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# Family Practice Forum

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## Risks of Referral

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Family physicians receive broad-based training, and an important component of their domain is the diagnosis and management of frequently occurring illnesses in their patients within the context of the family and community. Physicians in other specialties acquire in-depth knowledge of diseases that occur less frequently and possess skills to perform complex diagnostic and therapeutic procedures. Although family physicians provide definitive care for over 95 percent of patient encounters,<sup>1-3</sup> the remainder require consultation, referral, or both. With consultation, patient care is shared, but the responsibility remains with the primary physician. Referral denotes "a permanent, temporary or partial transfer of responsibility for care of the patient,"<sup>4</sup> although the primary physician may be expected to continue a supportive relationship that includes the psychological and social components of the problem for which the patient is referred.

Consultation and referral rates are influenced by patient factors such as age, marital status, and race<sup>4</sup>; physician variables such as age<sup>5</sup> and length of training<sup>6</sup>; and community variables such as payment sources,<sup>4</sup> location of practice,<sup>7</sup> and even the season of the year.<sup>1</sup> The major reasons for consultation and referral given by physicians in rank order of frequency are (1) to obtain a second opinion concerning patient management, (2) to compensate for lack of required facilities or specific skills, (3) to obtain a second opinion for diagnosis, and (4) to comply with the request of the patient or family.<sup>6</sup>

Both consultation and referral can confer major benefits to patient and physician. These benefits

include access to expert knowledge and sophisticated technical skills; nevertheless, there are risks. The major risk to the patient from consultation is confusion that can result from disagreement between the referring physician and the consultant. For referral there are additional risks as illustrated by the following brief examples.

A patient with recurrent urinary tract infections can pose a dilemma for the primary care physician, and referral to a urologist is a common consequence. According to Kunin,<sup>8</sup> "urethral dilatation is probably the most common procedure used by urologists to treat females with recurrent infection." Yet, careful measurements of the caliber of the distal urethra do not show decreased diameters in girls with recurrent urinary tract infection compared with those without infection, and urethral dilatation has no beneficial effect on preventing recurrences.<sup>9,10</sup> Additional costs and discomfort are incurred, therefore, without expectation of benefit.

A second example concerns children with recurrent acute otitis media and persistent middle ear effusions. Reduced hearing can be a consequence, and placement of ventilating tubes can be appropriate therapy. The procedure, however, is not without risk (general anesthesia is usually required) or complications (scarring, otorrhea, cholesteatoma, and others).<sup>11</sup> In a recent survey of 500 otolaryngologists, 32 percent of respondents insert tubes in one month or less, following diagnosis or referral.<sup>12</sup> It is true that the effusion could have been present for several months prior to the first visit to the otolaryngologist, but 40 percent of those surveyed felt that tubes were used too frequently. Early referral, therefore, carries a risk of an intervention that may be either premature or unnecessary.

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## BRIEF SUMMARY PROCARDIA\* (nifedipine) CAPSULES

For Oral Use

**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 those 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:** Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

**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.

**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.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

**ADVERSE REACTIONS:** The most common adverse events include dizziness or light-headedness, 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, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. 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.

**Laboratory Tests:** Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

**HOW SUPPLIED:** Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). 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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The last example concerns referral of patients with suspected or known coronary artery disease. In this case the dilemmas are both diagnostic and therapeutic. The choice of diagnostic tests available includes exercise stress tests, radionuclide perfusion studies, radionuclide ventriculography, and coronary artery angiography. "The major objective is to insure that the benefits of a diagnostic strategy exceed the risks and that the net benefits of the diagnostic strategy chosen are greater than those of the alternatives."<sup>13</sup> Yet, "coronary arteriography is not always resisted vigorously"<sup>14</sup> by physicians who care for patients with angina pectoris. Therapeutic decisions pose even greater problems. A positive stress test in an asymptomatic patient or a patient with atypical chest pain could lead to coronary angiography. Demonstration of significant coronary artery obstruction might eventually result in coronary bypass, although the benefits of such surgery in asymptomatic individuals have not been demonstrated. Even in symptomatic patients (except in selected subsets), the benefit of surgery is still a matter of contention.<sup>15-19</sup> In addition to these technical considerations, appropriate diagnostic and therapeutic decisions require information about illness behavior, family factors, patients' expectations, and a host of other variables. The family physician may have some of this information but is often not consulted or included in the decision-making process.

In these three examples, patients referred by family physicians could receive an unnecessary procedure, a procedure administered prematurely, or one in which decisions are made without full consideration of all the multiple and complex operative factors. Some of the factors that contribute to these patient risks include community variables, factors that relate to physician training, and those that involve interaction among the family physician, the consultants, and the patient.

Among the community variables is the issue of reimbursement for physicians' services. Is an hour of physician time spent doing a diagnostic procedure (such as cystoscopy) really worth considerably more than one hour of time spent obtaining a careful history, performing a thorough physical examination, and producing an assessment and plan? Large monetary rewards for complex diagnostic and therapeutic procedures are likely to



increase their use. In addition, a society that believes that all problems can be solved by technology is apt to encourage technological solutions.

In regard to physician training, skills in performing complex procedures receive major emphasis in postgraduate training. Physicians who acquire these skills value them and fear that they might atrophy if they are not applied with moderate frequency. A natural consequence may be the extension of indications for a given procedure when the caseload is low (such as the period spent establishing a practice). Emphasis on new technology and on procedures during the training period also tends to blunt considerations of alternative approaches that involve knowledge of the natural history of disease process without intervention.

Probably the most important variable contributing to patient risk for referral is impaired communication between family physician and consultant. That consultants receive insufficient information from referring physicians and that feedback from consultants to referring physicians is inadequate have received ample documentation.<sup>20-22</sup> In addition, neither has the role of the patient in sharing in decisions that involve uncertainty yet been clearly defined, nor has the science of making decisions under conditions of uncertainty been incorporated into clinical practice.

Several things can be done. Fee structures can be revised so that technological interventions are not unduly rewarded and, therefore, encouraged. Directors of residency training programs should consider community morbidity patterns in relationship to the curriculum for their residents. The family physician should provide the consultant with pertinent information and take part in both diagnostic and therapeutic decisions. Finally, the patient must be made an active participant in the decision process. Uncertainties about diagnosis and therapeutic outcome should be shared with the patient. What is ultimately involved is making decisions under conditions of uncertainty in which both the probabilities of outcomes and the values of the patient must be taken into account. The family physician can play an important, possibly unique, role in such principled gambling because of his knowledge of the patient and his family, the shared trust that has been developed over time, and his defined role as an advocate for the patient.<sup>23</sup> Although referral risks may not be entirely

eliminated, a trio of patient, consultant, and referring physician can reduce these risks and contribute to increased satisfaction for all parties.

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