

The Feasibility and Safety of Sharp Recanalization for Superior Vena Cava Occlusion in Hemodialysis Patients:

A Retrospective Cohort Study

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Short title: Sharp SVC Recanalization in HD patients

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Abstract

Introductions: Hemodialysis catheter-related superior vena cava (SVC) occlusions can cause considerable morbidity for patients and be challenging to treat if refractory to conventional guide wire transversal. This pilot study assessed the feasibility and safety of sharp recanalization of SVC occlusion in hemodialysis patients.

Methods: This study retrospectively enrolled hemodialysis patients treated in West China Hospital diagnosed with SVC occlusion who failed traditional guide wire transversal from January 2014 to November 2017. In brief, a guide wire from the femoral approach was advanced to the lower end of the obstructive lesion to act as a target, while the stiff end of hydrophilic wire was advanced through a jugular approach. Under fluoroscopic guidance in biplane imaging, the occlusive SVC lesion was penetrated with the stiff wire which was snared and pulled through. Graded dilation of the SVC and subsequent tunneled-cuffed catheter implantation were performed. Demographic information and clinical outcomes were recorded and evaluated.

Findings: 16 patients with a mean age of 62.13±12.62 years (13 females and 3 males) who received SVC sharp recanalization were included in this study. The sharp recanalization procedure was successfully performed in 14 patients (87.5%). Two patients were complicated with SVC laceration and hemopericardium but remained asymptomatic and required no surgical repair. One patient suffered ventricular fibrillation during procedure. Despite the return of spontaneous circulation, the patient unfortunately died of gastrointestinal tract bleeding after 3 days in ICU. Follow-up suggested the 6-month catheter patency to be 92.85% and 12-month catheter patency to be 58.33%. No long-term procedure-related complications were recorded.

Discussion: Sharp recanalization might be a feasible strategy in managing SVC occlusion in hemodialysis patients. The potential life-threatening complications (cardiac arrhythmia and SVC laceration) necessitate strict eligibility screening, skillful operation and avoidance of over-dilation of SVC.

Keywords: Sharp Recanalization; Hemodialysis; SVC; Central Venous Occlusion; Refractory.

Introduction

Despite the "fistula first" initiative, central venous catheter placement remains important for hemodialysis patients in case of urgent need for vascular access or failure in fistula creation(1). However, long term indwelling and repeated central venous catheter insertions are associated with various vascular complications such as thrombosis and central venous occlusion (CVO)(2). Superior vena cava (SVC) occlusion is a common subtype of CVO among hemodialysis patients. Endovascular intervention with angioplasty is the usual first choice for recanalization of occlusive SVC (3). For patients refractory to conventional guide wire transversal, SVC sharp recanalization might be an option(4). Several previous reports described the use of different sharp devices (21-G needle, TIPS needle, transseptal needle, stiff end of hydrophilic wire) for recanalization of occluded central veins(4-6).

Although sharp recanalization has long been readily available, its application is limited by the relative lack of control over the exact trajectory of the wire or needle, which could be too peripheral within the occluded vessel or even extravascular(7). In 2016, Arabi and colleagues reported a series of seven chronic hemodialysis patients with CVO successfully treated by sharp recanalization, however two major complications occurred including a right hemothorax and a small hemopericardium (8). Moreover, the close relationship between SVC and right atrium warrants special attention to potential cardiac complications during SVC angioplasty. Till date, few studies focusing on SVC sharp recanalization in hemodialysis population have been reported. The application of this strategy remains to be further validated. We hypothesized that SVC sharp recanalization to be a therapeutic alternative to SVC occlusion and this pilot study aimed to explore the feasibility and safety of sharp recanalization of refractory SVC occlusion basing on the data from maintenance hemodialysis patients.

