Biventricular Pacing - Hemodynamic Benefit for Patients with Congestive Heart Failure

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Summary

Congestive heart failure afflicts a large and increasingly widespread population. Currently available medications can improve the survival rate and clinical symptoms, but in many patients the progression of the disease cannot be stopped. Additional forms of therapy have been therefore developed; one of the most successful among them is simultaneous pacing of both ventricles. This report presents the hemodynamic examination results and the effects of biventricular pacing on the quality of life of 15 patients with dilative cardiomyopathy (mean age 66.9 ± 9.4 years). The left ventricular leads were advanced into the coronary sinus with the aid of an introducer kit. The leads were fixated in the lateral vein (high, 2; medial, 6; and apical, 2) as well as in the posterior (1) and antero-lateral (2) veins. The fluoroscopy time for the implantation of the complete pacemaker system was on average 35 ± 20 min. There were three lead dislocations, two in the early postoperative phase and one during the 4-week follow-up. The mean unipolar threshold at the implantation was 0.94 ± 0.59 V at the 0.5-ms pulse width. After an increase of up to 1.6 ± 1.2 V at the 4-week follow-up, the threshold returned to 0.95 ± 0.1 V chronically. Sensing amplitudes and pacing impedances were fully satisfactory. The mean ejection fraction of the left ventricle improved from 30 % ± 7 % (range 20 – 35 %) before implantation to 40 % ± 8 % (30 – 50 %) at 4 weeks after implantation. Biventricular pacing led to a clear reduction of mitral insufficiency level from 2.5 ± 0.4 before implantatioon to 1.5 ± 0.5 after implantation. Through the improvement of the cardiac condition, the quality of life of the patients could be clearly improved within 4 weeks.

Key Words

Biventricular pacing, congestive heart failure, ejection fraction, NYHA class

Introduction

Congestive heart failure afflicts a large and increasingly widespread population. In Europe, over 6.5 million patients have been diagnosed, and 580,000 new cases are added annually [1]. For hospitalized patients who are over 65 years old, congestive heart failure (CHF) is the most frequently made diagnosis [2]. Since most of these patients exhibit a greatly enlarged left ventricle with reduced contractility, standard drug therapy is applied to reduce both the preload and afterload, as well as to increase contractility and to influence the neurohumoral compensation mechanisms [3]. The optimal use of currently available medications makes it possible to improve the survival rate and manage the clinical symptoms; however, many patients have been observed in whom the progression of the condition cannot be stopped despite the administration of maximum pharmacological therapy [4]. For this reason, various additional forms of therapy have been developed in recent years to improve success of the treatment. A simultaneous pacing of both ventricles ranks as one of the most successful additional therapies.

Dilative cardiomyopathy (DCM) may result in disturbances in the conduction system, and, therefore, in a reduction of the effective pumping performance of the heart. Biventricular pacing makes it possible to resynchronize ventricular activity, which then leads to an

improvement in the cardiac ejection fraction. In order to achieve biventricular pacing, a standard lead is implanted in the right ventricle, and the left ventricle is paced across the lateral wall of the left ventricle using a lead positioned in the coronary cardiovascular system. The feasibility of this implantation method has already been shown in several research studies [5]. The effects of biventricular pacing on the clinical situation can already be seen in acute examinations in the form of an improvement of hemodynamics; the long-term effect is an improvement in symptoms, as determined by the NYHA class [6-7].

This report presents the hemodynamic examination results and the effects of biventricular pacing on the quality of life of patients with DCM. Also covered is the procedure for implanting a left ventricular (LV) lead.

Materials and Methods

In the previous 12 months, 15 patients (mean age 66.9 ± 9.4 years, 14 male, one female) received a coronary sinus lead for LV pacing. The unipolar leads Corox LV (Biotronik, Germany) were used in ten patients and the Aescula LV (St. Jude Medical, USA) in five cases. For biventricular pacing, both dual- (9) and triple-chamber systems (6) were used (Logos (3), Actros (6) by Biotronik; Talent (1) by ELA Medical, France; Affinity (4) by St. Jude Medical; and Frontier (1) also by St. Jude Medical).

