

Comparison of catheter patency between surgical inside-out technique and conventional femoral approach for tunneled cuffed catheter placement in patients with thoracic central venous occlusion

Nutsiri Kittitirapong, MD,^a Benjaporn Jeraja, MD,^b Piyanut Pootracool,^a Chaowanun Pornwaragorn, MD,^a Gorawee Tepsamrithporn,^a Surasit Sitthilor, BNS,^c and Suthas Horsirimanont, MD,^a *Bangkok and Chonburi, Thailand*

ABSTRACT

Objective: Femoral tunneled cuffed catheters (TCCs) can provide long-term hemodialysis access for patients with exhausted upper extremity access sites due to thoracic central venous occlusion. However, the use of femoral vein catheters (FVCs) has reportedly been associated with the risk of infection, malfunction, and discomfort. An inside-out technique will facilitate chest TCC placement by intentional retrograde extravascularization of the proximal occluded venous stump into the mediastinum. Next, the wire and small catheter are exteriorized to the skin at the base of the neck with a small skin incision. Then, the hemodialysis catheter is railed back down to the right atrium. With this technique, we placed the tip of the catheter into intrathoracic superior vena cava or brachiocephalic vein. In the present study, we compared the catheter patency of the inside-out technique vs a standard approach for FVC placement.

Methods: The present randomized controlled trial was conducted from May to December 2020. We included 22 patients requiring long-term hemodialysis with failed recanalization of thoracic central venous occlusion. The patients were randomized into the surgical inside-out (S-inside-out) group and FVC group.

Results: The S-inside-out and FVC groups included 10 and 12 patients, respectively. All 22 patients had undergone successful catheter placement. Catheter survival function was significantly higher for the S-inside-out group than for the FVC group (100% vs 50%, respectively; $P = .017$). In addition, the EQ-5D utility score was significantly better for the S-inside-out group ($P = .008$). Four cases of catheter infection occurred in the FVC group, but no catheter infection was found in the S-inside-out group. Procedural-related complications occurred in two patients; one case each of hemothorax and stroke in the S-inside-out group.

Conclusions: Use of the S-inside-out technique facilitated upper chest TCC placement for hemodialysis patients with exhausted access sites. This technique provided better catheter survival function, a better quality of life, and a lower infection rate, which outweighed the procedure risk. (*J Vasc Surg Cases Innov Tech* 2022;8:885-93.)

Keywords: Catheter patency; Femoral catheter; Hemodialysis; Inside-out; Tunneled cuffed catheter

Exhausted vascular access due to thoracic central venous occlusion (TCVO) is a challenging issue when attempting to place long-term tunneled cuffed

catheters (TCCs) in patients requiring hemodialysis. Femoral vein catheter (FVC) access will be the last resource for these patients.¹ However, using a FVC has been reported to be associated with the risk of infection, malfunction, iliac stenosis, and inferior vena cava (IVC) stenosis that can affect the outcome of future kidney transplantation and to cause discomfort.²⁻⁷

Inside-out central venous access was introduced in 2011 as a safe method of vascular access that allows for prepectoral placement of conventional pacing and defibrillation leads in patients with complex TCVO.⁸ This technique involves two procedural steps. The first step is intentional retrograde extravascularization of the proximal occluded venous stump using the wire and small catheter into the mediastinum and exteriorizing the skin at the base of the neck. The second step includes catheter insertion via a through-and-through wire technique.⁸⁻¹² The hemodialysis catheter is then railed down to the right atrium. With this technique, the tip of the hemodialysis catheter is placed at the intrathoracic right

From the Division of Vascular Surgery, Department of Surgery, Ramathibodi Hospital, Faculty of Medicine, Mahidol University, Bangkok^a; the Department of Surgery, Chonburi Hospital, Chonburi^b; and the Nursing Service Department, Ramathibodi Hospital, Faculty of Medicine, Mahidol University, Bangkok.^c

Author conflict of interest: none.

Correspondence: Suthas Horsirimanont, MD, Division of Vascular Surgery, Department of Surgery, Ramathibodi Hospital, Faculty of Medicine, Mahidol University, 270 Rama VI Rd, Bangkok 10400, Thailand (e-mail: h.suthas@gmail.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

© 2022 The Author(s). Published by Elsevier Inc. on behalf of Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.jvscit.2022.10.019>

brachiocephalic vein (BCV) or superior vena cava (SVC). Several small case series have shown high success rates and few complications.⁹⁻¹²

Variations of the devices used in the inside-out technique have been described, including the end of a wire,^{9,11} needle,¹⁰ and commercial devices.¹²⁻¹⁵ The various methods for accessing the wire out of the body at the supraclavicular area have included the percutaneous technique (needle and wire)^{10,12-15} and the surgical technique.^{9,11} The potential complications include pneumothorax and pneumohemothorax.^{10,14}

To the best of our knowledge, no comparative study has focused on the surgical inside-out (S-inside-out) and FVC catheter techniques for patients with exhausted access sites. In the present study, we compared these two techniques in terms of catheter patency. The secondary outcomes were quality of life, technical success, perioperative complications, and infection rate.

