

Approach, Technical Success, Complications, and Stent Patency of Sharp Recanalization for the Treatment of Chronic Venous Occlusive Disease: Experience in 123 Patients

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Abstract

Purpose To report the technical success and complications following sharp recanalization of chronic venous occlusions.

Materials and Methods A total of 123 patients, including 75 (61.0%) men and 48 (39.0%) women, with mean age of 50.5 ± 17.5 years (range 19–90 years), underwent sharp recanalization of chronic venous occlusions. The etiologies of occlusion were chronic deep venous thrombosis ($n = 43$; 35.0%), prior central venous access ($n = 39$; 31.7%), indwelling cardiac leads ($n = 21$; 17.1%), and occluded venous stents ($n = 20$; 16.3%). The sites of venous

occlusion included 59/123 (48.0%) thoracic central veins, 37 (30.1%) non-thoracic central veins, and 27 (22.0%) peripheral veins. Median length of occlusion was 3.2 ± 1.4 cm (range 1.3–10.9 cm).

Results Sharp recanalization was most commonly attempted with transseptal needles in 108/123 (87.8%), with a mean number of 1.2 ± 0.4 crossing devices per patient (range 1–4 devices). Targeting devices included a loop snare ($n = 92$; 74.8%), partially deployed Wallstent ($n = 21$; 17.1%), partially deployed Amplatzer vascular plug ($n = 8$; 6.5%), and an angioplasty balloon ($n = 3$; 2.4%). Technical success was achieved in 111 (90.2%) patients. There were 3 (2.4%) severe, 1 (0.8%) moderate, and 7 (5.7%) minor adverse events. Severe adverse events included 1 case each of pericardial tamponade, hemothorax, and inferior vena cava filter occlusion. 88 (71.5%) patients had venous stents placed; at the last follow-up examination, 68/86 (79.0%) stents were patent.

Conclusion Sharp recanalization has a high technical success and low rate of adverse events in the recanalization of chronic venous occlusions.

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Introduction

Chronic venous occlusions commonly arise as a sequela of deep vein thrombosis, chronic hemodialysis, implantable pacemaker wires, malignancy, and prior central access [1–3]. Clinically, patients present with pain and edema in the involved upper or lower extremity venous territory [1, 4]. Furthermore, chronic venous occlusions in hemodialysis patients are associated with high venous pressures which may lead to prolonged post-dialysis bleeding, access site pseudoaneurysms, and access failure [5].

Although most chronic venous occlusions may be crossed and treated with blunt recanalization using a guidewire and catheter, there are reports of failures requiring advanced techniques [6]. Sharp recanalization, in which a sharp wire or needle is passed through the occlusion under image guidance, has been described in several case series, the largest which included 39 patients, using a variety of devices and techniques with variable outcomes [6, 7].

The objective of this report is to describe the technical success and complications of a large series of patients who underwent sharp recanalization of chronic venous occlusions.

Materials and Methods

Patient Selection

Informed consent was not required for this retrospective review that was conducted with institutional review board approval (IRB HUM00140165) and complied with the Health Insurance Portability and Accountability Act. All patients who underwent sharp recanalization of chronic venous occlusive disease from May 2001 to August 2017 (198 months) were identified using the *Electronic Medical Record Search Engine*, a free-text medical record search tools, using the terms “sharp,” “recanalization,” and “vein(s)” [8].

Inclusion and Exclusion Criteria

Patients were included for review if they had undergone attempted sharp recanalization for a chronic central or peripheral venous occlusion, with occlusion signifying 100% narrowing and chronic defined as greater than 28 days in accordance with *Society of Interventional Radiology* guidelines [9]. Sharp recanalization was defined as an attempt to cross an occlusion with a needle or stiff end of a wire. Patients were considered for sharp recanalization if they had symptoms referable to a venous occlusion which was confirmed on venography, had failed blunt

recanalization, were medically stable for recanalization attempt, and did not have an uncorrectable coagulopathy.

Patient Demographic Data

In 123 patients, 75 (61.0%) patients were men with mean age of 50.5 ± 17.5 years (range 19–90 years). The etiologies of occlusion were chronic deep venous thrombosis ($n = 43$; 35.0%), prior central venous access ($n = 39$; 31.7%), indwelling cardiac leads ($n = 21$; 17.1%), and occluded venous stents ($n = 20$; 16.3%). No obstructions were due to malignancy.

