Improved success rate of cardiac resynchronization therapy implant by employing an active fixation coronary sinus lead

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Aims
Cardiac resynchronization therapy (CRT) is the standard treatment for heart failure with severe reduced left ventricular (LV) function and wide QRS complex. Coronary sinus (CS) lead implantation is challenging and accompanied by substantial dislocation rates. We evaluated the usage of an active fixation LV lead (Attain Starfix™, Medtronic, MN, USA) with deployable lobes in challenging lead positions.

Methods and results
Between September 2006 and August 2009, 678 CRT devices were implanted. In 82 patients (12%) (59 male, 70 ± 10 years, 39 ICM, 41 DCM, 2 valvular CM, LVEF 28 ± 9%, NYHA 3.0 ± 0.4, QRS 169 ± 29 ms), the Attain Starfix active fixation lead was used. The main reason was intra-operative dislodgement of one (n = 47) or two (n = 5) passive fixation leads during implantation or revision procedure (n = 30). Active fixation lead implantation was overall successful with 90% (n = 74). Anatomical peculiarity was mostly an optimal lead position in otherwise unstable proximal parts of the target vein or a circumscribed area of optimal threshold without phrenic nerve stimulation. At median follow-up of 99 days the threshold remained stable (1.2 ± 0.8 vs. 1.0 ± 0.5 V at 0.5 ms). Revisions due to instability in ectatic vein (n = 1) after 12 months and extractions (n = 2) because of device perforation/infection after 6/15 months were performed without complication.

Conclusion
The Attain Starfix active fixation lead proved to be an important option in anatomically challenging, otherwise unstable positions often located in the proximal part of the target vein. Lead revisions or extractions as late as 15 months after implantation were feasible.

Keywords
Cardiac resynchronization therapy • Active fixation lead • Challenging LV lead position • Dislodgement

Introduction
Cardiac resynchronization therapy (CRT) can be considered the standard treatment for patients suffering from heart failure (NYHA III–IV), severely reduced left ventricular (LV) function, and wide QRS complexes.1–7 Over the past years, the lead systems used to stimulate the left ventricle evolved technically from epicardial approaches to a transvenous access accompanied by a significant reduction of procedure-related complication rates. Additionally, development of specific implantation tools, lead delivery systems, and lead shapes resulted in easier CS ostium cannulation, and thereby shorter procedure times. This established transvenous LV pacing as a standard part of CRT. Most LV leads are pre-shaped and curved in one or multiple dimensions to ensure passive fixation in the target vein. However, even today, LV dislodgement rates ranging 5–10% and the instability of thresholds over time remain the greatest challenge in CRT with transvenous LV lead.8–10 Therefore, a special LV lead utilizing active fixation (the Attain Starfix™ active fixation lead) was developed. At the target location, three lobes at the distal end of the lead can be deployed, which compress gently against the vein wall and thereby provide enhanced fixation of the LV lead.

For this report, we selected a sub-group of CRT patients where a passive fixation LV lead failed to ensure stable LV stimulation and

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we evaluated the usefulness of the Attain Starfix active fixation lead to improve the success rate of CRT.

**Methods**

**Patients**

Between September 2006 and August 2009, 678 patients were implanted with a CRT device (518 CRT-D and 160 CRT-P). In 82 patients (12.1%), the Attain Starfix (Model 4195 by Medtronic, Minneapolis, MN, USA) active fixation LV lead was used to improve the CRT success rate. The LV ejection fraction was 28.1 ± 9.1% with QRS complexes of 169 ± 29 ms. On an average, the NYHA class was III (+ 0.4). The patients were 70.3 ± 10.1 years old, ranging from 21–85 years. The cohort was composed out of 59 male patients (72%) suffering from ICM (n = 39), DCM (n = 41), or valvular CM (n = 2). This includes three patients with AVR and one patient with MVR. An upgrade procedure for CRT was indicated for 16 of the patients.

**Device implantation**

The implantation procedures utilizing the Attain Starfix active fixation lead were performed using standard techniques. The implanted defibrillator (n = 62) or pacemaker (n = 20) devices were from the four main manufactures. In most cases, the right ventricular lead was placed to the right ventricular septum. The CS ostium was accessed using a long sheath over an EPS catheter followed by a balloon catheter angiography to identify the LV lead target position in the vein. The fluoroscopy time was 30.4 ± 24.0 min. In the final position, the fixation lobes were extended and correct positioning as well as lobe deployment in the target vein was fluoroscopically verified. The anatomical peculiarity was an optimal lead position in the proximal part of the target vein or a very circumscripted areal of optimal threshold.

