OBJECTIVES

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

- describe new findings in the differential diagnosis and treatment of various diseases;
- describe the advantages, disadvantages and controversies surrounding the latest advances in the diagnosis and treatment of disease;
- identify cost-effective treatment regimens;
- explain the advantages and disadvantages of new disease screening procedures.

[IN FUTURE ISSUES]

CPAP is Great, But Don't Forget About the Weight

Vitamin D and mortality: Meta-analysis of data from a large consortium of cohort studies from Europe and the United States

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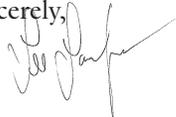
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Lee Landenberger
Continuing Education & Editorial Director