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Hybrid venous recanalization and cardiac implantable electronic device lead revision procedures: A single-center retrospective analysis of 38 patients☆

William M. Sherk[a], Minhaj S. Khaja[a,*], Eric D. Good[b], Ryan T. Cunnane[b], Narasimham L. Dasika[a], David M. Williams[a]

[a] Department of Radiology, Division of Vascular & Interventional Radiology, University of Michigan, 1500 E. Medical Center Drive, Ann Arbor, MI 48109, United States of America

[b] Division of Cardiology, Section of Electrophysiology, University of Michigan, 1500 E. Medical Center Dr, Ann Arbor, MI 48109, United States of America

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ABSTRACT

Purpose: The purpose of this study was to describe the safety and efficacy of hybrid recanalization procedures in a series of patients with obstructed central veins requiring cardiac implantable electronic device (CIED) revision.

Methods: Between 2008 and 2016, 38 consecutive patients (24 M; age 60.5 ± 16.2 years; range 25–87 years) with central venous obstruction underwent 42 recanalization interventions performed in conjunction with CIED revision or extraction. Fifty percent of patients (19/38) presented with veno-occlusive symptoms, and 13% (5/38) of patients had CIED leads with an ipsilateral upper extremity dialysis conduit.

Results: Ninety-one percent (38/42) of all procedures resulted in successful recanalization and CIED revision. Twenty-four percent (9/38) of all patients required secondary procedures due to recurrent stenosis, and 78% (7/9) of those requiring secondary procedures had indwelling dialysis conduits and/or clinical symptoms related to venous occlusion before the initial procedure. There were complications in 2 patients related to recanalization, and in 3 related to CIED revision.

Conclusions: Recanalization of central venous stenosis/occlusion in patients with CIED can be technically challenging but is successful in most patients. Symptomatic patients and those with dialysis conduits often require more aggressive revascularization interventions and may be at increased risk of complication or need for secondary interventions.

1. Introduction

As the population continues to age, the number of patient requiring transvenous cardiac implantable electronic devices (CIED) grows [1]. Many of these patients will require CIED revision due solely to veno-occlusive symptoms, while others will require CIED revision due to lead malfunction, need for device upgrade, or prophylactic lead management in the presence of concomitant veno-occlusive disease [1,2]. Venous stenosis or occlusion is frequently observed in patients following initial CIED implants (13–50%) and can significantly complicate plans for device revision [3–5]. The pathogenesis of venous occlusion following initial device implantation is complex and likely multifactorial, with number of indwelling leads, lead diameter and design, and patients' comorbidities suggested as risk factors [6–9]. Endovascular approaches to recanalization of chronically occluded central veins have been applied in the setting of CIED revision [10–14], but data are limited, especially in symptomatic patients and those with comorbid dialysis conduits. The purpose of this study was to describe the safety and technical success rates of venous recanalization procedures performed in conjunction with CIED revision.

2. Methods

2.1. Patient population, study design & data collection

Between May 2008 and March 2016, 38 consecutive patients underwent 42 attempted upper extremity or central venous recanalization procedures for CIED lead removal or revision at our tertiary-care center. Patients were selected from an existing venous recanalization database. Patients included in this analysis were adults > 18 years of age who

☆ Disclosures: consultant W.L. Gore & Associates and Boston Scientific Corp.

* Corresponding author.
E-mail addresses: wsherk@med.umich.edu (W.M. Sherk), mkhaja@med.umich.edu (M.S. Khaja), rcunnane@med.umich.edu (R.T. Cunnane), narasimh@med.umich.edu (N.L. Dasika), davidwms@med.umich.edu (D.M. Williams).

