190 June 1999

Cardiac Stimulation in Closed-Loop Controlled by Autonomic Nervous System versus Accelerometer - Comparative Analysis

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Summary

The aim of this study was to compare hemodynamic performance between the stimulation based on the sensor of contractility (Inos DR) and accelerometer (Dromos DR) during physical and mental stress. Thirty-five patients were included (43% female, 57% male, age 54 ± 5 years) and divided into three different groups: 10 patients using Inos DR pacemaker (Biotronik), 12 patients using Dromos DR pacemaker (Biotronik) and 13 patients without pacing system as control group. The quality of the rate adaptation in DDDR mode was compared by applying a set of standardized test protocols. The challenges included physical exercises, like treadmill ergometry and mental stress using M factor and visual memory. The heart rate (HR) and systolic arterial pressure data (SAP) were collected every minute, in both tests. The used statistical test was a variance analysis with a significance of 0.05. During the physical stress, the parameters of autonomic function had no longer statistical significance between the stimulation based on sensor of contractility and accelerometer. However, in the psychological test, we had a significant correlation between sensor of contractility (Inos DR) and the normal control group.

Key words

Cardiac pacing, closed-loop pacing, accelerometer, rate adaptation, intracardiac impedance

Introduction

New developments in therapeutic and diagnostic devices increasingly highlight the need for not only limiting symptoms but improving the patients' quality-of-life [6]. In order to achieve this goal, modern pacemakers tend to show pacing rates as similar as physiological cardiac stimulation.

The dynamic range of cardiac output is controlled by the autonomic nervous system (ANS) through changes in myocardial contractility. The ANS-controlled pacemaker uses this effector-level ANS signal (the inotropic state) to realize a physiologic closed-loop regulation of the pacing rate (Figure 1) [2]. Inos DR is one of these pacemakers.

Its sensor principle is determining changes in myocardial contractility through the local motion of the ventricular walls near the stimulating electrode [7]. The mechanical contraction is mapped to the time course of the unipolar intracardiac impedance signal. Since sympathetic influence changes myocardial contraction, the impedance signal inherently contains information about the sympathetic tone [2]. An adaptive rate is derived from this impedance-based ANS measurement, allowing closed-loop control of the heart rate (Figure 2). On the other hand, Dromos DR pacemaker determines its adaptive pacing rate from the sensor signal of an accelerometer, which is the most widely used sensors on the market today. It provides electrical signals that can be processed to achieve proportionality to the degree of exertion. These sensors are based on the sensing of body movement and acceleration forces, which signals are derived from external measurement parameters, such as motion, vibration and acceleration

June 1999 191

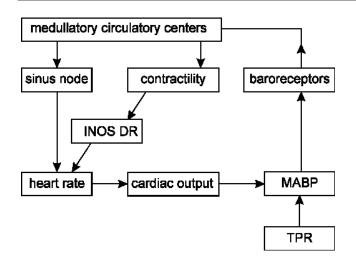


Figure 1. A schematic view for the restoration of chronotropic control by closed-loop pacing.

[3]. Since hemodynamic results lack a direct connection with the cardio-circulatory system, not all loads are responded to with an adequate pacing rate [1]. The present study attempts to compare the pacing rates of Inos DR and Dromos DR groups, who had undergone physical and mental stress tests, using a normal and healthy group.

Materials and Methods

We observed thirty-five patients (20 male and 15 female, mean age of 54 ± 5 years). Twenty-two with pacemaker (Inos DR or Dromos DR) and thirteen without (healthy subjects). Inos DR group was characterized by 10 individuals, all with chronotropic incompetence (sinus node disease).

Myocardiosclerosis in 8 and Chagas' disease in 2

Bruce's Protocol		Velocity	Inclination	
Stage	Time			
1" stage	3 min	1,7mph	10%	
2" stage	3 min	2,5mph	12%	
3" stage	3 min	3,4mph	14%	
Rest	4 min			

Table 1. Bruce's protocol and its three stages defined by velocity and inclination at treadmill ergometry; and rest (four minutes).

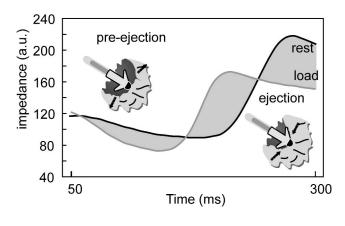


Figure 2. Schematic representation of the relationship between ventricular geometry and unipolar intracardiac impedance.

patients. They were in class I or II (NYHA).

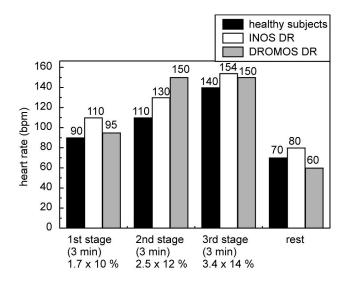
Dromos DR group was characterized by 12 patients, all with chronotropic incompetence (SND) and myocardiosclerosis in 10 and Chagas' disease in 2. They were in class I or II (NYHA). Healthy subjects were analyzed according to ECG, X-Ray and physical examination and we did not identify any cardiovascular disease.

