Coronary Artery Surgery: A Critical Review

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A Critical Review

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Preface

Coronary artery surgery in its present form has grown so rapidly during the last decade that in terms of dollar costs, patient-days involved in workup and treatment, and professional personnel utilization, it probably commands today more of our available medical resources than any other specific mode of therapy. Already the total monetary cost is approximately 1% of the annual national health expenditure. The scope of the potential application of the operation is underscored by the fact that coronary artery disease is the leading killer in the United States and Western Europe, and virtually the entire adult population is susceptible to the illness.

Coronary artery surgery has had an astounding growth, thanks to the technical prowess of the medical profession and medical instrument suppliers, and the tremendous energies and enthusiasm of the cardiac surgical teams and the patients they have treated. But despite proclamations of surgical success and near-universal acceptance of the operation by both patients and profession, substantial doubts remain about the efficacy of this mode of therapy. It has always been accompanied by controversy over the results and the proper sphere of its application. The history of medical therapeutics is that most treatments do not stand the test of time, especially those which are controversial within the profession.

The greater controversy has not been and is not about the surgical procedure *per se,* nor is the technical expertise of surgeons and cardiologists a question. The doubts raised are with respect to the methods of evaluation of the operation, the substantiation of the beliefs of the proponents, and the proper use of the operation. Since early in the present historical stage of coronary artery surgery, admonitions have come forth that this operation lacks scientific validation. Courageous editorialists have

observed and pointed out the lack of bona fide controlled studies supporting the claims of increased survival alleged to result from the operation.

Virtually everyone participating in this mode of therapy reports its unqualified success in relieving the symptom of angina. But it is remarkable that there has never been an investigation to determine if this dramatic symptomatic relief is due to the specific physiologic effect of the operation, i.e., blood flowing through the bypass grafts. I am reminded of a patient who, 4 days after saphenous vein bypass surgery, remained flat in bed with a turgid left leg elevated in hopes of relieving the painful swelling. He also had painful postoperative pericarditis, moderate shortness of breath, some incisional pain, and a temperature of 105° F (40.6° C). Prior to surgery this patient was assured of the probable success of the treatment, and he developed a very positive relationship with his doctors. When seen on rounds in the above-described condition, he responded that he hadn't felt as well in years, and that there were "parts of my body now receiving blood for the first time in 20 years." I marveled at the ability of this man to respond so positively despite his condition and pondered the meaning of positive responses from patients with less traumatic recoveries. This, of course, is simply one anecdote, but then, so are all such reports.

Despite numerous warnings that validation of the procedure was lacking, the profession raced forward as fast as was technically possible, with immense institutional and personal gains. Voices of caution were branded as reactionary and unenlightened, and the operation became established medical practice, thereby qualifying as legally correct therapy. The critics generally have been silenced by the order of the day, but the problems remain.

This book is an attempt to restate the basic question: Is coronary artery surgery in the best interest of the patient? Although this disarming question becomes exceptionally complex and may well remain unanswerable, to reject the question, or not attempt to answer it, would be the final abrogation of our obligation to

our patients. Therefore I have undertaken this critical analysis of coronary artery surgery not as an antisurgery vendetta, but as a supplementation to a form of treatment which ultimately will be judged not by this book, nor by all the past reports in the medical literature, but by the true value of the operation as it finally emerges. The book is addressed more to the methods of data production and collection and to the validity of conclusions than to the multifarious technical aspects of the surgical procedure and the innumerable reports in the literature. I have tried to include all significant developments through August 1976. The results of the next year or years may alter our conclusions about the efficacy of the operation, but they should not alter the principles of proper evaluation of therapy, which is what this book is about. As we have been recently reminded by our national political leaders, it is necessary to "let the chips fall where they may," but we must still safeguard the right of the chips to fall.

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I acknowledge the stimulation of the house staff who as a group have not learned to see the emperor's clothes, and who question the validity of unproven treatment. And especially I am grateful for the challenge of S. Eyre, who supplied me with data suggesting that a specific treatment I had recommended was unjustified on the basis of known facts. I am indebted to D. Spodick, T. Chalmers, and R. Ross, whose works have been an inspiration to me, and from whom I have borrowed extensively. I also thank R. Sutton, C. Oakley, G. Sutton, R. Balcon, H. Frick, W. Irnich, H. Lagergren, and O. Edhag for their assistance in collecting data.

