Selection of patients for cardiac transplantation


SELECTION of recipients for cardiac transplantation may be the most important factor in determining long-term survival, yet it remains difficult and controversial nearly 20 years after the first human heart transplant. Deciding who should have a cardiac transplant and when it should be done may be obvious decisions in very ill patients. But more commonly this decision requires the physician to use knowledge of prognosis and treatment of end-stage heart disease and on the state of the art of cardiac transplantation as well as considerable clinical judgment. Selection of patients who are “too sick” for cardiac transplantation is a disservice to the patient and may waste a donor heart. Similarly, selection of patients who are not sick enough may result in the premature death of a “successful” recipient. The current selection process, a combination of empirically derived contraindications with limited natural history data and considerable common sense, is a complex but absolutely necessary part of modern heart transplantation. Also, nonmedical selection criteria are important. In many cases, major financial limitations prevent transplantation and in some cases determine the immunosuppressive regimen, excluding expensive modern therapy.

In the late 1960s and early 1970s, a patient was accepted for cardiac transplantation only if he faced death within a matter of weeks. Since then, a generally accepted set of selection criteria evolved in the mid 1970s specifying functional class, age, absence of pulmonary hypertension, and absence of a variety of systemic diseases.\(^1,2\) Now, in the mid 1980s, we are experiencing a broadening of selection criteria with considerable institutional variation and controversy over age, functional status, which systemic illnesses should be limiting, and the priority of patients on mechanical support.

**Indications for heart transplantation.** End-stage heart disease may result from a diverse group of pathophysiologic processes, including congenital and acquired valvular disease, myocarditis, coronary artery disease, pericardial disease and cardiomyopathy.\(^3\) In our own experience with 102 recipients, ischemic cardiomyopathy and idiopathic cardiomyopathy have each accounted for 45% of etiologic diagnoses in recipients. Less common causes of end-stage heart disease have been documented viral myocarditis, postviral myocardopathy, postpartum cardiomyopathy, congenital malformations with associated myopathy, and postoperative heart failure. Other programs\(^4-7\) have had slightly different percentages of etiologies. According to the registry of the International Society for Heart Transplantation (ISHT), which reports on 2577 heart transplants from 1967 through 1985,\(^8\) worldwide etiologic categories by percentage were: cardiomyopathy 51%, coronary artery disease 40%, congenital heart disease 2%, and graft rejection 1%. Actuarial survivals after transplantation based on etiology were: cardiomyopathy 72% 1 year, 67% 5 years; coronary artery disease 70% 1 year, 63% 5 years; congenital heart disease 64% 1 year, 62% 5 years; and graft rejection 47% 1 year, 47% 5 years.

Limited prognosis is the common characteristic among all etiologic groups being considered for heart transplantation. When the prognosticated survival curve for any individual drops below expected survival with cardiac transplantation, that person may reasonably be expected to have a longer life with transplantation. Any surgical intervention besides transplantation with a reasonable chance of improving the patient’s condition should be favored before transplantation is considered.

Once “conventional” approaches have been eliminated, two major problems arise in making these clinical assessments. First is the difficult problem of predicting the future for patients with end-stage heart disease, and second, but fortunately much more secure than in previous years, is estimation of the chance of survival with cardiac transplantation.

In our experience, evaluation of rate of clinical de-
cline, response to medical therapy, and risk of death in
the ambulatory class III or IV patient is best made by a
cardiologist or cardiac surgeon who has been intimate-
ly involved in caring for the patient over a period of
time. Clearly this person has the best feeling for rate of
decline and perhaps the best intuition for when a major
clinical change may occur.

Objective evidence is critical to the evaluation. Ma-
jor clinical events in the patient’s course such as sud-
den death episodes, recurrent hospital admissions for
congestive heart failure, and decompensation in face
of minor viral illnesses are strongly in favor of pro-
ceeding to transplantation as are severe symptoms,
marked disability, chronic hypotension, declining
renal and hepatic function, and a tendency toward car-
diac cachexia.

