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INSIDE

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Should Patients with COPD Exacerbations Receive Beta Blockers?

ABSTRACT & COMMENTARY

By David J. Pierson, MD

Dr. Pierson is Professor, Pulmonary and Critical Care Medicine at The University of Washington, Seattle, and is editor of Critical Care Alert. *This abstract first appeared in the August 2008 issue of* Critical Care Alert.

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

Synopsis: *The findings of this retrospective study of 825 patients hospitalized with COPD exacerbations indicate that the use of beta blockers in such patients is not harmful and may actually be associated with reduced mortality.*

Source: Dransfield MT, et al. *Thorax.* 2008;63(4):301-305.

This study from the University of Alabama Hospital in Birmingham reviewed administrative data from all patients admitted with the primary diagnosis of acute exacerbation of chronic obstructive pulmonary disease (COPD), or because of acute respiratory failure with a secondary diagnosis of COPD exacerbation. The investigators excluded patients with asthma, and examined demographic data, co-morbidities, and medication use during hospitalization. Patients who received beta blockers were compared with those who did not, and multivariate analysis was performed to determine predictors of in-hospital mortality after controlling for known covariates and the propensity to receive beta blockers.

During the 7-year study period, 825 patients met inclusion criteria, 142 of whom received beta blockers. Patients who received beta blockers were older and more of them had concomitant cardiovascular disease. Overall, 5.2% of all patients died. By multivariate analysis, adjusting for potential confounders including the propensity score, mortality was less among patients who received beta blockers (odds ratio, 0.39, 95% CI 0.14-0.99). Mortality was also associated with older age, longer hospital stays, number of previous exacerbations, the presence of acute respiratory failure, congestive heart failure, and the presence of cardiovascular or liver disease (all, $p < 0.05$).

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The authors conclude that administration of beta blockers to patients hospitalized with COPD exacerbations is well tolerated and may be associated with reduced mortality.

■ COMMENTARY

One of the most firmly entrenched "things everybody knows" in managing patients with obstructive lung disease is that beta-blocking agents cause bronchospasm and should not be used in such patients. While few would argue with this admonition in managing patients with severe asthma, it basically turns out not to be true for patients with COPD—especially for the cardioselective beta blockers now widely used in managing cardiovascular disease. A recent Cochrane review[1] evaluated 20 randomized trials of cardioselective beta blockers in patients with COPD and found no significant effect on airway function (as assessed by forced expiratory volume in the first second, or the response to inhaled bronchodilator), either after single doses or with as much as 12 weeks of administration. In fact, there is an increasing body of evidence that beta blockers may improve outcomes in patients with COPD, whether or not they have overt cardiovascular disease.[2]

Because of their common link to cigarette smoking, as well as other potential factors, COPD and cardiovascular disease tend to occur in the same patients. There is compelling evidence that beta blockers improve outcomes in cardiovascular disease—not only in acute myocardial infarction, cardiac ischemia, and left ventricular systolic dysfunction, but also in hypertension and other settings.[2] However, because of fear of precipitating acute bronchospasm, and widespread acceptance of the idea that beta blockers are contraindicated in obstructive lung disease, these agents are used less often in patients with COPD when the established indications are present. In the current study, of the 306 patients in the cohort who were considered to have a clear indication for beta blocker administration, only 28% received this therapy.

Beta blockers are not contraindicated in COPD, either in the long-term management of stable patients or during hospitalization for an exacerbation. There is even the suggestion that beta blockers may be indicated for patients with COPD, although this hypothesis needs to be tested in randomized clinical trials. ■

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Small Intestinal Bacterial Overgrowth in Rosacea: Clinical Effectiveness of Its Eradication

ABSTRACT & COMMENTARY

By Malcolm Robinson, MD, FACP, FACG

Emeritus Clinical Professor of Medicine, University of Oklahoma College of Medicine, Oklahoma City.

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

Synopsis: *Rosacea patients have increased incidence of small bowel bacterial overgrowth vs controls, and the eradication of this overgrowth leads to almost complete and long-lasting skin lesion regression.*

Source: Parodi A, et al. *Clin Gastroenterol Hepatol.* 2008;6:759-764.