**Follow-up**

We evaluated the application and performance of the Attain Starfix active fixation lead for CS implantation during CRT retrospectively. Hospital discharge and follow-up data were collected at different points in time. During the implantation procedure, all threshold measurements were performed with an analyser at the pulse width of 0.5 ms. In contrast, during device follow-up, the LV thresholds were measured at varying pulse widths according to the discretion of the centre personnel.

**Results**

**Requirement for active lead fixation**

Over a time span of 36 months, 678 patients were treated with CRT in our institution. We treated 82 cases (12.1%) from these patients with the Attain Starfix active fixation lead. The main reason for using this LV lead in this patient cohort was intra-operative dislodgement of one (n = 47) or even two (n = 5) attempted passive fixation leads during implant procedure. Additionally, the Attain Starfix active fixation lead was used in clinically indicated LV lead revision procedures (n = 30) caused by unstable or high stimulation thresholds as well as dislodgement of the original passive fixation LV lead.

In 8 of the 82 patients, the active fixation LV lead was attempted but could not be placed successfully and optimal LV stimulation be ensured. Figure 1 illustrates the patient cohort in detail. In four cases, a conventional unipolar lead was finally implanted deeper in the target vein where phrenic nerve stimulation was thereby avoided. In one patient, a syphon-like part of the target vein was not passed by the Attain Starfix active fixation lead but by a passive fixation unipolar lead. In another case, the only stable lead localization in the target vein without phrenic stimulation was proximal near the CS utilizing a fixation with a screwing lead (Secure™; Model 3830 by Medtronic). In two patients (one with an atypical CS anatomy and one with a giant right atrium), no stable lead position including the usage of the Attain Starfix active fixation lead was reached. The first patient changed to an epicardial approach by cardiac surgery. The second patient denied cardiac surgery and received a single chamber ICD.

Mostly, the anatomical peculiarity was an optimal lead position in the proximal part of the target vein (50 lateral, 22 posterolateral, 1 anterolateral, and 1 Marshall vein) or a very circumscripted areal of optimal threshold without phrenic nerve stimulation or unacceptable thresholds. In Figures 2 and 3, two cases are described, where challenges related to a passive fixation lead were solved by using the Attain Starfix active fixation lead.

**Success rate**

Utilizing different lead types including the Attain Starfix active fixation lead, an overall success rate of 99% was achieved for the 678 CRT patients. Active fixation lead implantation in a patient cohort characterized by a high rate of revision procedures (37%: 30 of 82 patients) or dislocation of passive fixation leads during the same procedure (63%: 52 of 82 patients) yielded a successful rate of 90% (74 of 82 patients).

**Thresholds**

We evaluated the performance after a defined healing period of 28 days in those patients where the Attain Starfix active fixation lead was used for CS implantation. In the analysis, we excluded 15 patients from which only follow-up data of <1 week was available. The retrospective analysis of the data revealed that, for 16 patients, the LV lead threshold measurement at implantation and device follow-up were performed at the identical pulse width of 0.5 ms. Despite complex anatomies, the threshold remained stable in these 16 patients with initially 1.2 ± 0.8 V at implantation and 1.0 ± 0.5 V after a median follow-up time of 99 days.

**Revisions**

During the course of the follow-up time, one revision of the Attain Starfix active fixation lead had to be performed after 12 months due to instability in the ectatic vein. In two further cases, the Attain Starfix active fixation lead had to be fully explanted after 6 and 15 months because of device perforation or infection of the device. The one revision and two extraction procedures were all performed successfully only by applying manual traction to manipulate the active fixation lead. However, after one extraction procedure, the original target vein was thrombotically
Figure 1 Graphical description of the patient cohort treated with an Attain Starfix™ active fixation left ventricle lead.

Figure 2 (Top left) X-ray view showing a potentially lateral target vein (RAO 0°). It was attempted to place a passive fixation lead in the peripheral part of the vein but a high threshold (>5 V) was observed. When the lead was placed in the peripheral side branch instead, phrenic nerve stimulation occurred (positions indicated by the dotted arrows). (Top right) The left ventricle lead was therefore drawn back and positioned in the proximal side branch (arrow), where no phrenic nerve stimulation occurred and an acceptable stimulation threshold was measured. (Bottom left) Unfortunately, in the proximal side branch, the passive fixation lead was not stable and dislodged as indicated by the arrow. (Bottom right) An Attain Starfix™ active fixation left ventricle lead was used to target the proximal side branch of the vein. Note that three fixation lobes (arrow) were deployed in the side branch. In this position, left ventricle lead and stimulation threshold were stable. (Right graphic) Scheme visualizing the active fixation mechanism with deployable lobes from the Attain Starfix lead.
occluded. No procedure-related complication occurred in all three cases.