Noninvasively obtained information, including
findings from physical examination indicating low car-
diac output, cardiac failure, atrial and ventricular ar-
rythmias, muscle wasting, cardiac enlargement, pul-
monary edema and/or effusions, hepatomegaly, pedal
edema, etc., is helpful and particularly important in
the patient who is on “maximal medical therapy” with
digoxin, furosemide, and afterload reduction with
agents such as hydralazine or captopril.

Laboratory tests indicating prerenal azotemia, hypo-
natremia, hyperproteineemia, and hyperbilirubinemia
are standard in this group, and cardiac function testing
is markedly abnormal. In our last 30 consecutive pa-
tients, the mean ejection fraction, measured by ventri-
culogram or nuclear study, was 16.5% with a range of
5% to 28%. The mean left ventricular filling pressure
was 20 mm Hg (range 4 to 42). It is known in dilated
cardiomyopathy that an ejection fraction of less than
20% is associated with a negligible 2 year survival.9 A
left ventricular end-diastolic pressure of greater than
20 mm Hg is associated with a 50% 2 year mortality in
this group. Mortality may be higher in patients with
ischemic myopathy.10

No precise formula for combining all of these facts
into a prognostic index or projected survival curve
exists (see table 1). Therefore, in the end a judgment
must be made. Critical to this is a knowledge of what
expectations for survival and quality of life exist for
the patient with cardiac transplantation.

Cardiac transplantation survival rates have im-
proved dramatically since the late 1960’s, when 20% 1
year survival was the best available. Adherence to
selection criteria, results of the cardiac biopsy, im-
proved treatment of infectious complications, and the
use of cyclosporine have contributed to current surviv-
al rates, which in major institutions are in the range of
80% to 85% at 1 year and 50% to 70% at 5 years.*
Improvement in immunosuppressive techniques and
monitoring for rejection as well as the introduction
of new antiviral agents may lead to even better statistics.
In our own program, in the last 30 consecutive patients
starting in June 1985, there has been only one death.
Cardiac transplantation now offers a better chance of
survival than conventional surgical procedures per-
formed on “high-risk” patients.
The registry of the ISHT has documented a signifi-
cant improvement in actuarial survival worldwide
since the addition of cyclosporine to immunosuppres-
sive protocols, with 1 year survival jumping from 65%
to 78%. It also reveals that over 50% of the 2577
registered transplants were done in the past 2 years.
Thus much of the data from the last decade that we
currently rely on for decision making have been pro-
duced in established programs. Much of the data that
are forthcoming will be from new programs. The cur-
tent level of enthusiasm in new programs must be
viewed with some caution, since the track record of
one program may not be the same as that of another and
the level of expertise and commitment may vary.

The landmark declaration this year by the U.S. De-
partment of Health and Human Services that cardiac
transplantation is no longer considered experimental
responds to the excellent results of the cyclosporine
era. But criteria used to determine which centers will
be approved by HHS for cardiac transplantation in
Medicare patients will undoubtedly be selective and
require experience and good results.

Quality of life is another consideration in patients
with end-stage heart disease, and survival alone is an
inadequate measure of the condition of cardiac recipi-
ents. Rehabilitation of cardiac recipients in 90% of
survivors at 1 year has been possible for over a deca-
de.11 In our program, over 95% of 3 month survivors
have attained NYHA functional class I. Several have
made outstanding physical achievements such as run-
ning 10 kilometer races and triathlons, parasailing,
and racing thoroughbred horses. All survivors have
achieved a level of comfort and quality of life superior
to their pretransplant condition.

In summary, the indications for cardiac transplan-
tation are not clear in all cases, but survival and quality
of life after transplantation are well documented. Se-
lection of the candidate who may be expected to derive
benefit from transplant is to a large extent a function of
clinical judgment and use of prognostic indicators (ta-
ble 1) and contraindications as guides. Contraindia-

*Poster sessions: ISHT Meeting, April 1986.
TABLE 1
Poor prognostic factors in cardiomyopathy

<table>
<thead>
<tr>
<th>Factor</th>
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<tbody>
<tr>
<td>Age &gt; 50 yr</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Cardiomegaly</td>
</tr>
<tr>
<td>Cardiac index &lt; 2.5 l/min/m²</td>
</tr>
<tr>
<td>LVEDP &gt; 20 mm Hg</td>
</tr>
<tr>
<td>Ejection fraction &lt; 0.2</td>
</tr>
<tr>
<td>Arrhythmias, atrial and/or ventricular</td>
</tr>
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</table>

LVEDP = left ventricular end-diastolic pressure.

tions to transplantation have been defined empirically over time and constitute the most important selection criteria.