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Contents

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Introduction—Scope of the Problem

J. H. is a 57-year-old farmer who always worked hard and was "never sick." He is a heavy smoker and a nondrinker. He is married and has four children. He began having chest pain 20 months ago. At first the pain occurred only with vigorous exertion, such as struggling to lift heavy objects, and the pain quickly abated when he stopped working. Gradually the pain worsened, and 10 months ago it began to bother him during less vigorous activities. He noticed chest pain in walking up long hills, and the problem was exacerbated during the cold winter months. He visited his doctor who diagnosed angina pectoris and treated him with digitalis and nitroglycerin. Initially he obtained relief with nitroglycerin, although he still was subject to chest pain. He was cheered by what seemed to be an improvement, but 3 months later the pain episodes became more frequent, came on with less exertion, and increasingly occurred with sexual intercourse. He was forced to curtail his farm work and relegated most of the hard work to his son.

Unhappy with his condition, he returned to his doctor, who recommended referral to a medical center 75 miles away. The patient concurred and entered the hospital. A cardiac catheterization showed coronary artery disease and an operation was recommended. The patient agreed and had the operation, which lasted about 3 hours and was without complications. The surgeons placed two vein grafts between the aorta and two coronary arteries. The patient recovered quickly and was home 10 days after the operation. A month later he was walking a mile a day, and now, 6 months after the operation, he is working full-time and has no chest pain. He considers himself a new man.

S. W. is a 68-year-old banker. His wife is still living and his three children are grown. He first developed chest pain 6 years ago, but chest pain was an infrequent occurrence and did not restrict him. He could always relieve the pain by slowing or stopping his activity, and although bothered by the symptom he adjusted well to it. A year ago, while playing golf, he experienced a much sharper pain that did not abate after sitting down. He was frightened by the intensity and duration of the pain, and his golfing partners took him to a doctor. By the time he was seen by the doctor, about an hour after onset, the pain had largely subsided. The patient was admitted to the local hospital to rule out a possible myocardial infarction and all tests were negative. Because of the patient's history of chest pain, a cardiologist was consulted and he recommended coronary angiography. Based on the findings at angiography, the patient was told he needed an operation.

The operation was performed, and three vein grafts were placed in the heart; the operation was considered technically successful. After surgery the patient had fever for 5 days and some mild heart failure that was treated with drugs. Although pain was relieved by narcotics, the patient did not feel well until about a week after the operation. He was discharged from the hospital 2 weeks after the date of surgery, although at that time he was still bothered by pain and swelling in the leg from which the vein grafts had been taken. His recuperation at home was slow but steady, and he avoided physical exertion. When he did attempt strenuous activities, he had chest pain similar to the pain he had had for 5 years before the operation, but perhaps of less intensity. The same pain has continued to the present, yet when seen at the hospital for checkup he states that he is definitely improved and feels better. During a postoperative exercise tolerance test he walked 30 seconds longer before stopping than he had in the preoperative test. This was recorded as a significant objective measure of improvement of cardiac function. When questioned, his wife confided that he is less active than he used to be, and that he has learned to avoid activities that precipitate chest pain.

W. D. was a 61-year-old fisherman who smoked heavily. His wife died 3 years ago. They had no children. The patient had a heart attack 4 years ago, prior to which he had frequent chest pain associated with heavy exertion. After the heart attack the pain was less frequent but often lasted longer, and recently he also had been bothered by shortness of breath during the attacks. His physician treated him with nitroglycerin, digitalis, and a diuretic, but with continued worsening of the symptoms the patient asked the doctor about a possible operation. A cardiologist was consulted who performed coronary angiography and recommended surgery. By this time the patient was unable to continue working because of fatigue, shortness of breath, and exertional chest pain, and he consented to surgery.

At operation the coronary arteries were noted to be severely narrowed, as was appreciated on the coronary angiograms. Three grafts were placed without problems, but the surgeons had great difficulty at the end of the operation with low blood pressure and poor left ventricular contractility. Ventricular fibrillation ensued and was terminated with a single electrical shock. With the aid of pressor drugs the patient was taken to the recovery room, where an electrocardiogram showed a new myocardial infarction. His condition remained precarious but stable throughout the night, but the following day he became more hypotensive, went into shock, and suffered ventricular fibrillation. Despite extraordinary efforts for 45 minutes, nothing was of avail and the patient died.

These three case reports are anecdotes that represent three possible results of coronary artery surgery. Although real, and representative of some experiences, they represent nothing more than what is possible. They say nothing about what is probable for any patient awaiting surgery for coronary artery disease, nor do they have predictive value for large groups of patients, for farmers, bankers, or fishermen. Although these cases were selected to demonstrate the broad range of results of coronary artery surgery, nothing is learned from the experiences of these

three patients other than what happened to them. Indeed, 10,000 such case reports, although providing much greater detail of possible results, would give us no greater insight into predicting whether the operation is more likely than nonsurgical treatment to increase survival and decrease symptoms for a particular patient or group of patients.

