Heart Rate Variability over 24 Hours - Closed Loop Stimulation and Motion-Sensor Pacemakers Compared with Healthy Control Group

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Summary
The aim of modern pacemaker technology is not only to prolong life but to provide therapy that is orientated to the patient's individual needs, thus improving their quality of life. With the Closed Loop Stimulation (CLS) pacing method, the pacemaker becomes part of the natural control loop and, therefore, guarantees adequate pacing rates under all kinds of mental and physical loads. To prove this integration of the pacemaker into the cardiovascular system, the heart rate variability of 19 patients who received CLS pacemakers was determined and compared with a control group consisting of 20 healthy patients and with a group of 32 patients who received rate-adaptive pacemakers with a motion sensor. Both groups of pacemaker patients and the control group underwent 24-hour Holter monitoring. The heart rate variability of the CLS group shows a mean SDANN index of 86 ms and no significant difference (p=0.5) to that of the control group (mean SDANN index, 93 ms). The heart rate variability of the motion sensor group, with a mean SDANN index of 59 ms, is significantly different than the control group (p<0.01). The results illustrate that CLS provides a heart rate variability comparable to that of healthy people due to the integration of the pacemaker into the natural control loop. In contrast, the heart rate variability of the motion sensor group is limited and does not correspond to the actual needs of the patients.

Key Words
Closed Loop Stimulation, heart rate variability, motion sensors

Introduction
The cardiovascular system and its regulation of chronotropic function support the general stability of the hemodynamic state. With chronotropic incompetence, the functionality of the cardiovascular system is limited. Heart rate and mean arterial blood pressure (MABP) are not regulated according to the current load, so the patient suffers from a reduced capability. In the past, many rate-adaptive pacemakers were developed that used several sensor signals not derived from the cardiovascular system. All these systems tried to mimic the cardiovascular system, using an artificial regulation system without any information about the present need and the hemodynamic state of the patient. In contrast to these systems, Closed Loop Stimulation (CLS) reestablishes the disturbed natural closed loop. Information from the regulatory center is used and is attained by measuring the contractile state of the myocardium [4]. Consequently, the baroreceptor reflex — a quick regulation mechanism — again becomes a part of regulating MABP. This is why CLS pacemakers provide pacing rates adequate to not only physical but to mental and all other loads. As the pacemaker is part of the natural control loop, the suspicion exists that the pacing rate is mediated by the efferent sympathovagal signals that underlie heart rate variability (HRV) of healthy people.

The aim of this investigation is to demonstrate that the CLS pacing rate shows an HRV similar to those of healthy subjects and dissimilar to those of patients with systems deriving information for rate adaptation from a motion sensor; furthermore, the pacemaker becomes part of the natural control loop with CLS.
Materials and Methods

The investigations to analyze HRV were performed in two groups of patients and a control group. The indications for all pacemaker patients were complete AV block and chronotropic incompetence. The first group of patients (the CLS group) consisted of 19 patients who received CLS pacemakers [1,2], among them 13 single-chamber pacemakers (VVIR mode; NEOS PEP, BIOTRONIK, Germany) and 6 dual-chamber pacemakers (DDDR mode; DIPLOS PEP, BIOTRONIK, Germany). The average age of the patients was 29.5 years (range: 9 to 69 years). In the second group (the MOT group), 32 patients were included and received rate-adaptive systems based on motion sensor input, among them 22 single-chamber pacemakers (VVIR mode; METROS 01, BIOTRONIK, Germany) and 10 dual-chamber pacemakers (DDDR mode; ERGOS 03, BIOTRONIK, Germany). The average age of the patients was 58.2 years (range: 8 to 72 years). Both groups were compared with each other and with a control group (C group) consisting of 20 healthy subjects with a mean age of 18 years (range: 14 to 25 years).

All patients underwent 24-hour Holter monitoring that was performed in the clinic, so all patients and the control group had a similar diary. The gained recordings were analyzed with the Medilog® Optima (Oxford Instruments, United Kingdom), which evaluated the heart rate histogram, the mean heart rate and range of heart rates for all patients. To determine HRV, the SDANN index [3] was computed, which represents the standard deviation of the averages of all NN intervals in all 5-minute segments throughout the recording. The statistical difference between the groups was evaluated with the Students t-test.

Results

Figures 1 through 3 illustrate the mean pacing rate histograms of the patients from the corresponding groups. In the CLS group, the mean heart rate is 74.3±10.99 bpm and the pacing rate ranged from 60 to 135 bpm. This heart rate distribution is similar to that of the C group, with a mean heart rate of 71.76±12.6 bpm (range: 55 to 125 bpm). In contrast to these results, the MOT group shows 94% of all measured heart rates to be between 60 and 70 bpm. At the high end, a few pacing rates of up to 108 bpm were recorded. During the recording, all pacemaker patients were stimulated 100%.

In addition, the SDANN index was calculated for the three groups. In Figure 4 the results of the HRV analysis are illustrated, demonstrating the SDANN index and the measured range from the patients of each group. The CLS group shows a mean SDANN index of 86 ms (range: 71 ms to 94 ms). This is not significantly different (p=0.5) from the mean C group SDANN index of 93 ms (range: 88 ms to 105 ms). The mean SDANN index of the MOT group is 59 ms (range: 50 ms to 72 ms) and is, therefore, significantly different from the C group (p<0.01).

In contrast to the CLS group, the MOT group shows only little variation, because the pacemaker provides...
rate adaptation for the patients only when movement is detected. The pacemaker does not respond to the real needs.

Discussion
Concerning the CLS group, the results illustrate that due to the integration of the pacemaker into the natural control loop, the HRV provided by CLS is nearly analogous to that of the C group. The slight difference between the two groups can be explained by their age profiles. It is known from the literature that the SDANN index and the corresponding HRV are reduced with increasing age in healthy people as well. From this point of view, the HRV of the CLS group does not show any difference to that of the C group. CLS supplies the patient according to the actual load with an adequate pacing rate that is regulated by the body's own circulatory center.

References