First Implantation of the Triplos LV Three-Chamber Pacemaker: A Case-Report

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Summary

The integration of the left ventricle (LV) into the pacemaker therapy of patients with severe heart failure and intraventricular conduction disturbances appears to be very promising. Coronary sinus leads with optimized designs, as well as new implantation tools, have significantly increased the success rate for left-sided implantation. In addition, atrio-biventricular sequential pacing without additional adapters has been implemented with the use of a three-header pacemaker. This article describes the implantation of the newly developed Triplos LV pacemaker in a 73-year-old female patient suffering from heart failure of NYHA class III. A left bundle branch block was evidenced by the 180-ms width of the QRS-complex. Successful pacemaker implantation was able to shorten the QRS-duration to 158 ms.

Key Words

Three-chamber pacing, heart failure, coronary sinus lead, QRS-width

Introduction

The treatment of severe heart failure is of extreme clinical importance due to its high prevalence in the general population and the high hospitalization rate of the affected patients. The incidence of the disease is steadily increasing and is currently 3-10 persons per 1000 residents a year [1,2]. The therapeutic starting points with respect to heart failure lie in invasive as well as non-invasive therapy. The goal of standard drug therapy is to increase the ejection fraction by increasing the cardiac contractility, to reduce the peripheral vessel resistance, and to influence the cardiac remodeling. As usually, drug treatment has limitations with regard to side effects and life expectancy [3].

In cardiac pacing, it is becoming more and more important to integrate the left side of the heart into the therapeutic concept. The results of many scientific studies [5-13] show that cardiac function can be improved through synchronous pacing of both ventricles. It has been demonstrated that especially patients with NYHA class III and lengthened PR intervals, reduced left-ventricular ejection fractions, and widened QRS complexes (> 150 ms) can benefit from biventricular pacing thnks to the improved hemodynamics, a reduced NYHA class, increased exercise tolerance, and improved quality of life [4,7,8,10,14,15].

In addition, the implementation of left-sided pacemaker therapy has become significantly easier and more effective due to the development of new technologies, and because of the selection of the coronary vein system as a pacing site [16]. Left-sided pacemaker therapy is also improved by the use of implantation accessories [7,8,17-19] that help realize fast, safe, targeted positioning of the pacing lead in the coronary vein system. Additional progress was achieved with the development of a three-header pacemaker.

This case report describes the first implantation of the new three-header pacemaker Triplos LV and the newly developed left-ventricular Corox LV-P lead, as well as the first experience with the SCOUT introducer aid (all Biotronik, Germany).

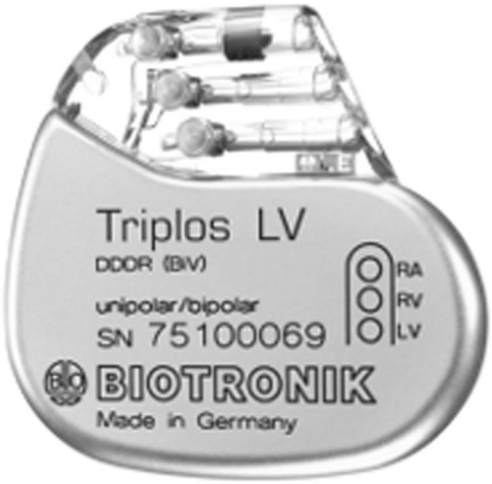

Figure 1. Triplos LV three-header pacemaker (Biotronik, Germany).

Materials and Methods

Patient

The patient was a female, aged 73 years, who suffered from NYHA-class-III heart failure caused by hypertensive heart disease. Echocardiography revealed an enlarged left ventricle with an end-diastolic diameter of 61 mm. The ejection fraction was 41 %. The ECG showed a sinus rhythm with a cycle length of 874 ms, a PR-interval of 200 ms, and a QRS-width of 180 ms. Under therapy with ACE-inhibitors, diuretics, and digitalis, a clinically stable situation was maintained. With no changes in treatment, symptomatic atrial fibrillation (AF) with tachyarrhythmia was observed in recent months. Under treatment with ß-blockers, the AF was cardioverted and sinus rhythm was maintained; however, a symptomatic sinus bradycardia resulted. Treatment with amiodarone was terminated due to hyperpigmentation of the skin. In light of the atrial rhythm disturbance, the relative indication for pacemaker implantation in combination with beta-blocker therapy was assessed. For existing heart failure with complete left bundle block, the indication for biventricular pacing was present.

