Multicenter Experience with the Surfacer Inside-Out Access Catheter System in Patients with Thoracic Venous Obstruction: Results from the SAVE Registry

Maurizio Gallieni, MD, Vladimir Matoussevitch, MD, Tobias Steinke, MD, Adrian Ebner, MD, Silke Brunkwall, MD, Maurizio Cariati, MD, Santiago Gallo, MD, Roman Reindl-Schwaighofer, MD, and Gürkan Sengölge, MD, PhD

ABSTRACT

Purpose: To report the device performance and safety for the Surfacer Inside-Out access catheter system in patients with thoracic central venous obstruction (TCVO) requiring central venous access (CVA).

Materials and Methods: Five sites prospectively enrolled 30 patients requiring a tunneled dialysis catheter between February 2017 and September 2018 in the SAVE (Surfacer System to Facilitate Access in Venous Obstructions) registry. Patient demographics, medical history, and type of TCVO were documented at enrollment. Device performance and adverse events were collected during the procedure and upon hospital discharge. Twenty-nine of the 30 patients enrolled required CVA for hemodialysis. Retrospective classification of TCVOs according to SIR reporting standards showed 9 patients (30%) had Type 4 obstructions, 8 (26.7%) had Type 3, 5 (16.7%) had Type 2, and 8 (26.7%) had Type 1 obstruction.

Results: Central venous catheters (CVCs) were successfully placed in 29 of 30 patients (96.7%). The procedure was discontinued in 1 patient due to vascular anatomical tortuosity. All 29 patients with successful CVC placement achieved adequate catheter patency and tip positioning. There were no device-related adverse events, catheter malposition, or intra- or postprocedural complications. Mean time from device insertion to removal for the 29 patients who successfully completed the procedure was 24 ± 14.9 (range, 6–70) minutes. Mean fluoroscopy time was 6.8 ± 4.5 (range, 2.2–25.5) minutes.

Conclusions: The Surfacer Inside-Out procedure provided an alternative option to restore right-sided CVA in patients with TCVO.

ABBREVIATIONS

AP = anteroposterior, AV = arteriovenous, BCV = brachiocephalic vein, CVA = central venous access, CVC = central venous catheter, IVC = inferior vena cava, RA = right atrium, RIJ = right internal jugular, SVC = superior vena cava, TCVO = thoracic central venous obstruction

From the Department of Biomedical and Clinical Sciences Luigi Sacco (M.G., S.B.), University of Milan, Milan, Italy; Department of Vascular Surgery (V.M.), University of Cologne, Kerpener Strasse 62, 50924 Cologne, Germany; Schön Klinik Düsseldorf (T.S.), Düsseldorf, Germany; Sanatorio Italiano (A.E., S.G.), Asunción, Paraguay; Department of Radiology (M.C.), San Carlo Borromeo Hospital, ASST Santi Paolo e Carlo, Milan, Italy; and the Department of Internal Medicine III (R.R-S., G.S.); Division of Nephrology and Dialysis, Medical University of Vienna, Vienna, Austria. Received June 21, 2020; final revision received June 23, 2020; accepted June 25, 2020. **Address correspondence to** V.M.; E-mail: vladimir.matoussevitch@uk-koeln.de; Twitter handle: @DMatoussevitch

None of the authors have identified a conflict of interest.

M.G. and V.M. contributed equally to this work and are co-first authors.

Table E1 can be found by accessing the online version of this article on *www.jvir.org* and clicking on the Supplemental Material tab.

© SIR, 2020. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

J Vasc Interv Radiol 2020; 31:1654–1660

https://doi.org/10.1016/j.jvir.2020.06.020

Thoracic central venous obstruction (TCVO) resulting from venous wall thickening associated with de novo neointimal hyperplasia, organized mural thrombus, fibrosis, or endoluminal obstruction is a common finding following repeated central venous catheter (CVC) insertions or prolonged use of catheters (1,2). Although the right internal jugular (RIJ) vein is the preferred anatomical location for CVC placement due to its ease of identification, large diameter, and direct path to the right atrium (3), the left internal jugular vein is often used for catheter placement when the RIJ is obstructed. Unfortunately, the use of the left internal jugular vein can result in reduced rates of CVC blood flow and increased risk of venous obstruction due to the tortuous route and resultant increased vessel trauma (4,5).