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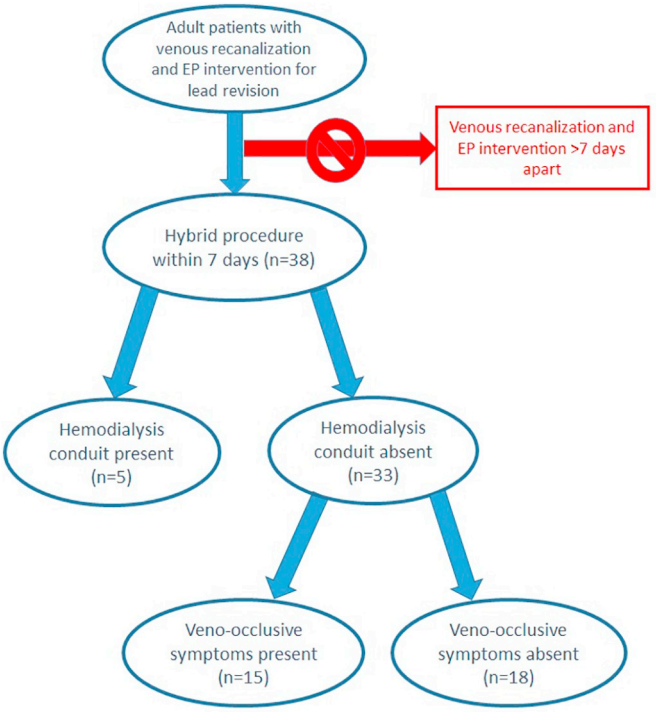

Fig. 1. Flow diagram of inclusion and exclusion criteria and included patients in the study.

underwent concurrent Electrophysiology (EP) and Interventional Radiology (IR) interventions in the same operative suite, or sequential procedures, first by IR, then EP in separate operative suites. Patients were excluded if they underwent recanalization > 7 days prior to EP intervention for lead revision (Fig. 1). Patients were categorized into one of three groups for analysis according to the presence of a hemodialysis conduit (n = 5), or the absence of a hemodialysis conduit and the presence (15) or absence (18) of symptoms of veno-occlusive disease. Patient characteristics are listed in Table 1. Three of the 38 patients (8%) underwent two or more combined IR and EP procedures.

Following Institutional Review Board approval, medical records of the included patients were retrospectively reviewed for patient demographics, clinical symptoms upon presentation, CIED and lead data, presence of dialysis conduit, recanalization intervention techniques (conventional guidewire or sharp recanalization, angioplasty, stent placement, etc.), and peri-procedural complications. Primary endpoints included technical success, defined by successful completion of lead revision or extraction via the recanalized vein, and safety, defined by incidence of post-procedural complications.

In all patients, upper extremity or central venous stenosis or occlusion were confirmed by venography, contrast-enhanced computed tomography (CT), or ultrasound (US) prior to intervention. Relevant clinical symptoms consisted of ipsilateral upper extremity swelling or SVC syndrome, the manifestations of which have been characterized elsewhere [15].

2.2. Interventions

Following a discussion between IR and EP to determine treatment goals, and in the majority of procedures, percutaneous upper extremity venous access was obtained using ultrasound through an ipsilateral brachial or basilic vein. Similarly, groin access was obtained in the greater saphenous and/or femoral veins. Standard contrast or CO2 venography was performed to highlight areas of stenosis or occlusion. All recanalization procedures initially employed standard catheter and wire techniques to cross the stenosis or occlusion (Fig. 2). Through-and-through access beyond the stenosis was thusly obtained in most instances.

Occlusions resistant to standard catheter and guidewire (e.g., 5 Fr angle taper Glidecath and 0.035″ angled Glidewire; Terumo; Shibuya, Japan) recanalization attempts were treated with sharp recanalization techniques [16]. In this scenario, catheters were advanced toward the occlusion through both the upstream and downstream vein. The intervening intravascular space was then eliminated by advancing either a transseptal needle (BRK-1; St. Jude Medical, Minnetonka, Minn.) and loop snare or by side-by-side balloon angioplasty. After through-and-through access was obtained, contrast was reinjected and intravascular ultrasound (IVUS) (Visions 035, Volcano Corporation; San Diego, CA) performed to confirm a secure tract. Balloon dilatation of the affected segment was then performed (Fig. 3). In patients with symptomatic venous obstruction resistant to balloon angioplasty alone, self-expanding stents, such as Wallstents (Boston Scientific, Natick, MA), were deployed after EP extraction any indwelling leads. In the case of superior vena cava (SVC) occlusion, all leads were removed prior to stent placement.

