

Section 10: Surgical Approaches to the Treatment of Heart Failure

Overview

Despite advances in medical management of heart failure (HF), there remain circumstances in which surgical procedures are the only or the best treatment option. Heart transplantation, the longest accepted surgical therapy, and procedures that (1) repair the heart, (2) reshape it, or (3) replace all or part of heart function are considered in this section of the guideline. Myocardial viability and revascularization are addressed in Section 13.

Recommendations

- 10.1 It is recommended that the decision to undertake surgical intervention for severe HF be made in light of functional status and prognosis based on severity of underlying HF and comorbid conditions. Procedures should be done at centers with demonstrable expertise and multidisciplinary medical and surgical teams experienced in the selection, care, and perioperative and long-term management of high risk patients with severe HF. (Strength of Evidence = C)**
- 10.2 Evaluation for heart transplantation is recommended in selected patients with severe HF, debilitating refractory angina, or ventricular arrhythmia that cannot be controlled despite drug, device, or alternative surgical therapy. (Strength of Evidence = B)**

Background

The short- and long-term success of heart transplantation is limited by shortage of donor organs. Only 2163 human heart transplants were performed in the United States in 2008, far below the 20,000 to 30,000 patients per year who could benefit from this therapy. Heart transplantation has demonstrated 1-year, 3-year and 5-year survival rates of 88%, 79% and 72%, respectively.¹ It thus provides a survival benefit in certain well-selected patients with an otherwise poor prognosis of survival at 1 year.²

Consideration of heart transplantation for HF patients should be based on a comprehensive multidisciplinary evaluation of risks. Referral for cardiac transplantation should be entertained for patients with considerable functional limitations from their cardiac disease despite optimal medical therapy.^{3,4} Such patients typically are screened with a cardiopulmonary exercise test. If peak aerobic capacity is severely limited as indicated by a VO_2 max < 14 mL·kg·min or $\leq 55\%$ of predicted for age and gender, transplantation may be considered.^{5,6}

In the presence of obesity, particularly in women, traditional VO_2 max measurements may not stratify risk effectively. In such instances, adjusting VO_2 max for lean body mass may be preferable.⁷ VO_2 max remains predictive of outcomes in patients taking beta blockers⁸ but the level at which the risk-benefit ratio favors transplantation is reduced and appears closer to ≤ 12 mL·kg·min. Patients may undergo transplantation evaluation without formal cardiopulmonary exercise testing when contraindications to maximal exercise exist including refractory debilitating angina or ventricular arrhythmias.

The comprehensive cardiac transplant evaluation is designed to select patients in whom the procedure is likely to improve survival and quality of life while simultaneously identifying medical and psychosocial barriers to successful transplantation.⁴ Thus, no single test can be used to define an appropriate candidate for transplantation. Widely accepted contraindications to cardiac transplantation include diabetes mellitus with widespread microvascular complications, irreversible chronic kidney disease or pulmonary hypertension, or other medical or psychosocial issues that would impact survival.³ Increasingly more complex patients with multiorgan failure present for evaluation of cardiac transplantation. These patients either are deemed “too high risk” or alternatively may be offered multiorgan transplants including heart/kidney, heart/liver and heart/lung. Patients with a recent history of non-skin malignancy have a relative contraindication for heart transplantation, but should be evaluated in collaboration with oncology experts. Patients with a poor prognosis due to prior malignancy should be excluded from cardiac transplantation.⁴

Recommendation

- 10.3 Isolated mitral valve repair or replacement for severe mitral regurgitation secondary to ventricular dilatation in the presence of severe left ventricular (LV) systolic dysfunction is not generally recommended. (Strength of Evidence = C)**

Background

There is little randomized clinical trial evidence to support the benefit of mitral valve repair, and the observational data are limited and conflicting. The pathophysiologic basis of mitral regurgitation results from ventricular dilatation with papillary muscle displacement and tethering of the chordae tendonae and mitral valve leaflets preventing normal coaptation. Papillary muscle ischemia or infarction, rupture of chordae tendonae and mitral leaflet pathology may also contribute to mitral regurgitation. Mitral regurgitation causes chronic volume overload of the left ventricle which worsens the LV dilation and has been associated with higher mortality.⁹ Previous reports of excessive operative mortality with mitral valve replacement in patients with end-stage cardiomyopathy limited enthusiasm for surgical mitral valve correction in patients with severe ventricular dysfunction and mitral regurgitation.

