# The use of lubricating solution as a novel method in facilitating left ventricular lead placement: A case series



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# Introduction

Despite improvements in implantation techniques and lead delivery tools including various sheaths and wires, the overall failure rate of left ventricular (LV) lead implantation remains at about 4% and ranges from 0 to 12% among published randomized trials.<sup>1,2</sup> The challenges related to placement of LV lead are often related to an unfavorable coronary sinus (CS) branch anatomy such as excessive tortuosity, acute ostial angulation, and small branch diameter. Most of the advances in cardiac resynchronization therapy (CRT) implantation techniques have been focused on the development of various sheaths and wires to increase lead stability. In this case series, we describe for the first time the use of lubrication to facilitate advancement of the LV lead through the sheath and into the desired CS branch.

Rotaglide (Boston Scientific Scimed, Maple Grove, MN) is a lubricant approved for intravascular applications that was initially designed for use with the ROTABLATOR Rotational Atherectomy System and later adopted for facilitating intracoronary stent placement.<sup>3</sup> This white emulsion is commercially available in 20 mL vials and contains ingredients derived from organic (olive) oil, egg yolk phospholipids, sodium deoxycholate, L-histidine, glycerin, disodium EDTA, sodium hydroxide, and water and therefore cannot be used in patients with allergic reaction to these products.<sup>4</sup> Rotaglide reduces friction during rotational atherectomy and stent placement and was used in this study because of its proven safety profile during intravascular use and ready availability in most cardiac catheterization laboratories.

Following an index case in which a lubricant was successfully utilized in a difficult-to-place LV lead, we systematically evaluated the use of Rotaglide in facilitating

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# **KEY TEACHING POINTS**

- Left ventricular (LV) lead placement remains one of the most challenging aspects of cardiac resynchronization therapy implantation procedures.
- Rotaglide (Boston Scientific Scimed, Maple Grove, MN) can safely be used to facilitate LV lead placement.
- Preliminary data suggest that Rotaglide is an effective tool to reduce the procedural time, although confirmation by a randomized trial is needed.

LV lead placement. Here, we describe the methodology and the results for this case series involving 11 patients.

# Methods

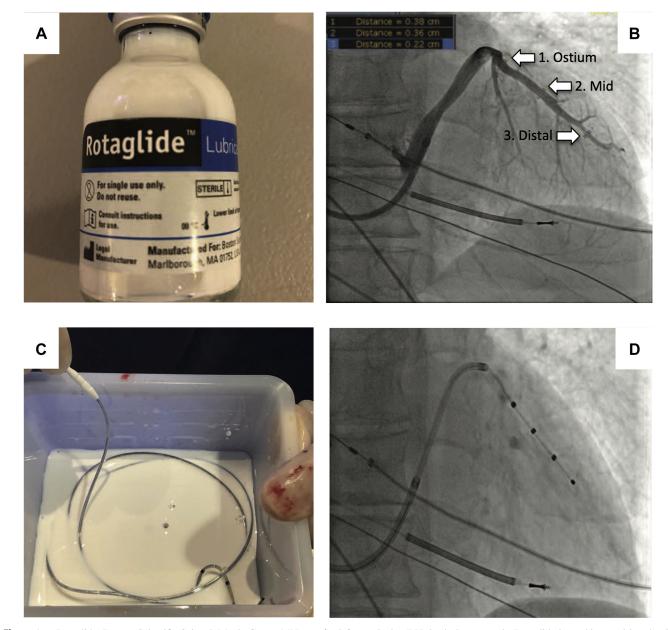
Between March and May of 2019, 11 consecutive patients who were scheduled for elective CRT implantation (5 CRT-D [defibrillator] and 6 CRT-P [pacemaker]) by a single implanter were included in the study. Informed consent was obtained and patients with allergy to egg or egg-containing products were excluded. Standard steps for CRT implantation were followed, including axillary venous access, sequential placement of appropriately sized peel-away sheaths, insertion of a CS sheath in the right atrium, and CS cannulation. An occlusive contrast venography of the CS in the left anterior oblique  $30^{\circ}$  view was obtained in every case prior to LV lead implantation. The diameter of the vein, targeted for LV lead placement, was obtained at the ostium and at mid and distal points along the length of the vein using offline image processing software (syngo Dynamics; Siemens, Munich, Germany) calibrated to the width of the CS sheath diameter. Once an ideal branch for LV lead placement was identified a quadripolar LV lead was prepared for implantation. The central lumen of the lead was flushed with sterile saline solution. Rotaglide solution (20 cc) was poured into a sterile surgical basin and the lead was submerged in the solution for 2–3 minutes to allow for complete coating of the lead (Figure 1). A 0.014-inch Whisper guide wire was placed inside the lumen of the lead while the lead was submerged in the lubricant. The total time from the insertion of the LV lead into the CS sheath until the final placement of the lead, referred to as LV placement time, as well as the number of attempts required for placement, a second fluoroscopy image in the left anterior oblique 30° view was obtained and

