#### CASE REPORT

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# **Coronary sinus reducer transfemoral extraction after intraprocedural device migration: A case report**

Matjaz Bunc<sup>1</sup> | Miha Sustersic<sup>1</sup> | Crt Langel<sup>2</sup> | Dimitrij Kuhelj<sup>2</sup> | Shmuel Banai<sup>3</sup>

<sup>1</sup>Division of Internal Medicine, Clinical Department of Cardiology, University Medical Center Ljubljana, Ljubljana, Slovenia

<sup>2</sup>Institute of Radiology, University Medical Center Ljubljana, Ljubljana, Slovenia

<sup>3</sup>Tel-Aviv Medical Center, Sackler School of Medicine, Tel-Aviv University, Tel-Aviv, Israel

#### Correspondence

Matjaz Bunc, Division of Internal Medicine, Clinical Department of Cardiology, University Medical Center Ljubljana, Zaloska 007, 1000 Ljubljana, Slovenia. Email: mbuncek@yahoo.com

#### Abstract

The coronary sinus Reducer migration during implantation procedure is a rare complication with no standard bailout strategy. Transfemoral extraction of the Reducer can be a safe and successful method, as demonstrated by this case report.

#### **KEYWORDS**

coronary sinus, device migration, reducer, refractory angina, snare, transfemoral extraction

# **1** | INTRODUCTION

The coronary sinus Reducer migration during implantation procedure is a rare complication with no standard bailout strategy. We present a case of a successful transfemoral snare extraction of an expanded Reducer which migrated into the right atrium. Transfemoral venous extraction was performed rather than trans-jugular due to more favorable femoral anatomy. This case demonstrates that transfemoral approach using a snare can be a safe and effective method of extracting a migrated coronary sinus Reducer.

Chronic disabling angina, refractory to medical and interventional therapies, is a common medical condition and a major public health problem. Refractory angina is common not only in patients who are not good candidates for revascularization, but also in patients following successful revascularization and in patients with microvascular dysfunction. Considering a relatively favorable prognosis of these patients, the goal of therapy should be targeted primarily toward improving quality of life and angina symptoms.

The 2019 ESR guidelines for the diagnosis and management of chronic coronary syndromes recommend enhanced external counterpulsation, spinal cord stimulation, and the Reducer as B level of evidence treatment options for refractory angina symptom relief.<sup>1</sup>

The coronary sinus (CS) Reducer is a device-based therapy for the treatment of refractory angina. It is designed to improve quality of life and functional capacity by reducing angina burden. The Reducer is a balloon-expandable stainless steel mesh, which is implanted using a right Jugular vein approach, via a 9F guiding catheter.

CS narrowing using the Reducer has emerged as an effective therapy for patients suffering from disabling angina. In the COSIRA double-blind, sham-controlled, multicenter clinical trial, Reducer implantation was associated with a significantly greater angina relief and improved quality of life

The work was performed in University Medical Center Ljubljana, Zaloska c. 7, 1000 Ljubljana, Slovenia.

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compared with the sham procedure, despite a high rate of placebo effect.<sup>2</sup>

The focal narrowing in the lumen of the CS created by the Reducer leads to increased backwards pressure that causes slight dilatation and a consequent reduction in the resistance to flow in the coronary microcirculation of the ischemic subendocardium. This subsequently causes a redistribution of blood from the less ischemic subepicardium to the more ischemic subendocardium. The enhancement of blood flow within the ischemic subendocardium reduces ischemia and leads to symptoms relief and improved quality of life.<sup>3</sup>

Recent cardiac magnetic resonance studies show the Reducer implantation to increase ejection fraction and improve myocardial strain.<sup>4,5</sup> The Reducer implantation also improves VO2 max and workload during cardiopulmonary exercise testing and is especially efficacious in ameliorating angina symptoms in patients with non- revascularized CTO lesions.<sup>6,7</sup>

We present a case of a successful transfermoral snare extraction of an expanded Reducer that migrated into the right atrium.

## 2 | CASE REPORT

A 76-year-old patient with previous multivessel chronic ischemic heart disease, ST-elevation myocardial infarction, aortic valve replacement, previous bypass graft (CABG) surgery, and multiple percutaneous coronary intervention (PCI) procedures presented at our clinic due to worsening of angina symptoms. Coronary angiography revealed occluded CABG grafts, no restenoses of the previously stented left main and left anterior descending arteries, and a severe ostial LCX stenosis. PCI of the LCX stenosis was attempted without success.