Femoral vein catheter placement is a frequently used alternative when thoracic central veins are obstructed, but this site is burdened by an increased rate of device malfunction and thrombosis (6). Alternative catheter placement through the lumbar approach in the inferior vena cava (IVC) or hepatic veins or access obtained through the obstruction through sharp recanalization are possible for patients with bilateral obstruction of the veins of the upper chest, but these techniques are technically difficult and may be associated with higher risk of complications (7–10).

The Surfacer System Inside-Out Access Catheter System (Bluegrass Vascular Technologies, San Antonio, Texas) was developed to provide an alternative method for gaining central venous access (CVA) in patients with TCVO. The device facilitates right-sided entry and position of CVCs through the establishment of a transient passage across venous obstructions. The SAVE (Surfacer System to Facilitate Access in Venous Obstructions) registry was initiated to evaluate the performance and safety of the device during routine clinical use in accordance with approved indications for use and to fulfill regulatory post-market surveillance obligations associated with the European Union medical device directive. During this prospective, single-arm, multicenter, international registry, the Surfacer system was used to obtain CVA to facilitate catheter insertion into the central venous system through the inside-out procedure approach for patients with limited or diminished upper-body venous access or pathology that impeded standard access methods (11,12).

MATERIALS AND METHODS

A total of 5 sites in Europe and South America enrolled 30 patients in the SAVE registry (**Table E1** [available online on the article's Supplemental Material page at *www.jvir.org*]). Physicians selected for participation in the registry were venous access specialists with experience performing interventional endovascular procedures. Following local institutional ethics committee approval, patients provided consent and were enrolled in the study. Enrollment began in February 2017 and was concluded in September 2018. Each site sequentially assessed patients who met the inclusion criteria and enrolled patients who did not have any of the exclusion criteria for the SAVE registry (**Table 1**). Eligible patients included those requiring CVA for hemodialysis, chemotherapy, nutrition, or delivery of pharmacological therapy.

Table 1. Inclusion and Exclusion Criteria for Patients Enrolled in the SAVE Registry

Inclusion Criteria
• Patients 18 to 80 years old were referred for placement of a central venous catheter
• Patients with limited or diminishing upper body venous access
• Pathology impeding standard vascular access methods
• Signed informed consent
Exclusion Criteria
• Vulnerable individuals or subjects incapable of giving consent
• Contraindications to CVA based on the treating physician's opinion or standard of care
• Occlusion of the right femoral vein
• Occlusion of the iliac vein
• Occlusion of the IVC
• Acute thrombosis within a vessel (IVC, brachiocephalic, and subclavian)

CVA = central venous access; IVC = inferior vena cava; SAVE = Surfacer System to Facilitate Access in Venous Obstructions.

Evaluations of each patient's medical history, laboratory findings, and current medications were conducted using data collected prior to the procedure (baseline), during the procedure, and upon hospital discharge. Baseline anteroposterior and lateral chest radiographs were obtained based on physician preference. Duplex/Doppler ultrasonography of the jugular and subclavian veins and the IVC were performed in all 30 patients. The use of baseline contrast-enhanced computed tomography (CT) to further define the pattern of obstructions and for patients with clinical signs of acute thrombus scans varied by site (**Table E1** [available online on the article's Supplemental Material page at *www.jvir.org*]), based on physician preference. Obstructions were retrospectively classified according to the Society of Interventional Radiology's reporting standards for thoracic central vein obstruction (1). **Figure 1** shows an example of a patient with a Type IV obstruction who was included in the SAVE registry. No additional diagnostic, monitoring, or clinical outcome data were recorded. Data were collected and recorded at each clinical study site by using electronic case report forms, entered into the electronic data capture system, and audited by the registry sponsor in accordance with Good Clinical Practice standards.