Once the stenosis or occlusion was crossed and venoplasty or stenting was performed, EP then performed the desired CIED revision procedure, either in the same operating room (joint procedure) or after transfer to a dedicated EP suite (tandem procedure) (Fig. 4). In the latter instance and prior to transport, a 4 or 5 Fr long vertebral tip catheter was advanced through a 6 or 7 Fr sheath, across the lesion and into the IVC in case subsequent EP venous access failed and accessory use of a fluoroscopic target catheter or balloon was necessary. The proximal, extra-luminal end of the catheter and sheath was secured to the patient under a sterile dressing.

Medical records following the procedure were examined to assess for patency of the recanalized veins, need for and number of repeat procedures, and anticoagulation regimen. Clinical recurrence of symptoms and follow-up imaging (venography, US, and CT) were factors in evaluation of clinical and imaging patency.

2.3. Statistical analysis

Results were presented as absolute or continuous variables and described by percentages or mean values ± standard deviation, as appropriate. Fisher's exact and Student *t*-tests were used to compare categorical and continuous variables between groups, respectively. A *p*-value of < 0.05 was considered statistically significant.

3. Results

3.1. Baseline characteristics

The clinical characteristics of the 38 patients included in this consecutive series are shown in Table 1. Table 2 shows the breakdown of devices and leads among patients. Patients were similar in age between groups. Patients with ipsilateral dialysis conduits more frequently had diabetes mellitus and chronic kidney disease relative to asymptomatic patients, with other cardiovascular comorbidities similar between groups.

The indication for CIED intervention was lead revision or replacement in 42% (16/38) of patients with successful recanalization procedures, device upgrade in 26% (10/38), lead extraction in 18% (7/38) and new device implantation in 13% (5/38). The average number of indwelling leads at the time of recanalization procedure was 1.9 ± 1.0. Following intervention, the average number of leads was 2.2 ± 1.3.

The most commonly observed sites of venous occlusion were in the subclavian vein (84%), followed by the innominate vein (50%), superior vena cava (SVC) (18%), and axillary vein (8%). Obstructions were noted in multiple veins in 44% (17/38) of patients.

Table 1
Patient characteristics.

A

Patient, n	38
Male, n	24 (63)
Age, yrs	61 ± 16
Hypertension, n	23 (61)
Dyslipidemia, n	20 (54)
Diabetes mellitus, n	11 (29)
Coronary artery disease, n	21 (55)
Congestive heart failure, n	31 (82)
Left Ventricular Ejection Fraction, %	39.9 ± 18.3
Peripheral arterial disease, n	8 (21)
Chronic kidney disease	12 (32)
Hemodialysis, n	6 (16)
History of malignancy, n	7 (18)
Prior venous thromboembolism, n	10 (26)
Pre-index OAC, n	25 (66)
Pre-index OAP, n	16 (42)

Data are shown as mean ± 1 standard deviation. Percent values are shown in parentheses.

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Data are shown as mean ± 1 standard deviation. Percent values are shown in parentheses. ICD = implanted cardioverter defibrillator; OAC – Oral anticoagulant therapy (aspirin, clopidogrel); OAP = Oral antiplatelet therapy (warfarin, apixiban).