Recent data indicate that mitral valve repair, which preserves the subvalvular apparatus and cardiac function better than mitral valve replacement, can be performed with an acceptable perioperative mortality (<2% at 30 days) and good medium-term survival at highly experienced centers.¹⁰ Mitral valve repair using an “undersized” annuloplasty ring effectively corrects mitral regurgitation,¹¹ improves symptoms and favorably remodels the left ventricle^{12,13} in patients with systolic HF; however, a subsequent small randomized trial indicated no benefit of mitral valve repair in patients with mitral regurgitation because of ventricular dysfunction.¹⁴ Development of risk stratification tools as well as controlled trials and registry data are needed before recommending this technique as an effective alternative to transplantation. A report by Mihaljevic and colleagues showed that over 5 years of follow up mortality in a cohort with ischemic mitral regurgitation was similar after coronary artery bypass graft surgery (CABG) with or without concomitant mitral valve repair.¹⁵ This non-randomized propensity matched cohort did demonstrate improved quality of life in the patients undergoing CABG with mitral valve repair.

Recommendation

10.4 Partial LV resection (“Batista procedure”) is not recommended in nonischemic cardiomyopathy. (Strength of Evidence = B)

Background

There is no compelling evidence demonstrating the benefits of this procedure.¹⁶

Partial left ventriculectomy is associated with significant operative mortality and both short term and long term mortality due to arrhythmias and recurrent severe HF. A randomized trial of this operation has never been completed.

Recommendations

10.5 Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant. (Strength of Evidence = B)

10.6 Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center. (Strength of Evidence = B)

10.7 Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac

transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a “bridge to decision.” These patients should be referred to a center with expertise in the management of patients with advanced HF. (Strength of Evidence = C)

Background

Left ventricular assist devices (LVADs) can restore a normal cardiac output and promote physiologic recovery in patients with end-stage class D HF.¹⁷⁻¹⁹ Mechanical circulatory support has been demonstrated to improve end-organ function in patients failing optimal medical therapy.^{20,21} Resolution of medically refractory pulmonary hypertension^{22,23} and improvements in functional capacity^{24,25} have also been demonstrated.

Several devices have been approved as a means to bridge critically ill patients to transplantation. Implantable first generation LVADs (pulsatile pumps) that are approved for bridge-to-transplantation include the Novacor LVAS (Left Ventricular Assist System), the HeartMate XVE LVAS,²⁶ and the Cardiowest Total Artificial Heart.²⁷ Portable battery-powered devices allow patients to be discharged from the hospital, typically while waiting for heart transplant.²⁸ Development of transcatheter energy sources that allow untethered circulatory support for prolonged periods of time are anticipated to improve quality of life and reduce the risk of infection in LVAD patients.

Newer generation LVADs that provide continuous flow are undergoing clinical evaluation. These devices offer the advantages of smaller size, a quiet operating mode, and enhanced durability. The recently published HeartMate II bridge-to-transplant trial demonstrated that 79% of patients were transplanted, alive on device support, actively listed for transplantation or had the device removed for recovery 6 months following enrollment.²⁹

The use of mechanical circulatory support in selected patients who are not candidates for transplantation is an increasingly utilized strategy in advanced HF centers. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial randomized 129 patients with end-stage HF ineligible for cardiac transplantation to implantation of an LVAD or optimal medical management.³⁰ The primary end point was all-cause mortality. Patients enrolled had New York Heart Association (NYHA) class IV HF for at least 90 days despite optimal medical therapy. At 1 year, survival in the LVAD group was significantly greater than in the medical therapy group (52% vs 25%, $P = .001$). However, at 2 years, only 23% in the LVAD group were alive, compared with 8% in the medical group. Serious adverse events were more frequent in the LVAD group, predominately caused by infection, bleeding, neurologic dysfunction, and device malfunction. A subsequent analysis of the trial

data reported that the majority of the benefit in this trial was restricted to the group receiving or dependent on intravenous inotropic therapy at time of enrollment. Several new trials and the development of a national registry for LVAD patients will dramatically increase the knowledge base and provide important insights regarding the efficacy of mechanical circulatory support in the near future.³¹

