

Writing an Exercise Prescription

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DR. JIM L. WILSON, (*Associate Professor, Department of Family Practice*): I will begin today by discussing briefly our philosophy and approach to dealing with lifestyle problems. Next, I will present a patient whom I saw recently at the Family Practice Center, and we will use this presentation as a background to outline and discuss the exercise protocol that Mrs. Walker and I have developed for use with patients who want to begin an exercise program.

Dealing with chronic disease is a very large part of what we do in family practice, and very often these diseases are much more amenable to prevention than treatment. Many problems such as smoking, alcohol abuse, obesity, hypercholesterolemia, occult gastrointestinal bleeding, hypertension, cervical cancer, breast cancer, glaucoma, stress, inadequate exercise, and injuries resulting from not using seat belts or infant car seats can be detected by utilizing screening techniques. With many of these, treatment exists if the problem is detected early, and beneficial results can be expected if habits are changed. From the physician's standpoint, dealing with patient denial may be the first hurdle that must be overcome. Many people believe that they will never develop any of those problems listed above.

The family physician is in an ideal position to implement a health maintenance program for patients under his or her care because: over long periods of time long-term health care records are maintained; the authority of the physician in matters of health may aid in behavioral changes; some prevention interventions require medical management; health screening could be done when people come for episodic care; and the family physician sees a large segment of the overall population.

Family physicians must be educated in the use of health promotion and health maintenance programs so that they can provide the kind of comprehensive care that patients need. Also, it is important to provide this training in residency programs so that future physi-

cians will have the appropriate background and experience to incorporate these ideas into their practice. There are still many questions about how it can best be done. One of the first steps is to assess patients' risk factors in many areas of their lives. Our department has always been interested and instrumental in developing the family systems approach with problem patients, including those with chronic illnesses, emotional problems, and somatizing disorders. Many of the interventions that are useful in modifying lifestyle changes are also amenable to the family systems approach.

Exercise is only one of the health maintenance problems for which we have developed a protocol. We also have developed protocols for dealing with patients who want to stop smoking, prevention of unintentional injuries, stress reduction, alcoholism, and various nutritional problems including obesity and dietary management of diabetes, hypertension, prenatal care, and well-child care.

At this point I briefly would like to tell you about the patient who recently came to see me specifically wanting an examination so that he could begin an exercise program.

A.X. is a 28-year-old, unmarried man, who works as a salesman for a local company. He asked for a complete physical examination, saying that he was concerned about the possibility of developing heart disease. His father developed coronary artery disease at the age of 45 years, which manifested with an acute myocardial infarction, and he also developed arteriosclerotic plaques in his carotid arteries. As a result his father was in bad health from the age of 45 years, required surgical intervention several times, and died at the age of 56 years from complications resulting from myocardial infarction and congestive heart failure. The patient's paternal grandfather also died from a "heart attack" at age 70 years, but the patient had no further information about his grandfather's medical history.

The patient himself said he has always tried to follow a healthy lifestyle including following a low-fat diet and exercising regularly. His exercise consisted mostly of repetitive exercises using lighter weights. He

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recognized that his job produced a moderate to heavy amount of stress, although he denied that the stress bothered him, and he stated that he did not consider himself a "type A personality." He does not smoke. He occasionally drinks low-alcohol beer when he is watching football games with his friends. Other than his father and his paternal grandfather, there were no other members of his family with heart disease. The family history was negative for hypertension, abnormal serum lipids, and diabetes. The patient had no past history of heart disease, hypertension, abnormal serum lipids, or other significant illnesses. A review of systems was unremarkable.

On physical examination, he appeared healthy, was muscular, and was not overweight for his height. The physical examination was totally unremarkable. Blood pressure was 110/70 mmHg. We obtained routine laboratory studies, including a complete blood count, urinalysis, and SMA-20. All of these results were normal including cholesterol of 175 mg/dL and triglycerides of 90 mg/dL. We discussed a variety of ways of maintaining a healthy lifestyle including reducing his alcohol intake and using his seatbelt all the time.

The area that the patient specifically wished to improve was his physical activity. At the time of examination, his main physical activity involved anaerobic exercise, ie, lifting weights. I counseled him about other physical activity, specifically aerobic exercise, using the protocol that we are going to discuss shortly.