METHODS

Trial design

The present single-center, prospective, open-label, randomized, controlled noninferiority trial was designed to compare the catheter patency between the S-inside-out and FVC techniques for TCC placement in patients with TCVO who had undergone failed intraluminal recanalization. All the patients who had fulfilled the inclusion criteria were randomly assigned to the S-inside-out group or FVC group with a 1:1 allocation using computer-generated randomization. All the included patients had provided written informed consent for participation. The trial was registered in the Thai Clinical Trials Registry (no. TCTR20210728003). The institutional human research ethics committee approved the study (approval no. MURA2020/752), which was performed in accordance with the principles of the Declaration of Helsinki. The study design is shown in Fig 1.

Participants

From May 2020 through December 2020, 22 patients for whom intraluminal recanalization of TCVO had failed were included. The primary aim of our study was to compare the catheter patency between the two groups. A literature review revealed that the FVC patency rate was 32.1% at 3 months.¹⁶ In contrast, the catheter survival rate of the inside-out technique was 100% at 3 months.¹² The sample size was calculated with two independent proportions (two-tailed test). The χ^2 test was to determine the two independent proportions with 80% power, a two-sided alpha level of 5%, and a beta level of 20%. The resulting target sample size was 14 patients.

Eligibility criteria

All the patients with TCVO who had undergone a failed prior attempt to place an upper central venous catheter (CVC) were included. All the included patients had

undergone evaluation for the anatomic criteria using computed tomography venography. The anatomic criteria included the position of the adjacent arteries posterior to the veins, no arterial or venous vessel malformations, and no skeletal abnormalities.^{8,12,15} The anatomic exclusion criterion for the present study was an occluded SVC below the azygos vein to avoid wire passage to the atrial appendage. The other exclusion criteria were patients with difficulty with introducing endovascular devices from the FVC up to chronic total occlusion sites at the BCV or SVC. In addition, patients were excluded from the study if they were aged <18 years, had refused the intervention, or had had a life expectancy of <6 months.

Randomization

After eligibility was confirmed and the patients had provided written informed consent, they were randomized in a 1:1 ratio via four-block randomization using the computerized randomization protocol in Stata, version 15 (StataCorp, College Station, TX). The patients were assigned to the FVC or S-inside-out groups at the outpatient clinic. The treatment assignment was concealed in an opaque sealed envelope by a research assistant to reduce any bias from the investigators. The CONSORT (consolidated standards of reporting trials) diagram for the present study is shown in Fig 1.

Procedure

All patients had undergone a preoperative assessment and had received routine preoperative antibiotic prophylaxis. Next, the procedure proceeded with use of the standard mobile C-arm.

FVC group. We performed the procedure for the FVC group in the operating room under ultrasound-guided puncture and fluoroscopic guidance. The patients underwent local or general anesthesia according to their condition using a standard technique. The tip of the catheter was placed in the disease-free area of the IVC.

S-inside-out group. Before the procedure, the anatomy was reviewed. The access should be patent from the FVC (right or left side), iliac veins, and IVC to allow for the introduction of the endovascular devices from the FVC up to the chronic total occlusion site at the BCV or SVC. Because this procedure requires good push-ability of the wire to penetrate the occluded stump of the central vein, the access should be straight and not tortuous. Thus, the right iliac vein was preferred over the left iliac vein. The straight line from the occluded central venous stump to the clavicle represents the imaginary line from the occluded venous stump to the head of the clavicle (Fig 2). This line indicates the route of wire passage in the mediastinum. The position of the adjacent arteries should be posterior to the veins and no arterial or venous vessel malformations and no skeletal abnormalities should be present.^{8,12,15} The normal anatomy of the

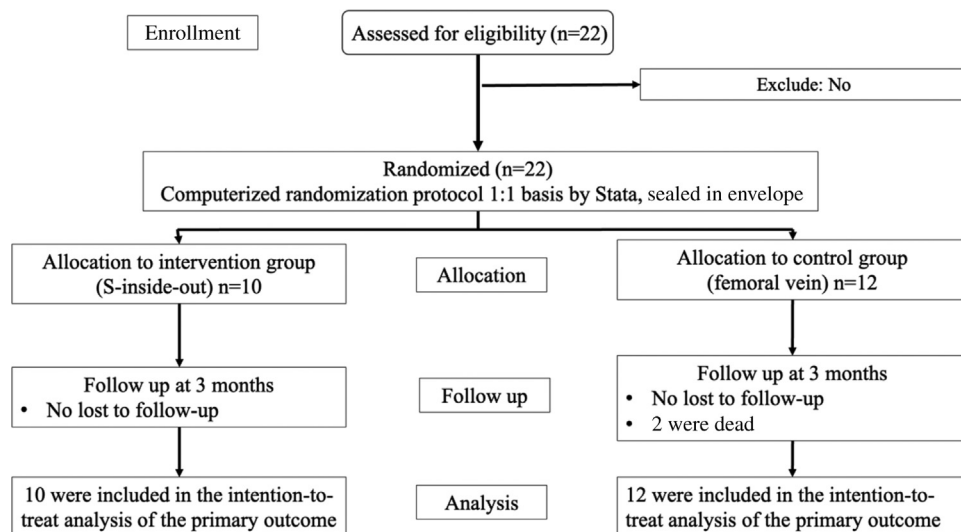


Fig 1. CONSORT (consolidated standards of reporting trials) diagram showing enrollment and outcomes. S-inside-out, Surgical inside-out.

great vessels at the mediastinum, including the aortic arch, innominate artery, and left carotid artery, is behind the venous system. The safe passage of the wire was anterior because no vital structure is anterior to the vein. The occluded SVC below the azygos vein was excluded to avoid wire passage to the atrial appendage to prevent hemopericardium and cardiac tamponade.

