

Closed Loop Stimulation is Sensitive to the Valsalva Maneuver

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Summary

Rate adaptive pacing has become a standard therapy in patients with bradycardia. In these patients, the baroreceptor reflex is greatly disturbed and most rate adaptive pacemakers fail to restore this basic mechanism in rate control. The pacing rate of these pacemakers depends on the analysis of information from artificial sensor systems lacking a direct connection to the natural cardiocirculatory control loop. The Closed Loop Stimulation of the Inos² CLS pacemaker is a new approach in rate regulation. The Inos² CLS offers the advantage of directly monitoring the action of the natural cardiocirculatory control loop on the myocardium. Thus, rate regulation of the Inos² CLS depends directly on the action of natural control loops such as the baroreceptor reflex. The aim of this study was to monitor the action of the baroreceptor reflex in patients implanted with Inos² CLS pacemakers. For this purpose, eighteen chronotropically incompetent patients implanted with an Inos² CLS pacemaker were asked to perform the Valsalva maneuver. In all patients, the Valsalva maneuver evoked characteristic changes in mean arterial blood pressure and paced heart rate. An initial increase in mean arterial blood pressure was followed by a decrease in blood pressure and a reflexive augmentation in heart rate, indicating a direct influence of the baroreceptor reflex on the pacing rate. These results demonstrate clearly that the Closed Loop Stimulation of the Inos² CLS pacemaker is integrated into the natural control loop.

Key Words

Baroreceptor reflex, Closed Loop Stimulation, Valsalva maneuver

Introduction

Several types of rate adaptive pacemaker systems have been developed to enhance exercise tolerance in chronotropically incompetent patients. Rate adaptation of these systems is based on the analysis of sensor signals that are thought to monitor the patient's physical activity. Signals are derived from external parameters such as motion, acceleration, or respiratory minute volume. Despite the advantages of technology and the computational power of pacemakers, these systems lack a direct connection to the cardiocirculatory system. Rate adaptation that is based on the information derived from artificial sensors does not cover all of the patient's needs and not all of the physical loads are converted into adequate pacing rates [1-3]. In order to overcome these problems, dual sensor systems combining information from artificial sensors with physiological parameters such as respiratory minute volume or the QT interval, have been developed. However,

even these very sophisticated systems lack some of the functionality of the cardiocirculatory system's golden standard [2].

The Closed Loop Stimulation (CLS) represents a new approach to rate regulation. The CLS integrates the pacemaker into the cardiovascular control system by monitoring permanently the contractile state of the myocardium and converting the intrinsic information into rate regulation. Since the contractile state of the myocardium is permanently modified by the action of the cardiocirculatory system, the regulation of this system is coupled directly with the cardiovascular system and integrated into the natural control loop [4-6].

One of the basic natural rate regulatory mechanisms is the baroreceptor reflex. This basic mechanism of rate control is ineffective in chronotropically incompetent patients. The baroreceptor reflex is a fast acting mechanism that regulates the heart rate in order to provide

optimal hemodynamics under varying conditions. In chronotropically incompetent patients, the functionality of this reflex is greatly disturbed. Changes in blood pressure are no longer compensated and the heart rate is not adjusted to the patient's need. Furthermore, an impaired baroreceptor reflex worsens the patient's prognosis and facilitates the occurrence of tachyarrhythmias and sudden cardiac death [7]. The artificial sensors in rate adaptive pacemaker systems are not capable of restoring the functionality of the baroreceptor reflex [1,3]. A pacemaker that performs Closed Loop Stimulation should reestablish rate control via the baroreceptor reflex. Therefore, the aim of the present study was to investigate whether the Closed Loop Stimulation of the Inos² CLS pacemaker (Biotronik, Germany) restores the baroreceptor reflex. For this purpose, we examined the effects of the Valsalva maneuver on patients implanted with the Inos² CLS.

Methods

So far, eighteen chronotropically incompetent patients (8 male, 10 female, mean age 72.5 ± 7 years) were enrolled in this study and received the Inos² CLS system. Indications were sick sinus syndrome ($n = 12$), SN-arrest ($n = 3$), and carotid sinus syndrome ($n = 3$). At the time of discharge, the pacemaker was set to the CLS mode. The programmed basic rate was set to 60 bpm and the maximum closed loop rate was 110 to 140 bpm according to the patients' need. The patients performed the Valsalva maneuver at the 3-month follow-up. During the Valsalva maneuver, the patients had to exhale against a pressure load of 30 mmHg. Their mean arterial blood pressure (MABP) was continuously recorded on a beat-to-beat basis by means of a finapress-system (Ohmeda, USA). A conventional ECG was used to monitor the paced heart rate.

