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Efficacy and safety associated with the use of the Surfacer® Inside-Out® Access Catheter System: Results from a prospective, multicenter Food and Drug Administration–approved Investigational Device Exemption study

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Abstract

Purpose: Thoracic central venous obstruction is commonly associated with the use of central venous catheters. The *Surfacer System to Facilitate Access in Venous Occlusions* Study was an Food and Drug Administration–approved US Investigational Device Exemption study designed to evaluate the performance and safety of the Surfacer System when used to facilitate central venous access in patients with thoracic central venous obstruction.

Methods: Thirty patients were enrolled in this prospective, multicenter, single-arm study between December 2017 and May 2019. Device performance and adverse events were collected peri-procedurally and at discharge. Enrollment included 15 female and 15 male subjects with a mean age of 55.5 ± 12.9 (range: 30–79) years. Twenty-eight patients (93.3%) required central venous access for hemodialysis access. Locations of thoracic central venous obstruction were graded from 1 to 4 based on severity and extension of venous occlusions. Seven patients (23.3%) had type 1, 6 (20.0%) type 2, 16 (53.3%) type 3, and 1 (3.3%) type 4 obstruction.

Results: Successful central venous catheter placement was achieved in 27 of 30 patients (90.0%). The procedure was discontinued in three (10.0%) due to tortuous anatomy discovered intraprocedurally. All 27 patients with successful CVC placement achieved adequate catheter patency and tip positioning with a mean overall procedural time and time to achieve central venous access with the Surfacer System being 44.1 ± 30.6 and 19.1 ± 25.1 min, respectively. There were no device-related adverse events or catheter malposition.

Conclusion: The results of the SAVEUS Study confirm the safety and efficacy of the Surfacer System and the Inside-Out procedure when used for the placement of right-sided central venous access in patients with thoracic central venous obstruction.

Keywords

Hemodialysis, catheter, central venous obstruction, inside-out

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Introduction

The use of central venous catheters (CVCs) is associated with a high rate of complications with resultant morbidity and mortality.[1,2] One such complication, thoracic central venous obstruction (TCVO), results from catheter-associated venous thrombosis and wall thickening and occurs in 25%–40% of patients utilizing CVCs.[3,4] The development of TCVO in patients can lead to arm swelling with accompanying pain, paresthesia, and potential loss of the same anatomical vein for subsequent central venous access (CVA).

While the right internal jugular (RIJ) vein is preferred for the placement of CVCs due to its large diameter and more direct access to the right atrium,[5] its occlusion often results in the use of the left internal jugular (LIJ) vein as an alternative access site. Left-side catheter placement is associated with higher rates of complications, including device malfunction and thrombosis, due in part to the greater tortuosity of the anatomy.[6,7] Catheter placement in the LIJ vein can also negatively impact the development and maturation of ipsilateral arteriovenous fistulas in hemodialysis patients.[8] While sharp recanalization is utilized as an approach to CVC placement in patients with right-sided TCVOs, this procedure can be technically challenging and associated with a high risk of complications.[9]

The Surfacer® Inside-Out® Access Catheter System (Bluegrass Vascular Technologies, San Antonio, TX, USA) was designed to facilitate right-sided CVA in patients with TCVO. The device permits entry and placement of CVCs for patients with upper body venous obstructions that preclude conventional CVA by using the percutaneous, endovascular inside-out CVA placement technique.[10–12] In this article, we report the results from a prospective, multicenter, single-arm study designed to evaluate the safety and efficacy of the Surfacer device in patients with TCVO.

Methods

Study design

The SAVE-US study (NCT03209050) was a prospective, multicenter, single-arm, US Food and Drug Administration (FDA)-approved Investigational Device Exemption (IDE) trial designed to assess the safety and effectiveness of the Surfacer System and the Inside-Out procedure when used to facilitate CVA in patients with TCVO. Thirty patients who met the inclusion/exclusion criteria (Table S1) were enrolled at seven sites in the United States from December 2017 to May 2019. The study was conducted in accordance with FDA regulations and with Institutional Review Board approval from each investigative site. All patients gave written informed consent prior to being enrolled in the study. An independent Data Safety and Monitoring Board (DSMB) reviewed the study's safety data and ensured study compliance.