**Contraindications to cardiac transplantation.** Since 1983, when cyclosporine became widely available to cardiac transplant programs, a relaxation in selection criteria has been evident. Most notably, younger and older patients and insulin-requiring diabetics have become recipients in increasing numbers. As multidrug therapy with lower doses of cyclosporine becomes more popular, it is likely that further broadening of indications will include healthier and sicker patients, patients with “cured” malignancies, and selected patients with histories of systemic or organ-specific diseases such as mild systemic lupus erythematosus and moderately severe chronic obstructive pulmonary disease. We are already seeing trends toward relaxed criteria, particularly in the area of mechanical interim support or “bridge to transplantation,” where the numbers of attempts with ventricular assist devices and total artificial hearts has been growing exponentially with surprisingly good results.

Criteria for selection taken from the Federal Register (1981), which reflect the pre-cyclosporine era, are shown in Table 2. These are contrasted with our current criteria in the same table and covered individually in the following discussion.

**Age.** The age restrictions for cardiac transplantation stem from the early experience at Stanford, indicating a significant decrease in actuarial survival of patients over the age of 50. In recent years, even before cyclosporine became available, our experience with carefully selected patients over the age of 50 and even 55 has failed to show decreased survival.

Since cyclosporine became available, we have in some instances performed transplants in patients over 55 (our oldest was 65) with satisfactory survival. The experience of other programs has been similarly encouraging (Frazier OW, Cooley DA: personal communication). The population of patients with ischemic heart disease who are in their 50’s and 60’s, accounting for a major portion of deaths from myocardial infarction, may in the next decade become the most common source of potential recipients.

The physiologic age and condition of the patient must always be carefully scrutinized, but absolute chronologic limitations are no longer applicable. The likelihood that a patient over age 50 or 55 may be a recipient decreases as age increases and in 1986 reaches zero at age 67, the oldest of recent recipients.

A trend in the other direction, with an increasing number of recipients 2 to 12 years old, has also occurred in the past few years. A few infants with hypoplastic left heart syndrome (Bailey L: personal communication) have also received transplants. All immunosuppressive protocols for heart transplantation in the pre-cyclosporine era had steroids as a major component and consequently inhibited growth in children. This plus the inevitable complications, the waxing and waning course, and the necessity for serial invasive and painful diagnostic techniques (heart biopsy) and therapy (antibiotics, antithymocyte globulin) constituted relative contraindications to heart transplantation in children. With the combination of cyclosporine plus azathioprine and minimal or no steroid therapy, inhibition of growth is no longer a consideration. Furthermore, the current postoperative course is characterized by more stability and fewer severe complications and thus is less threatening to the child and his parents.

**Pulmonary hypertension.** Fixed pulmonary resistance remains a major contraindication to orthotopic cardiac transplantation. We have included patients with calculated (mean artery pulmonary [mm Hg] – mean pulmonary artery wedge [mm Hg]/cardiac output [liters/min]) pulmonary vascular resistance of less than 8 Wood units. Attempts to demonstrate reduction in pulmonary vascular resistance at cardiac catheterization by administering 100% inspired oxygen or pulmonary vasodilators such as nitroprusside or nitroglycerin may succeed, but this has not correlated with post-transplant survival and is not advised. Rather, patients with PVR pulmonary vascular resistance over 8 Wood units should be excluded from orthotopic transplantation. Whether heterotopic (piggyback) transplantation will benefit such patients has never been demonstrated conclusively.

