Clinical Experience with ANS Controlled Cardiomyoplasty

D. BRAILE
Medical School, Universidade Campina, S. J. do Rio Preto, Brazil

P. R. BROFMANN
Department of Cardiovascular Surgery, Universidade Católica, Curitiba, Brazil

K. SHATAROV, A. SH. REVISHVILI, L. BOKERIA
A. N. Bakulev Institute of Cardiovascular Surgery, Moscow, Russia

M. SCHALDACH
Zentralinstitut für Biomedizinische Technik, Friedrich-Alexander-Universität Erlangen-Nürnberg, Germany

Summary

In three centers in Brazil and Russia, 38 patients with severe myocardial dysfunction were selected for cardiomyoplasty. Fractally coated stimulating electrodes are implanted close to the main portion of the neurovascular bundle and are connected to an implanted cardio-myostimulator (Myos). The myostimulator is based on a multiprogrammable, dual-chamber pacemaker, and in this study it was used both for chronotropic adjustment by synchronizing the stimulation to the QRS complex as derived from epicardial electrodes and for dromotropic adjustment by using the dynamic synchronization interval of the stimulator.

As fatigue resistance of the skeletal muscle is limited even after the training phase, the use of this muscle should be precisely controlled by proper selection of the stimulation pattern so as to achieve a minimum metabolic expenditure for the supporting muscle. The ANS-controlled burst modulation adapts the activation of the m. latissimus dorsi to the hemodynamic requirements by adjusting the burst length and by changing the ratio of supported cardiac activity up to 1:1.

The initial results from studies in 38 patients indicate that ANS-controlled cardiomyoplasty procedure significantly improves the functional status of the patients as evidenced by an improvement in the NYHA classification from IV or III to II or I postoperatively. Additionally, the technique significantly increases stroke volume and ejection fraction by 40% and 30%, respectively. ANS-controlled burst modulation of the m. latissimus dorsi can be used for efficient adjustment of the pumping support in response to hemodynamic requirements. Thus, the metabolic reserves of the m. latissimus dorsi can be effectively preserved by stimulation based on the ANS information as a control parameter.

Introduction

In several centers worldwide, dynamic cardiomyoplasty (CMP) has proven to be a promising therapeutical alternative when cardiac transplantation is not feasible.[1-6] The concept of cardiomyoplasty is to improve the pumping force of the myocardial muscle by stimulating the m. latissimus dorsi with a burst of pulses after wrapping it around the heart. In the present study, we evaluate the pumping efficiency of the m. latissimus dorsi by adjustment of autonomic nervous system (ANS) controlled burst modulation in response to changing hemodynamic requirements.

Materials and Methods

In three centers in Brazil and Russia, 38 patients with severe myocardial dysfunction were selected for cardiomyoplasty. Ten patients were female and the average age was 45.6±16.2 years (range 12 - 64 years), while 28 patients were male with an average age of 46.3±11.6 years (range 22 - 72 years). The age distribution of the entire study population is shown in Figure 1. Cardiomyopathy was of undetermined cause in 66%, related to Chagas disease in 21%, hypertensive in 5%, viral in 5 % and peripartum in 3%.

The pre-operative evaluation included clinical and laboratory examinations, which enabled the diagnosis and functional classification of the patients. 15 patients were NYHA functional class III, while the remaining 23 patients were functional class IV. Patients in NYHA class IV with an ejection fraction lower than 30% were submitted to intensive clinical treatment so that they were in functional class III or II by the time of surgery. Additional tests including thoracic radiography, pulmonary functional proofs, electrocardiography, cineangiocardiography and echocardiography were also performed pre- and postoperatively.

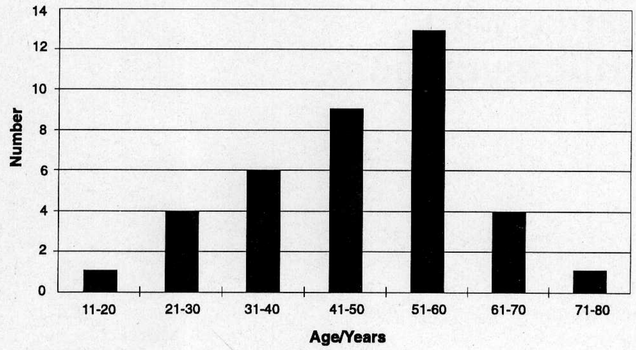

Figure 1: *Age distribution of CMP patients*

Surgical Technique

The skeletal muscle chosen to surround the heart was the latissimus dorsi. The surgery was performed according the technique described by Carpentier and Chachques,[7] with some variations.[8] The heart was generally completely enveloped by the m. latissimus dorsi muscle. The use of extracorporeal circulation was avoided.

