DEVELOPMENTS IN CARDIAC surgery over the last 30 years have made consideration of surgical treatment part of the evaluation of most patients with heart disease. Naturally, surgery's most active proponents and innovators have been, in general, surgeons. Nonsurgeons frequently have been passively skeptical concerning these new forms of treatment, and occasionally have been actively resistant to them. Interestingly, surgeons who have developed new operations have sometimes themselves later become skeptical about even newer procedures which threaten to make their procedure obsolete.1 The proponents and the skeptics of new operations have interacted in such a way that on occasion each has used techniques of persuasion that pass the bounds of scientific medicine. We must be cautious in criticizing these events too severely, for the world of cardiac medicine and surgery in our lifetimes has been interesting and highly productive. But from time to time we do need to review the rational process of evaluating the results of cardiac operations. Dramatic and sensational as some of the surgical advances have been, these characteristics are not useful in establishing their place in the therapeutic armamentarium.

Physicians and surgeons are cognizant of the importance to the individual patient of their direct patient care efforts. They work seriously and energetically with their patients, fully aware that death or disability lurks, ready to capitalize on their mistakes. When they embark upon an intervention for their patient, they must do so with confidence and conviction if there is to be a high probability of success. But these very considerations can make the doctor guilty of premature conviction in evaluating procedures such as cardiac surgery unless he addresses this evaluation with the same seriousness and skill he uses in treating individual patients. The effect on one's own patient of poor decision-making and unskillful intervention is usually very evident. The effect of an inaccurate evaluation of a cardiac surgical procedure on large numbers of unseen patients (unseen because they are under the care of other doctors) may not be so apparent.

In order to illustrate some ways of evaluating cardiac surgical procedures, the rest of this discussion will be concerned with two conditions: coronary arterial disease with unstable or preinfarctional angina, and double outlet right ventricle. The evaluation process must be rather different for each—one being a common condition and the other, relatively rare.

Unstable (Preinfarctional) Angina

In the last few years, a number of groups have reported their experience with emergency saphenous vein bypass grafting as treatment for unstable or preinfarctional angina pectoris. One report suggested that the preinfarction syndrome may present a major indication for coronary revascularization.2 Another states that aortocoronary bypass grafting prevents infarction in "selected cases" with preinfarction angina.3 A third paper states that patients in this category can undergo operation...
with a low mortality rate and that the operation can prevent myocardial infarction. 

These and other recent papers have stimulated considerable discussion between cardiologists and cardiovascular surgeons. Many cardiologists, remembering patients of their own with this syndrome who had done well on medical management, have been opposed to operating. Many surgeons, suspecting that these patients could be operated upon with good results, have favored operation. One hopes and believes that both cardiologists and surgeons proceeded in their evaluation of this surgical procedure in a similar way.

**Evaluation of Surgical Results**

**Definition of Patient Population**

We must start the evaluation by defining the patient population being discussed. Variability in the results of treatment of any clinical syndrome can of course result from varying criteria for defining the syndrome and thus for including patients within the treatment program. This has been a source of difficulty in evaluating the results of treatment of unstable or preinfarctional angina. This general problem has been discussed extensively by many, and we shall not dwell upon it further.

**Mortality Rate**

The evaluation of any surgical procedure must include a consideration of the risk of operation, as reflected in the hospital mortality rates. Interpretation of these mortality rates depends upon precise knowledge of the population treated, the techniques used in the operating room, and the postoperative care.

Favaloro et al. stated that the mortality rate for coronary bypass grafting in patients with preinfarctional angina was "low." Yet their data indicate a statistically significant difference in the hospital mortality rate for patients operated on for unstable angina as compared with those with angina pectoris.

