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End-Stage Heart Failure: Is There a Role for the Batista Procedure?

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ABSTRACT

Background: Medically refractory heart failure is traditionally managed with cardiac transplantation although some limited success has also been obtained in selected patients using dynamic cardiomyoplasty or mechanical assist devices. Recently, a new surgical alternative called partial left ventriculectomy (PLV) was introduced by Batista in 1995. The procedure attempts to relieve symptoms of congestive failure by reducing myocardial mass and restoring the normal mass-to-volume ratio of the left ventricle. Despite initial enthusiasm, the results of PLV are not yet known. The aim of this study was to determine survival and clinical outcomes in a group of patients submitted for PLV as a means of surgical treatment for end-stage heart disease (ESHD).

Methods: From November 1994 to December 1995, 15 patients with ESHD and dilated cardiomyopathy (DCM) were operated on by the technique described by Randas Batista. We compared preoperative and postoperative assessments of NYHA Functional Class (FC), Quality of Life index (QOL), echocardiographic, ergometric, radioisotopic ventriculography and hemodynamic data and at intervals of zero, one, three, six, nine, and twelve months postoperatively. Kaplan-Meier, student t-test and chi-square analysis were applied to the numerical and categoric variables.

Results: Survival was 80% at one month, 66% at three months, 53% at six months, 47% at nine months and 40% at one year. We also found that 6 of 7 patients (85%) with tricuspid regurgitation (TR) died compared to 4 of 8 patients (50%) without TR. This was the only risk factor indentified which influenced mortality. Postoperative echocardiographic evaluations demonstrated reduced left ventricular end-diastolic and end-systolic diameters at six months (LVESD 65.5 ± 8.3 mm preoperatively versus 56.83 ± 5.74 mm at six months, p=0.007 and LVEDD 73.84 ± 8.25 mm preoperatively versus 65.33 ± 5.72 mm at six months, p=0.009). Survivors enjoyed an improved clinical status according to both the NYHA functional class (preoperative Class IV=100% versus postoperative at six months: Class IV = 50%, Class III = 17% and Class II = 33%) and the Quality of Life index (100% were in grade 6 and 7 preoperatively versus 0% at six months). However, statistical significance was not reached in most of these data due to the small number of patients.

Conclusions: Actuarial survival in this series of patients was 53% at six months and 40% at twelve months with survivors showing fewer symptoms and clinical events than preoperatively (100% hospitalized preoperatively versus no patient hospitalized at six months). Therefore, the Batista Operation improves the quality of life for patients with dilated cardiomyopathy and can possibly be a new means for bridging to cardiac transplantation in severely ill patients who are not likely to survive long enough to recieve a donor heart. Additional improvements in late results will likely be seen after further experience, evolution of the surgical techniques and better patient selection.

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INTRODUCTION

Congestive heart failure (CHF) remains one of the most common causes of death and repeated hospitalization throughout the world. Despite recent advances in medical management [Armstrong 1993], survival and quality of life remained limited. The annual mortality rate for congestive heart failure with class III or IV symptoms is nearly 40% [Bigger 1987]. Surgical therapy for end-stage heart disease (ESHD) has offered symptom relief and prolongation of life to certain subgoups of patients. At present, cardiac transplantation does achieve the best overall symptom relief along with an expected 5-year post-transplant survival of approximately 63% [ISHLT 1996, Hosenpud 1996] . Other potential surgical options for ESHD include dynamic cardiomyoplasty (DCM) [Chiu 1993], mechanical circulatory support with implantable left ventricular assist devices (LVAD), or cardiac replacement with the total arti-

ficial heart (TAH) [Joyce 1988]. In patients prone to arrythmias and sudden death, implantable cardioverter/defibrillators (ICD) have reduced the likelihood of sudden death but the effect on long-term survival is limited principally by high non-sudden death rates [Sweeney 1995]. In addition, ICDs do not reduce congestive symptoms nor improve functional class.

