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#### LEFT VENTRICULAR LEAD STABILIZATION IN CORONARY SINUS VIA STENT CASE REPORT AND LITERATURE REVIEW

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#### ABSTRACT

Background: Left ventricular lead instability encounters some cardiac resynchronization therapy implantations affecting heart failure patient's responsiveness. We present a left ventricular lead stabilization in the coronary sinus via a drug-eluting stent in addition to the literature review of this technique. Methods: A 33-year-old male patient had advanced heart failure and implanted cardiac resynchronization therapy. Left ventricular lead dislocation mandated redo-implantation. Lead instability complicated the procedure until a drug-eluting stent anchored it in the posterolateral branch of the coronary sinus. Furthermore, we reviewed the literature to address all studies and reports of left ventricular lead stabilization via coronary stent in the coronary sinus during cardiac resynchronization therapy implantation. We explored words as left ventricular lead stabilization, lead stenting, coronary sinus stent, coronary sinus angioplasty. Results: A total of 14 studies spotted left ventricular lead stenting in the coronary sinus during biventricular pacing between 2000 and 2021; four observational studies: three case series: seven case reports. The studies included 400 patients, and mean follow-up was 20 months. Stenting the lead during the primary procedure (n=368) versus stenting in the redo procedure (n=32). Stenting for lead instability and phrenic nerve stimulation (n=374), whereas stenting due to unfavorable anatomy (n=26). Most patients received a bare-metal stent (n=396), a drug-eluting stent (n=2), and a bioabsorbable scaffold (n=2). Overall reported stenting the left ventricular lead since the first procedure description in years 2003 to 2011 was 390 stents and between the years 2012–2021 was ten stents. Conclusion: During cardiac synchronization therapy implantation, left ventricular lead retention in the coronary sinus by stent is feasible and effective.

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## **INTRODUCTION**

Cardiac resynchronization therapy (CRT) with optimal medical therapy is the mainstay approach in treating advanced heart failure (1,2). Complete implantation of left ventricular (LV) lead in the coronary sinus (CS) vein is still the preferable technique in CRT and can be accomplished in 90% of implantations (2,3).

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When trans-coronary sinus LV lead implantation is unfeasible due to access, recurrent dislodgement, or phrenic nerve stimulation (PNS), different techniques were described to implant LV lead asvein angioplasty and stabilize the lead by stenting (4,5), anchor balloon (4), or using gooseneck snare (6), transseptal endocardial LV lead implantation (7), use active fixation leads in CS (8,9), epicardial implantation of the lead is another technique in case of unattainable transvenous approach (10-12). Wireless LV pacing and His-bundle pacing are new and growing alternatives for conventional CRT implantation (13,14). In 2003, Van Gelder BM et al. reported the first case of LV lead emplacement using angioplasty and stenting of the occluded branch to reimplant the lead (5). In the 27th Congress of the European-Society-of-Cardiology, Gellér L et al. were the first to describe the possibility of CS sidebranch stenting as a tool for stabilization of LV lead (15).

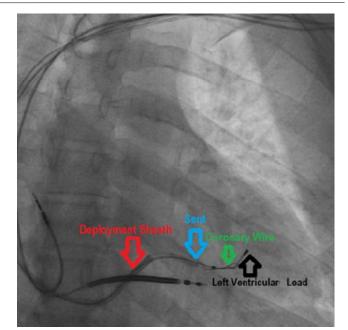
Maintaining LV lead at its intended site by stenting permits satisfactory pacing parameters, minimizing PNS, and reimplanting procedures (16,17). This study is the first literature review of anchoring the LV lead in CS by stent between 2003 till 2021.

#### **METHODS**

Case presentation: Our case is a 33-year-male with symptomatic severely dilated cardiomyopathy who had cardiac resynchronization therapy defibrillator (CRT-D). The Ejection Fraction<20 and Left Bundle Branch Block QRS duration was 156ms on the cardiac electrocardiogram. After two weeks, device interrogation revealed a high threshold and right ventricle capture. Fluoroscopy confirmed LV lead dislodgement outside the CS. Subsequently, we scheduled him for revision. In the reimplantation procedure, vancomycin was given. The patient was draped on with aseptic technique, and 30ml of 2% xylocaine was infiltrated into the implantation field.