Authorities do not always agree about which individuals require an assessment by a physician prior to beginning an exercise program. From guidelines developed by the American College of Sports Medicine, asymptomatic, physically active persons of any age with no history or risk factors for coronary heart disease usually require little supervision of their physical exercise.¹ We drew from several viewpoints to develop the algorithm shown in Figure 1.¹⁻⁶ We used these references in developing our protocol and in determining the extent of the workup for patients who desire to begin an exercise program. The cardiovascular system, muscles and joints, blood pressure, height and weight, and pulse rate are the areas most consistently mentioned as requiring assessment before beginning an exercise program. In general, those who should consult a physician before starting to exercise are the ones who have heart disease, such as a heart murmur, or previous infarction; pain or pressure in their chest with exercise; faintness or dizziness with exercise; extreme shortness of breath with mild exertion; elevated blood pressures, back, bone, or joint problems; family history of premature coronary artery disease or sudden unexplainable death; medical conditions affected by exercise such as diabetes mellitus; cigarette smoking; high cholesterol; or obesity greater than 20 pounds overweight. Those individuals who have contraindications such as the ones listed in the

algorithm should not become involved in an unsupervised exercise program.¹

Mrs. Walker will now discuss in more detail the process of writing an exercise prescription for patients. The information that she will present is the information we provide patients when counseling them about an exercise program.

MRS. GRACE WALKER (*Family Nurse Practitioner, Department of Family Practice*): The benefits of exercise are well documented, such as lowering blood pressure, lowering the incidence of coronary heart disease, increasing bone mass, increasing levels of high-density lipoproteins (associated with decreased risk of coronary artery disease) and creating a tendency for smokers to decrease or stop smoking as long as they are in an exercise program.⁷⁻¹⁰ Insulin requirements for diabetics are decreased,¹¹ and if these people are overweight, exercise can help them lose weight. Others will be at less risk of developing diabetes if they maintain an ideal weight through exercise. Additional benefits of exercise include improved self-image and sense of well-being, increased tolerance to stress, and improved efficiency of the heart.¹²⁻¹⁵

The components of an exercise prescription can be classified in various ways. We have selected the following five components: mode, warm-up, endurance (frequency, intensity, and duration of the exercise), cool-down, and rate of progression.¹⁶⁻¹⁸

To build cardiovascular fitness, the mode of exercise needs to be rhythmical, maintainable continuously, aerobic in nature, and involve a large fraction of the muscle mass.¹⁶ Activities fitting these criteria include walking, biking, jogging, swimming, skating, cross-country skiing, rowing, jumping rope, and some types of dancing. Variety can be encouraged to reduce monotony and help people become compliant in their exercise program. If people get bored with jogging, they can try other types of exercise. Some people prefer to play racquetball or to swim. The calories expended for a specific exercise vary in proportion to the person's weight; for example, a person who weighs 100 lb will burn one third the calories of someone who weighs 150 lb. Someone who weighs 200 lb will use 1 1/3 the calories of a 150-lb person. Exercising faster or harder will increase the calories used only slightly. To burn more calories, it is best to exercise for a longer period of time rather than to exercise faster or harder.

Before beginning the endurance phase of the exercise, a person needs to warm up to limber the body. A warm-up period results in a slow increase in body temperature, heart rate, and circulation. Muscles become pliable and contract with more force, which prevents cardiac rhythm problems and muscle injury. Five minutes is adequate warm-up according to most authorities, although some authorities recommend up to 15 minutes.¹⁷ Individuals in a swimming program can swim leisurely for five minutes before getting into the

