

Primary Care Reports



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Editor's Note—This is the final in a 3-part series on the medical problems of diving. Part I focused on diving medicine and physiology. Part II covered the medical problems of the sports diver, including panic, diver-blackout, exposure problems, injuries from marine animals, descent problems, ascent problems, arterial gas embolism, decompression sickness, and complications from medical problems of diving, including near drowning/drowning, shock, and cardiac arrest. The following manuscript will focus on medical standards for the different types of diving, female divers and pregnancy considerations, and finally, drugs and diving.

Medical Standards for the Different Types of Diving

The primary care physician (PCP) may be asked to perform medical examinations and give opinions regarding fitness for diving. Sport diving, regardless of the type, requires good physical and mental health. Medical clearance for sport diving, although based on objective as well as subjective considerations, must also consider the type of diving that will be done, namely, snorkel/breath-hold, SCUBA, or deep technical (see Table 1). There are absolute medical contraindications to diving for reasons of safety, aggravation of the condition, pre-existing conditions or performance requirements (see Table 2). If the condition is severe enough, the individual will usual-

ly choose not to dive.

Breath-hold/Snorkel Diving. Minimum if any medical screening is done for this type of diving. However, we recommend that if the PCP is aware of his or her patient's interest in this type of diving that they evaluate them for any conditions that could affect physical performance, stamina, and alertness. Cardiac arrhythmias may be precipitated by the stresses of breath holding, the diving reflex, and cold water. A history of epilepsy is considered by most authorities to be a contraindication to diving. Patients with a history of recurrent ear and sinus infections, while not a contraindication to diving, should be instructed in the proactive use of vasoconstrictors at the first

signs of middle ear and sinus congestion. Fitness and swimming ability should be established by the ability to swim several hundred yards comfortably in open water without swimming aids. Mild-to-moderate overweight is not a problem for this type of diving. Age, likewise, is not a contraindication. Children, with supervision, should be able to participate in this type of diving as soon as they can use fins, mask, and snorkel comfortably, usually at 6-7 years of age.

Sports SCUBA Diving. Although a medical examination is not required by the SCUBA diving certifying agencies in the United States to begin diving lessons, each student is required to complete a health questionnaire. If any of the

Medical Problems of Diving and the Primary Care Physician—Part III Medical Evaluation and Fitness for Diving

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answers are positive for disease conditions, a medical examination with medical clearance by a physician is required before allowing the prospective student to begin SCUBA diving training. While this is the essence of preventive medicine, it offers the certifying agencies protection from the liability of training a diver who is at risk for a serious MPD. Operators of most sports SCUBA diving charters require that their clients complete a similar health questionnaire, release from liability form before allowing the divers to use their equipment.

When a PCP is asked to provide a medical clearance in the above situations, guidelines can be helpful. For example, histories of asthma and ear, nose, and throat problems that are well controlled and do not interfere with physical performance are not contraindications for SCUBA diving. If there is any risk of pulmonary disease, a chest x-ray is advised. If the diver is older than 40 years, we recommend an electrocardiogram with exercise stress testing. Diabetes, moderate obesity, behavior problems, phobias (eg, to confined spaces), neuropathies, hearing loss, and residuals of severe musculoskeletal injuries are examples of relative contraindications to diving. A history of heart problems is also a relative contraindication to diving. Verification of fitness, stamina, and reasonable cardiac reserve is essential before giving an OK to SCUBA dive. The individual with such a history, but cleared to dive, should be encouraged to dive in areas that minimize exertional stresses, such as diving off a boat in warm, clear, calm waters. If the prospective diver is motivated, and complications have not developed from the problems considered to be relative contraindications, we generally allow him or her to dive. Advice should be given about avoiding injury, strict adherence to diving safety prac-

tices, and selection of a dive buddy who is competent and aware of the diver's limitations.