Description of Occlusion

The site of occlusion was classified as central if it involved the subclavian vein, brachiocephalic vein, superior vena cava (SVC), inferior vena cava, ilio caval confluence, or common iliac vein, with central thoracic venous occlusions further categorized by *The Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction* [9]. *Categorization of venous occlusions is shown in Table 1, and full description of all unique occlusion sites is shown in Supplementary Table 1.* Ninety-six (78.0%) occlusions were central. The most common individual sites of occlusion were the left subclavian vein ($n = 15$; 12.2%), superior vena cava ($n = 13$; 10.6%), and right subclavian vein ($n = 9$; 7.3%). The median occlusion length was 3.2 ± 1.4 cm (range 1.3–10.9 cm), as measured by an attending interventional radiologist on digital subtraction venography.

Sharp Recanalization Technique

All patients were seen in consultation by an attending interventional radiologist prior to the procedure. A total of 114 (92.7%) cases were completed under general anesthesia, and 9 (7.3%) were completed under moderate sedation with fentanyl and midazolam. When the operator determined blunt recanalization to be futile (whether due to lack of recanalization process or excessive fluoroscopy usage), sharp recanalization was performed as described previously [10–12].

Briefly, under fluoroscopic guidance, a vascular sheath (Cook Medical; Bloomington, IN) was placed adjacent to the site of venous occlusion, and a second access was obtained on the opposite side of the occlusion. After placement of the target device, the occlusion was crossed using a needle or the back end of a wire. Multiple orthogonal fluoroscopic views were employed to visualize the path of the crossing device. An exchange length 0.018-inch wire was then placed, establishing thru-and-thru access. The occlusion was dilated with a 4-mm angioplasty

Table 1 Description of occlusion and technical success

Variable	Number of cases	Technical success	<i>P</i> value (Chi-square)
Site of occlusion			0.60
Central vein	96 (78.0)	88 (91.7)	
Thoracic central vein	59 (48.0)	54 (91.5)	
Type 1C	26 (21.1)	24 (92.3)	
Type 2B	17 (13.8)	15 (88.2)	
Type 4	16 (13.0)	15 (93.8)	
Non-thoracic central vein	37 (30.1)	34 (91.9)	
Peripheral vein	27 (22.0)	23 (85.2)	
Lower extremity vein	19 (15.4)	17 (89.5)	
Upper extremity vein	8 (6.5)	6 (75.0)	
Length of occlusion			0.31
Less than or equal to 2.5 cm	32 (26.0)	29 (90.6)	
2.5 to 4.0 cm	52 (42.3)	49 (94.2)	
Greater than 4.0 cm	39 (31.7)	33 (84.6)	
Presence of occluded stent			0.90
Yes	19 (15.4)	17 (89.5)	
No	104 (84.6)	94 (90.4)	

Description of occlusion and initial technical success stratified by occlusion characteristics. All entries are of the form Number (%). Thoracic central vein occlusion classifications are per the Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction. Briefly, Type 1C obstructions are unilateral internal jugular or subclavian vein obstructions, Type 2B obstructions are unilateral brachiocephalic vein obstructions, and Type 4 is any obstruction that involves the superior vena cava [9]. *P* values refer to results of Chi-square analysis of the respective categorical variables

balloon, and repeat venography using half-strength contrast (Iovue 300; Bracco Diagnostics; Monroe Township, NJ) was performed to determine whether there was extravasation. If extravasation was noted, a 3-min prolonged balloon inflation (sized by the estimated diameter of the vessel) was performed followed by repeat venography.

Gradual balloon angioplasty of the occlusion was then performed, with stent placement if there was an extra-anatomic course, poor antegrade flow, residual stenosis, or thrombus noted on intravascular ultrasound or contrast venography. Stents were sized according to the diameter measured on intravascular ultrasound or contrast venography.

Variables and Outcomes

Crossing and targeting devices, technical success, complications, and stent patency were reported. Technical success was defined as successful venous recanalization with restoration of antegrade flow through the recanalized vein. Adverse events were prospectively documented and retrospectively classified as minor, moderate, or severe per the Society of Interventional Radiology Adverse Event Classification [13]. To assess long-term stent patency, the last date of imaging follow-up was used and was defined as the

last relevant vascular imaging exam (Ultrasound, contrast-enhanced computed tomography, or contrast venography).

Statistical Analysis

Calculations of percentages, means, and ranges were performed with statistical spreadsheet software (Microsoft Excel; Microsoft; Redmond, WA). Chi-square analysis was used to assess the impact of several variables on technical success, with a threshold of $P < 0.05$ representing statistical significance.

