Vascular and Endovascular Surgery
2017, Vol. 51(7) 447-452

DOI: 10.1177/1538574417717609
journals.sagepub.com/home/ves
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First Experience of Performing Hybrid Operations in Chronic Venous Obstructions of Iliofemoral Segments in Patients With Postthrombotic Syndrome

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Abstract

Objective: To assess the first results of hybrid operations in chronic venous obstructions of iliofemoral segments in patients with postthrombotic syndrome (PTS). **Methods:** Hybrid operations (open endovenectomy from the common femoral vein with arteriovenous fistula creation and iliac vein stenting) were performed in 12 patients diagnosed with PTS. All of the patients were diagnosed with severe chronic venous insufficiency. The degree of manifestations of PTS was assessed by means of the Villalta score 7 months before and after the surgical intervention. Diagnostic methods of study included ultrasound duplex scanning, magnetic resonance and/or multispiral computed venography, and contrast venography. **Results:** Technical success of the procedure was 92%. The outcomes of hybrid operations after 7 months were followed up in 6 patients and in 4 patients in 3 months. Secondary patency rates of the stented iliac veins amounted to 100%. No recurrences of venous ulcers were observed. Median Villalta scores improved from 15 to 7 ($P = .012$). **Conclusion:** The first experience of hybrid operations for obstructive lesions of veins of the iliofemoral segments demonstrated their high efficacy and safety.

Keywords

postthrombotic syndrome, chronic obstruction of iliofemoral veins, hybrid operations

Introduction

Deep venous thrombosis (DVT) of the lower extremities is considered to be one of the most widespread vascular conditions affecting 160 to 300 per 100 000 people per year.[1,2] Iliofemoral DVT is the most severe form of venous thrombosis.[3,4] Even with anticoagulant therapy, recanalization occurs in only 20% of the patients, postthrombotic syndrome (PTS) affects 40% to 60% of patients, and 1 of 10 patients develops venous ulcers.[5,6] Despite successful therapeutical approaches, a minimum of 20% to 25% of the patients may require surgical treatment due to severe manifestations of chronic venous insufficiency (CVI) and significant worsening in their quality of life.[7]

Percutaneous transluminal angioplasty and stenting have been increasingly used to correct iliac vein obstructions and had demonstrated sustainable good outcomes.[8-12] However, when inflow to the ilac segment is compromised by obstruction of the common femoral vein (CFV), especially when the outflow from profunda femoris vein (PFV) is also obstructed, the results of iliac vein stenting are frequently compromised.[13,14] Venous stenting below the inguinal ligament is currently the subject of considerable discussion.[15] Alternative surgical option is CVF endophlebectomy (endovenectomy, desobliteration, and desobstruction). Gloviczki and Cho, in 2001, became the first to describe this technique for Palma crossover bypass.[16] In 2004, Puggioni et al performed a series of reconstructive operations on deep veins by means of endophlebectomies.[17]

Previously described interventional strategies in cases of combined femoral and iliac obstructions include either staging procedures or correcting only iliofemoral segment.[18,19]

The objective of this study was to evaluate the first results of hybrid procedures of simultaneously performed interventions in femoral and iliac segment in patients with extensive chronic venous obstructions and PTS.

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Table 1. Demographic Data, CEAP Classification, Term of Disease, and Villalta Score Evaluation Before Treatment.

Demographic Data	Number of Patients
Patients	12
Gender	
Male	7
Female	5
Mean age (range), years	42.8 (34-52)
Comorbidities	
Hypertension	5
Diabetes	1
Coronary heart disease	2
Congenital defects	0
Term of disease, mean (range)	7.1 (2-12) years
Advanced CEAP classification	
$C_{4a,s}$	3
$C_{4b,s}$	4
$C_{5,s}$	4
$C_{6,s}$	1
E_S	12
$A_{D,S,P}$	12
$P_{R,O\ 5,7,8,\ 9,11,12,13,14,15,18}$	10
$P_{R,O\ 2,7,8,9,11,12,13,14,15,17,18}$	2
Score	Median (range)
Villalta score baseline	15 (9-18)

