Does Preoperative Ejection Fraction Predict Operative Mortality With Left Ventricular Restoration?

Joshua D. Adams, MD, Lynn M. Fedoruk, MD, Carlos A. Tache-Leon, MD, Benjamin B. Peeler, MD, John A. Kern, MD, Curtis G. Tribble, MD, James D. Bergin, MD, and Irving L. Kron, MD

Department of Surgery, University of Virginia, Charlottesville, Virginia

Background. **Ischemic cardiomyopathy and aneurysmal disease have been treated surgically with coronary artery bypass grafting in the past. The Dor technique for left ventricular restoration has demonstrated improved outcomes in patients with ischemic, akinetic ventricles. Our hypothesis was that even marked reduction in preoperative cardiac function (ejection fraction < .25) would not correlate with worse outcomes since the ventricle would be reshaped to improve function.**

Methods. **A retrospective analysis was performed on all patients who had undergone ventricular restoration with the Dor procedure from January 1996 through September 2005. Patients with a preoperative ejection fraction (EF) < .25 and those with a EF ≥ .25 were compared. All Society of Thoracic Surgeons database characteristics, mortality, length of stay (LOS), and need for intraaortic balloon pump (IABP) were analyzed.**

Results. **The study included 89 patients (69 men, 20 women), 28 of whom had preoperative EFs < .25 (mean, .183 ± .035; range, .08 to .25) and 61 had an EF ≥ .25 (mean, .334 ± .074; mean, .25 to .45). Overall operative mortality was 3.4% (3/89), with no statistically significant difference between the two groups (3.6% versus 3.3%). LOS was 7.4 ± 3.6 days versus 8.9 ± 15.6 days (p = NS), and need for IABP was 39.2% versus 8.1% ($p < 0.05$). Overall 5-year survival was 82%. Five-year survival in the EF < .25 cohort was 69.6% versus 88.3% in the EF ≥ .25 cohort ($p = 0.066$).**

Conclusions. **Ventricular restoration with the Dor technique is a safe procedure. Marked reduction in ejection fraction is not a contraindication to left ventricular restoration; however, increased usage of IABP should be anticipated.**

(Ann Thorac Surg 2006;82:1715–20)

Coronary artery disease, myocardial infarction (MI), and subsequent ischemic cardiomyopathy is the etiology of congestive heart failure (CHF) in approximately two thirds of existing cases [1, 2]. With aggressive revascularization and thrombolytic therapy, thin walled dyskinetic aneurysms from a full thickness scar are no longer the common end result of MI. Instead, the epicardial layer is salvaged, but necrosis at the endocardial level results in a variable thickness scar that remains stiff and akinetic. These akinetic segments result in loss of regional contraction and alter the ventricular geometry, causing the ventricle to take on a more spherical shape, known as ventricular remodelling. This causes deterioration of the heart's global systolic function and, ultimately, heart failure.

Dor and colleagues [3, 4] have demonstrated that left ventricular restoration is an effective surgical treatment for dyskinetic aneurysmal disease and akinetic dilated ventricles, resulting in improvements in both systolic function and New York Heart Association (NYHA) functional class. Widespread acceptance of this procedure has been slowed by many surgeons' reluctance to exclude normal appearing akinetic segments of the ventricle; therefore, coronary artery bypass grafting (CABG) alone is performed. Our institution has previously demonstrated that CABG with ventricular restoration is superior to CABG alone in patients with ischemic dilated ventricles. Specifically, significant improvements in postoperative ejection fractions, freedom from failure, and late mortality were observed in the ventricular restoration group [5].

The major question is whether severely reduced function would correlate with worse outcomes. Our hypothesis was that even marked reduction in preoperative cardiac function, which we defined as an ejection fraction of less than .25, would not affect results because the dilated ventricle would be reshaped. We therefore compared all patients who underwent left ventricular restoration to determine if severely decreased systolic function impacted postoperative outcomes.

