Interindividual Comparison of CLOSED LOOP Stimulation and Rate-adaptive Sensor Systems

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Summary

The Closed Loop Stimulation (CLS) realizes a new concept. The pacemaker functions as an integral component of the cardio-circulatory system and converts the information of the cardio-circulatory center into a heart rate. This study compares CLS with systems that evaluate external parameters for rate-adaptive pacing by means of sensors. To this end, 27 patients were subjected to physical and mental stress tests. The recorded results were analyzed in regard to the maximum rates reached during stress. Using the values from a control group of 15 patients with a healthy sinus node as a reference, the various systems were compared. The results show that each of the studied sensor-controlled systems was unable to determine an adequate pacing rate under at least one of the various load states. The dual-sensor systems had considerable problems in balancing the input of the two sensor signals when calculating the pacing rate. But the evaluation of one external parameter, such as the acceleration of the upper body with the accelerometer, also did not lead to an adequate pacing rate in many stress situations. In contrast to all sensor systems, CLS achieves a heart rate in agreement with those of the reference group in all physical and mental stress situations.

Key Words

Closed Loop Stimulation, sensor systems, color word test, physical loads

Introduction

To improve the patient's quality of life, DDD pacemakers have been increasingly replaced by a multitude of rate-adaptive systems in recent years. Rate adaptation is based on the analysis of a variety of sensor signals. These signals are derived from external measurement parameters, such as motion, acceleration, or respiratory minute volume (MV), which are used to judge the physical activity of a patient. Since these external parameters lack a direct connection with the cardio-circulatory system, not all loads are responded to with an adequate pacing rate. Combining two sensor signals attempts to compensate for the weaknesses of just one signal.

In contrast, CLS realizes a completely new concept which integrates the pacemaker into the cardio-circulatory system. It has the task to convert the intrinsic, rate-regulating information of the cardio-circulatory center into a heart rate. By integrating the system into the natural control loop, the pacing rate is once again coupled to the cardio-circulatory system. Thus, the heart rate is permanently monitored by the cardio-circulatory center, resulting in a rate that always remains in the optimum range.

This study examines the pacing rates of varied sensor-controlled systems under physical and mental stress tests versus those of CLS.

Materials and Methods

Included in the study were 27 patients (19 male, 8 female) with a mean age of 69.14 ± 4.49 years. Figure 1 shows the percentile distribution of indications for all patients, as determined by invasive as well as non-invasive diagnostic methods. The following pacemaker systems were implanted in the patients: 7 accelerometer (Relay or Marathon; Intermedics and Actros; BIOTRONIK), 5 MV (Chorum; ela-medical), 5 MV + piezosensor (piezo) systems (Kappa DR; Medtronic), 4 QT + piezo systems (Diamond II; Vitatron), and 6 CLS systems (INOS² CLS; BIOTRONIK). The four sensor-controlled systems use different principles and measuring values for rate-adaptive pacing.

The Relay and Marathon pacemakers determine their adaptive pacing rate from the sensor signal of an accelerometer. The physical activity of the patient detected in this way has a defined but non-linear correlation to the resulting pacing rate. The sensitivity of the sensors and the rate rise and decay can be programmed to several settings, ranging from gradual to dynamic [1].

The Chorum calculates the sensor-controlled rate from the MV exclusively. The pacing rate has a linear correlation to the MV, and the basic rate and the maximum rate provide its lower and upper limits. The rate attack and decay can either be programmed freely, or it is automatically adapted to the activity level of the patient by permanent MV analysis during rest and under load [2].

The integrated sensor rate-adaptive pacing of the Kappa DR is based on the evaluation of two sensor signals - the motion and MV sensors. Automatic adjustment during rate-adaptative mode decides how the actual pacing rate is determined. In certain rate ranges, the motion sensor dominates, while in others the MV determines the rate mostly or exclusively [3].

The Diamond II analyzes activity with a piezo and the QT interval to calculate the pacing rate. It can be programmed which sensor signal is preferred for determining the pacing rate (QT < activity; QT > activity; QT = activity). The rate attack and decay can be either programmed to fixed settings or be adapted automatically. In the last case attack and decay is adapted permanently to the patient by automatically evaluating the QT interval when the base rate is reached during night and evaluating the QT interval and the activity when the upper tracking rate is reached [4].