The primary performance endpoint for the study was the rate of successful CVC placements and establishment of a transient passage across venous obstructions. The primary safety endpoints for the study were the absence of acute safety and device-related serious adverse events during the procedure and through the 24 hours after the procedure or discharge, whichever occurred first. Because the SAVE registry was a regulatory mandated post-marketing surveillance study, adverse events were defined and reported

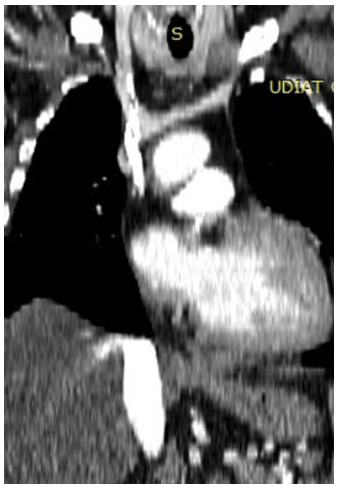

Figure 1. CT venography showing an example of a Type IV obstruction in a patient enrolled in the SAVE registry.

based on International Organization for Standardization standard 14155:2011 (Geneva, Switzerland), which stipulates Good Clinical Practices for clinical investigations of medical devices for human subjects. This standard included an adverse event related to the use of the medical device being studied, including those resulting from insufficiencies or inadequacies in the device's instructions for use, adverse events occurring during the use of the device, or any event resulting from an error in its use or intentional misuse.

Secondary performance measurements included the ability to advance the device from the femoral vein to the supraclavicular exit to facilitate CVC placement in conjunction with (*i*) the ability of the needle wire to exit at the desired entry site of the CVC in the supraclavicular region under fluoroscopic visualization; (*ii*) the ability of the peel-away introducer to facilitate placement of the CVC; (*iii*) procedure time, fluoroscopy time, and amount of contrast medium used; and (*iv*) the time required to achieve CVC placement, defined as the time from gaining femoral vein access to the time when the peel-away introducer was removed. Secondary safety endpoints for the study were the need for technique conversion with the associated causes and the incidence of catheter malpositioning.

Patient Population

A total of 30 patients were enrolled in the SAVE registry during the study period. Patient demographics and medical histories for the study population are listed in Table 2. A total of 29 of the 30 patients (96.6%) required a CVC for chronic hemodialysis. The type and location of venous obstruction for patients in the SAVE registry are shown in Table 3. All patients had 100% obstruction of the vessels identified. The type of obstruction was based on Society of Interventional Radiology's reporting standards for thoracic central vein obstruction and was assessed retrospectively because these data were published after the initiation of patient enrollment (1). Seventeen patients (56.7%) had either a Type 3 or a Type 4 obstruction.

Table 2. Demographics and Medical History for Patients Enrolled in the SAVE Registry (n = 30)

Demographics/Morbidities	Part (%)
Males/females (%)	18 (60%) / 12 (40%)
Mean ± SD age, y (range)	60.1 ± 12.8 (38-80)
Mean ± SD weight, kg (range)	68.0 ± 11.5 (48-91)
Mean ± SD height, cm (range)	160.4 ± 17.9(96-178)
Medical history	
Chronic kidney disease on dialysis	29 (96.7%)
Hypertension	24 (80%)
Diabetes	15 (50%)
Peripheral vascular disease	10 (33.3%)
Coronary artery disease, history of stroke	9 (30.0%) 3 (10.0%)
Pericardial effusion	2 (6.7%)
Pneumothorax	2 (6.7%)

SAVE = Surfacer System to Facilitate Access in Venous Obstructions.

