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Central Venoplasty in Patients with Cardiac Implantable Electronic Devices

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Abstract

Objective The aim of this study was to assess the safety and effectiveness of the central venous angioplasty in patients with central venous occlusion and cardiac implantable electronic device (CIED) without lead extraction.

Materials and Methods A retrospective study was used to evaluate the effectiveness of 37 central venous angioplasty procedure for 15 patients with CIED without lead extraction.

Results Technical success was achieved in 97% (*n* = 36/37) and clinical success was achieved in 89% (33/37) of the procedures. One procedure failed recanalization of chronic total occlusion of the left subclavian vein, and the patient required fistula embolization due to severe arm swelling. Another procedure failed initially to recanalize long-segment occlusion involving the right subclavian vein/brachiocephalic vein and superior vena cava in a patient with a history of Hickman line and left-sided CIED. This was successfully recanalized and angioplastied on a subsequent session. No lead fracture or dislodgment was documented in any procedure. No procedure-related complication was documented within 2 weeks after the angioplasty. Six-month primary patency was achieved in 62% (23/37) of the procedures. Ten patients (66%) required an average of 1.4 reinterventions (range: 1–4 interventions) during the follow-up time with mean time to reintervention of 318 days (5–1,380 days). Two patients required early reinterventions within 10 days due to catheter dysfunction.

Conclusion Findings of this study support the existing evidence on the safety and effectiveness of balloon angioplasty without lead extraction.

Keywords
- balloon angioplasty
- dialysis
- Occlusion
- pacemaker
- stenosis

Introduction

The incidence of central venous occlusion (CVO) after placement of cardiac implantable electronic devices (CIED) ranges between 13 and 64%. However, symptomatic venous stenosis is seen in less than 3% of patients due to presence of well-developed collaterals.[1-5]

In contrary, 70% patients with CIED and ongoing hemodialysis using arteriovenous fistula or tunneled dialysis catheters may develop symptoms related to central venous stenosis or

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occlusion. The combination of increased venous flow and the coexisting venous stenosis secondary to the CIED and dialysis catheter leads to the clinical manifestations of venous hypertension. Endovascular management of CVO related to CEID is increasingly being utilized and reported in the literature.[6] Despite the theoretical concerns related to possible device malfunction and leads integrity, balloon angioplasty and stent placement are reportedly safe and effective with no device-specific complications. However, data with long-term follow-up remain scarce and largely retrospective in nature.[1,6-15] This study aims to report our institutional experience with balloon angioplasty for CEID-related CVO in dialysis patients without lead extraction.

Materials and Methods

This retrospective study was approved by the institutional review board and informed consent was waived. This study aimed at evaluating the safety and effectiveness of central venous balloon angioplasty interventions in the presence of CIED leads.

Between April 2014 and September 2020, 1,500 venous angioplasty and dialysis interventions were reviewed. A total of 37 central venous balloon angioplasty interventions in 15 patients with CIEDs were included in this analysis. Patients' cardiac demographics are displayed in ►**Table 1**.

The mean age was 71 years (56–81 years), with left-sided device in 93% (14/15 patients), inserted via axillary vein in 47% (7/15) and subclavian vein in 53% (8/15). The patient with right-sided device inserted via subclavian vein.

Fourteen patients (93%) were on dialysis using fistula (n = 5) and tunneled dialysis catheter (n = 9); while one patient had central venous stenosis related to peripherally inserted central catheter and tunneled Hickman catheter. Detailed patients' demographics and characteristics are illustrated in ►**Table 2**.

Thirty procedures (81%) were done due to stenosis, and seven interventions (19%) were done for total venous occlusion. Procedures were performed for different indications: dialysis catheter dysfunction (n = 18/37), fistula dysfunction (n = 14/37), limb swelling (n = 7/37) superior vena cava (SVC) syndrome (n = 1/37), and facial swelling (n = 1/37).

Venous stenoses were located in SVC alone (35%), subclavian with brachiocephalic (22%), brachiocephalic alone (13%), SVC with brachiocephalic (11%), subclavian alone (8%), SVC with brachiocephalic and subclavian (8%), and SVC with subclavian (3%).

Angioplasty procedures were done by several interventional radiologists with 1 to 15 years of experience. All procedures were done using balloon angioplasty using various brands and pressures (progressive increments in size with maximum diameter 14 mm in SVC). No stents were implanted and no leads were extracted at the time of interventions.

Technical success was defined as the ability restore venous patency with less than 30% residual luminal narrowing with disappearance of venous collaterals or successful disruption of the fibrin sheath with restoration of catheter function. Clinical success was defined as restoration of catheter/fistula function or resolution of venous hypertension symptoms for at least 2 weeks post the procedure. The integrity and position of CIED leads after the procedure were checked on final procedural images. No specific follow-up protocol or scheduled CIED interrogation was recommended.

Time-to-reintervention and patency at last follow-up were recorded, in addition to postprocedural cardiac and noncardiac complications within 2 weeks interval.