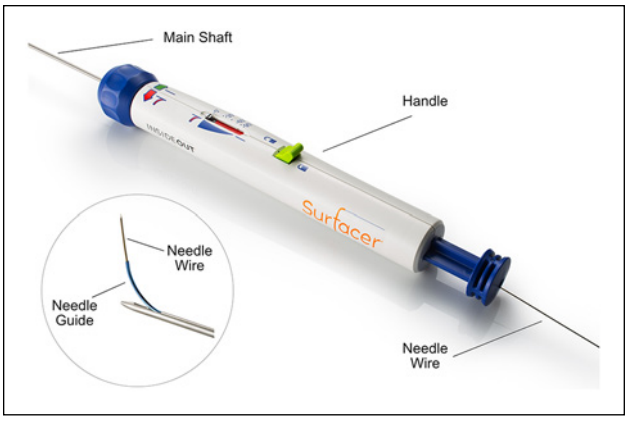

Figure 1. The Surfacer device.

Device description

The Surfacer device consists of four components: a 10F sheath for percutaneous femoral vein access; a delivery instrument designed to cross the venous obstruction into the supraclavicular space containing a guide at the distal end to direct the needle wire when it is deployed (Figure 1); a radiopaque marker which provides an external fluoroscopic target where the needle wire will exit; and a peel-away introducer sheath which is inserted over the externalized needle wire to gain access to the central venous system. The device facilitates the insertion and positioning of CVCs by establishing a passage across right-sided upper body venous occlusions.

Procedure overview

Technical details of the inside-out procedure have been previously described.[12] Briefly, percutaneous access was achieved via the right femoral vein and device sheath advanced into the superior vena cave (SVC) to reach the obstruction. The device delivery instrument was then inserted into the sheath, and under fluoroscopic guidance, passed through the obstruction to the supra-clavicular space. The image intensifier was then rotated until the distal tip of the device directly aligned with the external exit target when viewed under fluoroscopy (Figure 2). The degree of angulation of the fluoroscopic instrument, in the cranial projection, was recorded and input into the device handle to facilitate proper aiming of the needle guide and the correct angle of deployment of the needle wire toward the exit target. The needle wire was then advanced toward the external exit target, going through the occlusion and then the skin. A peel-away introducer was then advanced over the externalized needle wire until the tip passed beyond the point of occlusion of the venous system. The

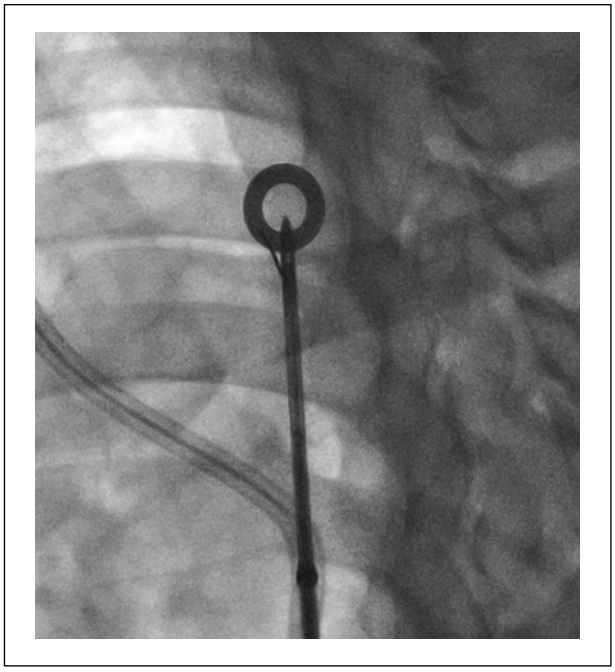

Figure 2. Alignment of external target under fluoroscopy.

CVC was then inserted through the peel-away introducer and advanced to the proper position. The device was removed once CVA had been established and a CVC or other access device had been properly placed.