Results

The Valsalva maneuver, first described in 1707, is a forced expiration against a closed glottis that leads to characteristic changes in MABP and heart rate. The maneuver can be divided into 4 phases (Figure 1). In the first phase, the increase in tension of the thoracic wall during expiration causes a rise in the mean arterial blood pressure. The second phase, however, is characterized by a decrease of the venous return to the heart due to the increased intrathoracic pressure. As a conse-

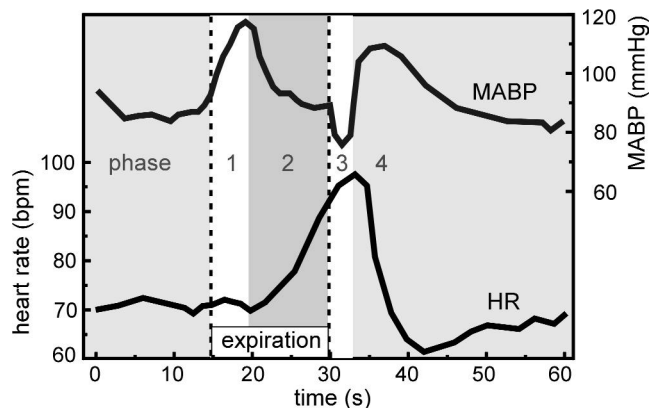


Figure 1. Definition of the phases of the Valsalva maneuver.

quence, the cardiac output decreases and peripheral vasoconstriction occurs. At this stage, the MABP decreases and the heart rate rises. The third phase begins with the onset of inspiration. In this phase, the intrathoracic pressure is lowered. The MABP decreases below the initial value followed by a further increase in heart rate. In phase 4, the cardiac venous return increases and elevates the cardiac output. At the same time, peripheral resistance is still high causing again a rise in blood pressure. This rise in MABP induces a reflexive drop in heart rate. At the end, MABP as well as heart rate are down and are regulated to their original value by the baroreceptor reflex. These characteristic changes in MABP and heart rate are not observed in chronotropically incompetent patients implanted with a rate adaptive pacemaker that relies on an artificial sensor system [1,3].

In our study, the Valsalva maneuver induced characteristic changes in MABP and heart rate in all patients implanted with a Inos² CLS pacemaker system. The observed changes resembled the alterations described above. An initial increase in MABP is followed by a decrease in MABP and a reflexive augmentation of the heart rate (Figure 2). In the first phase, the MABP was 95 ± 16 mmHg. In phase 2, MABP increased to 112 ± 23 mmHg. During phase 3, the MABP decreased to 82 ± 18 mmHg. In phase 4, the MABP showed again a transient increase to 100 ± 14 mmHg before it settled at 96 ± 9 mmHg. The corresponding mean heart rates were 71 ± 11 bpm at the beginning of the maneuver, 90 ± 14 bpm in phase 3, and 77 ± 9 bpm at the end of the maneuver.

Furthermore, we found a suspicious age-dependant trend. In comparison with patients under 70 years of

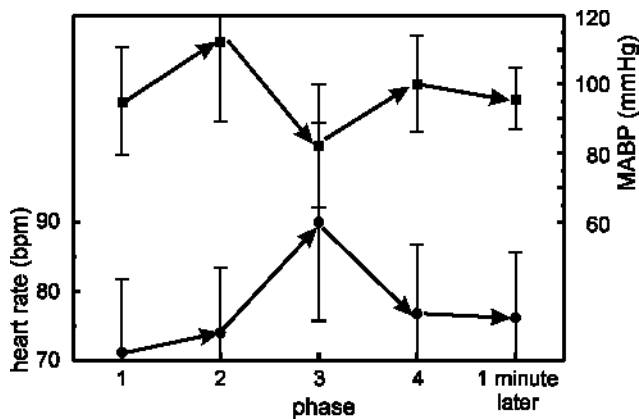


Figure 2. Mean arterial blood pressure and heart rate during the Valsalva maneuver.

age (n = 8), patients over 70 (n = 10) tend to exhibit a lower increase in MABP and heart rate during the Valsalva maneuver. As summarized in Table 1, MABP and mean heart rate were lower in patients over 70. However, due to the low number of patients in the study, this trend was not significant (p = 0.11, Man Whitney U-test).

Discussion

In this study, the reintegration of the baroreceptor reflex into rate regulation was tested in chronotropically incompetent patients performing the Valsalva maneuver. This maneuver is known to be sensitive to deterioration of the baroreceptor reflex [8,9] and was used by other investigators to test the response of several rate adaptive systems to physiological needs other than physical exercise [1,3]. Lau et al. reported that patients implanted with rate adaptive pacemakers either did not respond at all to the Valsalva maneuver or responded in a paradoxical manner [1].

In our study, all patients implanted with the Inos² CLS exhibited characteristic changes in MABP and heart rate. During Valsalva, the entire course of MABP and heart rate resembled the known changes of healthy subjects. Although we did not attempt to quantify the sensitivity of the baroreceptor reflex in our patients, our results demonstrate qualitatively the reestablishment of the baroreceptor reflex by the Inos² CLS pacemaker system.

In addition, we noted age dependant differences in the course of MABP and heart rate. Due to the low number of patients, these differences did not reach statisti-

Age	64.3 ± 6 years		77.3 ± 5.5 years	
Number	n = 8		n = 10	
	MABP	HR	MABP	HR
Phase 1	94 ± 16	75 ± 10	95 ± 10	72 ± 5
Phase 2	114 ± 28		110 ± 14	
Phase 3	87 ± 20	97 ± 13	80 ± 14	84 ± 11
Phase 4	100 ± 13		96 ± 12	
1 min later	94 ± 17	79 ± 7	95 ± 13	72 ± 7

Table 1. Mean arterial blood pressure and heart rate during the Valsalva maneuver in two age groups.

cal significance; however, this finding might point to a reduced sensitivity of the baroreceptor reflex in the elderly, and might be considered as physiological phenomenon [9]. This study shows that the Inos² CLS system is integrated into the natural cardiovascular control loop and offers optimal rate regulation in bradycardia dysrhythmia with chronotropic incompetence.

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