Dual Chamber Pacing and Closed-Loop Regulation - Clinical Results

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Summary

Physiological heart rate adaptation is achieved by a new concept monitoring the myocardial contractile state. Since a cardiac parameter is used for evaluating the circulatory demand of the organism, it works independently from the type of load. Furthermore, the rate adaptive principle works with standard pacing leads and does not need any additional sensor. The rate adaptive performance was clinically evaluated for various exercise types.
176 patients (40% female, age 64 ± 14 years) received an Inos DR or Inos²DR (BIOTRONIK) dual chamber rate adaptive pacemaker. The quality of the rate adaptation in DDDR-mode was validated by applying a set of standardized test protocols. The challenges include physical exercises like bicycle and treadmill ergometry and ambulatory tests. Mental stress was induced by a standardized protocol using mental arithmetic and by color-word-test. During slow walk the rate increased by 9±4 bpm, during brisk walk by 29±10 bpm with respect to the resting value. The observed rate responses are nearly identical to those for healthy subjects. Climbing up stairs caused a maximum pacing rate increase of 28±14 bpm, climbing down stairs resulted in 18±10 bpm in average. During mental stress test a rate increase of 12 ± 3.6 bpm was observed. This value is in good accordance with literature on the same test with healthy subjects (13.6±1.6bpm).
The contractility-controlled rate adaptation is sensitive to different types of exercise. The rate increase observed for the different challenges resembles the values known from literature for chronotropically competent subjects for different physical exercises and for mental stress.

Key Words

Cardiac pacing, rate adaptation, intracardiac impedance, closed-loop pacing, clinical evaluation

Introduction

Among various concepts providing rate adaptive cardiac pacing for chronotropically incompetent patients, the most attractive is the physiological restoration of the closed-loop chronotropic control [1]. The myocardial contractility is controlled by the same neural and humoral mechanisms as the physiological sinus rate and, as a consequence, the actual circulatory demand can be evaluated from the contractile state of the myocardium. In this study the performance of a pacemaker system which utilizes the ventricular contraction dynamics for rate adaptation was evaluated. Since the contraction dynamics reflect the instantaneous cardiac demand it shows all characteristics of an ideal sensor signal for rate adaptive pacing (see Table 1).

Proportionality	Rate response appropriate for exertion level
Response time/speed	Mimics the response of the circulation center
Sensitivity	Responds to every type of demand
Specificity	Insensitive to disturbance (e.g. motion pattern)
Circadian Variation	Appropriate variation of the average heart rate
Programming	Minimal physician input (MSR, BR)
Acceptance	Compatible with standard pacing leads

Table 1. *Characteristics of an ideal sensor for cardiac rate adaptation (modified from [1]).*

These characteristics have been clinically validated with various kinds of physical exercise and mental stress tests as well as 24 hour Holter monitoring.

Methods

Dual chamber pacemakers using this sensor principle for rate adaptation have been implanted in 176 patients (64 Inos DR, 112 Inos²DR, BIOTRONIK) with an average age of 64 ± 14 years (May 1997). The relatively low average age is due to a portion of patients suffering from the chronic form of Chagas' disease.

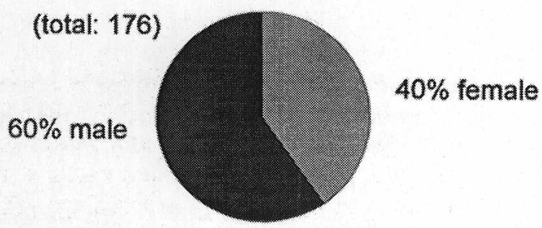

Figure 1. *Inos DR and Inos²DR (BIOTRONIK) implanted in 176 patients.*

Prior to imlantation, 72% of the patients had an indication for a rate adaptive stimulation mode due to chronotropic incompetence (Sick Sinus Syndrome: 59%, Bradycardia: 13%). An AV-block was diagnosed in 44%, most of them (70%) were complete.

