CARDIOPULMONARY BYPASS, MYOCARDIAL MANAGEMENT, AND SUPPORT TECHNIQUES

A COMPARISON OF THE EARLY AND MIDTERM RESULTS AFTER DYNAMIC CARDIOMYOPLASTY IN PATIENTS WITH ISCHEMIC OR IDIOPATHIC CARDIOMYOPATHY

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Objective: The main goal of this study is to determine the efficiency of the cardiomyoplasty procedure on patients with cardiomyopathy of different origins (ischemic and idiopathic origins). **Method:** Between June 1993 and August 1995, 24 patients underwent dynamic cardiomyoplasty with the left latissimus dorsi muscle in our institution. Early and midterm results, as well as the changes in hemodynamics and functional status during follow-up, were compared. **Results:** Early mortality rate was 20.8% (five patients). Concomitant coronary revascularization, a preoperative left ventricular ejection fraction below 20%, and a functional capacity of class IV (intermittently) were associated with early mortality. The mean follow-up time was 17.3 months. Survival analysis (including early mortality) extending to the twenty-fourth month revealed no difference between the ischemic and idiopathic groups (55% vs 85%, respectively, $p = 0.09$). Functional status improved in the both groups. Ejection fractions were improved after cardiomyoplasty in all patients, regardless of their cause. Cardiac indices were higher 6 months after the operation. Changes in pulmonary capillary wedge pressure, peak pulmonary artery pressure, and left ventricular end-diastolic volume were not significant. **Conclusion:** Although cardiomyoplasty improves functional capacity and hemodynamics in patients with both idiopathic and ischemic cardiomyopathy, the idiopathic group is thought to achieve optimal benefit with regard to lower complication rates and lower early mortality expectancy owing to the absence of concomitant coronary revascularization. (J Thorac Cardiovasc Surg 1997;113:173-81)

Since the first clinical application of cardiomyoplasty in 1985,¹ determining the patient group expected to have the maximum benefit after the procedure has been a major concern in many clinical and experimental trials. Although dynamic cardiomyoplasty has been performed on more than 500 patients and results in groups with different causes for cardiomyopathy have been reported, the efficacy

of dynamic cardiomyoplasty in the separate groups still needs to be clarified. In this study, we compared the early and midterm courses of our patients with ischemic and idiopathic origins for cardiomyopathy with regard to operative mortality, survival, functional capacity improvement, and certain clinical and hemodynamic parameters.

Patients and methods

Between June 1993 and August 1995, 24 patients underwent dynamic cardiomyoplasty with the left latissimus dorsi muscle in our institution. Two of the patients were female. The mean age was 43 ± 9 years. All patients were in New York Heart Association functional class III (six patients had been admitted to the hospital with class IV symptoms and had improved to class III with vigorous medical treatment). Our patient population was divided into two subgroups depending on the causes of the disease: ischemic cardiomyopathy group (11 patients) and

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Table I. Preoperative data

	Ischemic	Idiopathic	Total
Patient No.	11	13	24
Female/male	0/11	2/11	2/22
Mean age (yr)	43 ± 6	42 ± 11	43 ± 9
NYHA class III	8	10	18
NYHA class IV (intermittent)	3	3	6
Average C/T ratio	0.60	0.60	0.60
Major Holter arrhythmia	4	5	9
LVEF (MUGA) (%)	23 ± 4	27 ± 4	25 ± 4
PCWP (mm Hg)	17 ± 4	18 ± 10	18 ± 7
Cardiac index (L/min/m ²)	2.38 ± 0.2	2.44 ± 0.3	2.42 ± 0.3

C/T ratio, Cardiothoracic ratio; LVEF (MUGA), left ventricular ejection fraction determined by radionuclide ventriculography; NYHA, New York Heart Association; PCWP, pulmonary capillary wedge pressure.