However, the number of cases evaluated is small. One must also consider, on theoretical grounds, whether the risk of operation in patients with unstable or preinfarctional angina, rigorously defined, would be expected to be as low as when the procedure is done for ordinary angina pectoris. The evidence available at present suggests that a greater degree of myocardial ischemia is present in patients with preinfarctional angina than in those with ordinary angina pectoris, and that small scattered areas of necrosis develop in some patients with preinfarctional angina. On the basis of this, one can speculate that in a large series the hospital mortality rate for coronary bypass grafting during the state of unstable, preinfarctional angina will be somewhat higher than that done for ordinary angina pectoris. We shall assign a risk of 4%, without any way of knowing at this time that it is a correct one.

A requisite for saphenous vein bypass grafting is coronary arteriography, which also may contribute to hospital mortality rates. An analysis of the risk of this diagnostic procedure in patients with preinfarctional angina will not be undertaken here, but we shall assume it is less than 1%.

One of Favaloro's 16 hospital survivors developed nonfatal myocardial infarction during the early postoperative period. However, too few patients with unstable angina had been submitted to operation to allow any conclusions about the incidence of postoperative, nonfatal myocardial infarction. In coronary bypass grafting in general, this complication has occurred in about 10% of surviving patients and one can assume for the moment that it will occur in about this incidence in patients being operated upon for preinfarctional angina.

Few data are available at this point on late postoperative mortality in this group of patients. We shall assume it to be about 10% over a two year follow-up period.

**Late Morbidity and Functional Results**

Five of Favaloro's patients were restudied two to four months after operation, and in all, the grafts were patent. In general, about 80% of patients have patency of all their saphenous vein bypass grafts and thus the potential for benefit when studied up to two years after coronary bypass grafting, and one can assume for the moment that this same figure will pertain for those with preinfarctional angina. The incidence of nonfatal myocardial infarction which occurs in the years after operation is unknown.

The information with which we must presently evaluate saphenous vein bypass grafting for preinfarctional angina pectoris can now be summarized (table 1).

**Comparison with Medical Treatment**

The natural history of patients with unstable angina really is not known, and probably will not be known since at present no patient with preinfarctional angina pectoris can be allowed to go completely untreated. An analysis of the results of
Surviving after hospitalization.

Entering hospital
Surviving after arteriography
Surviving after operation
Surviving hospitalization
Surviving hospitalization without myocardial infarction
Surviving late without subsequent infarction
Surviving late with no or mild angina

*Follow-up = 24 months.

medical treatment should be possible. However, we shall see that study of the available data discloses as many questions here as in the area of surgical treatment.

The report of Nichol, Phillips, and Casten in 1959 contains interesting statements and data. They say that "comparable controls are not provided in this study, but the prophylactic benefit of prompt heparin therapy followed by oral anticoagulant therapy in patients showing signs of threatened myocardial infarction appears to be clearly demonstrated. ..."

Paul Wood reported on 150 patients with the syndrome of preinfarctional angina seen over a period of ten years. None had coronary arteriograms. Fifty patients were treated without anticoagulants and 100 with anticoagulants. Some effort was made at randomization early in the series. His data are shown in table 2.

Krauss, Hutter, and DeSanctis recently reviewed retrospectively a group of 100 patients with a diagnosis of acute coronary insufficiency or preinfarctional angina treated medically in their Coronary Care Unit. They acknowledge the obvious flaw in their study, which also existed in the ones discussed previously, namely that coronary arteriograms were not made on most of the patients. The patients' course in the hospital was surprisingly benign; only one died in the hospital and six suffered nonfatal myocardial infarctions. However, 22% of the patients died during the posthospitalization period, with a follow-up between 23 days and three years, seven months (average follow-up period was 20 months).

A further complexity in evaluating treatment of patients with preinfarctional angina becomes apparent from their study. Subgroups exist within this group of patients with preinfarctional angina. That subgroup with deterioration of condition reflected by chronic angina was found to have a much worse prognosis with medical treatment than the patients with "new" ischemic pain. In fact, many subgroups must exist within the group of patients said to have unstable or preinfarctional angina, no matter how one defines this group of patients. As an example, Smullens et al. found six of ten patients with unstable or preinfarctional angina to have a positive coronary sinus CK efflux without abnormal levels of the enzyme in peripheral blood. Presumably their patients were in at least two subgroups; those without myocardial necrosis and those with at least some small areas of necrosis.