Imaging studies

Pre-procedure imaging included a duplex ultrasound or venography within 7 days of the screening visit. Anterior-posterior and lateral chest X-rays or cine fluoroscopies were performed prior to the procedure to detect pre-existing pleural effusions or mediastinal widening. Patterns of obstruction(s) and absence of acute clot were confirmed by catheter venography at the time of the procedure. Correct placement of the CVC and absence of pleuro-pulmonary injury was established by post-procedural X-rays or cine-fluoroscopy. Advanced imaging (e.g. cone beam computed tomography, transthoracic echocardiography) was performed in patients with type 3 or 4 obstructions as defined by the Society of Interventional Radiology Reporting Standards for TCVOs[3] (Figure 3) or in patients with suspected tortuous vessels or otherwise challenging anatomy.

Study endpoints

The primary efficacy endpoints for the study were the rate of safe insertion associated with the use of the Surfacer System and the ability to establish patent CVA across the venous occlusions. The primary safety endpoints were defined as the absence of procedural complications at discharge and at 7-day post-procedure. The secondary effectiveness endpoints were the achievement of technical success, specifically the insertion of Surfacer System and successful supra-clavicular exit of the inside-out needle without any adverse events, and procedural success, the ability to utilize the device to facilitate placement of a functioning CVC. The secondary safety endpoint was the technique conversion rate defined as the need to use an alternative procedure in order to achieve CVA.

The Intent-to-Treat (ITT) safety subject population comprised all enrolled subjects in whom access was attempted and a component of the Surfacer System was inserted into the subject, regardless of whether or not the procedure was completed with the successful placement of a CVC. The per-protocol (PP) population included all enrolled subjects in whom the procedure was deemed a technical success. All primary and additional endpoints were evaluated on both an ITT and PP basis with ITT considered the primary analysis.

Data collection and management

Data were collected via electronic case report forms with initial inspection by the study coordinator and/or data management consultant for omitted data, gross data inconsistencies, and deviations. All data were monitored on site and 100% source data verified by the data management and the study sponsor. The study database was developed and maintained in compliance with applicable study regulations. Patient monitoring and follow-ups were performed at hospital discharge and 7 days postoperatively. Table S2 lists the schedule for study assessments and the data collected for each assessment period.

Sample size

The sample size was intended to provide sufficient data to assess basic safety and effectiveness with an acceptable level of outcome evaluation certainty based on the statistical analysis plan. The maximum Clopper-Pearson exact 95% confidence interval (CI) for the binary outcome for 30 patients was estimated to range from 31.3% to 68.7%, assuming an observed percentage of 50%. If observed device success rate was less than 78% (inability to obtain CVA in more than six subjects), then more than 30 subjects would need to be evaluated to ensure the observed success rate was not by chance.

Results

Thirty-eight subjects were consented with 30 subjects subsequently enrolled in this study. This included one patient who failed on the table as a result of the presence of pericardial effusion detected prior to insertion of the Surfacer System. The 30 patients in the ITT analysis group included 15 females and 15 males with a mean age of 55.5 ± 12.9