idiopathic cardiomyopathy group (13 patients). Ischemic cardiomyopathy was diagnosed by the occurrence of a dilated cardiomyopathy and documented coronary artery stenosis or typical enzymatic and electrocardiographic criteria for a previous myocardial infarction. The diagnosis of idiopathic dilated cardiomyopathy was assigned only to patients with angiographically normal coronary arteries and no other obvious cause for left ventricular dysfunction. There was no statistically important difference between the two groups regarding age and preoperative clinical or hemodynamic condition (Table I). Operative indications and contraindications and the surgical technique were the same as described by Carpentier and Chachques and their associates.^{2,3}

The operative procedure was left latissimus dorsi dynamic cardiomyoplasty. In four patients, dynamic cardiomyoplasty was supplemented with concomitant coronary artery bypass grafting. The operation was done on the beating heart without the use of extracorporeal circulation. Our indication for performing the concomitant coronary artery bypass procedure was angiographically important coronary stenoses associated with stable angina. In patients who had ischemic cardiomyopathy plus angina, we added coronary revascularization to the standard cardiomyoplasty procedure with the expectation of improvement due to perfusion of possibly hibernating local ventricular muscle and improvement of the symptoms (i.e., life quality) after the operation.

The use of prophylactic intraaortic balloon (IAB) support to improve patient stability during the procedure and in the early postoperative course seemed appropriate. Therefore, in the last 11 patients (two of the ischemic group and nine of the idiopathic group), we routinely inserted an IAB just after the induction of anesthesia. IAB counterpulsation lasted 1 or 2 days after the operation.

A Medtronic Cardiomyostimulator (model SP 1005A and model 4710; Medtronic, Inc., Minneapolis, Minn.) with a stimulation protocol described by Chachques, Grandjean, and Carpentier⁴ was used.

The mean follow-up time for the total cardiomyoplasty group was 17.3 months. Statistical analyses were performed by a certified statistician. The tests used for each item are described in the related part of the *Results*

section. Survival curves are estimated by means of the Kaplan-Meier method and compared by means of the log rank test. Because functional class is on a scale from I to IV, it is unlikely that the necessary distributional assumptions for a standard variance analysis will hold. Similarly, inadequate number of cases on the basis of ischemic and idiopathic subgroups necessitated nonparametric tests for comparison of the ejection fractions and functional status at certain follow-up periods. Therefore the Wilcoxon matched-pairs signed-rank test was used for performing pairwise comparisons of ejection fractions and functional capacities during the follow-up period. With this test we compared all possible pairs during a given follow-up period (e.g., preoperative to third postoperative month, preoperative to sixth postoperative month, third to sixth postoperative month) for the total group (appendix). Comparisons of these data between the ischemic and idiopathic groups at each follow-up period were performed with the Mann-Whitney U test. With this test we compared the differences from the baseline (preoperative) values for the ejection fractions or average functional classes from the two subgroups (ischemic and idiopathic) at the same follow-up period. For this purpose, the ejection fraction or functional class values obtained at postoperative months 3, 6, 12, and 24 were subtracted from the preoperative value. The changes from the preoperative period for each postoperative interval were obtained for both groups (idiopathic and ischemic). Then, using the Mann-Whitney U test, we compared these adjusted values (the change from the preoperative period) from those two subgroups (e.g., the difference at the third postoperative month for the idiopathic group was compared with that of the ischemic group). Because this is a multiple comparison situation (with ten comparisons in the total group between the periods during the follow-up and four between the subgroups at the same period), an adjustment for the *p* value was necessary. An adjusted *p* value (α) may be calculated as follows: For the pairwise comparisons for the ejection fraction or functional class improvement in the total group during follow-up (i.e., Wilcoxon matched-pairs signed-rank test), $\alpha = 0.05 / 10 = 0.005$. For the comparisons between the ischemic and idiopathic subgroups at each follow-up period (i.e., Mann-Whitney U test), $\alpha = 0.05 / 4 = 0.013$. Any significance depending on these adjusted *p* values is indicated in the appendix.

Univariate analysis for determining the factors associated with early hospital mortality was performed with Fisher's exact test. Proportions such as mortality rates are compared with the χ^2 test. A *p* value equal to or smaller than 0.05 was considered as statistically important.

