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Routine Preoperative Testing Before Cataract Surgery

ABSTRACT & COMMENTARY

Synopsis: *Routine preoperative testing before elective cataract surgery did not improve patient outcomes. Tests should be ordered only when the history or physical examination indicate a need for tests even without a planned surgery.*

Source: Schein OD, et al. *N Engl J Med* 2000;342:168-175.

To determine if routine testing before cataract surgery was beneficial, Schein and colleagues studied more than 18,000 patients undergoing elective cataract surgery at nine clinical centers. Study centers included private, academic, and community-based hospitals. Each patient was randomized to either a routine testing group (12-lead electrocardiogram, complete blood count, electrolytes, blood urea nitrogen, creatinine, and glucose) or no testing. Patients with testing done one month before the surgery or those with a myocardial infarction (MI) within the previous three months were excluded.

After randomization, adverse medical events were recorded on the day of surgery and for one week after surgery. Primary adverse events were MI, angina, arrhythmia, congestive heart failure, hypertension, hypotension, stroke, transient ischemic attack, respiratory failure, bronchospasm, oxygen desaturation, hypoglycemia, hyperglycemia, or other adverse events identified by a study coordinator.

No significant differences in complications were found on the day of surgery in the routine testing (19.2 events/1000 operations) vs. the nontesting group (19.7 events/1000 operations). Likewise, the adverse event rate for the postoperative period was also virtually identical (12.6/1000 operations vs 12.1/1000 operations). Subgroup analysis showed no benefit according to the age, ethnicity, sex, or health status.

COMMENT BY MARTIN LIPSKY, MD

Cataract surgery is the most commonly performed operation in elderly people in the United States. As a primary care physician caring for older patients, I am frequently asked to clear individuals

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for cataract surgery. Often these requests are accompanied by routine orders for preoperative testing. This elegant, randomized, large-scale study indicates that routine testing does not improve patient outcomes. Schein et al recommend that only those patients whose clinical evaluation would have indicated a need for testing even without a planned surgery should undergo testing. Clearly, with approximately 1.5 million annual operations performed in the United States, the potential cost savings are enormous. Since some of these tests are undoubtedly ordered as "defensive medicine," it is reassuring to have defensive evidence that a careful history and physical examination is a sufficient preoperative evaluation. I would expect that once the results of this study are disseminated among ophthalmologists, primary care physicians will see few routine requests for preoperative testing for cataract surgery. Also, as Schein et al suggest and I agree, it is reasonable to think about applying the results of this study to other low-risk procedures. ❖

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Changing Carriage Rate of *Neisseria meningitis* Among University Students

ABSTRACT & COMMENTARY

Synopsis: *Freshman college students, particularly those who live in dormitories, are at a modestly increased risk for meningococcal disease.*

Source: Neal KR, et al. *BMJ* 2000;320:846-849.

Neal and colleagues note that during the 1990s there have been major increases in the incidence of invasive meningococcal disease in many developed countries, with serogroup C disease being the most common, especially among teenagers and young adults. They also note that university undergraduates have higher rates of invasive meningococcal disease than young adults of the same age who are not attending a university. This longitudinal study was performed to determine rates of carriage and acquisition of *Neisseria meningitis*, together with risk factors for both, among university students in the absence of outbreaks.

The study was performed at Nottingham University in England. Students were recruited during their first week of attendance (October 1997). A detailed questionaire was completed to determine medical, immunization, and travel history, as well as risk behavior during the week prior to the survey (smoking, alcohol, bar attendance, kissing, etc.). Detection of *N. meningitidis* was accomplished by culture of a posterior pharyngeal swab. A follow-up culture was obtained during either the first week of November or December 1997. During the study period, one case of serogroup C disease occurred (2 more cases occurred in the spring of 1998).