In patients with pulmonary vascular resistance in the range of 6 to 8 Wood units, the danger of perioperative right heart failure and death may be decreased by “oversizing” the donor heart, which refers to using a
TABLE 2
Contraindications to heart transplantation

<table>
<thead>
<tr>
<th>1981A</th>
<th>1986</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Advancing age — e.g., beyond the age (normally about 50) at which the individual begins to have diminished capacity to withstand postoperative complications</td>
<td>Increased to 55 to 65 depending on “physiologic age” of patient</td>
</tr>
<tr>
<td>2. Severe pulmonary hypertension as reflected, for example, by a pulmonary arterial systolic pressure over 65 to 70 mm Hg and exceeding pulmonary arterial wedge pressure by about 40 mm Hg or more, or a calculated pulmonary vascular resistance above approximately 6 Wood units (applicable to orthotopic cardiac transplantation because of limited work capacity of the normal donor right ventricle)</td>
<td>&lt; 6–8 Wood units</td>
</tr>
<tr>
<td>3. Irreversible and severe hepatic or renal dysfunction (because of likelihood of exacerbation early postoperatively and because of interference with immunosuppressive regimens)</td>
<td>No change</td>
</tr>
<tr>
<td>4. Active systemic infection (because of likelihood of exacerbation with initiation of immunosuppression)</td>
<td>No change</td>
</tr>
<tr>
<td>5. Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation</td>
<td>Less absolute</td>
</tr>
<tr>
<td>6. A history of behavior pattern or psychiatric illness likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day with serious consequences in the event of their interruption or excessive consumption)</td>
<td>Less strict (see text)</td>
</tr>
<tr>
<td>7. Recent and unresolved pulmonary infarction or pulmonary roentgenographic evidence of abnormalities of an unclear etiology (because of the likelihood of pulmonary infection or its exacerbation with initiation of immunosuppression under such circumstances)</td>
<td>In nearly all cases this is just a temporary contraindication</td>
</tr>
<tr>
<td>8. Insulin-requiring diabetes mellitus (because of exacerbation by long-term corticosteroid therapy)</td>
<td>Insulin-requiring diabetes mellitus is no longer a contraindication</td>
</tr>
<tr>
<td>9. Symptomatic or documented severe asymptomatic peripheral or cerebrovascular disease (because of observed accelerated progression in some patients after cardiac transplantation and on long-term corticosteroid treatment)</td>
<td>This remains a relative contraindication and is subject to interpretation and to corrective surgery and reconsideration</td>
</tr>
<tr>
<td>10. Acute peptic ulcer disease (because of the likelihood of early postoperative exacerbation)</td>
<td>Temporary contraindication in most cases</td>
</tr>
<tr>
<td>11. The absence of adequate external psychosocial supports for either short- or long-term bases (because such support is generally necessary during the inevitable waxing and waning of the clinical status of the patient and for adherence to the lifelong medical regimen)</td>
<td>Much less strict (see text)</td>
</tr>
</tbody>
</table>

donor heart from a patient larger than the recipient. This, in combination with postoperative continuous infusion of isoproterenol and prostaglandin E₁, seems to improve early postoperative hemodynamics.

Hepatic and renal dysfunction. Severe dysfunction of either the liver or the kidney remains a contraindication to cardiac transplantation. We have never transplanted a recipient with severe and irreversible preoperative damage to either organ. In our experience, renal failure in the early postoperative period has been fatal in two of three patients. In the experience of others, combined cardiac and renal or hepatic transplantation has rarely succeeded and must be considered experimental.

Cyclosporine is nephrotoxic and is metabolized in the liver. Therefore extreme difficulty in treating patients with hepatic and/or renal failure is even more likely to be encountered than with conventional immunosuppressive therapy.

Active systemic infection. Immunosuppression exacerbates any active infection existing preoperatively. Such an infection, regardless of the cause, may become rapidly fatal in the presence of immunosuppression and therefore must be avoided.

Systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation. This very broad contraindication is obviously subject to interpretation and must therefore be the subject of some controversy. The intention of this contraindication is to provide all-inclusive “coverage” for specific illnesses not mentioned in the specific contraindication such as pulmonary infarction, diabetes mellitus, arteriosclerotic disease, peptic ulcer disease, hepatic and renal dysfunction, as well as infection. The most common category of patient excluded on the basis of this contraindication has been the patient with a history of malignancy. Most often these are patients with “cured” Hodgkin’s disease or lymphoproliferative disease who have, as part of their regimen, received doxorubicin and/or thoracic irradiation. In addition, we have seen a number of patients with a history of other malignancies, most commonly breast cancer without recurrence for 5 to 10 years. At present we have not accepted these patients for transplantation. A case could be made, however, for such acceptance of it were done in the context of a study. Unfortunately, the limiting factor is the lack of donor hearts, which combined with the number of patients without this contraindication generally weighs against such an investigation.