Materials and Methods

This is a retrospective review of prospectively collected data on 12 patients who underwent hybrid procedures on occluded iliofemoral venous segments from March 2014 to February 2016. There were 7 men and 5 women, from 34 to 52 years (mean age = 42.8 ± 5.7 years) in this series. All of the patients had severe CVI. The distribution of patients according to the Clinical-Etiologic-Anatomic-Pathophysiologic (CEAP) classification was the following: C4a, s—3 patients, C4b, s—4 patients, C5, s—4 patients, and C6, s—1 patient. The combinations of obstructive lesions were the following: critical stenosis of external iliac vein (EIV) and occlusion of CFV in 7 patients; occlusion of common iliac vein (CIV), EIV, and CFV in 3 patients; occlusion of CIV, stenosis of EIV, and occlusion of CFV in 2 patients. The time from the episode of acute iliofemoral venous thrombosis to treatment varied from 2 to 12 years (mean = 7.1 ± 3.3 years). The severity of PTS was evaluated with the Villalta score 7 months before and after surgical intervention in 6 patients.[20] Characteristics of patients are presented in Table 1.

The diagnostic methods included ultrasound duplex scanning (UDS; Vivid 7, GE Medical Systems, Horten, Norway), magnetic resonance venography (MRV; GE Healthcare, Signa Horizon, Hdxt 1.5T, USA) and multispiral computed venography (CTV, AQUILION 64, Toshiba, Japan), and contrast venography (INNOVA 3100, GE Healthcare, USA).

Statistical Analyses

Statistical data processing was performed with licensed statistical software package Statistica 10 (StatSoft, Tulsa, Oklahoma). The data were presented mean ± standard deviation. The Villalta score were compared using the Wilcoxon test. Differences with a $P < .05$ were considered statistically noteworthy.

Hybrid Procedure

Three days prior of procedures, the patients were started on platelet inhibition with aspirin 100 mg . The CFV, distal segment of EIV, saphenofemoral junction, PFV, and femoral vein (FV) were exposed, using a standard longitudinal inguinal incision. Small tributaries of the CFV were ligated and tourniquets were applied on the large tributaries. Patients were fully anticoagulated with 100 IU/kg of unfractionated heparin. Longitudinal venotomy of the distal segment of EIV and bifurcation of PFV and FV was performed. Dense fibrous tissue and web-like synechiae were removed with sharp and blunt dissection well into the distal EIV, releasing the orifice(s) of PFV and great saphenous vein (GSV; Figure 1 A and B). Special attention was paid to desobliteration of the orifice(s) of PFV. Subsequently, the lumen of the vein was either sutured with primary sutures (Prolene 7-0) or by patching using bovine pericardium or autogenous vein depending on the diameter of the lumen and the effectiveness of the endovenectomy (Figure 1C). Arteriovenous fistula (AVF) was created between the superficial femoral artery (SFA) and the CFV (Prolene 8-0), using free venous fragments or the tributaries of the GSV (Figure 1D).

An ascending venography was performed via an 8F to 10F sheath at the conclusion of the endovenectomy. After crossing the occluded segment and predilation, the segment was stented using either Wallstent (Boston Scientific Corporation, Natick, MA, USA; n = 11) or Smart (Cordis, Johnson & Johnson, New Brunswick, NJ, USA; n = 2). Fourteen to 18 mm stents were used for CIV and 12 to 14 mm for EIV. Three of the patients needed 2 stents, the rest was treated with a single stent. Stenting was followed by control venography. Successful recanalization was defined as the free flow of contrast medium through a stented venous segment emptying into the vena cava without collaterals. The segments with residual stenoses underwent postdilatation. Stages of endovascular intervention are shown in Figure 2A-C.

Patients started ambulation on the first postoperative day. Intermittent pneumatic compression for lower limbs was used postoperatively (Flowpac; Huntleigh Healthcare, Cardiff, United Kingdom), to promote flow through the stented segments of the vein. Elastic bandages were essential components of the postoperative care. Low-molecular-weight heparins (enoxaparin, nadroparin) were administered in therapeutic doses for 3 to 5 days with subsequent conversion to new oral anticoagulants (rivaroxaban) for 6 months along with aspirin.

Results

Initial technical success was 92% (12 of 13). The attempts to cross-occluded CFV and EIV were unsuccessful in 1 patient. Another patient developed venous stent and CFV thrombosis on the second postoperative day. The catheter-directed