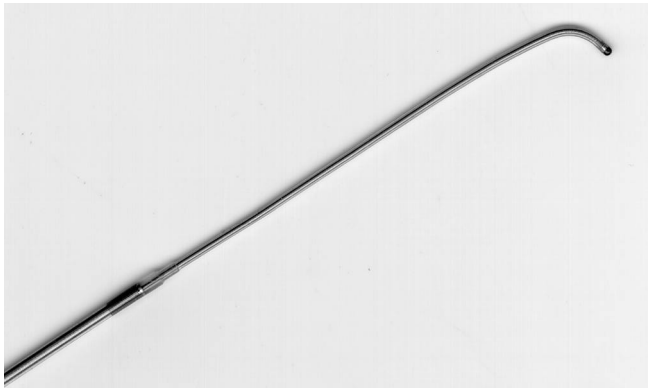

Figure 2. Corox LV-P lead (Biotronik, Germany).

Figure 3. Components of the SCOUT implantation accessory set (from top to bottom): Dilator, Guiding catheter, hemostatic vent.

Pacemaker

The Triplos LV (Figure 1) includes a triple header for the connection of a bipolar atrial lead and two unipolar leads for the right and left ventricles. In dual-chamber mode, the DDD- and DDT/V modes are available, with a bipolar pace/sense configuration between the left and the right leads. The DDT/V mode triggers biventricular pacing after an observed intrinsic ventricular event. For prevention of AF, an atrial overdrive algorithm (DDD^{+}) is available.

Leads

In the atrium and the right ventricle, YP 60/10-BP (Biotronik) leads were used. For pacing of the left ventricle, the new Corox LV-P lead, which was specially developed for implantation into the coronary vein system, was used. The lead is bent by 80° at the distal end (Figure 2). The 5-mm^2 lead tip is coated with fractal iridium. Through coaxial coil technology, the lead is stiffened in the proximal area (6.6 F). The distal share (4.4 F) has a length of 85 mm.

Implantation Accessories

The SCOUT implantation accessory consists of a guiding catheter with a hemostatic vent, a balloon catheter, and a probe catheter. The guiding catheter (Figure 3) consists of a plastic tube with a Shore hardness that decreases in stages, with its tip composed of especially soft material. The outer diameter of the guiding catheter is 10 F. The tube has an 80° bend at the distal end that should facilitate the probing of the coronary

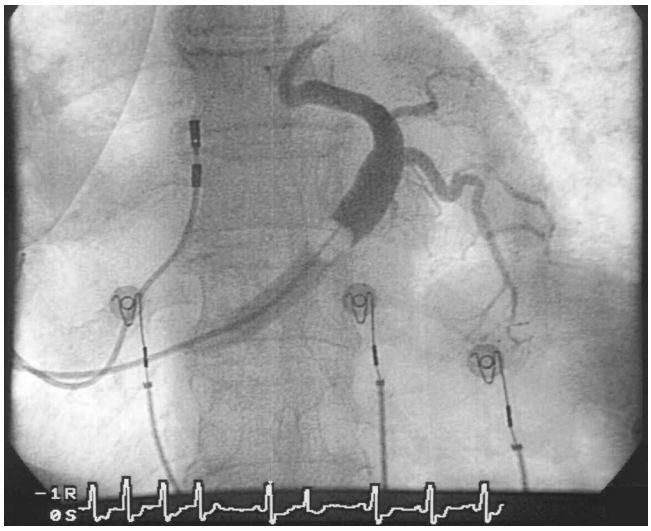

Figure 4. Venogram in anterior-posterior fluoroscopy position.

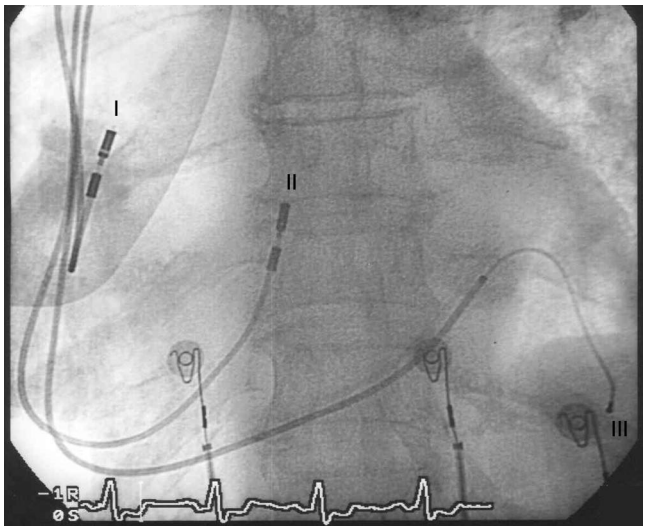

Figure 5. X-ray image showing the positions of the implanted leads in anterior-posterior fluoroscopy view: I = right-atrial lead; II = right-ventricular lead; III = left-ventricular lead (Corox LV, Biotronik).

sinus. In addition, the interior is provided with a lubricated coating in order to reduce the frictional resistance between the lead and the guiding catheter.