All the procedures were performed with the patient under general anesthesia in a setting capable of managing all possible significant complications. After sterile preparation, percutaneous access was established at the FVC under ultrasound guidance. A 6F, 10-cm sheath was placed in the common femoral vein using the standard Seldinger technique. A 5F Judkins right 4 catheter (100 cm; ADROIT Guiding Catheter; Cordis, Cardinal Health, Baar, Switzerland) and a 0.035-in. angle-tip hydrophilic guidewire (260 cm; Radifocus Guide Wire M; Terumo Corp, Tokyo, Japan) were passed through the IVC and placed at the distal end of the proximal stump of venous occlusion, which was either the SVC above the azygos vein or the right BCV. The coaxial system consisted of a 12F, 50-cm sheath (Braidin Hemostasis Introducer; APT Medical, Hunan, People’s Republic of China), an 8F, 60-cm sheath, and a 6F, 90-cm sheath (Dura-Sheath; Heraeus Medical Components, Medical International GmbH, Dresden, Germany). All coaxial systems were exchanged via a 0.035-in. guidewire (300 cm; Hi-Torque Supra Core; Abbott Laboratories, Chicago, IL). The tip of the 6F sheath was placed at the proximal end of the occlusion.

Venography was performed to visualize and verify safe passage. Safe passage was defined as an imaginary straight line from the stump of the venous occlusion to the head of the right clavicle. We used the back end of

the 0.035-in. hydrophilic wire supported by the 5-F Judkins right 4 catheter and coaxial sheath system for penetrating the wall of the occluded venous stump to the mediastinal space. With this technique, we intentionally perforated the stump of the occluded vein (BCV or SVC) into the mediastinum, not to recanalize the chronic total occlusion but creating a new passage (extravascular plane). The exit site following the path through the TCVO in the inside-out group was the right BCV or SVC, which was the intrathoracic and intravascular portion of the proximal part of the occluded vein.

In the mediastinum, we changed the back end of the 0.035-in. hydrophilic wire to the soft tip end of the wire. We used the knuckle wire technique and navigated the direction using the catheter. The route of the knuckle wire was anterior because no vital structure is present anterior to the vein. It pointed to the head of the right clavicle. The position of the C-arm changed from anteroposterior to a left anterior oblique 30° to 60° angle to visualize the wire direction. The wire and catheter were pushed under fluoroscopy guidance until the tip of the wire had reached the patient’s skin in the supraclavicular area. During the procedure in the mediastinum, we did not perform any angiography. Skin tenting was observed or the surgeon palpated the tip of the catheter. A small incision was created 1.0 to 1.5 cm over the wire tip. The wire was then pulled out, together with the catheter, and clamped at both the chest and the femoral exit sites to create a through-and-through wire. It then served as a guidewire for TCC insertion. The TCC was placed in the right pectoral area, and its tip was placed at the right atrium using the over-the-wire technique. The steps of the S-inside-out procedure are shown in Fig 2.

