Long-term outcome of Dynamic Cardiomyoplasty in France

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Abstract
Dynamic Cardiomyoplasty (DCMP) aims at improving cardiac function in cases of severe heart failure. It consists in anchoring Latissimus Dorsi Muscle (LDM) to failing ventricles. LDM is stimulated in synchrony with ventricular contractions by burst of impulses (6, 31 ms) delivered by a cardiomyostimulator (CM). A retrospective analysis of collective French experience (6 centers) is reported. Since 1985, 212 patients (mean age: 53+/-11y, LVEF = 22+/-9%, NYHA Class III) underwent DCMP in France. Pre-operative ventricular dysfunction was left (68%), right (9%) and biventricular (23%). Longest FU is 20 y. Freedom of cardiac death (or heart transplantation) depended on pre-operative ventricular dysfunction i.e. 78% at 5 y, 69% at 10 y for RV, 48% at 5 y, 30% at 10 y for LV and 39% at 5 y, 30% at 10y for BiV dysfunctions. During follow up, 88% of patients improved by more than 1 NYHA Class. Heart transplantation (HTx) was performed in 26 patients who did not benefit from CMP or had late recurrence of heart failure symptoms. For non-urgent cases, outcome was similar to those expected for primary HTx. Combination with cardiac rhythm management systems (DDD, CRT-P, CRT-D) was safely achieved in 22 patients fulfilling ESC indication guidelines. Dynamic cardiomyoplasty provides long-term cardiac benefits. Best long-term outcome is obtained for isolated RV failure. Implementation of latest findings regarding muscle preservation, activation, energy transfer from muscle to heart as well as combination with defibrillator and resynchronization devices have the potential to further improve survival and efficacy results. In case of recurrent heart failure, heart transplantation is still feasible. Therefore, in selected patients, dynamic cardiomyoplasty could be considered as a mid-term to long-term biological bridge to heart transplantation

Key Words: Dynamic Cardiomyoplasty, Functional electrical stimulation, Latissimus dorsi muscle, Heart failure, Cardiac Bioassist

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The Dynamic Cardiomyoplasty (DCMP) procedure aims at supporting the cardiac function of patients suffering of chronic heart failure by wrapping the latissimus dorsi (LD) muscle (usually left LD) around the failing ventricles and stimulating it electrically in synchrony with ventricular function. The first successful clinical case was performed in January 1985 (Broussais Hospital, Paris). Since then, more than 1000 cases have been performed worldwide. This retrospective analysis gives an overview of the Dynamic Cardiomyoplasty collective experience in France (212 cases, 6 centers) and is an update of data previously presented at surgical and cardiology meetings.

Materials and Methods

Surgical approach

Usually, the cardiomyoplasty procedure is performed in two successive stages [1]:

a) Elevation of the Latissimus Dorsi muscle:

The patient is placed in the right decubitus position. The left latissimus dorsi muscle is dissected free with preservation of its axillary neurovascular pedicle. Neuromuscular pacing electrodes are implanted. The muscle flap and pacing leads are then transferred into the left thoracic cavity after resection of a segment of the second rib.

b) Cardiac wrap:

The heart is then exposed via a median sternotomy. One or two epicardial leads are implanted in right or

left ventricles for myocardial sensing and/or pacing. The LDM is wrapped around both ventricles and fixed with interrupted sutures to the pericardium.

Depending on indications i.e. left ventricular (LV), bi-ventricular (BiV) or right ventricular (RV) failure, different wrapping approaches can be considered and have been used:

1) LV and BiV insufficiency:
   a) Reinforcement: the left latissimus dorsi muscle is wrapped around the dilated ventricles (posterior to anterior wrap) and reinforces the myocardium
   b) Substitution: the left latissimus dorsi is used to replace a portion of myocardium e.g. after aneurysm or tumor resection (posterior to anterior warp)
2) RV insufficiency (e.g. arrhythmogenic RV dysplasia (ARVD):

Reinforcement: anterior to posterior wrapping of the RV using the left latissimus dorsi muscle. Procedure is generally associated with tricuspid valve annuloplasty.