Patients and Methods

We retrospectively analyzed all patients with ischemic cardiomyopathy who underwent left ventricular restora-

Accepted for publication May 11, 2006.

Presented at the Fifty-second Annual Meeting of the Southern Thoracic Surgical Association, Orlando, FL, Nov 10–12, 2005.

Address correspondence to Dr Adams, University of Virginia, Department of Surgery 2702 E Hospital, Charlottesville, VA 22908; e-mail: jda2d@virginia.edu.

Published by Elsevier Inc

0003-4975/06/$32.00
doi:10.1016/j.athoracsur.2006.05.035

tion between 1996 and 2005 at the University of Virginia. Institutional review board approval was obtained for the chart review. Individual consent for the study was waived because ventricular restoration is an accepted treatment and individual patients were not identified. Follow-up was completed by means of ongoing institutional contact or telephone contact with the referring physician.

All patients with a region of left ventricular asynergy or dyskinesis and coronary artery disease were included in the study. Echocardiography, ventriculography, or rarely, magnetic resonance imaging was used to confirm ventricular dysfunction and calculate the ejection fraction. Angiographic diagnosis of left ventricular aneurysm was based of the accepted definition of a segment of the left ventricular wall protruding from the expected normal outline of the ventricular chamber with akinesis or dyskinesis in systole (CASS definition [6]). When available preoperatively, nuclear myocardial perfusion scans (either thallium 201 or more recently technetium 99 sestamibi) were used to confirm the presence or absence of viability. Unfortunately, the referring institutions did not routinely measure preoperative ventricular volumes.

Meeting these criteria were 89 patients (69 men, 20 women) who were divided into two groups determined by their preoperative ejection fractions: less than .25 (n = 28) (EF < .25) and .25 or greater (n = 61) (EF ≥ .25). All preoperative risk factors and postoperative outcomes as defined by the Society of Thoracic Surgeons database were analyzed. NYHA classification and preoperative symptoms were confirmed by chart review.

Surgical Technique

Intraoperative transesophageal echocardiography was used in most of the cases (especially after 1998) before cardiopulmonary bypass and cardioplegic arrest to evaluate the left ventricular and mitral valve function. Patients were then placed on cardiopulmonary bypass and had cardioplegia and left ventricular venting cannula placed. The cross clamp was then applied and the heart arrested with cold blood antegrade or retrograde cardioplegia, or both. Cold blood cardioplegia was reinforced on average every 20 minutes. A "hot shot" was administered before removal of the cross clamp since 2000. CABG was performed as necessary. Ventricular restoration and mitral valve procedures were performed before the proximal anastomoses. The mitral procedures were performed after the restoration procedure with the exception of the Alfieri repairs, which were performed through the ventriculotomy.

With the aortic cross clamp in place, the left ventricle was opened near the apex at least 1 cm lateral to the septum, most commonly in an ecchymotic area that was thinned, scarred, and often collapsed by the left ventricular vent. The ventriculotomy was then extended parallel to the left anterior descending artery to visualize the interior of the left ventricular wall. Internal inspection of the ventricle often delineated scarred and viable myocardium, with scar appearing white. The region of scar was also palpable as a thinned area, with the transition area often readily apparent.

A suture of 2-0 Prolene (Ethicon, Somerville, NJ) was then placed along the margin of the scar in circumferential or purse string fashion as described by Dor [3]. Care was taken to ensure this stitch was placed no deeper into the ventricle than the base of the papillary muscles. This was done to create a purse string to anchor the endoventricular patch and reduce ventricular volume. A Dacron patch (DuPont, Wilmington, DE) was then sewn to the ridge created by the purse-string suture with 2-0 or 3-0 Prolene in a running fashion. The ventriculotomy was then folded over the patch and closed with 2-0 Prolene, with or without Teflon (DuPont) strip reinforcement. Care was taken to ensure no distortion of the patch with closure. Additional sutures were applied as needed for hemostasis. Patients were then weaned from cardiopulmonary bypass with ionotropic agents and intraaortic balloon pump (IABP) as necessary.