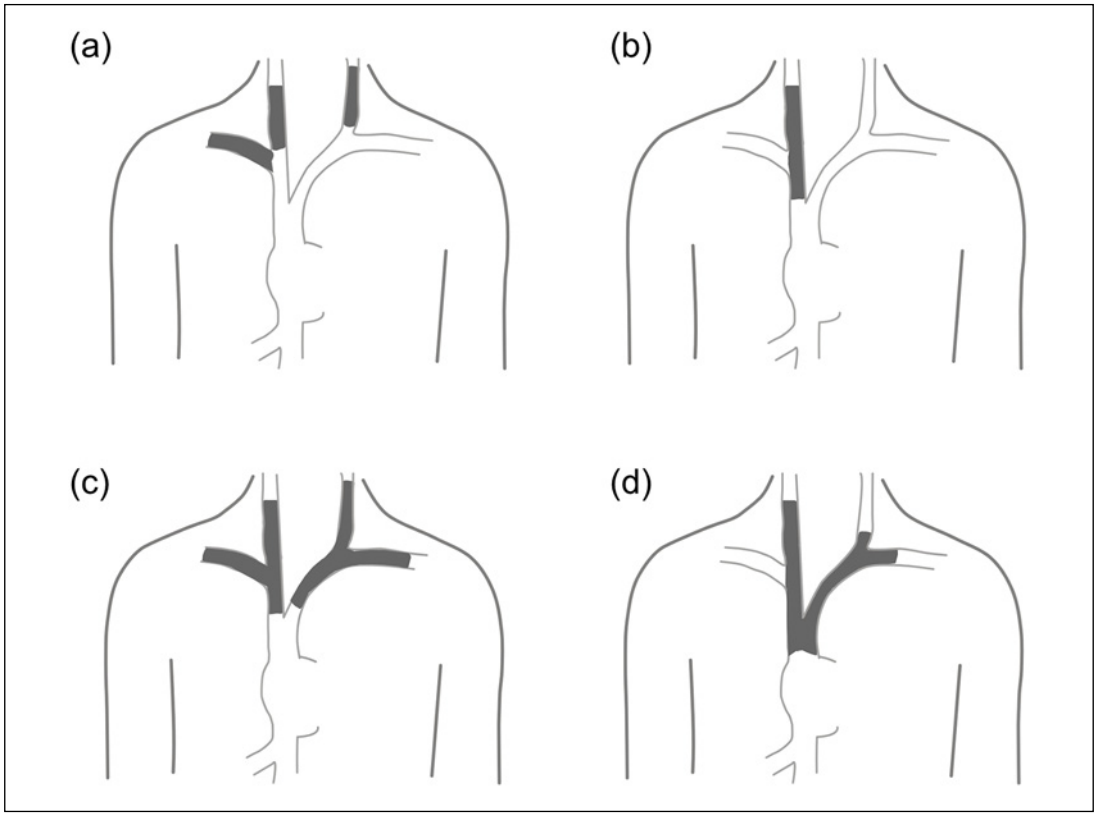

Figure 3. Types of thoracic central venous obstructions by anatomical location: (a) type 1, obstruction of right internal jugular (RIJ) vein with or without obstruction of left internal jugular or one subclavian vein; (b) type 2, obstruction of RIJ with extension into the brachiocephalic vein; (c) type 3, obstruction of bilateral brachiocephalic veins with involvement of cephalic superior vena cava; and (d) type 4, obstruction of the entire superior vena cava preventing flow to right atrium.

Table 1. Select demographic data and comorbid conditions for patients enrolled in SAVEUS study (ITT population) ($n = 30$).

Characteristic	Value
Age, mean ± SD (range)	55.5 ± 12.9 (30–79)
Sex	
Male	15 (50.0%)
Female	15 (50.0%)
Coronary artery disease	11 (36.7%)
Diabetes	14 (46.7%)
Type 1	2 (6.7%)
Type 2	12 (40.0%)
Hypertension	21 (70.0%)
Peripheral vascular disease (PVD)	10 (33.3%)
Dialysis	28 (93.3%)
TCVO type[3]	14 (46.7%)
Type 1: Bilateral IJ or one SC vein	7 (23.3%)
Type 2: Unilateral BCV	6 (20.0%)
Type 3: Both BCV, partially obstructed SVC	16 (53.3%)
Type 4: SVC obstruction preventing flow to right atrium	1 (3.3%)

SD: standard deviation; TCVO: thoracic central venous obstruction; BCV: brachiocephalic vein; IJ: internal jugular; SVC: superior vena cave.

(range: 30–79). Select demographic data and comorbid conditions are shown in Table 1. Twenty-eight (93.3%) of the patients required CVA for hemodialysis. All patients had obstructions of the SVC and/or the right jugular, subclavian, or brachiocephalic veins. Table 1 reports the type of TCVO, based on the Society of Interventional Radiology reporting standards for patients enrolled in the study.[3] Seven patients (23.3%) had type 1, 6 (20.0%) type 2, 16 (53.3%) type 3, and 1 (3.3%) type 4 obstruction. Additional baseline characteristics and medical histories are detailed in Table S3.

In 27 of the 30 patients (90%) included in the ITT population the device was successfully inserted via the femoral vein to the supra-clavicular exit, with subsequent CVC placement across the venous obstruction (95% CI: 73.5%, 97.9%). Attempted CVA was not successful in three patients due to tortuous anatomy detected intra-procedurally. There were no device-related adverse events or catheter malposition events reported in the 27 patients.

All 27 patients in the PP population (100%) had successful CVC placement. Mean overall procedural time from initial femoral access through skin closure for the PP population was 44.1 ± 30.6 min (range: 10–130 min) and mean time to achieve CVA with the Surfacer System

was 19.1 ± 25.1 min (range: 2–115 min). Mean fluoroscopy time was 11.2 ± 9.72 min (range: 2.5–49.4 min) and mean volume of contrast was 95.4 ± 107.3 mL (range: 5–360 mL).