We personally do not recommend that youngsters younger than their early teens be allowed to SCUBA dive. The reasons for this are 3-fold. First, most diving equipment is designed for larger sized individuals. Second, there is the potential for damage to growth centers of the bones due to gas bubbling in the venous sinusoids with their associated sluggish blood flow. In theory this would be a preferential environment for inert gas bubbling to develop. Finally, the question of maturity and judgment in decision-making is a consideration. In this regard, the age to OK SCUBA diving is analogous to driving an automobile. Others have suggested that it is OK for youngsters to SCUBA dive as long as they follow precautions like limiting the depths of their dives (30 feet or less), dive under optimal conditions, and have adult supervision. The decision for older aged individuals to dive must be based on physiological rather than chronological age. There are no specific upper age limits for SCUBA diving. Because of less muscle strength, stamina, and cardiovascular reserve, our advice to older individuals is to dive "conservatively." To date no modifications for diving tables or dive computers have been offered for the older aged diver.

Deep Technical Diving. We feel that the medical exam for this type of diving should be the same as for the commercial diver. That is, it should be done by a physician with special training in underwater medicine. The exams should be done prior to starting these types of diving activities and on a regular basis, at least every 5 years, thereafter. The exams, in addition to a comprehensive history, review of systems, and physical examination should include chest x-rays, blood chemistry panels, hemograms, audiograms, and possible x-rays of the major joints. This latter consideration is made for those divers who made deep and/or long dives that require decompression stops during ascent to ascertain that dysbaric osteonecrosis of juxta-articular bone has not occurred. If it has, continuation of diving using compressed gases is not advised.

Female Divers and Pregnancy Considerations

Anatomical and physiological differences. About one third of SCUBA divers are females, as is the ratio for diving instructors. Physiological, anatomical, and psychological differences do exist between sexes. These differences are relatively minor, but they could become important in the underwater environment. The female body contains more fat tissue and less muscle. This fact puts female divers at higher risks for decompression sickness (DCS), but gives some theoretical advantage in cold water since fat serves as insulation. Generally, females have lower physical work capacity and stamina. This could become important in situations like swimming against strong currents or freeing themselves from entanglements.

Even though a third of divers are female, the ratio of females to male deaths in diving is 1 in 10.¹ These differences may be explained by diving habits rather than anatomical or physiological differences from males. Females tend to select less dangerous or hazardous situations than men. We feel that for sport diving, female divers, after appropriate training, can reach the same level of performance as male divers. In some respects, females have selective advantages such as better tolerance to cold water, and because of their smaller size, more

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Table 1. Types of Sports Diving and the Pre-dive Examination

Considerations	Types of Diving		
	Breath-hold/ snorkel diving	Recreational SCUBA diving	Deep Technical
History	General health; fitness; disabilities	Ears, nose, and throat (ENT) pulmonary, and cardiovascular (CV); medications	Diving history; history of diving-related problems
Physical examination	Focused	General exam with special attention to ENT, CV, and pulmonary portions; mental status	Usually done by physician with undersea medicine training
Physical performance (PP)	General physical fitness, ability to swim	Exercise program; cardiovascular conditioning limitations in PP	Essentially no limitations in PP
Psychiatric status	Ability to follow instructions (eg, to avoid hyperventilating before breath-hold dives)	No major problems; reasons subject wants to dive	Demonstrated stability (Confined spaces and with physical and mental challenges)
Starting age	Late childhood (ie, 6-7 yrs)	Early teens (ie, after bone maturation and appropriate size)	Usually after 18 years

efficient use of their gas supplies.

Menstruation and Diving. There are 2 points that need to be discussed; 1) Psychophysiological considerations; and 2) Menstrual blood as an attraction for sharks. Premenstrual and menstrual periods are associated with specific changes in the physiology of women. These changes may or may not have psychological components. They can produce a range of symptoms that affect physical performance and psychological responses. In general, the individual woman diver must decide whether she wants to dive during these times. However, the change of environment (psychological diversion), the buoyancy effects of water, and the relaxation that a well-conducted dive can provide, in our opinion outweighs the symptoms, in all but their severest forms, of the premenstrual syndrome and menstruation. From a physiological point of view blood loss during menses is almost never severe enough to cause hemodynamic changes. However, females may be at increased risk for developing DCS.²⁻⁴ These studies, while being suggestive, do not provide a physiological explanation for the increased risk for DCS in women divers.

There is no evidence that menstruation increases the likelihood of shark attacks in the female diver. In fact, Edmonds and colleagues report that female divers experience a much lower incidence of shark attacks than male divers.¹ One hypothesis they use to explain this observation is that hemolyzed blood associated with menstruation may act as a shark deterrent.

