DDDR Pacemaker in Binodal Disease Using a Cardiac Contractility Sensor

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Summary

The treatment of AV conduction disorders associated to sick sinus node using DDDR pacemakers, has motivated the search for an ideal sensor. This study investigated a DDDR stimulation system which use the myocardial contractility state as a indicator for rate response. We selected 38 patients distributed around 15 Brazilian implantation centers selected from a multicentric study -Inos Project. All patients had total AV block and sinus node disease (Binodal Disease). This DDDR pacemaker system utilizes an intrinsic cardiovascular information (cardiac contractility from the measure of the unipolar cardiac impedance) for heart rate adaptation, in a closed-loop system that theoretically is adjusted to all physiological needs. The main objective was evaluate the heart rate response of the contractility sensor pacemaker during ambulatorial test (physical and mental stress) and during daily life activities. The system calibration and program adjust were performed 30 days after. We evaluated sensitivity and stimulation thresholds as well as a test of mental stress (mathematical and perception) and treadmill test monitoring heart rate using histograms recorded by the pacemaker. To atrium [ventricle] the mean acute stimulation threshold was 0.82 ± 0.45 V [0.55 ± 0.43 V], the mean sensitivity was 2.37 ± 1.49 mV [10.61 ± 4.92 mV], and the impedance was 567 ± 119 W [628 ± 139 W]. The mean chronic stimulation threshold was 1.44 ± 0.64 V [1.18 ± 0.57 V], and the mean sensitivity threshold was 2.81 ± 1.79 mV [6.32 ± 1.36 mV]. The heart rate varied from 5% to 128% on physical activities and from 5% to 80% on mental stress, with appropriated elevation in the beginning of activity. We conclude that the cardiac contractility sensor has an excellent performance on heart rate adaptation, with similar values produced from autonomous nervous system of normal people.

Key Words

Artificial Cardiac Stimulation, Cardiac Pacemaker, Heart rate response, Biosensor, Cardiac Contractility sensor, Sinus Node Disease, AV Block.

Introduction

The main purpose of the first artificial cardiac pacemaker were mortality reduction in patients with complete AV heart block. This aim was reached with the first pacemaker generation, the VOO pacemakers (asynchronous) and later with the VVI pacemakers (demand). Those patients had the same programmed heart rate during all day, which sometimes might present symptoms and lower physical capacity. Therefore, a new challenge must be reached to restore functional capacity and consequently increase the quality of life of pacemaker patients. The concern of improving the hemodynamic performance was first reached with A-V sequencial stimulation. In 1963, Nathan [1] described a pacemaker which stimulate the ventricle after sensing atrium activity. However, the epicardial implant technique, the mercury based batteries and the high energy consumption made this kind of stimulation available only in experimental studies for a long time. In the eighties, technology evolution improved the pacemaker manufacturing. Hybrid circuits (less energy consumption) Lithium batteries (more safe) in a completely sealed housing with bi-directional telemetry are some of the improvements. The leads became thinner, more flexible, resistant, biocompatible with different mechanisms for a better fixation and easier handling during the implantation. All these changes made possible dual chamber stimulation (DDD) [2,3,4].

During exertion the human body increases its metabolism, changing not only atrial rate but also, respiratory rate, blood pH, temperature, stroke volume, ventricular pressure, QT interval, blood pO2, body movement, cardiac contractility, etc. Any of these metabolic indicators can be monitored by the pacemaker so rate adaptation is possible. This metabolic indicator must be sensitive to any changes in cardiac output need, so it must have the following features: accurate, proportionality and response speed. Many other features must be considered such as: durability, trustworthy , easy handling, calibration and programming. Other important features of the system are: connector compatibility with conventional leads, heart rate variation according to circadian cycle, physical and mental activities. For this reason the best sensor is the own Autonomous Nervous System (ANS) of the patient, which regulates the cardiac output for hemodynamic demand. Any change in physical or mental activity involves many other organic changes such as: pulmonary, renal, cardiac, vascular and even cerebral.