ROSACEA, A VERY COMMON DERMATOSIS, IS CHARACterized by chronic central facial and eyelid inflammation. G.I. disorders have been frequently noted in rosacea patients including flatulence, dyspepsia, altered

bowel habits, and abdominal pain. Earlier publications describe association of rosacea with inflammatory bowel diseases, *Helicobacter pylori*, and other diagnoses. Various cutaneous rosacea lesions often improve with antibiotic therapy including agents such as metronidazole, macrolides, chloramphenicol, neomycin, and tetracyclines. Mechanism(s) for the efficacy of antibiotics remain unexplained. A few years ago, a study in the dermatology literature found that rosacea improved with reduction of GI transit time. The current authors decided to investigate possible involvement of small intestinal bacterial overgrowth (SIBO) in rosacea pathogenesis. Although they realized that the gold standard for SIBO would be a positive jejunal culture for > 10^5 organisms, they opted to use lactulose followed by glucose breath testing as validated surrogates. The study involved 114 consecutive rosacea patients (82 women and 32 men; 2 with flushing, 27 with erythrosis, and 84 with papulopustules) in an academic dermatology department along with 60 healthy age and sex matched controls. All patients had assessment of GI symptoms and their severity. Standard lactulose and glucose breath tests for methane and hydrogen were performed sequentially a week apart using a Quintron MicroLizer device. *Helicobacter pylori*, if present at baseline, was treated with triple therapy after the conclusion of the study, and these *H. pylori* positive individuals responded in the same way as those patients who had been negative for *H. pylori*. Breath testing was done at baseline, and patients with breath test-documented SIBO were randomized to receive rifaximin or placebo.

Rosacea patients had SIBO far more often than controls (52/113 vs 3/60, $p < .001$). Patients with papulopustules had SIBO more often than rosacea patients without such lesions (50/84 vs. 2/29, $p < .001$). Eradication of SIBO confirmed by breath testing was confirmed in 28 of 32 patients (87.5%), and these patients had significant reductions in reported gastrointestinal symptoms. Of the placebo recipients, 18 of 20 had unchanged rosacea, and 2/20 had worsened. Rifaximin recipients had complete clearance of rosacea in 20 of 28 patients (71.4%), and 6 patients had significant reduction in lesion severity. Only 2 patients had no benefit from treatment. Placebo recipients were subsequently treated with open label rifaximin, and eradication of SIBO could be accomplished in 45 of 52 patients (86.5%). Complete lesion eradication was achieved in 35 patients (78%) and improvement was noted in 8 patients (17.7%). Sixteen patients with no breath test evidence of SIBO were nonetheless empirically treated with rifaximin, and little clinical change was noted in rosacea lesions (partial improvement in 3 patients). Orocecal transit time was found to be significantly delayed in patients with SIBO. Clinical response to therapy was found to persist for at least 9 months after successful rifaximin therapy.

■ **COMMENTARY**

This study seems to confirm a high prevalence of SIBO in rosacea along with an excellent response to therapy with the nonabsorbable antibiotic rifaximin. The precise pathogenesis underlying the relationship between SIBO and rosacea is still unclear, but it is hard to argue with the demonstration that there is such a relationship. As the authors themselves agree, the study could have been even more compelling had SIBO been documented using jejunal culture. However, the invasive nature of jejunal culture and other technical pitfalls make their choice of diagnostic approaches quite reasonable. There was no blinding in this study, and this is a great pity since blinding is always preferred. Nevertheless, the striking results seem hard to dispute. Although further confirmatory data from other centers will be helpful, the evaluation of rosacea patients for SIBO seems reasonable as does antibiotic treatment of those found to have evidence for such infections. Rifaximin seems to be a particularly good choice for the management of SIBO in view of its very poor systemic absorption and its lower predilection for development of bacterial resistance. ■

Effect of Obesity and Lifestyle on Risk of Acute Coronary Events

ABSTRACT & COMMENTARY

By Harold L. Karpman, MD, FACC, FACP

Clinical Professor of Medicine, UCLA School of Medicine

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

Synopsis: *Obesity confers an elevated risk of ACS in subgroups of subjects with both healthy and less healthy lifestyle behaviors. However, adherence to healthy lifestyle behaviors is definitely associated with a lower risk even among obese individuals.*

Source: Jensen MK et al. *Circulation.* 2008; 117: 3062-3069.