The study revealed that of the 2453 first-year students who participated, a rapid increase in carriage of *N. meningitidis* occurred during the first week (from an initial 8% to 23%). Risk factors included male sex, active and passive smoking, intimate kissing, visits to halls and night clubs, and resident housing in coed halls. That is, factors that promote social mixing are those that also promote spread of the organism. Neal et al conclude, "Our findings support the recent introduction of meningococcal vaccination for university students."

COMMENT BY MICHAEL K. REES, MD, MPH

In 1998, the CDC in collaboration with the Council of State and Territorial Epidemiology and the Vaccine Preventable Disease Task Force initiated two studies to define the risk of meningococcal disease associated with college campuses. The results are essentially identical to this Nottingham study: freshman college students, particularly those who live in dormitories, are at a modestly increased risk for meningoccal disease.

A polysaccharide meningococcal vaccine is now available for the prevention of bacterial meningitis caused by *N. meningitidis* (meningococcus) serogroups A, C, Y, and W-135. It is most effective against serogroups C and Y. It does not protect against serogroup B. Protection lasts for 3-5 years. In a press release dated Oct. 20, 1999, the Advisory Committee on Immunization Practice advised that colleges take a more active role in alerting students and parents to the potential dangers of meningococcal disease. The American College Health Association now recommends that all college students, especially freshman living on campus, consider getting the vaccine (average cost is $65). The vaccine is routinely given to U.S. Army recruits. It should also be recommended for travelers under certain situations. For example, on April 21, the CDC reported meningitis in three New York City residents who either traveled to Saudi Arabia during the month of travel to Mecca or had close contacts who were diagnosed with the infection.

For current information on meningococcal infection and the vaccine, see the CDC website, http://www.cdc.gov/ncidod/dbmd/diseaseinfo, and the American College Health Association website, http://www.acha.org/special-prj/men/faq.htm. ❖

Can Hospital Selection Avoid Deaths?

ABSTRACT & COMMENTARY

Synopsis: *A significant number of deaths can be avoided by referring appropriate surgical and medical patients to HVHs and by actively working to prohibit these procedures from being performed in low-volume facilities.*

Source: Dudley RA, et al. *JAMA* 2000;283:1159-1166.

Each year, a large number of patients die following elective surgery; in fact, in the Medicare population alone, 17,000 patients died in 1995 after undergoing 10 types of elective surgical procedures. Many previously published studies have demonstrated that mortality rates for certain procedures and diagnoses are significantly lower in hospitals that perform a high volume of these procedures when compared to the mortality rate for the same procedures performed in low-volume hospitals (LVHs).[1]

Dudley and colleagues from the University of California performed an extensive review of the literature from Jan. 1, 1983, through Dec. 31, 1998, looking for the highest-quality studies assessing the mortality-volume relationship for many medical and surgical diagnoses and then calculated the odds ratios for in-hospital mortality comparing LVHs with high-volume hospitals (HVHs). The purpose of the current study was to identify procedures and diagnoses for which there is good evidence that a volume-outcome relationship exists and to estimate the annual number of deaths in California LVHs that can be attributed primarily to their low volume. Mortality was found to be significantly lower in HVHs for elective abdominal aortic aneurysm repairs, carotid endarterectomies, coronary angioplasties, heart transplantations, treatment of HIV syndromes, pediatric cardiac surgery, coronary artery bypass surgery, lower extremity arterial bypass surgery, esophageal cancer surgery, and cerebral aneurysm surgery. A total of 58,306 patients were admitted to LVHs in California for one or more of these procedures in 1997 and, for that one year, it was estimated that 602 deaths could be attributed simply to the fact that these patients were admitted to the LVHs.

