Cardiovasc Intervent Radiol (2018) 41:73–79
https://doi.org/10.1007/s00270-017-1787-x

Success Rate and Complications of Sharp Recanalization for Treatment of Central Venous Occlusions

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Received: 5 April 2017 / Accepted: 31 August 2017 / Published online: 6 September 2017

Abstract
Purpose To evaluate success and safety of needle (sharp) recanalization as a method to re-establish access in patients with chronic central venous occlusions.
Materials and Methods Thirty-nine consecutive patients who underwent this procedure were retrospectively reviewed to establish success rate and associated complications. In all cases, a 21- or 22-gauge needle was used to restore connection between two chronically occluded segments after conventional wire and catheter techniques had failed. The needle was guided toward a target placed through a separate access by fluoroscopic guidance. When successful, the procedure was completed by placing a catheter, ballooning the segment, and/or stenting.
Results The procedure was successful in 37 of the 39 patients (95%). The vast majority of the treated lesions were in the SVC and/or right innominate vein. Occlusions ranged in length between 10 and 110 mm, and the average length of occluded venous segment was 40 mm in the treated group. There were four minor (SIR classification B) complications involving pain management after the procedure. There were two major (SIR classification D) complications both of which involved hemorrhage into the pericardium treated with covered stents (5.1%).
Conclusions Sharp recanalization is a viable procedure for patients who have exhausted standard wire and catheter techniques. The operator performing this procedure should be familiar with potential complications so that they can be addressed urgently if needed.

Keywords Venous occlusion · Sharp recanalization · SVC syndrome

Introduction

Patients on chronic hemodialysis frequently develop central venous occlusions with a reported incidence of 29% [1]. Symptomatic central venous obstruction is less frequent in patients who are not dialysis dependent and can be caused by central line placement, malignant obstructions from tumors, and mediastinal fibrosis. Venous occlusions are associated with increased hemorrhage from the dialysis shunt after cannulation, upper extremity and facial swelling, and an increased rate of shunt thrombosis [2]. Treatment of these occlusions traditionally involves wire and catheter techniques followed by angioplasty with or without stenting. Patients who fail traditional recanalization methods have limited treatment options such as femoral catheters and grafts as well as last resort sites such as translumbar and transhepatic venous access. These options expose patients to increased risks of complications such as infection [3].

Gupta et al. [4] and Ferrell et al. [5] first described sharp venous recanalization in 1998 and 1999. The technique involved crossing an occluded segment of the vessel with the use of a needle followed by reentry into the lumen. Standard wire and catheter techniques were used along with angioplasty and/or placement of a stent to re-establish flow. The procedure was initially performed utilizing an 18G needle, but transition was made to a smaller 21G system.

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Several groups have published small case series of up to 33 such patients [4, 6–9]. In this retrospective study, we analyzed all patients who underwent sharp recanalization over a 3-year period to assess for success and safety of the procedure.

Materials and Methods

This is an IRB-approved retrospective study. For this type of study, formal consent is not required. Thirty-nine patients were referred to interventional radiology between May 17, 2012 and February 29, 2016, due to chronic occlusion of their central veins. The patients were referred for the procedure after diagnosis was made on an outside venogram during an attempt at recanalization of the occlusion. In these procedures, performed at the outside facility, the patients would have a venogram followed by attempts at re-establishment of the flow through the occlusion by standard guidewire and catheter techniques.

Indication for venous recanalization was symptomatic management in 28 of 39 patients (72%) and temporary catheter placement, for later conversion to a HeRO graft, in 11 patients (28%). Of these patients, there were 19 patients who had isolated facial or arm swelling and 12 patients who had both. These symptoms would typically worsen when the patient was reclining or when the patient had a shunt in the ipsilateral side and the shunt was used for hemodialysis.

Of these patients, 36 (92%) were on chronic hemodialysis with 8 receiving their treatments through groin access. The patients ranged in age between 29 and 81 years with a mean of 56 years. There was a slight majority of female patients (54%) (Table 1).

All patients had a CT of the chest obtained before the procedure. The majority of the patients (thirty-five) had a contrast-enhanced study (CT venogram). Four patients had a non-contrast study due to the lack of IV access. In cases where the patients had a long history of femoral catheter access, cross-sectional images of the abdomen and pelvis were included as well to assess for patency of lower extremity veins for additional routes of access. The information from the CT was then used to plan elements of the procedure such as initial access site, total length of occlusion, and patency of collateral pathways of drainage such as the azygos and internal mammary veins (Fig. 1).