Results

Mortality. There were five early and two late deaths (30-day hospital mortality was 20.8%). Early hospital mortality rate was 36.3% in the ischemic group and 7.6% in the idiopathic group. The difference between these two mortality rates did not reach statistical significance (*p* = 0.11).

As seen in Table II, in the early postoperative period, one patient from the idiopathic group died

Table II. Mortality causes

	Ischemic	Idiopathic	Total
Early			
Low cardiac output	2*	1	3
Cerebral embolism	1	—	1
Sepsis	1*	—	1
Late			
Congestive heart failure	1*	1	2

(*)Patients with associated coronary revascularization.

of low cardiac output. Four patients from the ischemic group died (two of low cardiac output, one of cerebral embolism, and another of *Klebsiella* pneumonia and sepsis). Three of those four patients with ischemic cardiomyopathy who died in the early postoperative period had also undergone concomitant coronary bypass grafting.

Postoperative complications. Early postoperative complications are summarized in Table III. Complications were more frequent in the ischemic group. Apart from the prophylactic use in the last 11 patients, an IAB was inserted in the early postoperative period in four additional patients for the treatment of low cardiac output.

Events in the follow-up period. Two deaths occurred in the follow-up period. One patient with cardiomyopathy of ischemic origin (the last surviving patient with concomitant coronary bypass) died of biventricular failure on postoperative day 110. Another patient (with idiopathic origin) died of cardiac failure on postoperative day 247. This patient had had a preoperative left ventricular ejection fraction of 11% and a left ventricular end-diastolic volume of 400 ml. One patient with ischemic cardiomyoplasty was hospitalized 1 year after the operation with atrial fibrillation refractory to medical therapy. Later his myostimulator was switched from 1:2 mode (latissimus dorsi muscle contracts with every second heartbeat) to 1:1 mode and sinus rhythm was restored. Apart from these, no other patient was hospitalized for congestive heart failure in the follow-up period.

Incremental risk factors for early hospital mortality. Univariate analysis (Fisher's exact test) was performed for the total group to determine the parameters associated with early hospital mortality. Age, type of cardiomyopathy (ischemic or idiopathic), concomitant coronary revascularization, prophylactic IAB support, a preoperative left ventricular ejection fraction below 20%, preoperative spirometric data below 50% of predicted, severe preoperative rhythm disturbances, preoperative functional classes (i.e., class III vs intermittent class IV), and

Table III. Early nonfatal postoperative complications

	Ischemic group (n = 7)		Idiopathic group (n = 12)	
	No.	%	No.	%
Low cardiac output	3	42.8	1	8.3
Rhythm disturbances				
Atrial fibrillation	2	28.5	1	8.3
Ventricular fibrillation	2	28.5	2	16.6
Frequent VPCs	4	57	1	8.3
Wound infection	2	28.5	1	8.3

VPCs, Ventricular premature contractions.

Table IV. Factors associated with early hospital mortality: Univariate analysis

	p Value
LVEF below 20%	0.0013*
Class IV (intermittent) functional capacity	0.018*
Concomitant coronary revascularization	0.018*
Age	0.486†
Severe rhythm disturbances	0.432†
Left ventricular end-diastolic pressure	0.09†
Ischemic etiology	0.111†
Spirometric data below 50% of predicted	0.452†
Prophylactic IABP	0.215†

LVEF, Left ventricular ejection fraction; IABP, intraaortic balloon counterpulsation.

*Statistically significant.

†Not significant.

preoperative left ventricular end-diastolic pressures were the factors to be analyzed for any association with early mortality. Univariate analysis indicated the associated coronary bypass procedure ($p = 0.018$), a class IV functional capacity (intermittently) ($p = 0.018$), and a preoperative left ventricular ejection fraction below 20% ($p = 0.0013$) as the factors associated with early mortality (Table IV).

