Study of a New Activity Driven Rate Responsive Pacemaker Programming Based on Standardized Tests Emulating Daily Life Activities

J. CLÉMENTY, JF. MEUNIER, A. LEMOUROUX, PH. LEMETEYER, M. HAISSAGUERRE
Service de Cardiologie A, Hôpital Cardiologique du Haut Lévêque, Pessac, France

Summary

Standardized tests that emulate daily activities allow the response of the accelerometer in the Dromos DR to be examined through a comparison to normal sinus rhythm. Twelve patients were studied. A score derived from the variations in sinus rate is compared to a theoretical rate. This allows a simple initial programming with the highest sensitivity, specificity, and proportionality which may be subsequently optimized for each patient.

Key Words

Rate-responsive pacing, accelerometer, sensor optimizion, daily life activities

Introduction

Rate-responsive pacemakers have transformed the quality of life for patients suffering from chronotropic insufficiency. Of the several sensors available for adapting the pacing rate to physical stress, activity sensors are utilized most frequently. Among them, accelerometers are more specific than the piezoelectric quartz [1][2][3]. The Dromos (DR, SR) pacemaker by BIOTRONIK includes an accelerometer (also the sensor principle of the new family of Actros (DR, SR, SLR, D) pacemaker) with a linear rate-responsive algorithm.

The goal of this study was to examine the response of this sensor to loads with standardized tests based on daily activities and to describe a programming method for the sensor applicable to the largest number of patients before a final tailored programming.

Material and Methods

The accelerometer of the Dromos DR

The programmable settings of the accelerometer are:

- The upper activity responsive rate at 100, 125 and 170 beats per minute (bpm) (default: 125 bpm).
- The sensitivity threshold: low, medium and high (default: medium).
- The gain, i.e., the slope of the relationship between the back-up rate and the upper activity responsive rate, offers 20 settings, ranging from 1 to 40 (default: 6).
- The speed of rate acceleration at load onset, i.e., sensor reaction. Settings include slow, medium, fast, and very fast (default: medium).
- The speed of rate deceleration, i.e., sensor reaction during recovery. Settings include very slow, slow, medium, and fast (default: medium).

Patient population

The 12 patients studied (3 male, 9 female; mean age: 69 ± 10 years) had each received a permanent pacemaker for correction of sinus node dysfunction and chronotropic insufficiency. The disorder was isolated in 5 patients, associated with atrioventricular block in 3 patients (after AV junctional ablation in 2 patients), and in the context of the bradycardia-tachycardia syndrome in 4 patients. Detailed pacemaker indications are shown in table 1.

Study protocol

The protocol consisted of standardized tests to reproduce daily activities, including climbing and descending stairs, squatting exercises, and hyperventilation. Each patient also underwent a 2-stage bicycle exercise at 30 and 60 W, each for 3 minutes, and a symptom-limited Bruce treadmill exercise.

Patient #	Sex	Age	Indications for permanent pacing
1	M	51	Electrical disease of the atria, atrial fibrillation, junctional rhythm with retrograde atrial activation, chronotropic insufficiency
2	F	73	Sinus bradycardia and chronotropic insufficiency
3	F	88	Electrical disease of the atria, sinus bradycardia, atrial fibrillation, s/p His bundle ablation
4	F	58	2nd degree AV block, sinus bradycardia
5	F	69	Asymmetric, obstructive, hypertrophic cardiomyopathy (mean ouflow gradient = 110 mmHg)
6	F	80	Electrical disease of the atria, sinus bradycardia, chronotropic insufficiency
7	M	70	1st degree AV block, atrial fibrillation
8	F	56	Vaso-vagal syncope, tilt-table test >o
9	F	73	Sinus bradycardia, ventricular extrasystole, chronotropic insufficiency
10	F	69	Sinus bradycardia
11	F	74	Electrical disease of the atria, sinus node dysfunction, s/p His bundle ablation, chronotropic insufficiency
12	M	66	Sinus node dysfunction, pulse generator replacement

Table 1. Patient data and pacemaker indications.