Table 1 Patient characteristics

Number of patients	39
Sex	
Male	18
Female	21
Mean age (years)	56 (range 29–81)
Diabetes	20
Hypertension	31
On hemodialysis	36
Existing femoral catheter	8
Symptoms	
Facial swelling	6
Arm swelling	13

On the day of the procedure, the access site was punctured under ultrasound guidance and a venogram was obtained (Fig. 2A). A repeat attempt at crossing the occluded segment with traditional catheter and wire techniques was then attempted, and while there were several cases where conventional techniques were successful, for the purpose of this article, only cases in which the sharp recanalization had to be resorted to are being reported.

Upon failure of conventional techniques, a vascular sheath was advanced as close to the site of occlusion as feasible. Next, a target was established distal to the occlusion. The target varied but was usually a balloon or snare advanced from a separate access site. Alternatively, an existing intraluminal device such as a stent or pacemaker wire was used based on the pre-procedure CT examination.

A manually angulated 21- or 22-gauge Chiba needle (Cook, Bloomington, IN) was used to carry out the sharp recanalization by slow advancement through the sheath under fluoroscopic guidance to avoid puncturing it. This was then repeated for the occlusion. Advancement of the needle was made with diligent attention to repeated rotation of the C-arm to obtain depth information with regard

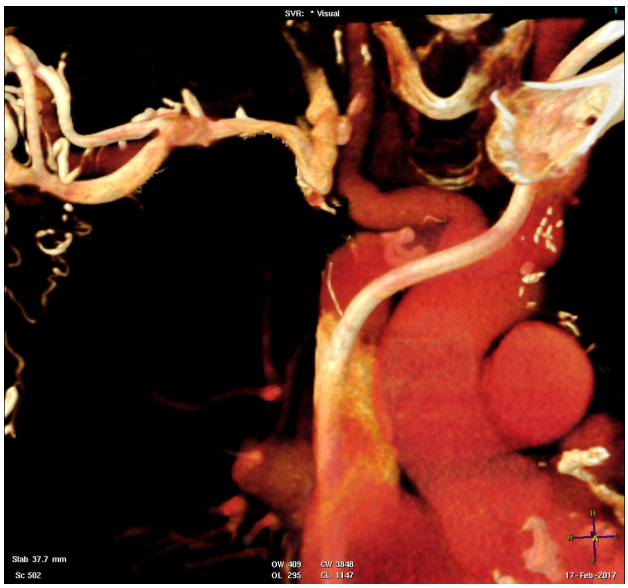
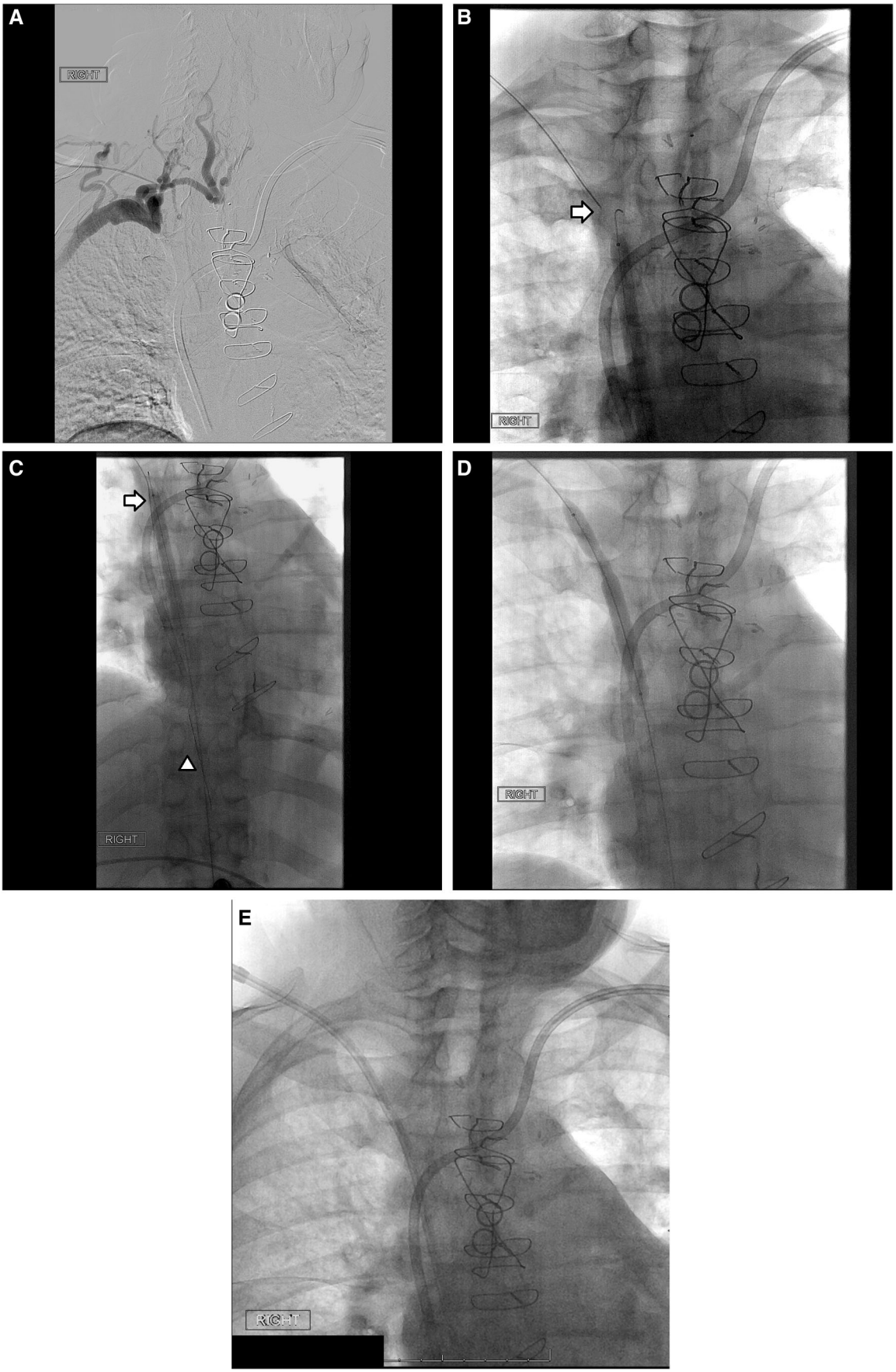