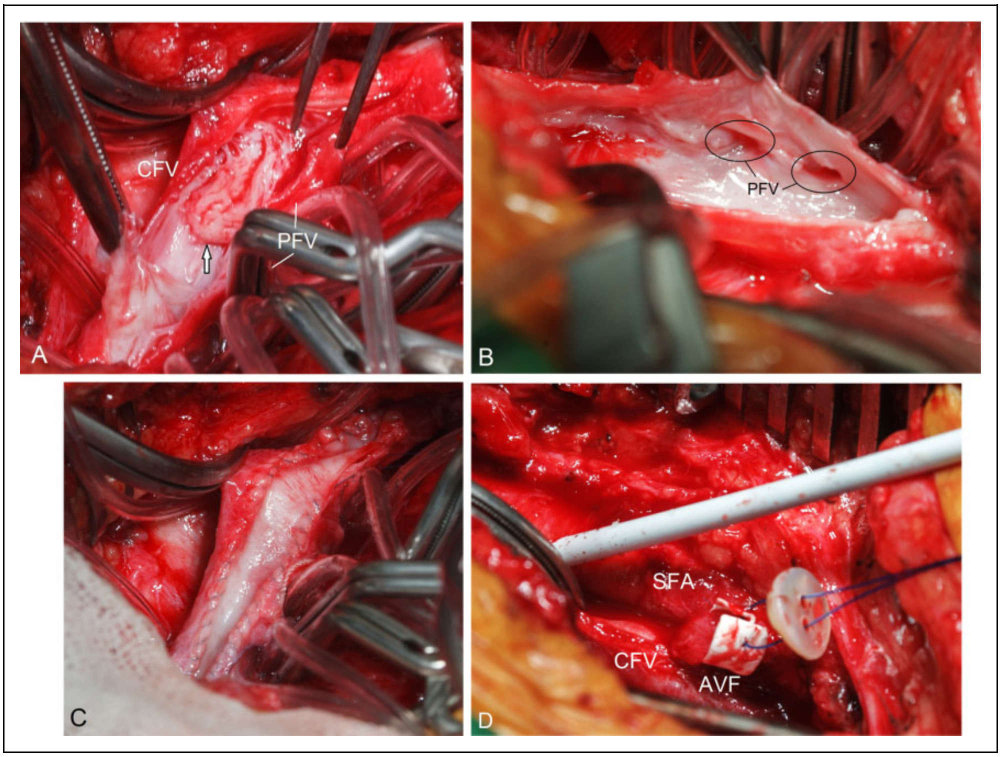

Figure 1. Stages of endovenectomy. A, A longitudinal venotomy in the CFV with removal of fibrotic tissue and synechiae (arrow). B, The lumen of the vein after endovenectomy and the orifices of the desobliterated PFV vein. C, Patch closure of the CFV with bovine pericardium. D, AVF between CFV and SFA wrapped in PTFE cuff with 2-0 Prolene suture bringing out through a sterile button that is placed on the subcutaneous tissue laterally (this area on skin is marked). Insertion of the sheath into the EIV. AVF indicates arteriovenous fistula; CFV, common femoral vein; EIV, external iliac vein; PFV, profunda femoris vein.

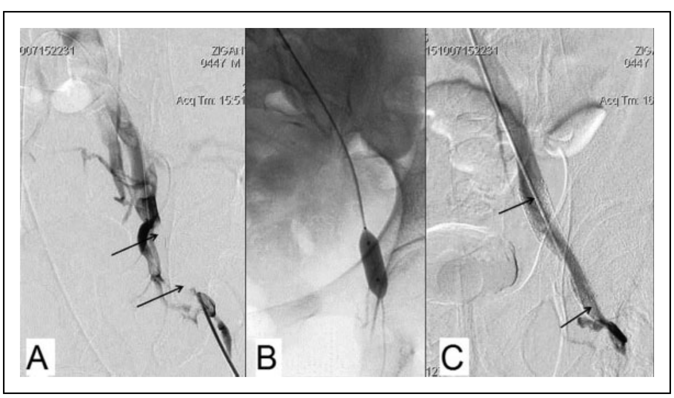

Figure 2. Stages of endovascular intervention. A, Ascending (pelvic) venogram using a sheath (EIV occlusion). B, Balloon angioplasty of EIV. C, Stent placement and control venography testifying to a free blood outflow to the inferior vena cava. EIV indicates external iliac vein.

thrombolysis was unsuccessful, and this case was considered as initial technical failure. No wound complications or pulmonary embolisms were recorded during the postoperative period. The patients underwent dynamic UDS before discharge from the hospital (Figure 3), also at 1, 3, and 6 months after the intervention (Figure 4).

Six patients were followed for 7 months and 4 patients for 3 months. One of the patients developed in-stent occlusion 4 months after the operation and underwent balloon angioplasty with stent recanalization with clinical improvement, despite residual stenosis of proximal part CFV (Figure 5). At present, a stenting segment of iliac veins is patent. The patient is planned to perform a stenting of residual stenosis of CFV. Thus, secondary patency rates of the stented iliac veins amounted to 100%. No recurrences of venous ulcers were observed. Median Villalta score improved from 15 to 7 ($P = .012$).

