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A Dedicated Device for Inside-Out Central Venous Catheterization

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Introduction

Thoracic central venous occlusion is extremely common in patients treated with hemodialysis because of the frequent use of central venous catheters (CVCs) for dialysis access. With an incidence rate as high as 40%, thoracic central venous occlusions remain a major clinical challenge in dialysis access care because of their potential to compromise the maturation and functionality of hemodialysis accesses.[1] Thoracic central venous occlusions can also have serious ramifications in patients who require central venous access for emergent hemodialysis.

Current Limitations

Guidewire recanalization with balloon angioplasty or stenting is currently recommended as the first-line therapy for thoracic central venous occlusion, but in a subset of patients, lesion crossing failure renders placement of thoracic CVCs or upper extremity accesses impossible.[2] A common approach in this situation is to exploit the remaining veins, but multiple failed attempts may hamper any chances of permanent access. Though open repair may be technically feasible, patients on hemodialysis commonly have comorbid conditions that may preclude them from such complex venous reconstruction procedures. It is in this quest to provide a solution for achieving central venous access in chronically occluded veins that John D. Gurley, MD,[3] developed the Inside-Out central venous access technique. This technique consists of a sharp retrograde dissection of the thoracic central venous occlusion through a groin approach, with externalization of guidewire in the supraclavicular region, over which a CVC is inserted into the right atrium. Early experiences involved off-label use of improvised hardware, including sharpened guidewires, trans-septal needles, and long dilators. Though reported outcomes were favorable, the improvised hardware was associated with technical challenges such as lack of rigidity, suboptimal directional orientation, and lack of control over the exit angle.[3]

Recent Developments

In response to these challenges, dedicated hardware for Inside-Out central venous access was designed. The Surfacer Inside-Out access catheter system (Merit Medical Systems) is an integrated system designed to achieve right-sided central venous access through chronically occluded veins. The device is rigid and provides a more controlled blunt dissection, with precise control of the puncture. Early experience in the Surfacer System to Facilitate Access in Venous Occlusions—United States (SAVE-US) trial,[4] in which the reporting institution participated, showed a

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technical success rate of 90%, with no device-related complications, leading to its US Food and Drug Administration clearance in February 2020. Though the device has proven to be a viable option for central venous access in patients undergoing hemodialysis, it may be argued that the technique's potential risks have not been fully explored. The proximity of the superior vena cava to the pleura and aorta undoubtedly poses a non-negligible risk of injury when performing this procedure under 2-dimensional fluoroscopic imaging guidance alone. In the reporting center's first successful case, an on-table, cone-beam computerized tomographic scan showed that the device had unexpectedly passed behind the brachiocephalic artery, close to the trachea (Fig. 1). Following this experience, cadaveric experiments were performed to better understand the trajectory of the device through the mediastinum and