Inadequate donor availability, significant long-term morbidity associated with anti-rejection therapy, late occurence of graft atherosclerosis, and the considerable economic costs associated with cardiac transplantation are responsible for its limited application in the vast majority of patients with ESHD. Additionally, for those who are transplant candidates, the waiting period for a donor heart (6 months to 1 year) can lead to a significant attrition through sudden death and/or circulatory collapse. In one report, there was only a 46% one-year survival rate in patients in whom transplantation was deferred due to mild symptoms. [Stevenson 1987].

Dynamic cardiomyoplasty has recently been applied to patients with poor left ventricular function, but improvements in ejection fraction (EF) and survival rates are marginal despite a measurable improvement in heart failure symptoms [Moreira 1995]. In addition, most of the benefit obtained from DCM is seen in NYHA Class III patients and cannot be reproduced in severe, NYHA Class IV cases. Mechanical circulatory pumps (TAH or LVAD) have been used successfully in pre-terminal heart failure, but mostly as a short-term bridge to transplantation. Permanent implants have been troubled by problems with thromboembolism, infection, anticoagulation-related hemorrhage, malfit, power delivery and overall cost. [Joyce 1988].

Idiopathic dilated cardiomyopathy (IDCM) is the leading cause of heart failure in 61% of the cardiac transplant candidate pool[ISHLT 1996]. Unfortunately, only 30% of such patients awaiting transplantation actually receive a donor heart [Bocchi 1996]. Other patients groups, including ischemic, valvular, congenital and infectious causes of cardiomyopathy further overburden the recipient list.

In 1995, a new surgical option for patients with end-stage heart disease was proposed by Randas Batista and coworkers from Hospital Caron in Campina G. Sul, Brazil [Batista 1995, Batista 1996]. Batista has observed that normal hearts maintain a constant ratio between ventricular diameter and muscle mass [Batista 1996]. In failing hearts, dilatation prompts a major increase in muscle mass as a compensatory mechanism. According to Batista, myocardial mass must then increase with the cube of the radius in order to maintain normal ventricular function. To restore function in dilated cardiomyopathy, Batista et al. have introduced a procedure to reduce LV diameter, called partial left ventriculectomy (PLV). These investigators have proposed that surgical reduction of left ventricular chamber diameter will restore the normal relationship between mass and dimension as well as reduce intracavitary wall tension and pressure.

Initial experimental data in support of their concept was obtained in a novel model of acute LV enlargement in sheep. In this setting, an acute benefit from restoring normal LV dimensions was observed [Batista 1996]. In the initial clinical case of PLV reported by Batista, the ejection fraction in a Functional Class IV patient with IDCM rose from 17% preoperatively to 44% at 2 months following surgery [Batista 1996]. Scattered reports from other centers performing this new procedure in patients with ESHD have now surfaced, but no clinical series or comparative trial has been reported to date. Additionally, there are no currently available long-term follow-up data or reports of clinical outcomes.

In our center, we have begun using the Batista PLV operation for patients who could not be considered for transplantation. Current indications for the procedure include: 1) a contraindication to transplantation in combination with a shortened life expectancy and a poor quality of life despite optimal medical therapy and/or 2) hemodynamic deterioration (reaching QOL stage 6 or 7) while awaiting transplantation. Although the number of patients in this initial series is small, all of them were chronic and critically ill. In this report, the authors provide an initial scientific assessment of the short and mid-term results of PLV by focusing on postoperative survival and changes in quality of life indicators.

MATERIALS AND METHODS

Case Mix and Selection

From November 1994 to December 1995, 15 patients with ESCHF underwent partial left ventriculectomy according to Batista. There were 11 males (73 %) and 4 females (26 %) with a mean age of 54.19 ±12.3 years (32 to 70 years old). The inclusion criteria were:

- A diagnosis of dilated cardiomyopathy, including the following etiologies:
  - Idiopathic-9 (60%)
  - Alcoholic-5 (33%)
  - Chagas Disease-1 (6%)
- A contraindication for transplantation.
- Quality of life score of grade 6 or 7 (see below).
- NYHA functional class IV.