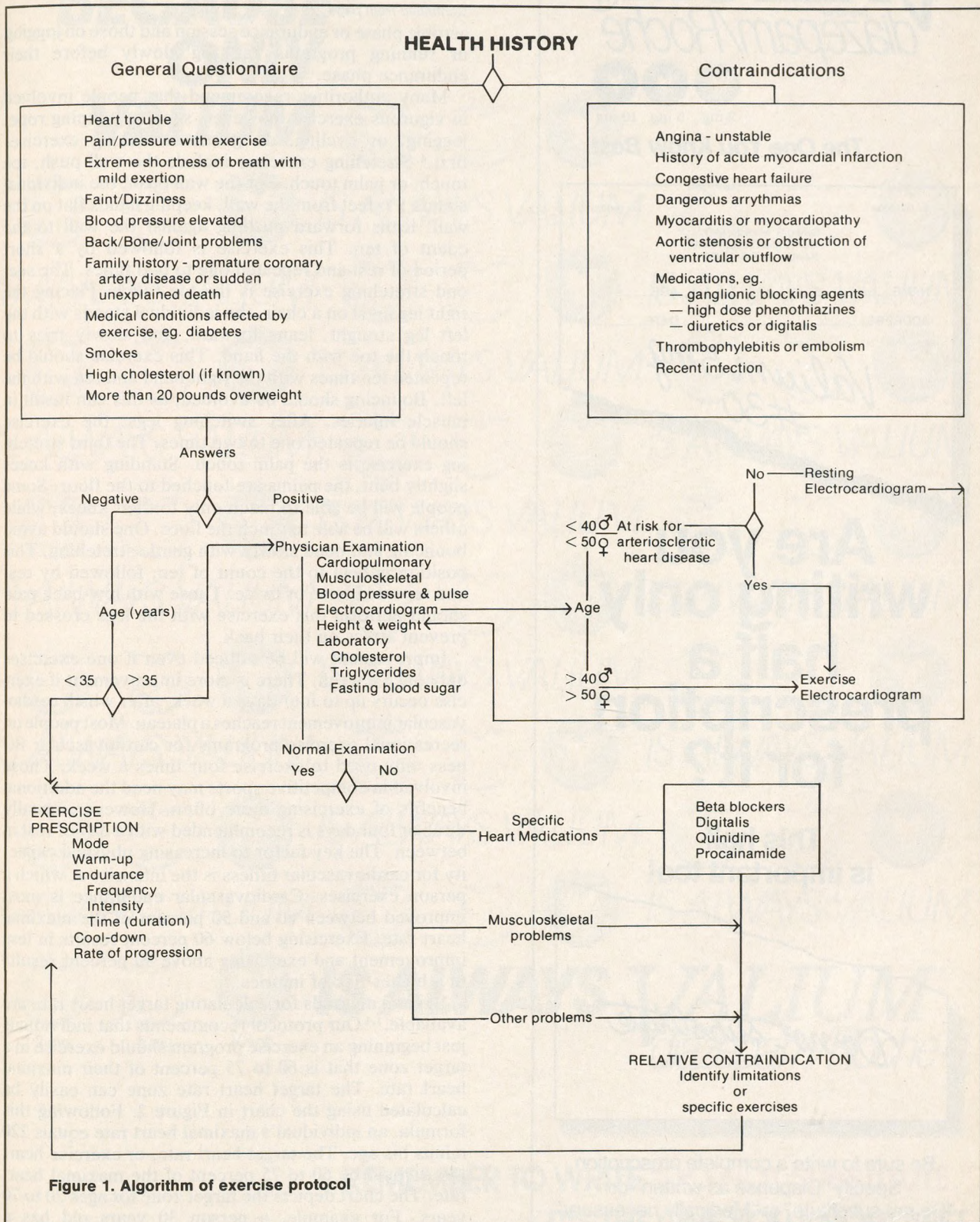


Figure 1. Algorithm of exercise protocol

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aerobic phase or endurance session and those on jogging or running programs can jog slowly before their endurance phase.

Many authorities recommend that people involved in vigorous exercise, however, such as jumping rope, jogging, or cycling, do gentle stretching exercises first.⁴ Stretching exercises include the wall push, toe touch, or palm touch. For the wall push, the individual stands 1½ feet from the wall, keeping hands flat on the wall, leans forward pushing against the wall to the count of ten. This exercise is followed by a short period of rest and repeated one to two times. The second stretching exercise is the toe touch. Placing the right leg level on a chair, the individual stands with the left leg straight, leans forward, and slowly tries to touch the toe with the hand. This exercise should be repeated ten times with the right hand and ten with the left. Bouncing should be avoided, as this can result in muscle injuries. After switching legs, the exercise should be repeated one to two times. The third stretching exercise is the palm touch. Standing with knees slightly bent, the palms are touched to the floor. Some people will be able to reach only to their knees, while others will be able to touch the floor. One should avoid bouncing and bend slowly with gentle stretching. This position is held to the count of ten, followed by rest and repeated once or twice. Those with low-back pain should perform this exercise with the legs crossed to prevent stress on their back.