The ANS modulates these organic changes after collecting data from its intrinsic sensors: pressure receptors, volume receptors, chemical receptors, etc. The ANS influence in the cardiac activity occurs through the neurohumoral system, which releases catecholamimes. Both heart rate (HR) and stroke volume (SV) are regulated by ANS through chronotropic and inotropic paths. Positive and negative feedbacks occur by mean arterial blood pressure and total peripherical vascular resistance monitoring. In cardiac conduction system diseases, chronotropic path is damaged, so a increase in cardiac output (CO) is limited by changes in venous return and myocardial contractility. However, the cardiac contractility still reflects the ANS influence. Therefore, cardiac contractility may be an optimal indicator to restore the closed-loop.

Objective

Evaluate the rate response in a contractility based pacemaker, in situations of physical and mental stress, at the ambulatory and during daily life activities, in patients with binodal disease using this kind of pacemaker.

Materials and Methods

From a multicentric study, called Inos DR project - Brazil [5], we used DDDR pacing system (Inos DR, Biotronik), with a cardiac contractility sensor, in 15 Brazilian implant centers. The pacemaker monitors a cardiovascular control parameter (cardiac contractility, measured by unipolar cardiac impedance), producing rate adaptation in a closed-loop system, which in theory, simulates a physiological behavior to all needs. From 85 patients, 38 (21 male, 17 female, mean age 57 years, from 13 to 83 years) with binodal disease were selected. All patients had sinus node disease and complete AV Block.

All the Inos DR pacemaker were implanted with bipolar endocardical leads. The sensor measured of the cardiac contractility by cardiac impedance monitoring, between the distal pole of ventricular lead, and the pacemaker can. The impedance variations, are mainly related to conductivity changes, near the distal pole of the ventricular lead. During isovolumetric contraction and ejection phases, blood volume and myocardial mass variations around the lead, change the conductivity, reflecting the tonic and geometric variations of myocardium. The impedance is therefore a very well correlated parameter with the cardiac contractility, and so, with sympathetic tonus. As the pacemaker monitors this parameter for rate adaptation, once it is calibrated, the pacemaker in theory, should permit a correct adjust to all physiological needs.

The calibration and programming was performed one month after implant, enabling an adequate myocardial lead interface maturation. During the programming and calibration procedures, the pacing thresholds, sensing thresholds and lead impedances were collected, both in atrium and ventricle. The calibration procedure, is intended to establish the rate adapting algorithm, for each patient. Myocardial impedance was measured, under rest and exercise, always with ventricular pacing. After calibration, the pacemaker starts to adjust automatically the rate, according to the car-

lower heart rate variation	5 %
higher heart rate variation	128 %

Table 1. Percentage of heart rate variations from pacemaker basic rate during physical activities for a group of 38 patients.

diac tonus, following the ANS variations.

All pacemakers were programmed to DDDR mode and the 24h internal rate recorder was started. All patients were oriented to write a diary, relating every daily life activities and stress situations, and symptoms. On the second day, after calibration, all patients were submitted to mental and physical stress tests. The mental stress test is a standard one:

1) mathematical test: the patient is oriented to perform simple mathematic operations, in great quantity and defined time of 4 minutes;
2) visual perception: the patient should select an ideogram in a short period of 40 seconds; this test was particularly used with illiterate patients.

Besides the treadmill test, all patients made stairs exercises (up and down), to evaluate the sensor behavior, During all tests, patients where monitored by 24 hours system, and oriented to correctly fill in the activity diary, and all heart rate variation was recorded by the pacemaker, with histograms.

Statistical Analysis

The test used to compare the mean values was the Student's t-test. For comparison of variables, variance analysis of repeated data was applied. Values of $p<0.05$ were defined as statistically significant.

lower heart rate variation	5 %
higher heart rate variation	80 %

Table 2. Percentage of heart rate variations from pacemaker basic rate during mental activities for a group of 38 patients.