We explanted LV lead smoothly over extra support wire. The first difficulty was re-accessing the CS by a deflectable catheter delivery system (attain,6227DEF, Medtronic) due to severe subclavian vein stenosis despite multiple stenotic dilations. Anyhow, we only accessed by a deeper puncture and cannulating the CS by using delivery integrated valve sheath (attain command + surevalve) and decapolar coronary catheter. CS venogram showed only one suitable posterolateral branch (PLV) approximately 2.5 mm in diameter. The second difficulty was pumping the lead (Attain Ability™ MRI SureScan<sup>™</sup> 4196, Medtronic, Minneapolis, MN, USA) out of the CS immediately. Finally, after three trials of unsuccessful reimplantation, we decided to stabilize the lead in PLV via a coronary stent. Using the same delivery sheath, we wired the vein by CHOICE PT Floppy wire (H749 12132-01J 2, **BOSTON SCIENTIFIC).** 

The drug-eluting stent (XienceXpedition, everolimus-eluting stent 2.75x12 mm, Abbott Vascular, Santa Clara, LA USA) passed through the surevalve over the wire. Then, we dragged the lead to the possible proximal PLV part where there was no diaphragmatic pacing, which we encountered before, and the threshold was less than one millivolt, impedance was 7550hm. The stent was positioned proximal to the distal lead end and then deployed at low pressure (10 atmospheric pressure) (Figure 1). After removing the balloon and wire, we tugged the lead for stability. Then, the attain sheath pealed successfully without affecting the lead position and parameters (figure 2). After confirming lead stability, it connected to the generator, and the wound was closed. The total procedure time was 185 min, all tools used in this procedure were based on availability in our catheterization laboratory. We discharged the patient on dual antiplatelets for three months. The short and long-term follow-ups showed a super device responder with a smooth healing course and stable lead parameters. With the literature search in PubMed, Wiley Online Library, and Google Scholar, we sorted out all published studies and reports that addressed the retention of LV lead via coronary stent in CS branches during CRT implantation between the years 2000-2021. Data subcategorized as study type, the chronology of the studies, patient numbers, patient demography, indication, procedure, results, follow-ups, and conclusions.



Red arrow: The delivery integrated valve sheath. Blue arrow: The drug-eluting stent. Green arrow: Coronary wire. Black arrow: left ventricular lead.

Figure 1. Shows the right anterior oblique view of stent deployment in the posterolateral branch of the coronary sinus over the left ventricular lead through the sheath.

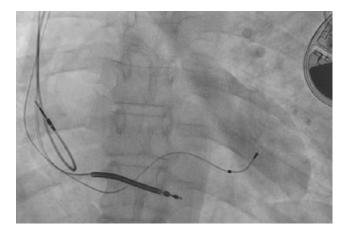


Figure 2 . Shows the right anterior oblique view of the stable left ventricular lead after pealing the sheath.

Words like left ventricular lead stabilization, left ventricular lead stent, coronary sinus stent, coronary sinus angioplasty were browsed.

#### RESULTS

With the aid of electronic search between the years 2000–2021, 14 studies were found concerning LV lead entrapment in CS by stenting: four observational studies(16–19): three case series(20–22): seven case reports(23–29). The studies included 400 patients, 74% male, mean age was 63.2 years, and mean follow-up was 20 months (range: 1–30 months). The LV lead stenting declined over the last decade or maybe underreported. The percentage of deployed stents to stabilize the LV lead since the first procedure described in the years 2003 to 2011 was 97.5% (stents no=390), and it dropped between the years 2012-2021 to 2.5% (stents no=10). Greatest stents used were bare-metal stents (n=396), a drug-eluting stent (n=2), and

a bioabsorbable scaffold (n=2). The most common indications for lead stenting were lead instability and PNS (n=374, 93.5%), where stenting due to unfavorable anatomy (n=26, 6.5% of the cases). All patients had bipolar leads, except for two who had quadripolar leads. The 349 patients of the four observational studies underwent ad hoc lead stenting because of PNS, anatomy obstacles, or in-procedure dislodgement. Minor sequences were seen during a mean follow-up of 23 (range: 11–30) months, such as micro-lead dislocation (n=2), perforation (n=1), later PNS (n=18), only seven of them required reposition, lead dislocation (n=2) and lead extraction (n=8), which was uneventful. No stent-related mortality was registered.