With the aid of an introducer kit (7/8 French in 6/9 patients, respectively), all the leads were advanced through a puncture in the vena subclavia, through the vena cava superior and the right atrium, and then into the coronary sinus. In order to position the LV leads (there was nine left-sided and six right-sided approaches), the appropriate Scout introducer (Biotronik) and the Alliance Left Heart Delivery System (St. Jude Medical) were employed. At the same time, the guiding catheters with hemostatic valves are introduced into the right atrium with the dilator. For probing the coronary sinus, a so-called obturator is provided in the Alliance system, and a steerable probing catheter comes with the Scout introducer. After successful placement, the probing aids are removed, and the lead can be advanced via the coronary sinus into the cardiovascular system. With Scout, this is simplified significantly by a hydrophilic inner coating of the introducer. In many cases, a suitable position is found using only the depiction of the cardiovascular system (venogram), for which suitable balloon catheters are provided. Finally, the introducer is carefully removed using the Peel Away technique. Both for better positioning of the lead and for fixation during the removal of the introducer set, a special stylet (Biotronik) is available whose diameter is tapered in the distal area.

The stable lead position was documented by means of a posterior-anterior (PA) X-ray and checked at the discharge of the patients after 3 days with a PA and lateral scan. The implantation and fluoroscopy time was recorded for the entire operation and was measured from the initial incision to the final suture. The threshold, the amplitude, and the electrical impedance were determined at the time of implantation, discharge, as well as at every follow-up (4 weeks, 3 months, 6 months, 12 months). The degree of mitral insufficiency and the ejection fraction of the left ventricle were determined by means of Doppler echocardiography both before the implantation and at the 4-week follow-up. Furthermore, quality of life was assessed by NYHA class. Data are presented as mean values ± standard deviation and as distributions of the individual parameters.

Results

The patients included were predominantly diagnosed with permanent atrial fibrillation (AF, n = 9); others had paroxysmal AF (1), AV-block III° (1), binodal disease (1), sick sinus syndrome (1), and two patients had no arrhythmia. DCM was the underlying cardiac condition for all patients (primary DCM was diagnosed in four patients, secondary DCM with coronary artery disease in eight, and secondary DCM with hypertonia in two) and one patient had valvular heart defect. Table 1 sum-

Medication	Number of patients
Antiarrhythmics	5
β–Blockers	13
ACE - Inhibitors	7
Digitalis	13
Diuretics	12
Antihypertonics	5
Others	1

Table 1. Prescribed medications in 15 patients studied.

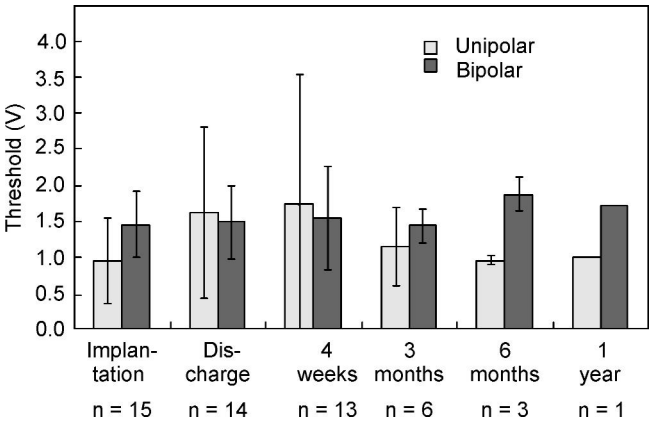

Figure 1. Left ventricular pacing threshold at the 0.5-ms pulse width (mean ± standard deviation). Only one patient reached one-year control.

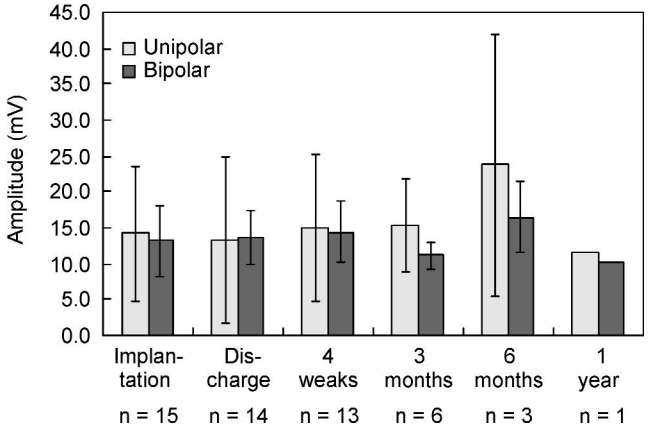

Figure 2. Mean and standard deviation of the ventricular signal sensed from the left ventricle. Only one patient reached one-year control.