Table 3. Location of Venous Obstruction (n = 30)

Type and Location of Obstruction	Number (%) of Patients
Type 1: Bilateral IJ or one SC vein	8 (26.7%)
Type 2B : Unilateral BCV	5 (16.7%)
Type 3 : Both BCV, partially obstructed SVC	8 (26.7%)
Type 4 : SVC obstruction preventing flow to RA	9 (30.0%)

Note–Type of obstruction is based on the Society of Interventional Radiology reporting standards for thoracic central vein obstruction (see Dolmatch et al [1]).
BCV = brachiocephalic; IJ = internal jugular; RA = right atrium; SC = subclavian; SVC = superior vena cava.

Surfacer System

The Surfacer system consists of 4 components, including a device (Fig 2) consisting of a 3-F × 10-mm needle guide, a 2-F × 180-cm needle wire, and a specialized handle. The Workstation sheath, which is 7-F in diameter and 95 cm in length, has a lumen which enables advancement of the device through the femoral vein. A radiopaque exit target is used as an external marker to indicate the desired exit site for the needle wire at the supraclavicular exit location. The system also includes an 18-F outer diameter, a 16-F inner diameter, and a 20-cm-long peel-away introducer used for percutaneous access to the venous system over the externalized needle wire.

The percutaneous endovascular inside-out CVA placement technique using the device is described in more detail elsewhere (11,12). Briefly, after access is gained through the right femoral vein, a 0.035-inch exchange guidewire is advanced through the IVC and then through the right atrium

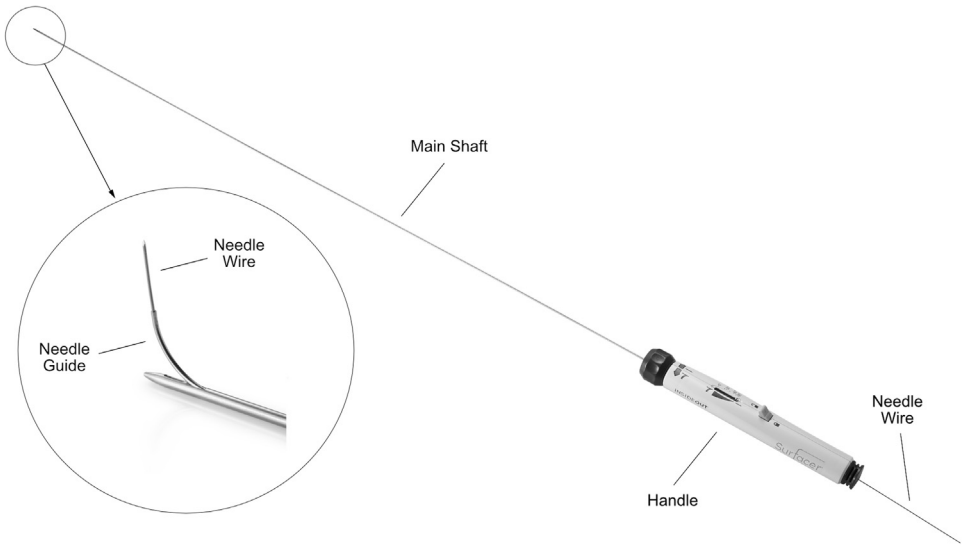

Figure 2. The Surfacer device (courtesy of Bluegrass Vascular Technologies).

until the obstruction is reached. The Workstation was then advanced over the guidewire to the point of the obstruction, and the guidewire was removed. The Surfacer device was inserted through the Workstation sheath and advanced (Fig 3a), using fluoroscopic guidance, to the obstruction, and venography was performed. The device was then advanced farther until the tip overlay the right clavicle when viewed using the anteroposterior projection. The tip of the device was then rotated to align with the external exit target positioned cranially to the clavicle, and the needle wire was advanced to the target location (Fig 3b). Once the needle wire exited the skin, the peel-away introducer was inserted over the externalized wire (Fig 3c), and a hemostat or clamp was attached to the distal end of the exposed needle wire distal to the peel-away introducer. The peel-away introducer was then pulled into the vasculature by pulling back on the device handle until the tip was past the point of obstruction. The hemostat/clamp was removed, and the needle wire was retracted, followed by insertion of a tunneled catheter through the sheath in a standard fashion.