superimposed on the original venogram image to determine the diameter of the vein at the tip of the LV lead implantation position. LV lead thresholds, impedance, and fluoroscopic times were recorded.

All patients were followed after the procedure and all procedure-related adverse outcomes within 24 hours of device implantation were documented.

A similar protocol was used for data collection in the consecutive control patients in whom no Rotaglide solution was used.

Data were analyzed using Stata software (StataCorp. 2017. Stata Statistical Software: Release 15. StataCorp



**Figure 1** Rotaglide (Boston Scientific Scimed, Maple Grove, MN) use for left ventricular (LV) lead placement. **A:** Rotaglide is a white emulsion that is commercially available in 20 mL vials. **B:** LV lead was immersed in the Rotaglide for 2–3 minutes before insertion into the delivery sheath. **C:** Occlusive coronary sinus (CS) venography was performed for each case and the diameter of CS branch was measured at the levels of ostium, mid and distal segments. **D:** Final LV lead position was confirmed in relation to the measured venography landmarks. Panels B and D illustrate a case in which advancement of the LV lead was not possible owing to acute angulation of the branch at its ostium despite the use of multiple 0.014-inch wires and a sub-selector sheath but became possible after the Rotaglide application.

**Table 1**Baseline demographic information of patients enrolled inthe study

Patient	Age (years)	Sex	Procedure
1	89	Μ	New LV + RV, CRT-D
2	82	м	CRT-P
3	77	F	CRT-P
4	70	м	CRT-D/ AVN
5	81	F	CRT-D/ AVN
6	57	М	HIS to CRT-D
7	77	F	CRT-P
8	58	F	CRT-D
9	81	м	CRT-P
10	95	М	CRT-P
11	76	F	CRT-P

AVN = atrioventricular node ablation; CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; HIS = HIS pacemaker; LV = left ventricular; RV = right ventricular.

LLC, College Station, TX). Continuous variables were expressed as means  $\pm$  standard deviation.

## Results

Baseline demographic and clinical characteristics are summarized in Table 1. Of the 11 patients in the study (55% male, mean age of 76.6  $\pm$  11.5 years), 5 and 6 patients received CRT-D and CRT-P devices, respectively. In total the average LV lead placement time was 72.9  $\pm$  89.0 seconds and 9 of the 11 patients were able to have the LV lead placed on the first attempt.

The total procedural fluoroscopy time was  $9.7 \pm 5.9$  minutes (Table 2), which included the total fluoroscopy for new CRT device implantation as well as adjunctive procedures performed, such as lead extraction and atrioventricular node ablation in some of the patients. No correlation was present between LV lead placement and total fluoroscopy times (Pearson correlation coefficient = 0.13, P = .7). The diameter of the CS branch in which the LV lead was placed was measured at the level of the ostium (4 ± 0.6 mm), mid

 $(3 \pm 0.5 \text{ mm})$ , and distal  $(2 \pm 0.5 \text{ mm})$  segments in 10 out of 11 of the patients (Table 2). One patient did not have fluoroscopic image measurement owing to technical difficulties in retrieving images. There was a negative correlation between the diameter of the CS branch ostium and the total LV placement time (Pearson correlation coefficient = -0.7, P = .02).

The control group included a total of 6 consecutive patients who underwent CRT device implantation. Total fluoroscopy and LV lead placement times were  $13.2 \pm 7.4$  minutes and  $210.2 \pm 226.6$  seconds, respectively.

At the time of discharge from the hospital all the devices were noted to be functioning normally with stable sensing and thresholds (Table 2). During follow-up, 1 of the patients died owing to worsening heart failure but her device was functioning normally throughout her hospitalization.

