

Inside-out access: A new method of lead placement for patients with central venous occlusions

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BACKGROUND Physicians will increasingly encounter patients who require rhythm management devices but have venous obstructions that prevent conventional access. Alternate access options, such as thoracotomy or transiliac approaches, exist but are associated with greater cost and morbidity.

OBJECTIVE The purpose of this study is to describe a novel method of vascular access that allows prepectoral placement of conventional pacing and defibrillation leads in patients with complex central venous occlusions.

METHODS Eight patients with central venous occlusions were referred for device implantation. Inside-out central venous access (IOCVA) was obtained via a percutaneous femoral approach. A catheter-dilator system was advanced via the right atrium to the most central point of venous occlusion. The occluded vein segment was punctured with a directionally guided needle, which was advanced along intravascular or extravascular tissue planes to the subclavian region. A solid wire needle was oriented toward the skin surface and advanced through the soft tissues until it exists from the body. The wire was used to pull rigid dilators through the

occluded segment. Standard transvenous leads were implanted through the newly created channel.

RESULTS All patients with total central venous occlusions (4 superior vena cava, 4 brachiocephalic and bilateral subclavian) had successful, prepectoral device implants (4 left-sided, 1 single-chamber, 4 dual-chamber, 3 biventricular). No procedure-related complications occurred. All patients had normal device function at follow-up of 485 ± 542 days.

CONCLUSION IOCVA is an effective method of pacemaker and defibrillator implantation for patients with central venous occlusions. Further clinical evaluation of this novel method is needed.

KEYWORDS Cardiac resynchronization therapy; Central venous occlusion; Defibrillator; Pacemaker; Subclavian vein occlusion

ABBREVIATIONS IOCVA = inside-out central venous access; SVC = superior vena cava

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Introduction

Permanent pacemakers and defibrillators usually are implanted with transvenous leads and pulse generators in the prepectoral area.¹ This arrangement provides the ideal combination of patient comfort, lead stability, defibrillation efficacy, and procedural safety. Unfortunately, prepectoral device placement is not always possible, and the most common reason for implant failure is central venous obstruction.^{2,3} Solutions to this problem include surgical and transiliac device placement, but both approaches have important drawbacks.

Transiliac leads have been used for more than three decades despite several limitations. In such cases, leads tend to be unstable, and atrial lead dislodgment is a recurrent problem.^{2–4} Defibrillation systems often require additional subcutaneous electrodes to compensate for the abdominal

pulse generator location and the lack of a superior vena cava (SVC) coil.² This technique is not suitable for left ventricular lead placement. Perhaps more important is the potential for life-threatening deep vein thrombosis⁴ and resultant pulmonary embolism. Likewise, surgical lead placement via thoracotomy has numerous disadvantages, including cost, morbidity, and suboptimal lead performance.^{5,6}

In this report, we describe inside-out central venous access (IOCVA), a novel method of central venous access that can be applied to patients with chronic, total SVC and subclavian vein occlusions that cannot be recanalized with currently available technology. The IOCVA method preserves all the advantages of a conventional transvenous lead system and prepectoral device location while overcoming the limitations of transiliac and thoracotomy-based procedures.

Methods

Patient population

All patients were referred for clinically indicated permanent pacemaker or defibrillator implantation in accordance with

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practice guidelines.⁷ Additionally, all patients had chronic SVC, brachiocephalic, and/or subclavian vein occlusions that prevented a standard prepectoral transvenous approach to device implantation. The occlusions consisted of long segments of densely fibrotic lumen obliteration that could not be recanalized by conventional interventional techniques using a variety of guidewires, catheters, and dilators. Specifically, occlusions were resistant to aggressive probing with 0.035-inch, stiff-shaft hydrophilic wires and supporting catheters. Probing was attempted from at least one direction and, in some cases, from both sides of the occlusion. None of the patients had collateral venous channels suitable for lead placement. Patients were informed and offered surgical and transiliac options for venous access and device implantation, but all declined. An attempt at inside-out central venous access was offered after explanation of potential risks, including the possibility of risks not yet known to the procedure. All patients provided written informed consent, and the study was approved by our institutional review board.