Survival comparison. Kaplan-Meier analysis (log rank) was used for survival comparisons. Operative mortality is included in this analysis. A p value less than or equal to 0.05 was considered as statistically important. Survivals for each group (ischemic, idiopathic, and combined) are presented in Fig. 1.

Kaplan-Meier survival analysis revealed no statistically important difference between the ischemic and the idiopathic groups ($p = 0.09$). At postoperative month 24, survivals were 55% versus 85%, respectively (Fig. 1). Survival for the total group was 71%.

Comparison of preoperative and postoperative hemodynamic data

Ejection fraction. The Wilcoxon matched-pairs signed-rank test was used for pairwise comparisons

% Survival ($p=0.09$, Not Significant)

	0	1st mo	6th mo	12th mo	18th mo	24th mo
<u>Idiop.</u>	13	12	12	11	6	5
<u>Ische.</u>	11	7	6	5	5	5
<u>Total.</u>	24	19	18	16	11	10

Fig. 1. Postoperative survival (including early hospital mortality) in patients with ischemic or idiopathic cardiomyopathy. Patient numbers entering each period from each group are described below the illustration. *Idiop.*, Idiopathic; *Ische.*, ischemic.

Table V. Hemodynamics

	Preop.	Postop.			
		3 mo	6 mo	12 mo	24 mo
Patient No.	24	19	18	16	10
LVEF (MUGA) (%)					
Total group	25 ± 4	34 ± 10	34 ± 6	32 ± 5	35 ± 6
Ischemic	23 ± 4	32 ± 9	34 ± 7	28 ± 3	31 ± 4
Idiopathic	27 ± 4	36 ± 11	35 ± 4	36 ± 4	39 ± 7
LVEDVI (ml/m ²)	115 ± 14*				121 ± 16*

LVEF (MUGA), Left ventricular ejection fraction determined by radionuclide ventriculography; LVEDVI, left ventricular end-diastolic volume index.

* $p = 0.453$ (not significant).

of ejection fractions during the follow-up period in the total group. A statistically important improvement was evident in the third, sixth, twelfth, and twenty-fourth postoperative months (see the appendix for exact p values) when compared with preoperative values (Table V and the appendix). The Mann-Whitney U test was used to compare the ejection fraction changes between the ischemic and idiopathic subgroups from the preoperative period

onward. No significant difference was found at any follow-up period (appendix). In other words, ejection fraction trends for the ischemic and idiopathic groups were roughly parallel in the first 2 years.

Cardiac index. We compared the preoperative and postoperative (sixth postoperative month) values obtained with cardiac catheterization. According to the Wilcoxon matched-pairs signed-rank test, the patients' cardiac indices improved after cardiomyoplasty ($p =$

0.03, Table VI). There were no important differences between the subgroups ($p = 0.857$).

Other comparative data. Pulmonary capillary wedge pressure, peak pulmonary artery pressure, and left ventricular end-diastolic volume (Table V) were not significantly affected after the operation, according to the Wilcoxon matched-pairs signed-rank test.

Functional class. The Wilcoxon matched-pairs signed-rank test was used for pairwise comparisons of average functional classes during the follow-up period in the total group. A statistically important improvement was evident in the third, sixth, twelfth, and twenty-fourth postoperative months when compared with preoperative functional classes (see the appendix for exact p values). A comparison between the ischemic and idiopathic groups was done with the Mann-Whitney U test at each follow-up period, as explained in the *Patients and methods* section. No significant difference between the subgroups was found at any postoperative time interval (appendix).

Preoperative mean functional class of 3.2 was improved to 1.3 after 2 years. This means an improvement of 60% in average functional class (Figs. 2 and 3).

Discussion

Various surgical methods have been proposed to treat end-stage heart disease. Transplantation and artificial organs have been used in these patients in limited numbers because of the scarcity of available donor organs for transplantation and clotting problems in artificial organs. Unavailability of donor organs resulting from socioeconomic problems and the lack of adequate infrastructure and organization strictly limit transplantation possibilities, especially in Turkey.

