Coronary Revascularization

To the Editor:

Dr. Sabiston’s discussion of coronary revascularization (Circulation, 43: 175, 1971) ably presents the state of the art. It was, therefore, disappointing to search this paean to twentieth century surgical technology for an equally contemporary approach to evaluation of its therapeutic results: there is no mention of controlled clinical trials. Instead, we learn that we shall have to depend on the traditional approach—the “natural history” of recurrent myocardial infarction. This is the common basis of claims for many discarded medical and surgical treatments—the tried and untrue method. Such treatments had performed spectacularly in publications by their originators and proponents.

The verdict of properly controlled trials of many pharmacologic therapies has usually been no improvement over placebo. By contrast, surgical methods have not been examined rigorously, excepting internal mammary ligation. Its advocates reported remarkable results, but carefully designed series yielded equal subjective and objective changes in control patients. More recently we have witnessed the same phenomenon—improvement in patients with occluded Vineberg implants.

In fairness, one cannot argue that coronary bypass can be viewed as skeptically as earlier methods. Rapid improvements in ventricular function are truly impressive, while longevity and the actual placebo-effect on angina remain uncertain. But need we continue the traditional, time-dishonored approach of trial-and-error, i.e., operations on large numbers of patients, followed by reviews to sort out what happened, identification of the mistakes, and then decisions on how they should have been applied for future use? Moreover, without prospective stratification (individual targeting for angina/dysfunction/longevity) and adequate standards of comparison (matched, randomly allotted control patients) the effort balances shakily on recollections of “natural history” which still suffers from “a lack of precise definition.”

The F.D.A., therapeutic trials committees, granting authorities, and responsible journal reviewers require airtight controlled trials of new (and, thank heaven, old) pills and injections. Somehow, the mystique of surgery—the presumed efficacy of a mechanical rearrangement of tissue—makes these natural referees suspend disbelief in a way that no pill could.

I can share Dr. Sabiston’s optimism for the future of direct revascularization. But for a valid trial, we must measure results by valid standards. Ethically, controlled trials are due as soon as technical feasibility is demonstrated, lest unworthy operations become petrified in our “armamentarium.” Such trials should be in the able hands of cardiologists and surgeons of the first rank like Dr. Sabiston.

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The author replies:

To the Editor:

The comments made in Dr. Spodick’s letter are thoughtful and meritorious. His primary point, the need for controlled clinical trials in the surgical versus nonsurgical management of ischemic heart disease, poses an exceedingly difficult problem. Dr. Spodick’s recent editorial on this topic (Revascularization of the heart. Numerators in search of denominators. Amer Heart J 81: 149, 1971) amply reviews the difficulties encountered in establishing and completing such studies.

In the development of a controlled clinical trial, those responsible should be convinced first that the study can be performed in a practical and workable manner that will produce results that are completely objective. In randomizing candidates for direct venous graft revascularization, many knowledgeable physicians doubt seriously that such a controlled study can be accomplished effectively. Dr. Eugene A. Stead, Jr., among others, has emphasized that once a group or center is recognized as randomizing such patients referral patterns become altered in a manner unfavorable for a proper study. Moreover,
many cardiologists are quite convinced of the clinical benefits of the current operative procedure and are unwilling to permit their patients to be randomized. As an example of the strong views on this subject, Stead holds that only those patients without a seriously interested family physician, internist, or cardiologist would be available for randomization.

Another feature that makes such controlled studies difficult is the fact that the patients themselves, when assigned randomly to the nonoperative group, may subsequently seek an operative procedure elsewhere. It should be repeated that the foregoing comments do not imply that the data from a randomized study would not be valuable; quite the contrary, and if such data can be obtained in an objective manner, the information would be most helpful. However, it is believed that the careful and detailed pre- and postoperative assessments of cardiac function in which the patient serves as his own control now being performed at the Massachusetts General Hospital and other centers will yield reliable and objective data. An additional consideration regarding randomization is simply when to randomize. Most statisticians agree that prognostic stratification and subsequent randomization within groups characterized by a homogeneous prognosis would represent an ideal experimental design. There are few examples in clinical medicine where this element of experimental design is as critical as in the evaluation of therapeutic interventions in patients with coronary artery disease. Indeed, a case can be made that randomization of all patients with clinically manifest coronary artery disease into surgical, versus nonsurgical groups, might well camouflage both the potential good and harm of the procedure. It would appear that the great challenge to the cardiologist and the surgeon alike is better definition of the natural history of coronary artery disease with identification of groups with a sufficiently similar and predictable outcome so randomization may be performed. Once that goal is achieved, then profitable evaluation of any number of potentially beneficial interventions, including direct revascularization, can be undertaken.

At present, a randomized cooperative clinical study of ischemic heart disease by operative and nonoperative means is being conducted by 11 Veterans Administration hospitals. In this particular setting, which may be more favorable for such a study, it is to be hoped that reliable data can be accumulated. Of interest, however, is that quite recently the Veterans Administration has requested administratively that any patient who does not wish to participate in the study may have a surgical operation performed in the participating hospitals if his physicians feel that it is in the patient’s best interest.

Finally, the Editorial emphasizes the need for an open attitude about direct revascularization and lists a critique of eight as yet unproven features concerning venous autografts. It concludes, “The answers to these critical questions are unavailable and can be made only when both time and appropriate postoperative evaluations permit.”

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Use of Propranolol in Preinfarction Angina

To the Editor:

In Dr. Hood's editorial1 the possibility of using propranolol for reduction of ischemic damage of the myocardium is mentioned. The observation that patients who present with acute myocardial ischemia (but not necrosis by electrocardiographic or enzymatic criteria) usually have a protracted clinical course with repeated anginal crises and corresponding continuously varying electrocardiographic ischemic changes despite bed rest, analgesics, and efficient anticoagulation, led us recently to try the use of propranolol in those cases. So far the results are encouraging, and an extended trial was performed.

In the last seven admissions in our department (four men and three women, ages 47 to 59 years) with acute coronary insufficiency (preinfarction angina), after an unsuccessful trial of the classical treatment for a mean time of 14 days, we started the administration of propranolol orally. A prompt favorable result with elimination of anginal crises was obtained in six patients (five with 60 mg and one with 80 mg propranolol daily), and in the seventh patient the same result was achieved after reaching the daily dose of 160 mg propranolol in a few days. The probability for obtaining seven consecutive successes by chance is found to be under 5%.2

The clinical amelioration was paralleled by the electrocardiogram: in four patients the ECG returned within normal limits, in two the ischemic electrocardiographic changes were significantly reduced, and in one they were stabilized. The patients remained free of cardiac failure clinically. (The patient receiving 160 mg propranolol daily was given, in addition, 0.25 mg digoxin prophylactically.)
Coronary Revascularization: The author replies:
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