Fulton et al. in Edinburgh are carrying out a prospective study of the natural history of patients with unstable or preinfarctional angina. An important fact emerging from their study is that "of the 85% of patients who did not develop myocardial infarction or die, the symptoms of unstable angina lessened or disappeared in 50% when assessed at three months. ..."

Admitting the incompleteness of the data, we must now try to summarize something about the course of patients with unstable angina treated medically with or without anticoagulants and compare it with that for coronary bypass grafting (table 1).

The truth is that a definitive evaluation of surgical as compared to medical treatment for unstable or preinfarctional angina pectoris has not been made. This indicates the moral and scientific propriety of a proper prospective randomized study of the subject. Noble Fowler and others have already commented upon the urgent need for the use of this technique in evaluating the results of cardiac surgery for this condition. Surgeons have
on occasion used the technique of prospective randomization to solve similar problems with great success, one of the most notable instances being the study by Goligher and his colleagues of the long term results of the three standard operations for duodenal ulcer.11 Fortunately, the Myocardial Infarction Research Units supported by the National Heart and Lung Institute have already initiated a proper prospective randomized study of surgical treatment for unstable or preinfarctional angina. During the several years that will be required for the study, many patients will, of course, be treated medically or surgically outside the study. Hopefully, in these patients as well, the criteria for identifying the clinical syndrome of unstable or preinfarction angina will be rigid, subgroups will be identified, treatment will be clearly defined, and early and late results tabulated with precision. In this way additional useful information will accumulate.

In the meantime, while advising and treating our individual patients in an incisive manner, we must avoid premature conviction as to the optimal treatment of unstable angina pectoris until more complete information becomes available.

**Double Outlet Right Ventricle**

The techniques of prospective randomization are, however, not a panacea for solving all the unanswered problems of cardiac surgery. The evaluation of operations for many cardiovascular problems must proceed somewhat differently, and as an example, the surgical treatment of a specific uncommon congenital malformation, double outlet right ventricle, is of interest.

In beginning the evaluation of an operation, one turns to reports containing a significant amount of useful information. We shall analyze and evaluate one of these, the important paper by Gomes et al.12 It reports results of surgical intervention in 18 patients with double outlet right ventricle. While truly admiring and respecting the authors, we do need to analyze their report in some detail. They state that "the present study reports data on all patients with double-outlet right ventricle without pulmonic stenosis who were

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**Figure 1**

Anatomic specimen of double outlet right ventricle with subaortic ventricular septal defect. The right ventricle has been opened widely. Aorta is to the right (d-position). The subaortic conus (to the left) is related to the ventricular septal defect (in the center). The pulmonary valve cusps lie above a sub-pulmonary conus.
operated on,” yet only those with a selected type of this malformation are included. Also, only one surgical technique is discussed in the paper, namely the realignment of the ventricular outflow tract by creating an intraventricular tunnel.\textsuperscript{13, 14} No mention is made of the fact that the great variability of the malformation of double outlet right ventricle necessitates the use of different techniques in some patients. Comments in this paper concerning the optimal age for operation may not have taken cognizance of the natural history of the malformation.

In fact, the paper appears to describe the results for a selected group of patients. Most of them had already survived by natural selection to five or more years of age. Patients who had already developed severe pulmonary vascular disease were quite properly excluded from the surgical series. The patients all appear to have one subtype of double outlet right ventricle, namely that characterized by concordant relation between the atria and ventricle, d-position of the great arteries, and subaortic ventricular septal defect (fig. 1).