B: by cohort

Demographic	Total patient population	Patients w/o VOS	Patients w/ VOS	*p* value	Patients w/ IDC	*p* value
Patient, n	38	18	15		5	
Mean Age, yr	63.8 ± 15.7	62.0 ± 15.7	65.9 ± 17.7	0.5121	65.6 ± 4.5	0.4024
Age Range, yr	25.0–87.0	38.0–90.0	25.0–87.0		59.0–71.0	
Male	24 (63)	11 (61)	8 (53)	0.6622	5 (100)	0.1013
LVEF (%)	39.0.9 ± 18.3	41.4 ± 17.6	33.7 ± 17.5	0.2187	53.8 ± 13.4	0.0814
Prior venous thromboembolism	10 (26)	5 (28)	2 (13)	0.3195	3 (60)	0.1906
Hypertension	23 (61)	10 (56)	9 (60)	0.8002	4 (80)	0.3326
Dyslipidemia	20 (54)	10 (56)	8 (53)	0.9000	2 (40)	0.5469
Diabetes mellitus	11 (29)	3 (17)	3 (20)	0.8077	5 (100)	0.0007
Coronary artery disease	21 (55)	9 (50)	8 (53)	0.8510	4 (80)	0.2417
Peripheral artery disease	8 (21)	4 (22)	1 (7)	0.2217	3 (60)	0.1122
Congestive heart failure	31 (82)	13 (72)	14 (93)	0.1273	4 (80)	0.7251
Chronic kidney disease	12 (32)	3 (17)	4 (27)	0.4933	5 (100)	0.0008
Hemodialysis	6 (16)	1 (6)	0	0.3422	5 (100)	< 0.0001
History of malignancy	7 (18)	3 (17)	4 (27)	0.4933	0	0.3328
Pre-index OAC	25 (66)	12 (67)	8 (53)	0.4421	5 (100)	0.1419
Pre-index OAP	16 (42)	9 (50)	5 (33)	0.3422	2 (40)	0.6985

†Data are shown as mean ± 1 standard deviation (SD). Percent values are shown in parentheses. IDC = ipsilateral dialysis conduit; VOS = veno-occlusive symptoms; OAC = Oral anticoagulant therapy (warfarin, apixiban, etc.); OAP = Oral antiplatelet therapy (aspirin, clopidogrel, etc.).

3.2. Procedure outcomes

Recanalization was successful in 91% (38/42) of all procedures and led to successful CIED revision or removal. Of the 38 successful procedures, 76% (29/38) involved angioplasty alone, and 24% (9/38) required angioplasty and stent placement in the affected veins. Sharp recanalization techniques were performed to traverse venous occlusions in 29% (11/38) of successful cases. Recanalization was performed for 19 (50%) patients who had symptoms of ipsilateral upper extremity swelling or SVC syndrome and in 5 (13%) patients with existing dialysis conduits. Following recanalization, stents were placed in 7 of 19 (37%) patients with symptoms and 2 of 5 (40%) patients with conduits. Sharp recanalization was required in 5 (33%) of the symptomatic patients and 2 (40%) of the patients with conduits. In contrast, no asymptomatic patients required stent placement, and 4 of 18 (22%) asymptomatic patients needed sharp recanalization. Following recanalization, the CIED procedures were successful in 11/11 joint procedures and 27/31 (87%) tandem procedures.

All but 3 treated patients (92%) were discharged on anticoagulation (enoxaparin, warfarin, rivaroxaban, or apixaban), antiplatelet (aspirin or clopidogrel), or a combined anticoagulant-antiplatelet regimen following intervention. This included 29% (10/35) on anticoagulant

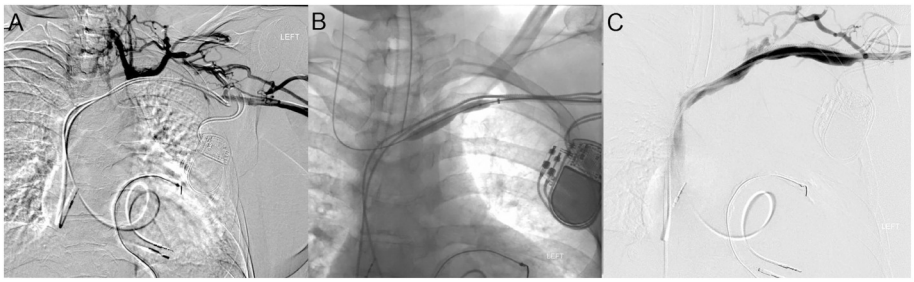

Fig. 2. (A) Initial contrast venogram revealed occlusions of the left axillary and left subclavian vein extending into the innominate vein and numerous surrounding collateral vessels. (B) A guidewire was advanced past the occlusion and into the contralateral internal jugular vein and balloon angioplasty performed. (C) Post-intervention venogram demonstrated patency of the subclavian and contrast flow into the right atrium. A catheter was positioned in the IVC, and the patient was transported for lead revision.