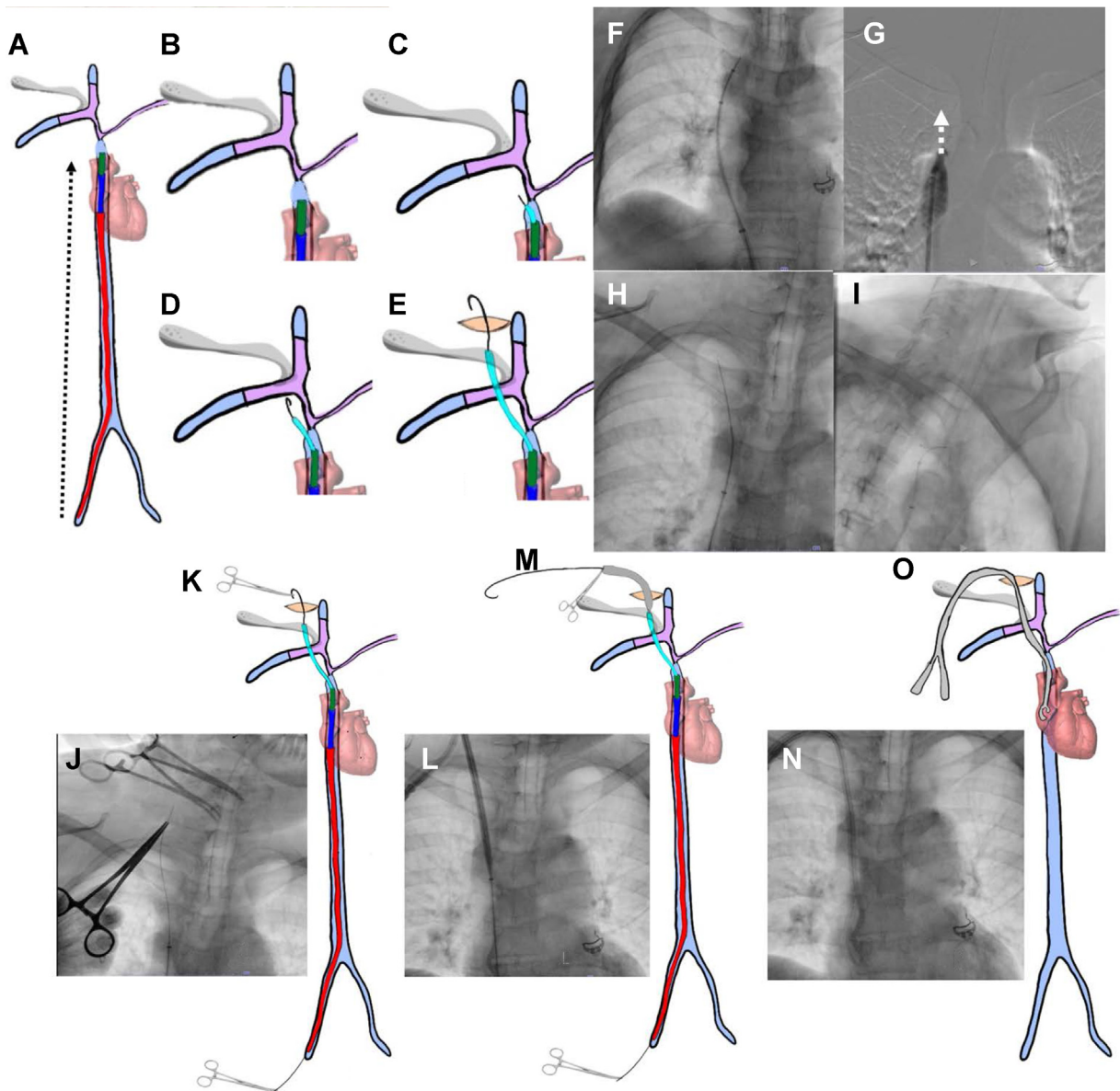


Fig 2. Surgical inside-out (S-inside-out) procedure. **A**, The coaxial system consisted of a 12F, 50-cm sheath, an 8F, 60-cm sheath, and a 6F, 90-cm sheath (corresponding to Fig F). The access should be patent from the femoral vein catheter (FVC), iliac veins, and inferior vein cava (IVC) to allow for introduction of endovascular devices from the FVC up to the chronic total occlusion site at the brachiocephalic vein (BCV) or superior vena cava (SVC). The access should be straight and not tortuous (*black dashed line*). **B**, The tip of the 6F sheath was placed at the proximal end of the occlusion (corresponding to Fig C, G, and H). We intentionally perforated the stump of the occluded vein (BCV or SVC) into the mediastinum and did not recanalize the chronic total occlusion but created a new passage (extravascular plane) using the back-end of the 0.035-in. hydrophilic wire supported by the 5F Judkins right 4 catheter and coaxial sheath system (corresponding to Fig H). **D**, In the mediastinum, we changed the back end of the 0.035-in. hydrophilic wire to the soft tip end of the wire. We used the knuckle wire technique and navigated the direction using the catheter (corresponding to Fig I). **E**, The wire was pulled out of the skin via a surgical incision. **F**, view of the coaxial system via fluoroscopy. **G**, Venography was performed to visualize and verify safe passage (defined as the imaginary straight line from the stump of the venous occlusion to the head of the right clavicle; *white dashed line*). **I**, The C-arm was positioned at a left anterior oblique 30° to 60° angle to visualize the anterior direction of the wire. **J** and **K**, The wire was pulled out with the catheter and clamped at both the chest and the femoral exit sites to create a through-and-through wire. **L** and **M**, A dilator and peel-away sheath were introduced via the through-and-through wire. **N** and **O**, A tunneled cuffed catheter was inserted over the through-and-through wire. The tip of the tunneled cuffed catheter was placed at the right atrium.

Postprocedure management

In the FVC group, the patients were observed in the postprocedure room for 30 minutes. If no complications had occurred, the patients were discharged and followed up at our outpatient clinic. In the S-inside-out group, the patients were observed in the postanesthesia care unit for 60 minutes, after which, they returned to the ward. The patients were discharged and followed up at the outpatient department if no complications had developed.

Outcome assessment

The perioperative and immediate postoperative outcomes were recorded. All the patients had visited an outpatient clinic at 2 weeks, 1 month, and 3 months postoperatively. The primary outcome was catheter patency. The secondary outcomes were technical success, perioperative complications, and the infection rate. The EQ-5D is a standardized patient-reported outcome measure of health-related quality of life comprising five dimensions: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. The EQ-5D-5L quality-of-life questionnaire was administered to the patients at 1 and 3 months after the procedure by a research assistant who was unaware of the intervention.

Statistical analysis

The categorical variables are reported as counts and percentages and were compared using the χ^2 test or the Fisher exact test according to the sample size. The continuous variables are reported as the mean \pm standard deviation and were compared using the unpaired *t* test for normally distributed variables. Non-normally distributed variables are reported as the median and interquartile range and were compared using the Mann-Whitney *U* test. A *P* value of $< .05$ was considered statistically significant. All analyses were intention-to-treat and performed with Stata, version 15 (StataCorp). Catheter patency was calculated using the Kaplan-Meier method and a Cox proportional hazards model. The human research ethics committee approved the present study protocol and acquisition of informed consent, and all included patients had provided written informed consent.

