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1 **TITLE PAGE**

2 **Title: Starfix lead extraction: clinical experience and technical issues**

3 **Brief title: Starfix extraction: technical issues**

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1 **ABSTRACT**

2 Transvenous lead extraction (TLE) of the Starfix coronary sinus (CS) active-fixation lead may
3 be challenging, due to undeployment of fixation lobes and venous occlusion. We report our
4 experience in Starfix TLE, in comparison with previous data.

5 A 78-year-old male, implanted in 2009 with Starfix lead, was referred to our institution for
6 TLE, due to infective endocarditis with lead-associated vegetations. The tip of Starfix lead
7 was located in distant, anterior position, in the Great Cardiac Vein, close to patent LIMA-to-
8 LAD anastomosis, and first-choice surgical removal had a prohibitive operative risk.

9 Conventional dilatation beyond CS os, as well as the use of a standard delivery catheter, was
10 ineffective. An off-label modification of the delivery, by cutting the distal soft tip, was
11 successful. However, the tip of the lead fragmented and was trapped in the innominate vein.
12 Then a gooseneck snare grasped the fragment, allowing complete retrieval.

13 TLE of Starfix leads may be particularly challenging, especially when its tip is located in a
14 distant anterior location. In these cases, important help may be obtained by dilatation within
15 the CS, by means of conventional or modified delivery catheters. Only experienced operators,
16 sometimes with non-conventional techniques, should perform TLE of Starfix leads.

17 Abstract word count: 197

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LEARNING OBJECTIVE

TLE of Starfix leads may be challenging, particularly when the tip is located in a distant anterior position. Dilatation with conventional tools may be precluded. In these cases modifications of the delivery catheters may be useful. Surgery should be avoided as first-choice procedure; only experienced operators, sometimes with non-conventional techniques, should perform TLE of Starfix leads.

Learning objective word count: 56

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2 INTRODUCTION

3 Implantation of left ventricular (LV) leads through coronary sinus (CS) may be challenging.

4 Dislodgements of LV leads accounts for 4¹-10% of cases,²⁻⁵ with threshold worsening, loss of
5 capture, phrenic nerve stimulation and inadequate cardiac resynchronization therapy (CRT).

6 Technology improvements, like preformed shapes of LV leads, were developed to maintain

7 adequate stability. Even more, active fixation leads were introduced (Attain Starfix OTW LV

8 Lead, Model 4195, Medtronic, Minneapolis, MN, USA). First experience with such leads was

9 reported in 2007,⁶ with only 0.7% dislodgement rates at two-year follow-up,⁷ and improved

10 success rate of CRT.⁸ However, the difficulty of using such LV active fixation leads was

11 confirmed, particularly with respect to transvenous lead extraction (TLE),⁹ even in recently

12 implanted leads.^{6,7}

13

14 CASE REPORT

15 A 78-year-old male patient was referred to our institution for TLE, due to pocket infection

16 with lead-associated vegetations.

17 *Clinical history.*

18 In 1991 the patient suffered an inferior myocardial infarction, and the same year he underwent

19 surgical revascularization with left internal mammary artery (LIMA) anastomisation to left

20 anterior descending (LAD). In 2009, due to depressed ejection fraction with inducible

21 ventricular tachycardia at electrophysiological study, the patient was implanted at another

22 centre with a single chamber ICD; a double coil passive fixation shock lead was used (Sprint

23 Quattro, Model 6944, Medtronic Inc., Minneapolis, MN, USA). From January 2011 the

24 patient experienced relapsing skin dehiscence at the generator pocket, with exposure of the

25 can and lead. The absence of systemic involvement was accepted, by the referring physicians