Fig. 1 Coronal 3D reformatted image from a patient's CT venogram demonstrates an occluded right brachiocephalic vein


A
RIGHT
B
RIGHT
C
RIGHT
D
RIGHT
E
RIGHT

◀**Fig. 2** **A** Venogram through the external jugular vein shows suspected area of occlusion along with several collaterals. **B** A needle (arrow) is advanced toward the target with fluoroscopic guidance. The target is a balloon in the SVC advanced through a separate right common femoral vein access. **C** Needle (arrow) has been advanced into the patent segment. This is confirmed by passage of a 0.018 wire into the right atrium and subsequently into the IVC (arrowhead). **D** The tract is dilated with an 8 × 40 mm balloon (Conquest; Bard Medical, Covington, GA). **E** Final image shows a non-tunneled catheter in place. This was converted to the outflow segment for a HeRO graft during the same day

to the needle and target (Fig. 2B). The depth information was obtained by noting the relative change of the needle to the target and a fixed anterior or posterior osseous structure such as the sternum or spine. The goal was to have no change in the needle tip distance with respect to the target. If there was a change in the distance, the change was compared with the known anatomical structure which determined whether the needle is located anterior or posterior to the intended target. If the needle and the known osseous structure moved in concert, then the needle was anterior (in the case of the sternum) or posterior (in the case of the spine) to the target. The opposite also holds true. The anterior or posterior location of the needle with respect to the target can also be ascertained by noting needle movement relative to the target when the C-arm is rotated. If the needle moves in the same direction as the C-arm relative to the target, then it is located posteriorly. If the needle moves opposite to the rotation of the C-arm, then it is located anterior to the target.

The patient, under moderate (conscious) sedation, was asked to report any new pain. It was noted early on that the patient should only have a small amount of pain in the chest at the beginning and end of the sharp recanalization when the initial and target (patent) vessel wall was being punctured.

Once at the target, a 0.018 guidewire was advanced through the Chiba needle (Fig. 2C). This wire was then advanced into the IVC for confirmation of the intraluminal location and to avoid mistaken placement in the pericardium or other structures that superimpose the right atrium and SVC on a frontal fluoroscopic projection. If difficulty was met with advancing the wire into the IVC, a snare was used from a femoral vein approach to capture the wire. This was only necessary in 2 cases. In all cases, balloon angioplasty of the tract was performed (Fig. 2D).