In contrast to all these systems, CLS uses the body's intrinsic receptors to determine the load state of the patient. The cardio-circulatory center processes the information from the receptors and provides a heart rate that is conveyed to the CLS system via the contractile state of the heart. The rate rise and decay adapt to the individual degrees of load for each patient. Programming temporal or load parameters for determining the rate rise and decay is not necessary [5].

The patients were subjected to physical as well as mental stress tests. To evaluate rate response during physical stress, the following exercises were performed:

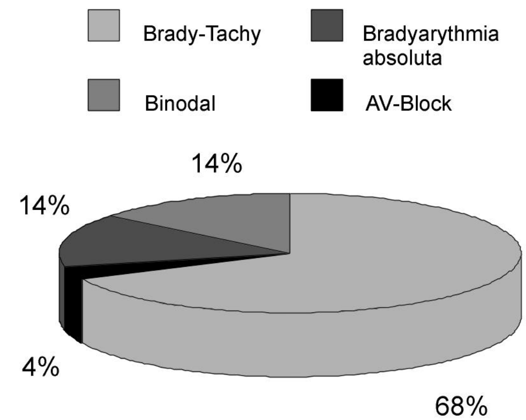

Figure 1. Indications of the 27 patients in per cent.

climbing and descending stairs, slow and fast walking, circular arm movements, and picking up an object. The individual stress phases were interspersed with two-minute relaxation phases. Additionally, the patients were subjected to mental stress with a color word test (CWT) on a PC. To guarantee reproducibility of the results, this two-minute test was repeated after a relaxation phase. The results were compared with a control group (CG) consisting of 15 DDD patients (5 male, 10 female; mean age of 68.6 years) with a healthy sinus node.

Results

Climbing and descending stairs

The analysis of the recorded rate courses showed for almost all systems a higher heart rate when climbing stairs than when descending stairs, which corresponds with expectations. Only the accelerometer displayed no significantly higher rate when climbing stairs (climbing: 97.8 ± 7.7 bpm; descending: 95.5 ± 10.4 bpm). Differences between the individual systems existed in the rate differences between the two loads and also in the absolute rates as compared to the control group. Figure 2 clearly shows that CLS delivers rates during stair climbing that are almost identical to those of the control group (climbing: CLS 108.3 ± 10.5 bpm; CG 109.3 ± 7.4 bpm). The MV pacemaker also shows hardly any differences to the control group. The dual-sensor systems, QT + piezo and MV + piezo, differ mainly in their absolute pacing rates. Compared to the

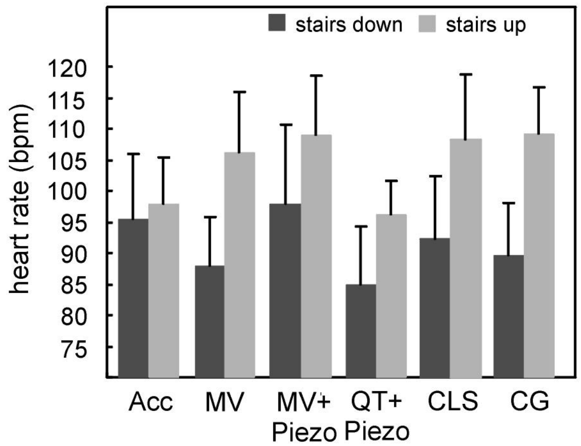

Figure 2. Average heart rates during stairs climbing, which are provided by the different systems and the control group.

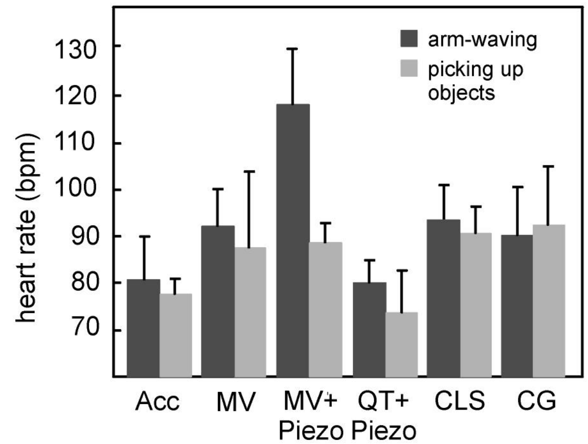

Figure 4. Average heart rates during the activities arm waving and picking up objects.

control group, the MV + piezo calculates a rate that is too high during stair descending (descending: MV + piezo 98 ± 6 bpm; CG 89.6 ± 8.5 bpm), which is due to piezo overvaluation. In contrast, the QT + piezo system calculates a pacing rate that is too low during stair climbing (climbing: QT + piezo 96.25 ± 5.44 bpm; CG 109.3 ± 7.4 bpm), which can be explained by the sluggish response of the QT signal. The accelerometer detects no significant difference between climbing and descending, setting pacing rates between 95 and 100 bpm.

