

Dynamic Cardiomyoplasty. Clinical Follow-Up in Argentina

Jorge C. Trainini, Jose L. Barisani, Jorge H. Mouras, Edraundo Cabrera Fischer and Benjamin Elencwajg

Department of Cardiovascular Surgery, President Peron Hospital, Anatole France 770, (1870) Avellaneda, Provincia de Buenos Aires, Republica Argentina

Abstract

The aim of the present study is to evaluate results obtained after applying dynamic cardiomyoplasty to patients with dilated cardiomyopathy and severe ventricular dysfunction (Functional Class III-IV, New York Heart Association).

A dynamic cardiomyoplasty procedure was performed in 15 patients with a mean age of 59.2 ± 6.4 years old. Despite the medical treatment with inhibitors of the converted enzyme or vasodilators, all of these patients required 2.2 ± 0.7 hospitalizations/patient/year owing to congestive heart failure in the year before dynamic cardiomyoplasty was applied. In 8 patients the etiology of the cardiomyopathy was idiopathic, ischemic-necrotic in 6 and Chagas' disease in the other.

Hemodynamic studies were done preoperatively in all patients and every six months postoperatively.

Twelve patients had a follow-up for two years. The following values related to two-years evaluation improved significantly in comparison with baseline: functional class (1.7 ± 0.6 versus 3.06 ± 0.2); radiolabeled left ventricular ejection fraction ($29.7 \pm 5\%$ versus $23.6 \pm 3\%$); fractional shortening ($20.6 \pm 5\%$ versus $15.6 \pm 4\%$). Walking test values increased from 332 ± 127 meters to 421 ± 102 meters. Left ventricular diastolic diameter remained unchanged (72.7 ± 7 mm versus 72.3 ± 8 mm).

Improvement was observed in functional capacity and left ventricle systolic function parameters two years after cardiomyoplasty was applied.

Key words: congestive heart failure, cardiomyopathy, latissimus dorsi muscle, cardiomyoplasty, skeletal muscle.

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Congestive heart failure (CHF) is an important cause of morbidity and death. Although heart transplant are a good alternative for patients with advanced CHF, they can only be applied to a reduced number of patients. Natural limitations, lack of donors [7] or clinical and socioeconomic contraindications restrict their use [14]. For CHF patients and even for those who have not reached the clinical stage of a transplant, dynamic cardiomyoplasty (DC) offers an alternative to improve functional class and life expectancy. Since its introduction in 1985 by Carpentier and Chachques [2], this technique has undergone different stages [1] with the aim of placing its role in the clinical practice.

The purpose of the present report is to evaluate immediate and long-term results of the DC in Argentina, concerning a group of patients with dilated cardiomyopathy.

Material and Methods

Population study

The study included idiopathic or ischemic-necrotic dilated cardiomyopathy patients with a left ventricle ejection fraction of less than 30% and a functional class (FC) III-IV according to the New York Heart Association (NYHA). These patients were refractory to habitual pharmacological treatments. Candidates for heart transplant or other specific surgical treatments were excluded. Fifteen patients (11 males and 4 females) were operated using a DC procedure. They ranged from 46 to 74 years old and their average age was 59.2 ± 6.4 years. Although they were treated with inhibitors of the converted enzyme or vasodilators, these patients required 2.2 ± 0.7 hospitalizations per patient per year owing to CHF decompensation in the year before DC was applied.

The etiology of dilated cardiomyopathy was idiopathic in 8 patients, ischemic-necrotic in 6 and Chagas' disease

in the other. The presence of myocardial viability was discarded in the second group of patients by means of radioisotopic studies.

Chest x-rays showed an average cardiothoracic ratio of 0.59 ± 0.04 and signs of venocapillary high blood pressure in 15 patients. Preoperative echocardiographic studies revealed a severe dilatation of the left ventricle. The average values were: left ventricle diastolic diameter (LVDD) $72.7 \text{ mm} \pm 3 \text{ mm}$; left atrial diameter (LAD) $55.5 \text{ mm} \pm 10 \text{ mm}$; fractional shortening (FS) $15.6\% \pm 4\%$.

The left ventricular ejection fraction (LVEF) measured by means of radioisotopic ventriculography with technetium 99 was $23.6\% \pm 3\%$, whereas the left ventricular end-diastolic pressure (LVEDP) evaluated during cardiac catheterization was $23.2 \text{ mm Hg} \pm 8 \text{ mm Hg}$. The oxygen consumption was $13.3 \text{ ml/kg/min} \pm 3 \text{ ml/kg/min}$.