COMMENT BY HAROLD L. KARPMAN, MD, FACC, FACP

Hospital referral initiatives have been extremely difficult to recommend due to the significant difficulties that exist when attempting to obtain reliable data that is uninfluenced by random events and can have significant effects on the mortality rates observed to occur in many medical conditions.[3,4] There are many reasons for the absence of appropriate referral initiatives; in fact, with rare exceptions, the lack of adequate data has influenced health plans and health care purchasers to avoid selectively referring patients to hospitals with low case-mix-adjusted mortality or to hospitals that perform high volumes of specific procedures.[2]

Dudley et al carefully evaluated the literature from multiple sources including MEDLINE, Current Contents, and First-Search Social Abstracts databases. They evaluated the percentage of LVH patients who were admitted through emergency departments and determined the additional distance that these patients would have had to travel to reach a HVH; this information permitted them to properly assess clinical and practical barriers that could influence the referral to the HVHs. They determined that a sig-

nificant number of deaths could be avoided in California through referral of patients to the regional HVHs. Statistically significant relationships between hospital volume and mortality were identified for the 10 surgical procedures and the one medical condition. The results revealed that, for example, patients were 64% more likely to die following abdominal aortic aneurysm repair in LVHs than in HVHs; if we extrapolate these numbers nationally, more than 4000 deaths per year could be avoided by referring patients with this surgical abnormality to HVHs.

Many techniques can be used for steering high-risk surgical patients to HVHs; however, it should be recognized that appropriate arguments can be offered against these steerages such as interference with the local continuity of care, the adverse effects that might occur particularly in rural areas because of the logistic problems, travel burdens, and the possible reduction of access to health care for rural patients—all of which could result in financial instability of local hospitals. On the other hand, many LVHs are not located in sparsely populated rural areas and, in fact, they are more commonly located in hospital-dense metropolitan areas in relatively close proximity to high-volume referral centers.[5] Therefore, fully 75% of California patients undergoing surgery at low-volume centers in 1997 would actually have had to travel fewer than 25 additional miles to reach the nearest HVH.

Despite the many problems and the need to acquire additional data, it would appear that the potential benefits achieved by referring patients to high-volume medical centers are too significant to simply ignore. The ability and willingness of patients to move to HVHs and the effects of such movement on local health care facilities should be carefully studied, however, despite all of the uncertainties of the data that have been reported thus far, payers such as employers, health plans, and government health care programs should immediately start to analyze data in great detail in order to determine if they should adapt policies regarding selective referral of patients for specific surgical and/or medical procedures to appropriate HVHs. In summary, Dudley et al have clearly demonstrated that a significant number of deaths can be avoided by referring appropriate surgical and medical patients to HVHs and by actively working to prohibit these procedures from being performed in low-volume facilities. ❖

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The Effect of Testosterone on Sexual Arousal in Women

ABSTRACT & COMMENTARY

Synopsis: *There is a lag in the effect of sublingually administered testosterone, perhaps due to the time it takes for neurophysiologic alterations in the brain.*

Source: Tuiten A, et al. *Arch Gen Psychiatry* 2000;57: 149-157.

Female sex steroids are necessary for the expression of sexual behavior in many mammals. Copulation is typically limited to the period of ovulation, except in higher primates (i.e., humans) who have sex outside the periovulatory period; testosterone is believed to be involved in this. A lack of testosterone (e.g., ovariectomy) is associated with a loss of libido, which is reversed upon replenishment.[1-2] Physiological responses to sexual stimuli are an important aspect of sexual functioning, marked by vaginal vasocongestion. In females with hypothalamic amenorrhea, testosterone substitution enhanced vaginal responsiveness, but not in a parallel group with panhypopituitarism.[3]

Tuiten and colleagues investigated the effect of a single, sublingual dose of testosterone in eight sexually functional women on physiological and subjective sexual arousal, using a double-masked, randomized, placebo-controlled, crossover design. Participants were tested within 10 days of the end of their period of menstruation, with five days separating the two periods of treatment. Subjects were exposed to pornographic or neutral videotape at six time intervals: immediately before, 15 minutes after, and every one-and-a-half hours for six hours after testosterone administration. Blood levels of testosterone were measured at all six intervals. Within 15 minutes of testosterone intake, there was a 10-fold+ increase in total testosterone levels and a return to baseline within 90 minutes. Compared to placebo, testosterone significantly increased genital responsiveness four-and-one-half hours after peak levels and was associated with increased genital arousal, as well as subjective reports of genital sensations and sexual lust. Tuiten et al concluded there is a lag in the effect of sublingually administered testosterone, perhaps due to the time it takes for neurophysiologic alterations in the brain.