The prevalence of overweight (ie, body mass index of 25-29.9 kg/m^2) and obesity (ie, body mass index equal to or greater than 30 kg/m^2) is increasing in most industrialized countries. In fact, the Centers for

Disease Control and Prevention's CDC Morbidity and Mortality Weekly Report of June 18, 2008 reported that 26% of U.S. adults were obese in 2007 compared to only 24% in 2005.[1-3] Hypertension, hypercholesterolemia, diabetes and high risk of coronary artery heart disease (CHD) are among the well-established adverse health effects associated with excess weight.[4]

It has been suggested by some,[5-6] but not all,[7-9] that physical fitness produced by exercise may improve the CVD risk associated with obesity. However, the effect of changes of other behavioral lifestyle factors on the CVD risk associated with obesity had not been previously clearly evaluated.

Jensen and her colleagues[10] therefore decided to follow 54,783 women and men from the prospective Danish Diet, Cancer and Health study who were 50 to 64 years old at baseline and who were free of CVD and cancer. The subjects were followed for a median time of 7.7 years and, after multivariable adjustments were made, each increase in one unit of body mass index was associated with a 5-7% higher risk of acute coronary events (ACS) among both men and women. Overweight and obesity was associated with a higher risk of ACS among both the physically active and inactive, in cigarette smokers and non-smokers, and even among those who adhered more or less to a heart-healthy diet. Finally, obese non-smokers had a somewhat lower risk than did obese smokers, and adherence to a healthy diet was associated with a ower risk of ACS in normal weight subjects but not in obese individuals.

■ COMMENTARY

In the past, the lack of statistical power, the small numbers of outcome events and the inadequate length of follow-up have been the assumed explanations for study results that have failed to find relationships between obesity, mortality and/or CVD risk. In addition, inconsistencies of findings between studies were probably related to differences in study populations and sampling, the measures of adiposity or obesity which were utilized and the statistical approaches which were used. The Jensen study[10] went to great lengths to avoid such pitfalls. BMI is a crude measure of overall obesity and is therefore often not the best predictor of obesity-related outcomes. In fact, there is evidence that measures such as abdominal adiposity are associated with the risk of CVD, independent of overall body adiposity[11] and therefore waist circumference measurements are probably a more useful measure of body fat distribution than is BMI.[12,13] In addition, published data have clearly demonstrated that low cardiorespiratory fitness is among the strongest risk factors for CVD and related mortality and, in addition, there is evidence that the poor metabolic risk profile of men with low cardiorespiratory fitness is associated with greater visceral adipose tissue accumulation after controlling for BMI.[14] In the Jensen study it should be noted that only 8% of study participants were in the healthiest group for all four behavioral lifestyle risk factors (ie, physically active for 3.5 hours/week or more, non-cigarette smoking, high score on the Mediterranean diet scale and light to moderate alcohol intake) and that only 4.1% of the ACS occurred in this group. In addition, the hazard ratio for ACS was 1.65 for the overweight subjects and 2.65 for the obese subjects.[10]

In summary, obesity confers an elevated risk of ACS in both healthy and less healthy subgroups of lifestyle behavior patterns and, equally important, adherence to healthy lifestyle behaviors was associated with a lower risk even among obese individuals. Dietitians, kinesiologists and behavioral specialists should be recruited to help clinicians achieve optimal management of lifestyle in order to avoid increased CVD risk factors because overweight and obesity are a major cause of CVD morbidity and mortality. From a public health point of view, increases in physical activity along with the establishment of healthy eating habits early in life may be the best and most cost-effective methods to combat obesity and reduce CVD risk, especially because weight gain is progressive as one gets older and because if weight loss is needed and achieved later in life, it is difficult to maintain. It is therefore clearly important that effective weight maintenance and obesity prevention approaches be developed and implemented for all individuals above normal weight no matter at what age these practices are implemented. In other words, it is most important to contain obesity, improve diet, and increase physical activities in everyone but especially in childhood, even in children as young as two years of age. ■

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Pharmacology Update

Diphtheria, Tetanus Toxoids, Acellular Pertussis and Inactivated Polio Vaccine (KINRIX™)

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

Dr. Elliott is Chair, Formulary Committee, Northern California Kaiser Permanente; Assistant Clinical Professor of Medicine, University of California, San Francisco; Dr. Chan is Pharmacy Quality and Outcomes Manager, Kaiser Permanente, Oakland, CA.