Results

Technical Aspects of Sharp Recanalization

Contrast venography was employed in 123 (100%) procedures, and intravascular ultrasound was employed in 110 (89.4%) procedures. The most frequently employed crossing devices were the BRK™ or BRK-1™ transseptal needles (St. Jude Medical; St. Paul MN), at least one of which was employed in 106/123 (86.2%) procedures (Figs. 1 and 2). The stiff (back) end of a Glidewire (Terumo; Tokyo, Japan) was employed in 11 (8.9%) procedures, and the stiff (back) end of a V-18 ControlWire

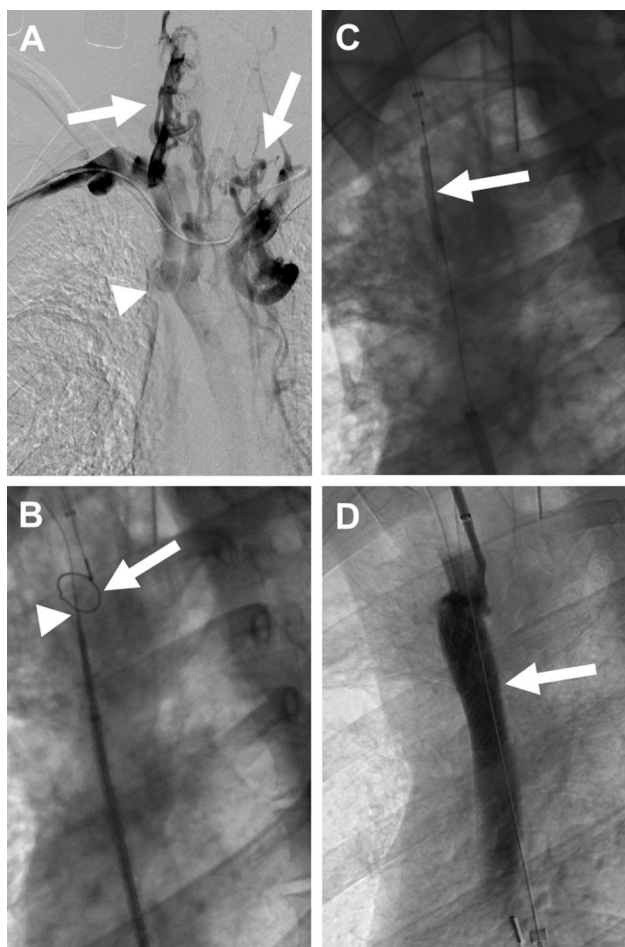


Fig. 1 A 25-year-old man with cystic fibrosis and multiple prior central venous lines and ports, complicated by chronic occlusion of the superior vena cava (SVC). Patient presented with chronic SVC syndrome. **A** Central venogram demonstrating occlusion of the brachiocephalic vein and superior vena cava with collaterals in the neck (white arrows) as well as prominent filling of the azygous vein (white arrowhead). **B** A BRK-1 (white arrowhead) needle (St. Jude Medical) was used to target an Amplatzer Gooseneck snare (ev3; Paris, France) positioned from a right neck approach (white arrow) for sharp recanalization. **C** Balloon dilatation of the recanalized segment was performed (white arrow). **D** Stent-graft reconstruction was performed using a Palmaz 3110 (Cordis) and an overlapping 16 × 60 mm Wallstent Endoprosthesis (Boston Scientific) which were dilated to 16 mm. Following stent reconstruction, contrast injection revealed free flow through the superior vena cava (white arrow)

(Boston Scientific, Marlborough, MA) was employed in 4 (3.3%) procedures. An average of 1.2 ± 0.4 crossing devices was employed per procedure (range 1–4 devices). *Description of all crossing devices employed is shown in Table 2.*

A targeting device was used in 121 (98.4%) procedures, which consisted of a loop snare in 90/123 (73.2%) procedures (Fig. 1), a partially deployed Wallstent endoprosthesis (Boston Scientific) in 20 (16.3%) procedures, a partially deployed Amplatzer vascular plug (St. Jude