Use of Oral Contraceptive Agents and Hormonal Replacement Therapy in Diving. Oral contraceptives have side effects. A significant one is the propensity for blood clotting. This causes increased risks for deep venous thrombosis,

pulmonary embolism, cerebrovascular accidents, and myocardial infarction. However, there is no evidence that oral contraceptives increase the risk of DCS or other diving-related problems. Also we did not find any data about harmful effects of intrauterine devices and/or barrier methods of contraception for female divers. Although hormonal replacement therapy may reproduce some of the physiological effects of menstruation, we found no information on this subject in women divers.

Pregnancy and Diving. Most authorities in diving do not recommend SCUBA diving during pregnancy due to the unknown effects of increased partial pressures of nitrogen on the fetus and the increased propensity for nitrogen deposition in the fetal-maternal lipid tissues. This may make the fetus more susceptible to the harmful effects of bubbling phenomena than the pregnant mother.⁵ In addition, if the pregnant female requires hyperbaric oxygen recompression treatment for DCS, the increased partial pressures of oxygen may have teratogenic effects on the fetus as had been noted in animal studies.⁶ Consequently, we feel that snorkeling is OK during pregnancy, but SCUBA diving should be discontinued until after parturition.

Drugs and Diving

Drugs are associated with diving in 4 ways: 1) treatment of concurrent diseases; 2) prevention of MPD; 3) treatment of MPD; and 4) for “recreational” purposes.^{1,7} The actions of drugs may be altered under pressure such that the side effects that were acceptable on land in a resting person will become unacceptable in the underwater environment during diving and physical activity.⁸ When a diver is on a prescription drug, 2 problems must be

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Table 2. Conditions that are Contraindications* for Sports Diving

Cardiovascular disorders

- Any cardiovascular problem that requires medication but function remains impaired
- Cardiac arrhythmias (Relative)
- Congenital heart defects (with impaired function)
- Congestive heart failure
- Hypertension, moderate to severe
- Ischemic heart disease
- Severe deconditioning (Temporary)

Pulmonary disorders

- Acute (Temporary) or chronic pulmonary infections
- Asthma (Relative)
- Chronic obstructive pulmonary disease (COPD)
- Chronic bronchitis
- Pulmonary cysts and adhesions
- Pulmonary fibrosis
- Spontaneous pneumothorax

Ear, nose, and throat disorders

- Acute (Temporary) or chronic otitis and/or Eustachian tube dysfunction
- Chronic sinusitis with or without nasal polyps
- Inner ear problems, Menier's disease
- Middle ear surgery
- Tympanic membrane rupture (Temporary)
- Unilateral deafness

Endocrine disorders

- Diabetes (Relative)
- Others with residual impairments even with the use of medications

Hematological disorders

- Active neoplasms
- Coagulopathies
- Polycythemias
- Severe anemia (Temporary)

Musculoskeletal disorders

- Amputations (Relative)
- Dysbaric osteonecrosis
- Crippling arthritis (Relative)
- Healing fractures (Temporary)
- Herniated disc (Temporary/relative)
- Severe traumas/soft tissue injuries (Temporary/relative)

Neurological disorders

- Alzheimer's disease
- Brain and spinal cord demyelating, degenerative diseases
- Cerebrovascular accident with residuals (Relative)
- Peripheral neuropathy/peripheral nerve injury (Relative)
- Severely impaired visual acuity (Relative)

Psychiatric disorders

- Attention deficit disorder (Relative)
- Confinement anxiety
- Exaggerated fear of open water (Hydrophobia)
- Mental illness requiring major tranquilizers and/or other psychotropic agents

Miscellaneous

- Age (Relative)
- Pregnancy (Relative)
- Smoking (Relative)

* The above listing is to be used as a guideline; certainly there are hundreds of other conditions that impose limitations on diving. Usually, the problem is so obvious that diving is not even a consideration as an activity for the patient. It is useful to consider the contraindications as absolute, temporary (ie, will resolve treatment interventions) or relative. For relative contraindications, diving may be OK with certain restrictions (see text).