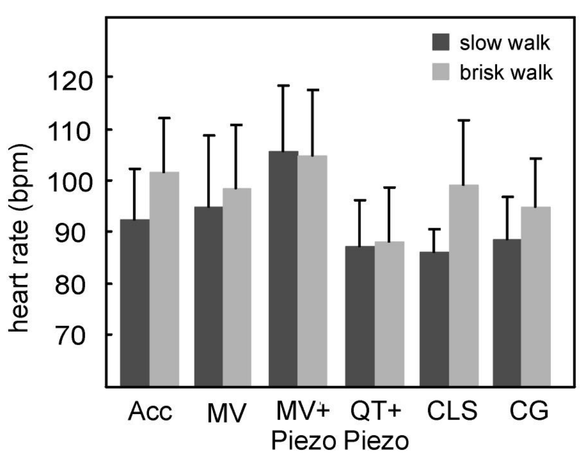

Figure 3. Average heart rates during walking, which are provided by the different systems and the control group.

Slow and brisk walking

Comparable to climbing stairs, a higher rate is expected for brisk walking than for slow walking, according to the heart rate response in the control group. The heart rate transmitted by CLS shows no significant deviation from that of the control group (figure 3). Good agreement in the pacing rates is also achieved with the MV sensors and the accelerometer. In contrast, the systems with two sensors do not recognize a load difference between slow and brisk walking. The QT + piezo system determines a pacing rate that is too low for brisk walking due to the programming (QT = piezo) the piezo signal is suppressed by the slowly reacting QT sensor (fast walking: QT + piezo 88.2 ± 10.8 bpm; CG 95 ± 9.6 bpm). Whereas, the MV + piezo system calculates a pacing rate that is clearly too high for both loads (brisk walking: MV + piezo 105 ± 13 bpm; CG 95 ± 9.6 bpm).

Circular arm movements and picking up an object

Results from the control group determine the expectations for both circular arm movements and the motion of repeatedly picking up an object. Figure 4 shows that the CLS patients are provided with a heart rate corresponding to that of a healthy person (circular arm movements: CLS 93.5 ± 8 bpm; CG 90.3 ± 10.2 bpm; picking up an object: CLS 90.6 ± 5.7 bpm; CG 92.5 ± 12.5 bpm). The MV system displays a similar response. Pronounced deviations become obvious when analyzing the pacing rates of the dual-sensor systems and the system with the accelerometer. Both

Load	Acc	MV	MV + piezo	QT + piezo	CLS	CG
Climbing stairs	97.8 ± 7.7	106.7 ± 9.8	109 ± 9.7	96.75 ± 5.4	108.3 ± 10.4	109.3 ± 7.4
Descending stairs	95.5 ± 10.4	88 ± 7.8	98 ± 6	85 ± 9.3	92.3 ± 10.1	89.7 ± 8.5
Slow walking	92.5 ± 9.9	94.8 ± 14.1	106 ± 12.8	87.5 ± 9	86 ± 4.5	88.6 ± 8.5
Brisk walking	102 ± 10.5	98.8 ± 12.3	105 ± 13	88.25 ± 10.8	99.5 ± 12.5	95 ± 9.6
Arm waving	89.8 ± 9.2	92.2 ± 8.[illegible]	118.4 ± 11.9	80 ± 8	93.5 ± 8	90.3 ± 10.2
Picking up object	77.6 ± 3.4	87.5 ± 16.4	88.6 ± 4.4	73.75 ± 8.9	90.6 ± 5.7	92.5 ± 12.5

Table 1. Survey of the average heart rates of all systems during the ambulatory tests.

