

AOA continuing medical education

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In 1973, the American Osteopathic Association established the requirement that each member maintain a minimum number of continuing medical education credits during a 3-year period in order to continue membership in the association.

Basis for implementation

The principal reasons for implementing this program are three: First, the profession foresaw the need for osteopathic physicians to keep their skills and knowledge current with the rapidly changing world of medicine. To provide their patients with the highest quality of care, physicians must stay abreast of state-of-the-art diagnostic procedures and therapeutic modalities. And, as has been seen from the many advances and changes in medicine during the last 13 years, this has proved to be a necessary and important step in osteopathic postgraduate education. Attendance at a certain number of Continuing Medical Education (CME) courses each year, or every 3 years, is one way by which physicians can keep their knowledge and skills honed.

Second, 22 states (listed in Table 1) have established minimum CME requirements to qualify for annual relicensure. The trend clearly seems to be in this direction, and other states are expected to follow.

Third, a large number of specialty colleges require a minimum of CME credits in order to maintain certification. Some specify a certain number of credits per year, others a certain number during a 3-year period. Some colleges also require completion of a large minimum number of CME credits before a physician is eligible to sit for certifying examinations.

Why was it necessary to make this program mandatory? The answer lies in the fact that while many osteopathic physicians regularly and willingly attend CME programs to keep themselves up-to-date, there also are several convenient excuses not to attend CME programs, and we all recognize them: "I'm too busy to get away from the practice"; "There's too much cost involved"; and the all-too-frequent feeling that "I already have the knowledge needed to take care of my patients." The list of reasons goes on, and so the AOA was convinced of the need for regular continuing education and equally certain

that all osteopathic physicians would have to participate if the requirements were to be equal and fair for all. Thus, the division of Continuing Medical Education was established within AOA's Department of Education.

CME program

Organizational procedures

The first groups to implement the new requirement in 1973 were the Coordinating Committee on Continuing Medical Education and a Special Committee to Set Up the Mechanics for the Program on Continuing Medical Education. However, in early 1973, the AOA Board of Trustees adopted a resolution to discontinue these two committees in favor of a new committee—the Committee on Continuing Medical Education—established under the aegis of the Bureau of Professional Education. This committee was given full responsibility to direct the new programs of continuing medical education.

The Committee on Continuing Medical Education consisted of representatives from the American Osteopathic State Executive Directors, the AOA Practice Organization Affiliates, the American Association of Colleges of Osteopathic Medicine, the Academy of Osteopathic Directors of Medical Education, two members from the AOA House of Delegates, and a chairman appointed at large by the AOA President. In October 1973, the Board of Trustees adopted a resolution providing for committee members to be appointed for staggered 3-year terms. Each member served an initial 3-year term; beginning in the fourth year (1976), certain members serve 1- or 2-year terms, so that new members could be appointed on a staggered basis. In all cases, new appointees represented the same segment of the profession as the retiring member.

Educational requirements

To accommodate various problems in defining CME categories, classifying educational programs, and addressing the usual problems that are to be expected in implementing such a large-scale program, an initial guide for Continuing Medical Education and several subsequent editions have been developed.

TABLE 1. STATES THAT REQUIRE CONTINUING MEDICAL EDUCATION CREDIT FOR RELICENSURE.

Alaska
Arizona
California
Florida
Iowa
Kansas
Maine
Maryland
Massachusetts
Michigan
Minnesota
Nevada
New Hampshire
New Mexico
Ohio
Oklahoma
Rhode Island
Tennessee
Vermont
Washington
West Virginia
Wisconsin

The present CME guide contains general categories of credit 1 and 2, with category 1 credits divided into six subcategories and category 2 credits into five subcategories. These were designed to encompass the wide range of educational programs available to practicing osteopathic physicians. Category 1 requires a minimum of 60 CME hours and category 2 permits a maximum of 90 hours in a 3-year reporting period. The total 3-year requirement of 150 hours allows for various combinations of category 1 and 2 credits, provided that the minimums and maximums in each general category are observed.