RESULTS

From May 2020 to December 2020, 22 patients had had a diagnosis of TCVO and were enrolled in the present study. Of the 22 patients, 10 were randomly assigned to the S-inside-out group and 12 to the FVC group. No patient was excluded from the present study. The two groups did not significantly differ in the baseline characteristics, including age, underlying disease, and history of femoral catheterization. One patient had undergone chest surgery with coronary artery bypass grafting. One patient had had curable cancer with a good prognosis. Most patients had had type 3 TCVO (45%), and the

Table I. Demographic data

Variable	S-inside-out group (n = 10)	FVC group (n = 12)	<i>P</i> value
Age, years	64 (IQR, 24)	58 (IQR, 35)	.766 ^a
Male gender	6 (60)	7 (58)	.999
Body mass index, kg/m ²	24 (IQR, 6)	24 (IQR, 5)	.391 ^a
Diabetes mellitus	3 (30)	6 (50)	.415 ^b
Hypertension	9 (90)	12 (100)	.455
Dyslipidemia	6 (60)	6 (50)	.691
Peripheral arterial disease	2 (20)	4 (33)	.484 ^b
Congestive heart failure	2 (20)	3 (25)	.999 ^b
Arrhythmia	3 (30)	3 (25)	.999 ^b
Autoimmune disease	1 (10)	0 (0)	.455 ^b
Cancer	1 (10)	1 (8)	.999 ^b
History of chemotherapy	1 (10)	0 (0)	.455 ^b
Previous chest surgery	0 (0)	1 (8)	.999 ^b
Previous abdominal surgery	0 (0)	1 (8)	.999 ^b
Previous femoral tunneled cuffed catheter	9 (90)	8 (67)	.323
HD frequency (times/wk)	3 (IQR, 0)	3 (IQR, 0)	NA ^a
Signs of upper extremity venous hypertension	3 (30)	5 (42)	.675 ^b
Type of TCVO			.217
1	0 (0)	1 (8)	
2	2 (20)	2 (17)	
3	4 (40)	6 (50)	
4	4 (40)	3 (25)	
Previous stent at TCVO	2 (20)	2 (17)	.999

FVC, Femoral vein catheter; HD, hemodialysis; IQR, interquartile range; NA, not applicable; S-inside-out, surgical inside-out group; TCVO, thoracic central venous occlusion.
Data presented as mean \pm standard deviation, number (%), or median (IQR).
^aMann-Whitney *U* test.
^bFisher exact test.

most common indication for intervention was bilateral TCVO (86%), which was the left BCV and right BCV or SVC occlusion. Of the 10 S-inside-out patients, 3 had undergone recanalization from the SVC to the skin at the base of the neck and 7 from the right BCV. The mean length of recanalization was 15.1 ± 1.4 cm. No difference was found in the type of TCVO, indication for intervention, or previous stent placement in the TCVO between the two groups (Table I).

The surgical procedures, related events, and outcomes are shown in Table II. All 10 patients in the S-inside-out group had received general anesthesia and had been admitted to the hospital in accordance with our procedural safety protocol. In contrast, most patients in the FVC group had received local anesthesia. Two patients had required general anesthesia because of their condition. The technical success rate was 100% in both groups.

Table II. Surgical procedures and results

Variable	S-inside-out group (n = 10)	FVC (n = 12)	P value
Inpatient admission	10 (100)	2 (17)	<.001 ^a
General anesthesia	10 (100)	2 (17)	<.001 ^a
Technical success	10 (100)	12 (100)	NA
Procedural-related complications	1 (10)	0 (0)	.455 ^a
Operative time, minutes	108 (IQR, 70)	35 (IQR, 15)	.007 ^b
Length of stay, days	4.3 (IQR, 6)	1.92 (IQR, 0)	<.001 ^b
Perioperative mortality	0 (0)	2 (17)	.481 ^a
Catheter patency within 90 days	10 (100)	6 (50)	.015
Infection within 90 days	0 (0)	4 (33)	.096 ^a

FVC, Femoral vein catheter; IQR, interquartile range; NA, not applicable; S-inside-out, surgical inside-out group.
Data presented as number (%) or median (IQR).
^aFisher exact test.
^bMann-Whitney U test.

Two procedural-related complications occurred in the S-inside-out group. One patient had developed a right pneumothorax and underwent immediate chest tube insertion for intraoperative treatment. The patient was admitted for 9 days and discharged without permanent damage.

Another patient in the S-inside-out group had experienced an in-hospital stroke. This patient had experienced atrial fibrillation and was receiving warfarin therapy, which had been stopped for 2 weeks before surgery by the referral doctor. The procedure was straightforward during the operation, and the hemodynamics were stable. She was awake during the immediate postoperative period, with full consciousness, stable vital signs, and no weakness. At 1 day after the procedure, the patient had developed right-side weakness. The symptom was on the same side of the procedure but did not correspond to the lesion if we had directly injured the right common carotid artery or innominate artery. Computed tomography of the brain showed a hypodensity lesion of the left internal capsule, likely from a cardioembolic cause. In this patient, the cause of stroke might have been a cardioembolic cause from stopping the anticoagulant therapy more than from the hemodynamic changes during the procedure.