Other conditions that would fall under this category as more clear cut contraindications include the following: severe systemic lupus erythematosus, other systemic collagen disease, cystic fibrosis, Crohn’s disease, and progressive neuromuscular disease associated with cardiomyopathy.

Behavior pattern or psychiatric illness likely to interfere with compliance. Our interpretation of this contraindication has included the following specific categories: active drug addicts (including alcohol), mental retardation, schizophrenia, and severely hostile or uncooperative behavior. We have found acceptable as candidates for heart transplantation reformed alcoholics, individuals who have overcome a drug habit of one kind or another, and individuals who have a history of dealing poorly with authority. In most cases, patients with behavior patterns that deviate somewhat from the mainstream have given us some anxiety in their postoperative period. Yet many of these patients have benefited significantly and survived for extended periods of time. We therefore find it very difficult to exclude patients with any but the most severe abnormalities in this category.

Recent and unresolved pulmonary infarction or roentgenographic abnormalities of an unclear etiology. Historically, pulmonary infarction has been a cause of posttransplantation pulmonary abscess and death. Since pulmonary infarction is a temporary condition, awaiting resolution with scarring has been advised. Other pulmonary roentgenographic abnormalities should be evaluated as vigorously as possible before transplantation and an etiology established. Once this has been done the infectious problems may be treated, the infarctions allowed to heal, and patients with malignancies eliminated as candidates for transplantation.

Insulin-requiring diabetes mellitus. Therapy with cyclosporine and azathioprine in the absence of steroids has been successful (Yacoub M: personal communication), thus allowing cardiac transplants in recipients with diabetes mellitus. Cyclosporine and azathioprine do not exacerbate the diabetes; therefore patients who may be expected to benefit and do have insulin-requiring diabetes are felt to be reasonable candidates. Patients who have severe associated arteriosclerotic disease, small-vessel disease, severe neuropathy, severe retinopathy, chronic infections of the feet, wasting, or extremely brittle diabetes mellitus would probably not be acceptable candidates. In our program, patients on insulin and otherwise in good condition have been accepted and have done well. In general, acceptable candidates would probably include adult onset diabetics but not most juvenile diabetics.

Severe symptomatic or asymptomatic peripheral or cerebrovascular disease. In our series of 102 transplants, we have seen one fatal postoperative cerebrovascular accident. We have not knowingly accepted any candidate
with severe cerebrovascular disease, but we have accepted one patient with a history of aortobifemoral grafting who is now 9 months after transplant and doing well. Our tendency would be to correct any severe disease amenable to conventional vascular surgery before, or, in the case of a patient with very unstable cardiomyopathy but who is otherwise a good candidate, after the transplant. Severe distal vascular bed disease for which no correction is available remains a valid contraindication.

**Acute peptic ulcer disease.** A gastric or duodenal ulcer must be viewed in the immunosuppressed patient not only as a threat for bleeding and for free perforation into the peritoneal cavity but also as a site of entry of certain infections. Commonly, *Candida albicans* and cytomegalic inclusion virus have been found invading gastric or duodenal ulcers. Sepsis in a recipient with ulcer disease should be considered secondary to the ulcer until proved otherwise.

Gastric and duodenal ulceration are fairly common complications in patients with no prior history. Steroids and aspirin in the recipient’s medication predispose to this problem. For this reason, active peptic ulcer disease should be allowed to heal before transplantation. Posttransplant treatment with ranitidine in addition to antacids and close endoscopic follow-up is indicated.

**Absence of adequate external psychosocial support.** Stress, anxiety, fear of death, insecurity, and depression are all common reactions in cardiac recipients and are exacerbated by the inevitable development of one or more postoperative complications. We believe there is less insecurity about sudden death from rejection in the cyclosporine era than in the conventional era. But, we have not yet been able to demonstrate a significant difference in the number of rejections (one per patient) and infections (one per patient) in the first 3 postoperative months in patients treated before 1983 with conventional immunosuppressive drugs and those treated since 1983 with cyclosporine.