Implantable stimulation system for cardiomyoplasty

To keep the LD muscle active, to prevent its atrophy and to support the cardiac function, the LD muscle needs to be activated in synchrony with ventricular contractions. The principle of function of the cardio-myostimulator is shown in Figure 1. The system enables the generation of burst electrical impulses synchronized on cardiac function. Muscle burst characteristics can be modified by telemetry e.g. amplitude, number of pulses, timing [1,2].

Stimulation protocol

In this clinical evaluation, the progressive stimulation protocol (Fig 2) developed at Broussais Hospital (Paris) was used in all patients [1]. This protocol was designed to allow for LD muscle to adapt to its new function. It consists in a 2 week post-operative rest period (i.e. no muscle stimulation) to allow for muscle recovery and adhesion to myocardium, followed by a progressive activation of LD muscle by a bi-weekly progressive increment of number of pulses in the burst. In the final setting, the burst contains 6 pulses (31 ms interval) and occurs on every other heart beat. The timing of the burst was adjusted by echocardiography.

Results

Clinical experience and Outcome

Since January 1985 (first clinical case), 212 cardiomyoplasty procedures have been performed in France (6 centers). Data presented below provide information on patient population and summarize the clinical experience and outcome, i.e survival and functional benefits [2,3].

Table 1 *General characteristics of patient population.*

Population	212 (176 M, 36 F)
Age	53 +/- 11 y (15-74)
Etiology	
Ischemic cardiomyopathy	95 (45%)
Idiopathic cardiomyopathy	96 (45%)
Other (valvular, tumor, RV dysplasia)	21 (10%)
Predominant ventricular dysfunction	
Left Ventricle	145 (68%)
Right Ventricle	19 (9%)
Bi-Ventricular	48 (23%)
NYHA Classification	*Mean=3.0*
Class II	18 (9 %)
Class III	172 (81 %)
Class IV	22 (10 %)

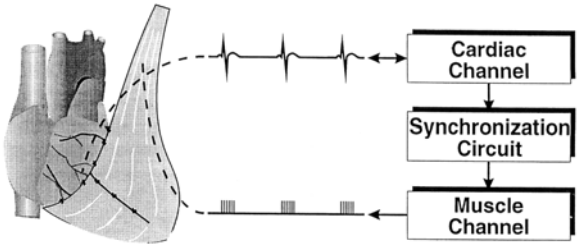


Fig 1 *Schematic description of cardiomyoplasty wrap and its electrical activation by the cardiomyo-stimulator. Muscle stimulation occurs during the heart systolic phase.*

