The novel active fixation coronary sinus lead: efficacy and safety of transvenous extraction procedure

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Aims
Benefits of cardiac resynchronization therapy (CRT) are well known for heart failure; however, some patients might experience complications related to the coronary sinus (CS) lead (high pacing threshold, phrenic nerve stimulation, and dislodgment) with unfavourable impact on quality of life, costs, and management. Lead stability is one of the most common unmet needs for CRT procedures.

Methods and results
Recently, new model Medtronic 20066 Attain Stability (Maastricht, The Netherlands) active fixation LV lead has been released, to overcome this issue. The lead has a small side helix of 0.20 mm (0.008 in.) that allows for secure placement of the lead within the vein at the desired location. We report our first experience with the extraction of this novel active fixation left ventricular lead.

Conclusion
In our case, to our knowledge the first reported in humans, the extraction of this new model of active fixation lead was proved to be a safe and effective procedure at 8 months after implantation. Indeed, under angiographic and fluoroscopic check, there was no documented dissection or damage to the CS during and after removal of the lead. The rotation manoeuvre was effective when combined with moderate traction of the lead itself.

Keywords
Coronary sinus lead • Transvenous lead extraction • Cardiac resynchronization therapy • Left ventricular active fixation lead

Introduction
The dislodgment of coronary sinus (CS) leads is an unusual (the reported rate ranging from 3 to 10%¹-³) but a real problem and lead stability is one of the most common unmet needs for cardiac resynchronization therapy (CRT) procedures. A novel left ventricular (LV) lead was designed to actively fixate in the target vein. The Medtronic 20066 Attain Stability (Maastricht, The Netherlands) lead has a small side helix of 0.20 mm (0.008 in.) that allows for secure placement of the lead within the vein at the desired location.⁴-¹⁰ The helix is designed to straighten when ~454 g (1.0 lb.) of force is applied to the lead body. Animal tests have demonstrated feasibility and safety of extracting the Attain Stability lead but so far there are no published data regarding lead extraction in humans. We report our first experience with the extraction of this novel active fixation LV lead.

Methods and Results
A 66-year-old male with LV non-compaction cardiomyopathy and heart failure (New York Heart Association Class III) underwent biventricular defibrillator implantation for primary prevention in February 2011 at another centre. In March 2014, the patient was referred to our institution for malfunctioning of the atrial lead and dislodgment of the LV lead. Transvenous lead extraction was performed: passive atrial lead through mechanical sheath (Cook Medical 8.5 Fr Byrd Dilator Sheath) and CS lead using manual traction. The right ventricular defibrillation lead was normally functioning and was left in the same position. In accordance with our standard protocol, the procedure was performed in our Electrophysiology (EP) Laboratory with a cardiothoracic surgery standby, with continuous 12-lead electrocardiogram and arterial blood pressure monitoring. During the same procedure, a new passive fixation atrial lead was implanted and due the particular CS veins anatomy the patient received a 20066 Attain Stability lead. We fixed it in
a postero-lateral branch (Figure 1). The new system was implanted in the same site of the previous one. For the next 8 months, the clinical status improved and the patient was a responder to CRT. However, in November 2014, the patient was admitted to hospital for fever and pocket infection. During the hospital stay, a transoesophageal echocardiogram showed evidence of an endocardial vegetation (1.5 cm × 3 mm) attached to the atrial course of the ventricular lead. As a Class I indication of the current guidelines, the patient underwent a lead extraction procedure. The procedure was performed under local anaesthesia by two expert electrophysiologists in our EP Laboratory with a cardiac surgeon on standby.

Prior to the LV lead extraction, the CS was cannulated with an Attain Command Delivery Straight catheter (Medtronic, Minneapolis, MN, USA), and an Attain Select 90° subselector (Medtronic) was placed through a delivery catheter at the beginning of the branch to document the integrity of the vascular system during and after the extraction through contrast injection. A Hybrid guidewire (Medtronic) was inserted inside the CS lead and the lead body was rotated counterclockwise five to six times in order to unhook the helix. The manoeuvre was not effective. Moderate tension was applied to the lead until the helix was disengaged resulting in the complete extraction of the lead. There was no dissection of the CS (Figure 2). The subsequent analysis of the lead showed that, when tension is applied to the lead body during the extraction, the helix begins to straighten and elongate (Figure 3). Fibrotic tissue was not observed on the surface of the lead body.