Cardiomyopathies secondary to pressure/volume overload, ischemia, congenital heart disease or those with coexisting systemic diseases of poor prognosis were excluded. All patients undergoing PLV were hospitalized and most were supported by intravenous inotropes. Very short life expectancy and minimal chance of hospital discharge were characteristic of each case. Preoperative transvenous myocardial biopsy was not routinely performed due to the non-specific histology usually found in patients with dilated cardiomyopathy. Immunoassays for Chagas disease were performed preoperatively in most patients. Additional cardiac findings in the surgical cohort were:

- Right heart failure - 8 of 15 patients (53%)
- Mild to moderate mitral insufficiency-14 of 15 patients (93%).
- Tricuspid regurgitation - 7 of 15 patients (46%).
- Preoperative atrial fibrillation - 6 of 15 patients (40%).

Postoperative Follow-up

A panel of diagnostic studies was performed preoperatively and then at 1, 3, 6, 9 and 12 months postoperatively, including radioisotopic ventriculography (MUGA), transesophageal and transthoracic 2D-color echo-dopplers, chest reontgenograms, maximum VO_2, and routine hematology, serology and urinalysis. Cardiac catheterization with coronary angiography and ventriculography were performed preoperatively. Ventriculography (without angiography) was repeated at 6 months.

Patients were also analyzed preoperatively and postoperatively using a Quality of Life (QOL) clinical scoring system according to the absence/presence of physical restriction as follows:

1. Grade I: No restriction.
2. Grade II: Light restriction (i.e. walks more than 200 meters and performs professional activity).
3. Grade III: Moderate restriction (i.e. walks no farther than 200 meters).
4. Grade IV: Severe restriction but able to perform personal care activities (i.e. hygiene and feeding).
5. Grade V: Severe restriction and dependent on assistance for personal care.
6. Grade VI: Hospitalized but not requiring inotropic drugs.
7. Grade VII: Hospitalized in the intensive care unit requiring intravenous inotropic drugs.

Results of this initial trial were statisically analyzed using Kaplan-Meier, student t-test and chi-square comparisons in an attempt to determine which of the following variable(s) correlated with the survival:

- Age
- Systolic blood pressure
- Right heart failure
- Preoperative atrial fibrillation
- Mitral regurgitation
- Tricuspid insufficiency
- Two dimensional echo-doppler data (Ejection fraction [EF], LVEDD, LVESD, left atrial dimensions)
- Treadmill test (maximum VO_2 in ml/Kg/min/m_2)
- Catheterization data (EF, cardiac index, pulmonary vascular resistance, systemic vascular resistance)

Surgical Technique

The primary procedure in each case was a partial left ventriculectomy as described by Batista [Batista 1995, Batista 1996]. Additional procedures during surgery were as follows:

1. Mitral valve replacement - 6 of 15 patients (40%)
2. Mitral valvuloplasty - 2 of 15 patients (13%)
3. Tricuspid (DeVega) annuloplasty - 3 of 15 patients (20%)
4. Coronary artery bypass grafting (CABG) - 3 of 15 patients (20%)

Each patient was approached through a median sternotomy with a slightly extended skin incision. Separate bicaval cannulation and caval tapes were used for venous return. Cardiopulmonary bypass flow averaged 2.2–2.4 L/min/m_2 and core temperature was routinely dropped to 30–32 degrees C. During core cooling, we usually performed any necessary right sided surgery (such as tricuspid annuloplasty) on the beating heart provided there was no atrial septal defect. When core temperature reached 32 degrees C cardiac arrest was achieved and maintained by intermittent infusion of antegrade isothermic, low volume blood cardioplegia. All venting and de-airing was accomplished through the opened left ventricle supplemented by an aortic root suction catheter.

After cardioplegic arrest, a stab wound was made at the apex of the heart and a pump sucker introduced into the left ventricle. The surgical field became bloodless following which a variable amount of the lateral left ventricular wall was resected up to the fibrous annulus of the mitral valve (Figures 1–3, ◎). In cases where mitral replacement was performed, the specimen included the mitral leaflets and both papillary muscles. The obtuse marginal branches of the circumflex were always resected with the specimen (Figures 1–2). We preferred to implant low profile porcine bioprosthesis (usually #29 to #31) in such cases.