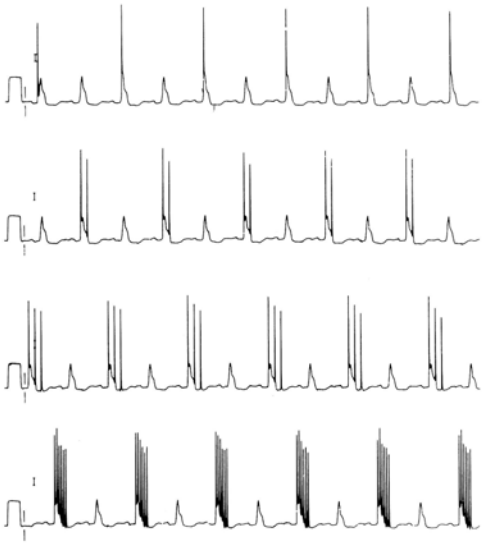
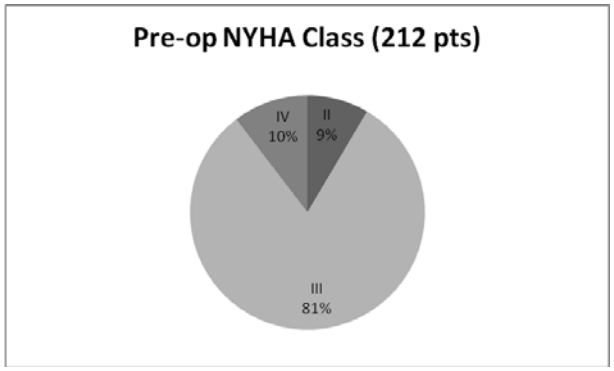
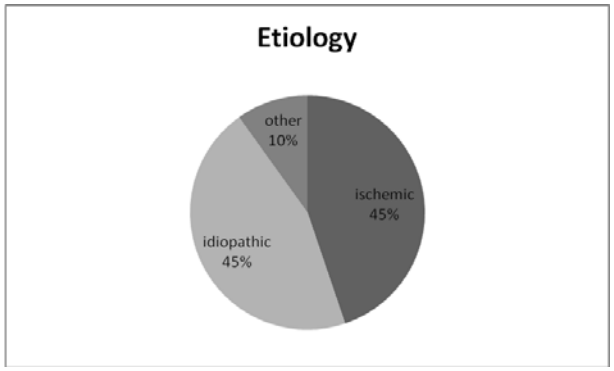
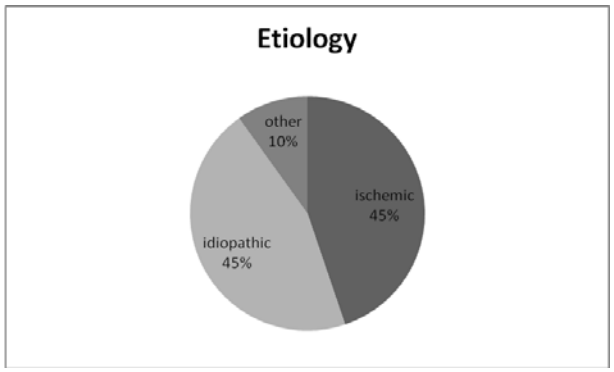


Fig 2 *Progressive stimulation protocol: to increase muscle activation, the number of pulses in the burst is increased every two weeks from 1 to 6 pulses. Burst is timed to occur during systole on every other heart beat.*







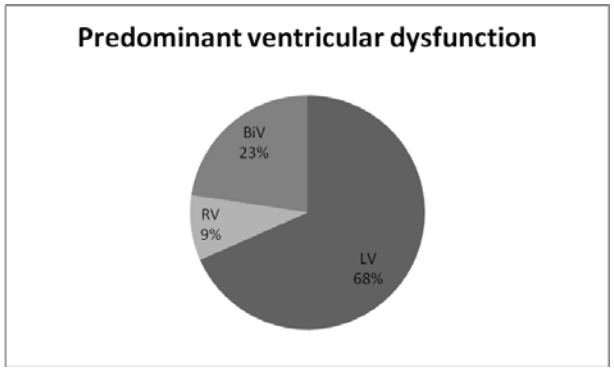
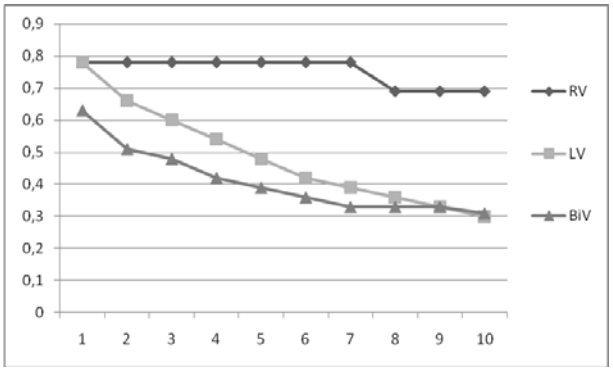
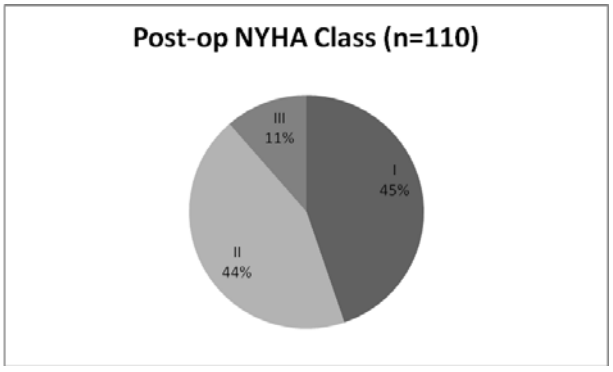