Materials and Methods

Patient selection and follow-up

This retrospective cohort study collected data from hemodialysis patients who received sharp recanalization of SVC from inpatient database of West China Hospital from January 2014 to November 2017. The inclusion criteria were as follows: (1) on maintenance hemodialysis through a central venous catheter, (2) admitted for tunneled catheter insertion of exchange, (3) diagnosed as SVC occlusion by digital subtraction angiography (DSA), (4) SVC occlusion refractory to standard recanalization procedures and received sharp recanalization. Patients were excluded from the analysis if he/she required angioplasty of other central veins simultaneously, which might also predispose to complications and become confounding factors. Patients receiving SVC angioplasty to salvage a dysfunctional fistula were also excluded. A chart review was performed on each patient to identify gender, age, primary disease, dialysis years, catheter years as well as number of previous line insertions. The patients were followed up for 12 months. Follow-up information was collected from outpatient medical record database as well as the hemodialysis database. For patients whose follow-up information was unavailable in

databases, they were contacted by telephone calls to document the current state of dialysis, complications, catheter patency as well as other therapeutic information. The study was approved by the institutional ethics committee and written informed consents were obtained from all participants.

Sharp recanalization of SVC occlusion

All of the procedures were performed under local analgesia plus procedural sedation as per the departmental protocol. Ultrasound examination of the neck and groin area was undertaken to identify patent jugular vein and common femoral vein, which were accessed under aseptic conditions. Fluoroscopy was performed at both side of the SVC occlusion lesion from femoral (Figure 1A) and jugular approach (Figure 1B) to document the true length of occlusion segment. If the occlusion could not be passed with regular wires and catheters after multiple attempts from both sides, the patient was then subjected to sharp recanalization after obtaining written informed consent from the patient or surrogate. A guide wire was advanced to the lower end of the obstructive lesion to act as a target, while a stiff hydrophilic wire (Terumo, Tokyo, Japan) was advanced through the jugular access towards the target under fluoroscopic guidance. Aided by two orthogonal projections in anterior-posterior view (Figure 2A) and side view (Figure 2B) under DSA, the occlusive SVC segment was penetrated using the straight stiff end of the hydrophilic wire (Figure 2C, Figure 2D) which was snared once it entered SVC remnant to achieve a jugular-femoral pull-through. Balloons of different sizes (8-12mm in diameter, 40-100mm in length) were sequentially passed over the guide wire to give graded dilations (Cordis Corporation, Milpitas, USA) (Figure 3A). After each dilatation, contrast medium was injected in order to rule out extravasation and verify the patency of the occlusive segment. Tunneled cuffed internal jugular catheter (Bard Corporation, Franklin Lakes, USA) was inserted in a standard fashion (Figure 3B). After the procedure, the position of catheter was again confirmed by fluoroscopy. The procedure was performed by experienced interventional nephrologists. Technical success was defined as successful sharp recanalization followed by balloon angioplasty and catheter insertion.

Data analysis

The demographic information, clinical outcome, length of operation, preoperative/postoperative complications, catheter patency, and patient prognosis were recorded and evaluated. Continuous measurement data were expressed as mean \pm standard deviation. Categorical data were express as percentages. The data analysis was performed using SPSS 19.0 software (SPSS Inc., Chicago, USA).

Results

Patient characteristics

A total of 16 patients receiving SVC sharp recanalization were included in this study. The demographics of the 16 patients are summarized in Table 1. The cohort consisted of 13 females and 3 males, with a mean age of 62 \pm 13 years-old and a

mean history of hemodialysis of 48 \pm 27 months. The patients had a history of 3 \pm 1 central venous catheterizations for hemodialysis, ranging from 2 to 7 times. Prior to the intervention, 3 patients were dialyzed through a contemporary femoral or jugular catheter and 13 patients through the in situ dysfunctional tunneled jugular catheter which provided insufficient blood flow. No patient was on regular anticoagulation or antiplatelet treatment.