Recently, the committee has found the guide to be in need of even further revision. While preserving the major elements of the program, the new edition will simplify the number of subcategories for awarding credit, preserve a system that includes all currently approved credit options, and retain the "Individual Activity Report," which is easy to read and comprehend.

The strength of our educational programs rests squarely on the recognition that all must be of highest quality and must meet the needs of practicing physicians in delivering the best health care to patients. The fundamental objectives are the growth of knowledge, the refinement of skills, and the deepening of understanding of each osteopathic physician. The stated goals of the CME program as a whole are to achieve continued excellence in patient care and to improve the health and well-being of each individual patient and the public at large.

These aspirations can be met only when all of our educational programs meet or exceed the minimum

criteria set forth in the CME guide. Most category 1 programs are presented by the AOA or its affiliated organizations at announced conventions and seminars. Everyone recognizes that these programs usually require the physician to bear the costs of travel and registration, as well as take valuable time from the office and hospital. Therefore, it is incumbent upon both the Committee on Continuing Medical Education and the sponsors of a program to ensure that the most current, most useful educational material is presented in a manner that facilitates learning. This is the most important responsibility of the Committee, and the guiding principle of anyone who contributes to osteopathic CME.

The Committee expects all CME planning groups to use three guidelines to ensure that the program provides a meaningful and valuable experience, as follows: (1) The program should provide a clear statement of its educational objectives; (2) the program should selectively utilize the faculty, format, and educational modalities best suited to the topic; and (3) the program should conclude with some form of evaluation to determine whether the educational objectives have been accomplished.

The responsibility for meeting these guidelines rests with the various groups that sponsor, structure, and present programs for postgraduate continuing medical education. Acting on the authority of the AOA, the Committee on CME monitors these programs and approves or disapproves them in terms of the criteria established for the profession. It is also the responsibility of the Committee on CME to monitor each nonexempt member of the American Osteopathic Association at the end of each 3-year cycle to determine whether he/she has met the requirements to remain eligible for continued membership in the association.

At the present time, several groups of physicians are exempt from the mandatory requirements. However, the Committee believes that the only physicians to be allowed exemption from these requirements should be those who are completely retired from practice (who no longer care for any patients) and those in formal training programs, including internships, residencies, and other postdoctoral training programs that lead to advanced standing in the profession. Of course, students in our colleges of osteopathic medicine are exempt as well. The Committee will soon recommend appropriate changes in the present rules and regulations to provide for these exemptions only. The Committee strongly believes that a physician who administers health care to any number of patients, large or small, should endeavor to keep up with recent developments in medicine.

Statistics for 1983-1985

During the 3-year cycle from January 1, 1983, to December 31, 1985, 24,369 osteopathic physicians were listed on the AOA office computer. Of this number, 12,214 were required to meet the CME requirements and 12,155, including nonmembers, life members, retired members, and members in postdoctoral training programs were found to be exempt.

In the required group, 68 percent met or exceeded the required number of logged credits. Of the remaining nonexempt physicians (32 percent), approximately 17 percent logged between 100 and 149 credit hours, about 7 percent recorded between 50 and 99 hours, some 5 percent recorded less than 49 hours, and approximately 3 percent had no hours of credit recorded. Of the exempt members, 6 percent met or exceeded the required number of CME credit hours. Of the remaining 94 percent, approximately 8 percent reported between 100 and 149 hours, about 10 percent recorded between 50 and 99 hours, some 26 percent logged between 1 and 49 hours, and approximately 50 percent had no hours of credit recorded. The deadline for reporting was extended to May 31, 1986, and, by the end of the grace period, it was estimated that less than 8 percent of all osteopathic physicians had failed to meet their CME requirements.