Transesophageal echocardiography confirmed contractility, mitral valve function, and ventricular size. All patients recovered in the thoracic and cardiovascular postoperative unit and were discharged home on angiotensin-converting enzyme inhibitors, diuretics, and β-blockade per protocol unless these were contraindicated. Follow-up was performed by the referring cardiologist after the initial 3-week visit in the surgical clinic.

Statistical Analysis

Statistical analysis of patient characteristics and postoperative outcomes between the two groups were performed with a two-sample Student t test. All p values are two-tailed. The results are presented as means ± SD. The χ^2 test was used for comparison of proportions. Analysis of survival was performed using Kaplan-Meier statistical curves. Times were taken as time from operation to time of death or last known follow-up. Patients lost to follow-up were censored for Kaplan-Meier survival analysis from the date of last known contact.

Results

Baseline Characteristics

Preoperative characteristics (Table 1) of the two groups were compared and revealed no significant differences in the age or gender of the patients between groups. Mean patient age was 61.8 ± 10.7 years (range, 39 to 85 years). Mean NYHA functional class was 3.3 ± 0.7 (range, 1 to 4). As expected, NYHA scores were significantly worse ($p <$ 0.05) in the EF < .25 group (3.6 ± 0.5) than in the EF ≥ .25 group (3.1 ± 0.7). Mean preoperative ejection fractions measured with echocardiogram were .28.6 ± .095 (range, .15 to .45). Twenty-eight patients in the EF ≥ .25 cohort (45.9%) had nuclear medicine viability studies (either thallium or MIBI). Lack of uptake was demonstrated apically in 16, anteriorly and apically in 4, inferioapically in 6, and anteriorly, apically and inferiorly in 2. Eighteen patients (58.0%) in the EF < .25 group also had nuclear viability studies. Nonviable myocardium was demon-

Table 1. Preoperative Characteristics

	EF < .25 (n = 28)[a]	EF = ≥ .25 + (n = 61)[a]
EF[b]	18.3 ± .035	33.4 ± 7.4
NYHA[b]	3.6 ± 0.5	3.1 ± 0.7
Symptoms		
nil	1 (3.6)	2 (3.3)
Dyspnea	9 (32.1)	16 (26.2)
Symptom		
Angina[b]	0	11 (18.0)
Angina + dyspnea	9 (32.1)	19 (31.1)
Shock/pulm edema	5 (17.9)	4 (6.5)
Vtach	1 (3.6)	1 (1.6)
TIA	0	1 (1.6)
Cerebrovascular dis	3 (10.7)	16 (26.2)
Chronic lung dis	8 (28.6)	12 (19.7)
Previous CVA	2 (7.1)	10 (16.4)
Diabetes	8 (28.6)	21 (34.4)
Hypertension	20 (71.4)	47 (77.0)
Pre-op creatinine (mg/dL)	1.2	1.1
Periph vasc dis	3 (10.7)	11 (18.0)
Renal dysfunction	3 (10.7)	4 (6.5)
Smoker	21 (75)	46 (75.4)
AICD	5 (17.9)	6 (9.8)
Procedure		
Elective	16 (57.1)	43 (70.5)
Urgent	11 (39.3)	17 (27.9)
Emergent	1 (3.6)	1 (1.6)
Mean pre-op PA (mm Hg)	29	22
Pre-op degree of MR	1.7	0
Pre Med RX[b]	24 (85.7)	22 (36.1)

[a] Data are means ± SD or numbers (%). [b] $p < 0.05$.

EF = ejection fraction; TIA = transient ischemic attack; CVA = cerebrovascular accident; AICD = automatic implantable cardioverter defibrillator; PA = pulmonary artery pressure; MR = mitral regurgitation.