According to the NYHA classification, 14 of the patients were in PC III and 1 in FCIV (average 3.06 ± 0.2). To get an objective FC, patients were subjected to a 6-minute walking test, developing an average distance of $332 \text{ meters} \pm 127 \text{ meters}$. Three patients had atrial fibrillation with controlled ventricular frequency, the others were in sinus rhythm.

Surgical technique

One month before surgery, patients started doing programmed exercises to develop their latissimus dorsi muscle (LDM) to the full.

DC was performed on a two-way approach. The patient being in right lateral decubitus, the left LDM was dissected, keeping its neurovascular pedicle. Two flexible electrodes (Medtronic SP 5528 or 4750 Medtronic, Inc., Minneapolis, Minn.) were placed in the muscular flap. After a muscular stimulation test, the muscle was brought into the pleural cavity through a window made by resecting 6 cm of the anterior arc of the second rib.

Secondly, the patient was placed supinely and the heart was exposed, through sternotomy. The LDM was moved to the mediastinum through a posterior pericardiac hole. This procedure is excellent to obtain necessary muscular length to wrap ventricles to the full. It is advisable to perform this from the posterior of the heart and in a perpendicular way to the interventricular septum.

In two patients, it was not possible to wrap both ventricles completely with the muscle. This was achieved interposing the pericardium. Two electrodes (Medtronic SP 5548 or 4755) were implanted in the right ventricle to sense ventricular function while the generator was placed in a left subcostal position at a subaponeurotic level.

One patient had a previous revascularization surgery and another one had moderate mitral regurgitation requiring concomitant mitral annuloplasty.

Latissimus dorsi muscle stimulation

A two-chamber programmable pacemaker (Elite 7074, Medtronic) was used in 5 patients, the SP 1005 Medtronic cardiomyoestimulator in 6 patients and a Transform 4710 Medtronic cardiomyoestimulator in the other 4 patients.

Stimulation began after the first two weeks, in order to favor muscle adhesions to the epicardium and the development of collateral circulation. Stimulation was then started on a progressive and regular basis [6]. Thus, definite programming was set around the tenth week. The following technical aspects were taken into account: 1) the pulse train was set in the final period of QRS so that the stimulus could coincide with the closing of the mitral valve checked by echocardiography; 2) the maximum amplitude reached did not surpass the total stimulation threshold measured during surgery. The latter is defined as the minimum voltage that enables the total contraction of the muscle; 3) programmed stimulation remained at a 1:2 sequence in relation to heart rate.

Follow up protocol

Ventricular function was measured in all the patients before surgery and every 6 months postoperatively by means of echocardiography and radioisotopic ventriculography (technetium 99). Functional class was monitored through a 6-minute walking test, FC (NYHA) and oxygen consumption.

The long-term study excluded patients with a postoperative period of less than two years. Twelve patients were included in this evaluation.

Statistical analysis

Standard statistical methods were used to compare clinical, radioisotopic and echocardiographic parameters during follow-up. Variance and t test for group means, or chi square tests of proportions were applied as appropriate.

Results

Immediate postoperative period

Only one death (6.6%) occurred in the hospital, twenty-four hours postoperatively because of ventricular arrhythmia. All the patients required pharmacological support with inotropics, although only three of them remained with this medication for more than 48 hours. Four patients showed low cardiac output syndrome and 2 of them renal failure. No patient required mechanical circulatory support (Table 1).

The average postoperative bleeding was $352 \text{ ml} \pm 123 \text{ ml}$ and there was no need to reoperate on. There were no respiratory complications as a consequence of intrathoracic muscular mobilization. The period of mechanical respiratory support was $12.5 \text{ hours} \pm 8.3 \text{ hours}$.

There were supraventricular tachyarrhythmias in 4 patients and ventricular tachyarrhythmias in other 3. A patient suffered from a temporary ischemic stroke 12 days after surgery was performed, but there were no definitive after-effects. In three cases, there was seroma in the injury of the thoracotomy but it was stopped by means of compression. In one patient, there was an infection in this incision which was controlled through local treatment. At present, patients are subjected to an early compression of the thorax in order to avoid seroma.

Dynamic cardiomyoplasty. Clinical follow-up in Argentina

Table 1. Early post-operative morbi-mortality (n. 15 patients).