Improvement will be noticed even if one exercises only once a week. There is more improvement if exercise occurs up to four days a week, after which cardiovascular improvement reaches a plateau. Most people on recreational exercise programs for cardiovascular fitness only need to exercise four times a week. Those involved in competitive sports may need the additional benefits of exercising more often. However, usually three or four days is recommended with a day of rest in between. The key factor to increasing physical capacity for cardiovascular fitness is the intensity at which a person exercises. Cardiovascular endurance is most improved between 60 and 90 percent of the maximal heart rate. Exercising below 60 percent results in less improvement and exercising above 90 percent results in a higher risk of injuries.

Several methods for calculating target heart rate are available.¹⁻⁴ Our protocol recommends that individuals just beginning an exercise program should exercise in a target zone that is 60 to 75 percent of their maximal heart rate. The target heart rate zone can easily be calculated using the chart in Figure 2. Following this formula, an individual's maximal heart rate equals 220 minus his age. The target heart rate, or exercise heart rate, would be 60 to 75 percent of the maximal heart rate. The chart depicts the target zone for ages 20 to 70 years. For example, a person 30 years old has a target heart rate zone of 114 to 142 beats per minute.

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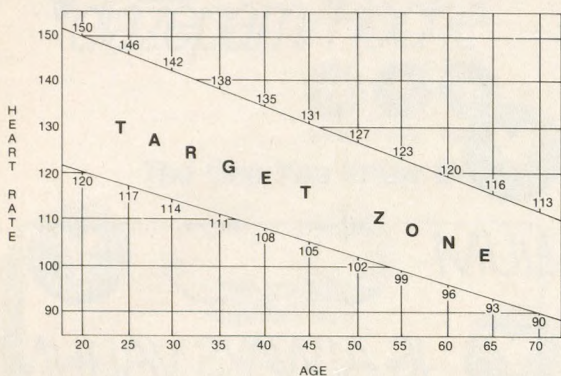


Figure 2. Target heart rate equals 60 to 75 percent of maximal heart rate

Someone who is 50 years old, according to the chart, has a target zone of 102 to 127 beats per minute.

The third factor of the endurance component is time. The time is duration, or number of minutes, of exercise occurring in the target zone. Usually the beginning exerciser should work out 15 to 30 minutes in the target zone depending upon his condition. Some people may be able to exercise in their target zone only for ten minutes, progressing gradually to 60 minutes. Some people will notice improvement in two weeks, while other less conditioned individuals may not notice improvement until six weeks.

Following the endurance component, a cool-down period is needed. The purpose of cooling down is to allow gradual slowing of the heart rate and constriction of blood vessels. Abrupt cessation can result in an insufficient amount of blood to the brain, resulting in dizziness, fainting, and nausea. Abrupt cessation, followed by lying down, increases the overload on the heart. Usually cool-down lasts five to 15 minutes. The pulse is taken during the endurance phase about every five minutes initially until the individual learns how hard to exercise to get the heart rate to the target zone. During cool-down, the pulse is taken every five minutes. If the pulse rate has not approached the resting rate, then an additional five minutes may be necessary. If the heart rate does not decrease after 10 to 15 minutes, the exercise period was too strenuous, and during the next session the individual should exercise less strenuously.

Showering should be postponed until perspiration has evaporated. People on a jogging or walking program may slow down to a slow jog or walk or repeat the warm-up stretching exercises. People on a swimming program can remain in the water for an additional five minutes. Water prevents the body temperature from rising, and the water pressure helps the circulation to adjust.

The rate of progression in an exercise program is

divided into three phases—to reduce discomfort, to achieve progress at a safe level, and to maintain a new level of fitness. People who have been exercising and want some counseling on their exercise program may skip the initial stage altogether. Those who are just beginning an exercise program should stay with stretching exercises, light calisthenics, and easy aerobics. This reduces the soreness and discomfort and prevents the patient from becoming discouraged and quitting the exercise program. During this stage some people may not even be able to exercise in their target heart rate zone because of stiffness and soreness. An older person or an obese person may need to do light calisthenics and stretching for four to six weeks before beginning to exercise in their target heart rate zone.