During rewarming, the left ventriculography was repaired using a 2-layer closure with continuous 3-0 polypropylene suture. The first layer supports the entire tension of the ventricle by approximating the full thickness of the myocardium. The second layer is epicardial/myocardial and is used as a final security for hemostasis. After de-airing from the still opened cardiac apex, the two sutures were tighted at their ends while light suction was applied to the aortic root. Declamping of the aorta was almost always associated with spontaneous resumption of cardiac contractions. The final appearance of the remodeled ventricle is shown in Figures 7 ◎ and 8 ◎ below. The volume of resected left ventricular muscle mass (Figure 9, ◎) weighed from 32 to 128 grams (depending on the initial LV dimensions).

RESULTS

In this initial series of partial left ventriculectomy, the surgical mortality (0–30 days) was 13.3% (two patients) and each death was due to LV rupture and hemorrhage. The longest follow-up period for the survivors in this initial series of PLV was 12 months. The actuarial survival rates determined by the Kaplan-Meier curve were 80% at 1 month, 66% at 3 months , 53% at 6 months , 47% at 9 months and 40% at one year. The modes of late death were :

1. Sudden death-7 (46 %)
2. Refractory heart failure/cardiogenic shock-2 (13 %)
3. Infection (sepsis)-1 (6 %)

Postoperative echocardiographic evaluation showed reduced LV dimensions, reaching statistical significance, with p=0.007 for LVESD and p=0.009 for LVEDD (LVESD 65.5 ± 8.3 mm preoperatively versus 56.83 ± 5.74 mm at six months and LVEDD 73.84 ± 8.25 mm preoperatively versus 65.33 ± 5.72 mm at six months).

Risk-factor-analysis data demonstrated that 6 of 7 patients (85%) with tricuspid regurgitation died as compared to 4 of 8 patients (50%) without tricuspid regurgitation. Although this difference did not reach statistical

significance due to the small sample size, this was the only preoperative factor which suggested risk for late mortality. Postoperative echocardiographic evaluation showed significant reductions in LV dimensions (LVESD 65.5 ± 8.3 mm preoperatively versus 56.83 ± 5.74 mm at six months, p = 0.007, and LVEDD 73.84 ± 8.25 mm preoperatively versus 65.33 ± 5.72 mm at six months, p=0.009). Survivors did enjoy improved clinical status according to the NYHA functional class (preoperative Class IV=100%) versus postoperative at six months :

1. NYHA Class I: 0 %
2. NYHA Class II: 33 %
3. NYHA Class III: 16 %
4. NYHA Class IV: 50 %

In addition, for those surviving six months the Quality of Life assessment score improved with none of the survivors remaining in grade 6 or 7 (whereas 100% were in grade 6 and 7 preoperatively). Clinical evaluation is now showing a trend toward worsening of symptoms after the 6th postoperative month, but the data is incomplete at this time.

DISCUSSION

In Brazil, idiopathic dilated cardiomyopathy is the predominant etiology of ESHD in our transplant population. For this reason, IDCM was also the most common cause of ESHD included in our initial experience with the Batista operation. One case of Chagas disease was included and this was the most difficult procedure. Chagas patients have transmural plaques of thin fibrosis scattered throughout the LV wall. Chagas myocardial plaques are quite irregular in shape and invariably the LV wall is diffusely thinned with minimal or no hypertrophy. We believe these conditions pose a significant technical challenge during reconstruction of the left ventriculography.

Ischemic patients are probably not favorable candidates for PLV as the morphology of the disease points toward fibrosis and thinning of the LV wall combined with a minumun of functioning muscle. Although we did perform CABG in 3 patients undergoing PLV, in each case the coronary disease was secondary and by no means responsible for any symptom. Valvular patients were excluded because of the observed trend towards LV recovery and remodeling after successful repair or replacement. By introducing routine mitral valve replacement after our 8th case of this series, we were only aiming to achieve a wider margin of LV resection rather than targeting correction of any valvular insufficiency [Lucchese 1995]. Wider resections appeared to conform to the surgical goal of restoring ideal mass-to-volume ratio in these grossly enlarged hearts.