MORTALITY,	1 p (6.6%)
LOW CARDIAC OUTPUT	4 p
ACUTE RENAL FAILURE	2 p
M R S (> 24 HOURS)	2 p
SUPRA VENTRICULAR ARRHYTHMIAS	4 p
VENTRICULAR ARRHYTHMIAS	3 p
STROKE	1 p
SEROMA (LATERAL INCISION)	3 p
LOCALIZED INFECTION (LATERAL INCISION)	1 p

References, p : patient; MRS: mechanical respiratory support.

The patients remained in the intensive care unit during 4.7 days $\pm$ 1.9 days. The total hospitalization time was 21.7 days $\pm$ 1.1 days.

Long-term evolution

From the 14 patients discharged from hospital, 1 died two months later before completing the stimulation protocol. This was due to CHF progression. The other 13 completed the stimulation protocol; 12 of them surpassed the absolute postoperative period of two years, with an average of 31.3 months per patient.

This long-term evolution study will include the 12 patients who had a postoperative period of more than two years. After a one year follow-up, these patients had an FC (NYHA) of 1.8 ± 0.6 , whereas after a two years follow-up their FC was of 1.7 ± 0.6 . Only small doses of specific medication were required in the postoperative period.

One year before surgery, this group had had an average of 2.2 ± 0.7 h capitalizations per patient, whereas two years after DC the average was 0.4 ± 0.5 hospitalizations per patient ($p = 0.002$).

Data concerning ventricular function evaluation (echo-

cardiography, radio isotopes), and functional capacity (FC, 6-minute walking test, oxygen consumption) are shown in Table 2.

Discussion

Dissection and geometry of the muscular flap

This is considered a fundamental issue. The dissection of the LDM has to be tidy and vascularization must be preserved to avoid ischemia and a possible contractile deficit. Muscular trauma and excessive electro coagulation must be avoided, as well as thoracic hemorrhages.

Muscle orientation, defined as geometry, includes the passage of the muscular flap to the mediastinum and its perpendicular position as regards the cardiac axis [10]. In order to obtain a better wrapping of the left ventricle it is advisable to wrap the heart from the posterior, placing the flap forward. Recently, it has been effective to apply the "flap sliding" and "non-cardiac" techniques [4] used by the Broussais Hospital because they avoid excessive manipulation of the heart and reduce the possibility of arrhythmias.

Although single-pulse stimulation was applied five times with satisfactory results [17], it is preferable to use cardiomyostimulation with pulse train to obtain proper muscular transformation and cardiac support.

Immediate evolution

This technique should be performed with low morbimortality to justify its insertion in the habitual practice. It must be remembered that this surgery provides benefits after a long period of time and involves patients with advanced CHF that have to be subjected to surgery. The total death rate during surgery and follow-up should be smaller than the number of deaths occurred with pharmacological treatment. The right choice of patients as well as the consideration of the technical aspects mentioned above help achieve low morbi mortality.

Table 2. Summary of the results (two years) (n. 12 patients).

	Preop	Post-op One	Post-op Two	p Value
FC(NYHA)	3.06 ± 0.2	1.8 ± 0.6	1.7 ± 0.6	<
Hosp/y/p	2.2 ± 0.7		± 0.5	0.0001
WALKING TEST	332 ± 127	406 ± 119	421 ± 102	= 0.002
(m) VO_2 (ml/kg/m)	13.3 ± 3		14 ± 3	= 0.019
LVEF (%) LVDD	23.6 ± 3	28 ± 2	± 5	NS =
(mm) FS (%) LAD	72.7 ± 3	73.6 ± 7	20.6 ± 5	0.001
(mm)	15.6 ± 4	15 ± 4	53.2 ± 10	NS =
	55.5 ± 10	55.6 ± 5		0.003

References. FC: functional class (New York Heart Association); Hosp/y/p: Hospitalizations/year/patient; VO_2 : oxygen consumption; LVEF: left ventricular ejection fraction; LVDD: left ventricular diastolic diameter; NS: not significative; FS: fractional shortening; LAD: left atrial diameter; NS*: $p = 0.07$ NS trend.

Although there was morbidity in this group (Table 1), it was overcome satisfactorily. Mortality during postoperative period was 6.6%.