Fig 3 *A, Pre-operative NYHA Classification; B, Etiology of cardiomyoplasty patients (n=212), i.e. ischemic (95), idiopathic (96) and others (21) i.e. tumor (6), RV dysplasia (7), valvular (8). C, Predominant systolic dysfunction of cardiomyoplasty patients (n=212)*





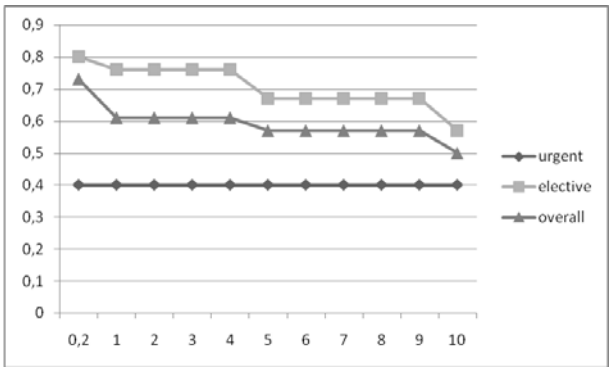


Fig 4 *A, Freedom from cardiac death or heart transplantation (n=208). B, Post-operative NYHA Class of patients currently alive (55, mean FU=10+3 y) or at the time of death i.e. sudden death (37, mean FU=4.1+2.7 y) or non cardiac death (18, mean FU = 5.4+3.6 y.). Mean NYHA Class = 1.66. Data exclude patients who died of heart failure (44, mean FU 3.4 + 3.3 y.), not discharged from hospital (29) and patients transplanted (26). C, Survival after heart transplantation in cardiomyoplasty patients (n=26)*

Patient population

Two hundred twelve (212) patients (mean age: 53 + 11y, LVEF=22+9%) with chronic heart failure symptoms (average NYHA Class = 3.0) underwent dynamic cardiomyoplasty procedure (Table 1).

The majority of patients (81%) were in NYHA Class III while 10% were in Class IV and 9% in Class II at

the time of surgery (Fig 3, A). Etiology (Fig 3, B) was ischemic (48%), idiopathic (45%) or other (7%), i.e. tumor (6), RV dysplasia (7) and valvular (8). Predominant ventricular dysfunction (Fig 3, C) was left (68%), right (9%) or biventricular (23%). The surgery was performed as described above, and was done as an isolated procedure in 74 % of cases and without the need for extracorporeal circulation. It was associated with additional procedures in 26% of patients, including LV resection (7.3%), tricuspid repair or replacement (7%), CABG (6.6%), heart tumor resection (2.7%), mitral valve repair or replacement (2.4%). Hospital death (within 30 day of surgery) occurred in 29 patients (14%) and was, as expected, higher in patients with greater severity of pre-operative heart failure symptoms i.e. 31.8% for NHYA Class IV, 12.4% for NYHA Class III and 5.8% for NYHA Class II. The most frequent cause of hospital mortality was heart failure (83%).

