CASE REPORT

Usefulness of a novel active fixation left ventricle lead in cardiac resynchronization therapy

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Abstract

Cardiac resynchronization therapy has demonstrated important benefits for selected patients suffering from heart failure. Those benefits include clinical and/or echocardiography assessed improvement, as well as hospitalizations and all-cause mortality reduction. However, about 30% of patients do not benefit from the therapy. Suboptimal left ventricle lead position, post-implant lead dislodgements and undesired phrenic nerve stimulation are potential causes for not responding and it is not always possible to avoid them during the implant procedure. We report a case in which we used a novel left ventricle lead which is actively fixated to the cardiac vein or to the coronary sinus, by means of a helix, in a patient with very limited options to implant the lead. In this patient, a traditional, passively fixated lead would fail to get implanted. This design can help the implanting physician to implant the lead in the desired position, minimizing the possibility of dislodgement, even in very basal positions where traditional leads are more likely to dislodge.

Keywords

Heart failure, Cardiac resynchronization therapy, Implantable devices, Cardiac pacing

1 Introduction

Cardiac resynchronization therapy (CRT) has demonstrated important benefits for those patients suffering from heart failure and who fulfil the criteria specified in the current clinical guidelines (i.e. wide QRS, left ventricle ejection fraction < 35%, NYHA class II, III or IV) [1]. Those benefits include clinical and/or echocardiography assessed improvement, as well as hospitalizations and all-cause mortality reduction [2-5].

The implant procedure of a CRT device consists of placing a pacing lead in the right ventricle, another lead in the right atrium and a third lead in a cardiac vein, advancing it through the coronary sinus, which will pace the left ventricle epicardially (LV lead). The two first leads listed before are implanted in the same manner as conventional dual-chamber pacemakers are. Implanting the LV lead is usually the main challenge of this procedure, due to several reasons. First, cardiac anatomy can be unfavorable to progress the lead to the target position. Second, the pacing threshold of the LV lead may be too high due to the epicardial nature of the stimulation. Also, the LV lead is at risk of stimulate the phrenic nerve, causing discomfort to the patient. Finally, the LV leads are fixated to the vein passively, and may dislodge several hours,

days or months after implant. All these facts contribute to the approximately 30% of patients who are considered non-responders to the therapy, according to several clinical trials [3, 6].

We present a case where we implanted a novel LV lead which is designed to actively fixate to the target vein by means of a helix attached to the lead body.

2 Case presentation

A 58-years-old male with heart failure was indicated for CRT implantation at our center. He had non-ischemic dilated cardiomyopathy, left ventricle ejection fraction < 30%, New York Heart Association class II, QRS duration of 170 ms with left bundle branch block, and no other known risk factors. 1 The patient was qualified for the CRT-D system implantation.

After cannulating the coronary sinus using a dedicated catheter, a venography was performed, showing only one lateral vein with a large diameter (see Figure 1).

A Medtronic Attain Stability lead (model 20066) was then progressed into the vein. Contrary to traditional LV models, this lead has a fixed side helix, placed 36 mm proximal to the tip. The fixation mechanism is simple: when the implanting physician progresses the lead to the target location, the lead body is rotated achieving active fixation by means of the helix. In this case, although we tried to fully insert the distal portion of the lead into the lateral vein, only the tip of it could be placed there, forcing us to attach the fixation helix to the main coronary sinus (see Figure 2).

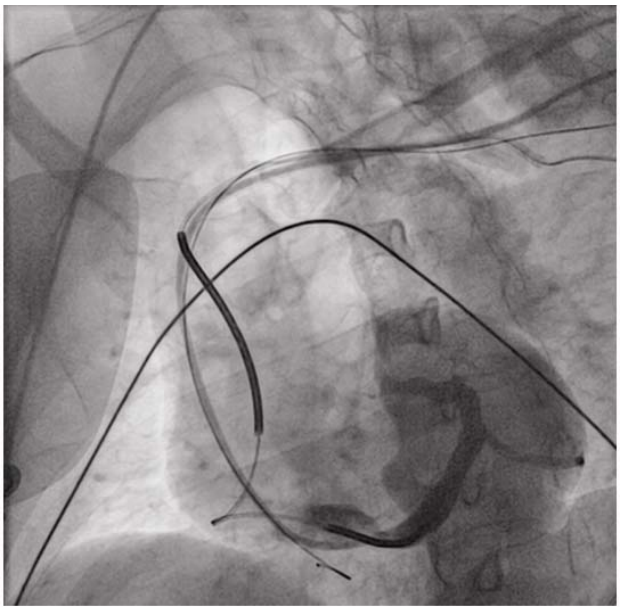

Figure 1. Cardiac venography showing only a lateral, large vein.