COMMENT BY DONALD M. HILTY, MD

Testosterone may have an important clinical role in

terms of sexual functioning. In aging men, testosterone levels decline with age and are correlated with symptoms of depression. Testosterone replacement is being evaluated at the present time. In HIV-positive men who often have hypogonadal symptoms, testosterone is well-tolerated and appears to restore libido and energy.[4] A recent study estimated that 43% of women suffer from sexual dysfunction, mainly low sexual desire (22%), sexual arousal problems (14%), and sexual pain (7%).[5] Intermittent testosterone may be helpful, though the four-hour delay in response may be an impediment to use. The "correct" dose is yet unclear and its use has potential adverse events. At doses 4-8 times normal levels, 4% of patients may become hypomanic; at 8+ times normal levels, over 18% of patients demonstrated psychosis or euphoria.[6] (*Dr. Hilty is Assistant Professor of Clinical Psychiatry, University of California, Davis, Sacramento, CA.*) ❖

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Pharmacology Update

Pneumococcal Conjugate Vaccine 7-Valent (Prevnar-Wyeth Laboratories)

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

The fda has approved a new pneumococcal vaccine for use in children. The 7-valent pneumococcal conjugate vaccine (diphtheria CRM_{197} protein) was given approval in February for the prevention of invasive pneumococcal disease in infants and young children. *Streptococcus pneumoniae* is a leading cause of serious illness in young children including bacteremia, meningitis, pneumonia, and upper respiratory tract infections such as otitis media. The 7-valent vaccine covers serotypes that account for approximately 80% of invasive pneumococcal disease in children younger than 6 years of age.[1] The vaccine is marketed by Wyeth-Ayerst Laboratories under the name of Prevnar.

Indications

The vaccine is indicated for active immunization of infants and toddlers against invasive disease caused by *S. pneumoniae* due to capsular serotypes (4, 6B, 9V, 14, 18C, 19F, and 23 F).

Dosage

The routine immunization schedule is 2, 4, 6, and 12 - 15 months of age. For previously unvaccinated infants 7-11 months of age, two doses should be administered at least four weeks apart and the third dose after the 1-year birthday, separated from the second dose by at least two months. For children 12-23 months of age, two doses should be administered at least two months apart. For children 24 months or older through 9 years of age, one dose should be administered. However, two doses, two months apart, should be administered to children 24-59 months in high-risk groups (e.g., sickle cell disease or anatomic or functional asplensia, HIV infected or immunocompromised, chronic illness such as nephrotic syndrome, diabetes, chronic pulmonary conditions, and symptomatic heart conditions). The dose is 0.5 mL administered intramuscularly.[2]

Potential Advantages

The conjugate vaccine is more immunogenic than the existing polysaccharide vaccine that is not effective in children younger than 2 years of age since it is T-cell independent and does not induce immunologic memory. Vaccination of infants at 2, 4, 6, and 12-15 months with Prevnar has been shown to be efficacious in preventing invasive pneumococcal disease caused by serotypes included in the vaccine.[2,10] Efficacy based on an intent-to-treat analysis (including all children who received at least 1 dose) was 93.9% (95% CI: 79.6-98.5%) for serotypes included in the vaccine. Per protocol analysis (events occurring ≥ 14 days after the third dose) showed efficacy of 97.4% (95% CI: 82.7-99.9%). The efficacy against all serotypes was 89% (95% CI: 73.7-95.4%).[1,10] Data also suggest that the vaccine reduced acute otitis media (AOM) caused by *S. pneumoniae* and AOM-related outcomes such as visits, episodes, frequent and severe otitis, and ventilatory tube placement.[9,10]

Potential Disadvantages

Prevnar will not protect against *S. pneumoniae* dis-

ease caused by serotypes other than those included in the vaccine. It is contraindicated in patients with known hypersensitivity to diphtheria toxoid. Side effects include fever, irritability, restless sleep, vomiting, diarrhea, and injection site reactions.[2] It is not certain how or if immunization against the seven serotypes would result in emergence of less common serotypes.