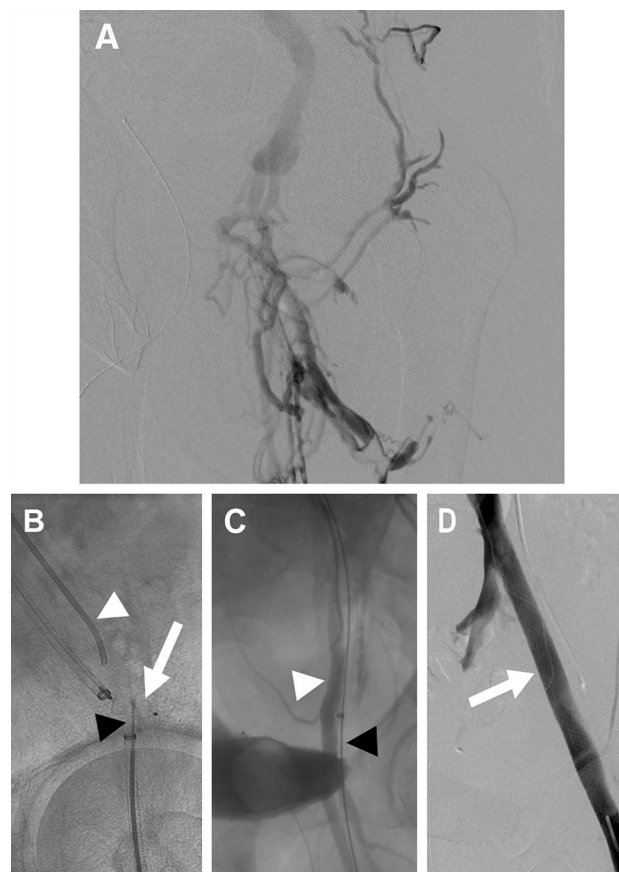


Fig. 2 A 62-year-old man with chronic left lower extremity deep vein thrombosis and history of intravenous drug abuse. He presented with a chronic left lower extremity wound and venous stasis ulcers resistant to optimal medical therapy. **A** Venography of the left pelvis revealing occlusion of the left external iliac vein and collateral vessel formation. **B** Sharp recanalization was performed from a transpopliteal approach using a BRK-1 needle (black arrowhead) which was used to puncture the expanded 8 mm Amplatzer plug target (white arrow). Intermittent injection of contrast through the arterial catheter was performed (white arrowhead) to ensure the femoral or external iliac arteries were not traversed. **C** The Amplatzer plug was reconstrained thereby obtaining through-and-through access (black arrowhead). Arterial injection (white arrowhead) once again revealed no evidence for arterial injury. **D** Stent reconstruction of the left external iliac vein was performed using overlapping 16 mm × 60 mm and 14 mm × 60 mm Wallstents. These were dilated to 14 mm. Digital subtraction venography reveals a widely patent stent reconstruction

Medical) in 8 (6.5%) procedures (Fig. 2), an angioplasty balloon alone in 1 (0.8%) procedure, a snare and angioplasty balloon in 1 (0.8%) procedure, and a partially deployed Wallstent, snare, and angioplasty balloon in 1 (0.8%) procedure. There were 2 (1.6%) cases of technical failure in which no target was introduced, as even with sharp methods, not even the proximal component of the occlusion was recanalized, so there was no need for a target. The median targeting device size was 15 mm (range

Table 2 Devices employed for crossing venous occlusion

Crossing device	N (%)
BRK (18G) transseptal needle (St. Jude Medical, St. Paul MN)	73 (59.3)
BRK-1 (18G) transseptal needle (St. Jude Medical, St. Paul MN)	50 (40.7)
Stiff end of a 0.035 Glidewire (Terumo; Tokyo, Japan)	11 (8.9)
Stiff end of V-18 ControlWire (Boston Scientific)	4 (3.3)
Stiff end of Amplatz Super Stiff Guidewire (Boston Scientific)	3 (2.4)
Rosch-Uchida Transjugular Liver Access Needle (Cook Medical; Bloomington, IN)	2 (1.6)
Chiba biopsy needle (Cook Medical; Bloomington, IN)	1 (0.8)
Rosen needle (Skylar Surgical; West Chester, PA)	1 (0.8)
Brockenbrough transseptal needle (Medtronic; Minneapolis, MN)	1 (0.8)
Total N = 146	

These numbers describe the total number of each device used. Some patients had more than one crossing device employed for recanalization. Therefore, total N is larger than the total number of patients. All entries are of the form Number (%)