The improvement stage occurs when minutes are added to the endurance phase based on the individual's age. The three ways one can improve include increasing one of the three factors of the endurance component. Never should more than one factor of the endurance phase be increased at a time. Increasing the time is the best method for improvement because there is less chance of injury. Those aged 30 years or younger can add five minutes to the endurance session every two to three weeks, those aged 30 to 40 years can add five minutes every three to four weeks, those aged 40 to 50 years can add five minutes every four to five weeks, those individuals aged 50 to 60 years can add five minutes every five to six weeks, and those people aged 60 to 70 years may add five minutes every six to seven weeks. The maintenance stage results when an individual has reached the desired level of maintenance with the endurance component maintained at a constant level. Decreasing any one factor of the endurance component will result in deconditioning.

Compliance with an exercise program is greater and maintained over a longer period of time if it is perceived to be associated with better health. If individuals believe that disease affects their life, and that an exercise program reduces their susceptibility to or the severity of the disease, they will be more compliant with an exercise program. Compliance is often improved when the exercise is enjoyable. Suggesting a jogging program for someone who dislikes jogging will likely be unsuccessful. It may be better to suggest an exercise such as stationary bicycling in front of the TV news, a walking program, or swimming. Another important factor to consider is what the patient perceives to be important. If the patient does not perceive the exercise session to be important, then he or she is not likely to continue. Stressing the positive aspects and potential benefits of exercising to one's health may be helpful.

Two additional factors may help reduce the patient dropout rate from exercise programs. First, encourage additional support systems by suggesting that the patient exercise with other people. Sometimes stressing

the social aspects, such as getting a group of neighborhood friends together to walk or to swim, is helpful. Encouraging another family member to get involved with the exercise activity may also reinforce exercise. Another critical factor is the clinician's attention to the patient's needs.

Studies have shown that people are more likely to be compliant if they sign a contract. The one we use mentions very basic things such as beginning on a certain day and exercising in the target heart zone. Studies have shown that people in a control group who did not sign a contract had a 75 percent dropout rate; people who signed a contract only had a 35 percent dropout rate.¹⁹

Continuous reinforcement is the fastest method to establish new behavior, but when reinforcement is withdrawn, that behavior may be extinguished. We recommend continuous reinforcement initially followed by partial reinforcement. Research shows that it takes six weeks to establish a habit pattern.¹⁹ Therefore, we recommend following up with the patient weekly for six weeks, biweekly for two weeks, and monthly for one time. Of course, this may be adjusted to the individual's needs.

DR. WILSON: Next, I want to review some warning signs that people in an exercise program should recognize. Occurring with exercise, symptoms such as chest pain, sudden dizziness, fainting, or breathlessness should be not ignored but reported to a physician when they occur. Sudden development of symptoms may indicate that the individual is doing too much in the prescribed program. Even if the target heart rate has been correctly calculated according to the individual exercise test, it is possible that several factors may cause the heart rate to climb faster than expected. For example, exercising in hot weather when previously tested in an air-conditioned room or exercising under circumstances of competition may increase the heart rate. An individual who has not had an exercise test to determine a precise target rate may be exercising at too great a rate. Warning symptoms can occur during exercise or may occur anywhere from two to 24 hours later. All people on exercise programs should observe the following warning signs and should consult a physician before resuming exercise if any occur: any abnormal heart action, such as irregular beats; sensation of pain or pressure in the center of their chest; dizziness; lightheadedness; or fainting.

A physician should also be consulted for any of the following problems if the individual is unsuccessful with self-care: a rapid heart rate that persists five to ten minutes after finishing the exercise program (ie, if the heart rate does not decrease to normal during the cool-down period), or flare-up of a joint problem.

Self-care for the individual would probably be appropriate if any of the following develop: nausea and vomiting immediately after exercise, breathlessness lasting more than ten minutes, fatigue, shinsplints, insomnia, calf pain, side stitch, or charley horse. None

of those would be considered significant enough to warrant discontinuing the exercise program.