Comments

Prevnar is a pneumococcal vaccine prepared by the conjugation of seven serotypes of pneumococcal polysaccharide to protein carrier reactive molecule 197 (CRM 197). CRM 197 is a nontoxic variant of diphtheria toxin isolated from cultures of *Corynebacterium diphtheriae* strain C7 (ß197). The conjugated vaccine induces T cell-dependent immune response and is therefore immunogenic in children younger than 2 years of age.[6,7] The efficacy trial involving 37,816 infants (18,906 Prevnar and 18,910 control) was conducted at Kaiser Permanente of Northern California. The control vaccine was an investigational meningococccal group C conjugate vaccine (CRM_{197}).[2,10] Efficacy was more than 93% for serotypes included in the vaccine and 89% for all pneumococcal serotypes. Black and associates also reported efficacy against visits, episodes, frequent and severe otitis, and ventilatory tube placement of 8.9%, 7.0%, 9.3%, and 20.1%, respectively, with $P < 0.04$ for all.[1] In a study conducted in Finland, Eskola and associates reported a per protocol reduction of 57% (95% CI: 44-67%) in culture-confirmed serotype specific AOM, a 34% (95% CI:21-45%) reduction in cultured-confirm pneumococcal (any serotype) AOM, and a 6% (95% CI: -4-16%) reduction in AOM irrespective of etiology.[9]

Clinical Implications

The previously available polysaccharide pneumococcal vaccine is not effective in children younger than 2 years of age. The development of the pneumococcal 7-valent conjugate vaccine has the potential to prevent significant *S. pneumonia*-related morbidity and mortality in children. The seven serotypes, out of about 90 known serotypes, are responsible for approximately 80% of invasive pneumococcal disease and 60% of AOM in children. The seven serotypes account for 74% of penicillin-nonsusceptible (intermediate or high-level resistance) *S. pneumoniae* (PNSP) and 100% of pneumococci with a high level of penicillin resistance.[1,4] *S. pneumoniae* is the most common cause of bacterial meningitis in children and is associated with 8% mortality as well as neurological sequelae and hearing loss.[5] The vaccine has been reported effective in preventing invasive disease, reducing AOM due to vaccine serotypes, reduction in AOM of any serotype, and reduction in AOM visits, episodes, frequent otitis, and ventilatory tube placement.[2,9,10] The preliminary recommendation of The Advisory Committee on Immunization Practices (ACIP) for Prevnar includes immunization of the birth cohort, catch-up immunization of infants up to 23 months of age, and children ages 24-59 months who are at risk for pneumococcal disease. These include children with sickle cell disease or anatomic or functional asplensia, HIV-infected or immunocompromised, chronic illness such as nephrotic syndrome, diabetes, chronic pulmonary conditions (excluding asthma), and symptomatic heart conditions. The vaccine may also be considered for children in certain ethnic groups such as American Indians, Alaskans, and African Americans.

Wyeth-Ayerst is required to submit monthly adverse event reports to the FDA for the first year. It is also committed to conduct Phase IV postmarketing studies in previously unvaccinated children receiving "catch-up" therapy for all age groups.[8] The vaccine costs $58 per dose. ❖

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CME Questions

28. Which of the following tests are helpful for evaluating an elderly patient with chronic stable hypertension before cataract surgery?

a. Electrolytes
b. Bun and creatinine
c. An electrocardiogram
d. None of the above