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

A SINGLE INJECTION HAS BEEN APPROVED FOR A fifth dose of DTaP and the fourth dose of inactivated polio (IPV) in children 4 to 6 years of age. The combination vaccine is marketed by GlaxoSmithKline as KINRIX.

Indications

DTaP-IPV is indicated as the fifth dose of DTaP and the fourth dose of IPV in children ages 4 to 6 who have previously been vaccinated with INFANRIX and/or PEDIATRIX for the first three doses and INFANRIX for the fourth dose.[1]

Dosage

The dose is 0.5 ml administered intramuscularly. The DTaP components of KINRIX are the same as that in INFANRIX and PEDIATRIX. The inactivated polio component is the same as that in PEDIATRIX.[1]

Potential Advantages

The combination vaccine reduces the number of injections and the time to administer the immunizations and is considered non-inferior to administration of separate injections of DTaP and IPV.

Potential Disadvantages

Pain and Grade 3 pain were statistically higher for the DTaP-IPV compared to separate vaccine (57% vs 53.3% and 1.6% vs 0.6% respectively).[2]

Comments

Randomized multicenter studies show similar immunogenicity and reactogenicity between DTaP-

IPV and DTaP and IPV given separately.[1,2,3] Non-inferiority of the DTaP-IPV vaccine to separate DTaP and IPV vaccines was demonstrated for all DTaP antigen booster response rates and poliovirus geometric mean titers of antibody ratios. Solicited adverse events during the 4-day follow-up were similar between groups although any pain and Grade 3 pain was higher in the combination group (57% vs 53.3% and 1.6% vs 0.6%).[2] Unsolicited adverse events reported by children were similar between groups, 30.5% for the combined vaccine and 29.2% for separate vaccines. The DTaP-IPV vaccine also had no negative effect on the response to co-administered MMR vaccine.[3] ■

Clinical Implications

The vaccination schedule for children ages 4-6 are DTaP (5th dose), IPV (4th dose), MMR (2nd dose), and varicella (2nd dose).[4] DTaP-IPV provides an effective vaccination of DTaP and polio and requires one less injection, from 4 injections to 3.

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CME Questions

29. Rosacea patients were found to have SIBO in what percentage of cases:

a. approximately 45%
b. approximately 78%
c. approximately 17.7%
d. less than 10%
e. more than 90%

30. The elevated risk of ACS in obese patients:

a. is not higher in cigarette smokers.
b. is not higher in subjects who do not smoke cigarettes.
c. was diminished if they were active 1-3 1/2 hours per week when compared to sedentary subjects.
d. was the same in individuals with the most healthy diet vs obese individuals with a less healthy diet.

Answers: 29 (a); 30 (c)

CME Objectives

The objectives of *Internal Medicine Alert* are:

- to describe new findings in differential diagnosis and treatment of various diseases;
- to describe controversies, advantages, and disadvantages of those advances;
- to describe cost-effective treatment regimens;
- to describe the pros and cons of new screening procedures.

Clinical Briefs

By Louis Kuritzky, MD, Clinical Assistant Professor, University of Florida, Gainesville
Dr. Kuritzky is a consultant for GlaxoSmithKline and is on the speaker's bureau of GlaxoSmithKline, 3M, Wyeth-Ayerst, Pfizer, Novartis, Bristol-Myers Squibb, AstraZeneca, Jones Pharma, and Boehringer Ingelheim.

Is Bipolar Disorder Overdiagnosed?

It has been suggested that bipolar disorder (BPD) is underdiagnosed, and is hence sometimes regrettably discovered subsequent to unmasking with treatment instituted for presumed unipolar depression. The MIDAS project of Rhode Island (Methods to Improve Diagnostic Assessment and Services) has to-date examined psychiatric diagnostic accuracy and recognition in 2500 patients attending an outpatient psychiatric practice affiliated with an academic medical center.