Table 3 Size of employed targeting devices

Targeting device size	N (%)
≤ 5 mm	1 (0.8)
> 5 mm but ≤ 10 mm	43 (35.0)
> 10 mm but ≤ 15 mm	68 (55.3)
> 15 mm but ≤ 20 mm	6 (4.9)
> 20 mm	6 (4.9)
Total N = 124	

These numbers describe the total number of devices used. Some patients had more than one device deployed for recanalization. Therefore, the total N is larger than the total number of patients in which targets were employed. All entries are of the form Number (%)

Table 4 List of stents employed in stent reconstruction

Stent	N (%)
Wallstent (Boston Scientific)	77 (87.5%)
Viabahn (Gore)	7 (8.0%)
Palmaz (Cordis)	6 (6.8%)
Z-Stent (Cook Medical)	3 (3.4%)
cTAG (Gore)	1 (1.1%)
Endurant (Medtronic; Minneapolis, MN)	1 (1.1%)
AneuRx (Medtronic)	1 (1.1%)
Fluency (Bard; Murray Hill, NJ)	1 (1.1%)
iCAST (Atrium Medical)	1 (1.1%)
SmartControl (Cordis)	1 (1.1%)
Total N = 99	

These numbers describe the total number of patients that had at least one of a stent type used. Some patients had more than one stent type employed for recanalization. Therefore, the total N is larger than the total number of patients that underwent stent reconstruction. All entries are of the form Number (%)

4–40 mm). *Full description of target sizes is shown in Table 3.*

Stent reconstruction was performed in 88 (72%) patients, with a median of 3 stents per reconstruction (range 1–12). Of the 88 patients who underwent stent reconstruction, 77 (87.5%) received Wallstents (Boston Scientific), 7 (8.0%) received Viabahn stent-grafts (Gore Medical; Flagstaff, AZ), and 6 (6.8%) received Palmaz stents (Cordis; Milpitas, CA), *with full list of stents in Table 4.* The most common stent lengths employed were 60 mm (N = 179), 40 mm (N = 53), and 90 mm (N = 29), *with full description of stent lengths in Supplementary Table 2.* Balloon-expandable stents were employed in 7 (5.7%) patients for treatment of occlusions of the SVC (N = 5), right brachiocephalic vein (N = 1), and right subclavian vein (N = 1).

Technical Success of Sharp Recanalization

In 123 patients, 111 (90.2%) patients had a technically successful recanalization on the first procedure. Four out of 12 (33.3%) initial technical failures underwent a repeat intervention, and 2/4 (50.0%) were successful. There was no significant difference in initial technical success rate when stratified by site of occlusion (P = 0.60), length of occlusion (P = 0.31), or presence of prior occluded stent (P = 0.90) (Table 1).

Adverse Events

There were 3/123 (2.4%) severe adverse events. Specifically, in 1 (0.8%) procedure, there was perforation of the right brachiocephalic vein with resulting right hemothorax during a successful recanalization of an occluded right jugular vein with a transseptal needle and loop snare, managed with placement of a 10 mm × 4 cm Fluency

covered stent (Bard, Murray Hill, NJ) and uncomplicated placement of chest tube. In 1 (0.8%) procedure, after successful crossing of an occluded superior vena cava with a transseptal needle and vascular plug target, the guidewire entered the pericardial recess, with resulting hemopericardium without evidence of tamponade. A pericardial drain was placed, and a 10 × 30 mm iCast covered stent (Atrium Medical, Hudson, NH) was placed at the site of injury, with no further sequelae. In 1 (0.8%) procedure, there was re-occlusion of the inferior segment of the patient's already-present inferior vena cava filter after successful sharp recanalization of an occluded right ilio-caval confluence, which was treated successfully with pharmacomechanical thrombolysis.

There was 1 (0.8%) moderate adverse event, when after a successful recanalization of an occluded infrarenal inferior vena cava with a transseptal needle and loop snare, during placement of a Wallstent in the right common vein, the stent migrated upstream, requiring placement of an additional overlapping Wallstent. There were 7/123 (5.7%) minor adverse events, which included 4 (3.3%) cases of self-limited retroperitoneal extravasation and 1 (0.8%) case each of self-contained extravasation into the mediastinum, pelvis, and left upper arm. The rate of adverse events was not impacted by the length of occlusion ($P = 0.54$).

Long-Term Patency

Eighty-six out of 88 (97.7%) patients that underwent stent reconstruction had follow-up vascular imaging, with a mean follow-up of 28.5 ± 25.0 months (range 0.1–124 months). At the last follow-up examination, 68/86 (79.0%) were patent. Fifty-five out of 69 (79.7%) central reconstructions were patent, and 13/17 (76.5%) peripheral reconstructions were patent.

