Clinical Experience with Closed Loop Pacing Systems in Patients with Congestive Heart Failure

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Summary

Pacemaker patients with congestive heart failure (n = 16) were re-implanted with Closed Loop Stimulation systems. Examinations in the acute phase after pacemaker implantation and at follow-up examinations 3 to 6 months after implantation revealed overall an improvement in maximum working capacity (from 62.2 W to 118.9 W) and a positive shift in NYHA classification. A patient-subgroup that especially benefited was a population (n = 6) who suffered from artificial AV block and atrial fibrillation. In these patients the maximum working capacity increased from 38.2 W to 94.5 W, and NYHA classifications of I and II increased from 33% to 83%. The study showed that the pacing rate provided by Closed Loop Stimulation physiologically responded to the physical load in patients with congestive heart failure. Moreover, Closed Loop Stimulation led to diminished signs of heart failure and a general positive shift in NYHA classification.

Key Words

Closed Loop Stimulation, congestive heart failure, NYHA classification, AV block, atrial fibrillation

Introduction

Conventional stimulation systems maintain rate adaptation by using parameters that only indirectly reflect hemodynamic demands. Closed Loop Stimulation (CLS) differs from conventional systems in that it uses information from an internal parameter of the cardiovascular system, i.e., the pacemaker system is integrated into the natural circulatory regulation of the organism. Through continuous feedback about the actual cardiac state provided by the body, CLS ensures the most adequate cardiovascular regulation without overstressing the cardiac reserves [1-4]. Clinical studies have proved that CLS shows excellent performance in heart rate regulation in heterogeneous patient groups [1-6]. The aim of our study was to assess the clinical consequences of CLS pacemaker therapy in patients with congestive heart failure (CHF).

Materials and Methods

At the Kaunas University clinic, 29 patients (pts) had received CLS pacemakers: 18 pts, NEOS PEP (BIOTRONIK); 9 pts, DIPLOS PEP (BIOTRONIK); 2 pts, INOS^2 DR (BIOTRONIK). In 16 cases (6 female, 10 male) the implantation was an exchange. The mean age of the patients at re-implantation was 55.7 ± 12.4 years (range: 27 to 71 years). Indications for pacemaker implantation were: total AV block in 6 pts (due to ischemic heart disease in 5 pts, congenital in 1 pt); artificial AV block and atrial fibrillation in 6 pts (underlying ischemic heart disease in 3 pts, arterial hypertension in 2 pts, myocarditis in 1 pt); sick sinus syndrome (SSS) in 1 pt and SSS and AV block in 3 pts (underlying ischemic heart disease in 2 pts, arterial hypertension in 2 pts).

The study protocol included:
· a general clinical evaluation;
· an echocardiographic investigation before pacemaker re-implantation;
· assessment of maximum working capacity before and 3 to 6 months after re-implantation;
· pacing rate and blood pressure monitoring at rest and during bicycle ergometry during acute testing and at follow-up (after 3 to 6 months); and
· 24-hr ECG Holter monitoring.

All Reimplants

Reimplanted Patients with AV block and AF

NYHA class

NYHA class

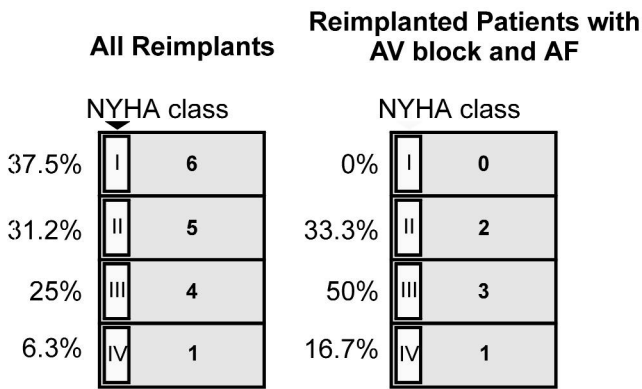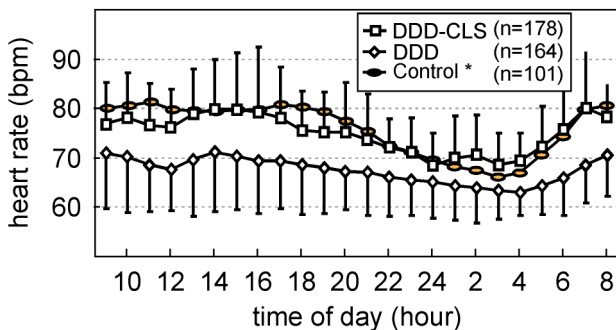|	All Reimplants		Reimplanted with AV block and AF	
37.5%	I	6	0%	I	0
31.2%	II	5	33.3%	II	2
25%	III	4	50%	III	3
6.3%	IV	1	16.7%	IV	1