During the 3-month follow-up, the catheter patency was significantly better in the S-inside-out group than in the FVC group (100% vs 50%; $P < .015$). The catheter infection rate in the S-inside-out group tended to be lower than that in the FVC group (0% vs 33%; $P = .096$; Table III). The Kaplan-Meier survival curve showed that the 300-day catheter patency rate in the S-inside-out group was significantly higher than that in the FVC group (100% vs 50%; $P < .015$; Fig 3). No reinterventions were required for the S-inside-out group. In the FVC group, one patient had developed a catheter-related bloodstream infection and three patients had had a

nonfunctioning TCC. We removed the FVC and inserted the new femoral TCC after controlling the catheter-related bloodstream infection. For the nonfunctioning TCC, two patients had undergone rewiring exchange of the catheter and one patient had undergone inside-out TCC.

Two patients in the FVC group had died of non-catheter-related underlying disease progression. All the patients were in the same allocated group for the intention-to-treat analysis. The first patient had had renal cell carcinoma. After FVC TCC insertion, open radical nephrectomy was performed. During the postoperative period, the patient's underlying disease worsened, and he denied further treatment, including hemodialysis. The second patient had died of a cardiac problem 1 month after FVC TCC insertion.

The EQ-5D 5L quality-of-life questionnaire was used to evaluate the patients' quality of life (Table III). The EQ-5D utility score for the S-inside-out group was significantly better than that for the FVC group (0.08 vs 0.38; $P = .008$). In addition, the pain/comfort domain in the S-inside-out group was significantly better than that for the FVC group.

DISCUSSION

According to the 2019 Society of Interventional Radiology reporting standards for thoracic central vein obstruction,¹⁷ TCVO can be categorized into four types. TCVO often occurs in the right internal jugular vein (IJV).¹⁸ The options for a CVC for patients with an occluded right IJV are the left IJV, right SCV, and FVC insertion. Left-side catheter placement can result in reduced catheter blood flow, a higher risk of venous thrombosis or stenosis,¹⁹ and interference with ipsilateral arteriovenous fistula maturation and access survival.^{20,21} These disadvantages led to the concept of the "always right approach." However, right SCV catheterization can

Table III. Assessment of quality of life using utility score and EQ-5D 5L quality-of-life score after procedure

Variable	S-inside-out group (n = 10)	FVC group (n = 12)	P value ^a
Utility score after intervention	0.97 (0.08)	0.82 (0.38)	.008
EQ-5D 5L quality-of-life score	79.9 (15)	75.5 (20)	.204
Mobilization postoperatively			.537
No problem	7 (78)	4 (40)	
Minimal problem	1 (11)	2 (20)	
Moderate problem	0 (0)	1 (10)	
Severe problem	1 (11)	1 (10)	
Could not walk	0 (0)	2 (20)	
Self-care postoperatively			.068
No problem	7 (70)	2 (18)	
Minimal problem	3 (30)	4 (37)	
Moderate problem	0 (0)	2 (18)	
Severe problem	0 (0)	2 (18)	
Could not perform self-care	0 (0)	1 (9)	
Daily activity			.577
No problem	7 (70)	5 (46)	
Minimal limitation	2 (20)	1 (9)	
Moderate limitation	1 (10)	2 (18)	
Severe limitation	0 (0)	2 (18)	
Cannot perform activity	0 (0)	1 (9)	
Pain/comfort			.017
No problem	9 (90)	3 (27)	
Minimal problem	1 (10)	3 (27)	
Moderate problem	0 (0)	4 (37)	
Severe problem	0 (0)	0 (0)	
Very severe problem	0 (0)	1 (9)	
Depression/anxiety			.432
No problem	9 (90)	6 (55)	
Minimal problem	1 (10)	1 (9)	
Moderate problem	0 (0)	2 (18)	
Severe problem	0 (0)	1 (9)	
Very severe problem	0 (0)	1 (9)	

FVC, Femoral venous catheter group; S-inside-out, surgical inside-out group.

Data presented as median (interquartile range) or number (%).

^aMann-Whitney U test.

lead to problematic future ipsilateral arteriovenous fistula function.¹⁸ This disadvantage has led to the idea of the "never subclavian approach." According to these two concepts, some patients with an occluded right IVJ will undergo CVC at the FVC to preserve future bilateral extremity vascular access.

For patients with bilateral TCVO, alternative techniques for achieving CVC via the lumbar, hepatic, renal, or femoral veins or traversing the obstruction using a sharp recanalization procedure have been reported.²² Each of these techniques can increase the risk of procedure-related adverse events, decreased catheter patency, and loss of candidacy for kidney transplantation.^{5,21,22} Peripheral arterial disease is common in patients with

end-stage renal disease, accounting for 25%, especially in patients with prolonged dialysis.^{23,24} Peripheral arterial disease was one of the contraindications for creating an arteriovenous bridge graft at the lower extremity to prevent steal syndrome. The inside-out technique is potentially beneficial for patients with bilateral TCVO, those who require the "always-right approach," and those who need the never-subclavian approach.¹²

To the best of our knowledge, the present study is the first randomized controlled trial to compare the catheter patency after TCC insertion using the S-inside-out technique for hemodialysis patients with TCVO vs conventional FVC TCC insertion. The catheter function in the S-inside-out group showed 100% patency at the

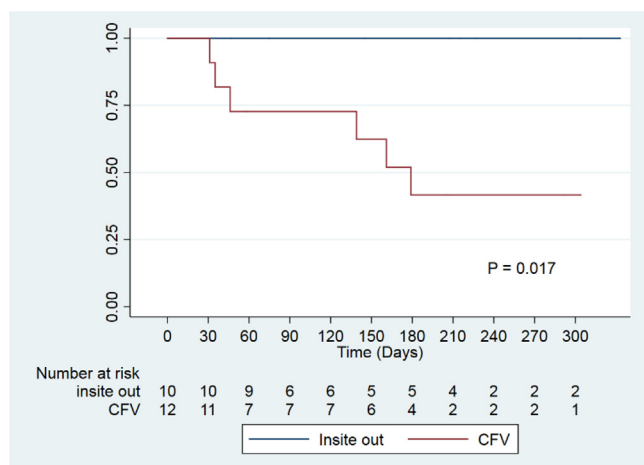


Fig 3. Kaplan-Meier survival analysis of catheter patency. CFV, Conventional femoral venous catheter.