Clinical outcomes and safety

The sharp recanalization procedure was successfully performed in 14 out of 16 cases (technical success rate 87.5%). The procedure was unsuccessful in a patient with a 7cm-long obstructive segment (Figure 4A, 4B) and terminated in another patient complicated by ventricular fibrillation (described below). The mean length of occlusion segment is 2.81 \pm 1.55 cm, ranging from 1cm to 7cm. The mean operation time was 72.38 \pm 10.42 minutes. New catheter tips were placed central to the obstructive lesions as confirmed by fluoroscopy.

There were a total of 3 episodes of major complications encountered in 3 patients according to the Society of Interventional Radiology reporting guidelines(9). Two patients were complicated with SVC laceration and mild hemopericardium (Class D) as indicated by contrast leakage into pericardial cavity (Figure 4C). Monitored closely by cardiologists, both of the patients remained stable in hemodynamics without symptoms of pericardial tamponade and warranted no specific intervention. The patients were contemporarily dialyzed under citrate regional anticoagulation and successfully discharged home in one week. One patient presented with transient ventricular fibrillation after sharp transversal and balloon angioplasty. The operation was immediately ceased, and CPR and mechanical ventilation were performed immediately. Despite the return of spontaneous circulation, the patient died of gastrointestinal tract bleeding after 3 days in the Intensive Care Unit unfortunately (Class F). It is also worth mentioning that, all these 3 complicated patients received 12mm diameter balloon angioplasty, while most of the patients in the complication-free group received 8mm or 10mm diameter balloon dilation (Table 2).

Catheter patency

All the 14 patients who received successful sharp recanalization and catheter insertion had satisfactory blood flow (>250ml/min) for hemodialysis postoperatively. During the first 6 months of follow-up, only one patient encountered low flow rate (<150ml/min) in catheter venous line at the 4th months, which was restored after thrombolytic locking (10000 IU of urokinase + 1000 UI of sodium heparin for 30 minutes before dialysis, total volume 2ml). From month 6 to month 12, two patients were censored (fatal hemorrhagic stroke, kidney transplant). Three more patients required urokinase thrombolysis and another patient needed catheter exchange. Due to poor peripheral vascular condition, none of these patients received fistula or graft placement during follow-up. The 6 month and 12-month primary patency were 92.86% and 58.33%, respectively. No long-term procedure-related complications were recorded in this cohort.

Discussion

This retrospective pilot study suggested that sharp recanalization might be a feasible alternative in managing SVC occlusion in hemodialysis patients. Sharp transversal followed by conventional angioplasty was capable in restoring SVC patency in the majority of the included patients. However, practitioners should be well aware of the relative high risk of complications such as cardiac arrhythmia and SVC laceration when considering this therapeutic option.

CVO is a common long-term complication in hemodialysis patients using central venous catheters and the mechanism remains unclear. The blood flow turbulence and mechanical stimulation caused by hemodialysis catheters may incite endothelial inflammatory, thrombotic and fibrotic responses, hence resulting in intimal hyperplasia and occlusion of the SVC lumen. SVC occlusion threatens the availability of vascular access for hemodialysis, not only jeopardizing catheter patency, compromising venous drainage, but also making it difficult for new catheter insertion or fistula maturation(7). Several endovascular techniques including thrombolysis, percutaneous transluminal angioplasty (PTA), stent placement have been widely applied in CVO in hemodialysis patients with variable success rates and long-term patency(10). Patients who were resistant to standard interventional techniques would be sometimes provided with atypical access such as transhepatic and translumbar catheters, but the durability of these catheters are often questionable. Radiofrequency wire for the recanalization of CVO has been reported by several case reports and series in the literature, which appears to be of particular value in long segments resistant to standard angioplasty (11-13). However, the heated tip allows the wire to advance extraluminally easily and efforts should be made to avoid such misadventures(14). Another method involves the use of an Outback (Cordis, Milpitas, USA) reentry device in the revascularization of an occluded central vein by adapting a similar technique used in arterial recanalization(15). SVC conduit to the right atrium has also been reported in small case series (16), but complex bypass surgery is usually referred as the last resort for its high comorbidity.

