First Clinical Experience Using an Automatic Closed Loop System in DDDR Stimulation Controlled by Autonomous Nervous System

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Summary

The current state of the art in the rate adaptive pacing field is the search for an ideal sensor. Improvement in the physiological response and the simplicity to program are two very important keys in a "gold standard " sensor. Our objective is to evaluate the programming simplicity and the physiological appropriateness of the response in a new closed loop DDDR pacemaker controlled by autonomous nervous system. The Inos² CLS pacemaker (Biotronik, Germany) was implanted in 11 patients (5 female, 6 male) from September 1998 until April 1999. The mean age was 62.18 ± 11.66 years . Six patients suffered from total AV block, 3 patients had symptomatic 2nd degree AV block, and 2 patients had total AV block plus sick sinus syndrome. The Inos² CLS pacemaker adjusts the heart rate by monitoring of the myocardial contraction dynamics via right ventricular impedance measurement. Since the contraction of the ventricle reflects the physiological needs, physical as well as mental stress will be satisfied. The pacemaker provides an automatic initialization, which was activated after implantation, to adjust its algorithm to the individual condition of the heart. We performed three follow-up examinations (6 weeks, 3 months and 6 months after implantation). We checked the chronic stimulation threshold and performed an ambulatorial test covering the following activities: walking, rest sitting, standing, stairs up and down climbing. Additionally, we performed a mental test that consisted of a simple mathematics exam. Heart rate during daily life activities was recorded by use of internal 24 h trend recording. All patients stated better clinical performance during daily life activities. We had no adverse events like intermittent or complete loss of capture, intermittent or complete loss of sense, diaphragmatic muscle / phrenic nerve stimulation, lead dislodgment, infection, arrythmias or inappropriate sensor response. The closed loop system (CLS) showed adequate heart rate response in all patients provided by a very easy and automatic sensor programming.

Key Words

Cardiovascular regulation, Closed Loop Stimulation, heart rate, automatic initialization, rate controlled pacing

Introduction

Various parameters are involved in a complex process, called cardiovascular circulatory control, to supply the organism with appropriate arterial blood pressure and perfusion: heart rate, stroke volume and total peripheral vascular resistance. Impaired functionality of one of these variables results in a more intense use of the remaining quantities which, therefore, can serve as ideal indicators of the circulatory demand. Conventional rate adaptive systems are based on the use of one or more artificial sensors. These sensors measure parameters that are only indirectly correlated to the patients' hemodynamic demands. The ideal method for realizing a physiologic pacemaker system would be the integration of the pacing device into the cardiocirculatory system. The principle of closed loop chronotropic control is, nowadays, the most attractive strategy for reestablishing adequate heart rates. Even under pathophysiological conditions, the dynamics of the myocardial contractile force still reflect the information from the circulatory center. Because inotropic regulation affects the contraction dynamics of the ventricular myiocardium, measuring changes in myocar-

dialcontractility can access the hemodinamic state and requirements. Based on that relationship, the Closed Loop Stimulation (CLS) pacemaker transfers changes in myocardial contractility into individual pacing rates. First experiences with CLS was gained with a system that required manual, patient-specific initialization. Further developments allowed to equip the system with an automatic initialization which provides adequate heart rate response within 3 to 5 days after starting the CLS pacing mode. The performance of the automatic initialization has been validated during physical exercises and mental stress.

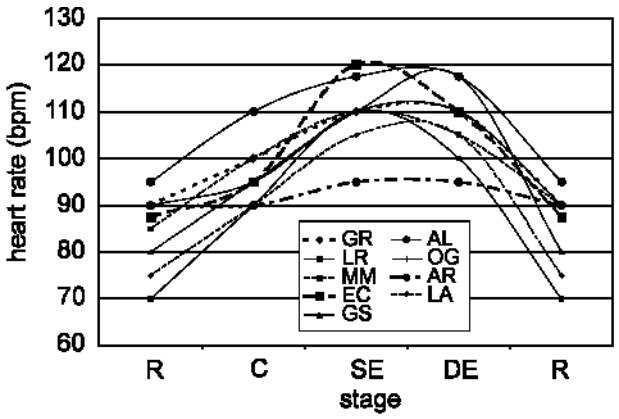

Figure 1. 6-week ambulatory test.