3-month follow-up, which was significantly better than that in the FVC group (50% malfunction). In addition, our study's technical success rate for S-inside-out TCC placement was 100%. This result is consistent with those from other studies, mainly case series. The patency and technical success rate of the inside-out technique has exceeded 82% and 97% to 100%, respectively.^{8,10-15} Therefore, considering the high technical success rate and longer patency, our results have confirmed that the S-inside-out approach for patients with TCVO will provide better catheter function than the FVC technique.

The S-inside-out group also showed a lower rate of infection. Despite the lack of statistical significance, the 33% catheter infection rate in the FVC group at 3 months is highly valued in clinical practice. This higher infection rate had probably resulted from differences in cleanliness between the location of the catheter in the groin area and that in the chest and because the chest location facilitated easier catheter self-care.

The EQ-5D scores were divided into five essential daily life function domains to assess the quality of life. The patients in the S-inside-out group had had significantly better pain/comfort scores than those in the FVC group. The other domains (mobilization, self-care, daily activity, and depression/anxiety) also tended to be better for the S-inside-out group than for the FVC group. These findings might indicate that patients who undergo S-inside-out TCC placement will have a better quality of life than those who undergo FVC TCC placement.

One patient in the S-inside-out group had developed a procedure-related complication (pneumohemothorax). This patient had had type 4 TCVO with extensive collateral vessels. According to the literature,^{8,12,15} the long-occluded segment and marked collateral vessels might

have been the factors that caused this complication. Some series have reported procedure-related complications in one or two patients.^{8,10-15} Hadziomerovic et al¹⁰ reported that two of nine patients had developed pneumothorax using the inside-out technique for TCC insertion. Galas and Shahverdyan¹⁴ reported a case series using a Surfacor commercial set (Bluegrass Vascular Technologies, San Antonio, TX) for inside-out TCC insertion in 10 patients, of whom 2 had developed pneumohemothorax during the procedure. To avoid this complication, first, the anatomic criteria for a safe inside-out technique should include TCVO with ≥ 1 cm of patent SVC above the right atrium and no significant collateral vessels.¹⁴ Second, during the procedure, the wire should be kept in the medial and anterior direction during the passage of the wire in the mediastinum.¹⁰ To visualize the wire passage, the C-arm position should be changed from an anteroposterior to a left anterior oblique 30° to 60° angle to visualize the wire direction. The feedback sensation of resistance is essential. The absence of feedback sensation of the wire in the pleura and the direction of the wire in the lateral direction to the apex of the lung will result in hemothorax or pneumothorax. Immediate detection and prompt intraoperative treatment with a chest tube are essential to treatment. No perioperative deaths occurred in the S-inside-out group in the present study.

Overall, S-inside-out TCC insertion resulted in longer catheter patency, better catheter usage, a better quality of life, and less infection. However, it requires a skilled operative technique, involves a certain level of operative risk, requires awareness of the possible complications, and has a higher cost. Nevertheless, concerning the clinical application, S-inside-out TCC insertion is a good option for patients with an active lifestyle, a long life expectancy, and a low operative risk among those with bilateral TCVO, those who require the "always right approach," and those who require the never-subclavian approach. In addition, the S-inside-out technique is valuable for kidney transplantation candidates to prevent further iliac vein and IVC occlusion from catheter placement.

Study limitations. The main limitation of the present study was the small sample size, which resulted from the rare condition of exhausted access sites for patients requiring hemodialysis. Future studies should recruit more patients, extend the follow-up time, and examine the effects of catheter placement for future kidney transplantation.

CONCLUSIONS

The S-inside-out technique facilitated upper chest TCC placement for hemodialysis in patients with exhausted

access sites. In addition, using an upper chest catheter provided better catheter survival function, a higher utility score, a better quality of life, and a lower infection rate compared with the FVC technique.

The authors gratefully acknowledge Nipapan Choonu for the statistical analysis and Pattawia Choikrua for illustrating the diagram. The authors also thank Angela Morben, DVM, ELS, from Edanz (www.edanz.com/ac), for editing a draft of our report.