A caring supportive spouse and family or friends may help return the patient to a more stable environment, but we have found that the social framework that surrounds the patient is often stressed severely by the procedure. Divorce, problems with role changes, relocation, psychological and financial stresses, impotence and decreased libido, and problems with teenage family members tend to be very common among recipients. The family often comes to the transplant with considerable psychosocial problems and the transplant situation often makes them worse.

Thus the psychosocial support of a patient is a complex problem. Exclusion of patients on psychosocial grounds, except for the most severe of problems, is highly subjective. In our opinion, many strong individuals who have an established record for doing well without outside support or in a stressed psychosocial situation could be excluded. Fifteen of our 102 recipients came from backgrounds without strong psychosocial support systems. In two of these cases death was associated to some degree with failure to adequately cope. In the same group, however, we find many long-term survivors who have cared very well for themselves.

Another problem in the psychosocial area is the patient himself. No matter how much support is present, how intelligent and driven to socially worthwhile goals he may be, he may turn out to cheat himself of the best opportunity for survival. In many cases we have seen denial prevent recipients from self-diagnosis or from seeking proper medical attention. On occasion, such type A individuals have died after denial, having neglected signs of rejection or infection.

**Bridge to transplantation.** Left ventricular assist devices and total artificial hearts have been used for interim support before transplantation in increasing numbers over the past year. Our experience in August 1985 with a 25-year-old man dying of end-stage dilated idiopathic cardiomyopathy was the first successful use of the total artificial heart as a bridge. Nine and one-half days after implantation of the Jarvik-7 our patient received a transplantation and he is now alive and working full-time. A detailed discussion of this complex experimental area is not appropriate here, but it is clear that the major cause of mortality for patients selected as potential cardiac recipients is the waiting period before transplantation. Twenty to 25% of patients are lost during this time. Furthermore, there is no doubt that potential recipients who are dying can be returned to hemodynamic stability with mechanical support. Which of the family of support devices should be used, what indications for implant and transplant are reasonable, and how to incorporate this new technology into an area already plagued by new technology are all questions that need to be addressed formally.

**Donor selection.** The usual criteria for acceptable heart donors are shown in table 3.

Often in the case of distant donor heart procurement, a cardiologist is asked to examine, study with two-dimensional echocardiography, and occasionally catheterize a potential donor. The transplanting team must have a heart that will immediately take over the circulation and often cannot evaluate the donor adequately by telephone. Of greatest importance in evalu-
TABLE 3
Criteria for acceptable heart donors

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>Brain death declared, signed donor consent</td>
</tr>
<tr>
<td>Age male $\geq$ 35, female $\leq$ 45</td>
</tr>
<tr>
<td>ABO blood group compatibility</td>
</tr>
<tr>
<td>Normal heart</td>
</tr>
<tr>
<td>1. History</td>
</tr>
<tr>
<td>2. Examination</td>
</tr>
<tr>
<td>3. Function (maintenance of physiologic blood pressure on reasonable inotropic support)</td>
</tr>
<tr>
<td>Inotropic requirement $&lt; 10 \mu g/kg/min$ dopamine with adequate venous pressure (5–10 cm H$_2$O)</td>
</tr>
<tr>
<td>Absence of</td>
</tr>
<tr>
<td>1. Malignancy (exception cerebral malignancy)</td>
</tr>
<tr>
<td>2. Cardiac trauma</td>
</tr>
<tr>
<td>3. Infection (this is very important)</td>
</tr>
<tr>
<td>4. Q waves on ECG</td>
</tr>
<tr>
<td>Anticipated ischemic time $\leq$ 4 hr</td>
</tr>
</tbody>
</table>

...ation of the donor heart is its current function. Brain death is known to damage the heart, cause electrocardiographic changes, and eventually lead to a decline in hemodynamic function.\textsuperscript{22-24} Distant transport with an obligatory ischemic time of 2 to 3 hours is associated with some irreversible cardiac ultrastructural damage.\textsuperscript{25} Therefore, at the time of evaluation, the heart must have excellent function. Even so, our data\textsuperscript{23} indicate that locally procured hearts (ischemic time 54 ± 3 min) are associated with 85% 4 year survival compared with regionally procured hearts (ischemic time 129 ± 3 min) and distant procurement (ischemic time 172 ± 7 min), which both are associated with 4 year survival of about 40%. Statistically the survival curves were significantly different (p < .05), with an early and consistent separation after 3 months. Unfortunately, local donors are not generally available and most established programs depend on distant procurement.