The introduction of the Quality of Life Index is very important since the NYHA functional classification blends together too many different levels of symptoms. For example, NYHA class IV would include patients who are hospitalized but not dependent on intravenous inotropics as well as those who remain symptomatic despite high doses of and dependency on continuous inotropic support. In order to provide more accurate preoperative and postoperative life quality assessment, we felt it was necessary to introduce the Quality of Life Index outline in this report. The results have shown that significant improvement in symptoms of ESCHF are achieved with the Batista operation and that NYHA classification is indeed a less sensitive method for detecting this improvement. Echocardiographic data also demonstrated a significant reduction in LV dimensions at six months thus reinforcing one of the purpose of surgery, namely ventricular diameter reduction.

The hemodynamic and radioisotopic ventriculographic data obtained at the 6th month interval did not change as much as we expected. This observation was at variance with the improved symptomatic status of the patients as judged by the Quality of Life Index. Echocardiographic data did demonstrate a reduction in LV dimensions, although not statistically significant due to the small number of cases. Despite equivalency in the the ejection fraction and other cardiac performance data when compared with preoperative baselines, most patients were doing well. The surgical team observed an immediate and dramatic clinical improvement as soon as the patent left the operating room.

Evolution of our surgical experience with the Batista Operation appeared to involve two distinct phases. First, we attempted to complete the resection and remodeling of the free left ventricular wall while leaving the mitral apparatus alone, if possible, or performing mitral annuloplasty. However, the results were not ideal. In the second phase (beginning with patient #8), a greater mass of LV muscle was taken, making it necessary to remove the mitral apparatus en bloc with the resected specimen. Secondarily, the number of associated procedures appeared to increase artifactually.

In essence then, the Batista procedure may be conceived as a combination that includes partial left ventriculectomy and mitral valve replacement as well as reduction of every affected heart chamber through different approaches. This is easily performed on the left side of the heart. Conversely, it is not so easy in the right side. One should guide a decision based on the intraoperative findings and surgical expertise. The cardiomyopathic process should affect the right ventricle as well as the right atrium and they may be dilated as well. The right atrium is easily plicated but this is not so true regarding the right ventricle. Most important is to adequately perform tricuspid annuloplasty, especially if there is severe pulmonary hypertension, as TR is responsible for a worsened prognosis.

As discussed, there were two perioperative deaths related to LV rupture at the very beginning of our experience. Both occurred in the first twelve hours and were related to hypertensive peaks. Acute postoperative hypertension has also been associated with posterior rupture of the LV following mitral valve replacement. Nevertheless, we must also caution that these ruptures could have occurred from a weak suture line or technical error. Thus, we emphasize the need to accurately close the LV wall in concert with diligent control of the mean arterial pressure immediately after surgery. Once we earned our expertise in this complication we have not had any further cases of ventricular dysruption.

Ventricular arrhythmias are a natural consequence of DCM and 30% to 50% of such patients eventually die suddenly presumably from ventricular tachycardia and/or fibrillation. The myocardium in DCM has many areas of transmural scarring which are responsible for disintegration of conduction wavefronts and subsequent arrhythmias. It is possible that the additional scar resulting from partial left ventriculectomy could play an important role in creating new arrhythmogenic foci in these patients. Currently, this a matter of suspicion and has not been proven. Indeed, the percentage of postoperative sudden death in our series (46.6% at one year) is similar to that seen in untreated IDCM. Nevertheless, after this initial series we have operated on five additional patients using an expanded protocol where we favor implantation of a cardioverter/defibrillator in some cases guided by the results of pre- and postoperative electrophysiologic studies.