Table 2. Operative Characteristics

	EF < .25 (n = 28)[a]	EF ≥ .25 (n = 61)[a]
CAB + DOR[b]	17 (60.7)	51 (83.6)
CAB + MVR + DOR	5 (17.9)	3 (4.9)
DOR	0	6 (9.8%)
DOR + MVR	3 (10.7)	0
CAB + DOR + Other	3 (10.7)	1 (1.6)
CPB time	137.5 ± 40.5	136.4 ± 46.1
cross clamp time	83.9 ± 50.4	93.3 ± 47.4
# bypasses	2.6 ± 1.3	2.4 ± 1.3
MV repair-alfieri	4 (14.3)	2 (3.3)
MV repair - ring	4 (14.3)	2 (3.3)
Pre-op IABP[b]	5 (17.9)	1 (1.6)
Intra-op IABP[b]	6 (26.1)	4 (6.7)

[a] Data are numbers (%) or means ± SD. [b] $p < 0.05$.

EF = ejection fraction; CAB = coronary artery bypass; DOR = Dor procedure; MVR = mitral valve repair; CPB = cardiopulmonary bypass; IABP = intraaortic balloon pump.

strated at the apex in 13 patients. As well, there was no uptake in the anterior and apical regions in 1 patient and the anterior, septal, and apical regions in 4 patients. Mean ejection fraction was .183 ± .035 in the EF < .25 group and was .334 ± .074 in the EF ≥ .25 group. Preoperative IABP were placed in 17.9% of patients in the EF < .25 group and in 1.6% of patients from the EF ≥ .25 group ($p < 0.05$).

Operative Characteristics

Although there were no significant differences in the number of bypass grafts between the two groups (Table 2), concomitant mitral procedures and intraoperative placement of IABP were significantly higher in the EF < .25 group, of whom 32.1% (9/28) underwent mitral valve procedures versus 8.2% (5/61) of the EF ≥ .25 patients ($p < 0.05$). Intraoperative IABP placement was performed in 26.1% (6/23) of the EF < .25 group, but only 6.7% (4/60) of the EF ≥.25 group needed mechanical support (patients with preoperative IABP were excluded from the calculation).

Postoperative Characteristics

Overall operative mortality, defined as death within 30 days of operation, was 3.4% (3/89) for all patients, with one death occurring in the EF < .25 group (1/28) and two deaths occurring in the EF ≥ .25 group (2/61) (3.6 % versus 3.3%, p = NS). Overall 5-year survival was 82%. Five-year survival in the EF < .25 cohort was 69.6% versus 88.3 % in the other cohort ($p = 0.066$) (Fig 1). IABP placement was compared (Table 3) and revealed significantly increased use in the EF < .25 group of 39.2% (11/28) compared with 8.2% (5/61) of the EF ≥ .25 group ($p < 0.05$) and 18.0% (16/89) of the total cohort. In an attempt to lessen the impact of selection bias, patients

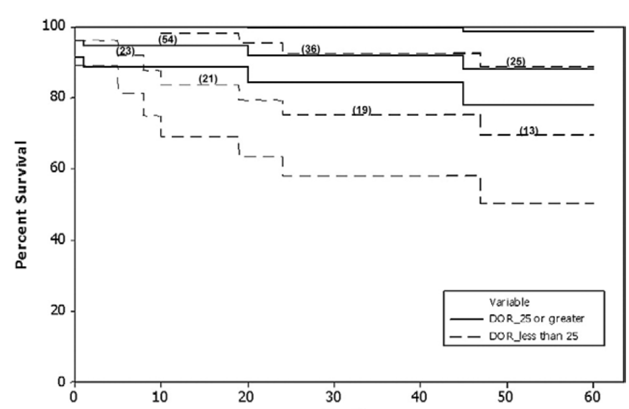

Fig 1. The 5-year survival comparison of the two groups. The solid line shows the group with an ejection fraction < .25, and the dashed line shows the group with ejection fraction ≥ .25. Confidence intervals displayed in the same line style (p = 0.066) Numbers in parenthesis are patients at risk for time intervals. (DOR = Dor procedure.)