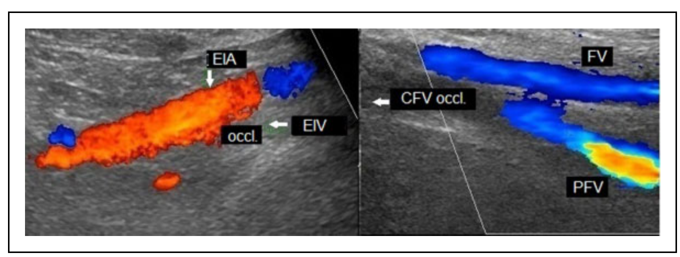

Figure 3. Ultrasound images of iliofemoral segment of the patient before the hybrid procedure. The CFV and EIV occlusion. CFV indicates common femoral vein; EIA, external iliac artery; EIV, external iliac vein.

Discussion

Iliac vein stenting has become the method of choice in the treatment of venous obstructions of iliofemoral segments.[21,22] The widespread use of this technique increased significantly in

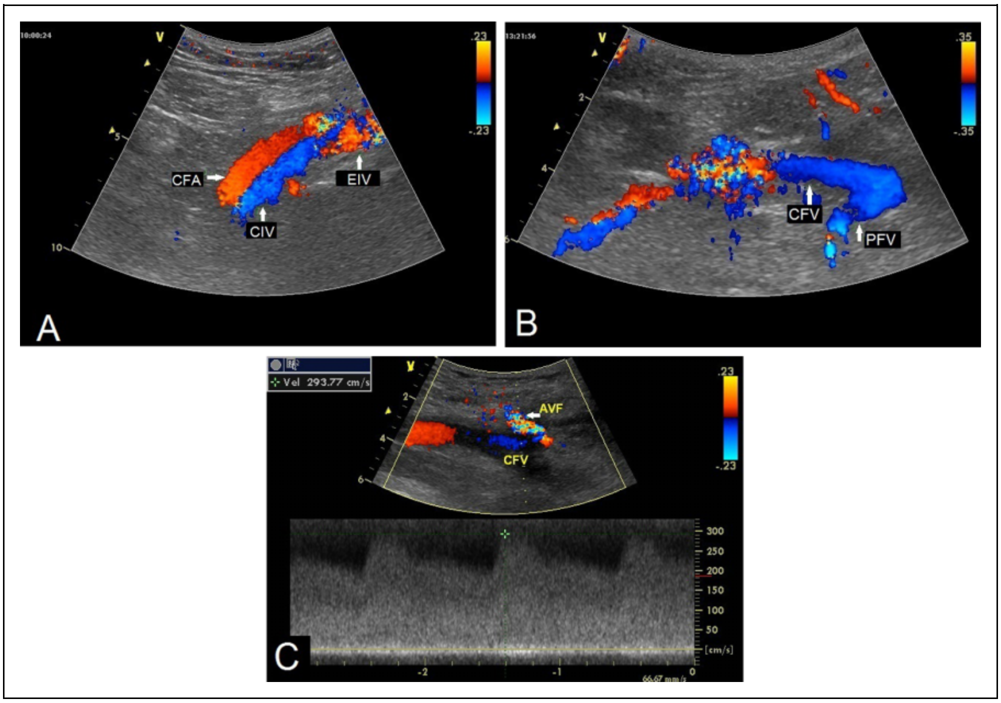

Figure 4. Ultrasound images of the same patient 1 month after the intervention. A and B, CIV, EIV, and PFV are patent (arrow). C, Ultrasound image of well-functioning AVF (arrow). AVF indicates arteriovenous fistula; CIA, common iliac artery; CIV, common iliac vein; EIV, external iliac vein; PFV, profunda femoris vein.