Materials and Methods

At the "Irmandade Santa Casa de Misericórdia de Porto Alegre", from September 1998 to April 1999, 11 patients were submitted to a cardiac dual chamber pacemaker implantation, model Inos² CLS (Biotronik, Germany) providing closed loop rate adaptation by monitoring the myocardial contraction dynamics. Six of this group were male (54.5%) and 5 were female Sex (45.4%), with mean age of 62.1 ± 11.6 years. The inclusion criteria in this study group were: patient's agreement, indication criteria for the pacemaker DDD implantation and the absence of contraindication to accomplish exercises. The patients were followed up for 4.9 ± 2.3 months.

After implantation, the pacemaker remained in DDD mode until the patient's hospital discharge, when we evaluated: sinus rate, atrial and ventricular pacing threshold, atrial and ventricular sensing. The pacemaker was programmed according to these parameters and the stimulation mode was changed to DDD-CLS.

A minimum of 6 weeks later, the first follow-up took place covering the same tests as during discharge. Additionally, the patients were asked to perform an ambulatorial test (Table 1). During each test, heart rate changes as well as atrial and ventricular event types were recorded. The next pacemaker follow-up with similar investigations was scheduled three months postimplant.

Six months after implantation, the last examination of this study took place. The patients were submitted to a mental "stress" test (Table 1), which consisted of 2 consecutive time limited arithmetic subtraction tests (Module 1 and 2). The patient was constantly stimulated. The observer constantly reminded the patient to perform the calculations quickly.

Ambulatory Test

Stage	Duration
Resting (R)	1 min
Walking (W)	2 min
Standing	2 min
Stairs up (SU)	2 min
Standing	2 min
Stairs down (SD)	2 min
Standing	2 min
Resting (R)	2-5 min

"Stress" Test

Stage	Duration
Resting (R)	10 min
Test Explanation (EXP1)	2 min
Module 1 (M1)	3 min
Test Explanation (EXP2)	2 min
Module 2 (M2)	3 min
Recuperation (RE)	3 min

Table 1. Ambulatory test and stress test.

Results

The investigations proved that the Closed Loop Stimulation of the Inos² CLS pacemaker adjusted the heart rate appropriately to physical activity during ambulatorial effort (Figures 1, 2, 3, 4). All patients being included present an important heart-rate increase during the stages of walking as well as stairs up and

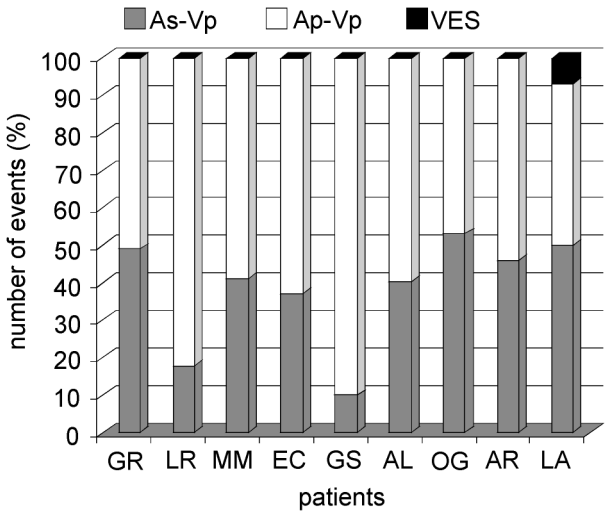

Figure 2. Atrial and ventricular activity sensed and paced during the 6-week ambulatory test. (Ap = Atrial paced activity; As = Atrial sensed activity; Vp = Ventricular paced activity; VES = Ventricular Extrassystoles).