Table 3. Drugs that are not Recommended and/or Contraindicated in Diving

Drugs/Substances	Mechanisms	Side Effects/Possible Problems in Diving
Antihistamines/ motion sickness remedies	Block of histamine receptors	• Sedation, drowsiness → impaired cognitive and psychomotor performance
Tranquilizers/sedatives	CNS depression, sedation	• Sedation, drowsiness leading to impaired cognitive and psychomotor performance
Antihypertensive drugs	Decrease BP	• Decreased ejection fraction and cardiac output leading to impaired physical performance, increased risk of DCS
	Mechanisms are different for different classes	• Bradycardia leading to decreased cardiac output
Beta-blockers	Block of beta-receptors	• Bronchoconstriction increasing risk of AGE
ACE inhibitors	Blockade of ACE	• Dry cough initiating respiratory dysfunction
Calcium channel blockers	Block of calcium channels	• Orthostatic hypotension causing dizziness, syncope
Insulin and oral hypoglycemic	Decrease of the blood glucose level	• Hypoglycemia causing altered level of consciousness and/or weakness
Decongestants	Local vasoconstriction	• Rebound phenomena; intensifies nasal congestion after effects wear off and makes equalization in the ears and sinuses even more difficult
Caffeine	Inhibition of phosphodiesterase	• Tachycardia and increased BP precipitating cardiac arrhythmias • Diuretic action leading to dehydration
Amphetamines	CNS stimulation by releasing biogenic amines from storage sites in the nerve terminals	• Behavioral changes causing erratic diving, increased risk taking, and/or increased risk of accidents • Lowered threshold for oxygen seizures
Cocaine	CNS stimulant, blocks neuronal uptake of norepinephrine	• Hypermetabolic state causing fatigue, mental depression, acidosis, and the ability to respond promptly to life-threatening emergencies • Cardiac toxicity initiating sudden cardiac arrest; arrhythmias • Irritation of nasal mucous membranes and cartilage erosion • Increased likelihood of an oxygen seizure
Opiates	Stimulation of opioid receptors	Respiratory depression, altered mood, and/or impaired psychomotor performance
Tobacco/nicotine	Stimulation of nicotine receptors	<i>Acute effects:</i> Nicotine increases blood pressure and heart rate; it causes coronary vasoconstriction and bronchoconstriction; it decreases oxygen-carrying capacity of the blood, which interferes with physical performance.

Table 3 continued. Drugs that are not Recommended and/or Contraindicated in Diving

Drugs/Substances	Mechanisms	Side Effects/Possible Problems in Diving
Tobacco/nicotine	Stimulation of nicotine receptors	<p><i>Chronic effects:</i></p> <ul style="list-style-type: none"> • Chronic obstructive pulmonary disease with bronchospasm, air trapping, and increased risk of extra-alveolar air syndromes • Nasal congestion increasing likelihood of sinus and middle ear barotrauma
Alcohol	CNS depressant	<ul style="list-style-type: none"> • CNS depression with decrements in mental and physical performance; increased risk of vomiting • Reduction in blood glucose levels causes weakness and confusion • Blood vessel dilation interferes with preservation of body temperature in cold water • Diuretic action promotes dehydration
Marijuana/Cannibis	CNS depressant	<ul style="list-style-type: none"> • Impaired cognitive and psychomotor performance causing problems with attention and coordination • Tachycardia and increased oxygen consumption • Reduces divers' cold tolerance and breath-holding capability • General discomfort, unexplainable apprehension, euphoria, anxiety, and a desire to terminate a dive prematurely

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solved. First, it is necessary to know why the patient requires the medication and does it have any contraindications for diving? Second, it is necessary to consider possible side effects of the drug, which could have an additive effect to the MPD. For example, drugs with sedative side effects will likely make the diver more susceptible to nitrogen narcosis. Drugs with stimulant effects may lower the threshold for oxygen toxicity.

Divers may use “recreational” drugs, legally or illegally. Examples include tobacco, alcohol, amphetamines, cocaine, opiates and marijuana, and a number of other “designer” drugs. For diving purposes, these substances can be considered to have either “downer” (ie, depression) or “upper” (ie, stimulant) effects.⁹ A Los Angeles, Calif, coroner reported that 20% of diving deaths in Southern California were associated with the use of drugs.¹ Alcohol intoxication has been implicated in 50% of drowning (including SCUBA divers’) deaths. When considering drugs and diving, appropriate decisions can be made as to whether the drugs are absolute or relative contraindications to diving based on their categories of action (see Table 3). In general, there is no place for drugs in diving. However, exceptions

exist such as using vasoconstrictors to help with middle ear pressure equilibration and in the situations where the diver may be on a prescribed medication for a condition that could impose relative contraindications to diving.