Sharp recanalization was first described by Gupta et al in 1998.(5) and Ferrell et al in 1999(17), using a needle or other sharp agents to cross an obstructive vascular segment. Application of sharp recanalization in SVC occlusion has occasionally been mentioned in several reports. In 2011, Sadarmin and colleagues reported using a 21F Colapinto needle (Cook Medical) to penetrate blocked SVC to facilitate ICD lead implantation(18). Arabi et al. reported in 2016 upon the successful sharp central venous recanalization using the transseptal needle in 7 hemodialysis patients, among which one patient achieved restoration of SVC patency to alleviate occlusion symptoms and restore fistula function(8). More recently, Cohen et al. described the recanalization of obstructed SVC using a 21- or 22-gauge needle among 9 patients(19).

In the present study, sharp recanalization had a technical success rate of 87.5% in 14 out of all 16 dialysis patients with SVC

occlusion, while previous literature reported success rates ranging from 93.9% to 100%(4, 8, 19, 20) for all types of CVO. The discrepancy in technical success rates might be partially attributed to the different sharp devices used (stiff hydrophilic wire vs. other sharp agents) and vascular segments recanalized (SVC occlusion vs. all types of CVO) and need further verification by larger scale studies. The procedure failed in 1 patient with long-segment SVC occlusion which is usually difficult to manage(21). Dictated by the length of occlusive lesion and angle of approach, sharp recanalization is disadvantaged by the lack of operator's control over the exact wire trajectory. Patients with long-segment occlusion should be therefore evaluated carefully for eligibility of sharp recanalization to balance risk and benefit. The present patient cohort achieved a 6-month catheter patency of 92.86% and 12-month patency of 58.33%, respectively. In a recent large case-series of 123 patients with chronic CVO receiving sharp recanalization, 79.0% of the stents were patent at the end of follow-up (22). A relative high re-intervention rate remains a challenge for sharp recanalization as a therapeutic strategy for CVO.

Although endovascular recanalization is considered as a comparatively safe procedure with a low complication rate compared with open surgery, potential fatal complications such as SVC laceration and pericardial tamponade were reported in sharp recanalization(18, 19). There were 2 SVC laceration episodes and 1 ventricular fibrillation, which unfortunately ended up with in 1 death event. As a matter of fact, the pericardial reflection is highly variable and the pericardium recess extends up to 4 cm above the right atrium–SVC transition(12). Recanalizing the infra-azygos SVC increases the likelihood of pericardial tamponade(23). Meanwhile, the close anatomic relationship of lower part of SVC to the right atrium might also possibly increase the risk of cardiac adverse events during SVC angioplasty. It is worth mentioning that all the 3 cases encountering complications received 12mm diameter balloon dilation while patients without complication episodes received a mean diameter of 8.67 ± 1.30 mm. Hence it might be reasonable not to oversize angioplasty balloon so as to avoid potential laceration of fibrotic SVC and excessive stimulation to the adjacent right atrium. More studies are in indeed warranted to confirm the association between SVC angioplasty and cardiac outcomes, as well as to compare the sharp transversal strategy with alternatives such as open surgical reconstruction or radiofrequency recanalization.

The results of the current study should be interpreted within the context of its limitations. Due to the small sample size, the epidemiological characteristics might not be representative, such as the gender ratio (the majority of the patients were female). In addition, this research was a single center retrospective study and its applicability in other hospitals needs to be verified by more practitioners. It is also important to note that without stent placement, the present study did not aim to restore SVC patency, but to gain a sufficient space to permit passage of the hemodialysis catheter, which was different from previous studies enrolling patients using fistulas.

In conclusion, sharp recanalization might be a feasible strategy in managing SVC occlusion in hemodialysis patients. The potential life-threatening complications (cardiac arrhythmia and pericardial tamponade) necessitate strict eligibility screening, skillful operation and avoidance of over-dilation of SVC. Prospective controlled trials with larger sample size are needed to explicit the indication and safety for SVC sharp recanalization in hemodialysis patients.