**Financial limitations.** Financial limitations that were an overwhelming barrier to cardiac transplantation in the late 1960s and early 1970s have become less restrictive as cardiac transplantation has become more widely recognized as a therapeutic procedure. Before the HHS announcement this year that cardiac transplantation is no longer listed as an experimental procedure, the private sector third-party insurers had, for the most part, already arrived at this conclusion. Eighty-five percent of polled private insurers had adopted a policy of paying for cardiac transplantation. Medicare has not yet established a policy and we expect that will take some time. They have announced an intention to publish criteria for the establishment of Medicare heart transplant centers in the Federal Register, to wait for a period of public response, and then to publish a final set of criteria and await applications of various centers. Undoubtedly this will be restrictive to some extent, based on survival statistics and the number of transplants performed in various centers, but even when it is in effect a large number of patients who need transplants will not be covered. The Medicare ruling is not an entitlement ruling; therefore it applies only to Medicare-eligible patients. To obtain Medicare eligibility, a patient must be totally disabled for 29 months. This effectively excludes most patients with cardiomyopathies who might require transplant since their survival curve drops to zero within the first year of being chosen as possible candidates. Although there may be a number of patients who are Medicare-eligible and have cardiomyopathies, during the period of patient accrual for the National Heart Transplant Study, when a total of 15 heart transplants were to be funded by Medicare, over a year passed before that number was found in the entire United States. Thus, although the Medicare ruling sets a precedent for a governmental institution recognizing cardiac transplantation, it fails to cover many patients who do not have financial resources at the present time.

The financial restrictions still remain significant for cardiac transplantation. Each hospital involved in such procedures has its own rules, but typically it is required that prior approval of the procedure be obtained from the insurance company or a deposit of a certain amount of money be made before transplantation. At the University Medical Center in Tucson this deposit is $43,500. The range of down payments extends as high as $125,000 at some institutions in this country.

Medicaid programs in many states cover cardiac transplantation; however, Medicaid restrictions are such that only the very lowest income patients are eligible, leaving a considerable “notch group” with no Medicaid coverage, no Medicare coverage, no financial resources, no insurance through work, and no Veteran Administration benefits. There is little hope that patients in this group can obtain cardiac transplantation at the present time. Solutions to their problem have generally involved fund raising. Approximately 10% of our patients have gone through this means of financially qualifying for cardiac transplantation. Approximately 18% of our patients chosen for transplantation have died while waiting for funds to reach the required level. It thus appears that cardiac transplantation is a procedure for the well-to-do, the very poor, and those who are lucky enough to have a good medical insurance policy through their company or another source. This qualifies as discrimination and raises the question of limits in our society.
Finally, in our program, the cost for one year of cyclosporine therapy is about $4000,\textsuperscript{12} making this drug too expensive for some patients. In one case we have had to resort to conventional immunosuppression to save money. This, plus other postoperative costs such as that of cardiac catheterizations, constitutes a major barrier to optimal long-term care of transplant recipients.

**Summary.** Selection of potential cardiac recipients is not a simple process. Identification of patients who are declining from end-stage cardiac disease and may be expected to die within 12 months or less and deciding which of a number of cardiac invalids are reasonable candidates for cardiac transplantation involves prognostication as well as a working knowledge of the expected benefits and survival rates in cardiac transplantation. Screening by means of the currently accepted contraindications for cardiac transplantation is somewhat more difficult in 1986 than it was 10 years ago when these contraindications were changing less rapidly. However, for optimal use of the limited supply of donor organs and maintenance of reasonable survival rates such screening is absolutely necessary. A second area of restriction that is less approachable by the physician is that of financial limitations. It would appear that the working poor and lower middle class may be deprived of the opportunity for cardiac transplantation much as they are deprived of the opportunity for optimal medical care in our society today.

**References**

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