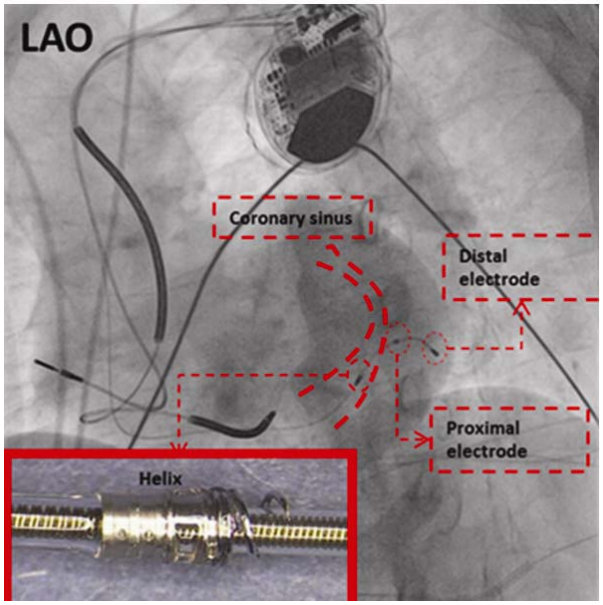

Figure 2. Final LV lead position fixated to the main coronary sinus. A photograph of the helix is shown at the bottom of the figure.

The final position of the lead was probably impossible to get to with a traditional lead, since the passive fixation mechanism of older leads would be insufficient to avoid a potential dislodgment. There have been no reports about perforations due to the active fixation of this lead.

After fixation, we measured the electrical parameters which were within acceptable ranges (see Table 1).

Table 1. Electrical parameters at implant

Parameter	Value
R wave amplitude	10.2 mV
Pacing threshold	2.9 V at 0.5 ms
Pacing impedance	639

After 2 months of follow-up, electrical parameters remain stable, and the patient refers clinical improvement.

3 Discussion

We present a case where we were able to implant a LV lead in a very basal location, thanks to a novel active fixation lead design. In this case, the final lead location was imposed by the patient cardiac anatomy, due to the impossibility to further progress the lead into a more theoretically stable position. In any case, there are other reasons to consider a basal location as a good option. Traditional LV leads obey a law: the more apical the lead is implanted, the more stability is achieved. However, apical LV positions have been associated with a higher percentage of non-responders, compared to basal or middle positions. In a subanalysis of The Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT), the apical lead position was associated with an increased risk for death (hazard ratio = 2.91) [7]. Two recent trials have investigated the point of latest left ventricle activation to guide the LV lead implantation using echocardiographic techniques [8, 9]. They found that up to 47% of patients have their optimal LV pacing site in the basal region, where the stability is theoretically less than desired.

According to a review of 1307 patients by Biffi et al [10], an apical LV pacing site is associated with over six-fold higher risk of unwanted phrenic nerve stimulation. The solutions to avoid the phrenic nerve stimulation included both invasive (e.g. replacement of the lead) and non-invasive (e.g. reprogramming) procedures. In the extreme case, there are a number of patients who need to suspend the therapy due to the inability to avoid the phrenic nerve stimulation. Another new technique of avoiding phrenic nerve stimulation is implanting LV electrode with possibility of multifocal stimulation (quadripolar coronary venous lead). This transvenous lead offers various pace/sense configurations depending upon the programming options of a compatible device (passive fixation lead design). However, even with this catheter phrenic nerve stimulation is not avoided in all patients and for small veins the stability could be difficult to get.

Finally, lead dislodgement requiring reintervention may occur even when a theoretically stable position has been obtained during implant. Large trials report a rate of reinterventions of 4.9%-8% [2, 11], which would be potentially diminished with the usage of active fixation LV leads.

Other solutions have been proposed to achieve LV active fixation during the last years. Lead stenting has demonstrated to be effective and safe [12], but it is a challenging technique. Another LV lead model (Medtronic 4195) also included an active fixation mechanism. In this case, the mechanism consists of 3 deployable lobes that are expanded at the moment of implant, increasing the effective diameter of the lead and getting fixated by pressure over the vein. Although this solution achieves the desired stability, it has added additional complexity to the subsequent extraction procedures, due to the nature of the fixation itself [13]. The helix of the novel lead used in this case is designed to lose its shape if a pull force of 0.5 kg is applied on the lead, allowing for an easier extraction procedure.

4 Conclusion

This case demonstrates the usefulness of a novel fixation method for the LV lead in the Cardiac Resynchronization Therapy. With this lead design, the left ventricle pacing can be made from very basal positions, what can be beneficial for some patients, without compromising the lead stability.

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