Concluding Remarks

The information in this article should help the PCP add another dimension (ie, the primary care of the sports diver), to his or her practice. The extent of involvement may be haphazard, ie, the rare situation of caring for an established patient who develops a MPD, or proactive. The proactive approach is for the PCP to establish networks with diving certification agencies, sports diving clubs, hyperbaric units, and/or the Diver Alert Network and become known for his or her interest and willingness to provide care for the sports diver as well as doing diving physicals and medical certifications. This approach is analogous to the PCP becoming involved as a team physician.

Nothing gives the diver a greater sense of confidence in the physician who is performing his or her diving physical or managing the diving problem than to know that the physician is a diver also. There are many opportunities for the PCP to

become an “expert” in undersea medicine. Many physician continuing medical education diving medicine courses (most with associated SCUBA diving activities) are conducted each year. Many are listed on the internet or in *Pressure*, a publication of the Undersea and Hyperbaric Medicine Society (UHMS, 10531 Metropolitan Ave, Kensington, MD 20895, Tel.: 301-942-2980; Fax: 301-942-7804; Internet: www.uhms.org; e-mail: uhms@uhms.org). For the most comprehensive training, the PCP should consider the annual NOAA (National Oceanographic and Atmospheric Administration) 2-week course held in Seattle, Wash. With completion of this course, the PCP will have training sufficient to manage all aspects of the MPD including those requiring use of the recompression chamber. Another alternative is for the PCP to take a 1-year fellowship in hyperbaric medicine. Upon completion of the fellowship and accompanying clinical experiences, the physician becomes eligible to obtain board certification in undersea medicine under the auspices of the American Board of Preventive Medicine.

We appreciate that the subject of diving medicine is much greater than can be presented in a single review article. Many excellent textbooks and review articles are available for those who desire additional information on this subject.^{10,11,1,12-16} However, we feel that our paper meets the 3 objectives stated in Part I and will provide the PCP a background for appropriately dealing with the sports divers in his or her practice.

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Physician CME Questions

42. Which of the following is a recommendation for a mother who wants to start her 7-year-old SCUBA diving?
 - a. There are no contraindications.
 - b. Let the child SCUBA dive if he or she is a strong swimmer.
 - c. Limit diving to shallow depths.
 - d. SCUBA diving is OK if supervised by adults.
 - e. Defer until child is older; encourage supervised snorkel diving.
43. The earliest age to start SCUBA diving is:
 - a. there are no age restrictions.
 - b. late childhood (9-10 years of age).
 - c. mid-teens (14-15 years of age).
 - d. late teens (18-19 years of age).
 - e. None of the above
44. A history of which of the following conditions is *not* a contraindication for diving?
 - a. Hypertension severe enough to require medications to control
 - b. Recent spontaneous pneumothorax
 - c. Epilepsy
 - d. Middle ear surgery
 - e. Severe confinement anxiety
 - f. Peptic ulcer disease
45. All of the following drugs may have undesirable side effects for the diver while diving *except*:
 - a. antihistamines.
 - b. aspirin.
 - c. motion sickness remedies.
 - d. sedatives.
 - e. beta blockers.
46. The pre-dive training medical evaluation for the sports SCUBA diver should include:
 - a. a history questionnaire.
 - b. clearance by a physician if any questions are positive on the history.
 - c. special medical assessment if the diver candidate is older than 40 years of age.
 - d. All of the above
 - e. None of the above