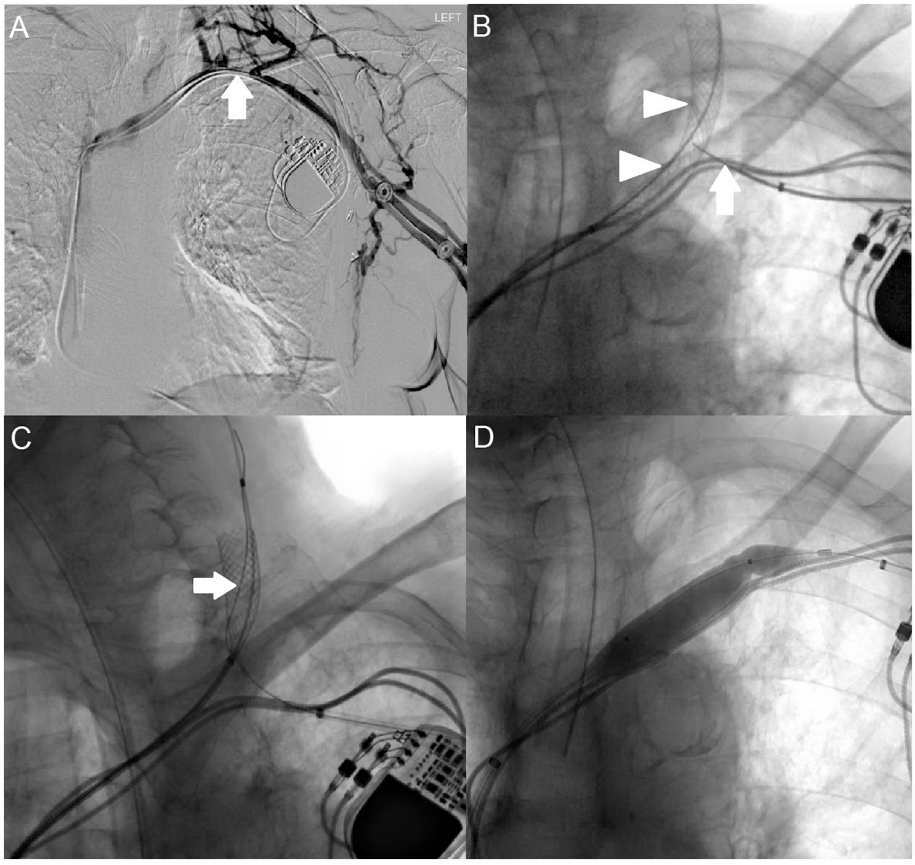

Fig. 3. (A) Initial venogram showed occlusion of the left subclavian vein (arrow). (B) Despite several attempts, a guidewire was unable to be advanced from either the downstream or upstream vein past the occluded segment. From the greater saphenous vein access, a stent was positioned in the ipsilateral internal jugular vein and partially deployed (arrowheads). This acted as a target for the trans-septal needle (arrow), which was carefully advanced toward and through the stent. (C) After sharp recanalization, the guidewire (arrow) was retracted with the stent into the sheath, thereby attaining through-and-though access. (D) Balloon angioplasty was then performed across the stenosis. The patient subsequently underwent lead revision.

therapy only, 17% (6/35) on antiplatelet therapy only, 6% (2/35) on dual-antiplatelet therapy, 31% (11/35) on both anticoagulant and single antiplatelet therapy, and 17% (6/35) on anticoagulant and dual antiplatelet therapy. Twenty-five percent (9/36) of patients with an initially successful procedure required additional angioplasty, new stent placement, or catheter thrombolysis after the initial procedure because of recurrent obstruction. The average number of additional procedures was 2.0 (range 0–8) for patients with dialysis conduits and 0.6 for those without, including 1.1 (range 0–7) for symptomatic and 0.2 (range 0–2) for asymptomatic patients. One patient underwent 7 separate procedures, and a second underwent 8 additional procedures. Both patients were symptomatic from venous occlusive disease prior to