People who have already experienced some type of heart disease need to be in a program that is supervised by a physician.²⁰ A program of this type should consist of medical treatment for any underlying health problems that the patient has and also should focus on reducing or eliminating risk factors. The physician's judgment on how far and how fast a person should advance is a key factor.

Elderly patients and patients with documented coronary artery disease should receive special consideration when the physician is contemplating starting them on an exercise program. Also, the caloric requirements of an exercise program are important to consider. A discussion of these topics would be too lengthy to include here.

DR. PERRY DICKINSON (*Assistant Professor, Department of Family Practice*): Going back to your comments about initial workup, how well documented are the criteria for obtaining an exercise electrocardiogram? In a healthy individual who has been active and who has no symptoms, I would question whether an exercise electrocardiogram is necessary.

DR. WILSON: There are varying recommendations on that, and I really don't know how well it has been researched. In preparing our protocol, we found probably at least three separate authorities who have slightly different recommendations, particularly concerning the age at which an electrocardiogram should be done. We chose the middle of the range, because this was something we felt was safe and that we were comfortable with.

A FAMILY PHYSICIAN: What would you recommend for a patient in the 30- to 40-year age group or older who is already involved with an exercise program? Do they need an electrocardiogram?

DR. HENRY C. MULLINS, JR. (*Chairman, Department of Family Practice*): I think you should be careful about that. You would need to determine whether their exercise program is one that is sufficient in intensity and time. The person who walks or jogs at the same pace for the same distance every day may not really be in good physical condition.

The other comment I want to make has to do with our own physical fitness. You know, many diseases are communicable, and health may be something that is communicable, too. Maybe we could make progress toward fitness in patients if we and our staffs were practicing it.

DR. WILSON: If there are no further questions or comments, this concludes today's program. Thank you for your interest and participation.

Acknowledgment

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GLUCOTROL® (glipizide) Tablets

Brief Summary of Prescribing Information

INDICATIONS AND USAGE: GLUCOTROL is indicated as an adjunct to diet for the control of hyperglycemia in patients with non-insulin-dependent diabetes mellitus (NIDDM, type II) after an adequate trial of dietary therapy has proved unsatisfactory.

CONTRAINDICATIONS: GLUCOTROL is contraindicated in patients with known hypersensitivity to the drug or with diabetic ketoacidosis, with or without coma, which should be treated with insulin.

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (*Diabetes*, 19, supp. 2:747-830, 1970).

UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2-1/2 times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of GLUCOTROL and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may also apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS: Renal and Hepatic Disease: The metabolism and excretion of GLUCOTROL may be slowed in patients with impaired renal and/or hepatic function. Hypoglycemia may be prolonged in such patients should it occur.

Hypoglycemia: All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemia. Renal or hepatic insufficiency may increase the risk of hypoglycemic reactions. Elderly, debilitated or malnourished patients and those with adrenal or pituitary insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. Hypoglycemia may be difficult to recognize in the elderly or people taking beta-adrenergic blocking drugs. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when alcohol is ingested, or when more than one glucose-lowering drug is used.

Loss of Control of Blood Glucose: A loss of control may occur in diabetic patients exposed to stress such as fever, trauma, infection or surgery. It may then be necessary to discontinue GLUCOTROL and administer insulin.

Laboratory Tests: Blood and urine glucose should be monitored periodically. Measurement of glycosylated hemoglobin may be useful.

Information for Patients: Patients should be informed of the potential risks and advantages of GLUCOTROL, of alternative modes of therapy, as well as the importance of adhering to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure should also be explained.

Drug Interactions: The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including non-steroidal anti-inflammatory agents and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, monoamine oxidase inhibitors, and beta adrenergic blocking agents. *In vitro* studies indicate that GLUCOTROL binds differently than tolbutamide and does not interact with salicylate or dicumarol. However, caution must be exercised in extrapolating these findings to a clinical situation. Certain drugs tend to produce hyperglycemia and may lead to loss of control, including the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported. Whether this interaction also occurs with the intravenous, topical, or vaginal preparations of miconazole is not known.