1 and in contrast to Expert Consensus,¹⁰ as warranting repeated two local repair procedures,
2 with deep relocation of the exposed lead and pulse generator, and one generator replacement
3 with preservation of the lead. Even so, due to worsened heart failure with left bundle branch
4 block, the device was upgraded to a biventricular system in November 2011. Permanent low-
5 rate atrial fibrillation led to implantation of a new LV lead only. Lateral and postero-lateral
6 CS branches were not suitable for implantation, and stability issues resulted in the choice of
7 an active fixation lead (Attain Starfix LV OTW Lead, Model 4195, Medtronic Inc.), which
8 was anteriorly located in the mid-portion of the great cardiac vein (GCV). A biventricular
9 device (Concerto II CRTD D 294 TRK, Medtronic) was implanted, with the atrial port
10 capped. The procedure was complicated by pocket hematoma, requiring surgical revision one
11 month later. On June 2014, new skin erosion was evident, with further exposure of one lead.
12 A transoesophageal echocardiography disclosed lead-associated filiform images, along the
13 transatrial segment of both right ventricular shock and LV CS lead, finally and clearly
14 convincing the colleagues of the need of TLE.

15 *Patient evaluation and diagnostic work-up.*

16 After admission to our centre, control coronary angiography showed proximal occlusion of
17 the LAD, Circumflex and Right coronary arteries, with myocardial perfusion due completely
18 to a patent LIMA-to-LAD anastomosis. Myocardial perfusion with ⁹⁹Tcm-
19 methoxyisobutylisonitrile (MIBI) stress/rest SPECT disclosed a wide irreversible inferior and
20 infero-lateral defect, and a small partially reversible apical defect. Therefore, the only viable
21 myocardial tissue was that located in the anterior position, perfused through the above-
22 mentioned LIMA-to-LAD graft.

23 Cardiac surgeons ruled out surgical lead extraction as first-choice procedure, due to expected
24 difficulty and risk of removing a lead implanted in close proximity with a working LIMA-to-
25 LAD anastomosis (Figure 1, Panel A; **Video 1**).

1 *Transvenous lead extraction.*

2 TLE was performed under local anaesthesia in the Electrophysiology Lab, with a cardiac
3 surgery team on active duty and with support of an Anaesthesiologist and with working
4 anaesthesia equipment in the room. We used manual traction with conventional and locking
5 stylets, and dilation with polypropylene sheaths (Cook Vascular Inc., Leechburg, PA, USA).
6 The size of the sheaths, all provided with bevelled ends, ranged from 7 to 11.5 French. We
7 used the single-sheath technique described by Bongiorno,¹¹ and counter-traction.

8 First, the Sprint Quattro lead was extracted with conventional polypropylene Byrd mechanical
9 dilators (Cook Vascular Inc.), up to the 11.5-French inner XL *öwhiteö* one (Figure 1, Panel B;
10 **Video 2**). A subsequent selective retrograde CS venography disclosed an occlusion at the mid
11 portion of the main CS (Figure 1, Panels C and D). A 0.014 *ö* Hi-Torque Balance
12 Middleweight guide (Abbott Vascular, Santa Clara, CA, USA), inserted through the Swan-
13 Ganz lumen, was able to gain access to the distal CS (Figure 1, Panels E and F; **Video 3**). The
14 LV lead was cut as usual, and a long standard CS stylet (Model 6054, 0.016 *ö*, 110 cm,
15 Medtronic) was inserted and secured with ties. Advancing the push tubing of the Starfix along
16 the lead body resulted in a partial undeployment of the proximal lobes only. A manual
17 traction attempt was ineffective; therefore, dilatation was performed along the LV lead using
18 the inner 7.0-French and 8.5-French XL Byrd dilators, with the bevel stopping immediately
19 after CS entrance (Figure 1, Panel G; **Video 4**). A 57-cm long 7-French CS delivery (Attain
20 Command CS Cannulation Catheter, Model 6250VI-57S, Medtronic) was advanced over the
21 LV lead near the origin of the GCV (figure 1, Panels H and I; and Figure 2, Panels A to D;
22 **Video 5**). Then, as previously described,¹² the soft tip collar of the delivery was cut, in order
23 to produce a greater pushing force along the lead. This off-label modified delivery was able to
24 reach the proximal series of the fixation lobes, resulting in their further undeployment (Figure
25 2, Panels E to H; **Video 6**). The distal end of this modified delivery was firmly anchored to