Figure 1. NYHA classification of the patient groups before CLS-Implantation. left: CLS re-implant patients; right: CLS re-implant patient subgroup with artificial AV block and atrial fibrillation.
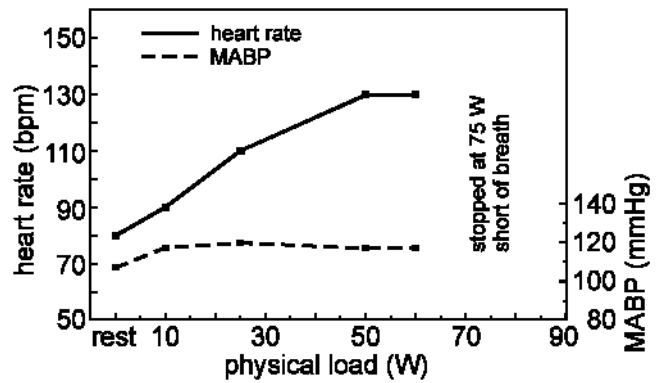

Figure 2. Pacing rate (PR) and mean arterial blood pressure (MABP) dynamics in acute testing during bicycle ergometry in patients with CLS pacemakers.

Results

General clinical evaluation of the patients before implantation of the CLS pacemakers revealed that the majority of patients were in NYHA Classes II to III (Figure 1A); a separate group of patients with artificial AV block and paroxysmal atrial fibrillation predominated NYHA Class III (Figure 1B).

Echocardiographic investigation prior to pacemaker implantation revealed: left ventricular (LV) hypertrophy and LV impaired relaxation in 10 pts, LV dilation in 5 pts, left atrium (LA) dilation in 9 pts, mitral regurgitation (grade II-III) in 4 pts, and a mean LV ejection fraction of 50.1% $\pm$ 4.7%. In patients with artificial AV block and atrial fibrillation (n = 6), the echocardiographic data collected were as following: LV hypertrophy and impaired relaxation in 5 pts, LV dilation in 2 pts, LA dilation in all 6 pts, mitral regurgitation (grade

II-III) in 4 pts, and a mean LV ejection fraction of 60.5% $\pm$ 9.2%.

After CLS pacemaker implantation, acute testing revealed a typically physiologic pacing rate response to bicycle ergometry with a mean arterial blood pressure (MABP) remaining nearly constant in all patients (Figure 2). In patients with AV block and an intact sinus node, changes in the pacing rate during exercise closely correlated with the sinus rate.

Twenty-four-hour ECG Holter monitoring showed perfect correlation with daily activities (Figure 3), with elevated diurnal rates (81 $\pm$ 11 bpm) versus nocturnal rates (67 $\pm$ 16 bpm). 3 to 6 months after CLS pacemaker implantation, repeated bicycle ergometry tests

* J.B. Kostis et al., The Effect of Age on Heart Rate, Circulation 65, 1 (1982) 141-145

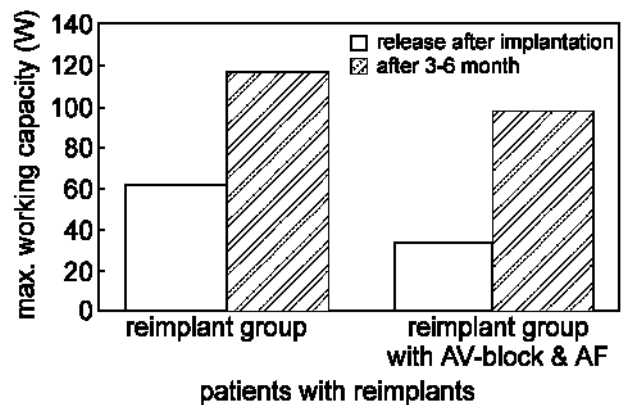*Figure 3. 24-hour heart rate trends from the CLS database.*

Figure 4. Changes in maximum working capacity 3 to 6 months after CLS pacemaker implantation. left: CLS re-implant patients; right: CLS re-implant patient subgroup with artificial AV block and atrial fibrillation (AF).
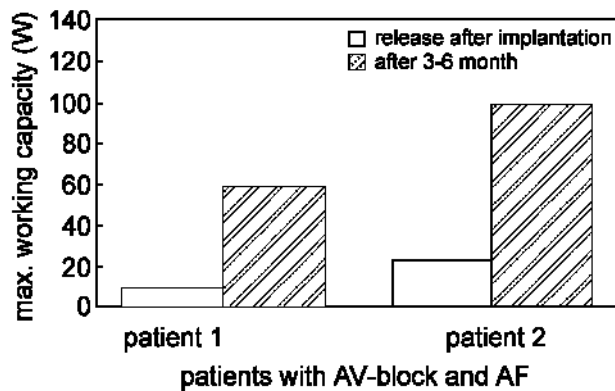
Figure 5. Changes in maximum working capacity 3 months after lNOS2 DR pacemaker implantation in 2 patients with AV block and atrial fibrillation.