Carcinogenesis, Mutagenesis, Impairment of Fertility: A 20-month study in rats and an 18-month study in mice at doses up to 75 times the maximum human dose revealed no evidence of drug-related carcinogenicity. Bacterial and *in vivo* mutagenicity tests were uniformly negative. Studies in rats of both sexes at doses up to 75 times the human dose showed no effects on fertility.

Pregnancy: Pregnancy Category C. GLUCOTROL (glipizide) was found to be mildly fetotoxic in rat reproductive studies at all dose levels (5-50 mg/kg). This fetotoxicity has been similarly noted with other sulfonylureas, such as tolbutamide and tolazamide. The effect is perinatal and believed to be directly related to the pharmacologic (hypoglycemic) action of GLUCOTROL. In studies in rats and rabbits no teratogenic effects were found. There is no adequate and well controlled studies in pregnant women. GLUCOTROL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible.

Nonteratogenic Effects: Prolonged severe hypoglycemia has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. This has been reported more frequently with the use of agents with prolonged half-lives. GLUCOTROL should be discontinued at least one month before the expected delivery date.

Nursing Mothers: Since some sulfonylurea drugs are known to be excreted in human milk, insulin therapy should be considered if nursing is to be continued.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In controlled studies, the frequency of serious adverse reactions reported was very low. Of 702 patients, 11.8% reported adverse reactions and in only 1.5% was GLUCOTROL discontinued.

Hypoglycemia: See PRECAUTIONS and OVERDOSAGE sections.

Gastrointestinal: Gastrointestinal disturbances, the most common, were reported with the following approximate incidence: nausea and diarrhea, one in 70; constipation and gastralgia, one in 100. They appear to be dose-related and may disappear on division or reduction of dosage. Clostridial jaundice may occur rarely with sulfonylureas: GLUCOTROL should be discontinued if this occurs.

Dermatologic: Allergic skin reactions including erythema, morbilliform or maculopapular eruptions, urticaria, pruritus, and eczema have been reported in about one in 70 patients. These may be transient and may disappear despite continued use of GLUCOTROL, if skin reactions persist, the drug should be discontinued. Porphyrin cutanea tarda and photosensitivity reactions have been reported with sulfonylureas.

Hematologic: Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas.

Metabolic: Hepatic porphyria and disulfiram-like alcohol reactions have been reported with sulfonylureas. Clinical experience to date has shown that GLUCOTROL has an extremely low incidence of disulfiram-like reactions.

Endocrine Reactions: Cases of hyponatremia and the syndrome of inappropriate antidiuretic hormone (SIADH) secretion have been reported with this and other sulfonylureas.

Miscellaneous: Dizziness, drowsiness, and headache have been reported in about one in fifty patients treated with GLUCOTROL. They are usually transient and seldom require discontinuance of therapy.

OVERDOSAGE: Overdosage of sulfonylureas including GLUCOTROL can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose at a level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours since hypoglycemia may recur after apparent clinical recovery. Clearance of GLUCOTROL from plasma would be prolonged in persons with liver disease. Because of the extensive protein binding of GLUCOTROL (glipizide), dialysis is unlikely to be of benefit.

DOSE AND ADMINISTRATION: There is no fixed dosage regimen for the management of diabetes mellitus with GLUCOTROL; in general, it should be given approximately 30 minutes before a meal to achieve the greatest reduction in postprandial hyperglycemia.

Initial Dose: The recommended starting dose is 5 mg before breakfast. Geriatric patients or those with liver disease may be started on 2.5 mg. Dosage adjustments should ordinarily be in increments of 2.5-5 mg, as determined by blood glucose response. At least several days should elapse between titration steps.

Maximum Dose: The maximum recommended total daily dose is 40 mg.

Maintenance: Some patients may be effectively controlled on a once-a-day regimen, while others show better response with divided dosing. Total daily doses above 15 mg should ordinarily be divided.

HOW SUPPLIED: GLUCOTROL is available as white, dye-free, scored diamond-shaped tablets imprinted as follows: 5 mg tablet—Pfizer 411 (NDC 5 mg 0049-4110-66) Bottles of 100; 10 mg tablet—Pfizer 412 (NDC 10 mg 0049-4120-65) Bottles of 100.

CAUTION: Federal law prohibits dispensing without prescription.

More detailed professional information available on request.

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