Fluoroscopy was used to confirm that the catheter tip was correctly positioned and that blood or saline could be aspirated and flushed freely through the CVC. Postprocedure dressing and infection prevention care were performed according to each institution's standard of care. A successful procedure was defined as the presence of a patent femoral-iliac-IVC axis.

RESULTS

CVCs were successfully placed in 29 of 30 patients (96.7%) enrolled in the SAVE registry. The procedure was aborted in 1 patient (3.3%) due to vascular anatomical tortuosity with subsequent conversion to a tunneled catheter placement through a femoral vein. The patient's right iliac vein followed an excessively curved path that did not allow the device to be advanced beyond a certain point, despite various attempts (Fig 4). Furthermore, the rigidity and linearity of this device prevented it from being used in veins following this winding path. The vascular anomaly was not identified prior to the procedure because angio-CT scans were performed only for the chest and neck vessels and not the abdominal vessels in advance. Adequate catheter patency was achieved in all 29 patients who underwent successful CVC placement and desired catheter tip positioning. Acute device safety was confirmed with no device-related adverse events or catheter malposition, nor were postprocedural complications reported for any patients enrolled in the registry.

The mean time from initial insertion to removal of the Workstation sheath for the 29 patients completing the procedure was 24 ± 14.9 (range, 6–70) minutes. The mean time from when the device was inserted into the sheath until the needle wire exited the skin was 5.4 ± 10.9 (range, 0–60) minutes. Mean fluoroscopy time was 6.8 ± 4.5 (range, 2.2–25.5) minutes, and the mean volume of contrast medium used was 29.7 ± 22.2 (range, 6–100) cm^3.

DISCUSSION

This study assessed the use and clinical outcomes of the Surfacer Inside-Out Access Catheter System during clinical routine use in patients with central thoracic venous obstruction requiring CVC placement. Successful catheter placement was achieved in all but 1 of the patients (96.7%) with no device-related complications reported. Although 3 of the sites in the present study have previously published their experiences with this device (11,13), the patients enrolled in the SAVE registry were separate and distinct from those included in those previous reports.

The present study demonstrated the percutaneous, endovascular CVA placement technique described enables right-sided placement of CVCs across a range of obstruction