During the 3-year cycle, the AOA Division of Continuing Medical Education processed a very large number of credit hours for our membership. In category 1, 2,872,830 hours of CME credit were processed; of these, 53 percent were earned in formal osteopathic programs, 33 percent encompassed osteopathic medical teaching, and 12 percent involved hospital-based osteopathic education. In category 2, 689,378 hours of CME credit, including 62 percent in formal programs under the aegis of recognized sponsors (category 2-D) and 24 percent in home study activity, were processed.

Combined totals for both category 1 and 2 were rather astounding. The Division of CME processed 3,562,208 hours of CME credit for the profession during 1983-1985, in 54,915 separate reports from osteopathic physicians.

This is evidence that the CME program of the AOA is working. Osteopathic physicians are responding to the growing number of available educational programs, and sponsors are being careful to meet the needs and desires of the physicians. Best of all, our patients are the ones who benefit most. They receive better health care and develop more trust in their physician.

Reduction or waiver of requirements

Depending on individual circumstances, certain

situations may call for granting a reduction or waiver of the CME requirements. Severe illness, moving outside of the U.S.A., and change in practice status are a few examples cited in the requests for reduction or waiver of requirements received by the Committee. Some of these circumstances are found to be acceptable, while others are not. All requests must include detailed information of individual circumstances if the Committee is to act in a responsible manner and make proper decisions. All requests are kept strictly confidential, and deliberations of the Committee are conducted in closed session.

Appeals

An appeal mechanism has been established for physicians who are denied credit for certain programs or whose requests for reduction or waiver of the requirements are denied. Procedures for reconsideration and appeal are described in a formal document, which is available upon request from the Division of Continuing Medical Education of the AOA. All requests for reconsideration and appeal should be made as soon as possible after the decision in question has been made. Generally, the first step is to request reconsideration by the Committee on CME. If that is denied, the next step provides for appeal of the Committee's decision to the AOA Bureau of Professional Education. A denial by the Bureau can then be appealed to the AOA Board of Trustees, which is the final authority.

Comments

Recently, one of my colleagues remarked that the American Medical Association has a similar, although voluntary, CME program, which is known as the Physician's Recognition Award. It has categories and credit hour requirements similar to the AOA's program, including the use of minimum requirements in category 1 and maximum allowances in all other categories. That the AMA has such a program available to its members is additional evidence that CME programs have widespread validity, as well as acceptance, and that they fill a need along with the requirements for continued membership in state medical societies, reregistration of a license to practice medicine, and malpractice self-insurance plans. These all point to a trend that appears to be spreading across the nation—the calling for a renewal of concern for continued educational growth for all physicians and better patient care everywhere.

Since its founding, one of the goals of the American Osteopathic Association has been to assist the profession in becoming the best that it can be. Over many years, osteopathic physicians have faced ad-

versity and yet somehow have managed to overcome, survive, and prosper. This heritage has, indeed, helped us to become the best that we can be. Our concept of continuing medical education, with its mandatory participation, is not another barrier; rather, it is an opportunity to show the world that we have dedicated ourselves as physicians to be well trained, qualified, and determined to remain at the forefront of American medicine. I applaud the wisdom and foresight of our AOA leadership in establishing and carrying out this vitally important program.

The CME program can be totally successful only if we strive to have full participation of all AOA members. We must continue to insist that sponsors produce programs of excellent quality. These pro-

grams must meet the needs of our members in scope as well as in quality. We must continue to monitor all aspects of the program so that credibility is guaranteed. Your Committee on Continuing Medical Education pledges its continuing efforts to maintain the high standards that the profession expects, deserves, and, hopefully, appreciates.