Abbreviations and Acronyms

CBCTA	cone-beam computerized tomographic angiography
CVC	central venous catheter

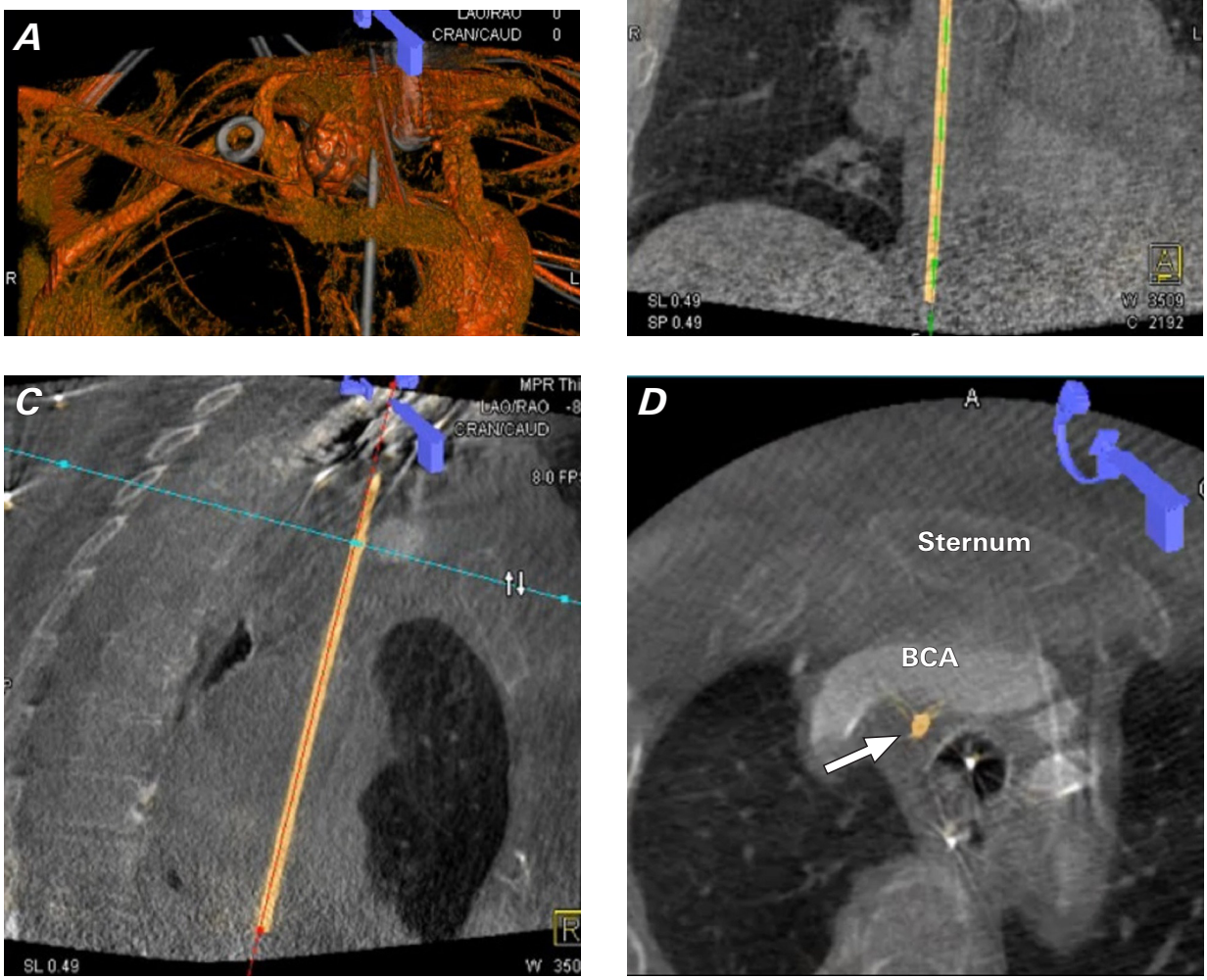

Fig. 1 Cone-beam computerized tomographic angiogram shows the Surfacer device passing posterior to the brachiocephalic artery and close to the trachea in (**A**) a 3-dimensional reconstruction, (**B**) a coronal view, (**C**) a sagittal view, and (**D**) an axial view.

BCA, brachiocephalic artery.

to evaluate its potential risks, such as perforation of the pleura and supra-aortic vessels (Fig. 2). These insights led to the development of an advanced intraoperative imaging protocol consisting of cone-beam computerized tomographic angiography (CBCTA) to map the trajectory of the device before advancing it through the occlusion under fusion guidance. In a published series of 17 attempted procedures, 3 attempts were aborted based on CBCTA findings, which showed the device to be aiming for the subclavian artery in 2 instances and the right pleura in 1 instance.[5] In a more recent case,[6] the right internal mammary artery was inadvertently injured, leading to a large hemothorax. The post hoc review of intraoperative CBCTA images revealed that the artery was lying within the projected path of the device, thus underscoring the ability of this imaging protocol to accurately predict potential injuries. One major limitation of this imaging technique is the increased exposure to radiation. This exposure is mitigated by the surgical team briefly exiting the radiation zone during the C-arm machine's spin. Another challenge is the additional operating time required for CBCTA, but the benefits in terms of enhanced safety supersede these limitations.

Future Directions

The Surfacer Inside-Out central venous access system remains an exciting technology that facilitates the preservation of central venous access sites and makes CVC placement possible in patients for whom it would otherwise be impossible. We have integrated intraoperative CBCTA into the technique used at our institution, but to date, no comparative study has evaluated its effectiveness and, to the best of the authors' knowledge, this protocol has not been replicated in any other institution. More studies are therefore warranted to refine the proposed imaging protocol and establish its role in enhancing the safety of the Surfacer Inside-Out technique.

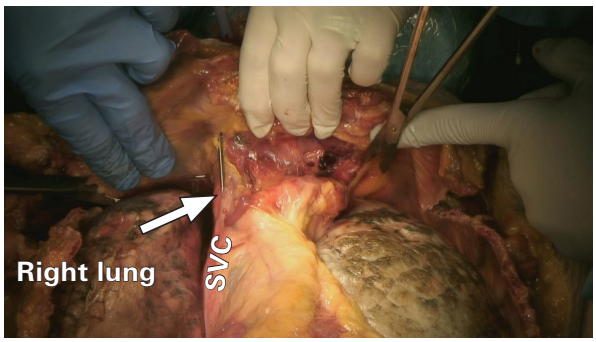

Fig. 2 A cadaveric experiment demonstrates the trajectory of the Surfacer device through the mediastinum. The arrow points to the exit point of the Surfacer device from the superior vena cava.

SVC, superior vena cava.

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