MIDAS has corroborated that utilization of semistructured interviewing using DSM-IV diagnostic criteria coupled with self-administered questionnaires identifies more cases of BPD than simple clinician interview. Zimmerman et al in this communication investigated whether persons who carried a clinical diagnosis of BPD might have been overdiagnosed; ie, how many persons with a clinical diagnosis of BPD might fail to have their diagnosis confirmed using a semistructured interview and questionnaire.

Structured interviews of 145 persons carrying a clinical BPD diagnosis corroborated the diagnosis in only 45%. Although it is certainly possible that DSM-IV criteria for diagnosis of BPD are too narrow, this degree of discrepancy suggests that overdiagnosis of BPD is common—indeed, it may be more commonplace than BPD underdiagnosis. ■

Zimmerman M, et al. Clin Psychiatry. 2008;69(6):935-940.

One out of Three Prescriptions Are Never Filled

Clinicians would like to think that once a treatment is suggested and prescription written, the prescription will be filled. For a variety of reasons, that is too often not the case. It is not always easy to reliably track prescription filling, but data from the metropolitan area of Copenhagen, Denmark simplify that through the Danish National Electronic Pharmacy Register. Public Health Insurance in Denmark covers 50% of expenses $90-$215, 75% of expenses $215-$510, and 85% of any additional expenses. Private insurance is available to cover the difference.

The Danish Medicines Agency electronically registers all prescriptions from all physicians and pharmacies in the entire nation, all of which are accessible by treating physicians. The population studied in this communication includes only dermatology patients who received a new prescription for a treatment never previously used.

Among 322 evaluable patients, 30.7% had not filled one or more prescriptions 4 weeks later. Patients who did fill prescriptions generally did so promptly (3 days median). No particular demographic distinguished adherence/nonadherence, although geriatric patients were most adherent, and persons with chronic disorders requiring chronic treatment, like psoriasis, were least adherent. The authors remind us in their closing statements that "treatment failure" may sometimes simply represent unrecognized "failure to be treated." ■

Storm A, et al. *J Am Acad Dermatol.* 2008;59:27-33.

Skin Cancer Screening in the U.S.

In the United States, skin cancer (S-CA) is the most common cancer, and although usually curable, is responsible for over 10,000 deaths annually. Major groups that provide clinical guidelines differ in their recommendations: the ACS (2007) suggested that S-CA examination should occur as part of the cancer-related check-up at the periodic health examination, whereas the USPSTF found insufficient evidence to recommend for or against routine screening for S-CA.

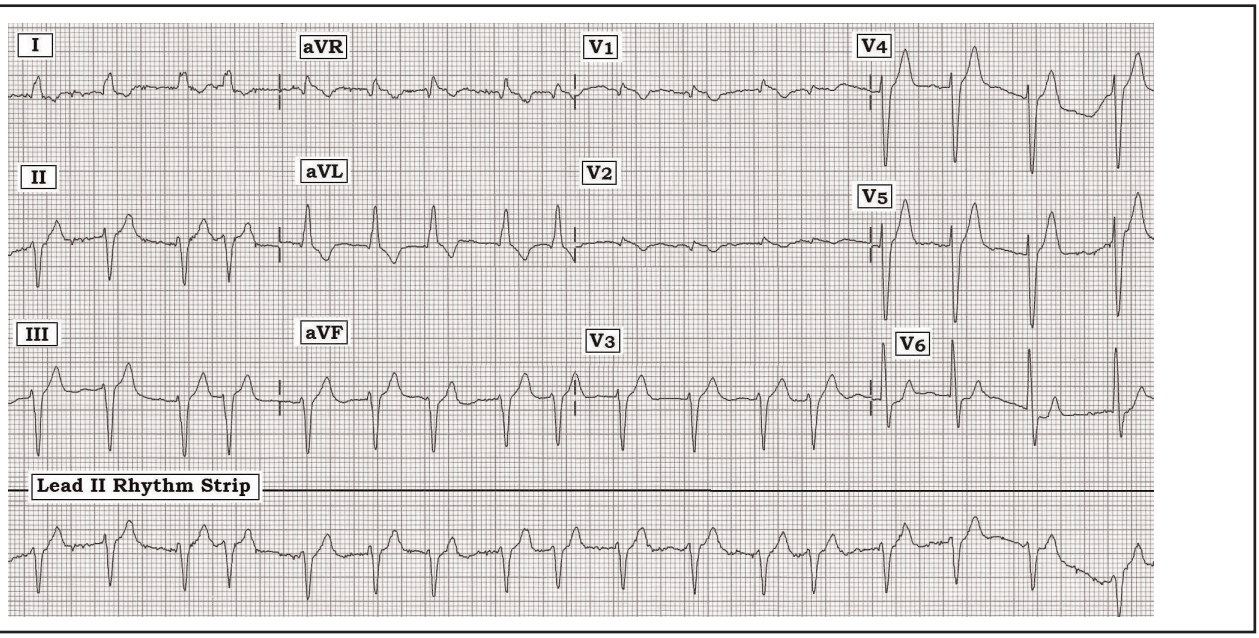
The National Center for Health Statistics conducts an annual, in-person survey of almost 20,000 adults. In 2000 and 2005, subjects were queried about having a head- to-toe skin check for cancer. Over 38,000 adults were interviewed, of whom 69% had seen a healthcare provider in the past year, yet only 8% acknowledged having received a skin examination.