marizes the distribution of the prescribed medications. The coronary sinus lead was positioned successfully in all patients. The use of the introducer set was especially important in cases involving a narrow coronary sinus. In only three cases, a venogram had to be prepared for suitable positioning of the lead. The leads were fixated in the lateral vein (high, 2; medial, 6; and apical, 2) as well as in the posterior (1) and anterolateral (2) veins. The fluoroscopy time for the implantation of the complete pacemaker system was on average 35 ± 20 min.

In the early, postoperative phase, before the patients were discharged, two dislocations were observed. One of the two leads was removed and the second was repositioned, as it had been brought into a peripheral position in the lateral vein. No other dislocations were observed for the newly fixated lead. An additional dislocation was recorded during the 4-week follow-up. The lead had become detached from the anterolateral vein and needed to be repositioned. No lead dislocations were observed at a later time.

The patients were followed for 3.1 ± 3.3 months after biventricular system implantation. The mean unipolar threshold at the implantation was 0.94 ± 0.59 V at the 0.5-ms pulse width. After an increase of up to 1.6 ± 1.2 V at the 4-week follow-up, the threshold returned to 0.95 ± 0.1 V chronically. Bipolar threshold was measured in several cases and was usually higher than the unipolar threshold. Detailed results are provided in Figure 1.

The sensing amplitudes were comparable for all examinations in both the unipolar and bipolar configurations. The mean amplitude at implantation was 14.2 ± 9.5 mV, showing no significant changes over time. Detailed results are provided in Figure 2. At implantation, mean pacing impedance amounted to 819 ± 297 Ω, varying later between 750 and 850 Ω.

The ejection fraction of the left ventricle was 30 % ± 7.4 % (20 – 35 %) in the preoperative measurement. Among other causes, this was traced back to the significant mitral insufficiency of most patients. Already 4 weeks after the implantation, there was a definite improvement in the ejection fraction, up to 40.4 % ± 7.7 % (30 – 50 %) on average. The detailed results of the pre- and postoperative echocardiographic examinations are summarized in Figures 3 and 4. In most cases, biventricular pacing led to a clear reduction of mitral valve regurgitation. Already after a short time, the average mitral insufficiency class was reduced from 2.5 ± 0.4 to 1.5 ± 0.5. Through the improvement of the cardiac condition, the quality of life of the patients could be clearly improved within four weeks. The pre- and postoperative details are presented graphically in Figure 5.

Discussion

For geometric reasons, it turned out to be advantageous to perform the implantation of a biventricular pacing system from the left side. The LV lead should be positioned first, as already implanted leads for the right ventricle or the right atrium may hinder the localization of the ostium and positioning of the introducer. Depending on the coronary sinus size and accessibility, it may be necessary to use an introducer to advance

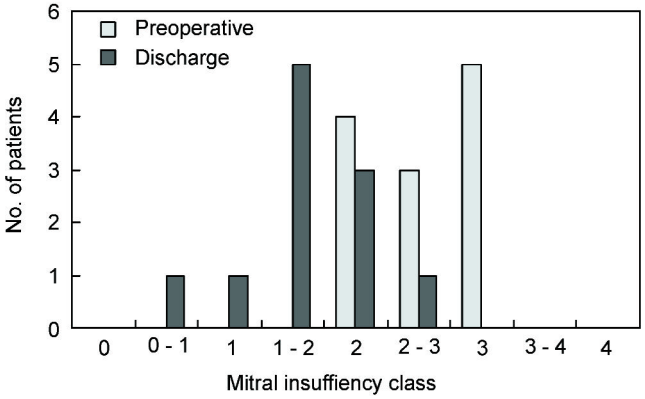

Figure 3. Mitral insufficiency class in the studied population.