Results

For the atrium [ventrikel] the mean acute pacing threshold was 0.82 ± 0.45V [0.55 ± 0.43V] with unipolar configuration, and the mean sensitivity threshold in bipolar configuration was 2.37 ± 1.49mV [10.61 ± 4.92mV]. During pacemaker calibration, performed one month after implantation, the mean pacing threshold was 1.44 ± 0.64V [1.18 ± 0.57V] and sensitivity threshold was 2.81 ± 1.79mV [6.32 ± 1.36mV]. The intraoperative results, due to the use of conventional endocardical leads, are superimposed to earlier implants. Chronic thresholds, collected one month after implant, are about 100% higher than acute values, and a reduction in the atrial and ventricular sensitivity by 50%, revealing that the heart lead interface did not reach the total maturity.

In the case of physical activity an increase in the heart rate was observed immediately after the beginning of the exercise, reaching a value from 5% to 128% at the exercise peak higher than the programmed basic rate (Table I). It is important to note, that arterial pressure also varied, similarly with comparable healthy individuals. The upstairs exercise (20 steps) demonstrated that the increase in the heart rate is significantly higher during climb (28 ± 14bpm) than during downstairs (18 ± 10bpm). It reflects the higher metabolic requirements, demanded during climbing, and show the adequate rate response variation from the pacemaker.

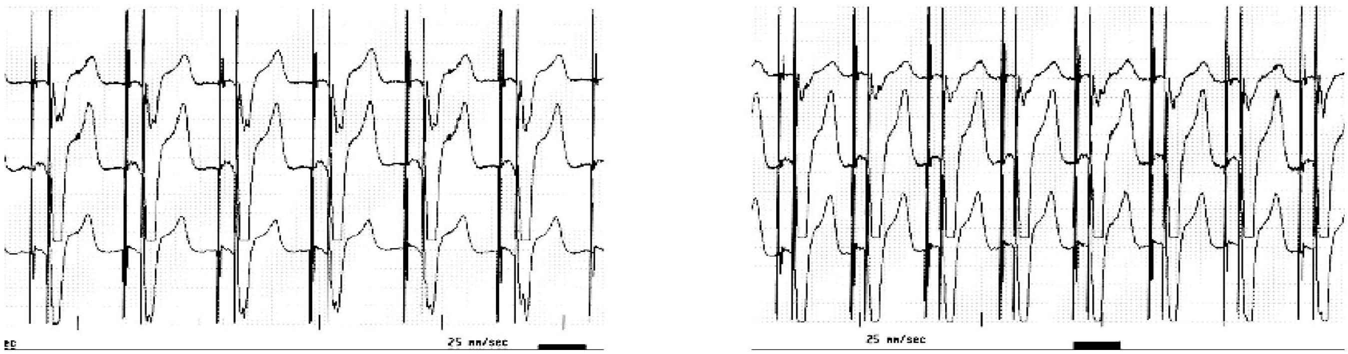

Figure 1. Example of rate change during mental stress in patient MLO before and during mathematical test, i.e., ECG before test and ECG during test is shown.

Figure 2. Important rate change in patient patient DCN (female, 64 years) watching a TV program, i.e., ECG before stress and ECG during stress is shown.

For mental activity, the evaluation of mental stress and 24h Holter reveal that heart rate changed from 5% to 80% during tests which is presented in Table II. Figure 1 and 2 show considerable variations, even during situations when the patients were exposed to mental stress, such as: emotions; frights. The heart rate variation during sleep reflects the relation of the sensor and ANS influence. Since the cardiovascular system is closely related to ANS, the heart responds immediately to ANS demand. The ANS acts over the heart by 2 ways: the chronotropy and inotropy through the heart rate and myocardial tonus. Although the heart rate changes during physical stress is higher than during mental stress, both are important to define the cardiac output. Thus, it is the great advantage of the contractility sensor monitoring the cardiac tonus to be sensitive to physical and mental stress which permits a correct adjustment of pacing rate. It was demonstrated that such heart rate variations are similar to healthy individuals, since that the upper rate doesn't limit the sensor rate.

Conclusion

The cardiac contractility sensor allows a good heart rate adaptation during physical and mental activities. The pacemaker response is fast, almost immediate, very similar to the ANS from healthy individuals, granting an excellent performance to the sensor. As a great number of pacemakers implanted in Brazil are performed to Chagas disease patients, where changes in heart rate are related to cardiac contractility, this system could maintain a appropriated heart rate in an advantageous way.

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