Discussion

In this report, we show that the Attain Starfix active fixation lead can be used successfully to target anatomically challenging veins where passive fixation leads failed to ensure stable LV stimulation. Additionally, we performed revision or extraction procedures of this LV lead without complication 6, 12, and 15 months after implantation.

Constant and optimal stimulation of the left ventricle is a prerequisite for CRT. Furthermore, utilizing a transvenous access route, the aim is to implant an LV lead that is stable in the final position in the target vein. Obviously, to ensure the patients comfort, no phrenic nerve stimulation is allowed to occur. Early reports from investigators comparing the Attain Starfix active fixation lead with leads with passive fixation reported significantly reduced dislodgment rates and stable thresholds. In this report, we present a patient cohort where passive fixation leads failed to ensure stable LV stimulation. Therefore, we implanted these patients with the Attain Starfix active fixation lead. In accordance with other reports, we were able to show that this fixation mechanism ensures stable LV lead positioning in the target position even in anatomically challenging veins and appears to be superior to passive fixation leads in 74 of the 82 cases.\textsuperscript{11,12} Therefore, with the exception of eight cases, the Attain Starfix LV lead represents an alternative treatment option for CRT implantation.

In earlier publications, concerns were raised in regard to the possibility of extracting or replacing an active fixation lead, especially the one utilizing deployable lobes. In certain cases, due to non-tolerable phrenic nerve stimulation, LV lead repositioning was clinically indicated. In some cases, as early as 4 weeks after the original implantation, the LV lead extraction procedures were reported to be extremely difficult.\textsuperscript{11} However, in another report, the presented data indicated that in most cases (83%) manual traction is sufficient for the removal of the Attain Starfix active fixation lead.\textsuperscript{13} In conclusion, it is still elusive whether the improved stability of an active fixation lead resulting in reduced LV lead repositioning rates outweighs a potential risk increase during LV lead extraction. In our patient cohort, we performed successfully and without major complication one revision and two extraction procedures. Especially, the last extraction case occurred as late as 15 months after the initial implant procedure without complication.

In our opinion, the observed device infection rate of \(<1\%\) in our institution requiring a lead extraction procedure is no reason to withhold from \(>10\%\) of the patients suffering from unstable passive fixation leads the option of an active LV lead fixation ensuring stable lead positions. Additionally, one has to bear
in mind that the presented patient cohort was composed of patients where a passive fixation lead had already failed to show stable thresholds due to challenging vein anatomies. Even worse, some patients actually needed invasive procedures as a result of LV lead instability. When we considered the portfolio of different LV leads of the main four manufacturers, in our hands and to the best of our knowledge, the usage of the Attain Starfix active fixation lead was the best option to ensure successful CRT in these patients with challenging coronary vein anatomy. Generally, the availability of different LV leads produced by different manufacturers during CRT implantation, regardless of the manufacturer that supports the implantation, should be recommended for a successful procedure.

Taking into account the immense mortality of severe symptomatic heart failure—untreated up to 50% within the first year—an optimal treatment with a maximum supply of biventricular systems in patients with dysynchrony is demanding to reduce the patient’s mortality and health costs. Regarding this aspect, a rate of 7.5% of patients without an implanted CRT device in the CRT group due to ‘technical difficulties in positioning the CRT pacing lead in the coronary vein’ during the MADIT-CRT trial remains a remarkable percentage. In patients with an unsuccessful CRT implantation using conventional (passive fixation) leads, all options should be explored to ensure CRT, including leads with an active fixation mode as presented in this report. In other case reports, alternative fixation of a passive LV lead with an endovascular stent has been described. However, this technique is affiliated with the significant disadvantage that no correction of LV lead position or a potential future lead explantation—for example, in case of infection—can be performed. As shown in our report, we successfully used in one of our cases a screwing in a proximal vein position as an implant alternative for rare situations. Further new concepts like quadri-polar leads, which also allow stimulation in proximal vein segments with a stable, deep position in the target vein, could be valuable treatment options.

In conclusion, the Attain Starfix active fixation lead with deployable lobes is an important therapy option for CRT implantation. From our experience, we suggest using active fixation leads especially for patients in whom previous passive fixation leads have failed or, from the experience of the implanters, will be unlikely to perform optimally due to a challenging target vein anatomy. In our three cases, lead revision or extraction procedures even after 15 months can be performed without major complication. Manufacturers should be encouraged to develop further and optimized mechanisms for active LV lead fixation.

Conflict of interest: G.L., W.K., R.G., E.W., J.T. have no disclosures. G.H. is an employee of Medtronic GmbH, Meerbusch, Germany.

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