29. The polysaccharide vaccine against *Neisseria meningitis* provides some level of protection against all of the following serogroups *except*:

a. A
b. B
c. C
d. Y
e. W-135

By Louis Kuritzky, MD

Awareness During Anaesthesia: A Prospective Case Study

Patient recall of events occurring while under operative general anesthesia is traditionally regarded as a rare event, reportedly occurring in less than 1% of individuals. On the other hand, patient concern about pain or other stressful experiences under anesthesia is commonplace, with as many as half of patients reporting such concerns. Sandin and colleagues did a prospective evaluation of patient recall of awareness during surgery by personal interview of adults older than 15 years of age (n = 11,785) who received general anesthesia in two Swedish hospitals. Interviews were taken, immediately postoperatively, at days 1-3, and days 7-14 postoperatively.

Only 18 women and seven men, (slightly < 0.2% of the total evaluated population) reported intro-anesthesia awareness. The most common underlying factor in reported awareness was the use of neuromuscular block during surgery. Patients who did not receive neuromuscular block did not report intraoperative awareness. Additionally, more than half of persons reporting operative awareness had previously experienced a similar phenomenon. Whether monitoring techniques designed to detect intraoperative awareness will actually reduce this experience will be difficult to determine, since 50,000 patients would be needed to demonstrate a halving of intraoperative awareness from the demonstrated level in this study of less than 0.2%. ❖

Sandin RH, et al. Awareness during anaesthesia: A prospective case study. Lancet 2000;355:707-711.

Meta-Analyses of the Relation Between Silicone Breast Implants and the Risk of Connective Tissue Disease

Alleged association of silicone breast implants (SBI) with a variety of consequences, including connective tissue/autoimmune diseases, has sparked substantial medical and legal debate. Though three other meta-analyses of breast implants exculpated them, study characteristics were felt to still leave the issue inconclusive. Janowsky and colleagues performed a meta-analysis specifically to conclusively address whether SBI is associated with these adverse outcomes. Substrate for their report included 20 different studies.

No evidence of an association between SBI and connective tissue diseases was discerned. A trend toward increased risk of Sjogren's syndrome was not statistically significant. One method of analysis suggested that the frequency of all connective tissue diseases combined, and Sjogrens syndrome, were slightly elevated, though the clinical relevance of this increase appears dubious. With the exception of the effect induced by a single study, which when included suggests a minimal increased risk, Janowsky and colleagues demonstrate that data accrued thus far do not support any important relationship between SBI and connective tissue diseases. ❖

Janowsky EC, et al. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. N Engl J Med 2000; 342(11):781-790.

Causes and Severity of Ischemic Stroke in Patients with Internal Carotid Artery Stenosis

Carotid stenosis (cs) is a common concomitant of stroke. In persons with demonstrated CS, the likelihood of subsequent stroke referable to that stenosis has been poorly defined. Barnett and colleagues followed 2885 patients for five years who had been determined to have more than 70% symptomatic CS, delineating the underlying pathology of subsequent stroke. The population was derived from the North American Symptomatic Carotid Endarterectomy Trial, a study spanning the 1987-1997 interval.

As anticipated, most stroke was ischemic in origin (more than 95%). Large artery stroke was more than twice as frequent as cardioembolic and lacunar etiologies combined. In carotid arteries demonstrating 70-99% stenosis, as many as 20% of subsequent strokes are not apparently related to the underlying ipsilateral carotid disease. Final treatment strategies should take into account that carotid surgery alone does not entirely eliminate risk of subsequent stroke; incorporation of knowledge about the patients subsequent risk for lacunar and cardioembolic stroke is essential for maximum risk reduction. ❖

Barnett HJ, et al. Causes and severity of ischemic stroke in patients with internal carotid artery stenosis. JAMA 2000;283:1429-1436.

Lateral Atrial Flutter?