No attributable acute periprocedural complications due to Rotaglide use, including hypersensitivity reactions or LV lead dislodgment, were observed.

## Discussion

This case series demonstrated the safety and feasibility of Rotaglide in facilitating LV lead placement. The average LV lead placement time was just over 1 minute and in more than 80% of cases placement was achieved in a single attempt. Furthermore, no periprocedural complications, including allergic reaction or lead dislodgment, were observed.

Although confirmation of Rotaglide efficacy in reducing procedural failure and time requires a randomized controlled trial, the data from a few consecutive patients who underwent CRT implantation without the use of lubricant were provided for comparison. The LV lead placement time in the control group was almost 3 times longer and fluoroscopy was longer by 4 minutes in the control group. Furthermore, the average time for LV lead placement was also significantly shorter than contemporary published results of over 12–18 minutes.<sup>5</sup> We hypothesize that by facilitating advancement of the LV

 Table 2
 Procedural characteristics and outcomes of left ventricular lead placement

	Diameter of coronary sinus branch (cm)		LV lead functional parameters			Procedure times (s)		
Patient	Ostium	Mid	Distal	Threshold	Impedance (ohms)	LV lead placement	LV lead placement	Total fluoroscopy
1	0.42	0.3	0.18	1 V @ 1 ms	620	Posterolateral	34.45	492
2	0.47	0.27	0.18	0.6 V @ 0.4 ms	1573	Posterolateral	31.1	318
3	0.39	0.3	0.24	1.25 V @ 0.5 ms	940	Posterolateral	73	480
4	0.38	0.36	0.22	0.9 V @ 0.5 ms	614	Lateral	25.3	1416
5	0.47	0.37	0.23	1.3 V @ 0.5 ms	957	Posterolateral	24.7	306
6	0.41	0.24	0.15	0.5 V @ 0.5 ms	1075	Posterolateral	168.26	552
7	N/A	N/A	N/A	1.6 V @ 0.5 ms	1402	Posterolateral	35	474
8	0.43	0.32	0.2	1.5 V @ 0.5 ms	810	Mid-lateral	34.27	180
9	0.47	0.39	0.31	1.75 V @ 1.0 ms	610	Posterolateral	38.2	978
10	0.36	0.27	0.2	2.25 V @ 0.5 ms	810	Lateral	28.07	462
11	0.28	0.25	0.16	3.5 V @ 0.5 ms	533	Mid-lateral	309.97	774

LV = left ventricular.

The diameter of coronary sinus branch where the LV lead was placed was measured at its ostium and at mid and distal level. Lead parameters were obtained at the time of implant. LV lead placement time refers to the total time from the insertion of the LV lead into the coronary sinus sheath until the final placement of the lead.

lead within the CS sheath and CS branch, the LV lead can be deployed faster and to smaller and more tortuous branches with the aid of Rotaglide compared to traditional implantation technique.

Additionally, the diameter of the branches in which the LV lead was placed was comparable with previously published data, demonstrating that the patients in the current case series were representative of typical patients undergoing CRT implantation.<sup>6</sup> In 40% of cases, the distal diameter of CS branch diameter was less than or equal to 1.8 mm, which is equal to the diameter of the quadripolar LV lead (1.7 mm), suggesting that the lead was advanced maximally into the venous branch.

Failure to cannulate and navigate the CS accounts for 30%–53% of LV lead placement failures.<sup>2</sup> This difficulty often stems from challenging anatomies that prevent placement of the LV lead in a satisfactory position for optimal and effective CRT therapy. So far the research and developments to address this problem have primarily focused on development of various sheaths and guide wires to allow for better stability and support during lead placement. This case series highlights a new approach to facilitate LV lead placement by reducing the mechanical friction of the LV lead as an adjunct to the available implantation tools. Furthermore, Rotaglide has been tested and approved for intravascular use and is readily available.

The study has several limitations. This was a relatively small case series, with no control arm, and had a short follow-up. With this limitation in mind, it demonstrated the feasibility, efficacy, and safety of Rotaglide use as a novel method in LV lead placement. Whether the use of Rotaglide would reduce the LV lead placement failure and the overall procedure time requires confirmation by a randomized controlled trial.

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