The idea of cardiomyoplasty is to wrap the latissimus dorsi muscle around the heart and to bring extra support both passively and dynamically while simultaneously contracting the muscle with the myocardium to augment the generated power. Contribution of the latissimus dorsi to cardiac activity may vary with the nature of the heart disease. We compared the outcome of patients undergoing cardiomyoplasty for two different types of cardiomyopathy to investigate the efficacy of the procedure. One group consisted of 11 patients with ischemic cardiomyopathy and the other consisted of 13 patients with idiopathic cardiomyopathy.

Age, prophylactic IAB pumping, preoperative spirometric data below 50% of predicted, severe preoperative rhythm disturbances, and preoperative left ventricular end-diastolic pressures were found to be the factors having no important influence on

Table VI. Cardiac index ($L/m^2/min$)

	Ischemic subgroup	Idiopathic subgroup	Total group
Preop.	2.38 ± 0.2	2.44 ± 0.3	2.42 ± 0.3
Postop. (6 mo)	2.60 ± 0.5	2.68 ± 0.7	2.67 ± 0.6
p Value	0.03	0.04	0.04

early mortality. Univariate analysis indicated an associated coronary bypass procedure, a class IV functional capacity (intermittently), and a preoperative left ventricular ejection fraction below 20% as the factors being associated with early mortality. Our relatively high rate of early mortality in the ischemic group might have been influenced by the associated coronary artery bypass procedure in this group. For more detailed information, logistic regression analysis could be performed after a sufficient number of cases for this analysis was obtained.

Many studies emphasize various incremental risk factors for early mortality. In a study by Magovern and associates,⁵ biventricular failure (especially with a right ventricular ejection fraction lower than 40%) was described as an important risk factor for early mortality. Biventricular failure was emphasized as a contraindication for cardiomyoplasty in the study by Carpentier and colleagues.²

In our patient population, the course in the intensive care unit was more complicated for the ischemic group than for the idiopathic group. Furthermore, concomitant surgery is frequently required in patients with ischemic heart disease, bringing additional problems that influence both mortality and morbidity. Carpentier and associates² documented that concomitant surgery is an incremental risk factor in the cardiomyoplasty population. Lorusso and associates⁶ operated on nine patients without any associated procedure, and only one of their patients died—as a result of respiratory distress syndrome in the first postoperative month. However, in some reports early mortality was found to be independent of associated surgical procedures.⁷

Minimal doses of inotropic drugs in combination with the perioperatively inserted IAB is logical in the cardiomyoplasty population, a group in which high perioperative risk is anticipated. Although statistical analysis revealed no effect on early mortality, prophylactic IAB support during the operation and for the first 48 hours of the postoperative period still seems logical to provide a smoother postoperative course and a more comfortable course during the surgical procedure. Of the last 11 patients with a prophylactic, preoperatively inserted IAB, only one

Fig. 2. The course of functional classes in the idiopathic group. *NYHA*, New York Heart Association.

Fig. 3. The course of functional classes in the ischemic group. *NYHA*, New York Heart Association.

patient died (of a noncardiac event—sepsis). On the other hand, of the 13 patients without this prophylactic measure, four died (three of low cardiac output). Therefore we advise the prophylactic perioperative insertion of an IAB as a routine procedure. However,

especially in patients with ischemic cardiomyopathy, a full Doppler evaluation of the lower extremity peripheral arteries should be done before considering such prophylactic use of the IAB, because of the extensive nature of the atherosclerotic process.

Follow-ups extending to the twenty-fourth postoperative month showed no statistically important difference in the Kaplan-Meier survival analysis between the ischemic and idiopathic groups.

Left ventricular ejection fractions are improved after cardiomyoplasty. Between the subgroups, postoperative trends in the ejection fractions were roughly parallel during the follow-up period. Improvement in the ejection fractions without significant change in left ventricular end-diastolic volumes suggested some beneficial effects of cardiomyoplasty.

A statistically important improvement in functional class (an improvement of 60%) for the total cardiomyoplasty population was established. This improvement did not differ in degree for the two etiologic subgroups.