Table 3. Postoperative Characteristics

	EF < .25 (n = 28)[a]	EF ≥ .25 (n = 61)[a]
Length of stay (days)	7.4 ± 3.6	8.9 ± 15.6
Septicemia	1 (3.6)	3 (4.9)
ReOp Bleed/tamponade	2 (7.1)	2 (3.3)
A fib	6 (21.4)	18 (29.5)
Cardiac arrest	2 (7.1)	0
Pneumonia	0	5 (8.2)
Prolonged ventilation	4 (14.3)	6 (9.8)
Renal failure/dialysis	1 (3.6)	3 (4.9)
Operative mortality	1 (3.6)	2 (3.3)
IABP (all)[b]	11 (39.2)	5 (8.1)

[a] Data are numbers (%) and means ± SD. [b] $p < 0.05$.

EF = ejection fraction; IABP = intraaortic balloon pump.

with preoperative IABP placement were dropped from both groups before calculations. Even when patients with preoperative IABPs were dropped, the difference between groups was still statistically significant ($p < 0.05$). Mean length of stay was 8.4 days ± 9.5 for all patients and was not significantly different between the two groups.

Comment

Acute MI and subsequent ventricular remodeling from aneurysmal disease leads to significant changes in ventricular volume and shape. The normal elliptical shape becomes dilated and spherical, impairing the ventricle's diastolic and systolic function. Ultimately, heart failure develops [2]. Left ventricular restoration has been shown in multiple studies to reshape the ventricle and decrease left ventricular volume significantly. This enhances ventricular contraction via multiple mechanisms, including decreasing wall stress and myocardial oxygen consumption, improving wall compliance, and enhancing the angle of systolic fiber contraction [7]. Left ventricular function as measured by ejection fraction improves.

Recently, the RESTORE Group (Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape to the left ventricle) reviewed nearly 1200 patients who had undergone left ventricular restoration from 1998 to 2003 and demonstrated it to be a highly effective therapy in the treatment of ischemic cardiomyopathy [8, 9]. Mean ejection fraction increased from .29 to .39, left ventricular end-systolic volume index (LVESVI) decreased from 80 mL/m^2 to 56 mL/m^2, overall 30-day mortality was 5.3%, and IABP was used in 8.2% of patients. Risk factors for death at any time postoperatively included preoperative ejection fraction ≤ .30, LVESVI ≥ 80 mL/m^2, concomitant mitral repair, advanced NYHA functional class, and age ≥ 75 years.

These risk factors clearly identify a high-risk population of surgical candidates for ventricular restoration. We found, however, that our patients in this group were able to benefit from reshaping of the ventricle with no significant increase in length of stay or early mortality. The long-term (5-year) mortality in our patient group was 69.6% in the EF < .25 group and 88.3% in the EF ≥ .25 group. Although not statistically significant ($p = 0.066$), it must be considered that this approaches significance and may represent a type 2 error. Regardless, the overall 5-year survival of 82% is significantly improved compared with the 5-year survival of patients undergoing CABG alone or medical management.

In addition, 32% of our high-risk group underwent concomitant mitral repair with no deaths. This is different than the findings of Mickleborough [10], who ultimately considered severe mitral regurgitation as a relative contraindication for operative therapy. With 89.9% of these patients also undergoing CABG at the same operation, we were able to surgically treat three of the pathologic aspects of heart failure, including the ventricle, the valve, and the vessels.

Both ejection fraction and LVESVI have been used in the past to help prognosticate outcomes associated with ischemic cardiomyopathy. White and colleagues [11] have demonstrated that the prognosis of ischemic cardiomyopathy is more closely related to left ventricular volume than ejection fraction, especially in patients with an ejection fraction of less than .35. A sample pre-LVESVI and post-LVESVI from our more recent patient population demonstrated an average reduction of LVESVI from 92.0 ± 27.2 mL/m^2 to 59.1 ± 23.8 mL/m^2 (Fig 2). However, the report by White and colleagues also demonstrated that ejection fraction is a highly significant predictor of cardiac mortality ($p < 0.001$). We have chosen ejection fraction for our primary delineation because this is still the most commonly recognized measurement of function. Although ejection fraction can certainly be misleading if only echo is used, evidence of basal contractility can be appreciated. This may be as important a finding as ejection fraction alone. Biplane ventriculograms may have better prognostic value but are not uniformly performed.

