BLUEGRASS VASCULAR

Inside-Out® Upper Body Venous Access: First-in-Human Experience with a Novel Approach using the Surfacer® Inside-Out® Access Catheter System

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OVERVIEW

As part of a safety and feasibility study, 12 patients (27-63 years of age) with compromised upper venous occlusive disease consented and were treated with the Surfacer® Inside-Out® Access Catheter System. This report presents one of the cases as well as the results from the entire series.

METHODS

Access was gained from inside of the body out. The operator inserted the Surfacer System via standard femoral access, transversed the central circulatory system to the head of the clavicle (i.e., the safe spot), and exited the skin above the clavicle. A standard central venous catheter was then inserted over the same wire.

RESULTS

The average access time was 32.8 minutes. All patients received an access catheter, which remained in place and was functional for 14 days. All safety and performance endpoints were met with no complications or adverse events, and product design was validated in this human experience. Conclusion: The procedure is repeatable allowing physicians to preserve venous real estate increasing the success of permanent vascular access for therapies such as dialysis, chemotherapy and nutrition. This study shows that the novel Surfacer System provides safe and effective percutaneous central venous access.

BACKGROUND

Severe renal dysfunction and venous occlusive disease is a major cause of morbidity, mortality and increased medical costs, especially within the dialysis population. The long-term risks of central venous access include occlusion, which can occur within days of catheter placement and is a common problem in patients requiring repeated access or semi-permanent access. Central venous occlusion can deprive patients of vital therapies such as hemodialysis, cardiac pacing, chemotherapy, and drug infusion. As simple central venous occlusions force providers to sacrifice secondary veins, patients often endure the morbidity of venous hypertension and the mortality risk of an access crisis. Central venous occlusive disease is entirely iatrogenic, highly destructive, and vastly underappreciated by the general medical community.

The mechanism of venous occlusion/obstruction includes mechanical disruption of blood flow, endothelial injury, inflammation, scarring and activation of coagulation factors.[1] The placement of long term access catheters presents multiple challenges for patients, including infection and the inevitability that each attempted access point will have less than optimal patency and eventually result in total blockage. When the upper body veins (internal jugular and subclavian) are used to access the central venous system, venous occlusive disease will develop over time and prevent these patients from receiving their lifesaving medical treatment. Multiple central venous occlusions can cause significant long-term morbidity. The loss of one internal jugular (IJ) vein is usually well tolerated because venous drainage from the head continues through the remaining jugular vein. However, when both IJ veins become occluded,

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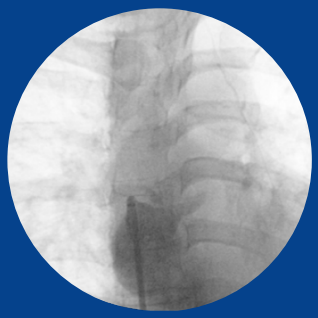

Figure 1: Totally occluded superior vena cava

Figure 2: Components of the Surfacer® System

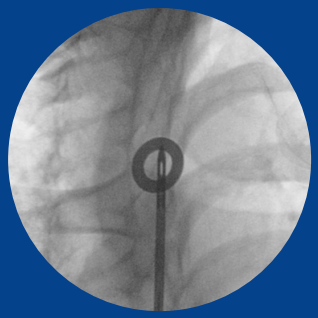

Figure 3: Exit Target aligned with targeting window of the Surfacer® Delivery Instrument

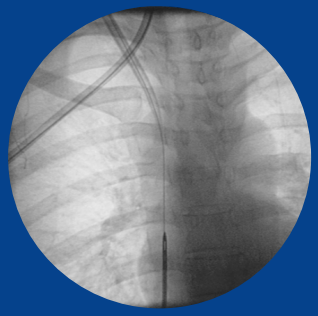

Figure 4: Introducer sheath locked onto needle wire and pulled into right atrium

patients can develop venous hypertension affecting the head, face and brain.[2] This can produce chronic headaches that increase when lying down, swelling of the face, visual disturbances, and neurological abnormalities. Occlusion of the subclavian veins occurs so readily that they are generally reserved for permanent pacemakers and defibrillators (which benefit from lead stability) or for venous access as a matter of last resort. Other access options include femoral veins, which can be utilized for long term central venous access when the upper body sites are not available. However, femoral venous catheters are relatively unstable with leg movement and have higher rates of infection and thrombotic complications.[3,4,5]

CASE STUDY

A 30 year-old woman with renal failure required central venous access for hemodialysis. Angiography demonstrated chronic total occlusion of the IJ and subclavian veins, as well as total occlusion of the superior vena cava (SVC) at the level of the right atrium. Attempts to obtain access by conventional methods failed, and the patient was referred for inside-out access using the Surfacer® Inside-Out® Access Catheter System (Bluegrass Vascular Technologies, San Antonio, TX).