Increasingly patients present with advanced HF that require urgent deployment of mechanical circulatory support to sustain life and or prevent or reverse end organ dysfunction. Often a thorough assessment cannot be completed to definitively determine if they patient is a suitable candidate for transplantation. Under these circumstances an LVAD should be implanted as a “bridge to decision” pending further assessment and determination of the best treatment plan in the post operative period. A prospective cohort of patients in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry showed that strategy for treatment is dynamic and 20% of patients changed from various categories during the initial 3 months after device implant.³²

Emerging Surgical Techniques

Infarct Exclusion Surgery. Primary indications for surgical treatment of LV aneurysm consist of LV failure, angina pectoris, thromboembolism, and tachyarrhythmias. It has been well recognized for decades that, after ventricular aneurysmectomy, patients can experience improved HF symptoms.³³ This concept recently has been expanded from dyskinetic (aneurysmal) ventricles to include akinetic ventricles, which previously were considered unlikely to improve following ventricular reconstruction. Linear aneurysmectomy has been widely performed as a standard procedure for post-infarction LV aneurysm. However, this technique remains unsatisfactory because LV distortion occurs postoperatively and an akinetic or dyskinetic area persists in the ventricular septum, resulting in limited improvement of cardiac function.³⁴ To overcome these problems, Dor and associates excluded all akinetic or dyskinetic myocardium from the left ventricle, including the septum, and placed a tight circumferential suture around the aneurysmal base to reduce the LV volume and return the LV contour to near normal (endoventricular circular patch plasty, or EVCPP). Recently, EVCPP has attracted interest as a treatment for post-infarction large akinetic scars. Dor’s group has reported on the use of this technique on more than 750 patients.³⁵ Results were clinically satisfactory and in more than 90% of cases with ventricular aneurysm, the 1-year left ventricular ejection fraction was superior to the preoperative function. More recently, the same group reported on 44 patients treated with EVCPP with previous transmural anterior myocardial infarction.³⁶ They found that LV shape became more elliptical in systole than it was in diastole (eccentricity index closer to 1), but new onset mitral regurgitation occurred in 25% of patients.

A minor modification of the procedure described by Dor is referred to as the surgical anterior ventricular endocardial

restoration (SAVER) operation. A large, multicenter prospective registry reported on 439 consecutive patients who received this operation with impressive medium-term survival. Based on this, the Surgical Treatment for Ischemic Heart Failure (STICH) trial, a large, National Institutes of Health-funded study of both CABG and ventricular reconstruction has been initiated. Still, the limited experience with this procedure and the concern that mitral valvular disease could be worsened leaves insufficient grounds for a recommendation of this technique at this time. The STICH trial demonstrated that surgical ventricular reconstruction did not offer significant benefit over coronary bypass surgery alone. The addition of surgical ventricular reconstruction to CABG reduced the LV volume, as compared with CABG alone, but this anatomical change was not associated with a reduction in the rate of death or hospitalization for cardiac causes.³⁷

Passive Restraint. Another technique uses passive containment of the ventricles with a surgically placed epicardial prosthetic wrap constructed of either preformed knitted material³⁸ or nitinol.³⁹ The Acorn trial examined outcomes in 300 patients randomized to receive a cardiac restraint device or standard therapy.⁴⁰ More patients who received the cardiac support device achieved the primary end-point (alive, free of major cardiac procedures and ≥ 1 NYHA functional class improvement) than the patients treated with standard therapies, however there was no difference in mortality between groups. Early and sustained improvements in LV remodeling indices were also noted.⁴¹ The Paracor HeartNet device has more limited observational data supporting its use, but preliminary studies suggest improvements in exercise performance, quality of life and cardiac structure with use of this device.³⁹

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