Results

Technical success was achieved in 97% (n = 36/37) (►**Figs. 1** and **2**) of the procedures. Clinical success was achieved in 89% (33/37) of the procedures. One procedure

Table 1 Patient's cardiac demographics

Case	CIED type	Manufacturer	Side	No. of leads	Indication for CIED placement
1	Pacemaker	St. Jude	L	2	Complete heart block
2	Pacemaker	Medtronic	L	2	Complete heart block
3	Pacemaker	St. Jude	L	2	Complete heart block
4	Pacemaker	Medtronic	R	2	recurrent syncope
5	Pacemaker	Medtronic	L	1	Atrioventricular block 2nd degree
6	Pacemaker	Medtronic	L	1	Recurrent syncope
7	Pacemaker	St. Jude	L	1	Complete heart block
8	Pacemaker	St. Jude	L	2	Sick sinus syndrome
9	Pacemaker	Medtronic	L	2	Complete heart block
10	Pacemaker	Medtronic	L	2	Sick sinus syndrome
11	Pacemaker	St. Jude	L	1	Atrioventricular block 2nd degree
12	Defibrillator	St. Jude	L	3	Ischemic cardiomyopathy and LBBB
13	Pacemaker	Medtronic	L	2	Atrioventricular block 2nd degree
14	Pacemaker	Medtronic	L	1	Sick sinus syndrome
15	Defibrillator	Medtronic	L	1	Recurrent syncope

Abbreviations: CIED, cardiac implantable electronic device; LBBB, left bundle branch block.

Table 2 Patient's demographic and clinical characteristics

Case	Age	Sex	Vein involved	Presenting symptoms	Comorbidity
1	71	M	SCV + BC	Dysfunctional fistula	CHF
2	74	F	SCV	Dysfunctional fistula	DM, HTN
3	66	F	SCV + BC	Dysfunctional fistula, catheter dysfunction, upper limb swelling	No
4	66	M	SCV + BC	Dysfunctional fistula	DM, HTN
5	73	M	BC	Catheter dysfunction, upper limb swelling	DM, HTN, hypothyroidism
6	62	F	SVC	Catheter dysfunction	HTN
7	81	F	SVC	Dysfunctional fistula, catheter dysfunction	DM, HTN, hypothyroidism
8	75	F	SCV + BC	Catheter dysfunction, SVC syndrome	DM, HTN
9	75	M	BC	Dysfunctional fistula, limb swelling	DM, HTN
10	71	F	SVC	Catheter dysfunction	DM, HTN, cirrhosis
11	81	M	SVC	Catheter dysfunction	DM, HTN
12	56	M	SVC	Face swelling	DM, CHF
13	71	M	BC	Dysfunctional fistula	DM, HTN
14	63	F	SCV + BC	Catheter dysfunction	DM, HTN, CHF
15	79	F	SVC + SCV + BC	Dysfunctional fistula, limb swelling	DM, HTN

Abbreviations: BC, brachiocephalic vein; CHF, congestive heart failure; DM, diabetes mellitus; HTN, hypertension; SCV, subclavian vein; SVC, superior vena cava.

failed recanalization of chronic total occlusion of the left subclavian vein, and the patient required fistula embolization due to severe arm swelling. Another procedure failed initially to recanalize long segment occlusion involving the right subclavian vein/brachiocephalic vein (SCV/BCV) and SVC in a patient with history of Hickman line and left-sided CIED. This was successfully recanalized and angioplastied on a subsequent session.

No lead fracture or dislodgment was documented in any procedure. Electrocardiographic (ECG) changes occurred in two patients within 2 weeks postinterventions. One patient had premature atrial complexes on day 1 postprocedure with no subsequent CIED interrogation. The same patient had three subsequent angioplasty procedures with no reported ECG changes. The other patient had borderline ECG changes for lateral myocardial infarction 5 days postintervention. Both incidents were not related to device malfunction.

Even 2 weeks after the procedure, no procedure-related complication was documented. One of the patients developed hypotension 10 days after the angioplasty, and another patient had confusion; both were related to their underlying heart failure as documented by their primary physician.

Six-month primary patency was achieved in 62% (23/37) of the procedures. Ten patients (66%) required an average of 1.4 reinterventions (range: 1–4 interventions) during the follow-up time with mean time to reintervention of 318 days (5–1,380 days). Two patients required early reinterventions within 10 days due to catheter dysfunction. A total of 14 patients (93%) remain patent or with functional catheter at a mean follow-up time of 3.6 years (0.96–6 years). The last patient required fistula embolization due to failed recanalization of chronic occlusion of left subclavian vein.