Survival

From January 1985, mortality occurred in 99 patients (mean time to death: 4 years). Causes of death were heart failure (44 (44.4 %), mean time to event: 3.4 y), sudden death (37 (37.4%), mean time to event: 4.1 y) and of non cardiac causes (18 (18.2%) mean time to event: 5.4 y). After cardiomyoplasty, twenty-six (26) patients received a heart transplant for recurring symptoms of heart failure (see below). Data, analyzed for freedom of cardiac death and/or transplantation for the different predominant ventricular dysfunction i.e. LV, RV or BiV, are shown in Figure 4 A.

Best outcome has been obtained for isolated right ventricular dysfunction (78% at 5 y., 69% at 10 y) while LV and BiV dysfunctions indications reached 48% and 39% at 5 year, respectively, and 30% at 10 y. Data were also analyzed for freedom from severe cardiac decompensation episodes (n=179).

Sixty-one percent (61%) of patients did not experience any severe decompensation episodes at 5y, 51 % at 10 y and 43% at 15 years. Globally, during follow up, 88% of patients improved clinically as measured by their NYHA class which improved by at least 1 class.

Excluding patients who died of heart failure, the average NYHA class of patients currently alive or just before sudden death or death of non cardiac cause (total 110 patients) was 1.66 i.e. Class III (11%), II (44%), I (45%) (Fig 4 B), an improvement of 1.34 Class.

Long-term muscle stimulation

The effect of latissimus dorsi muscle stimulation, the efficacy of its contraction and its need to be stimulated were not tested prospectively. However, some clinical observations could be done when for instance the stimulator reached its end of service i.e. device not replaced on time (battery depleted) as patient lived overseas or when muscle stimulation stopped due to lead failure. Majority of these events occurred more than 10 years after cardiomyoplasty. In each of these cases, the patient returned to hospital with recurring symptoms of heart failure. Correction of the problem e.g. exchanging the stimulator and/or repairing the lead allowed the patient to progressively recover to previous clinical condition.

These anecdotal observations confirm that muscle function can be preserved at the long term and also that long term muscle stimulation is needed to maintain clinical benefits.

The LD muscle active contraction was also observed at 10 y follow up via cine-x-ray.

Heart Transplant after Dynamic cardiomyoplasty

Cardiomyoplasty does not preclude heart transplantation [5,8,9,12]. In this cohort, heart transplantation (HTx) was indicated in 26 patients (12%) [4]. Indications were persistent heart failure i.e. no immediate cardiac improvement after CMP (19%) and recurring heart failure symptoms (81%) mostly due to progression of the underlying cardiac disease. Mean age was 51+11 y. and average time after CMP was 2.3+ 3 y (range 0 to 16.7 y.). Aetiology was mostly ischemic (50%) and idiopathic (42%). Left ventricular ejection fraction at CMP surgery was 19+6%. Predominant ventricular failure at CMP indications time were: Left Ventricle (76%), Bi-Ventricle (19%), and Right Ventricle (5%). Heart transplants were performed in a standard fashion without particular technical difficulties. Surgical procedure has been described elsewhere [5,8]. In short, the LDM flap was divided as far as possible inside the left pleural cavity and its vascular pedicle was obturated. The proximal portion of the muscle as well as the intramuscular pacing electrodes was kept in place in the left pleural cavity. The adhesions between the flap and the heart were not released so as to achieve an "en bloc" resection of the heart and muscle flap. The LDM was divided using electrocautery. The incidence of bleeding from the skeletal muscle stump was generally low. During removal of the recipient's heart, care was taken not to injure the left phrenic nerve that was frequently in tight relation to the latissimus dorsi muscle. Heart transplantation was then performed in a routine

Table 2 *Survival of heart failure patients treated with cardiomyoplasty and heart transplantation (HTx)*

Survival	**# pts**	**< 2 mo.**	**1 y.**	**5 y.**	**10 y.**
Overall	26	73%	61 %	57%	50%
Group 1 (HTx<4mo)	5	40%	40%	40%	40%
Group 2 (HTx>4mo)	21	80%	76%	67%	57%

manner, the donor heart being anastomosed to remnant atria and great vessels.