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Statement of Ethics: The study was approved by the institutional ethics committee and written informed consents were obtained from all participants.

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Author Contributions: Ling Yang was responsible for study design, literature research and manuscript drafting. Letian Yang was responsible for literature research and data collection. Yuliang Zhao was responsible for study design, data interpretation and statistical analysis. Yating Wang and Yang Yu were responsible for data verification. Stephen Salerno and Yi Li were responsible for manuscript revision. Ping Fu and Tianlei Cui were responsible for the study design and manuscript revision.

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Figure legends:

Figure 1. SVC occlusion identified by DSA. A: venography from femoral approach. B: venography from jugular approach.

Arrow head: SVC occlusion. Triangle: dilated azygos vein. (SVC: superior vena cava.)

Figure 2. SVC occlusion sharp recanalization. A: anterior-posterior view before puncture. B: side view before puncture. C: anterior-posterior view after puncture. D: side view after puncture.

Figure 3. Balloon dilation and catheter insertion. A: Occlusive SVC dilated with balloons. B: Tunneled cuffed-catheter implanted. Arrow head: SVC obstructive lesion. (SVC: superior vena cava.)

Figure 4. A: 7cm-long SVC occlusion (femoral approach). B: 7cm-long SVC occlusion (jugular approach). C: SVC laceration and hemopericardium. Arrow head: SVC occlusion. While arrow: opacification of pericardial cavity.

Table1. Demographic information of patients receiving the SVC sharp recanalization

Patient number	Gender	Age (years)	Primary disease	Dialysis months	Previous Catheterizations	Current Access
1	F	64	DN	24	2	Right jugular tunneled
2	F	78	CGN	26	2	Right jugular tunneled
3	F	63	HN	55	4	Left femoral non-tunneled
4	F	47	CGN	130	3	Right femoral non-tunneled
5	M	56	CGN	61	2	Right jugular tunneled
6	M	62	DN	26	2	Right jugular tunneled
7	F	45	IgAN	70	7	Right jugular tunneled
8	F	47	NS	54	2	Right jugular tunneled
9	F	61	MN	11	3	Right jugular non-tunneled
10	F	76	DN	47	2	Right jugular tunneled
11	F	72	Unknown	37	3	Right jugular tunneled
12	M	67	NS	62	2	Right jugular tunneled
13	F	72	DN	28	3	Right jugular tunneled
14	F	63	CGN	30	4	Left jugular tunneled
15	F	82	Unknown	59	5	Right jugular tunneled
16	F	39	Unknown	52	3	Right femoral tunneled
Mean	-	62+/-12	-	48+/-27	3+/-1	-

DN: diabetic nephropathy, CGN: chronic glomerulonephritis, HN: hypertensive nephropathy, IgAN: IgA nephropathy, NS: nephrotic syndrome, MN: membranous nephropathy, SVC: superior vena cava, RIV: right

innominate vein, IJV: internal jugular vein, CTA: computed tomographic angiography.

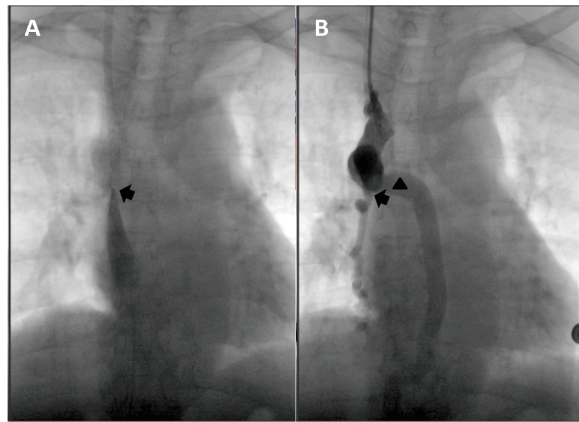
Table 2. Clinical outcomes and complications of patients receiving SVC sharp recanalization