Another observation from our study included the significantly increased use of IABP in the EF < .25 group

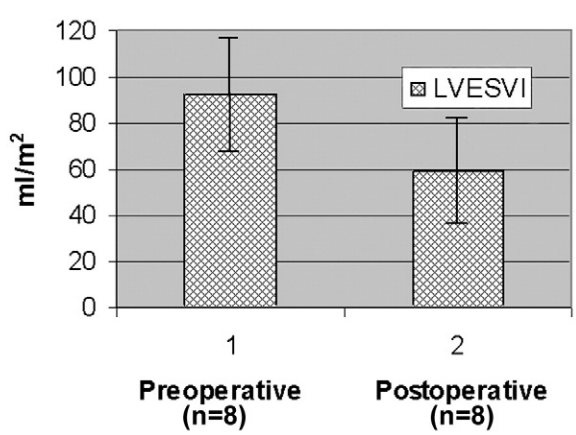

Fig 2. Preoperative and postoperative comparison of left ventricular end-systolic volume index (LVESVI). Data are presented as means ± SD.

than in the EF ≥ .25 group. Indications for IABP at our institution are similar to currently accepted indications [12] and include cardiogenic shock, post-MI refractory to other medical management (ionotropic agents and pressors), ongoing ischemia (especially post-MI), CHF, and perioperative low cardiac output syndrome. Compared with other authors' reports, we tended to use IABP support in a much higher percentage of patients. Some of this bias may be inherent in our patient population, given that our mean preoperative ejection fractions tended to be lower than that of other institutions [8]. The timing of IABP placement in our patients included all phases of the perioperative period. All of the preoperative IABPs ($n = 6$) were placed for preoperative cardiogenic shock. The rest were placed intraoperatively for low cardiac output syndrome or failure to wean from cardiopulmonary bypass, or both.

Torchiana and colleagues [13] reported their experience with more than 4700 cases of IABP support at MGH since 1968 and compared their most recent data with that of two other large institutional experiences [13–15]. The MGH patients, who underwent preoperative IABP placement more commonly (70% versus 35% and 18% in the other institutions), had significantly lower mortality rates (16% versus 28% and 44%). Although the association could not be proved causal, it was their impression that liberal use of IABP support stabilized medically refractory ischemia preoperatively. This may contribute to our good outcomes with the EF < .25 group, because unstable angina, with or without cardiogenic shock, was the indication for IABP support in four fifths of the patients who underwent preoperative IABP placement in this cohort. Two deaths in our cohort occurred in patients who received IABP support intraoperatively for low cardiac output syndrome. It may be that outcomes associated with IABP support are more a function of "why" it was used and not "when" it was used.

Urgency of operation is another recognized risk factor for outcomes. Most of our patients were followed-up preoperatively by cardiologists with an interest in heart failure and whenever possible were optimized before surgery. This may have contributed to our good outcomes.

In summary, the objective of this study was to help determine if extremely low preoperative ejection fraction should be a contraindication to ventricular restoration using the Dor technique. Although it is retrospective and observational and therefore subject to inherent bias, our experience does support the hypothesis that this procedure is safe for patients with markedly reduced preoperative cardiac function.