Figure 6. NYHA class before and after CLS pacemaker exchange from the CLS database.

revealed an increase-from 62.2 W to 118.9 W-in maximum working capacity in the whole group. In the patient subgroup with artificial AV block and atrial fibrillation, the increase was from 38.2 W to 94.5 W (Figure 4). Figure 5 illustrates the dramatic increase in maximum working capacity in specifically 2 patients with artificial AV block and atrial fibrillation who received the INOS[2] DR pacemaker as a re-implant.

For all patients, the NYHA classification shifted in a positive direction. According to the CLS stimulation database, 97.9% of the patients who received the CLS pacemaker as a re-implant were re-classified in NYHA Classes I and II (Figure 6). A significant shift in the NYHA class was noted in the patients with AV block and atrial fibrillation (Figure 7): after CLS pacemaker implantation, the NYHA Class shifted from: IV to III in 1 pt, III to II in 2 pts, III to I in 1 pt, II to I in 2 pts. The number of patients with NYHA classifications of I and II thus increased from 33% to 83% in this subgroup.

Discussion

The most marked improvements in clinical status, maximum working capacity, and NYHA classification were noted in the subgroup of patients with artificial AV block and atrial fibrillation. Retrospective analysis of clinical and echocardiographic data revealed that in this group of patients LV diastolic dysfunction of congestive failure origins predominated. As in the majority of patients, exams revealed LV hypertrophy and impaired relaxation with normal LV ejection fractions.
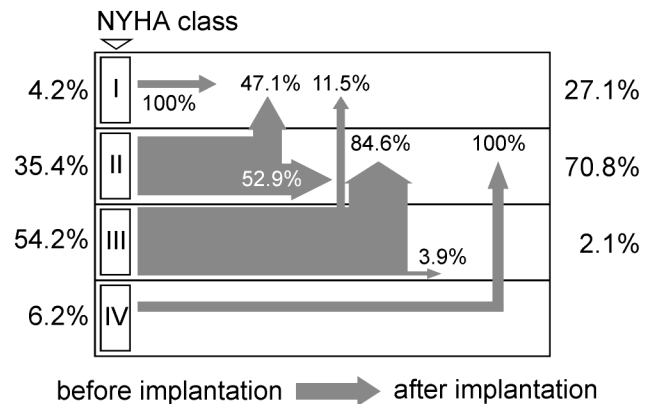
In the case of impaired LV relaxation, the atrial contribution was noted to increase stroke volume markedly. Loss of the atrial contraction during atrial fibrillation or ventricular stimulation in these patients led to signs of heart failure [7]. These patients are thus called atrial function dependent.

From 1986 to 1997, 65 patients presenting paroxysmal atrial fibrillation with palpitations and exercise, rest dyspnea or drug resistance underwent AV node radiofrequency ablation at the Kaunas University clinic. During follow-up after VVI pacemaker implantation, 42.8% of these patients remained in the NYHA Classes III-IV. Implantation of conventional rate adapting pacing systems were ineffective in diminishing signs of heart failure in 7 patients. Only application of CLS systems, which maintain physiologic and precise rate adaptation, made it possible to minimize the nega-
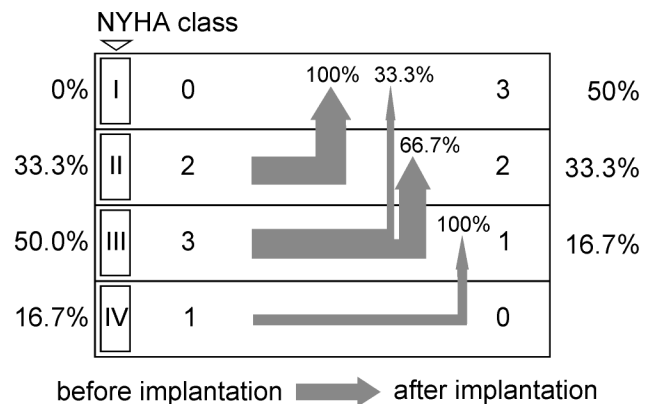

Figure 7. NYHA shift after CLS system implantation in patient subgroup with AV block and atrial fibrillation.

tive consequences of the absent atrial contraction, to relieve patients from their symptoms, and to improve the quality of life.

Conclusion

The study shows that the pacing rate of the Closed Loop Stimulation system physiologically responds to physical loads in patients with congestive heart failure. Follow-up studies revealed that Closed Loop Stimulation guarantees a significant improvement in patient maximum working capacity, especially in patients with AV block and atrial fibrillation. Closed Loop Stimulation leads to a diminishing of signs of heart failure and an overall, positive shift in NYHA classification.

References

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