## DISCUSSION

Ideally, the pacing of the mid-lateral wall of the LV through the lateral and PLV of the CS in cardiomyopathy causes enhancements in functional capacity and LV function(30-32). Anyhow, large PLV present in only 68% of hearts(31). The size and distribution of the CS branches differ widely; large branches in heavier hearts or severely dilated cardiomyopathy (33,34). Where small or absent in ischemic cardiomyopathy (35). Even with the availability of PLV, implanters still confront several difficulties such as lead instability and PNS during CRT implantation because of the anatomical and the electrical disparity in these patients (36-39). Diaphragmatic stimulation occurs in up to 37% of CRT implantations and switches off 5% of the device (3,36,40). The left phrenic nerve crosses the mid-region of left marginal veins in 53.3% (41). Leaving the preferred area for LV lead implantation (the marginal and posterior veins) is in jeopardy of PNS (42). The first-year incidence of LV lead dislodgement after cardiac resynchronization therapy implantation occurs in about 10.6% of the patient (43). LV lead instability is due to lead or anatomical-related factors. Lead-related factors owed to unsuitable lead slack, the discrepancy between the lead and vein diameters, and the way of attachment inside the chosen vein (44). On the other hand, the anatomical obstacles of CS are ostium orientation or obstruction, venous valves, vein direction and angulation, vein deformity caused by cardiac dilation, and anomalies (45-47). In this review, 93.5% (n=374/400) of the leads stabilized by stent were due to lead instability and PNS, where stenting based on unfavorable anatomy was 6.5%.

The non-uniform circumferential stress of the stent and the vessel wall grabbed the lead between the stent and the partially embedded veins in the myocardium (48). As well, shear stress is caused by parallel friction of the lead against the vein wall and the stent (49). LV lead stabilization by stent was applied in some centers commonly. For instance, the Semmelweis University group (Hungary, 2004–2009) and the University of Bologna group (Italy, 2009–2010) stented 39.7% and 30% of CRT patients, respectively. 97.5% of stents were deployed between the years 2003 and 2011. After that, stenting was less reported (only 5 case reports and one case series of 5 patients). All over, ten stents were deployed between the years 2012-2021. During the first procedure, immediate lead stenting was done in 349 patients who met specific criteria, as reported in four observational studies (16-19). The most extensive series was from Budapest. Gellér et al. (2011) included 296 of 312 patients who had lead stenting during the first procedure due to intraoperative lead instability or PNS, reoperation was required

in two patients, and 18 patients had PNS during a median follow-up of 28.4 months (17). In Szilagyi S et al. (2007) study, 29 patients had in procedure lead dislocation that required direct stenting without fluoroscopic dislocation during follow-up (11.5 +/- 5.5, 2-23 months)(19). As noted in Biffi M et al. (2014) study, early recognition of alarming coronary vein anatomy that predisposes to lead dislodgement such as coronary sinus branch has an ascendant path, branch adjacent to the coronary sinus ostium or branch with a flat take-off at a more than 80° angle from the CS may predict and necessitate ad hoc LV lead stabilization, in this study 16 patient had ad hoc lead stenting based in these coronary sinus anatomical features, none of them had adverse events during  $23.8 \pm 3.1$ months follow-up(16). Due to these favorable results, randomized trials with more significant numbers of patients to assess the long-term efficacy and cost-effectiveness of ad hoc lead stenting in the first cardiac resynchronization implantation are needed.

Some implanters advocate using short and smaller stent diameter by approximately 0.5 mm for lead stabilization to ease extractions if needed (50). However, still believe that using at least 1:1 sized stent in a distensible vein can hold the lead in place, adapt the jailed lead without affecting their integrity, and prevent stent and lead dislocation. Also, the necessity for lead extraction is low, and all cases that required extraction were done smoothly without complication, as reported in this review (16,17,51). As well, the microscopic examination of two coronary sinus specimens in which the lead stabilized with stent showed that the lead and stent were separated and covered by an intact intimal tissue layer. There was no particular damaging effect on the vascular system after extraction (52). Moreover, the examination of stented coronary sinus lead by optical, confocal, x ray, and scanning electron microscopy demonstrated multiple surface injuries were created on the insulation without affecting their electronic integrity (53).

## **CONCLUSION**

Stenting the left ventricular lead during cardiac synchronization therapy implantation in discriminated cases seems safe and effective without adverse events such as loss of lead integrity or coronary vein distortion. Large randomized trials are needed to support using this technique in biventricular pacing implantation procedures. **Funding:** None

Conflict of interest: none declared.

#### **Patient consent**

The patient gave his informed consent for publication. The scientific and research ethics committee of the royal medical service (Jordan) approved the protocol of this study.

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