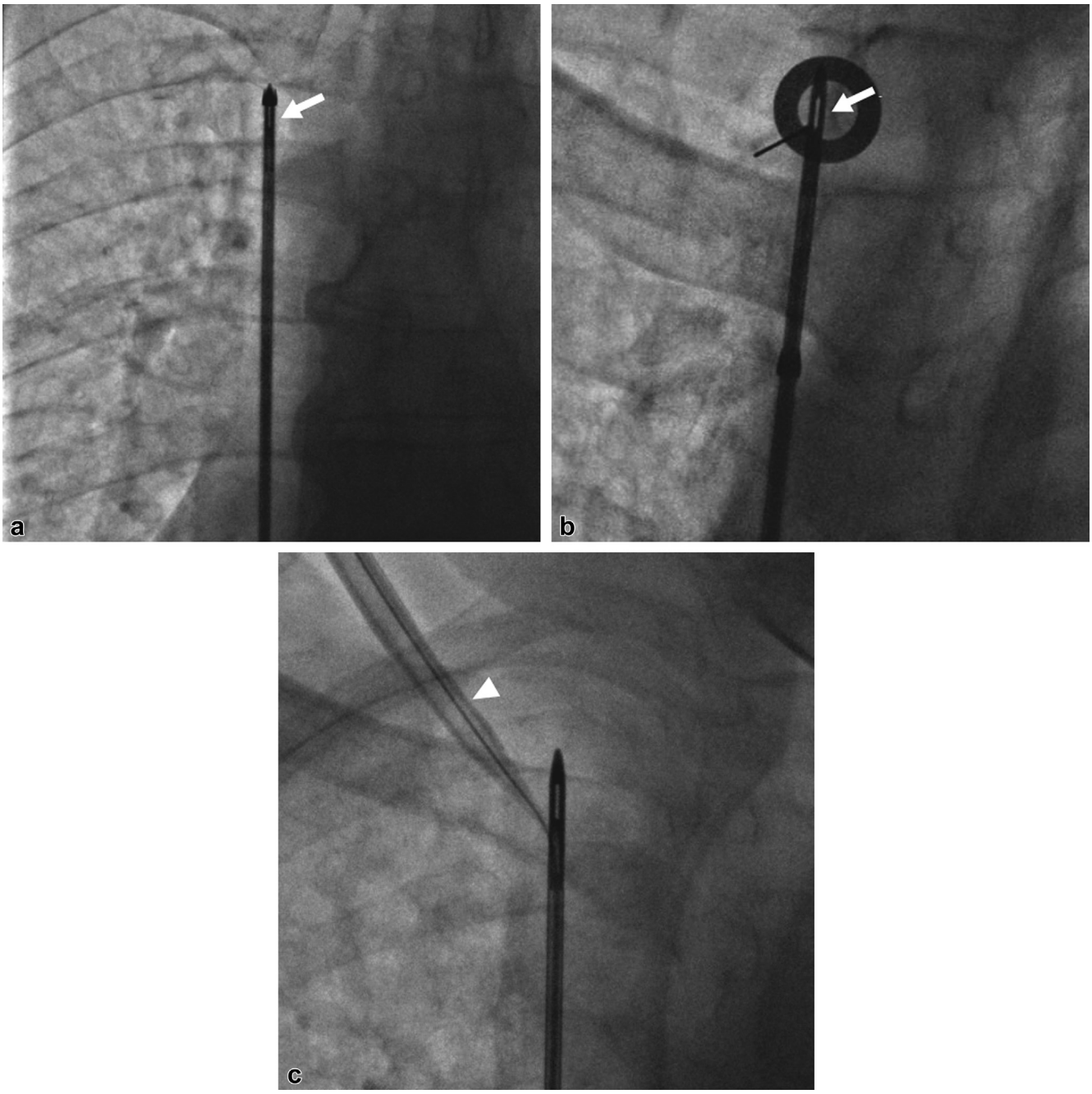

Figure 3. Anteroposterior fluoroscopic images show steps from the Surfacer System Inside-Out procedure. **(a)** Device is being advanced through the obstruction. **(b)** The device tip is rotated to align with external exit target, and the needle wire is advanced through the target. **(c)** Peel-away introducer is inserted over the externalized needle wire.

types, with more than half of the patients in the SAVE registry having the most severe Type 3 or Type 4 obstruction (1). Options for catheter placement are limited for patients with this degree of venous obstruction, and for hemodialysis patients placements may impact their ability to continue to receive dialysis therapy (14). Catheter placement through a femoral vein is a commonly used alternative in dialysis patients with occluded central veins. This placement location has been shown to be associated with shorter primary patency than catheters placed through the RIJ and with an increased risk of ipsilateral lower-extremity deep vein thrombosis (6,15). Other catheter placement procedures sometimes used in this patient population include placement through transhepatic and transrenal approaches and placement through a translumbar approach directly into the IVC (14). These procedures are more difficult to perform than conventional catheter placement and pose insertion-related complications specific to the anatomy associated with each procedure (7,8). Although sharp central vein recanalization is another alternative approach, complications have been