References

1. Gheorghiade M, Bonow RO. Chronic heart failure in the United States: a manifestation of coronary artery disease. Circulation 1998;97:282–9.
2. Mills RM Jr, Young JB, eds. Practical approaches to the treatment of heart failure. Philadelphia: Williams & Wilkins; 1998:2.
3. Dor V. Reconstructive left ventricular surgery for post-ischemic akinetic dilatation. Semin Thorac Cardiovasc Surg 1997;9:139–45.
4. Di Donato M, Sabatier M, Dor V, Toso A, Maioli M, Fantini F. Akinetic versus dyskinetic postinfarction scar: relation to surgical outcome in patients undergoing endoventricular circular patch plasty repair. J Am Coll Cardiol 1997;29:1569–75.
5. Maxey TS, Reece TB, Ellman PI, et al. Coronary artery bypass with ventricular restoration is superior to coronary artery bypass alone in patients with ischemic cardiomyopathy. J Thorac Cardiovasc Surg 2004;127:428–34.
6. CASS Principle Investigators. Coronary artery surgery study (CASS): a randomized trial of coronary artery bypass surgery. Survival data. Circ 1983;68:939–50.
7. Sallin EA. Fiber orientation and ejection fraction in the human left ventricle. Biophys J 1969;9:954–64.
8. Athanasuleas CL, Buckberg GD, Stanley AW, et al; RESTORE Group. Surgical ventricular restoration in the treatment of congestive heart failure due to post-infarction ventricular dilation. J Am Coll Cardiol 2004;44:1439–45.
9. Athanasuleas CL, Stanley AW Jr, Buckberg GD, Dor V, DiDonato M, Blackstone EH. Surgical anterior ventricular endocardial restoration (SAVER) in the dilated remodeled ventricle after anterior myocardial infarction. J Am Coll Cardiol 2001;37:1199–209.
10. Mickleborough LL, Carson S, Ivanov J. Repair of dyskinetic or akinetic left ventricular aneurysm: results obtained with a modified linear closure. J Thorac Cardiovasc Surg 2001;121:675–82.
11. White HD, Norris RM, Brown MA, et al. Left ventricular end-systolic volume as the major determinant of survival after recovery from myocardial infarction. Circ 1987;76:44–51.
12. Baskett, JFB, Ghali WA, Maitland A, Hirsch GM. The intraaortic balloon pump in cardiac surgery. Ann Thorac Surg 2002;74:1276–87.
13. Torchiana DF, Hirsch G, Buckley MJ, et al. Intraaortic balloon pumping for cardiac support: trends in practice and outcome, 1968 to 1995. J Thorac Cardiovasc Surg 1997;113:758–69.
14. Creswell LL, Rosenbloom M, Cox JL. Intraaortic balloon counterpulsation: patterns of usage and outcome in cardiac surgery patients. Ann Thorac Surg 1992;54:11–20.
15. Naunheim KS, Swartz MT, Pennington DG. Intraaortic balloon pumping in patients requiring cardiac operations: risk analysis and long-term follow-up. J Thorac Cardiovasc Surg 1992;104:1654–61.

DISCUSSION

DR JOHN V. CONTE (Baltimore, MD): Josh, excellent job. I think your mentors at the University of Virginia should be justifiably proud. You did a very nice job with the presentation. Thank you also as well for a copy of the manuscript, which I read on the plane and it was enjoyable reading.

As I have done more and more of these operations, I have been struck by the finding, at least it's my impression, that there are really two groups of patients who undergo this operation: those patients who have heart failure and those who have coronary disease with left ventricular dysfunction who have the operation done at the time of another operation. Can you tell me in your group of patients what the breakdown was, how many patients had an operation done for heart failure or those who had the operation done in conjunction with another operation?

I know a couple of years ago Dr Mickleborough from the University of Toronto looked at her series of several hundred patients and found that those who were operated on for heart failure did considerably worse than those who were operated for other indications.

The second area I would like to ask you to comment on is the area of ejection fraction. We all know that that is a very nonspecific and hard to determine number. There are many things that go into that variable, and how did you look at that specifically? Was it done by cath, echo, a combination of the two, how you actually arrived at that?

Thirdly, did you use any other parameters to try and quantify how sick these patients were? Do you have any other way that you can look at them, for example, hormonal levels, BNP, plasma norepinephrine levels, or anything along those terms, six-minute walk test, oxygen consumption studies, some of which have been found in various studies to be useful?