Implanted Stimulation System

An epicardial sensing electrode (DM 50-UP or ELC 54-UP, Biotronik GmbH, Berlin) was fixed on the myocardium. The lead for stimulation of the skeletal muscle - CM 60-BP (Biotronik GmbH, Berlin) has two stimulation coils. The electrode poles are fractally coated with Iridium resulting in very low stimulation thresholds and, thus, allowing powerful muscle contractions with low-energy pulses. Initial stimulation thresholds were 0.8 V±0.3 V. These threshold values were confirmed to be stable by measurements after battery depletion.

The cardiomyostimulators used, Myos-BP or Myos (Biotronik GmbH, Berlin), are both based on multi-programmable dual chamber pacemakers, with the atrial channel being used as the sensing input for intrinsic rate detection and the ventricular channel being used to trigger the programmable burst generator (see Figure 2).

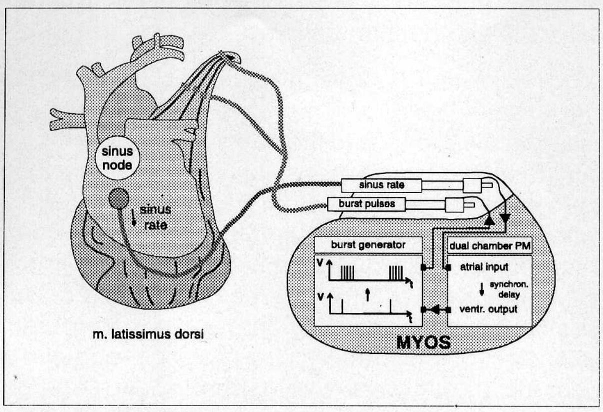

Figure 2: *Principle of the Myos cardiomyostimulator*

Burst stimulation can be performed in a "fixed" mode, i.e., a programmed number of burst pulses (1 to 8) is emitted synchronously with cardiac activity with a selected reduction ratio between 4:1 and 1:1 (see Figure 3).

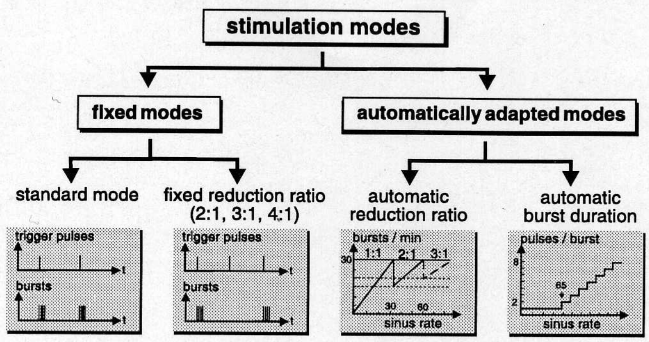

Figure 3: *Stimulation modes of the Myos cardiomyostimulator*

The Myos cardiomyostimulator also features automatic adaptation of burst stimulation parameters controlled by the ANS signal, i.e., the intrinsic heart rate. When the "automatic burst duration" scheme is selected, the burst duration (the number of pulses per burst) is steadily increased with a rise in the intrinsic sinus rate. Alternatively, the "automatic reduction ratio" scheme is controlled by the intrinsic sinus rate so that 30 bursts per minute is never exceeded. By using these adaptive burst schemes, the skeletal muscle is adapted to the changing hemodynamic needs whilst avoiding overstressing of the muscle.

Cardiac output (CO) and hence mean arterial blood pressure (MABP) control the sinus rate and inotropic cardiac status by way of a closed-loop ANS-controlled homeostatic mechanism. After CMP, the ANS-controlled burst generator positively supports this control loop (Figure 4).