The patient suffered from severe disabling angina in every minimal effort. Canadian Cardiovascular Society (CCS) III class angina was diagnosed despite optimal anti-anginal medical therapy (comprising acetylsalicylic acid 100 mg per day, metoprolol 50 mg per day, telmisartan 40 mg and hydrochlorothiazide 12.5 mg per day, rosuvastatin 20 mg per day, and warfarin according to the scheme).

Considering the previous unsuccessful revascularization efforts, further revascularization was not attepted. Objective evidence of myocardial ischemia in the left circumflex artery (LCX) territory was obtained by perfusion scintigraphy. Reducer implantation was indicated to mitigate angina symptoms and improve quality of life.

Under local anesthesia and ultrasound guidance, a standard right internal Jugular vein approach was performed, followed by multipurpose catheter insertion and CS angiogram. A 9F guiding catheter with the Reducer (Neovasc Inc) was placed inside the CS at the chosen implantation segment. The catheter-mounted balloon was inflated to 6 atm for 30 seconds, expanding the Reducer into its functional shape (Figure 1). The recommended 10-20% device oversizing relative to the CS cross-section was achieved in order to prevent device migration and induce endothelization of the stent's mesh structure.<sup>2</sup> No contrast leak was observed distal to the inflated balloon. After balloon deflation, venography showed an appropriate Reducer position.

Careful extraction of the guiding catheter and the deflated balloon was then initiated, with no resistance on the guiding catheter felt by the operator. Fluoroscopy revealed that during this maneuver, the Reducer had been displaced into the right atrium, while the support wire remained in the CS (Figure 1). The decision to extract the Reducer through the right femoral vein was then made. Femoral venous access was established by inserting a 16F introducer (St. Jude Medical Inc, St. Paul, MN) using the Seldinger technique (Figure 2). The guide wire with the Reducer on it was carefully withdrawn from the CS into the inferior vena cava. A snare catheter was inserted through the femoral vein introducer. The Reducer and the guiding catheter were grasped by the snare loop and extracted through the femoral introducer.

Careful fluoroscopic examination showed no apparent damage to the coronary sinus or other vessels involved in the extraction procedure.

During the same session, a new Reducer was successfully implanted more distally into a narrower part of the CS (Figure 3), without further periprocedural complications.

The patient received a 6-month dual antiplatelet therapy. At 3-month follow-up, he reported a reduction of angina severity from CCS class III to II.

## **3** | **DISCUSSION**

Several complications may theoretically occur during or after Reducer implantation, including CS dissection, perforation, thrombotic occlusion, and Reducer migration.<sup>2</sup> So far, there have been one CS perforation, one periprocedural device migration without device extraction, and one device extraction reported.<sup>8-10</sup>

Reducer migration during or after device implantation is an unusual complication. We can only speculate as to why it occurred in this case. The following hypotheses may be proposed:

- 1. Entanglement of the improperly deflated balloon in the central narrow part of the Reducer during the retrieval of the balloon;
- Overexpansion of the Reducer frame during the balloon inflation resulting in stent deformation and entrapment of the balloon;
- 3. An unobserved operator error.





FIGURE 1 Coronary sinus Reducer implantation and its extraction to the right atrium. A, Coronary sinus venography. Also visible is the surgical material after coronary artery bypass grafting (CABG) and aortic valve replacement (AVR). Amplatz extra support wire and the guiding catheter are inserted in the CS. B, The Reducer stent with tree markers inside the guide catheter. C, Proximal angiography showing no contrast leak after balloon inflation up to 6 atm. D, Guiding catheter extraction to the right atrium with the migrated Reducer stent attached to the tip of the catheter. E, A close up of the slightly deformed Reducer stent after pullout to the right atrium

An ex vivo re-inflation of the balloon was successfully performed without air leaks. An immediate debriefing of the Reducer implantation team revealed no deviations from the standard procedural checklist. Therefore, no definite conclusions regarding the etiology of the described difficulties may currently be made. Further detailed inspection of the material may be warranted to help pinpoint the exact cause.

Transfemoral rather than trans-jugular snaring and final extraction were decided for based on the comparatively more favorable femoral anatomy, both in terms of larger vessel caliber and lesser significance of the adjacent structures prone to damage.

