Inside-Out Upper Body Venous Access

The first-in-human experiences with a novel approach using the Surfacer inside-out access catheter system.

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Severe renal dysfunction and venous occlusive disease are major causes 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 semipermanent access. Central venous occlusion can deprive patients of vital therapies such as hemodialysis, cardiac pacing, chemotherapy, and drug infusion. Because 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, such as 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 [IJ] and subclavian) are used to access the central venous system, venous occlusive disease will develop over time and prevent patients from receiving lifesaving medical treatment. Multiple central venous occlusions can cause significant long-term morbidity.

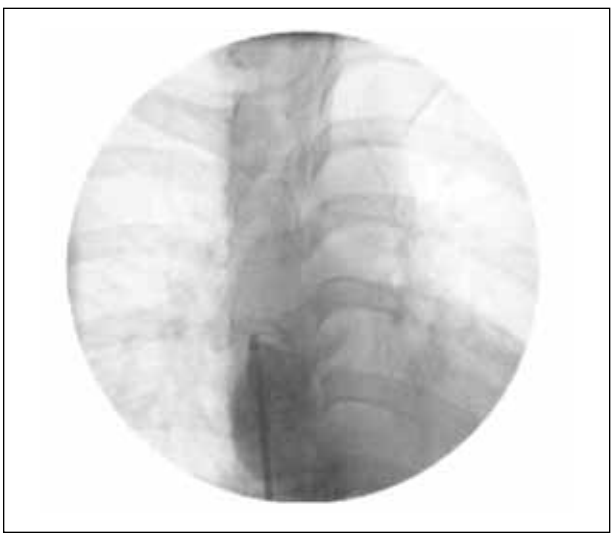

Figure 1. A totally occluded superior vena cava (SVC).

The loss of one 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, 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,

Figure 2. The components of the Surfacer system.

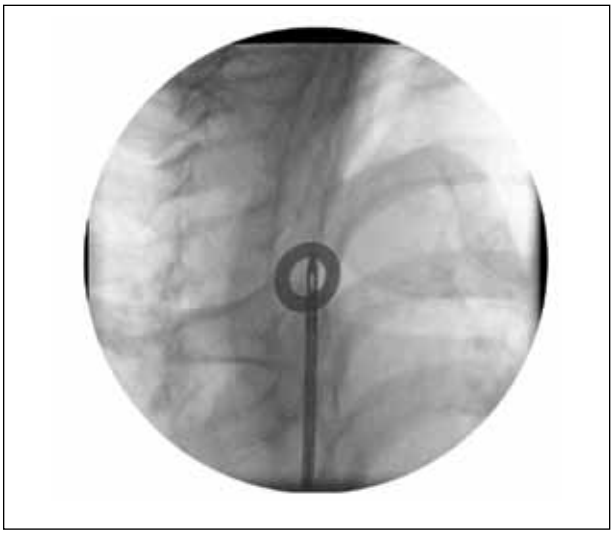

Figure 3. The exit target is aligned with the targeting window of the Surfacer delivery system.

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. Another access option is the femoral veins, which can be used 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. [3-5]

CASE STUDY

A 30-year-old woman with renal failure required central venous access for hemodialysis. Angiography

TABLE 1. PROCEDURAL RESULTS

Subject No.	Procedure Time (min)	Fluoroscopy Time (min)	Contrast Volume (mL)
1	31	10.4	20
2	34	10.5	20
3	24	10.3	20
4	36	9.3	20
5	70	10.4	25
6	60	9.5	10
7	29	4	10
8	19	4.6	10
9	25	5.3	20
10	35	4.8	10
11	17	4.4	15
12	13	5.7	10
Average	**32.8**	**7.4**	**15.8**
Standard deviation	**16.9**	**2.8**	**5.6**