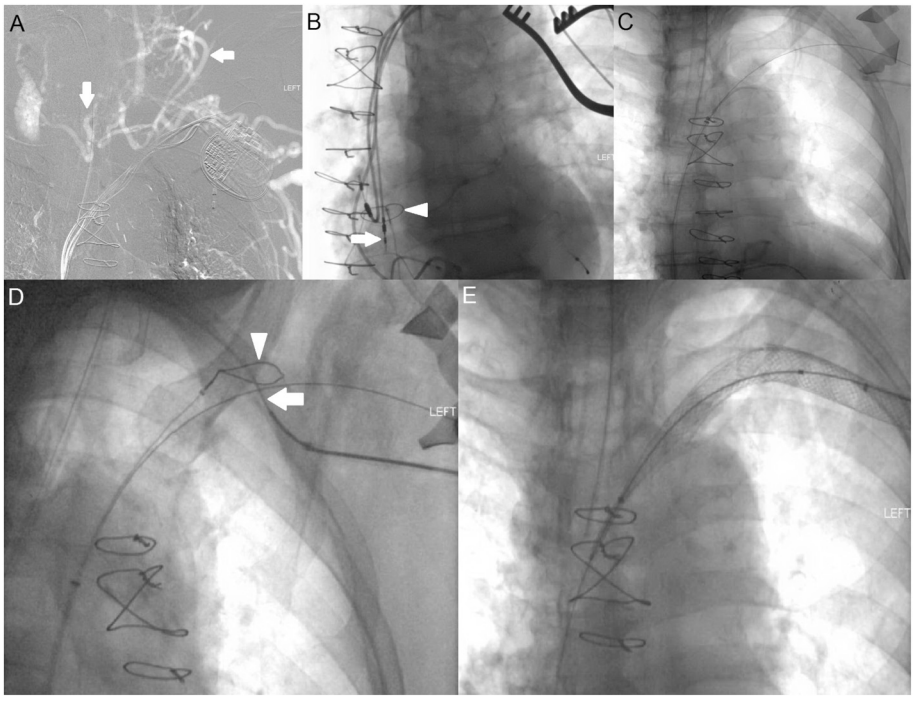

Fig. 4. (A) CO_2 venogram demonstrated long segment occlusion of the subclavian and innominate veins and SVC with multiple collaterals (arrows). (B) To assist in right atrial lead extraction, a loop snare (arrowhead) was advanced into the right atrium and used to capture the free end of the partially extracted lead (arrow). Tension from the subclavian wound pocket and counter-tension from the femoral access allowed laser extraction. (C) After the lead removal, a stiff guidewire was advanced through the sheath back into the right atrium and captured with the loop snare, thereby establishing through-and-through access from right femoral vein to wound pocket. The remaining leads were extracted. (D) Vertebral tip catheters in the upstream and downstream veins were advanced toward the remaining occluded segment. To eliminate the remaining 3–4 cm gap between the catheters, a trans-septal needle was advanced from the brachial access toward the transfemoral loop snare and captured. The needle trocar was exchanged for a guidewire. Angioplasty was then performed (not shown). (E) Stents were deployed from the left axillary vein to innominate-SVC junction. The new generator and leads were then placed.

Table 2
CIED characteristics.

Pre-intervention generator type (n = 42)	
None	7 (17)
Pacemaker (single chamber)	4 (10)
Pacemaker (dual chamber)	9 (21)
Pacemaker (atriobiventricular)	2 (5)
ICD (single chamber)	1 (2)
ICD (dual chamber)	11 (26)
ICD (biventricular)	8 (19)
Directionality	
Left	31 (74)
Right	4 (10)
N/A	7 (17)
Indwelling transvenous leads (n ± SD)	
Pre-intervention	1.9 ± 1.0
Post-intervention	2.2 ± 1.3

†Data are shown as mean ± 1 standard deviation (SD). Percent values are shown in parentheses.

initial intervention. The second patient had an indwelling upper extremity dialysis fistula and previously had been treated for ipsilateral innominate vein occlusion. The other 7 patients underwent a total of 13 additional procedures, one of whom underwent only 1 repeat intervention. A total of 29 patients required only a single intervention with average follow-up of 548.0 ± 470 days.