The rates dictated by the pacemaker were compared to those associated with normal sinus function based on references derived from age-matched healthy subjects who had undergone the same tests.

To quantify the comparison of measurements obtained from control subjects versus those from study patients, two scores were created which describe, respectively, the rate increase (RI) and the acceleration increase (AI) associated with exercise, as well as the rate decrease (RD) and deceleration decrease (DD) following exercise. Rate increase and decrease characterize the quantity of rate adaptation, rate acceleration and deceleration its quality.

The value of these scores was set at 0 for the control subjects, with a normal range spanning ± 2.5. A score > + 2.5 defined a hyperchronotropic, and < - 2.5 a hypochronotropic sensor.

Testing procedures

If possible, the tests were performed 2 to 4 days after pacemaker implantation, before the patient left the hospital (T0). The device was programmed with default settings. With the same settings, the tests were repeated 3 months later (T1). Comparing the scores of T1 versus T0 allowed examination of sensor function stability. After optimizing device programming, the series of tests was repeated (T2). A fourth series of tests (T3) was performed 6 months after device implantation with the optimized settings.

Results

Initial programming

The back-up rate was set at 65 bpm in 11 patients and at 60 bpm in 1. The upper activity responsive rate was set at 125 bpm in 11 patients, and at 120 bpm in one patient. Threshold, gain, and speed of rate acceleration were at default settings in 10 patients, and higher than the default settings in 2 patients who showed no rate response at default settings.

Rate response at initial programming

Figure 1 illustrates the stability of the rate response. The scores measured at T0 were comparable to the scores at T1 ($p > 0.25$). The scores represented the characteristics of the rate response well.

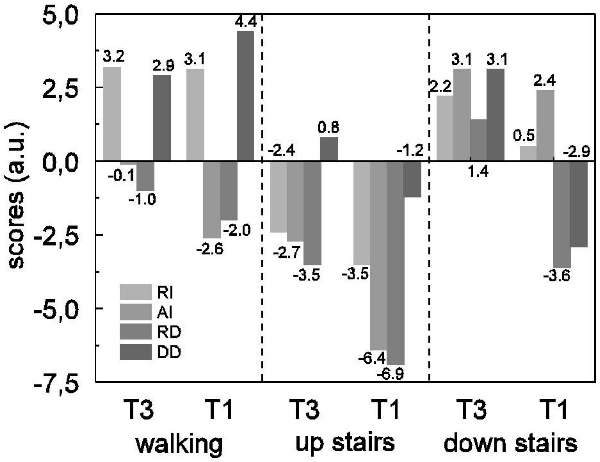

Figure 1. Stability of the rate response.Comparing the scores of T1 (3-month) and T3 (6-month) versus T0.

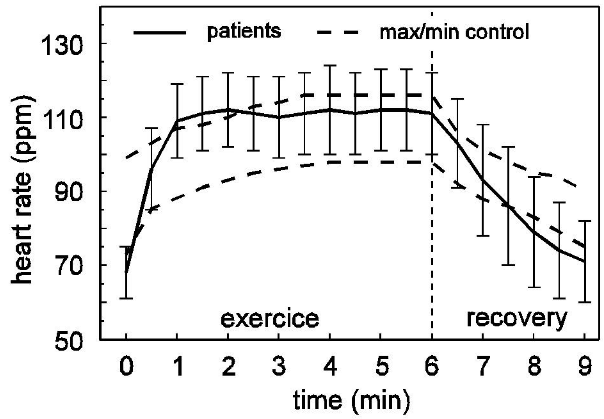

Figure 2. Comparision of the heart rates during walking in 3-month T1 test.

Walking

A dissociation was observed between a considerable increase in pacing rate (+ 3.1), and a blunted acceleration (- 2.6). During recovery, the decrease in pacing rate was appropriate (- 2.6), though the deceleration was excessive (+ 4.4). This phenomenon is illustrated in figure 2. The sensor imposed the maximal rate at the onset of walking, reached a plateau, decelerated abruptly upon cessation of exercise, and then leveled off again.