Overall survival results after HTx (mean FU: 5.5 y, longest FU: 13.5 y.) are shown in Table 2 and for two sub-groups depending on the time of HTx indication i.e. no clinical benefit after CMP (Group 1: urgent HTx done within 4 mo, mean: 1 mo, range 0.1 to 2.1 mo) or clinical benefit after CMP (Group 2: HTx after > 4mo, mean: 3 y. range .5 to 16.7 y.) Hospital mortality was higher for the "urgent" group 1 than for group 2 i.e. 60% vs. 17%. Early death causes were septicaemia (2) and graft failure (5). Late death causes were graft failure (4), reject (1) and gastric bleeding (1). At heart transplant time, LD muscle was found to be well preserved in 9 patients (35%), with slight hypertrophy and mild fibrosis in 11 patients (42%) and with severe ultrastructural impairment and atrophy in 6 patients (23%). Tight adhesions between the LDM and the heart walls were frequently observed [5]. This experience confirms that cardiac transplantation after CMP is technically feasible. As expected hospital mortality was higher when urgent HTx was required due to post-op heart failure or to early inefficient CMP support. Operative mortality was within expectations when elective HTx is performed late after CMP due to progression of underlying cardiac disease resulting in CMP inefficiency. Long-term survival (Fig 8) is similar to those for primary HTx [5]. Cardiomyoplasty, when it fails to provide cardiac benefits, does not preclude heart transplantation, and when indicated, CMP could be considered as a long-term biological bridge to heart transplantation.

Implantation of additional cardiac rhythm management (CRM) devices.

Concomitant implant of cardiomyostimulators and cardiac rhythm management (CRM) devices (pacing devices and/or defibrillators) can be safely achieved provided some precautions are taken.

Since 1985, new heart failure electrical therapies have been developed and have become accepted methods for heart failure treatment e.g. transvenous implantable defibrillators for treatment of tachycardia and arrhythmias, and cardiac resynchronization for patients with left bundle branch block (QRS > 130 ms) and heart failure symptoms. Some CMP patients

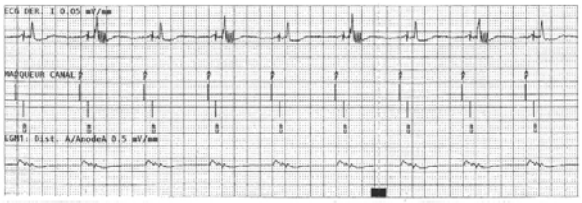


Fig 5 *Electrocardiogram recording of patient with concomitant implant of cardiomyostimulator and cardiac resynchronization devices*

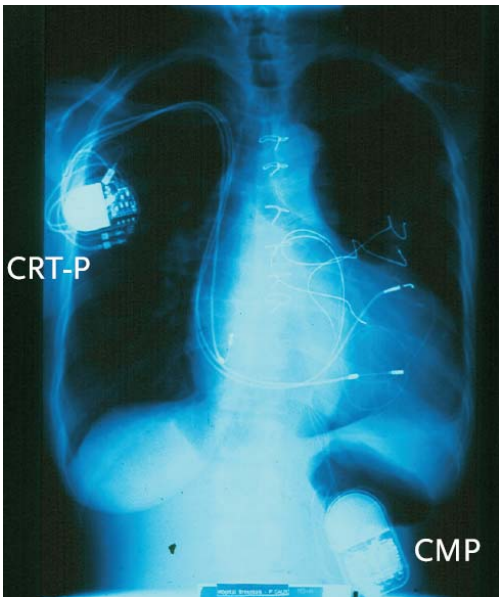


Fig 6 *X-ray of patient implanted with cardiomyostimulator (CMP) and cardiac resynchronization (CRT-P) systems*

fulfilled criteria for these more sophisticated cardiac rhythm management treatments (DDD, CRT, ICD) and were implanted with CRM systems. Muscle bursts generated by the cardiomyostimulator and /or pacing spikes or defibrillation shocks could potentially disturb respective device functions. Cases of combination of cardiomyostimulator with defibrillators have been reported before [5,9,12,14]. The results below document our experience with the safety of combining DDD, CRT and/or ICD devices with cardiomyostimulators [6]