To pass judgment on the relative benefits and risks of coronary artery surgery based on these three anecdotes would be absurd. What about a judgment based on 10,000 anecdotes? Is that equally absurd or less so? Anecdotal knowledge of the results of 10,000 coronary artery operations would give us precise knowledge of what happened to those 10,000 patients but would tell us nothing about whether this form of treatment was, overall, beneficial for those patients, compared to how they would have fared had they not been operated on. By the standards of scientific measurement and medical history, evaluations of therapy based on anecdotal experience are of no real value. Yet 99% or more of our knowledge of the effects of coronary artery surgery is derived from anecdotal experience. Is it proper, in a scientific world, to base treatment on such evidence?

Coronary artery disease is a major cause of suffering and disability and the leading cause of death of adults over the age of 40 in the Western world.[1,2] In the United States in 1973, cardiovascular diseases accounted for 54% of all deaths in the country, and ischemic heart disease was responsible for 64% of the cardiovascular deaths, or 35% of all deaths in people of all ages.[3] Ischemic heart disease (coronary artery disease) is the leading cause of death in men after the age of 35 and in all persons after the age of 45, accounting for 684,000 deaths in the United States in 1973. The coronary artery disease death rate for the United States is approximately 3.5 per 100 per year for men between the ages of 45 and 54, a figure exceeded only in Finland. Coronary artery disease is newly recognized in 1 out of 100 white males of all ages every year. The prevalence of coronary artery disease was 3,990,000 in the United States in 1973, or approximately 2% of the total population.[3] In a study of a community of 30,000 in which necropsies were obtained for 67% of all patients over 20 years old

who died, coronary artery disease was the cause of death in 41% of men and in 22% of women. Moreover, 74% of the adult population had from 25% to complete occlusion of one or more major coronary arteries.[4]

The problem of coronary artery disease is unquestionably widespread in the Western world. With a prevalence of about 4,000,000 persons in the United States with clinical coronary artery disease (a history of heart attack and/or angina pectoris), the number of operations now being performed is probably limited by the present capacity for diagnostic evaluation and operation. Those with subclinical or unapparent anatomical coronary artery disease are in the order of 10 times more prevalent than those with clinical disease. The numbers of patients who are potential candidates for coronary artery surgery are staggering, but such are the possibilities for the operation.

The coronary artery bypass operation is physiologically sound on the basis of delivering more blood to the ischemic myocardium. The only known physiologic cause of angina is ischemia, and almost all patients with angina have demonstrable anatomic coronary artery disease. Bypassing stenotic or occluded coronary artery lesions theoretically restores normal blood flow to previously ischemic areas of the myocardium. The physiologic premise of the operation is that restoration of normal coronary arterial blood flow eliminates ischemia, thus alleviating symptoms and protecting against myocardial infarction and possibly death.

The operability of coronary artery disease can be evaluated only with coronary angiography for assessment of coronary artery obstructions and left ventriculography and hemodynamic measurements for assessment of left ventricular function. The typical cardiac catheterization for workup of coronary artery disease takes 1 to 2 hours, and requires introduction of catheters through either the brachial or the femoral artery. Complications are discussed in Chapter 3.

The operation for coronary artery disease entails introduction of one or more grafts connecting the aorta to points distal to obstructions of the coronary arteries. In the operation most commonly employed, the grafts are saphenous veins taken from the

patient's leg, or legs, requiring additional incisions in one or both legs. The saphenous vein is cut into appropriate lengths and ends sutured to the ascending aorta and the recipient coronary artery, allowing blood flow from aorta to coronary artery beyond the obstruction. Less commonly, the graft is the internal mammary artery. This artery is dissected free from the chest wall, and the cut end is anastomosed to the coronary artery. The operation requires endotracheal intubation, the insertion of chest tubes for postoperative drainage, artificial ventilation after the operation, and continuous electrocardiographic monitoring. Patients usually remain in a postoperative intensive care setting for 1 to 3 days. Possible complications of the operation include incisional pain, pneumonia, pulmonary embolism, pericarditis, wound infection, cardiac conduction defects, leg swelling or infection, psychotic reactions, myocardial infarction, and, occasionally, death.

The present operation, aortocoronary artery bypass grafting, may well be the greatest step forward in the history of coronary artery disease, but doubts remain. Physicians commonly use this operation for relief of a patient with angina pectoris, so the procedure is practically universally accepted in this country and in great demand by patients. It seems imperative to look more critically at the operation, its results, and the factors that led to its widespread use so that all concerned may have a rational and scientific basis for it.