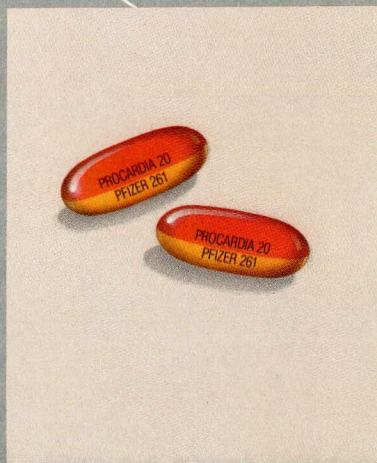
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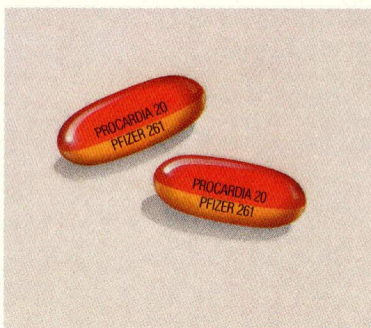
PROCARDIA[®]
(NIFEDIPINE)

NEW **20**mg
Capsules



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Brief Summary

PROCARDIA[®] (nifedipine) Capsules

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta-blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See WARNINGS.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina and/or Myocardial Infarction: Rarely, patients, particularly those who have severe obstructive coronary artery disease, have developed well documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting PROCARDIA or at the time of dosage increase. The mechanism of this effect is not established.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See WARNINGS.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Laboratory tests: Rare, usually transient, but occasionally significant elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT and SGPT have been noted. The relationship to PROCARDIA therapy is uncertain in most cases, but probable in some. These laboratory abnormalities have rarely been associated with

clinical symptoms, however, cholestasis with or without jaundice has been reported. Rare instances of allergic hepatitis have been reported.

Limited clinical studies have demonstrated a moderate but statistically significant decrease in platelet aggregation and increase in bleeding time in some PROCARDIA (nifedipine) patients. No clinical significance for these findings has been demonstrated.

Positive direct Coombs test with/without hemolytic anemia has been reported.

Although PROCARDIA has been used safely in patients with renal dysfunction and has been reported to exert a beneficial effect in certain cases, rare, reversible elevations in BUN and serum creatinine have been reported in patients with pre-existing chronic renal insufficiency. The relationship to PROCARDIA therapy is uncertain in most cases but probable in some.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Coumarin anticoagulants: There have been rare reports of increased prothrombin time in patients taking coumarin anticoagulants to whom PROCARDIA was administered.

Cimetidine: A study in six healthy volunteers has shown a significant increase in peak nifedipine plasma levels (80%) and area-under-the-curve (74%) after a one week course of cimetidine at 1000 mg per day and nifedipine at 40 mg per day. Ranitidine produced smaller, non-significant increases. If nifedipine therapy is initiated in a patient currently receiving cimetidine, cautious titration is advised.

Carcinogenesis, mutagenesis, impairment of fertility: Nifedipine was administered orally to rats for two years and was not shown to be carcinogenic. When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose. *In vivo* mutagenicity studies were negative.

Pregnancy: Pregnancy Category C. Nifedipine has been shown to be teratogenic in rats and embryotoxic in rats, mice and rabbits. There are no adequate and well controlled studies in pregnant women. PROCARDIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS: The most common adverse events include dizziness or lightheadedness, peripheral edema, nausea, weakness, headache and flushing, each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, shortness of breath, diarrhea, constipation, gastrointestinal cramps, flatulence, inflammation, joint stiffness, shakiness, jitteriness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, sexual difficulties, thrombocytopenia, anemia, leukopenia, purpura, allergic hepatitis, gingival hyperplasia, erythromelalgia, depression, paranoid syndrome, transient blindness at the peak of plasma level, and arthritis with ANA (+). Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

HOW SUPPLIED: PROCARDIA soft gelatin capsules are supplied in:
Bottles of 100: 10 mg (NDC 0069-2600-66) orange #260; 20 mg (NDC 0069-2610-66) orange and light brown #261. Bottles of 300: 10 mg (NDC 0069-2600-72) orange #260; 20 mg (NDC 0069-2610-72) orange and light brown #261. Unit dose packages of 100: 10 mg (NDC 0069-2600-41) orange #260; 20 mg (NDC 0069-2610-41) orange and light brown #261.

The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

More detailed professional information available on request.

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