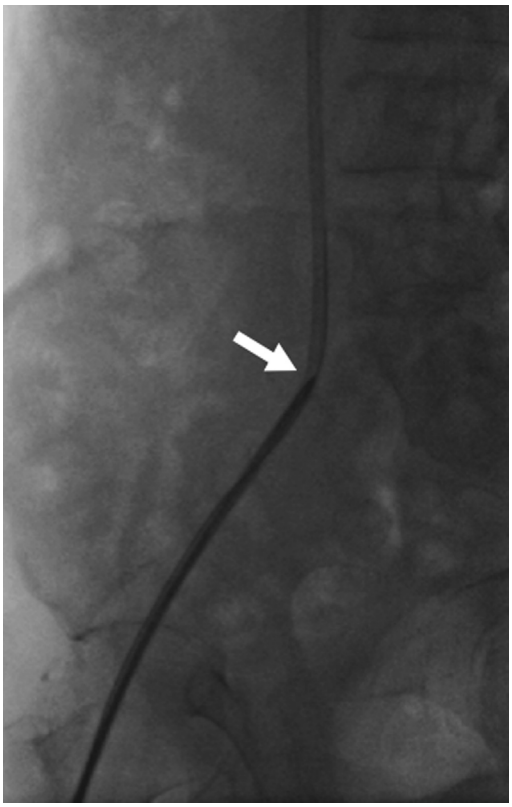

Figure 4. Anteroposterior fluoroscopic image shows the vessel tortuosity which prevented the Surfacer device from being advanced to the venous obstruction in the patient. The procedure was aborted.

reported to occur in 2.3%–28.6% of patients undergoing that procedure (9,10,16–18).

Although the inside-out technique has applications across a range of patient populations with TCVO who may require catheter placement, nearly all the patients enrolled in the SAVE registry were hemodialysis patients with chronic renal disease. The ability to achieve right-sided access and avoid catheter placement through left-sided veins can be advantageous as left-sided placement of a catheter negatively affects permanent arteriovenous (AV) access (AV fistula or graft) maturation and cumulative AV access survival when this access is placed on the ipsilateral side (5,13). Additional studies are needed to confirm that the use of the inside-out technique can support efforts to place permanent AV access in hemodialysis patients.

In patients with tortuous vascular anatomy, the use of the inside-out procedure should be carefully evaluated by using advanced imaging modalities to confirm the ability to track from the femoral vein to the supraclavicular exit site. Technical issues associated with the ability to gain CVA with the Surfacer device in patients with iliac tortuosity has previously been reported elsewhere (11). Although the use of the device for patients enrolled in the SAVE registry simplified the ability to perform the inside-out procedure in patients with challenging anatomies, the pattern of venous obstruction should be predefined using imaging prior to attempting the procedure.

Several limitations to this study need to be considered. Although the SAVE registry represented a heterogeneous clinical experience with the Surfacer System, the observed results may not be predictive of results obtained in patient populations not represented in this series. There is also the possibility that selection bias was introduced into the study due to patient referral patterns for each site or as each investigator determined which patients would be approached about participation in the registry. Information for potential patients who met the criteria for enrollment in the registry but were not approached or who declined enrollment was not available for analysis. This, in combination with the inherent lack of a control group for a single-arm registry, limits the ability to generalize the study's findings.

Data from the SAVE registry indicate the inside-out endovascular procedure can be performed efficiently and safely by experienced vascular access specialists using standard fluoroscopy. For patients with central venous obstruction requiring catheter placement, the Surfacer system provides an alternative option for achieving right-sided CVA.

ACKNOWLEDGMENTS

The authors thank Laura Minarsch for logistical support for the SAVE registry and assistance with preparation of the manuscript. The authors acknowledge the support provided by Meditrial- related logistical and data collection support for the SAVE registry.