After obtaining informed consent, the patient was prepped under conscious sedation (midazolam and fentanyl) and local anesthesia. An 8F introducer sheath, Surfacer Workstation, was inserted via the right femoral vein and advanced over a .035 in. guide wire to the right atrium. Contrast angiography confirmed chronic total occlusion of the superior vena cava at its junction with the right atrium (Figure 1). The Surfacer Delivery Instrument (Figure 2) was advanced into the occluded venous segment to the level of the right clavicle. A circular metallic skin marker was placed at the desired exit site. Without moving the Delivery Instrument, the fluoroscopy system was rotated until the tip of the Delivery Instrument overlay the Exit Target (Figure 3). The degree of cranial angulation was recorded. Maintaining this fluoroscopic position, the Delivery Instrument handle was rotated until the opening in the tip was visible and revealed a maximum window.

The knob on the handle was then rotated to advance the Needle Guide out of the tip of the Delivery Instrument. It was confirmed that the indicator on the handle matched the degree of cranial angulation previously recorded. The Needle Wire was advanced out of the Needle Guide through the soft tissues and punctured the skin at the center of the Exit Target. A 16F introducer sheath, Surfacer Exit Introducer, was locked onto the Needle Wire and pulled into the right atrium (Figure 4).

A standard, tunneled dialysis catheter was inserted and sutured into place. Standard central venous catheters 24, 28, 30 or 32cm sizes can be used depending on anatomy. There were no complications. Total Surfacer® Inside-Out® access procedure time including introduction to exit was 4 minutes. Total procedure time including placement of the CVA catheter was 34 minutes.

DISCUSSION

As part of a safety and feasibility study, a total of twelve patients (27-63 years old) were consented and treated with the Surfacer® Inside-Out® Access Catheter System. All patients presented with severe renal dysfunction and compromised upper venous occlusive disease. All patients required hemodialysis and had two or more occluded upper body venous access points; one patient was diabetic. The study was performed at the Italian Hospital in Asuncion, Paraguay.

Patients underwent routine chest radiographs and ECG or venous duplex venography and were sedated with intravenous midazolam plus fentanyl. All patients had Creatinine levels averaging 10.0. Average procedure time was 32.8±16.9 minutes (Table 1) and decreased with increased operator experience (Figure 5). Average contrast used was approximately 16cc. All twelve patients received an access catheter which remained in place and was functional for 14 days. Results show that this novel approach provides safe and effective percutaneous central venous access, despite chronic occlusion of the SVC. Inside-out central venous access should be further explored as a new option for patients with upper body venous occlusive disease. As

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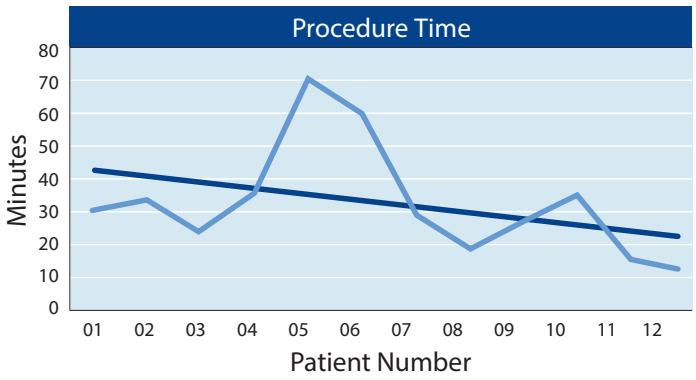
Table 1: Procedural Results

Subject ID	Procedure Time (min)	Fluoroscopy Time (min)	Contrast Volume (cc)
01	31	10.4	20
02	34	10.5	20
03	24	10.3	20
04	36	9.3	20
05	70	10.4	25
06	60	9.5	10
07	29	4.0	10
08	19	4.6	10
09	25	5.3	20
10	35	4.8	10
11	17	4.4	15
12	13	5.7	10
AVG	32.8	7.4	15.8
STDEV	16.9	2.8	5.6

Figure 5: Procedure Time



REFERENCES

1. López JA, Chen J. Pathophysiology of venous thrombosis. Thromb Res. 2009;123 Suppl 4:S30-4.

2. Riutta JC, Cheville AL, Trerotola SO. SVC syndrome with a patent SVC: treatment of internal jugular venous occlusion after surgical and radiation therapy of esophageal cancer. J Vasc Interv Radiol. 2005 May;16(5):727-31.

3. Bertrand M, Presant CA, Klein L, Scott E. Iatrogenic superior vena cava syndrome. A new entity. Cancer. 1984 Jul 15;54(2):376-8.

4. Stephens WP, Lawler W. Thrombus formation and central venous catheters. Lancet. 1982 Sep 18;2(8299):664-5.

5. Joynt GM, Kew J, Gomersall CD, Leung VY, Liu EK. Deep venous thrombosis caused by femoral venous catheters in critically ill adult patients. Chest 2000;117:178-83.

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The Surfacer® Inside-Out® Access Catheter System (Catalog Number 600200) has received CE Mark approval and is commercially available in countries recognizing the CE Mark, or with applicable health authority registrations.

The Surfacer® Inside-Out® Access Catheter System is not available for sale in the United States.

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