Table 3 *Indications, cardiac rhythm management (CRM) device type and time of concomitant device implantation.*

DCMP indication	CRM indication	CRM device type				CRM device implant time	
		DDDR	CRT-P	CRT-D	ICD	pre DCMP	post DCMP
LV(2), BiV(1), RV(1)	A-V Block, chronotropic incompetence	6	0	0	0	0	6 (at mean 9.4 y)
RV(5), LV(1)	arrhythmia, VT/VF	0	0	0	6	5	1 (at 5 y)
LV(5), BiV(3)	recurrent HF w/ QRS>130 ms	0	5	5	0	0	10 (at mean 9.2 y.)

In this patient cohort, twenty two patients (22, 10.4 %) received concomitant cardiac rhythm management (CRM) device implants for the following indications: 6 dual chamber pacemaker (DDD) for A-V block and/or chronotropic incompetence, 10 cardiac resynchronization systems [CRT-P (5), CRT-D (5)] for left bundle branch block (QRS > 130 ms) and recurrent heart failure symptoms and 6 defibrillators for ventricular tachycardia/arrhythmias. Indications for and time of CRM device implant are listed in Table 3. All implants were successful using standard endovenous implant procedures and testing. Devices interactions were checked at implant and at regular follow-ups using respective Marker Channel, electrocardiograms and device memory readings. To minimize far field sensing, whenever possible, sensing and pacing were programmed to bipolar mode. Muscle burst sensing could always be avoided by adjusting sensitivity, number of pulses in the burst, pulse interval and/or burst delay. As an additional safety feature for patients with defibrillators, the cardiomyostimulator was programmed to turn its muscle stimulation OFF when being in the VT/VF detection zone. In one patient , the ICD defibrillation shock treatment disabled the muscle channel. It could be reprogrammed at post-shock follow up visit. Figure 5 shows one example of an electrocardiogram collected in a patient implanted with a cardiomyostimulator and a cardiac resynchronization system and documents appropriate function of both systems. Figure 6 shows an X-ray of a patient with dual implants i.e. CMP and CRT-P.

This experience indicates that concomitant implant of cardiac rhythm management devices (DDD, CRT-P, CRT-D, ICD) in cardiomyoplasty patients can be done safely and confirms previous case reports of combination of cardiomyostimulators with implantable defibrillators. Appropriate respective device function can be maintained long-term. The cumulative follow-up experience in this cohort amounts to 54 patient-years. Device interactions must be verified after implant and systems adjusted to avoid any interaction of bursts with cardiac rhythm detection function. After defibrillation shock treatment, checking of cardiomyostimulator muscle function is recommended either by ECG or cardiomyostimulator telemetry readings.

Discussion

This retrospective analysis reports on 212 consecutive dynamic cardiomyoplasty procedures done in six cardiac surgery centers in France, starting with the first case done in January 1985 at Broussais Hospital, Paris. Therefore, the 30 day hospital mortality reported (14%) includes the pilot and feasibility phase during which the surgical method was further refined. As expected the hospital mortality was linked to the pre-operative NYHA Class i.e. 31.8% for NYHA class IV, 12.4% for class III and 5.8% for class II. With implementation of surgical and clinical management improvements, later multi-center studies e.g. C-SMART in the USA, focused on NYHA Class III patients and using risk stratification strategies, reported a 30 day hospital mortality of 4 %.