If the re-established vessel lumen demonstrated adequate flow without contrast extravasation, the procedure was terminated (Fig. 2E). Stenting was undertaken when slow flow, greater than 30% residual luminal narrowing or contrast extravasation, was suspected. Alternatively, if the patient was scheduled for a Hemodialysis Reliable Outflow (HeRO) Vascular Access Device (Hemosphere Inc, Minneapolis, MN) graft, a non-tunneled catheter with or without a stent was placed and the patient was transported to the OR suites the same day. The patients did not receive anticoagulation or antiplatelet therapy routinely after the procedure.

Results

The procedure was successful in 37 of the 39 patients (95%). 32 out of 39 crossed lesions were in the SVC and/or innominate veins. The average length of the occluded segment was 39 mm. Table 2 further details lesion location. Occlusions ranged in length between 10 and 110 mm and were measured in 5-mm increments using the balloon markers as a tool to calibrate the images. The average length of occluded venous segment was 40 mm in the treated group excluding the two patients whose lesions could not be crossed.

A total of 22 stents were deployed in 22 patients, of which 8 were covered stent grafts (self-expanding) and 14 were non-covered self-expanding stents. The stent diameter ranged from 8 to 14 mm, and stent length ranged from 40 to 80 mm. The completion venogram at the end of the procedure did not reveal contrast extravasation in any patient in all except one patient who is described below as a complication.

There were four minor (SIR classification B) complications involving pain management after the procedure. There were two major (SIR classification D) complications (Table 3). Mild chest pain after the procedure in four patients was attributed to the dilatation of an occluded vein

Table 2 Occluded venous segment treated and average length of occlusion

Location	Number	Range (mm)	Average length (mm)
SVC	8	20–40	33
Left SC	1	n/a	35
Left SC and BC	1	n/a	50
Left BC	4	10–80	37
Left Ax	1	n/a	110
Right SC	2	20–40	30
Right SC and BC	2	50–55	53
Right BC	16	10–110	38
Right Ax	1	n/a	40
Right IJ and BC	2	40–80	60
Right BC and SVC	1	n/a	50

Ax axillary, *BC* brachiocephalic, *IJ* internal jugular, *SC* subclavian, *SVC* superior vena cava

Table 3 SIR complications classification

Minor complications
A. No therapy, no consequence
B. Nominal therapy, no consequence; includes overnight admission for observation only.
Major complications
C. Require therapy, minor hospitalization (<48 h)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 h)
E. Have permanent adverse sequelae
F. Result in death

and/or deployment of a stent. This is frequently seen in patients who have these procedures performed during the maintenance of their dialysis access without the use of sharp recanalization. It was therefore managed conservatively with over-the-counter pain medications such as acetaminophen and in one case required the prescription of a 5-day course of narcotic pain medication (acetaminophen 325 mg/oxycodone 5 mg).

The two major complications comprising 5% of the cases were due to hemorrhage either during or after the procedure. The first, a pericardial hematoma, was noted during the procedure in a patient suffering from a groin line infection. The patient had findings of tamponade including a narrowed pulse pressure and tachycardia after reentry into the SVC. A venogram through the sheath demonstrated contrast extravasation. The balloon which was previously used to dilate the tract was re-inflated to gain control of the hemorrhage, and the patient stabilized allowing for discussion of the case with the cardiothoracic surgery service. A decision was made to place a pericardial drain after consultation. A drain was placed yielding 120 ml of sanguineous fluid, and the patient's vital signs normalized. A covered stent, Fluency (Bard Peripheral Vascular, Tempe, Arizona), was placed in the SVC. The procedure was completed after placement of a non-tunneled dialysis catheter through the stent. The patient was observed in the ICU overnight, and after a capping trial, the drain was removed the following day. He was returned to the IR suite for conversion of the non-tunneled catheter to a tunneled dialysis catheter 3 days later.

A second complication occurred as an indirect consequence of the procedure. After uneventful sharp recanalization and placement of a non-tunneled access for HeRO graft placement, the patient was transferred to the OR for the graft placement. Unfortunately, the patient suffered a myocardial infarction during anesthesia induction in the OR. He was given anticoagulants emergently and developed a small right hemothorax. The hemothorax remained stable after withdrawal of anticoagulation; however, since the patient needed continued anticoagulation for his infarction, he was returned to the interventional suite. A venogram at the time of the procedure did not reveal any contrast extravasation; however, since the patient had already a hemorrhage and required continued anticoagulation, it determined that the best option was to deploy a stent graft (Fluency) in the SVC in case a subtle or intermittent bleed was present. He was discharged from the hospital after 19 days.