The true complexity of the entity of double outlet right ventricle is evident from the papers of Neufeld et al.\textsuperscript{15, 16} Lev et al.\textsuperscript{17} Van Praagh\textsuperscript{18} Hallermann et al.,\textsuperscript{19} Kiser et al.,\textsuperscript{20} Pacifico and Kirklin,\textsuperscript{21} and others. A discussion of surgical

\textbf{Figure 2}

\textit{Repair of double outlet right ventricle with subaortic ventricular septal defect is accomplished by creating an intraventricular conduit which a) conducts left ventricular blood to the aorta and over which b) right ventricular blood passes to pulmonary artery. The anterior part of the conduit is molded knitted Dacron, and the posterior part is the cardiac tissue. (Reproduced with permission from J W Kirklin, R A Harp, D C McGoon: Surgical treatment of origin of both vessels from right ventricle, including cases of pulmonary stenosis. J Thorac Cardiovasc Surg 48: 1026, 1964)}
EVALUATING CARDIAC SURGERY

Table 3

Surgical Categorization of Double Outlet Right Ventricle

<table>
<thead>
<tr>
<th>Concordant relation of atria and ventricles</th>
<th>d-position of great arteries</th>
</tr>
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<tbody>
<tr>
<td>d-position of great arteries</td>
<td>subaortic VSD</td>
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<tr>
<td></td>
<td>subpulmonary VSD</td>
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<td></td>
<td>noncommitted VSD</td>
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<td>doubly committed VSD</td>
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<td></td>
<td>l-position of great arteries</td>
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<tr>
<td>Discordant relation of atria and ventricles</td>
<td>l-position of great arteries</td>
</tr>
<tr>
<td></td>
<td>d-position of great arteries</td>
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</tbody>
</table>

VSD = ventricular septal defect.

treatment should take into account this complexity (table 3) and that of the various surgical maneuvers required.

Realignment of the ventricular outflow tracts so that a normal series-type circulation results is the operation usually performed for the commonest type of double outlet right ventricle (fig. 2), the one referred to by Gomes and colleagues. However, the appropriate procedure may be different for different individuals in the same subgroup of double outlet right ventricle, and is very different for the different subgroups. The correct procedure often can be determined only at operation after study of the precise spatial relations between the semilunar valves, the ventricular septal defect, and the atroventricular valves.

Gomes et al. have implied that the ideal age for definitive operation in patients with double outlet right ventricle is four to seven years, and that a few patients may require pulmonary arterial banding as a preliminary palliative procedure in infancy. Yet the natural history of these patients, all of whom have severe pulmonary hypertension from infancy, is probably at least as unfavorable as that of patients with simple large ventricular septal defects. Clearly some untreated patients with double outlet right ventricle die in infancy of congestive heart failure. Some have developed such severe pulmonary vascular disease by two years of age that successful operation is no longer possible. Some that have successful operation at four to seven years of age already have moderate or severe pulmonary vascular disease, and according to Gomes’ report 36% of the patients died late postoperatively, usually from progression of the pulmonary vascular disease. Considering all these facts, an alternative opinion could be entertained, namely, that patients with double outlet right ventricle without pulmonary stenosis should receive definitive intracardiac repair before the age of two years, and that those developing chronic heart failure or evidence of increasing pulmonary vascular resistance should have definitive repair whenever this occurs, which may be in the early months of life. Our experience to date with definitive management of these lesions in infancy supports this opinion. Continuing precise evaluation of results will be required to settle these points.

Discussion

The tedious and time-consuming evaluations that we have made of these two conditions, unstable angina pectoris and double outlet right ventricle, are really quite incomplete. Hopefully they do illustrate that a variety of techniques of evaluating the results of cardiac surgery must be used. If we are to provide the best possible care for all patients coming to us with heart disease now and in the future, we must do many things, including the continual evaluation of the results of our cardiac operations and a comparison of these results with those of other patient management programs and with the natural history of the disease. Such is a part of the science of surgery.

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