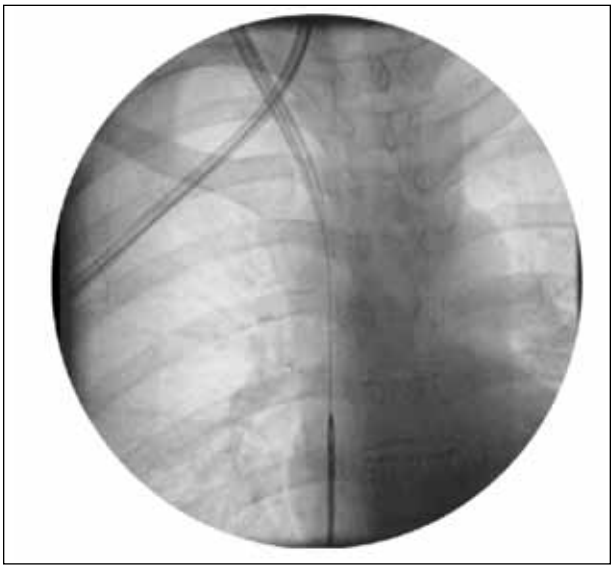

Figure 4. The introducer sheath is locked onto the needle wire and pulled into the right atrium.

showed chronic total occlusion of the IJ and subclavian veins, as well as total occlusion of the SVC at the level of the right atrium. Attempts to achieve 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, Lexington, KY).

After obtaining informed consent, the patient was prepped under conscious sedation (midazolam and fentanyl) and local anesthesia. An 8-F introducer sheath was inserted via the right femoral vein and advanced over a 0.035-inch guidewire 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, center) was advanced into the occluded venous segment to the level of the right clavicle. A circular metallic exit target was placed on the skin at the desired exit site. Without moving the delivery instrument, the fluoroscopy system was rotated until the tip of the delivery instrument overlaid 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.

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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 16-F introducer sheath 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 catheter sizes (24, 28, 30, or 32 cm) can be used, depending on the patient's anatomy. There were no complications, and the total procedure time was 22 minutes.

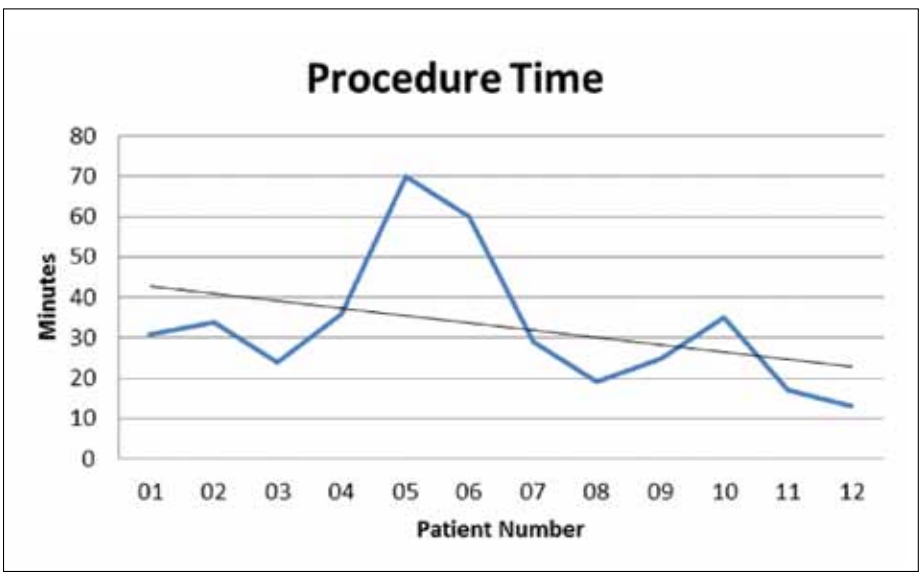

Figure 5. Procedure times for the 12 patients who were treated using the Surfacer inside-out access catheter system.

DISCUSSION

As part of a safety and feasibility study, a total of 12 patients (ranging from 27–63 years of age) consented and were treated with the Surfacer inside-out access catheter system. All patients presented with severe renal dysfunction and compromised upper venous occlusive disease. They also 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.

The patients underwent routine chest radiography and echocardiography or venous duplex venography and were sedated with intravenous midazolam plus fentanyl. All patients had creatinine levels averaging 10. The average procedure time was 32.8 ± 16.9 minutes (Table 1) and decreased with increased operator experience (Figure 5). The average amount of contrast used was approximately 16 mL. All 12 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. Therefore, we believe that inside-out central venous access should be further explored as a new option for patients with upper body venous occlusive disease. ■

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