Of the cancer screenings reviewed by national organizations, these data on S-CA are the most bleak. However, they may not be perfectly accurate, as no chart assessment was done to corroborate patient report. A patient who has undergone colonoscopy or colposcopy would be anticipated to accurately recollect whether or not such a screening had taken place. It may well be that clinicians are doing a much more frequent job of screening for S-CA, but simply not "announcing" it. These sobering statistics suggest that either clinicians need to increase their frequency of S-CA screening, be more forthright about pointing out to patients that a S-CA screening is being performed, or both. ■

LeBlanc WG, et al. J Am Acad Dermatol. 2008;59:55-63.

What's There to Worry About?

By Ken Grauer, MD, *Professor, Department of Community Health and Family Medicine, University of Florida*
Dr. Grauer is the sole proprietor of KG-EKG Press, and publisher of an ECG pocket brain book.



Clinical Scenario

The ECG shown above was obtained from a 63-year-old man with chest pain. How would you interpret his tracing and accompanying lead II rhythm strip? *What is there to worry about?*

Interpretation/Answer

There is a lot to be concerned with on this tracing. The rhythm is irregularly irregular at an average rate of more than 100/minute. Although there are fine undulations in the baseline, no definite P waves are seen. Thus, the rhythm is atrial fibrillation with a fairly rapid ventricular response. The QRS complex is clearly wide. QRS morphology in leads V_1 and V_6 is consistent with a bifascicular block pattern of RBBB (right bundle branch block) with LAHB (left anterior hemiblock). However, the monophasic R wave in lead I is not consistent with RBBB, but rather with a LBBB (left bundle branch block) pattern. Description of QRS morphology in this tracing might therefore better be classified as IVCD with LAD (intraventricular conduction delay with left axis deviation). In view of this patient's presentation (ie, chest pain) — the most important finding on this tracing is the subtle appearance of Q waves with slight but definite ST segment coving and elevation in leads V_1 and V_2. T wave inversion in these two leads is an expected accompaniment of RBBB, but the ST segment elevation is not. At times, a QR rather than RSR' complex may be seen in lead V_1 with RBBB — but a Q wave will usually not be seen in both leads V_1 and V_2 with RBBB unless there has been infarction.

Detection of acute myocardial infarction is always more challenging in the presence of a conduction defect. This is especially true with LBBB, since infarction Q waves are rarely written, and ST-T wave changes will often be masked by the underlying LBBB. Recognition of acute ischemia or infarction is still challenging in the presence of RBBB, but the findings seen in leads V_1 and V_2 of this tracing in the setting of new-onset chest pain should suggest the possibility that acute infarction may be occurring. Clinical correlation and comparison with a prior tracing on this patient would help clarify if the findings in leads V_1 and V_2 are new or old. ■

In Future Issues: **Coffee Consumption and Mortality: Reanalyzing the Data**