REFERENCES

1. Dolmatch BL, Gurley JC, Baskin KM, et al; for the Central Vein Work Group, Technology Assessment Committee. Society of Interventional Radiology reporting standards for thoracic central vein obstruction. J Vasc Interv Radiol 2018; 29:454–460.
2. Collin G, Jones RG, Willis AP. Central venous obstruction in the thorax. Clin Radiol 2015; 70:654–660.
3. Vascular Access 2006 Work Group. Clinical practice guidelines for vascular access. Am J Kidney Dis 2006; 48(Suppl 1):S176–S247.
4. Salik E, Daftary A, Tal MG. Three-dimensional anatomy of the left central veins: implications for dialysis catheter placement. J Vasc Interv Radiol 2007; 18:361–364.
5. Salgado OJ, Urdaneta B, Colmenares B, et al. Right versus left internal jugular vein catheterization for hemodialysis: complications and impact on ipsilateral access creation. Artif Organs 2004; 28: 728–733.
6. Maya ID, Allon M. Outcomes of tunneled femoral hemodialysis catheters: comparison with internal jugular vein catheters. Kidney Int 2005; 68: 2886–2889.
7. Power A, Singh S, Ashby D, et al. Translumbar central venous catheters for long-term haemodialysis. Nephrol Dial Transplant 2010; 25: 1588–1595.
8. Smith TP, Ryan JM, Reddan DN. Transhepatic catheter access for hemodialysis. Radiology 2004; 232:246–251.
9. Keller EJ, Gupta SA, Bondarev S, et al. Single-center Retrospective review of radiofrequency wire recanalization of refractory central venous occlusions. J Vasc Interv Radiol 2018; 29:1571–1577.

10. Cohen EI, Beck C, Garcia J, et al. Success rate and complications of sharp recanalization for treatment of central venous occlusions. Cardiovasc Intervent Radiol 2018; 41:73–79.
11. Hentschel DM, Minarsch L, Vega F, Ebner A. The Surfacer® Inside-Out® Access System for right-sided catheter placement in dialysis patients with thoracic venous obstruction. J Vasc Access 2020; 21: 411–418.
12. Quek LHH, Tan TSM, Tan GWL, Pua U. Salvage of exhausted neck access using a novel inside-out device in dialysis-dependent patients. Hemodial Int 2019; 23:E111–E114.
13. Reindl-Schwaighofer R, Matoussevitch V, Winnicki W, et al. A novel inside-out access approach for hemodialysis catheter placement in patients with thoracic central venous occlusion. Am J Kidney Dis 2020; 75: 480–487.
14. Vachharajani TJ, Agarwal AK, Asif A. Vascular access of last resort. Kidney Int 2018; 93:797–802.
15. Burton KR, Guo LL, Tan KT, et al. Patency of femoral tunneled hemodialysis catheters and factors predictive of patency failure. Cardiovasc Intervent Radiol 2012; 35:1396–1402.
16. Athreya S, Scott P, Annamalai G, et al. Sharp recanalization of central venous occlusions: a useful technique for haemodialysis line insertion. Br J Radiol 2009; 82:105–108.
17. Lang EV, Reyes J, Faintuch S, et al. Central venous recanalization in patients with short gut syndrome: restoration of candidacy for intestinal and multivisceral transplantation. J Vasc Interv Radiol 2005; 16:1203–1213.
18. Arabi M, Ahmed I, Mat'hami A, et al. Sharp central venous recanalization in hemodialysis patients: a single-institution experience. Cardiovasc Intervent Radiol 2016; 39:927–934.

Table E1. Number of Patients Enrolled in the Registry by Site and Type of Imaging Studies Performed

Site number	Location	Number of Patients Enrolled	Imaging Studies Performed*
1	Köln, Germany	5	Patients underwent a CT scan of the thoracic and abdominal region prior to the procedure. All patients had venograms performed intraoperatively.
2	Milan, Italy	5	Patients underwent contrast-enhanced thoracic CT scans prior to the procedure. All patients had venograms performed intraoperatively
3	Vienna, Austria	6	Patients underwent CT scans and venograms prior to the procedure. Ultrasonograms of the femoral and iliac veins were also performed preoperatively. All patients had venograms performed intraoperatively.
4	Düsseldorf, Germany	4	Patients underwent CT scans and venograms prior to the procedure. Ultrasonograms of the femoral and iliac veins also performed preoperatively. All patients had venograms performed intraoperatively.
5	Asunción, Paraguay	10	No preoperative imaging studies were performed. All patients had venograms performed intraoperatively.

*Duplex/doppler ultrasound of the jugular and subclavian veins and the inferior vena cava was performed preoperatively for all patients.