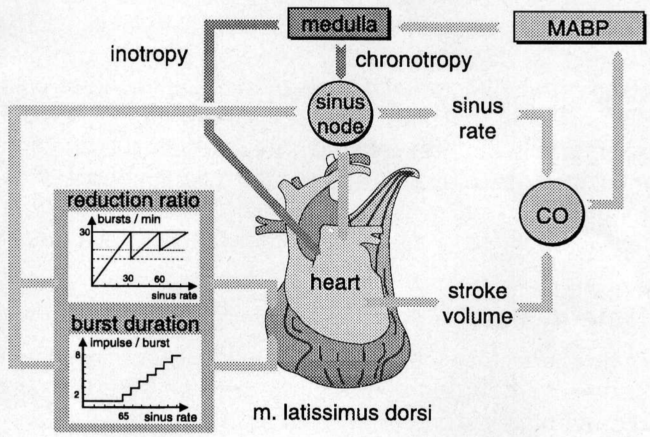

Figure 4: *Control loop of the heart after CMP*

Results

Five patients (13%) did not survive the first postoperative month, three of them having severe Chagas cardiomyopathy. The remaining patients left the hospital and had a satisfactory evolution during the training period of the m. latissimus dorsi.

The total follow-up time was 861 months, with an average of 26.1±16.5 months per patient. The rate of late mortality was 24% (8/33), with a mean survival period of 12.5 month. The survival rate in the first year was 84%, 74% after 2 years and 59% from the third year up to the 6th year of follow-up.

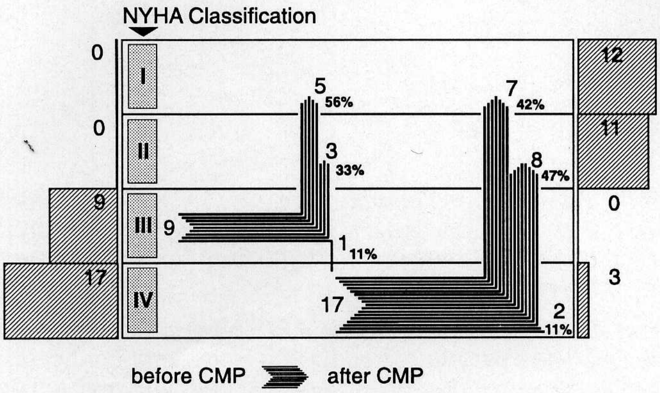

Figure 5: Survivors' NYHA class transition from before CMP to status at study end

Of the 17 patients who were preoperatively in NYHA class IV, 42% returned to class I and 47% to class II. Of the 9 patient in class III prior to CMP, 56% returned to class I and 33% to class II (Figure 5). The comparison between the mean values of the hemodynamic parameters in the pre- and postoperative periods showed a significant increase in stroke volume by 40% ($p<0.001$), an increase in ejection fraction by 30% ($p<0.01$) and a reduction in the systolic diameter by 14% ($p<0.05$) within 6 months of the CMP.

Discussion

Cardiomyoplasty, indicated in patients with dilated cardiomyopathy, has revealed satisfactory results when compared to clinical treatment.[5] In addition, the results from this study compare favorably to that described by other investigators.[2, 7, 9] Of the 26 patients who were preoperatively in NYHA class III and IV, 12 (46%) evolved to class I and 11 (42%) to class II. The survival rate of 84% and 59% in the first and 6th year, respectively, was satisfactory.[6]

CMP was effective in left ventricle assistance, elevating the average value of ejection fraction from 37.7% to 49.0% and reducing systolic diameter from 76 to 65 mm. These hemodynamic changes are also satisfactory when compared to the literature.[5] Satisfactory results could not be obtained for Chagasic patients, however, the survival rate is generally lower for this population of patients.

Patients selected for cardiomyoplasty must withstand an acute post-operative period without muscular help, thus the timing of the surgery seems to be critical for both surgical success and ultimate survival. More importantly, however the success of the CMP approach also depends upon careful patient selection, with life expectancy significantly improved for the more thoroughly selected patients.

Cardiomyoplasty represents a viable alternative, especially if supplemented with a precise physiological control of the muscle support via automatic adjustment of the burst stimulation based on the ANS information. Using this technique, effective cardiac support is achieved without early skeletal muscle fatigue. In chronotropically incompetent patients the burst control could be based on contractility information rather than the intrinsic sinus activity. Stimulation systems which use this information are already available[10] and should be extended for use in CMP.

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