47. SCUBA diving is contraindicated in the pregnant female because:
- the physical activity could be harmful for the fetus.
 - swimming is not advised for the pregnant woman.
 - there is risk of ascending infection into the uterus.
 - the material-fetal tissues may preferentially load nitrogen.
 - of altered buoyancy due to the fetus.
48. Which of the following statement(s) about menstruation and SCUBA diving is/are correct?
- Menstrual blood serves as an attraction for sharks.
 - SCUBA diving during menstruation is contraindicated.
 - Blood loss during menstruation is often severe enough to cause hemodynamic changes.
 - Diving during the menstrual period may have undesirable psychological effects.
 - All of the above
49. Opportunities for continuing medical education in diving medicine for the primary care physician include:
- SCUBA diving trips to exotic areas with associated diving medicine programs.
 - National Oceanographic and Atmospheric Administration Annual physician undersea and diving medicine course.
 - one-year fellowships in undersea and hyperbaric medicine at selected institutions.
 - hyperbaric medicine orientation courses.
 - All of the above
50. Excellent sources of information for the physician desiring more information on diving medicine include all of the following *except*:
- articles in medical journals.
 - movie and television dramas dealing with diving and/or water accidents.
 - the Divers Alert Network.
 - The internet.
 - All of the above
51. Real and potential benefits for the primary care physician to become knowledgeable about diving medicine include:
- ability to manage most patients' diving questions.
 - becoming recognized by the diving community as a source for diver medical clearance examinations.
 - opportunity to dive in exotic areas while obtaining continuing medical education in diving medicine.
 - opportunity to work in the field of undersea and hyperbaric medicine.
 - All of the above

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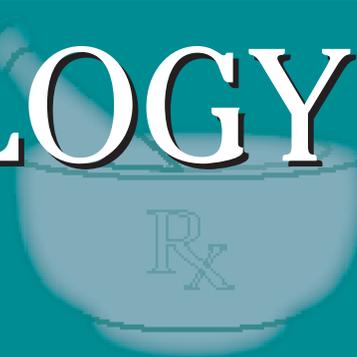
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In Future Issues:

**Sleep Disorders—
Michael H. Bonnet, PhD, George Burton, MD,
and Donna Arand, PhD**

PHARMACOLOGY WATCH



Forgot Your Ginkgo? Forget About It, Study Shows

The \$15 billion dietary supplement industry took a bruising in the last month with reports that some of the most popular over-the-counter treatments are little more than expensive placebo. Ginkgo, the commonly used memory enhancing agent, was evaluated in 230 men and women older than the age of 60 who had normal memory and were in good health. Patients were randomly assigned to receive ginkgo 40 mg 3 times a day or matching placebo for 6 weeks. Neuropsychological tests were administered at the end of the study, which revealed no significant differences between treatment groups on any of the outcome measures including verbal and nonverbal learning and memory, attention and concentration, naming and expressive language, self-reported memory, and companion scoring. The study concluded that ginkgo did not facilitate learning memory tension or concentration in adults older than the age of 60 (*JAMA*. 2002;288:835-840). In a separate study from The Netherlands, 652 adults older than age 60 were given a multi-vitamin/mineral supplement, 200 mg of vitamin E, both, or placebo in a study to evaluate whether the supplements would reduce the incidence and severity of acute respiratory tract infections. Patients were followed for nearly 1.5 years. No difference was found among any of the groups with regard to incidence or severity of acute respiratory infections, except for the finding of worsening severity of disease in the vitamin E group (19 days illness with vitamin E vs 14 days illness with placebo; $P = 0.2$). (*JAMA*. 2002;288:715-721.)

On the other hand, a homocysteine-lowering therapy with a combination of B vitamins effectively improves clinical outcomes after percutaneous coronary interventions. Folic acid,

vitamin B₁₂, and vitamin B₆ were tested in a randomized, double-blind, placebo-controlled trial involving more than 550 patients in Switzerland who had undergone successful angioplasty. The participants received a combination of folic acid 1 mg/d, vitamin B₁₂ 400 μ/d, and vitamin B₆ 10 mg/d, or placebo. The main outcome measure was the composite outcome of major adverse events including death, nonfatal myocardial infarction, and the need for repeat revascularization evaluated at 6 months and 1 year. The composite end point was significantly lower at 1 year in the vitamin-treated patients (15.4%) compared to the placebo group (22.8%) (RR, 0.68; 95% CI, 0.48-0.96; $P = .03$) primarily due to reduce rate of revascularization. (*JAMA*. 2002;288:973-979).