The balloon catheter (6 F, 80 cm) is constructed with two lumens. One lumen is planned for the delivery of contrast media, and the other lumen serves toward inflating and deflating the balloon located near the catheter tip (max. ∅ 1.0 cm).

The probing catheter is based on the principle of an electrophysiological mapping catheter. The catheter tip can be controlled directly using the push-pull technique. The probing catheter is used when it is not possible to attain a stable position in the ostium of the coronary sinus with the guiding catheter alone.

Implantation

After left-sided puncture of the subclavian vein and the use of a 9-French introducer, the right-ventricular lead was implanted first. For the subsequent implantation of the left-ventricular lead, the existing introducer was replaced by an 11-French introducer. With the Seldinger technique, the guiding catheter was advanced into the right atrium along the guidewire, which was introduced into the dilator. After removing the wire and dilator, it was then unsuccessfully attempted to access the coronary sinus. After about 15 min, it was decided to use the probing catheter. After an additional 5 min, a stable position of the guiding catheter could be attained.

In the anterior-posterior (AP) fluoroscopy view, a venogram was displayed in the next step with the aid of the balloon catheter in order to determine the optimal vein for implantation (Figure 4). In this case, the post-lateral coronary vein was selected as the optimal implantation site.

After removal of the balloon catheter, the lead was positioned in the selected coronary vein. Using a stylet, the lead was advanced through the coronary sinus to the end of the vein. Through a short retraction of the stylet, the distal bending of the lead was used for access to the target vein. The lead could thus easily be advanced into the vein. By advancing the stylet farther, the lead was then advanced farther into the vein and fixated at the mid-ventricular level.

After documenting the electrical parameters, diaphragmatic pacing was ruled out for pacing voltages of 10 V and pulse widths of 0.5 ms. Thereafter, the atrial lead was implanted and its parameters were determined. Figure 5 shows the positions of the implanted leads in an AP fluoroscopy projection. The leads were then connected with the Triplos LV.

Results

Table 1 shows the intraoperatively measured electrical parameters of the leads.

A total implantation time of 115 min, as well as a fluoroscopy time of 17 min, was documented. Of these,

Lead	Threshold (V) at 0.5 ms	Sensing threshold (mV)	Impedance (Ω)
Atrial	0.7	1.5	320
Rightventricular	0.4	6.0	410
Leftventricular	0.4	30.0	920
Biventricular	1.0	29.0	1000

Table 1. Intraoperative measurements.

55 min and 15 min, respectively, were due to the placement of the left-ventricular lead. Intraoperatively, a reduction of the width of the QRS-complex from 180 ms (intrinsic) to 158 ms was observed with biventricular pacing. The QRS duration was 218 ms for asynchronous left-ventricular pacing, and 204 ms for exclusively right-ventricular pacing (Figure 6).

Discussion

As already explained above, the further development of drug therapy for this patient group has stagnated. This gives rise to the need for improvement of alternative treatments.

The resynchronization of both ventricles through left- and biventricular pacing, in particular, promises success for patients with drug-refractory heart failure and concomitant interventricular conduction disturbances. In clinical studies, the effectiveness of this form of therapy has been proven for the disease description given above. Since direct access to the left ventricle cannot be achieved through the venous system, different methods of left-ventricular pacing are discussed in the literature. The transseptal access is notable here [14], but is not preferable as a standard therapy due to the considerable risk of thrombus formation. An additional possibility is to apply epicardial leads in the course of a thoracotomy or a thoracic endoscopy. However, this is also not appropriate as a standard procedure due to the considerable surgical invasiveness and unstable thresholds (exit blocks) [20,21].

By comparison, endocardial left-ventricular pacing via the coronary vein system has recently been established by the development of special lead design and implantation aids.

The use of a guiding catheter makes stable access to the coronary sinus possible, so that the risk of lead dislocation back into the right atrium during the implantation procedure is minimized. In addition, a balloon catheter can be easily introduced into the coronary sinus in order to help create a venogram. This is important due to the great interindividual variability in the anatomy of the coronary vein system, since a target vein for the implantation of the lead can then be identified ahead of time. The implantation duration and fluoroscopy time can thus be reduced; in addition, the therapeutic success can be increased through targeted steering into a primarily lateral vein.

A stiff proximal end should provide the best possible handling of the guiding catheter. For easy probing of the coronary sinus, it is also more favorable for the distal end to be bent, and it is somewhat more flexible. This allows for problem-free adaptation of the anatomy near the ostium of the coronary sinus, which can differ greatly between individuals.