## 4 | CONCLUSION

The main teaching points derived from this case report are as follows:

- 1. The position of the Reducer should be verified before the removal of the support guidewire;
- 2. If Reducer migration is observed, the guidewire should be kept in place and a bailout strategy prepared;
- 3. Careful extraction of the Reducer into the right atrium may be attempted; if experiencing resistance, surgical options should be considered;

FIGURE 2 Right femoral vein snare extraction of the Reducer: A, the Reducer extracted to the right atrium near the ostium of vena cava superior, fixed on guiding catheter. The guidewire is still inside the CS; B, guidewire redirection into the vena cava inferior, toward the right femoral vein. C and D, right femoral vein cannulation and 16F sheet (St. Jude Medical Inc, St. Paul, MN) introduction; E, a snare with an open lasso sliding on the guidewire; F, a snare grasping the guiding catheter and the Reducer; G and H, pulling of the snare and simultaneous pushing of the guiding catheter into the right femoral vein sheet; I, final extraction of the Reducer through the right femoral vein sheet, followed by the displacement of the sheet and closure of the femoral vein with an "8" suture (not depicted)



- 4. Transfemoral snaring of the Reducer may be a safe and relatively simple bailout strategy;
- 5. Provided there is no fluoroscopic evidence of damage to the Reducer or other vessels involved in the extraction, a new Reducer device may safely be implanted during the same session.

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Published with written consent of the patient.

## **CONFLICT OF INTEREST**

Shmuel Banai is the Medical Director of Neovasc, Inc. The other authors have no conflict of interest.

## AUTHOR CONTRIBUTION

MB: performed the procedure, made substantial contributions to conception, design, and analysis and interpretation of data, and wrote the manuscript; MS: performed the procedure and was involved in the design and interpretation of data. CL:



wrote and reviewed the manuscript. DK: performed the procedure and was involved in the design and interpretation of data. SB: was involved in the design and interpretation of data, wrote, and reviewed the manuscript.

### ETHICAL APPROVAL

Images were obtained with written informed permission.

## ORCID

Matjaz Bunc D https://orcid.org/0000-0001-7269-8944

### REFERENCES

- Knuuti J, Wijns W, Saraste A, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. *Eur Heart J*. 2020;41(3):407-477.
- Verheye S, Jolicœur EM, Pettersson T, et al. Efficacy of a device to narrow the coronary sinus in refractory angina. *N Engl J Med.* 2015;372(6):519-527.
- Konigstein M, Giannini F, Banai S. The Reducer device in patients with angina pectoris: mechanisms, indications, and perspectives. *Eur Heart J.* 2018;39(11):925-933.
- Tzanis G, Palmisano A, Gallone G, et al. The impact of the coronary sinus reducer upon left ventricular function in patients with refractory angina pectoris. *Catheter Cardiovasc Interv.* 2020;95:1104-1108.
- 5. Palmisano A, Giannini F, Rancoita P, et al. Feature tracking and mapping analysis of myocardial response to improved perfusion

reserve in patients with refractory angina treated by coronary sinus Reducer implantation: a CMR study. *Int J Cardiovasc Imaging*. 2020. https://doi.org/10.1007/s10554-020-01964-9

- Zivelonghi C, Konigstein M, Azzano A, et al. Coronary sinus Reducer implantation results in improved oxygen kinetics at cardiopulmonary exercise test in patients with refractory angina. *EuroIntervention*. 2020.
- Zivelonghi C, Verheye S, Timmers L, et al. Efficacy of coronary sinus reducer in patients with non-revascularized chronic total occlusions. *Am J Cardiol.* 2020;126:1-7.
- Cortese B, di Palma G, Latini R. Coronary sinus perforation during reducer implantation. *Catheter Cardiovasc Interv*. 2018;91(7):1291-1293.
- Gallone G, Armeni P, Verheye S, et al. Cost-effectiveness of the coronary sinus Reducer and its impact on the healthcare burden of refractory angina patients. *Eur Heart J Qual Care Clin Outcomes*. 2020;6(1):32-40.
- Ciardetti M, Coceani M, Pastormerlo LE, et al. Let's go fishing: snaring a Reducer coronary sinus stent in the right atrium. J Cardiovasc Med (Hagerstown). 2020;21(1):73-74.

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