Procedure description

All procedures were performed in a setting that was capable of managing major complications. Procedures were performed with patients under conscious sedation (intravenous midazolam and fentanyl) and local anesthesia (lidocaine infiltration). After sterile preparation, a 12-cm, 8Fr introducer sheath (FAST-CATH, St. Jude Medical, Minnetonka, MN, USA) was percutaneously placed in the right femoral vein. A 5Fr angiographic catheter (100 cm BER II, Cordis/Johnson & Johnson, Bridgewater, NJ, USA) was advanced over a 0.035-inch, J-tipped guidewire (Cook Medical, Inc., Bloomington, IN, USA) under fluoroscopic guidance to the SVC. In cases of SVC occlusion, the angiography catheter was advanced to the point of obstruction. Similarly, in cases of brachiocephalic or subclavian vein occlusion, the catheter was advanced as far as possible to the most peripheral point of obstruction. The point of occlusion was defined by contrast venography using approximately 3 to 5 mL of manually injected contrast (Figures 1A and 1B). The reverse end of a 0.035-inch, superstiff, hydrophilic guidewire (Terumo Medical, Somerset, NJ, USA) was advanced through the angiographic catheter and pushed as far as possible into the occluded segment. It was understood that the wire could penetrate a residual lumen or pass adventitiously along the anterior border of the occluded segment. The angiographic catheter was removed over the guidewire and replaced with an 8Fr dilator from a transseptal sheath set (8Fr adult transseptal with 67-cm dilator, Medtronic, Inc., Minneapolis, MN, USA, or 8Fr FAST-CATH SL1 with 67-cm dilator, St. Jude Medical). The guidewire was removed, and a modified transseptal needle (71 or 89 cm BRK, St. Jude Medical) was advanced to the tip of the dilator. From that location, it is important to note that the transseptal needle was used only as a steerable guidance device to target the point of exit anteriorly. The inside-out puncture was made with a smaller-diameter needle inserted

through the lumen of the transseptal needle. The inside-out needle was fabricated by sharpening the reverse end of a 0.018-inch-diameter spring steel wire (Steelcore 0.018-inch Extra Support, Abbott Vascular, Santa Clara, CA, USA). The desired location of exit (below the clavicle and in the vicinity of the pulse generator pocket) was anesthetized and tagged with a radiopaque skin marker (e.g., local anesthetic needle, Figure 1C). With correct orientation of the transseptal needle assured, the sharpened 0.018-inch wire was inserted into the transseptal needle and advanced through the body tissues toward the desired exit site. Accurate alignment of the needle was accomplished by fluoroscopy in at least two orthogonal projections. In some cases, small amounts of contrast (<1 mL) were injected through the needle and used to identify extravascular tissue planes (Figure 1C). Once the sharpened 0.018-inch wire exited the skin (Figure 1D), the transseptal needle and dilator were “locked” to the 0.018-inch wire by placing a clamp on the femoral end of the wire (Figure 1E). As the 0.018-inch wire was pulled upward (Figure 1F), the clamp was drawn against the hub of the transseptal needle, and the needle/dilator assembly was drawn upward and out of the body (Figure 1G). The transseptal needle and 0.018-inch wire were removed, leaving a hollow dilator with tip exposed above and hub exposed below. A standard 0.032-inch guidewire (Amplatz Extra Stiff Wire Guide, 180-cm length, Cook Medical) was passed through the dilator until the ends were exposed at both the chest and the groin. A peel-away hemostatic introducer (SafeSheath 6–9 French, 13 or 25 cm length, Pressure Products, Inc., San Pedro, CA, USA) was placed over the chest end of the wire and secured with a clamp (Figure 1H). The 0.032-inch wire was grasped at its groin end and pulled (Figure 1I), drawing the sheath into the right atrium (Figure 1J). In cases where the placement of two or three leads was required, multiple guidewires and sheaths were placed via the same channel using an adaptation of the standard double-wire technique described initially by Dawson et al⁸ (Figure 1K). With access established, lead and device implantation proceeded as a conventional procedure (Figure 1L). Transvenous pacing and defibrillation leads were inserted without any modification of hardware or technique. In all cases, the leads were anchored to the pectoralis fascia, and pulse generators were placed in prepectoral, subcutaneous pockets. Defibrillation testing was performed to achieve at least a 10-J safety margin. Postprocedure chest fluoroscopy was performed to confirm proper lead positions and the absence of complications (view of device insertion, Figure 2, examples 1 and 2).

Follow-up

All patients were hospitalized for overnight observation in a telemetry ward. Chest radiographs were obtained and device interrogations were performed prior to hospital discharge. Outpatient follow-up consisted of wound inspection and device interrogation at 1 week. Subsequent visits included device interrogation at 1 month and then at 6-month intervals.

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