Unexpectedly, we found that three of our patients had a significant decrease in pulmonary vascular resistance (Wood units) when studied at the 6th postoperative month. All of three patients had an initial contraindication for transplantation based on elevated pulmonary vascular resistance at the time of PLV. Following PLV, their pulmonary vascular resistance fell to within ranges for reconsideration of transplantation. In fact, one of them was successfully transplanted 16th months after initial PLV. The second patient is currently doing well and will not accept transplantation; the third patient died suddenly.

The series of patients in this current report is small (n=15) but is characterized by the very complexity, severity and graveness classic for this disease. As mentioned above, all patients were critically ill with most residing in the ICU and dependent on IV inotropes. Unlike the current candidate pool for dynamic cardiomyoplasty, a short life expectancy and minimal chance of hospital discharge were hallmarks in every case. Patients of this severity carry a poor prognosis with any form of medical or surgical therapy. While some investigators have reported slightly better initial results with the Batista operation, their groups included patients in NYHA III [Moreira 1996] or only short-term follow-up (60 days) [Bombonato 1996] whereas our population consisted exclusively of NYHA Class IV patients with twelve months of follow-up. From the outset we reserved this operation for our worst and sickest patients. This decision surely affected the overall results obtained in this series. Indeed, it is very possible that improved functional and survival data will be achieved when PLV is performed before the pre-terminal phase of heart failure.

In summary, despite failure to reach statistical significance in most data from this small cohort, we can demonstrate that partial left ventriculectomy (or Batista operation) has an acceptable in-hospital mortality and effectively reduces left ventricular dimensions. Mitral valve replacement is almost always required to achieve an adequate resection of ventricular mass. Despite the magnitude of the resection, a dramatic clinical improvement immediately after surgery is usually seen. In patients with elevated pulmonary vascular resistance preoperatively, there is preliminary evidence that PVR may come down to normal within 6 months of PLV. However, results are probably worse in terminal patients, especially those with tricuspid regurgitation.

Most important is our finding that PLV undoubtedly improves the quality of life in the surviving patients. The Batista operation is also a relatively cost effective and inexpensive bridge to transplantation with an acceptable 66% survival at three months and 53% at six months. Based on our initial experience reported here, PLV should be considered as a first choice procedure for inotropic dependent pre-transplant patients when no donor heart is available. However, we emphasize the need for additional clinical experience, refinements in the surgical techniques, and longer follow-up studies in order to more accurately evaluate the role of this new surgical approach in the management of end-stage heart disease.

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REVIEW AND COMMENTARY

1. Sinisa Gradinac, MD, writes:

We have performed 10 BPLV operations in critically ill, NYHA IV, idiophatic CMP patients in Belgrade, Yugoslavia. Nine are at home up to four months. None of them have experienced serious ventricular arrhythmias, while 6 of 7 patients converted to sinus rhythm. We feel that full dose amiodarone can significantly reduce serious arrhythmias. Our first patient died on the 12th postoperative day due to probable embolization (which has been mentioned as possible complication). Our third patient (now 3 months out) had additional mitral valve reconstruction, with MR improving from 3+ to 1+. His EF now is 55% (15% preoperatively), but his MR is again 3+ and we are considering mitral valve replacement. Two more patients deteriorated from trace MR to 2+, and we also feel that more agressive treatment of mitral insufficiency is needed initially. I would also appreciate suggestions on reoperation in BPLV patient mentioned above.

Authors' Response by José Frota, MD:

I am grateful for your comments and congratulate you on your excellent results which are a little different from what we reported in this first series of patients. Our center has now performed a total of 40 cases of Batista PLV (including patients out of our protocol). I can reply that some aspects and results have now changed in my second series of patients.

I agree that loading patients with amiodarone lessens the risk of life threatening arrhythmias. In our second series of 17 patients, all were are loaded with amiodarone preoperatively which was continued postoperatively. So far we've had only one case of arrythomgenic death in this second group. This patient died on the day of surgery due to intractable VF. Interestingly this patient was having an uneventful recovery (EF raised to 54%) without a sole ectopic beat and already loaded with amiodarone. Ventricular fibrillation was the initial and fulminating event.