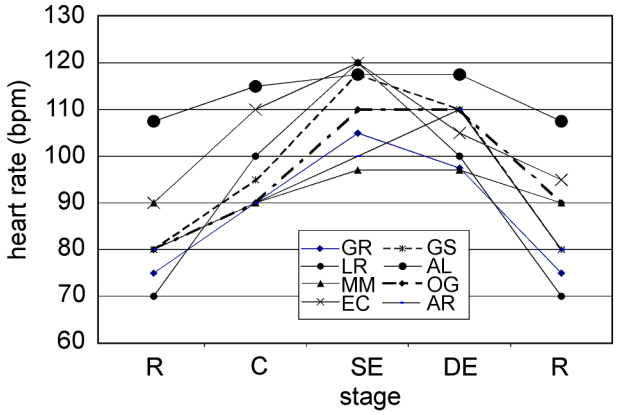

Figure 3. 3-month ambulatory test.

down climbing. However, it was observed that the heart rate increased in some patients not only due to the sensor but also following the sinus rhythm.

Table 2 summarizes the atrial and ventricular event type during the first (6 weeks) and the second ambulatorial test (3 months) compared to the cardiac activities during the last 24 hours before the follow-up.

The mental "stress" tests, which are still under completion, have shown that the reaction depends directly on the patient's intellectual capacity. Two third of the patients presented an increase in heart rate during the explanation of the test (Table 3). We interpret this reaction of the sensor to be related to the unexpected situation provoking mental stress in the patient.

	As-Vp (%)				Ap-Vp (%)			
	6 week	Amb 1	3m	Amb 2	6 week	Amb 1	3m	Amb 2
GR	26	49	27	36	74	51	73	64
LR	18	18	19	24	82	82	81	76
MM	24	41	44	44	62	59	56	56
EC	24	37	29	58	76	63	71	42
GS	10	10	8	12	90	90	92	88
AL	38	40	38	89	61	59	61	11
OG	33	53	33	46	67	47	67	54
AR	61	46	29	10	39	54	71	90
LA	32	50	-	-	57	43	-	-

Table 2. Atrial and ventricular activity sensed and paced in the last 24 hours to the evaluation and after the physical effort test. (Amb 1 = 6-week physical effort test; 3m = 3 months; Amb 2 = 3-months physical effort test).

Conclusion

Patients who are chronotropically incompetent (sick sinus syndrome) or even suffering from AV block may benefit from being implanted a DDD-CLS pacemaker. The results obtained during this clinical study demon-

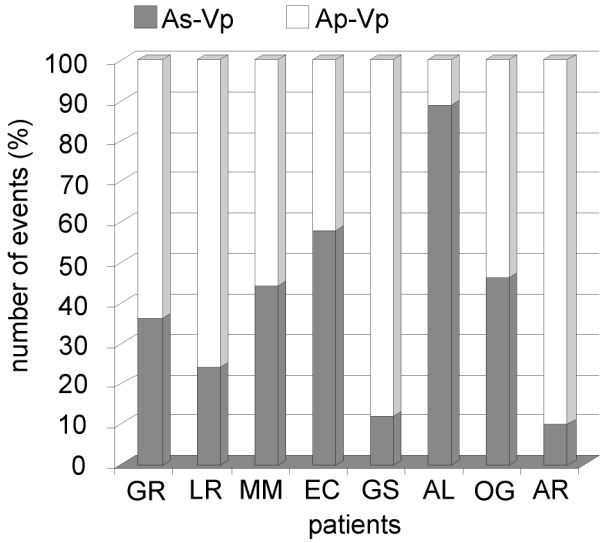

Figure 4. Atrial and ventricular activity sensed and paced during the 3-months ambulatorial test.

	RHR (bpm)	SHR (bpm)	Acré. FC (%)	Moment SHR	NM
GR	90	100	11.1	M1	2
LR	70	100	42.9	EXP	1
MM	85	120	41.2	EXP	2
EC	88	-	-	-	0
GS	80	90	12.5	EXP	2
AL	70	80	14.2	EXP	1

Table 3. "Stress" test (RHR = Resting heart rate; SHR = Stress heart rate; M1 = module 1;EXP = Explanation; NM = number of modules).

strate adequate responses of the regulated heart rate. The pacemaker adapts to the individual patient automatically without any need for programming special parameters. The achieved heart rates over 24 hours during daily life, as well as those during short exercise tests, show close correspondence to values from healthy control groups described in literature. The automatic initialization substitutes the previous manual procedure, requiring shorter time periods for follow up. Moreover, this feature is always active in CLS mode providing long-term stability of the system.

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