The guiding catheter used in the case described also has a soft catheter tip in order to guarantee that the procedure is as atraumatic as possible. The case presented also demonstrates the importance of the optional prob-

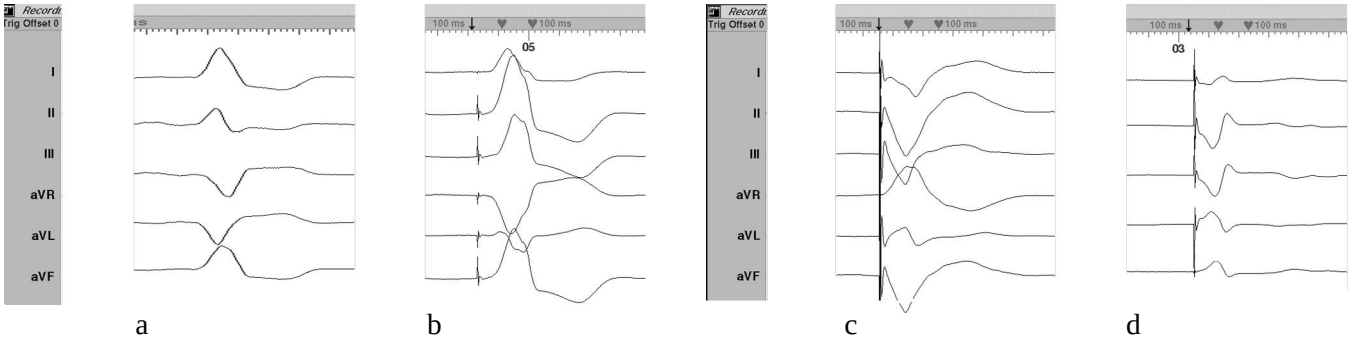

Figure 6. Intraoperative ECG recording. QRS complexes: a) without pacing (intrinsic); b) for right-ventricular pacing; c) for left-ventricular pacing; d) for biventricular pacing.

ing catheter. Without such a tool, coronary sinus probing would not have been possible. The use of a probing catheter is thus recommended for difficult anatomies, since the controllable tip offers an additional possibility for successfully intubating the coronary sinus. Due to the anatomy of the coronary vein system, special lead designs are necessary. In particular, the steerability of the lead in the distal part, the diameter of the lead body, and the fixation mechanism play important roles.

A stable proximal lead body is necessary for simple lead positioning, since the manipulations made by the implanting physician at the proximal end of the lead are better transferred to the lead tip. Especially turning motions that are necessary to reach the vein entry from the coronary sinus are possible only to a very limited degree in unstable leads. The distal end of the lead must have a diameter that is as small as possible in order to be able to be advanced as far as possible in veins with very narrow lumens.

An active bracing mechanism is utilized for lead fixation, since this conforms itself to the anatomical relationships and thus assures stable lead positioning even in vessels with very large lumens.

The requirements given above are fulfilled by the Corox LV-P lead that was used. Its coaxial construction in the proximal part makes the lead stable enough to allow the physician to perform the manipulations necessary for implantation. Due to the narrowing of the diameter over a length of 85 mm on the distal end, implantation is easily possible even in extremely narrow veins. The small lead diameter also allows advancement of the lead to the mid- or apical area of the coronary vein system in order to provide especially good conditions for the pacing of the left ventricle. This is evidenced in the case described here by the extremely good electrical values for the Corox LV-P lead, which were previously only seen in right-ventricular leads. The 80° bend in the lead tip was considered in the fixation of the lead even in vessels with large diameters, so that a stable lead position is always assured.

The development of a three-chamber pacemaker makes it possible to realize biventricular pacing without implanting an adapter. The advantages are less foreign material, reduction of errors due to additional interfaces, and simpler intraoperative handling. The Triplos LV also has an atrial overdrive algorithm. For this patient, who suffers from intermittent AF, this therapeutic option could generate an additional benefit. The extent of intra- or interventricular conduction disturbances, and thus of asynchronous ventricular excitation is indicated by the width of the QRS complex. Resynchronization of the two ventricles is effected by biventricular pacing; this was evidenced by the reduction in the QRS duration. This generally results in improved hemodynamics. Intraoperatively, a reduction in the QRS duration by 13 % could be observed for biventricular pacing vs. intrinsic conduction. It is thus to be expected that this patient's NYHA class and quality of life will improve.

Conclusion

The case presented here shows that three-chamber pacing can be carried out when appropriate systems are available. The positive intraoperative observations must, however, be confirmed by further implantations. We are monitoring the short- and long-term clinical benefit to the presented patient.

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