The patients were examined over a period of 7 ± 3 months (maximum 20 months) with regular follow-up intervals of 3 to 6 months.

The rate adaptive performance of the pacing system was proven by tests starting with an initial rest interval of about 2 minutes. Afterwards the patient performed multi-level physical exercise for 2 to 10 minutes before he rested again during the recovery period. The patients were imposed to various types of exercise to evaluate the sensitivity of the sensor principle. During bicycle and treadmill ergometry it was striven for reaching at least 80% of the patients maximum capacity. Criteria for reaching the individual maximum workload were signs such as dyspnoea, fatigue or feeling of faintness. All ergometry tests were performed under ECG-control to stop in case of ECG abnormalities. Ambulatory tests provided various load levels during slow and brisk walk as well as stairs down and stairs up climbing. All tests were limited on patients request. For data evaluation slow walk was classified as 20-50% of patients maximum workload, brisk walk and stairs up climbing as 50-80%. Knee bending was always included in the 20-50% class.

In 11 patients, additional mental stress tests were performed to evaluate the rate response of the pacemaker system to psychological load. During the so called "Color Word Test" [2], the patients were forced to solve conflicts between meaning and color of continuously presented words on a computer screen. Some patients performed mental arithmetic with serial subtractions of 7 from 700. During the test they were repeatedly asked to go faster to increase their individual stress.

The pacemakers 24h Holter function recorded the heart rate during non-rate adaptive DDD mode prior to the initialization as well as during DDDR pacing in the same individual. The collected data were analyzed with regard to average rates and diurnal variation.

Results and Discussion

Figure 2, as an example, shows the heart rate trend measured during a multi-level bicycle ergometry test. The onset of rate acceleration starts within 10 seconds after work load increase. As in healthy subjects the rate reaches a level proportional to load within the next 2 minutes. During recovery the pacing rate decreases down to the resting value.

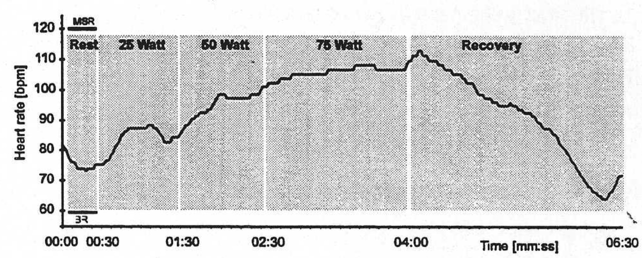

Figure 2. *Adaptive pacing rate of a chronotropically incompetent patient during three-level bicycle ergometry.*

The heart rates of all physical exercise tests following a well documented protocol were averaged and displayed in Figure 3. The physiological heart rate in healthy subjects is directly proportional to the level of exercise. The minor heart rate increase during the third load step (80-100% of maximum load) is caused by the nearby maximum sensor rate of 120ppm in all patients.

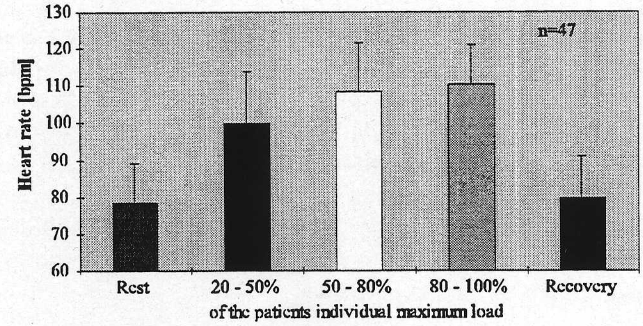

Figure 3. Average heart rate during rest, maximum rate during physical exercise and the final rate after recovery recorded during bicycle and treadmill ergometry, ambulatory tests and knee bending.

In a subset of patients the Mean Arterial Blood Pressure (MABP) was recorded during bicycle ergometry. The slight increase of MABP (Figure 4) proves that the increase in pacing rate (Figure 3) was adequate to maintain an appropriate blood pressure at various load levels.