Regarding the problems you are experiencing with postoperative mitral regurgitation, we realized from the very beginning that these patients do not tolerate any degree of postoperative mitral regurgitation, as well as other valve insufficiencies. When in doubt, we implant a bioprosthesis into the mitral position (60% of our cases up to now). I continue to resect the LV wall alongside the external border of the papillaries, when needed, but started preserving all of the mitral apparatus together with intra-annular implantation of a low-profile mitral bioprosthesis. Annulo-papillary continuity is achieved and valve competence is guaranteed. If necessary, I've detached the papillaries and reimplanted them elsewhere in the remaining LV wall. I would not hesitate in advising you to reoperate on your patients for valve insufficiency, either tricuspid or mitral. The sooner the better.

2. Reviewer XA5 writes:

Survivals on our cardiac transplant waiting list are far better than the 53% at 6 months and 40% at 12 months that this author reports postoperatviely from the Batista patients. We lose about 10% of the patients on our waiting list in the first 6 months after listing and about 10% in the next 6 months making our 1 year survival on the waiting list about 80%. We, of course, do have an ongoing steady attrition after that point.

Authors' Response by José Frota, MD:

Dear colleague...First of all, congratulations on your survival rate on your heart TX waiting list. Nevertheless, you'll find that we've included only non-tranplant candidates, pre-terminal, quite ill and failing patients, with far advanced end-stage heart disease. Our cohort is unique regarding this point as well as our experience. I've not heard about any similar sample worldwide including the same features. The statement which, in fact, is important is the following: from such an expiring population we achieved a

56% survival at six months and 40% at twelve months. Further, three cases reverted their pulmonary vascular resistance within ranges for reconsideration for transplantation and Quality of Life improved. The questions should be how many of such patients would be alive without Batista Partial Left Ventriculectomy within a one year interval? What would be their Quality of Life in their remaining days ?

It was not the aim of this paper to compare outcomes in transplant versus non-transplant lists due to the fact that all patients in this series were non-transplant patients. I do assume that this comparison will be of utmost importance in a randomized trial that includes patients within the same stage of disease, a homogenous population.

After the preliminary series reported in this article, we have operated on 13 additional patients and so far we have included some patients on the active transplant list in which the results are even better. Ejection fraction, for example, has increased at least 100% from preoperative values and all data show a trend toward relief of symptoms and good Quality of Life.

3. Reviewer XA5 writes:

Now, I am keenly aware that the Brazilians are in a very different system and are dealing with a different patient population. However, it is for just this reason that this operation may not be nearly as applicable to our patient population here in the US.

Authors' Response by José Frota, MD:

Please, excuse me but I don't agree with you again. End-stage heart disease poses the same spectrum of challenges regardless of country or place. In general and except for some etiologic differences, ESHD requires all current therapeutic methods.The choice for a specific treatment instead of another is based, most times, on the necessity for treating patients, the available resources and the experience of the institutions with one or various methods. These simple parameters serve as guidelines for decision making and assembling medical and surgical programs.

I do agree that heart transplant is the best treatment for these patients but what will we do when no donor is available and/or there is contraindication for transplantation? In this set, Batista Partial Left Ventriculectomy is offering its initial results. I direct your attention to the fact that BPLV is in its embryonic movements. You surely remember heart transplantation in its very early stages of development. Looking backward to those early days of TX, one would not realize that it could achieve the state of the art we are seeing today.

Regarding the relevance of BPLV to the USA population I firmly believe that Cleveland, Buffalo and other ensuing experiences will provide answers better than mine."Time is worth ten thousand words".

4. Reviewer AX44 writes:

The authors have reported on an interesting series of patients. They have evaluated their patients, I think, fairly. I think that this paper is important in that it begins to give us an idea of the results of this operation. This procedure, of course, is on the forefront of our specialty and has achieved a certain amount of wide spread notoriety both in the professional and lay press. The role of this operation remains to be clarified and I believe that this paper begins that process. The results are clearly not spectacular. The authors recognize this and offer a likely explanation, that is, that their patients were "pre-terminal". I believe the authors have approached this group of patients in an objective manner. I do not think that they are overly zealous in "selling" the procedure.