Stair climbing

The sensor was generally hypochronotropic upon ascent and generally normochronotropic upon descent. It is noteworthy that the variations in pacing rate going upstairs were quantitatively equivalent to those measured going downstairs.

Traditional exercises

Bicycle and treadmill testing were generally associated with hypochronotropism. However, one should note that during bicycle exercise, despite a quantitatively insufficient increase in pacing rate, rate acceleration and deceleration were appropriate. Treadmill exercise was the most homogeneous and closest to the normal response (± 2.5), though it was generally hypochronotropic (- 2.5 and - 5) during exercise, and during recovery (- 3.3 and - 2) (figure 3). The sensor was found to be hypochronotropic in all patients during squatting exercises and with hyperventilation.

Optimization of programming

A decrease of the gain from 6 to 4 was needed in 6 patients whose pacing rate was 110 bpm or higher during walking for 6 minutes (table 2). Two patients reached the maximal sensor-driven rate in 30 seconds and experienced palpitation during walking. Rate deceleration was decreased and set on "slow" in 8 patients, and "very slow" in 4 patients.

Verification of optimal programming at 6 months

Walking

A distinct improvement in scores was observed without fundamental changes in the sensor behavior. Recovery was slower and closer to the normal references.

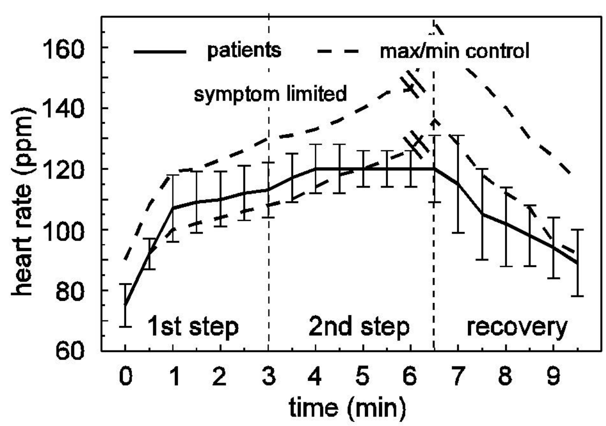

Figure 3. Comparision of the heart rates during treadmill exercise in 3-month T1 test.

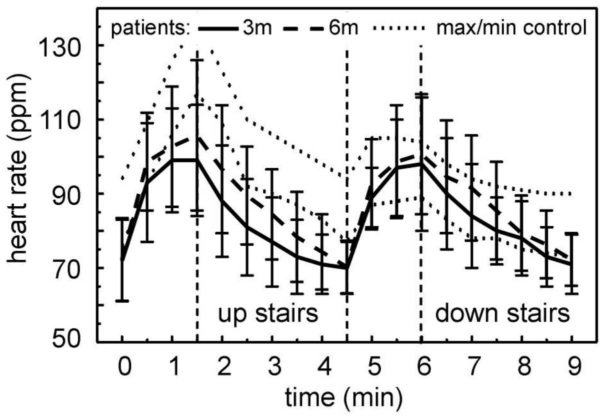

Figure 4. Comparision the 3-month versus 6-month pacing rate during climbing and descending stairs.

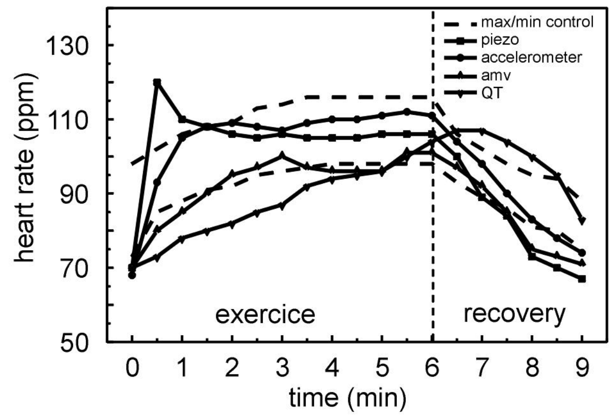

Figure 5. Comparision of different sensor based pacing rates during walking test.