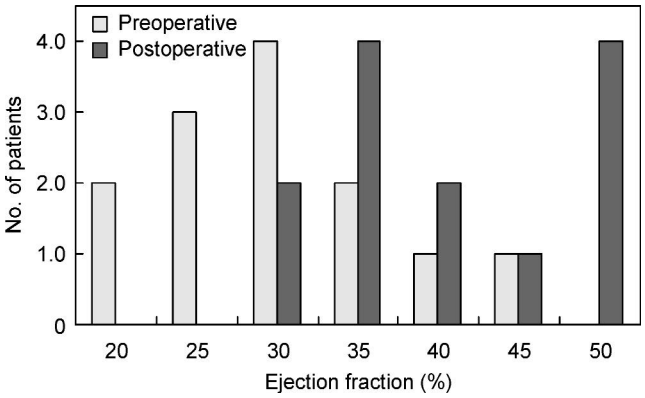

Figure 4. Ejection fraction distribution in the studied population.

the lead into the coronary sinus. In several cases, the ostium was localized right away and the introducer and the lead were advanced into the coronary sinus. With thin leads, the introducer is always helpful since a decidedly better push can be provided and a loop formation in the right atrium is avoided. The recording of a venogram is necessary if no vein access can be found or the lead needs to be put into a predetermined vein. In most cases, however, the positioning of the lead in the lateral vein was successful without depicting the cardiovascular system.

In view of the necessary materials and the anatomic conditions, the implantation of LV leads is accompanied by significantly higher time- and operative costs; this is also reflected in the fluoroscopy times. It must be remarked, however, that with the previously mentioned implantation tools and the increasing routine-nature of the operation for the physician, the implantation of a LV lead may be accomplished in less than 10 minutes. Lead dislocations occurred shortly after implantation only in few cases with the first implantations. In general, the fixation of the lead is impaired in cases of a very narrow cardiovascular system, in which the lead cannot be advanced far enough into the periphery, and in veins with large, above-average diameters. The insertion and fixation of the lead in a tributary vein making a sharp angle with the coronary sinus was paticularly difficult. The LV pacing thresholds (intraoperatively between 0.5 and 1.5 V) and sensing amplitudes are most favorable in the mid-lateral and apical-lateral positions.

The ejection fraction was used for the assessment of the therapeutic effects of biventricular pacing, since this parameter permits effective, prognostic statements in regard to the patient's probability of survival [8]. Preoperatively, ejection fraction was clearly depressed in all patients. This can be traced back to the intraventricular conduction disturbances that frequently accompany DCM and strongly interfere with the course of physiologic contraction in the ventricles. Furthermore, in patients with coronary heart disease, the efficiency of the myocardium is limited by a non-optimal oxygen supply, which further reduces the ejection fraction.

Through biventricular pacing in this patient collective, an increase of the ejection fraction and, therefore, an improvement of the hemodynamic situation was achieved; this is upheld by results recorded in previous literature [9]. In first place, these benefits are achieved by improved ventricular filling through resynchronization of both ventricles. Secondly, pacing of the left ventricle results in well-ordered contraction behavior and a more physiological interaction between the ventricle and the heart valves. This is demonstrated by the

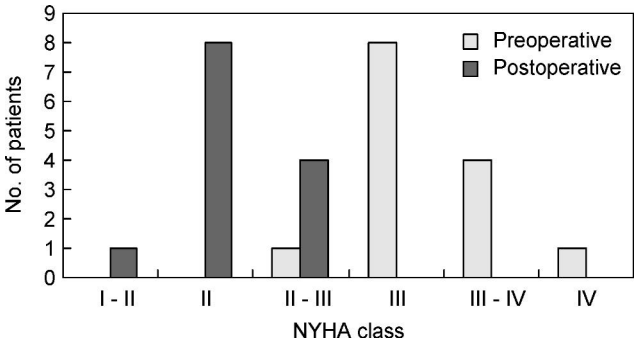

Figure 5. Distribution of patients' functional class according to New York Heart Association (NYHA).

measured reduction in mitral insufficiency. Consequently, ejection performance improved significantly already within the first 4 postoperative weeks. According to previous studies, it is not possible to increase the ejection fraction to a value > 50 % by means of pacemaker therapy. It remains to be seen to which extent ejection fraction can be increased in the long term.

Another important criterion of therapeutic success is the assessment of symptoms and their effect on the patient's quality of life. Although the subjectivity of evaluation by the patient and physician must always be considered when this parameter is evaluated, the detected changes have the potential to best reflect direct effect of the therapy on the patient. It has been demonstrated that biventricular pacing significantly improves patients' quality of life as well.

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