The idea of this procedure as a "bridge maneuver" to transplant is interesting. That would avoid the mechanical devices and their attendant complications. Being able to have a non-instrumented patient is certainly attractive from an infection standpoint prior to transplantation. The down side of this procedure as a bridge maneuver is that there is less than perfect hemodynamic restoration associated with this procedure. The authors have suggested that possibly operating on patients that are earlier in their disease progression is attractive and likely would translate into better surgical results. The management of end-stage congestive heart failure, however while difficult, certainly is improving.

The authors point out that coronary artery disease patients, as well as valvular heart disease patients, are not good candidates for this procedure. That fact certainly detracts from the usefulness of the procedure in the majority of patients seen with end stage heart failure in our country.

Authors' Response by José Frota, MD:

Many thanks for your commentary and questions. This is not aimed to be a paper focusing on the surgical technique of BPLV but rather a reportable experience with a selected group of pre-terminal patients.

BPLV as a bridge for transplantation is an attractive idea due to actuarial curves at 3 and 6 months follow-up, the decrease in pulmonary vascular resistance in some patients, the avoidance of circulatory assistance devices and their related complications, as well as the low cost of BPLV. In fact this is one of our more important conclusions within the limits of our initial experience.

Valvular and ischemic patients were excluded from our series not because there is an absolute contraindication for surgery but mainly as an atempt to bring the sample more homogenous with most cases of dilated cardiomyopathy. Moreover, regarding valvular patients, we share the opinion that valve reconstruction or replacement must be tried before any other procedure as this is enough and successful in a large number of patients. In regard to ischemic patients, we really think that most of them are not favorable candidates to BPLV due to the reasons pointed out in the paper. Additionally, we also share the opinion that complete revascularization must be tried before any alternative procedure. Nevertheless, I recognize that these are controversial points and I emphasize the need for additional clinical experience in order to further clarify the scope of surgical indications for BPLV.

5. Reviewer JZ39 writes:

The patient population is too small to draw any comparative analysis legitimately between the various patient groups with or without tricuspid valve regurgitation and with or without mitral valve replacement.

The authors do note a complication of left ventricular rupture that has not been described, to my knowledge, by Batista in the literature.

The fact that these patients seem to improve when they where hospitalized, either on ionotropes or at bed-rest implies that they are truly a quite ill population and it is encouraging that 40% of the patients were alive at one year, especially in view to the fact that two died probably unnecessarily due to ventricular rupture from hypertension.

Authors' Response by José Frota, MD:

Thank you for your commments. I agree with you when you say that comparative analysis between groups in this small sample may be hard to achieve. In regard to ventricular rupture, immediate mortality can be quite low as experience increases. So far, I know about one more case operated in the United Kingdom who died on day one of sudden hemorrhage from the ventricular suture line though there is no mention of hypertensive peak.

6. Reviewer DK3X writes:

Another issue which should be considered is that of resource utilization. Considerable interest exists about the treatment of patients and their costs near the end of life. How does this option compare to other strategies with respect to "cost" per additional patient life year? I agree that this operative strategy/technique is still new and being developed, but I feel the resource utilization issue also needs to be acknowledged.

Authors' Response by José Frota, MD:

I am sure this is not easily done. Firstly, BPLV is a novel procedure and although we have been performing it since 1994, I think that such a complex "cost per additional patient life year", mainly if compared to other strategies, is not suitable with such a small number of patients. Secondly, BPLV costs the same as any standard cardiac surgery such as mitral replacement or a simple ASD closure. What does it mean in the context of such a complex and comparative analysis? I really don't know yet but intuitively I realize that it is less than any other surgical option for ESHD. Third, I see your comment as a valuable suggestion for forthcoming analysis by adequate personnel and in appropriate scientific medium. Additionally, I think that "patients and their costs near the end of life" is still a controversial ethical and policy subject and deserves a special forum, other than Internet, as patients are people,costs are money and the end of life is an already unknown frontier for the human being...most times belonging and relating to gods and goddesses...as Phoenix is only a myth.