By Ken Grauer, MD

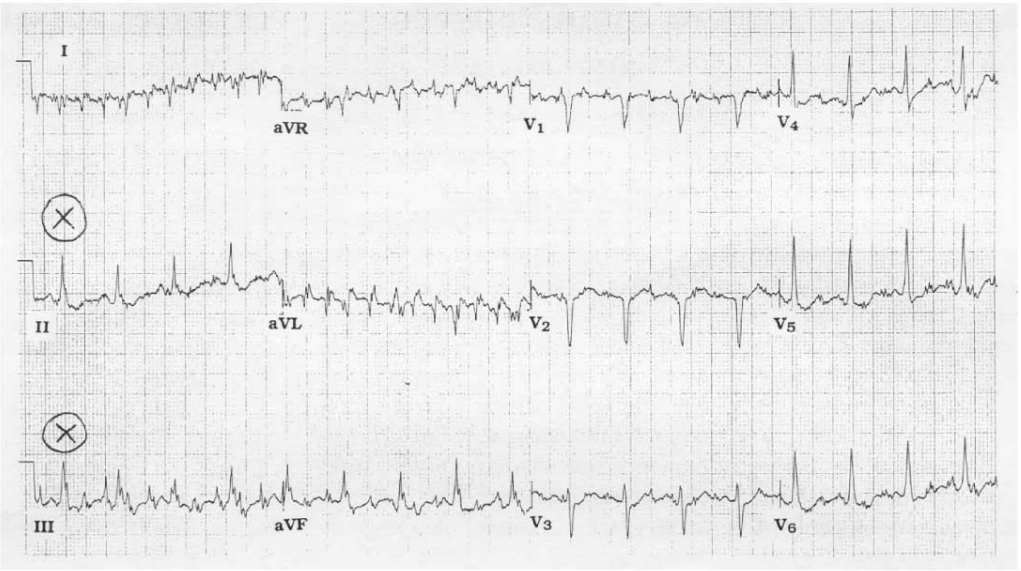

Figure. ECG obtained from a patient with acute pulmonary disease. Are flutter waves most evident in leads I and aVL?

Clinical Scenario: The ECG shown in the figure was obtained from a patient with an acute exacerbation of long-standing pulmonary disease. In follow-up to last month's ECG review (*Intern Med Alert* 2000;22:56), is the tracing in the figure another example of atrial flutter, with the arrhythmia in this case being most evident in leads I and aVL?

Interpretation: Initial inspection of leads I and aVL suggests that the rhythm in the figure might be atrial flutter (with a flutter rate for atrial activity of just under 300/minute). Inspection of QRS morphology in other leads, however, suggests that this is not the case. The key to interpretation of this rhythm lies with remembering that the ECG in the figure is a *simultaneous* three-channel recording. Thus, leads I, II, and III are all recorded during the same period of time (and point X in leads II and III is recorded at the identical *instant* in time). Whereas superficial inspection of lead I might suggest the possibility of atrial flutter—a very different impression is suggested from review of lead II. That is, the rhythm in lead II appears to be sinus, as determined by the presence of an upright P wave that precedes each QRS complex in this lead and seems to be conducting. The fine undulations that alter the baseline of lead II look to be artifactual. Inspection of the ECG appearance in the third simultaneously recorded lead in this initial lead grouping (lead III) reveals an especially erratic and irregular spiky pattern that is highly characteristic of the presence of artifact.

The key to making a positive diagnosis of artifact lies with being able to detect the underlying normal cardiac rhythm that continues throughout—*not* affected in the least by artifact activity (as seems to occur here in lead II, and more subtly in lead III). Although identifying the underlying cardiac rhythm amidst a background abundant in artifact is often a task much easier said than done—one *can* follow regular QRS activity in lead III of this tracing *despite* the distracting artifactual distortion by beginning at point X, and walking out with calipers (at a regularly occurring R-R interval) the QRS complexes that occur throughout the rest of the tracing. Clinically, the ECG in this figure should be repeated in the hope of improving recording quality minimizing artifactual distortion. ❖

In Future Issues:

Monitoring Osteoporosis Therapy with Bone Densitometry