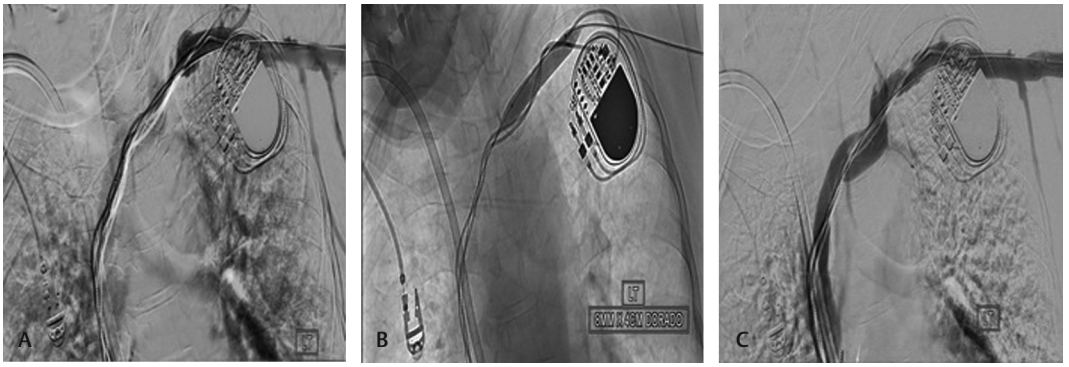

Fig. 1 (**A**) Focal stenosis at the subclavian vein at the point of lead insertion. (**B**) Balloon dilation with an 8 × 40 mm balloon. (**C**) Interval improvement of the stenotic area following the dilation.

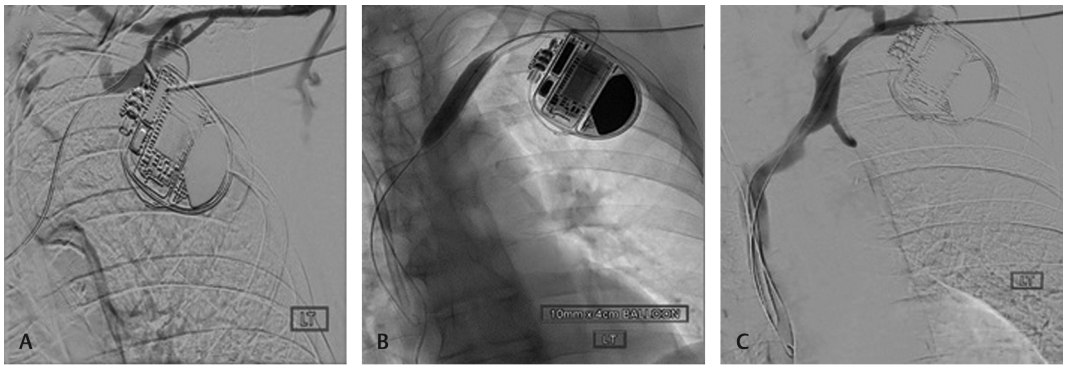

Fig. 2 (**A**) Another example of occluded subclavian vein where the lead was inserted. (**B**) Dilation with a 10 × 40 mm balloon. (**C**) Postballoon angioplasty with complete opacification.

Discussion

Balloon angioplasty without stent placement is currently the preferred method for the management of central venous stenosis related to either CIED or hemodialysis catheters.[5] Despite the concerns regarding the possible damage to CIED leads and further lead endothelialization, several studies have demonstrated the safety and effectiveness of balloon angioplasty across the CIED leads with no impact on wire integrity, position, or function on subsequent evaluation and lead interrogation.[1,5,7,8,12,14] Asif et al reported the outcomes of balloon angioplasty in 28 hemodialysis patients with central venous stenosis due to CIED leads. Clinical success was achieved in all patients with no procedure-related complications. The primary and secondary patency rates were 9 and 86% at 12 months, respectively, requiring an average of 2.1 procedures/year.[7] In the present study, primary patency at 6 months was 62%, and primary assisted patency without stent placement was 93% at a mean follow-up time of 3.6 years. In cases of stenoses refractory to balloon angioplasty, stent placement may be considered with or without lead extraction. Safe stent placement over CIED wires has been previously reported,[9,11-15] however, concerns remain regarding the long-term consequences of metallic stents on the function and integrity of entrapped CIED wires and the potential need to remove the leads in cases of malfunction and infection. Sotiriadis et al successfully treated five symptomatic patients with CEID-related CVO using sinus XL stents without lead extractions.[6,14] Only one patient reported early battery dysfunction requiring replacement 2 years sooner than expected.[14] Saad et al treated 14 patients with different stents and stent grafts across the lead wires with no complications related to device failure.[12] In a pooled analysis of 104 patients who underwent management of CEID-related CVO, 25 patients were treated with stent placement jailing the leads in 72% (18/25) of patients, with no reports of any adverse outcomes within median follow-up time of 9.5 months.[6] Other studies reported successful central venous recanalization and angioplasty with stent placement following lead extraction,[1,8,10,16] however, this approach is more invasive and associated with higher costs.[6,14] The American Society of Diagnostic and Interventional Nephrology recommends to avoid entrapment of CIED leads with stents, and to extract the leads whenever stent placement is deemed necessary.[5]

This study is limited by its small sample size, retrospective data collection, missing information on the date of pacemaker insertion, missing technical details related to balloon pressures and duration of inflation, and lack of systematic follow-up protocol and assessment of cardiac devices, including the scheduled CIED interrogation. However, findings of this study support the existing evidence on the safety and effectiveness of balloon angioplasty without lead extraction.

Conflict of Interest

None.

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