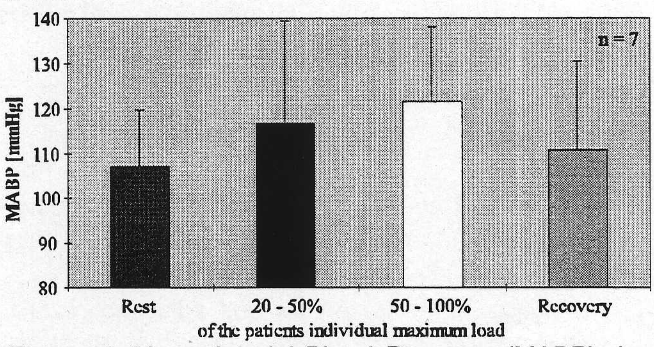

Figure 4. Mean Arterial Blood Pressure (MABP) during bicycle ergometry with two load steps.

The attack rate at onset or change of exercise level as well as the decay rate at recovery represent physiological values which are set by the circulatory control system. As Figure 5 shows, the attack rate is maximal at load onset (0.38 bpm/sec) and decreases during the following load steps. The attack rate is proportional to the additional amount of exercise since the magnitude of the load steps decreases as well. Proportionality between exercise level and attack rate is also seen in healthy subjects [3]. The average decay rate value during recovery (0.36 bpm/sec) is comparable to the onset attack rate.

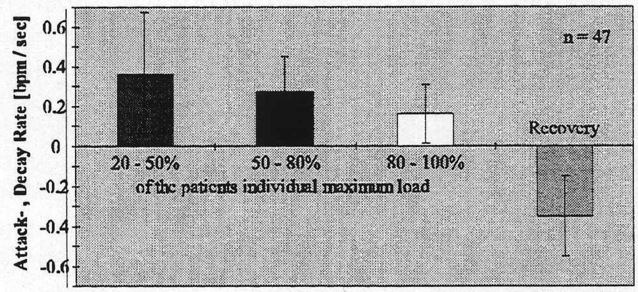

Figure 5. Average attack- and decay rates during bicycle and treadmill ergometry, ambulatory tests and knee bending.

The heart rate increase compared to rest during slow (9±4 bpm) and brisk (29±10 bpm) walking as well as stairs up (28±14 bpm) and down (18±10 bpm) climbing shows reasonable values which are comparable to that of healthy subjects [4, 5] (Figure 6). Accordingly, the rate adaptive principle is sensitive to major aspects of the patient's daily life and, additionally, highly specific to the circulatory demand, since stairs up climbing produces higher pacing rates than stairs down.

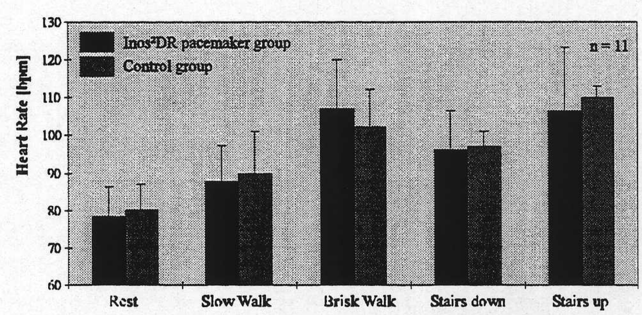

Figure 6. The adaptive pacing rate during ambulatory exercise is comparable to the heart rates of healthy subjects [4, 5].