Discussion

Patients on long-term dialysis frequently exhaust their accesses due to poor flow and/or infection. The restoration of the upper extremity venous pathways increases the durability of upper extremity shunts, allows replacement of femoral dialysis catheters with an access located in the chest, and enables the placement of a HeRO graft in the appropriate population. There have been several approaches and continued development of diverse techniques from different groups to help achieve this aim.

The use of radiofrequency wires for the recanalization of occluded veins has been studied extensively resulting in the publication of several case reports and series in the literature with up to 42 patients [10–14]. The reported success rate ranges between 75 and 100% with only a 4% serious complication rate (pericardial tamponade and a tracheal perforation) [12, 14].

Another method involves the use of an Outback (Cordis, Milpitas, CA) reentry device by two groups [15, 16]. In these 3 cases, the authors succeeded in re-establishing flow by adapting a similar technique used to regain access to the true lumen in arterial recanalization.

A recent modification has also been reported in which a stent is partially deployed in the target segment and initially used as a target [17]. Upon successful recanalization with a needle, a wire is advanced into the partially deployed stent and the stent is then retracted, thereby capturing the wire. This technique described by Khaja et al. in 16 patients uses the stent as a target and a snare to facilitate the performance of the procedure.

Finally, surgical bypass has also been advanced as a mean to restore flow in the occluded veins. Bypass grafting

to the right atrium with or without a sternotomy has been reported in small case series [18, 19].

Sharp recanalization was first described in two case series by Webb et al. [4] and Gupta et al. [20] in 1998. Since then, there have been several case series demonstrating the utility and relative safety of this technique. A recent case series from 2016 included two complications, one a hemothorax and another a small hemopericardium [21]. In this series of seven patients, the authors used an 18-gauge needle for 6 out of 7 cases and a 22-gauge needle in the remaining one. Their technique is otherwise similar to the one described here. They noted a similar finding that the complications did not occur until after the tract was dilated which was similar to what was noted in this series.

Our data suggest sharp recanalization is a viable and effective in crossing complete occlusions of the SVC and more proximal central veins. The costs versus benefits must be weighed in each patient, but in patients with symptomatic venous occlusions such as SVC syndrome or those in which vascular access is limited, this procedure can help relieve symptoms and provide additional dialysis options.

The current series of 39 patients, who underwent sharp recanalization, represents the largest number of reported cases using this technique. Hemorrhagic complications encountered in sharp recanalization are feared, but occur relatively infrequently (5% in this case series). They can be attributed to the fact that the operator will deviate from the occluded lumen of the vessel, especially when restoring flow in longer lesions. This exposes the patient to the risk of bleeding once the tract is dilated. If this is suspected during the case, it may be beneficial to obtain an over-the-wire venogram with the outer 4 French portion of the transition set over the 0.018 wire to opacify the tract traversed previously by the needle. Any contrast extravasation can be addressed immediately by replacement of the catheter through which the tract was being studied after reinsertion of the transition set. This can be followed by placement of a covered stent measured to cover both entry and exit sites of the needle after study of the initial run and the just obtained tract study to eliminate the extravasation. In addition, it was felt that the use of conscious sedation would aid in detection of crossing a non-target mediastinal structure. As stated above, the patient should only experience pain during the advancement of the needle through a patent segment of vein at either the start or end of the tract.

In the two reported complications, self-expanding stents were used since the distances between the needle exit site and reentry were 8 and 11 cm.

Limitations of the study include its retrospective nature and the inherent presence of a selection bias toward the right-sided access for the procedure, which is shorter in length and less tortuous in its course. Other limitations include the small number of patients and the lack of direct comparison with other techniques as well as outcomes data.

Conclusions

With sharp recanalization, we have an additional tool to extend or renew the use of the upper extremity accesses, especially in the hemodialysis population where maintenance of central venous access is often a challenge. Hemorrhagic complications are rare but can cause significant morbidity and mortality with any recanalization technique including sharp recanalization. A detailed study of each patient's vascular anatomy with the aid of a CT examination and awareness of steps to diagnose and treat complications is important for patient safety.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflicts of interest.

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