Functional capacity

FC improvement was observed one year after the operation with significant results [IS, 19]. The preoperative value changed from 3.06 ± 0.2 to 1.8 ± 0.6 . The FC improvement was kept after two years with a value of 1.7 ± 0.6 ($p < 0.0001$). This symptomatic recovery was observed during the 6-minute walking tests, from 332 meters $\pm$ 127 meters in the preoperative period to 421 meters $\pm$ 102 meters after two years ($p = 0.019$). One important fact coincided with the FC improvement. There was an important reduction in the number of hospitalizations, from 2.2 ± 0.7 patients/year, recorded one year before surgery to 0.4 ± 0.5 two years after it ($p = 0.002$).

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Ventricular junction

In the analysed patients as well as in other studies previously published, [3] an important improvement in ventricular function was observed one year after DC; LVEF increased significantly from $23.6\% \pm 3\%$ to $28\% \pm 2\%$ one year after surgery and FS grew from $5.6\% \pm 4\%$ to $18\% \pm 4\%$ over the same period.

Values two years after the operation showed an LVEF of $29.7\% \pm 5\%$ ($p = 0.001$) and an FS of $20.6\% \pm 5\%$ ($p = 0.003$). This showed a trend to keep improvement parameters achieved one year after surgery. Ventricular function and functional capacity were better compared to preoperative data.

As regards LVDD, the values obtained one year after the operation did not decrease compared to the preoperative period. They ranged from $72.7 \text{ mm} \pm 3 \text{ mm}$ to $73.6 \text{ mm} \pm 7 \text{ mm}$. Ventricular diameter did not progress in its dilatation, although this was observed two years after surgery with a diameter of $72.3 \text{ mm} \pm 8 \text{ mm}$ (NS).

The group of patients studied in this report show FC and echocardiographic parameters similar to previous investigations. However, our patients had higher preoperative averages (23.6%) of LVEF compared to the statistics reported by Carpentier and Chachques [4] (16%) and Moreira [13] (19.8%). Instead the age average of the group we showed was much more higher (59.2 years old) in relation to the other mentioned series: 50 years old and 48.2 years old respectively [4, 13]. This point should be taken into account because in this pathology, the higher the average age, the greater the chances of morbi-mortality during the operative period.

Another point to be considered during follow-up is the observation of a certain reduction of the left atrial diameter. Values ranged from $55.5 \text{ mm} \pm 10 \text{ mm}$ during the preoperative period to $53.2 \text{ mm} \pm 10 \text{ mm}$ two years after surgery. Although the statistical trend is $p = 0.07$, a desirable sequence could be inferred considering a controlled ventricular diameter progression, a decrease in mitral ring diameter and an improvement in diastolic function.

So far, no clinical signs of muscular contraction impairment have been observed during individual follow-up [11]. It is fundamental to preserve the LDM as much as possible and avoid an extensive overstimulation that could lead to its progressive damage. For this purpose it has been decided: a) not to surpass the total stimulation threshold measured during surgery and, b) to have a 1:2 heart to muscle contraction ratio, unless clinical needs require otherwise.

Conclusions

It is not the purpose of this report to discuss experimental developments or physiological assumptions. Only the interpretation of data obtained in the clinical stage will be analysed here. Thus, from 15 patients submitted to DC 12 patients (80%) survived for a minimum period of two years. Two patients died, which represents a good percentage in relation to FC III patients under exclusive medical treatment. The mortality rate in the latter amounted to at least 30% over the same period of time [15,16]. It must be remembered that the former accumulated an average of 31.3 months, whereas Moreira [12] reported only a 27% survival rate for patients under exclusive medical therapy during a period of 2 years.

In patients with a severe functional class the use of this technique can help to achieve a higher survival rate and a better quality of life [6]. However, inclusion parameters must be respected, there must be a strict preservation of the muscle during its manipulation and stimulation, and a proper control must be kept during follow-up [8,9,20,21]. The results obtained in this experience concerning ventricular function and evaluation of FC showed a considerable improvement compared to preoperative data. DC had proved to be a technique capable of being applied to CHF patients.

Address correspondence to:

Dr. Jorge Trainini, Department of Cardiovascular Surgery, President, Peron Hospital, Anatole France 770, (1870) Avellaneda, Provincia de Buenos Aires, Republica Argentina, home phone 541 3023810, business phone 541 204 1021128, business fax 541 3023810.

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Dynamic cardiomyoplasty. Clinical follow-up in Argentina

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