1 the proximal lobes, allowing repeated traction to be effective in extracting the lead from the
2 CS (Figure 2, Panel I; **Video 7**). The tip of the Starfix lead, with its distal fixation lobes
3 deployed, not protected inside a dilator, was trapped in the proximal innominate vein,
4 immediately before the costo-clavicular angle narrowing (Figure 3, Panel A). Manual traction
5 resulted in fragmentation of the lead, with its tip retained, and consequent occlusion of the
6 vein (figure 3, Panel B). A Lassos snare catheter, 90° loop angle, 30 mm loop diameter
7 (OSYPKA AG, D-79618 Rheinfelden-Herten, Germany) was unsuccessful in catching the
8 lead fragment (Figure 3, Panel C). A 0.025ö J Tip PTFE guide wire (Medtronic Inc.), driven
9 by a 7-French MPA 1 guiding catheter (Cordis Corp., Miami Lakes, FL, USA), could pass
10 through the occlusion, and the lead tip was partially freed (Figure 3, Panel D). An Amplatz
11 Goose Neck 6-French snare catheter, with a 30mm loop snare (ev3 Inc., Plymouth, MN,
12 USA), was then used to grasp the tip (Figure 3, Panels E to G), thereby allowing complete
13 retrieval of the tip fragment through a 18-french long femoral sheath (Cook Vascular)(Figure
14 3, Panels H and G; **Video 8**). Subsequent course was uneventful. Particularly, no pericardial
15 effusion was observed.

16

17 **DISCUSSION**

18 The extraction of the Attain Starfix lead clearly can be particularly challenging, even with
19 recently implanted leads (within 4 weeks).⁶ Previous experiences of Starfix TLE are reported
20 in Table 1, with regard to dwelling time, implant site, undeployment of fixation lobes,
21 technique used and progression of sheaths within the main CS, beyond CS entrance, or its
22 branches. Only cases with intention-to-treat indication to TLE were considered, while
23 repositioning and implant revisions were not taken into account. Moreover, TLE was defined
24 according to HRS Expert Consensus.¹⁰ Dwelling time of extracted Starfix leads was
25 599,1±271.1 days (range 69 to 1029). The Starfix tip, as referred by the Authors or as could

1 have been gathered from the analysis of the published images, was located in a posterolateral,
2 lateral or anterolateral position. The bevel of the dilators could reach the main CS in 15 out of
3 19 patients, where information could be have been gained, and a CS branch only in 7.
4 Undeployment of fixation lobes was frequently prevented,^{7, 13-16} often occurring only with
5 proximal ones.¹²⁻¹⁴ Such a mechanism may be responsible for acute failures in extracting
6 leads, while chronically venous occlusion, due to reduction and slowing of blood flow with
7 consequent thrombosis,¹⁷ may collaborate with worsening effect. Success rate for Starfix TLE
8 is approximately 73%, clearly below the 96-98% reported rate for intracardiac conventional¹⁸
9 and passive fixation CS leads.¹⁹

10 Our described case confirms some key points about TLE of the Starfix lead: the
11 undeployment of fixation lobes, the venous occlusion (in our case affecting the main middle
12 CS, not just the collateral venous branches), the impossibility of conventional mechanical
13 dilatation just beyond CS entrance, and the effectiveness of dilatation within the CS by means
14 of conventional and/or modified CS delivery catheters.

15 To the best of our knowledge, with respect to published data, some features of this case are
16 unique and should be highlighted.

17 The dwelling time of the Starfix lead was 988 days, well beyond the majority of extracted
18 case (only one cases of the Cleveland population was implanted as long as 1029 days).¹³ Our
19 patient is the only one in which the Starfix lead was located in an anterior position, in the mid
20 portion of the GCV. Such a distant location increases the difficulty of reaching the distal tip
21 and performing dilatation along the lead. The progression of sheaths is even more difficult,
22 due to the wide and almost complete curve along the main CS, and the narrow distal
23 angulation of the vein where it reaches the interventricular groove.