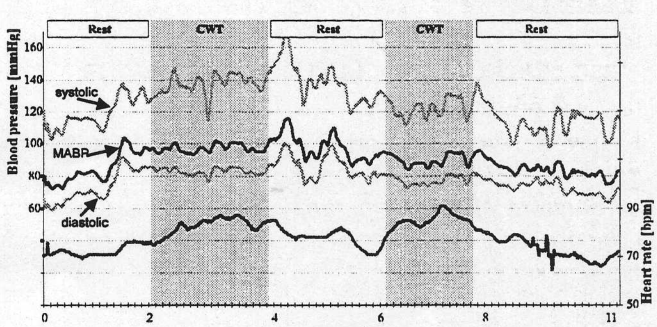

Figure 7. Heart rate (bottom) and blood pressure during two periods of mental stress (Color Word Test).

In addition, the investigated pacemaker system is not only sensitive to physical load but also to mental stress. As demonstrated by Figure 7 the performance of the so-called Color Word Test [2] is followed by a distinct increase of the pacing rate. This behavior is repeatable after a recovery period with the pacing rate dropping to the rest value. The blood pressure remained high after the first CWT-period indicating that the patient felt slightly excited during that rest period.

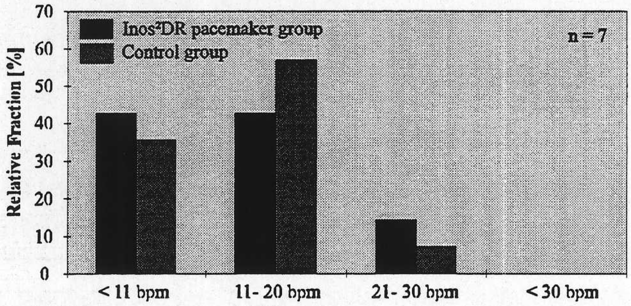

Figure 8. *During mental arithmetic the pacing rates of the Inos²DR pacemaker patients as well as the heart rates of the control population [6] raised by comparable amounts.*

The same response to mental stress applies for standardized mental arithmetic [6], the results of which are collected in Figure 8. The increase of the pacing rate (12±4 bpm) was found to be very comparable to that of the heart rate of a healthy control population (14±2 bpm) [6].

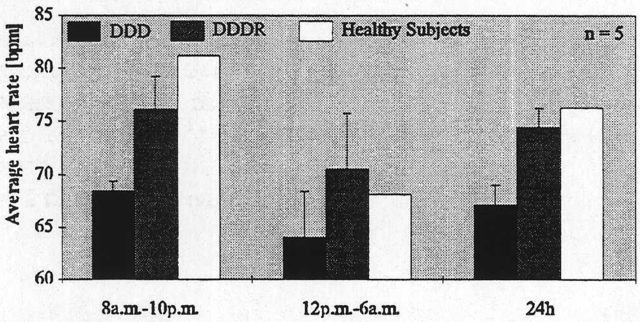

Figure 9. *Average heart rates during daytime (8a.m.-10p.m.), nighttime (12p.m.-6a.m.) and 24 hours of chronotropically incompetent patients during non-rate adaptive and rate adaptive pacing as well as elderly healthy subjects.*

Diurnal heart rate variation is a well known phenomenon in healthy subjects with average heart rates of 81 bpm during daytime (8a.m.-10p.m.) and 68 bpm during night (12p.m.-6a.m.) [7]. As figure 9 shows the average heart rates during day and night are significantly lower in chronotropically incompetent patients in non-rate adaptive pacing mode. After switching to rate adaptive mode the average daytime heart rate (68 => 76 bpm) as well as the diurnal variation (4 => 6 bpm) increases.Moreover, since all normal pacing leads can be used, the implantation of the Inos DR and Inos²DR is as simple and secure as that of any non-rate adaptive dual chamber pacemaker.

Conclusion

By the concept of the investigated pacemaker the intrinsic neural and humoral control mechanisms regain control over the pacing rate, and therefore it fulfills all the criteria of an optimal sensor system for closed-loop rate adaptive pacing. These characteristics have been evaluated and proven in a number of clinical studies with various kinds of physical exercise and mental stress protocols. Physiological pacing rates were obtained, with characteristics comparable to sinus rates of healthy subjects.

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