Although no differences in objective (ejection fraction) or subjective (functional status) criteria were detected during the postoperative follow-up period between the two groups, the idiopathic group is thought to obtain optimal benefit with regard to lower early complication rates and lower early mortality expectancy. The advantage is that these patients do not need concomitant coronary revascularization, which is associated with early mortality.

In our study, the early mortality rate for the ischemic group was 36.3% whereas it was 7.6% in the idiopathic group. This difference did not reach statistical significance with Fisher's exact test ($p = 0.11$), which was used for the analysis of the factors to be associated with early mortality in this study. On the other hand, when another test (comparison of two proportions, z-test) is done, the p value reached 0.04. This difference may be due to the relatively low number of cases, and tests must be repeated after more cases are available for analysis. Thus better results may be expected in the idiopathic group in terms of early mortality and complication rates. This could probably be attributed to the difference in nature between the two etiologic conditions. Metabolic imaging studies in the ischemic cardiomyopathy group had revealed large defects covering more than 15% of the cross-sectional area of the left ventricle; however, such large defect zones had only rarely been observed in nonischemic cardiomyopathies.⁸ Residual function of the heart may be an important factor in the overall performance of the dynamic cardiomyoplasty.⁹ This might explain why dynamic cardiomyoplasty has been reported to be less efficient in such severe myocardial dysfunction.

In the light of the current study, we believe that risk is greater in ischemic than in idiopathic cardiomyopathy as a result of the pathophysiologic differ-

ences, as well as additional risks from the expected concomitant procedures (i.e., coronary bypass grafting). Hence higher mortality and morbidity could be expected in the early postoperative period. However, after a certain period of convalescence, the courses for the two groups became parallel. The data contain only the midterm results, and later follow-up will supply more information about the long-term prognosis of patients with different underlying causes.

In conclusion, in our 24-patient cardiomyoplasty group, we found an improvement in ejection fractions and in functional classes at the end of a follow-up period of 24 months. Survivals did not differ between the idiopathic and the ischemic subgroups. The current study considers early and midterm results. Because of the progressive nature of the disease, long-term results must also be obtained to clarify obscured points and perhaps to accentuate the possible differences between the etiologic subgroups that are currently not apparent.

Addendum

Since the submission of this manuscript, seven more patients have successfully undergone dynamic cardiomyoplasty in our institution. Hence our cardiomyoplasty experience has currently reached 31 cases. However, because the statistical interpretation of these patients has not been performed at this time, related data are not included in this study.

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Appendix. Statistical analysis of the follow-up data

<i>Compared parameter</i>	<i>Comparison</i>	<i>Compared periods</i>	<i>p Value</i>	<i>Significance*</i>	<i>Statistical test used for the analysis</i>
Ejection fraction (objective)	Within subject (total group, during follow-up)	Preop.-3 mo	0.0009	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-6 mo	0.0007	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-12 mo	0.001	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-24 mo	0.0031	Significant	Wilcoxon matched-pairs signed-rank test
		3 mo-6 mo	0.7333	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		3 mo-12 mo	0.2719	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		3 mo-24 mo	0.3139	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		6 mo-12 mo	0.2213	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		6 mo-24 mo	0.398	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		12 mo-24 mo	0.1551	Nonsignificant	Wilcoxon matched-pairs signed-rank test
	Between subject (ischemic vs idiopathic)	Preop.-3 mo difference between ischemic and idiopathic	0.6723	Nonsignificant	Mann-Whitney U test
		Preop.-6 mo difference between ischemic and idiopathic	0.3696	Nonsignificant	Mann-Whitney U test
		Preop.-12 mo difference between ischemic and idiopathic	0.0486	Nonsignificant	Mann-Whitney U test
		Preop.-24 mo difference between ischemic and idiopathic	0.4647	Nonsignificant	Mann-Whitney U test
Functional status (subjective)	Within subject (total group, during follow-up)	Preop.-3 mo	0.0001	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-6 mo	0.0002	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-12 mo	0.0007	Significant	Wilcoxon matched-pairs signed-rank test
		Preop.-24 mo	0.0031	Significant	Wilcoxon matched-pairs signed-rank test
		3 mo-6 mo	0.3613	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		3 mo-12 mo	0.593	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		3 mo-24 mo	0.3173	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		6 mo-12 mo	0.593	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		6 mo-24 mo	1	Nonsignificant	Wilcoxon matched-pairs signed-rank test
		12 mo-24 mo	1	Nonsignificant	Wilcoxon matched-pairs signed-rank test
	Between subject (ischemic vs idiopathic)	Preop.-3 mo difference between ischemic and idiopathic	0.2697	Nonsignificant	Mann-Whitney U test
		Preop.-6 mo difference between ischemic and idiopathic	0.3511	Nonsignificant	Mann-Whitney U test
		Preop.-12 mo difference between ischemic and idiopathic	0.0976	Nonsignificant	Mann-Whitney U test
		Preop.-24 mo difference between ischemic and idiopathic	0.0312	Nonsignificant	Mann-Whitney U test