**What’s new?**

- The new model Medtronic 20066 Attain Stability® active fixation LV lead has been released to overcome the issue related to CS lead stability in CRT.
- We report our first experience with the transvenous extraction of this novel active fixation left ventricular lead (to our knowledge the first reported in humans).
- The rotation manoeuvre combined with moderate traction of the lead was proved to be safe and effective for Attain Stability® extraction at 8 months after implantation.

**Discussion**

Left ventricular lead stability is a critical issue in CRT. Benefits of CRT are well known for heart failure patients, and recommendations have been recently extended to less symptomatic patients (NYHA Class II). However, some patients might experience complications related to the CS lead (high pacing threshold, phrenic nerve stimulation, and dislodgment) with an unfavourable impact on quality of life, costs, and management. Dislodgments with CS lead are reported in 3–10% of all implants. Recently, new Model 20066 Attain Stability active fixation LV lead has been released, to overcome this issue.

In a recent multicentre clinical study, Yee et al. reported a 98% implant success rate of the model 20066 LV lead (95% of success of implant in the target vein) and no dislodgment at 12-month follow-up. Also Johar and Luqman recently reported their experience with Attain Stability® implants in eight consecutive patient’s candidate for CRT (100% implant success rate). Authors concluded that the new Attain Stability active fixation LV lead can be successfully and safely deployed in the coronary venous vasculature.

A common problem of lead extraction remains the development of fibrotic attachments along the course of leads, in the vascular and endocardial spaces. It is well known that the CS does not usually develop such resistant fibrotic adherences, with the exception of the ostium. Recent published data on 125 cases of CS lead extraction confirm that it is a rather simple procedure requiring simple traction in 91.4% of the cases. This is in accordance with our experience, wherein CS lead was extracted by simple traction in 95% of our cases.

In 2008, the Attain Starfix model 4195 lead (Medtronic, Maas-tricht, The Netherlands) was introduced to ameliorate the problem of lead dislodgement. It is a 5-Fr, unipolar, steroid-eluting CS lead with an extendable lobe active fixation mechanism which, when deployed, was designed to fixate the lead in place in the chosen CS branch location. It is important to note that Starfix (Medtronic Inc.) represents an exception for CS lead extraction. Despite the excellent results of Starfix on rates of dislodgment, a multicentre report on Starfix lead extraction including 12 cases revealed that there was significant tissue growth into the fixation lobes of the
lead resulting in difficulty in retracting those fixation lobes. Indeed, fixation lobes were completely retracted in only 1 of the 12 cases, and extra support assistance was required for lead removal in all cases. One lead could not be removed transvenously and required surgical extraction.11

In 2013, Adler et al.7 reported their experience with chronic extractions of Attain Stabilityw in animals: the study has shown that it is possible to safely extract the model 20066 lead with around 1 lb. of force. This extraction force is similar to the one used to extract passive fixation LV leads.7 In fact, the helix of Attain Stabilityw was designed to straighten when traction force exceeds a safe level, thus lessening risks during lead extraction.5

Conclusions
We have reported our experience regarding the feasibility of a 6-month-old active fixation CS lead extraction, to our knowledge the first reported in humans.

In our case, the extraction of this new model of active fixation lead was proved to be a safe and effective procedure at 8 months after implantation. Indeed, under angiographic and fluoroscopic check, there was no documented dissection or damage to the CS during and after removal of the lead. The rotation manoeuvre was effective when combined with moderate traction of the lead itself.

The Attain Stabilityw lead was designed to actively fixate in the target vein to reduce the possibility of dislocation in CS. Transvenous lead extraction of CS lead is usually a simple procedure, with some exceptions such as the Starfix active fixation lead. Our first experience demonstrates the extraction of the new Attain Stability active fixation lead as a feasible and safe procedure, after a 8-month implant.

References