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2

Historical Development of Operations for Coronary Artery Disease

The first known proposal for an operation aimed at coronary artery disease was made in 1899 by Francois-Franck,[1] who proposed sympathectomy as a surgical treatment for angina pectoris. The first actual clinical operation was in 1916 in Bucharest, by Jonnesco,[2] who performed bilateral extirpation of the cervical sympathetic chain and removal of both first dorsal ganglia. The object of the operation was to cut the nerve fibers that transmit afferent signals from the source of the pain, and Jonnesco's operation apparently was successful, as his patient had marked relief of chest pain. From that historic operation there ensued a great many operative variations. However, each operation had the common purpose of relieving the pain of angina pectoris by cardiac denervation. The proliferation of procedures over the next decade led Cutler[3] in 1927 to complain of "the tangled mess of operative procedures" which made it difficult to evaluate the effect of any given procedure. Cutler reported on 50 patients who had a denervation procedure of some sort, with four operative deaths, or an operative mortality of 8%. Of the 46 survivors, 35 were improved (27 had a "good" result, 8 were improved), 7 had no relief, and 4 were listed as questionable. Therefore 76% were improved after the operation, and if one adds the questionables the figure rises to 85%. Nevertheless, results varied from procedure to procedure, and Cutler concluded that "we have not yet found the proper connections between the heart and the central nervous system."

Over the next two decades, further operations were designed to produce cardiac denervations, including sectioning of the aortic

plexus, posterior rhizotomy, and pericoronary neurectomy. It was noted that operative mortality increased with the more difficult and prolonged procedures, whereas the simpler procedures had an acceptably low mortality rate. In 1950 Lindgren[4] in Sweden reported on 105 patients having thoracic sympathectomies, 9 of whom died during or shortly after the operation. The survivors reported that alleviation of pain referred to the arms was "practically 100%," whereas precordial pain "was abolished or considerably diminished in 80%." Complications vitiating the favorable effect were postoperative neuralgia, increased cardiac decompensation, and spreading radiation of pain to the neck and jaw, lower chest, and abdomen.

White, Smithwick, and Simeone,[5] writing in 1952, reported a further 159 patients treated with excision of the upper thoracic ganglia. All cases were severe, few were able to perform any kind of work, and 22 had pain at rest. After operative deaths (17%), approximately one-third were entirely pain-free, a further one-half were improved (about 83% pain-free or improved), and one-sixth were no better.

Cardiac denervation persisted into the 1960s until it slowly faded from a lack of enthusiasm and the competition of newer procedures. Commenting on the decline of this type of operation, Harken et al.[6] in 1955 stated, "Although control of pain by this means is at times dramatic, it is not consistent. Furthermore, in our experience the late mortality of 50% in a 2 1/2 year period after operation suggests that the progress of the primary disease had not been significantly altered." Then in 1958 Harken and coworkers[7] stated that "denervation has been largely abandoned because equally safe operations have been devised, which are just as effective in pain relief, and, in addition, provide at least a theoretical opportunity for increase in the blood supply to the myocardium." Nevertheless, the experience of these operations showed that all painful impulses from the heart eventually pass through the upper four or five thoracic ganglia, their rami communicantes, and the corresponding thoracic posterior spinal nerve roots. Accordingly, in 1963 Palumbo and LuLu[8] reported a more radical procedure to excise the sympathetic chain from the

first to the fifth ganglia, with division of their rami. They had no operative deaths, and of 18 patients with angina, half had "marked or complete" relief of pain, and the other half had "definite benefit."

It is interesting to note that this type of operation was not abandoned on the grounds of ineffectuality in relief of pain, but because of complications and the opinion, fast growing in the 1950s, that coronary artery surgery should be physiologic, i.e., the operation should increase the blood supply to the myocardium. In all, the various cardiac denervation procedures were carried on for about 50 years and perhaps longer before quietly yielding to more advanced procedures. The total number of such operations performed is almost impossible to estimate, but was probably in the order of 1,000 to 3,000, with an average mortality of approximately 10%.

Claude S. Beck, a surgeon from Cleveland, pioneered the next phase of coronary artery surgery, which in general was an attempt to increase and/or redistribute the myocardial blood supply. As long before as 1880, Langer[9] in Vienna gave evidence that the coronary circulation has definite extracardiac anastomoses because of vascular ramifications from the pericardium, bronchi, and diaphragm. Moritz and co-workers[10] in 1932 noted from autopsies that there was a significant increase in extracardiac anastomoses when death was caused by pericarditis. They also noted blood vessels in the fat at the base of the heart anastomosing the coronary system with branches from the aorta. Beck[11] also had an experience during an operation of cutting a band of adhesions compressing the heart, and "found that each end of the transected adhesion bled briskly." He concluded, "This is the first observation that such bands of adhesions can, and actually do, transport blood to the human pulsating heart."

This led to Beck's work which was based ultimately on thousands of animal experiments. Beck showed that artificially creating inflammation of the epicardium resulted in the development of anastomotic blood channels that could supply blood from surrounding tissue to the epicardium, or surface of the heart. He furthermore reasoned that if a more vascular structure were