Preop., Preoperative; 3 mo, postoperative third month; 6 mo, postoperative sixth month; 12 mo, postoperative twelfth month; 24 mo, postoperative twenty-fourth month.

*Significance is determined according to the *p* value adjustment. Adjusted *p* value = 0.05/10 = 0.005 for the Wilcoxon matched-pairs signed-rank test and 0.05/4 = 0.013 for the Mann-Whitney U test. See *Patients and methods* in text for details.

Commentary

This article reports the institutional experience of the authors with cardiomyoplasty. It is of interest because it indicates how the results claimed by the pioneering centers can be reproduced by others. The authors also attempted to analyze the outcome using the cause of cardiomyopathy (ischemic vs idiopathic) as a variable. However, such institutionally based data also suffer from some limitations. The obvious one in this series is the small sample size, which reduces the statistical power. For example, the hospital mortality for the ischemic group was 36.3%, almost five times that of 7.6% for idiopathic group, but the difference did not reach statistical significance ($p = 0.11$). Likewise, they reported no difference in 24-month survival ($p = 0.09$) between these two groups, even though the survivals were 55% versus 85%. Another weakness with small sample size is the difficulty in carrying out subgroup analysis. In this series, 24 patients were divided into two groups: 13 in the idiopathic and 11 in the ischemic group. In fact, the ischemic group contains four patients who underwent concomitant coronary revascularization, an important confounding factor that was not analyzed, perhaps because the number of patients was too small to do so.

It could be of interest to compare these findings with the results available in the larger database maintained by Medtronic Inc. for the Worldwide Cardiomyoplasty Group. As shown in Fig. 1, 216 patients with idiopathic cardiomyopathy had a survival curve similar to that of 130 patients whose heart failure was due to ischemia, although those with multivessel diseases may have higher postoperative risk. In contrast, the 45 patients who had concomitant coronary bypasses had a significantly higher risk of perioperative death. Preoperative New York Heart Association class IV was a significant risk factor. Unlike this series from Turkey, however, most coronary bypasses were carried out with

extracorporeal circulatory support, while cardiomyoplasty procedures are being done with pump standby.

In reviewing not only the survival, but also the functional and hemodynamic outcome, one wonders how they compare with alternate therapies, such as conventional medical management for heart failure. A prospective randomized trial to answer this is still in progress in North America. However, results of the phase II trial, in which a medically treated matched reference group served as control, are now available and will be published shortly.¹ For example, the hospital mortality was 12%, as compared with 20.8% reported in this series, and postoperative functional improvement was similar. Ejection fraction increases 6 and 12 months after the operation were statistically significant, but of lesser magnitude. Concomitant procedures and preoperative New York Heart Association class IV were avoided in the phase II study, so that some of the differences noted may be related to case selection. Together with often unique individual institutional experience, such multicenter studies, with their greater statistical power, contribute to our understanding and progress of cardiomyoplasty, and other novel surgical innovations.

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Fig. 1. Survival of idiopathic versus ischemic group.