There were 2 complications (5.3% of total interventions) related to recanalization procedure and 3 (5.7%) related to CEID implantation. One patient underwent surgical repair of a greater saphenous vein pseudoaneurysm related to percutaneous access during recanalization. An additional patient had recurrent venous occlusion the same day of the recanalization procedure, necessitating an additional intervention. CEID-related minor complications included 1 hematoma, 1 incisional wound dehiscence requiring pocket revision, and 2 pocket infections. No CEID-related major complications occurred.

4. Discussion

Central vein recanalization in patients with obstruction who require CIED revision is technically successful in most instances and has a low rate of complications. Additionally, it avoids the unnecessary use of contralateral central veins and obviates unconventional implant approaches by the electrophysiologist such as lead tunneling from the contralateral side.

Successful recanalization and lead revision procedures necessitate close collaboration and procedural planning between the electrophysiologist and interventional radiologist. Of fundamental importance is the ability to achieve through-and-through guidewire and catheter access across the occluded segment. Not only is this necessary for PTA, but through-and-through access also facilitates extraction of chronic leads by providing a visual reference to the luminal course of the vessel, which is often distinct from an endothelialized lead body, and also provides a 'rail' against which laser or other extraction tool may be guided. Reciprocally, extraction tract patency is often lost during simple traction or advanced transvenous lead extraction (TLE) techniques. Performing through-and-through access before lead extraction not only secures a conduit for subsequent revision, but also provides the IR with fluoroscopic and anatomic information about the vessels' course.

In instances of tandem procedures, immediate transfer of care to EP with trans-stenotic access in-place avoids the risk of acute re-occlusion of the patent veins, especially in the cohort of patients with co-morbidities (end-stage renal disease, etc.) predisposing to venous thrombosis. In this series, the timing of this was generally within a few hours of recanalization, and the patient was transferred directly from IR to EP with trans-stenotic access catheters in-place. In a few instances, however, clinical factors and/or procedural scheduling necessitated a tandem procedure time interval of between several hours and several days. In these instances, standard dose-adjusted heparin infusions were started and discontinued an hour prior to EP intervention. If the tandem procedure time interval was expected to exceed several days, warfarin anticoagulation was started concomitantly and the subsequent EP CIED revision procedure was performed on therapeutic warfarin anticoagulation with INR in the range of 1.7–3.2.

In patients with flow-limiting stenosis following balloon venoplasty, stent placement was performed only after indwelling lead extraction to avoid jailing the leads between the stent and vessel wall. Venous access is a primary concern in both CIED and dialysis patients, and lead extraction rather than abandonment is favored at our institution to avoid potential associated risks with retained leads [17,18]. Limited reports of central venous stent placement alongside leads have suggested overall low risk of lead malfunction, but chronic pressure effects by stents on electrode insulation are not known [12,19].

The incidence of stent placement versus angioplasty alone was higher relative to that in asymptomatic patients in the subset of patients with veno-occlusive symptoms (0 vs 37%, $p = 0.0048$) and coexisting dialysis conduits (0 vs. 40%, $p = 0.0060$) (Table 3). The use of sharp recanalization, in contrast, was not significantly different in asymptomatic patients compared to symptomatic patients (22% vs. 26%, $p = 0.7748$) and patients with dialysis conduits (22% vs. 40%, $p = 0.4335$). Symptomatic patients and those with dialysis conduits required re-intervention sooner to maintain ipsilateral central venous patency (Table 4).

The predisposition to central vein stenosis in hemodialysis patients is well known [20–24]. However, the complicated relationship between chronic CIED leads, dialysis fistulae, and the development of chronic venous stenosis remains poorly understood. Studies show that fibrin deposits on lead insulation within one week of initial implantation, eventually forming a capsule around the lead [25,26]. Gradually, a monolayer of endothelial-like cells cover the capsule, providing a mechanism for foreign body persistence. Microscopic dystrophic calcification in the surrounding fibrin capsule accumulates with higher frequency in patients with end-stage renal disease [27]. The high flow induced by an ipsilateral dialysis conduit may also exacerbate existing endothelial damage caused by trauma from initial placement, lead insulation degradation, or lead fractures, thereby promoting intimal hyperplasia, thrombosis, and eventual occlusion [20]. Studies have shown that anticoagulation and/or antiplatelet therapy can interrupt this cascade and reduce the likelihood of occlusion [28,29].In addition, certain operator implant techniques, such as careful attention to sheath side-port flushes and leading sheath insertion with a wire to avoid sidewall trauma have demonstrated to be associated with reduction in vascular trauma and occlusion [30].