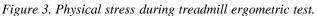
A treadmill ergometry test was applied into all thirtyfive patients in order to evaluate the sensor's capacity to yield an adequate adaptative pacing rate, when they are under physical stress conditions and compare their values with the healthy subjects group.

This test was performed using Bruce's protocol, which established the following requirement: all patients had to be submitted at least three stages, as shown in Table 1. Every-minute HR and SAP data were collected during thirteen minutes (period this test lasted), when curves of HR and SAP were being drawn using these values from each individual.

The mental stress conditions could be summarized as a test in which twenty-five different pictures were shown to all patient, who had one minute to remind as many pictures as possible. This test also included a four-minute rest after the visual-memory challenge. HR and SAP measurements were obtained at three different moments of the time course: before the test's beginning, during the time of recognition the pictures and after the rest. Individual HR and SAP curves were drawn in accordance with the collected values.

192 June 1999





healthy subjects **INOS DR** DROMOS DR 160 155₁₅₀152 145 140 143 140 140 135 130 110 T 120 heart rate (bpm) 110 100 80 60 40 20 1st stage 2nd stage 3rd stage rest (3 min) (3 min) (3 min) 1.7 x 10 % 2.5 x 12 % 3.4 x 14 %

Figure 4. Sistolic Blood pressure during treadmill ergometric test.

Results

At first, Table 2 demonstrates the results of comparative study between Control; Inos DR and Dromos DR groups based on pacing performances in different stress situations (physical and mental stress).

During physical stress study using heart rate (HR) measurement as a parameter, the results showed an equal relationship between control, Inos DR and Dromos DR groups. The heart rate collected from the control group increased during exercise, as also detected in the Inos DR group and in the Dromos DR group. At res the heart rates have returned to normal values. So, no significant difference between these groups was observed. Thus, a physiological pacing performance in physical stress situation was observed in the patients with Dromos DR and Inos DR pacemakers during the protocol's stages (Figure 3).

Figure 4 demonstrates no significant difference while

the three stages and rest between control, Inos DR and Dromos DR groups in physical stress situation while systolic arterial pressures (SAP) were being measured as a parameter. The SAP values observed during the study in each group were closer one another.

During the analysis of Control, Inos DR and Dromos DR groups, which were under mental stress, the difference between final mean heart rate (HR2) and initial mean heart rate (HR1) was measured. As demonstrated by Figure 5, there is no significant difference between control and Inos DR groups.

On the other hand, the patients which Dromos DR pacemaker were implanted, no variety was observed in (HR2-HR1)-parameter (its HR value stood in the stage of 60). Thus, in the Dromos DR system (accelerometer) a physiological pacing performance was not observed as it was in Inos DR system (sensor of con-

Variable	Control	inos DR	Dromos DR	Analysis
Physical stress: HR (bpm)	152.60	150.23	151.20	n. s.
Physical stress: SAP (mm Hg)	166.66	149.24	154.34	n. s.
Mental stress: HR ₂ -HR ₁ (mm Hg)*	7.33	6.80	0.00	P<0.05

Table 2. A comparison between two different systems (Inos DR and Dromos DR) based on physical and mental stress analysis and a normal group composed of patients without heart disease. HR(Heart rate), SAP (Systolic arterial pressure), HR1 (initial heart rate); HR2 (final heart rate).

June 1999 193

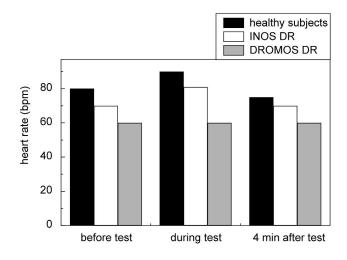


Figure 5. Behavior of heart rate during mental stress.

tractility) which exhibited a strong association with the control group and a consequent physiological stimulation.

Discussion

Although differences between the individual systems were detected in the heart rate, the analysis of the obtained results showed for all groups a similitude when in physical stress situation, which corresponds with expectations.

In the present study, the closed-loop stimulation (CLS) responded similarly good in psychological and physical stress situations. During physiological stress, the difference between final mean heart rate (HR2) and initial mean heart rate was similar to physiological values. Even in the physical stress, the sensor of contractility showed satisfying responses when compared to sinus node reference group.

Since the accelerometer only detects upper body acceleration, it displays a good correlation to the control group just during physical stress. There is significant difference in the psychological stress test to Inos DR. In contrast to all sensor systems, CLS provides a heart rate without any significant deviatations from the heart

rate of the healthy test subjects under physical and mental load conditions. The body's intrinsic receptors detect every load state of the patient and transmit these information to the cardio-circulatory center. It responds to the CLS system via the contractile state of the heart. Thus, CLS guarantees an adequate heart rate even during mental stress.

Conclusion

As we can observe, the parameters of autonomic function were not different when the patients were under physical stress. A comparison of the pacing rates based on the sensor of contractility and accelerometer may confirm this fact. However, this paper also presents an evident correlation between Inos DR group (sensor of contractility) and the sinus node group (control) during mental stress.

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