REFERENCES

1. Vascular Access 2006 Work Group. Clinical practice guidelines for vascular access. *Am J Kidney Dis* 2006;48(Suppl 1):S176-247.
2. Silberzweig JE, Sacks D, Khorsandi AS, Bakal CW. Reporting standards for central venous access. *J Vasc Interv Radiol* 2003;14:S443-52.
3. Vanholder R, Canaud B, Fluck R, Jadoul M, Labriola L, Marti-Monros A, et al. Catheter-related blood stream infections (CRBSI): a European view. *Nephrol Dial Transplant* 2010;25:1753-6.
4. Zaleski GX, Funaki B, Lorenz JM, Garofalo RS, Moscatel MA, Rosenblum JD, et al. Experience with tunneled femoral hemodialysis catheters. *AJR Am J Roentgenol* 1999;172:493-6.
5. Maya ID, Allon M. Outcomes of tunneled femoral hemodialysis catheters: comparison with internal jugular vein catheters. *Kidney Int* 2005;68:2886-9.
6. Khalifeh A, Reif M, Tolayamat B, Karanja J, Sarkar R, Toursavadkoti S. Iliofemoral deep venous thrombosis in kidney transplant patients can cause graft dysfunction. *J Vasc Surg Cases Innov Tech* 2019;5:7-11.
7. Parienti JJ, Mongardon N, Mégarbane B, Mira JP, Kalfon P, Gros A, et al. Intravascular complications of central venous catheterization by insertion site. *N Engl J Med* 2015;373:1220-9.
8. Elayi CS, Allen CL, Leung S, Lusher S, Morales GX, Wiisanen M, et al. Inside-out access: a new method of lead placement for patients with central venous occlusions. *Heart Rhythm* 2011;8:851-7.
9. Murga AG, Chiriano JT, Bianchi C, Sheng N, Patel S, Abou-Zamzam AM Jr, et al. Placement of upper extremity arteriovenous access in patients with central venous occlusions: a novel technique. *Ann Vasc Surg* 2017;42:317-21.
10. Hadziomerovic A, Hirji Z, Coffey N. Modified inside-out technique for continued use of chronically occluded upper central veins. *J Vasc Interv Radiol* 2017;28:757-61.
11. Freeman BM, Tingen JS, Cull DL, Carsten CG III. The inside-out technique for tunneled dialysis catheter placement with central venous occlusion. *J Vasc Surg Cases Innov Tech* 2019;5:350-5.
12. Reindl-Schwaighofer R, Matoussevitch V, Winnicki W, Kalmykov E, Gilbert J, Matzek W, et al. A novel inside-out access approach for hemodialysis catheter placement in patients with thoracic central venous occlusion. *Am J Kidney Dis* 2020;75:480-7.
13. Hentschel DM, Minarsch L, Vega F, Ebner A. The Surfacor® Inside-Out® Access System for right-sided catheter placement in dialysis patients with thoracic venous obstruction. *J Vasc Access* 2020;21:411-8.
14. Galas N, Shahverdyan R. Use of the Surfacor® Inside-Out® Catheter Access System to obtain central venous access in dialysis patients with thoracic venous obstructions: single-center series. *Vasc Endovascular Surg* 2021;55:228-33.
15. Gallieni M, Matoussevitch V, Steinke T, Ebner A, Brunkwall S, Cariati M, et al. Multicenter experience with the Surfacor inside-out access catheter system in patients with thoracic venous obstruction: results from the SAVE Registry. *J Vasc Interv Radiol* 2020;31:1654-60.e1.
16. Burton KR, Guo LL, Tan KT, Simons ME, Sniderman KW, Kachura JR, et al. Patency of femoral tunneled hemodialysis catheters and factors predictive of patency failure. *Cardiovasc Intervent Radiol* 2012;35:1396-402.
17. Dolmatch BL, Gurley JC, Baskin KM, Nikolic B, Lawson JH, Shenoy S, et al. Society of Interventional Radiology reporting standards for thoracic central vein obstruction: endorsed by the American Society of Diagnostic and Interventional Nephrology (ASDIN), British Society of Interventional Radiology (BSIR), Canadian Interventional Radiology Association (CIRA), Heart Rhythm Society (HRS), Indian Society of Vascular and Interventional Radiology (ISVIR), Vascular Access Society of the Americas (VASA), and Vascular Access Society of Britain and Ireland (VASBI). *J Vasc Access* 2019;20:114-22.
18. Lok CE, Huber TS, Lee T, Shenoy S, Yevzlin AS, Abreo K, et al. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis* 2020;75(Suppl 2):S1-164.
19. Salik E, Daftary A, Tal MC. Three-dimensional anatomy of the left central veins: implications for dialysis catheter placement. *J Vasc Interv Radiol* 2007;18:361-4.
20. Salgado OJ, Urdaneta B, Colmenares B, García R, Flores C. Right versus left internal jugular vein catheterization for hemodialysis: complications and impact on ipsilateral access creation. *Artif Organs* 2004;28:728-33.
21. Shingarev R, Barker-Finkel J, Allon M. Association of hemodialysis central venous catheter use with ipsilateral arteriovenous vascular access survival. *Am J Kidney Dis* 2012;60:983-9.
22. Rahman S, Kuban JD. Dialysis catheter placement in patients with exhausted access. *Tech Vasc Interv Radiol* 2017;20:65-74.
23. Rajagopalan S, DelleGrottaglie S, Furniss AL, Gillespie BW, Satayathum S, Lameire N, et al. Peripheral arterial disease in patients with end-stage renal disease: observations from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Circulation* 2006;114:1914-22.
24. O'Hare AM, Hsu CY, Bacchetti P, Johansen KL. Peripheral vascular disease risk factors among patients undergoing hemodialysis. *J Am Soc Nephrol* 2002;13:497-503.

Submitted Jul 25, 2022; accepted Oct 31, 2022.