the QT + piezo system and the accelerometer system calculate pacing rates that are too low (picking up an object: accelerometer 77.6 ± 3.39 bpm; CG 92.5 ± 12.5 bpm; QT + piezo 73.8 ± 8.9 bpm). With the accelerometer, this response is because the patient's upper body is either not accelerated enough or not in a distinct direction. Therefore, the sensor does not recognize the presence of a load. While with the MV + piezo system the pacing rate during picking up an object agrees well with the expected value, the rate during circular arm movements is clearly too high (circular arm movements: MV + piezo 118.46 ± 11.9 bpm; CG 90.3 ± 10.2 bpm). The MV measuring method is probably the underlying reason. The strong influence of circular arm movements on the upper body feigns a higher MV. All results concerning the ambulatory tests are summarized in table 1.

Mental stress by CWT

For a clear depiction of the results, the rates measured during stress were related to the resting rate prior to the test. The response of the various systems during mental stress is illustrated in figure 5. The literature discusses the rate response during mental stress (arithmetic test) in many ways [6][7]. Higher rates during such loads are generally found in the studied test subjects in varying degrees. During the CWT test performed in this study, only the CLS showed the expected rate increase. During the test, both an adequate rise of the heart rate (rest: CLS 65.3 ± 4.5 bpm; CWT 83 ± 14.1 bpm) and a fall during the relaxation phase can be found. All other systems do not succeed in detecting the mental load to the patient with their sensors. Therefore, the pacing rate is not adapted, and an adequate supply of blood to the patient is not guaranteed.

Discussion

The study results show that all sensor-controlled systems have clear weaknesses in determining the pacing rate, for at least one form of load. The underlying cause is the sensors used for calculating the pacing rate. Since they evaluate the load to the patient with solely external parameters and their reaction time is often too long, an adequate rate can be determined for only certain loads.

Since the accelerometer only detects upper body acceleration, it displays a good correlation to the control group just during walking. Climbing and descending stairs already overtaxes the system. There is no significant difference in the pacing rates for climbing and descending. This situation, as well as circular arm

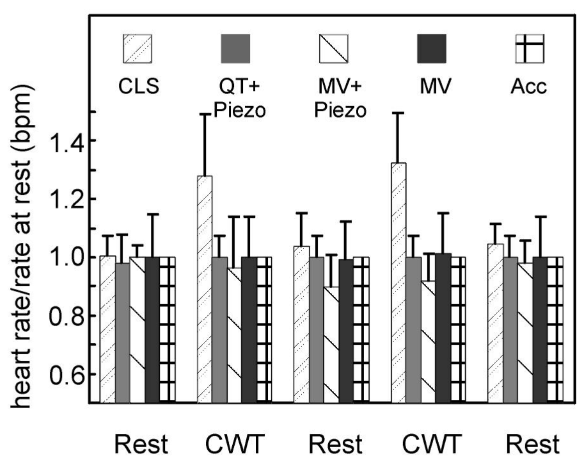

Figure 5. Average heart rates normalized to the rate at rest during the mental stress test.

movements and picking up an object, already leads to misjudgments of the patient load state. The MV system delivers pacing rates that do not significantly deviate from those of healthy test subjects during all kinds of physical stress. Only during the mental stress test, there is no rate-adaptation since MV does not change under such loads. Thus, an adequate supply is not guaranteed.

The dual-sensor systems have the additional problem of optimally coordinating the individual sensors. The MV + piezo overemphasizes the input of one of the sensors when determining the heart rate for the patient, thus leading to pacing rates that are too high for both circular arm movements and walking. An agreement with the control group exists only for climbing stairs and picking up an object. The QT + piezo system calculates an adequate rate only for slow walking. Under all other loads, pacing rates that are too low are a result of the sluggish QT sensor. In view of the numerous and complex programming options for dual-sensor systems, a better balance of the sensors might possibly be achieved with extensive testing. But even with sensor optimization, these systems cannot meet the requirements during mental stress.

In contrast to all sensor systems, the CLS provides a heart rate without any significant deviations from the heart rate of the healthy test subjects under all physical and mental load conditions. The body's intrinsic receptors detect every load state of the patient and transmit this information to the cardio-circulatory center. It responds to the information with a heart rate that is conveyed to the CLS system via the contractile state of the heart. Thus, the CLS guarantees an adequate heart rate - even during mental stress.

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