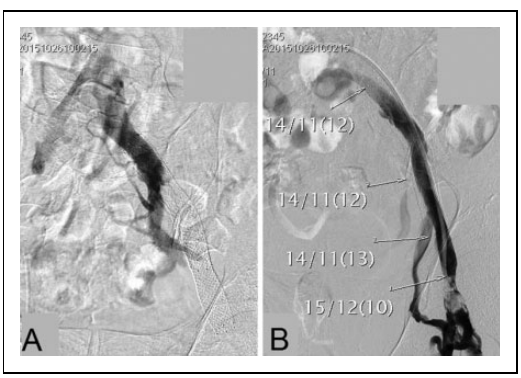

Figure 5. Ascending (pelvic) venogram 4 months after the hybrid procedure. A, Stent occlusion. B, Balloon angioplasty with restoration of stent patency. On venogram residual stenosis of proximal part CFV is defined. CFV indicates common femoral vein.

recent decades due to high effectiveness of the procedure as well as its reliable long-term outcomes. Cumulative primary, assisted-primary, and secondary patency after stenting during the period up to 72 months have been reported as 50% to 80%, 76% to 82%, and 82% to 90%, respectively, and are accompanied by low rates of complications.[9,23,24] However, the stent is extended below the inguinal ligament, the risk of stent thrombosis increases at least 3.8 times that most often occurs due to extension of the obstruction to the CFV.[14] The contemporary pool of diagnostic methods for chronic iliofemoral occlusions includes UDS, MRV, CTV, intravascular ultrasonography (IVUS), and contrast venography. Those methods are used in different combinations during the diagnostic and treatment stages. Noninvasive methods such as MRV and CTV are considered to be preferred on the diagnostic stage. During the endovascular procedures, IVUS is considered as a method of choice to evaluate the extension and severity of the morphological lesions of iliac veins, and it is considered as the gold standard in diagnostic modalities.[25] However, the following issues should be taken into consideration: IVUS is expensive (machine and disposable catheter); reimbursement for IVUS may not cover costs; and some US and nonUS hospitals can't "afford" it. A new look on iliac venograms (Micro-Dicom assessment of 3 segments of CIV and 3 segments of EIV; "Bull's eye" sign; venogram 180° view; balloon contouring test (identifying waist) gives an equal distribution of positive IVUS findings.[26]

We believe that the ultrasound-guided multiplane contrast venography performed using the popliteal vein access is an essential component of the preoperative assessment and provides adequate information, especially in postthrombotic lesions of iliac vein. Ultrasound duplex scanning is a reliable noninvasive method for the hybrid operation effectiveness.

In recent years, the hybrid procedures consisting of open intervention on CFV, angioplasty, and iliac vein stenting have been successfully used for occlusions extending to the CFV.[13,18] Common femoral vein and PFV vein orifice desobliteration provides maximal venous outflow from the tight and distal parts of the lower extremity as well as increases venous blood flow to the iliac veins and inferior vena cava. Arteriovenous fistula created between the CFA or SFA and CFV vein significantly decreases the probability of in-stent thrombosis in recanalized iliac veins.[13] Although there are no distinct indications for AVF creation and ways of its formation in caudal and cranial directions,[19] we prefer the caudal portion of the desobliterated CFV for AVF creation. We usually remove the AVF after 6 to 8 weeks (period of endothelialization of the stent) by means of a unique remote method of ultrasound-guided fistula ligation that we devised. It consists in a distant elimination of fistula under ultrasound control by tightening of polypropylene suture brought through a small skin incision till disappearance of Doppler signal from fistula. This method is simple and reliable, and it doesn't require traumatic redo surgery. Safety and effectiveness of endophlebectomy and AVF in venous disease have been described in a small number of studies.[14,25]

Accumulation of experience and optimization of the stent design play an essential role in improving the outcomes of stenting. It should be noted that hybrid procedures were preceded by a considerable experience in stenting of iliac vein obstructions in 69 patients (73 extremities).

Conclusion

Our first experience of the hybrid procedures in venous obstruction of iliofemoral segment demonstrated their high efficiency and safety. Good results of the operation were proved by significant clinical enhancement and high patency levels of recanalized venous segments.

The hybrid operation improvement of results is intimately linked to the development of clear indications for the procedures, careful selection of the patients, and accumulation of experience and optimization of venous stent design.

Authors' Note

Igor Ignatyev and Anatoly Pokrovsky contributed to conception and design; Igor Ignatyev, Anatoly Pokrovsky, and Evgeny Gradusov contributed to analysis and interpretation; Igor Ignatyev and Evgeny Gradusov contributed to data collection; Igor Ignatyev and Evgeny Gradusov contributed to writing the article; Igor Ignatyev, Anatoly Pokrovsky, and Evgeny Gradusov contributed to critical revision of the article; Igor Ignatyev, Anatoly Pokrovsky, and Evgeny Gradusov contributed to final approval of the article; Igor Ignatyev and Evgeny Gradusov contributed to statistical analysis; Igor Ignatyev contributed to overall responsibility.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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