Climbing and descending stairs

The climbing scores improved unexpectedly while the descending scores remained satisfactory. Comparing the 3-month versus 6-month pacing rate curves explains how the slowing of rate deceleration during recovery improves the exercise scores, while maintaining a high pacing rate during exercise (figure 4).

Discussion

The Dromos DR rate-response sensor has the characteristics of an accelerometer, as clearly illustrated by the walking test (figure 5). The rise in heart rate was brisk, as is observed with piezoelectric sensors, and unlike "physiologic" sensors, which dictate a more gradual rate acceleration. The walking test allowed the response of the accelerometer to be distinguished from that of a piezoelectric sensor. The latter causes a rate overshoot following the initial acceleration, while the accelerometer maintains a lower curve. The stair-climbing test is useful to separate the response of activity-driven from other types of sensors.

The pacing rate increase is stronger during descending stairs than ascending them as a result of the body weight being shifted to the forward foot. The sensor, therefore, is not proportional, but it is highly sensitive. The difference between ascending and descending stairs was notably reduced with the Dromos DR sensor. It was stable over time, as demonstrated in the comparisons between the pre-discharge and the 3-month tests. This stability allows an early fine-tuning of the sensor.

This sensor is particularly active and appropriate during sustained physical activity or with total body motion since brief static exercises such as squatting, which usually require a burst of chronotropic response, were associated with a weak sensor acceleration.

The specificity of the sensor was relatively high since no significant acceleration was observed with hyperventilation. This study clearly illustrated the limitations of sensor programming based on the typical exercise tests applied in cardiology, particularly bicycle ergometry. Bicycle ergometry was accompanied by an insufficient increase in pacing rate. Conversely, treadmill testing was much more suitable than with other activity-driven sensors, be they accelerometers or piezoelectric quartz. Indeed, the heart rates recorded during level walking versus treadmill exercise were hardly different, whereas, usually, activity-driven sensors are associated with a hypokinetic response with walking compared to treadmill testing. The default settings chosen by the manufacturer were evidently hyperchronotropic. Our results propose a standard initial setting based on the following elements:

- Back-up rate: 60 to 65 bpm, on a case-by-case basis
- Upper sensor-driven rate: 100 or 125 bpm, depending on the clinical condition and activity level of the patient
- Activity threshold: "medium"
- Gain: 4
- Rate acceleration: "medium" or "slow" (to keep the sensor from reaching the upper rate within the first minute after onset of walking). We recommend the

"medium" setting when the upper rate is set to 100 bpm and the "slow" setting when the upper rate is set to 125 bpm.

- Speed of deceleration at the end of exercise: "slow" or "very slow" when upper rate is set to 100 bpm and "slow" when upper rate is set to 125 bpm.

These settings serve as a starting point for an optimal programming which may be achieved either on the basis of standardized tests that emulate everyday activities or with treadmill testing - a distinction of the Dromos DR sensor. This optimization may be achieved before discharging the patient from the hospital. The patient will then return after 3 months for a series of tests and long-term programming of the pacing pulse output. Optimization can also be postponed for 3 months; at which time, optimization of the long-term pacing output and exercise testing can be performed in the same session.

References

[1] Lazarus A, Mitchell K. A prospective multicenter study demonstrating clinical benefit with a new accelerometer-based DDDR pacemaker. PACE 1996; 19 (part II): 1694-1697.

[2] Lau CP, Stott JRR, Toff WD, et al.Selective vibration sensing: A new concept for activity-sensing rate-responsive pacing. PACE 1988; 11: 1299-1309.

[3] Rickards AF, Norman J. Relation between QT intervall and heart rate: New design of physiological rate adaptive pacemaker. Br Heart J 1981; 45: 265-271.