And can I have my first slide up, please. We did a similar study that we presented at the ISHLT last year, a similar number of patients, and we broke our patients down to about the same, 20% above and below. The difference was all of our patients were done for profound heart failure. Anybody who was done without that indication was excluded in this analysis. And we similarly came up with the same results you did, and I think this tends to verify your results in that there was really no long-term statistical difference. At the time we presented this last year we had about 18-month follow-up. We now have about 36-month follow-up in these patients, and these survival curves tend to hold consistently at three years.

(Slide) However, when we looked at New York Heart Classifications, which were categorized pretty rigidly by some of our cardiologists, we actually did come close to finding a difference, at least it looks that way, and in fact at three years, there was a difference. And so that gets into really the second question that I asked you. What does ejection fraction really mean and is it the parameter that we should be using on these patients?

And then the third and final question I will ask you is, and I will sit down to listen to your answers, the results that you have are pretty spectacular, and it is not just the experienced eye that you have. It may be in the use of balloon pumping. About 40% of your patients have balloon pumps in place, and most of them were not put in because of preoperative angina. They were put in really based on the gestalt of the operating surgeon. Are there any other parameters that you could quantify for us that might be helpful for those of us who are doing this operation as to when we might want to prophylactically put in the balloon pump? Could it be the degree of mitral regurgitation, multivessel infarction, anything along those lines?

Again, thank you very much for a job well done.

DR ADAMS: Thank you very much, Dr Conte. I will attempt to answer those questions in order. As to the indication for operation in our patients, I believe that about two thirds of the patients were operated on for pure heart failure and the remaining one third were primarily for ischemia.

As for the way that we calculate our EF at the University of Virginia, it has been established in combination of both ventriculograms and/or echocardiography. As to some of the more technical questions presented by Dr Conte, I would like to defer to D. Kron, if I may, to help answer some of those questions.

DR KRON: In terms of the issues about the balloon pump, a lot of the times the decision was made by the referring cardiologist. In other words, a patient would be referred to us for transplant or a VAD and then get a balloon pump. Then we would realize they were blood type O and 250 pounds, there was no way they were getting a heart, and then suddenly they were ours to do. So I think most of the time the gestalt was actually by the referring cardiologist, and that is the way it goes. But I must tell you that if some of these guys with really bad ventricles had any difficulty, they get a balloon pump. This has worked for us.

DR KEVIN D. ACCOLA (Orlando, Florida): I would like to expand on Dr Conte's questions somewhat as it was a very nice presentation. I think that ejection fraction sometimes is misleading. It can be somewhat subjective relative to preoperative inotropic support as well as depending on who is reading the echo or who is reading the catheterization. Have you considered looking at end-diastolic volumes or indexes, because I think there is a significant difference between a left ventricle with an end-diastolic volume of, say, 250 or 260 cc and an ejection fraction of 10% than one that has an end-diastolic volume, of 110 or 115 cc with an ejection fraction of 10%? I think both of those patients can be treated with this technique but yet obviously the patient's outcomes with the smaller end-diastolic volumes should do much better.

In regards to the intraaortic balloon pump, we have done over 80 of these now, and we have not used many intraaortic balloon pumps postoperatively except, as Irv had mentioned, when they come to the operating room with a balloon pump. My indication would be if you feel uncomfortable about the revascularization, that is if you don't feel that you have fully revascularized the patient. As Irv mentioned, if they struggle at all, we have no hesitation to put one in, but typically are not necessary. Thank you again, I enjoyed your presentation.

DR ADAMS: Thank you Dr Accola, and thank you for your question. To address the first part of your question, our data was collected from 1996 through 2004 and during that time there have been some more recently published studies looking at using end-diastolic volume rather than EF. As the technology has been evolving over that time period, we're also evolving towards using volume more frequently, and more recently, we have begun using MRI to calculate those ventricular volumes as well.