Table 3
Intervention type divided by cohort.

Procedure	Lead revision, ASX (n = 18)	Lead revision, VOS (n = 19)	*p* value	Lead revision, IDC (n = 5)	*p* value
Unsuccessful recanalization	2 (11)	2 (11)	1.0000	0	0.4455
PTA alone	16 (89)	10 (53)	0.0174	3 (60)	0.1403
PTA and stent placement	0	7 (37)	0.0048	2 (40)	0.0060
Sharp recanalization	4 (22)	5 (26)	0.7748	2 (40)	0.4335

†Percent values are shown in parentheses. ASX = asymptomatic; VOS = veno-occlusive symptoms; IDC = ipsilateral dialysis conduit.

Table 4
Number of re-interventions for ipsilateral central vein occlusion with or without corresponding CIED revision and average length of time to first re-intervention.

Procedure	Patients without VOS (n = 18)	Patients with VOS (n = 15)	*p* value	Patients with IDC (n = 5)	*p* value
Number of patients requiring re-intervention	2 (22)	5 (33)	0.1257	2 (40)	0.1403
Number of re-interventions per patient	0.2 ± 0.63	1.1 ± 2.06	0.0843	2.0 ± 3.10	0.0258
Average time to first re-intervention (d)	649.5 ± 429.5	185.0 ± 236.7	0.0004	72.5 ± 10.5	< 0.0001

†VOS = veno-occlusive symptoms; IDC = ipsilateral dialysis conduit.

In this series of patients, anticoagulation and antiplatelet regimens following intervention were highly variable and guided by individual patient clinical variables and underlying cardiovascular diseases. After stent placement, patients were continued on anticoagulation and prescribed aspirin and clopidogrel when not already prescribed. Acute in-stent thrombosis with reappearance of clinical symptoms occurred in two patients 13 and 15 days post-procedure and was an indication for re-intervention. For those patients requiring secondary interventions after balloon angioplasty, the same factors that caused the initial stenosis presumably contributed to recurrence. However, the explanation for subacute and chronic occlusion of central venous stents placed at the time of CIED revision was more ambiguous. A previous study by Neglen et al. analyzing long-term stent-related outcomes in iliofemoral venoocclusive disease suggested recurrent thrombotic events as the cause of stent occlusion rather than slowly evolving narrowing related to progressive in-stent stenosis [31]. The overlap of the histologic entities of organizing thrombus and intimal hyperplasia adds to the confusion [32]. Strict adherence to an anticoagulant and antiplatelet regimen immediately post-intervention, during the postoperative hospitalization, and afterward may mitigate some risk of recurrence. The ideal anticoagulant/antiplatelet regime and timing of initiation in the presence of CIED revision, however, is uncertain, may lead to post-intervention bleeding complications or re-occlusion, and warrants further investigation. Similarly, newer techniques such as scoring or drug-coated balloon angioplasty deserve further investigation in this patient cohort [33,34].

This study has several limitations. This is a single-center experience using retrospective methodology. Additionally, this study presents a heterogeneous population of patients with varying complexity of recanalizations. For 10 of the 38 patients, the patency of the recanalized veins was only assessed by immediate post-intervention venography. Rigorous long-term assessment of both clinical and radiographic patency was therefore limited, guided by clinical factors rather than protocol. Additional recanalization tools such as radiofrequency wires were not investigated in our series and warrant further study in the setting of indwelling CIED leads. Clearly, a more thorough understanding of the pathologic and biomechanical development of central venous stenosis will contribute to further advances in lead technology, placement and extraction techniques, and revision strategies.

5. Conclusion

Venous recanalization procedures performed concurrently with electrophysiology interventions facilitate lead revision in patients with central venous obstruction.

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