Patient number	Technical success	Length of occlusion (cm)	Operation time (minutes)	Balloon diameter (mm)	Complication	Catheter tip position	Prognosis	6-month patency	12-month patency
1	Yes	2	70	8	-	IVC	Discharged	Patent	Thrombolysis
2	Yes	2	67	10	-	IVC	Discharged	Patent	Patent
3	No	2.5	55	12	Ventricular fibrillation	-	Died in ICU	-	-
4	No	7	79	-	-	-	Discharged	-	-
5	Yes	1	77	8	-	RA	Discharged	Patent	Patent
6	Yes	3	90	8	-	IVC	Discharged	thrombolysis	Thrombolysis
7	Yes	3	85	8	-	RA	Discharged	Patent	Fatal hemorrhagic stroke
8	Yes	2	60	8	-	IVC	Discharged	Patent	Patent
9	Yes	1	65	10	-	IVC	Discharged	Patent	Patent
10	Yes	4	69	8	-	SVC	discharged	Patent	Thrombolysis
11	Yes	4.5	59	8	-	RA	discharged	Patent	Patent
12	Yes	3	68	12	SVC laceration and hemopericardium	IVC	discharged	Patent	Changed catheter
13	Yes	1	71	8	-	IVC	discharged	Patent	Patent
14	Yes	3	88	12	-	IVC	discharged	Patent	Transplant
15	Yes	4	73	8	-	IVC	discharged	Patent	Patent
16	Yes	2	82	12	SVC laceration and	IVC	discharged	Patent	Thrombolysis

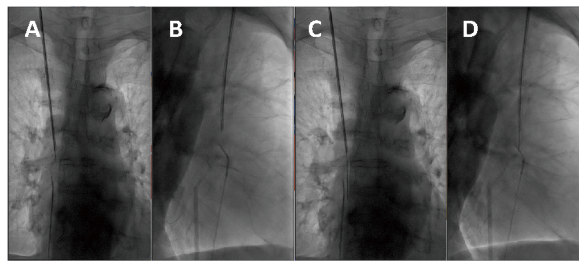
hemopericardium

Mean	-	2.81+/-1.55	72.38+/-10.42	9.33+/-1.80	-	-	-	-	-
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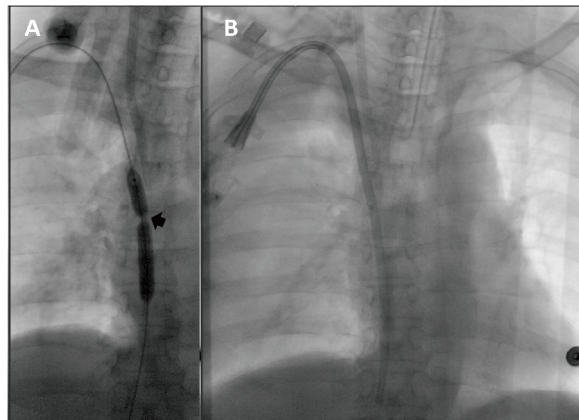
SVC: superior vena cava, IVC: inferior vena cava, RA: right atrium, ICU: intensive care unit.



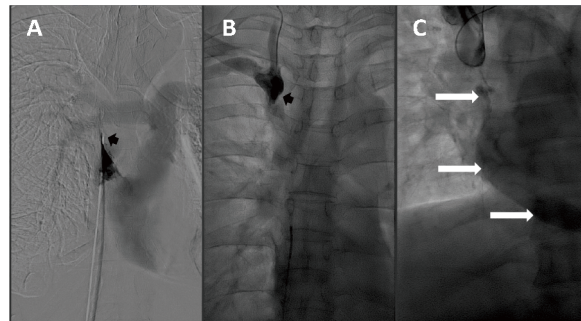
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