All adverse events were adjudicated by the DSMB. There were no device-related adverse events reported during the study. A total of five procedure-related events were reported for 4 of the 30 patients (13.3%) in the ITT population. These included the following: bleeding at the CVC exit site occurring in two patients which was managed with a pressure dressing and ligation, respectively; bleeding requiring transfusion; hemodynamic instability resulting from kidney failure which was resolved with fluid management; and unintended embolization of a thrombus noted at prior tunneled dialysis catheter entry site which was asymptomatic and resolved with anticoagulation. The primary safety endpoint for acute device safety was met in 86.7% (95% CI: 69.3%, 96.2%) for the ITT population and 85.2% (95%CI: 75.7%, 99.1%) for the PP population.

Discussion

The present study assessed the safety, efficacy, and feasibility of using the Surfacer System to perform the percutaneous, endovascular inside-out procedure to establish CVA in patients with obstructed central veins. The primary study endpoint, defined as safe device insertion and establishment of patent CVA across venous occlusions, was achieved in 27 of 30 patients. The inability to safely cross occlusions in three patients due to challenging anatomical tortuosity resulted in no CVA access.

The primary safety endpoint was achieved in 86.7% of the 30 patients in the ITT group. Procedural complications, the predefined safety endpoint for the study, were reported in four patients (13.3%). None of these were considered device related. There were no instances of other acute procedural complications (e.g. hemopericardium, hemothorax, pneumothorax). The results from the present study are consistent with those reported in conjunction with the use of the Surfacer device in other retrospective patient series.[10–12] Reindl-Schwaighofer et al.[10] recently reported on a larger series of patients where the device was used successfully to establish CVA in 38 of 39 (97%) attempted procedures in hemodialysis patients with TCVO. This included seven patients in which the Surfacer procedure was repeated due to failure of the CVC and inability to change out the catheter during the study observation. All catheters were properly functioning 3 months following insertion.

For hemodialysis patients, left-sided placement of a CVC can negatively affect maturation of a permanent arteriovenous access and also impact cumulative AV access survival when this access is placed on the ipsilateral side.[8,13] The Surfacer system can be used to maintain right-sided access and avoid catheter placement on the left, should arteriovenous access be anticipated. Additional studies to confirm the hypothesis that the use of the Surfacer System can lead to improved overall AV access outcomes in hemodialysis patients are needed.

An important limitation of our study was the lack of a control group for comparison of the safety and effectiveness of this approach to alternative approaches used to obtain access in patients with TCVOs. While procedure length and the rate of complications reported in the present study are less than those in the literature for sharp recanalization,[9] no direct comparison of these two approaches is available at this time. For the present study, the determination was made that there was no equivalent device to use as a comparator and it was not possible to identify an appropriate control group since the approach to achieving CVA varies depending upon the type and location of the obstruction.

Other limitations include the lack of longer term monitoring of catheter performance, although the Surfacer is used to gain access and place a catheter and does not influence the maintenance or functionality of the catheter. Patient monitoring was limited to 7-day post-procedure per study definitions and requirements. As in other series,[10–12] there was a limited number of patients with type 4 obstructions in this patient population. The distribution of the obstruction types treated in the present study is reflective of the epidemiology of type 4 lesions and hence enrollment in this study is representative of the general population of patients with TCVO who need CVC.

Conclusion

Use of the Surfacer System as a part of the percutaneous, endovascular inside-out procedure safely and effectively enables the right-sided placement of CVCs in patients with TCVOs. The device has application for patients who have limited access options due to obstruction of multiple thoracic veins or in patients where the placement of right-sided catheters is desired in order to avoid the use of other alternative venous options.

Authors' contributions

M.K.R., E.P., E.S., J.A., T.A.P., H.W., and Z.H. performed the procedures. All authors were responsible for data collection. M.K.R. prepared the manuscript and all authors read and approved the final manuscript.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: M.K.R. and E.S. are consultants to Bluegrass Vascular Technologies. All remaining authors have no financial interests to disclose related to this study.

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Supplemental material

Supplemental material for this article is available online.

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