The DCMP procedure provides long-term cardiac benefits as demonstrated by an average reduction of NYHA Class by at least 1 class observed in 88% of patients discharged from hospital. Preoperative average NYHA Class was 3.0 and post-operative NYHA Class was 1.66 at an average follow up time of 7.2 years (n=110)

Long-term event-free survival defined as absence of cardiac death or heart transplantation depended on cardiac indication. It was best for isolated right ventricular failure (78 % at 5 y) vs. 48% and 39% for predominant left ventricular or biventricular failure, respectively. This difference is likely to be related to the lesser energy required for the support of right ventricular function than for left ventricular function. Therefore a stronger muscle at short term and long-term as well as improved wrapping techniques could be beneficial.

Muscle contraction can be maintained at the long term. Although not tested in a prospective way, cases reports where the muscle stimulation system stopped due to battery depletion or lead failure clearly demonstrated the effects and benefits of muscle contraction on cardiac function as these patients reported to hospital with recurring heart failure symptoms while they had been stable since cardiomyoplasty (in some cases for more than 10 years). Replacement of the cardiomyostimulator or repair of lead and progressively resuming of muscle activation allowed for patient recovery. In this study cohort, all patients followed the original progressive stimulation protocol developed at Broussais Hospital which includes a rest period of 2 weeks after surgery followed by a progressive activation of muscle by increasing the stimulation rate. Implementing recent advances in muscle physiology understanding and adapting stimulation protocols to patient's physiological status e.g. customizing stimulation pattern to muscle response allowing for a mixed fiber composition, use of skeletal muscle pharmacological support would certainly provide improved results. For instance, the "on demand cardiomyoplasty protocol" proposed by Ugo Carraro's group [11] and which allows for muscle rest during period of patient non activity was not used in this patient cohort. Also, when proven to be safe, improvement of outcome could first result from a protocol/procedure that would obviate the need for the muscle rest period after surgery as this would allow for cardiac support during the early post-operative phase. This could be the result of preoperative preparation of LD muscle prior to its transfer (e.g. electrical, pharmacological, surgical, cells

transplant and/or physiotherapy). Also stimulation regimes that would allow for a mixed fiber composition resulting in a fatigue resistant and stronger muscle would be beneficial for improving cardiac support. Finally, surgical improvements (i.e. improved cardiac wraps) aiming at optimizing energy transfer from muscle to cardiac hemodynamics could be important. During the course of this follow up, 26 patients (re)developed symptoms of heart failure and were indicated for heart transplantation (5 urgent, 21 elective). The experience reported here confirms that heart transplantation is feasible and safe after cardiomyoplasty. For non urgent transplants, results are similar to those reported for standard transplant procedures. Since 1985, new forms of cardiac rhythm managements have become available e.g. endovenous implantable defibrillation, cardiac resynchronization therapy. In this study cohort, some patients fulfilled criteria and symptoms for such treatments. Our experience described here shows that the combination of defibrillators, cardiac resynchronization devices and cardiac pacemakers with cardio-myostimulator can be safely achieved. As 37% of late death observed during follow-up are sudden, combining or developing a cardio-myostimulator including defibrillation therapy appears the most promising way to improve clinical outcome. The addition of ventricular resynchronization therapy can be an added benefit for selected patients and should be considered in combination with defibrillation therapy. This is especially valid for patients requiring frequent ventricular pacing as it is now recognized that right ventricular apical pacing exacerbates heart failure development [15].

In conclusion, this collective experience shows that cardiomyoplasty provides long-term cardiac benefits. Implementation of latest findings regarding muscle preservation, activation, energy transfer from muscle to heart as well as combination with defibrillators and resynchronization devices have the potential to improve survival and efficacy results. In case of recurrent heart failure, heart transplantation is still feasible. Therefore, for selected patients, dynamic cardiomyoplasty could be considered as a mid to long-term biological bridge to heart transplantation.

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