Celebrex OK for Asthma Patients

Celecoxib (Celebrex®) may be safe to use in patients with a history of aspirin-induced asthma. Patients with known aspirin sensitivity, or aspirin-exacerbated respiratory disease (AERD), are generally unable to take aspirin or any NSAID. In a study from San Diego, 60 patients with AERD were challenged with celecoxib, a COX-2 inhibitor, or placebo over 48

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hours. During the study period, none of the 60 patients experienced any symptoms or changes in nasal examinations or declines in FEV₁. The following day, all 60 patients were exposed to aspirin and all showed sensitivity. The study concluded that inhibition of COX-1 is the critical initiating event in respiratory reactions in patients with AERD (*Arthritis Rheum.* 2002;46:2201-2206).

Losartan Not Superior to Captopril

The angiotensin II receptor blocker losartan is not superior to the ace inhibitor captopril after complicated acute myocardial infarction. The large OPTIMAAL trial (Optimal Trial in Myocardial Infarction with the Angiotensin II Antagonist Losartan) looked at 5477 patients in 7 European countries with confirmed acute myocardial infarction and heart failure. Patients were randomly assigned and titrated to target dose of losartan 50 mg once daily or captopril 50 mg 3 times daily. The primary end point was all-cause mortality. During a mean follow-up of 2.7 years, there were 499 (18%) deaths in losartan group and 447 (16%) in the captopril group (RR 1.13; 95% CI, 0.99-1.28; *P* = 0.07). Because of this nonsignificant trend in total mortality in favor of captopril, the study suggests that losartan cannot be generally recommended in this population. It is noted however that losartan was better tolerated than captopril, and associated with significantly fewer discontinuations (*Lancet.* 2002;360:752-760).

Alfa-Interferon Could Help Fight West Nile

The number of West Nile virus cases is mounting in the United States, Canada, and Mexico where 37 deaths have been attributed to the virus, now the first case has been reported in California, and other cases are the result of organ donation from infected donor. Researchers are hoping that alfa-interferon may be of help. The drug has been effective against St. Louis encephalitis, a similar virus, and is the drug of choice for treatment of hepatitis C. Researchers are enrolling patients in the New York area where the virus first appeared 3 years ago. Although infection with the mosquito-borne virus rarely causes serious illness (< 1%), the elderly and chronically ill are particularly prone to encephalitis. alfa-interferon will be given for 2 weeks and should be started within the first few days of ill-

ness, prior to the onset of encephalitis. Research is also progressing on 3 West Nile virus vaccines, which should be in human trials by 2003.

Sertraline Effective Against Depression

Depression is common in patients with coronary artery disease and represents a significant independent risk factor for both first myocardial infarction and cardiovascular mortality. A new study shows that the selective serotonin reuptake inhibitor sertraline is safe and effective for treating major depression in patients with recent myocardial infarction or unstable angina. A total of 369 patients on 3 continents with major depressive disorder were enrolled and randomized to sertraline 50-200 mg/d or placebo in a double-blind fashion for 24 weeks. The main outcome was change in left ventricular ejection fraction (LVEF) while other outcomes included surrogate cardiac measures and cardiovascular adverse events. Sertraline had no significant effect on LVEF, and also did not increase ventricular premature complex runs, QTc intervals, or other cardiac measures. The incidence of severe cardiovascular adverse events was 14.5% with sertraline and 22.4% with placebo. Depression scores were better in the sertraline group. The authors conclude that sertraline is safe and effective for trading depression in patients with recent MI or unstable angina (*JAMA.* 2002;288:701-709).

FDA Actions

Procter & Gamble has announced that it expects an over-the-counter form of omeprazole (Prilosec) to be available by early 2003. The company has received an approval letter from the FDA but needs to clarify language on the package label so that consumers will clearly understand how to use the drug. Procter & Gamble is planning a study to make sure consumers understand the drug labeling, a process which will take several months. The FDA has approved fluoxetine (Prozac) for the treatment of panic disorder. The indication was previously only granted to paroxetine (Paxil) and sertraline (Zoloft), and it has been heavily promoted by the manufacturers of these drugs. Fluoxetine is also recently approved for long-term treatment of bulimia. The drug has been available as a generic for more than a year, and as such represents a lower cost alternative for patients with these conditions. ■