24 Our case is the first one in which the tip of the Starfix lead is located in close proximity to a
25 patent coronary artery anastomosis. Our surgeons refused elective surgical removal of the tip,

1 because of its risky location, of the redo procedure, with presumably tough dissection of old
2 adherences surrounding the heart, and of high surgical risk of the patient. In other cases,
3 failure of transvenous extraction of the Starfix lead was treated by urgent surgical
4 intervention.¹⁵ In our patient, a surgical emergency procedure would have been prohibitive.

5 **Conclusions.**

6 Starfix lead extraction may be challenging due to the impossibility of undeployment of
7 fixation lobes, with increasing difficulty for the frequently observed venous occlusion around
8 the fixation mechanism. However, some important help may be obtained by dilatation within
9 the CS, by means of conventional or modified delivery catheters. This approach must always
10 be attempted, even in presumably difficult cases, due to the long dwelling time, unfavourable
11 and distant anatomic location, and prohibitive surgical risk.

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14 **Conflict of interest.** None to declare.

1

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1 FIGURE LEGENDS

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3 Figure 1.

4 Panel A: coronary angiography, showing a patent LIMA-to-LAD anastomosis in the
5 interventricular groove, in close proximity to the tip of the Starfix lead. Circumflex and right
6 coronary arteries are occluded, with myocardial perfusion entirely depending on this working
7 anastomosis. Panel B: ICD shock lead extraction, with standard polypropylene Byrd dilators.
8 Panel C and D: selective retrograde CS venography. The mid portion of the main CS, just
9 beyond the inflated Swan-Ganz catheter balloon, is occluded. Panel E and F: a 0.014ö Hi-
10 Torque BMW guide, inserted through the Swan-Ganz lumen, gains access to distal CS.
11 Panel G: advancing the push tubing of the Starfix along the lead body results in a partial
12 undeployment of the proximal lobes only. Therefore, dilatation along the LV lead is needed,
13 using the inner 7.0-French XL Byrd dilator, with the bevel stopping immediately after CS
14 entrance. Mechanical dilatation cannot progress just beyond CS os. Panel H and I: a 57-cm
15 long 7-French CS delivery (Attain Command CS Cannulation Catheter, Model 6250VI-57S,
16 Medtronic) is advanced over the LV lead into the mid portion off the main CS.

17

18 Figure 2

19 Panel A to C: further progression of the delivery into the CS. Panel D: the distal portion of
20 the main CS is reached, just before the origin of the GCV in the interventricular groove.
21 Panel E: off-label modification of the delivery, by cutting the soft distal collar of the catheter.
22 The modification produces a greater pushing force along the lead, so reaching the origin of
23 the GCV. Panel F to H: the distal end of this modified delivery is firmly anchored to the
24 proximal lobes. Panel I: extraction.

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1 Figure 3

2 Panel A: during extraction, the tip of the Starfix, not protected inside a dilator, is trapped into
3 the innominate vein, just before the costo-clavicular angle narrowing. Panel B: manual
4 traction results in fragmentation of the lead, with its tip retained. Due to the traction forces
5 carried out, the fixation lobes are forced against the vessel wall, and again fully deployed, so
6 causing venous occlusion. Panel C: a Lassos snare catheter, 90° loop angle, 30 mm loop
7 diameter is unsuccessful in catching the lead fragment. Panel D: a 0.025ö J Tip PTFE guide
8 wire (Medtronic Inc.), driven by a 7-French MPA 1 guiding catheter (Cordis Corp., Miami
9 Lakes, FL, USA), can pass through the occlusion, so allowing a selective venography,
10 confirming the occlusion. As a consequence of these manoeuvres, the lead tip is partially
11 freed. Panel E and F: an Amplatz Goose Neck 6-French snare catheter, with a 30mm loop
12 snare (ev3 Inc., Plymouth, MN, USA) catches the tip of the Starfix lead. Panel G: the traction
13 over the tip undeploys the lobes, as can be see at the mid innominate vein level. Panel H and
14 I: the tip fragment of the Starfix lead is extracted through a long 18-French femoral sheath.

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