Discussion

Sharp recanalization is an alternative recanalization method for patients who have failed blunt recanalization that has been described in case series, the largest of which included 39 patients [6, 7]. In this report, sharp recanalization was performed in 123 patients who had chronically occluded central or peripheral veins. The technical success rate in this series was 90.2% and the location of occlusion, prior stenting, and length of occlusion did not have a significant impact on the likelihood of technical success. Severe or moderate adverse events were reported in 3.2% of the cases, which is in the range of complications reported in prior series (0–5.1%) [6, 7]. This series strengthens the available data for the use of sharp recanalization, demonstrating that it is a safe and

efficacious therapy for patients who have failed blunt recanalization techniques in the central and peripheral veins.

Sharp recanalization was first reported by Gupta in 1998, who crossed a right brachiocephalic vein occlusion with an 18-gauge, beveled, hollow-core puncture needle [14], and by Murphy in 1999 [15], who crossed an occluded right subclavian vein with an 20-gauge Chiba needle. Subsequent series have employed both straight [6, 14–19] and curved [15, 20–22] needles for sharp recanalization. Goo et al. retrospectively evaluated 33 recanalization procedures in occluded thoracic central veins using a Rosch-Uchida needle, reporting a technical success rate of 94%. Recently, Cohen et al. [6] reported a technical success rate of 95% in a series of 39 patients with occluded central veins crossed using a manually angulated 21- or 22-gauge Chiba needle. The technical success rate in this manuscript series is similar to these prior series, despite the fact that the average occlusion length in this series was twice that reported in Goo et al. [7].

Alternative non-sharp advanced recanalization techniques have been reported, including the use of radiofrequency guidewires, the largest series which was reported by Guimaraes et al. [23] who reported a 100% success rate in the recanalization of 42 central venous occlusions. Though this technique may be useful in long-standing venous occlusions that are not amenable to sharp recanalization, the radiofrequency wire may easily cross any soft tissue plane and may increase the risk of inadvertent venous perforation [10, 23, 24].

In this series, a transseptal needle was used as the crossing device in 107/123 (87.8%) patients. The use of this device has been previously reported in several series, the largest including 7 patients [11, 25, 26]. The transseptal needle provides several advantages relative to other needles including a smaller gauge, which reduces the severity of perforations, an ability to provide angulation and directionality, and the ability to adjust of its curve according to the projected course [26].

This series also demonstrates that a variety of targeting devices may be used to help cross the occlusion depending on the length and location. Prior series have employed snares, angioplasty balloons, or catheters as targets [6, 7]. Though 92/123 (74.8%) procedures in the current series employed loop snares, 29 (23.6%) procedures employed either partially deployed Wallstents or partially deployed vascular plugs as targets, as previously described in a 16-patient series [11]. Relative to snares, Wallstents and vascular plugs offer several advantages including a larger three-dimensional target, facilitation of expansion of the targeted vein, and maintenance of patency in the target segment during multiple needle passes. These properties are particularly advantageous in the maintenance of

patency over long, curved trajectories, such as the confluences of the iliac veins or the confluence of the brachiocephalic vein and the superior vena cava [11].

This series differs from prior reports of sharp recanalization which have focused exclusively on thoracic central venous occlusions [6, 7]. In this series, the central veins were the most common anatomic site of occlusion, but 22.0% of the occlusions were peripheral. There are several case reports describing sharp recanalization of large peripheral veins, but no prior series [22, 27]. This series shows a high technical success rate using sharp recanalization techniques for large peripheral veins which did not differ from the success rate in central venous occlusion. This technique may be useful in patients with chronic iliofemoral occlusion due to May–Thurner disease or in patients on chronic hemodialysis.

This series is limited by its single-center nature, which may result in patient- and institution-specific biases. Specifically, sharp recanalization technique and specific equipment choice varied by operator, reducing generalizability. Additionally, reporting of complications is limited by reliance on notes written in the electronic medical record at the time of the procedure, and thus, the rate of minor adverse events may be underreported.

Conclusion

Sharp recanalization has high technical success in the recanalization of chronic venous occlusions resistant to blunt recanalization techniques. A variety of devices may be used with a low rate of complications.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent This study has obtained Institutional Review Board Approval, and the need for informed consent was waived.

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