Clinical outcomes after direct and indirect surgical venous thrombectomy for inferior vena cava thrombosis

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ABSTRACT

Objective: Inferior vena cava thrombosis is rare, but patients are at high risk for development of a post-thrombotic syndrome (PTS) in the long term. Surgical approaches include indirect transfemoral venous thrombectomy (iTFVT) and direct open venous thrombectomy (dOVT). This study reports patient outcomes after iTFVT and dOVT for inferior vena cava thrombosis covering a 25-year follow-up period.

Methods: The study period was from January 1, 1982, to December 31, 2013. Data were retrieved from archived medical records, and patients were invited for a detailed phlebologic follow-up examination (DPFE). Health-related quality of life was assessed with the 36-Item Short Form Health Survey questionnaire. Patient survival, patency rates, and freedom from PTS were calculated using Kaplan-Meier estimation with log-rank testing. The χ^2 test with Yates continuity correction and logistic regression analysis were applied to identify associations between risk factors or coagulation disorders, mortality, and PTS.

Results: Complete medical records were available for 152 patients. Patients' 5-year survival was 91% ± 3%, and 5-year primary and secondary patency rates were 80% ± 3% and 94% ± 2%. Freedom from PTS after 25 years was 84% ± 6%. No differences for patient survival, patency rates, or freedom from PTS were identified between iTFVT, dOVT, and a combination of both procedures. Antithrombin III deficiency was the most common coagulation disorder, and patients' physical function and social function were impaired compared with those found in German normative data ($P < .05$). No risk factor or coagulation disorder was associated with survival or PTS.

Conclusions: Open surgical venous thrombectomy is safe and delivers satisfying short- and long-term outcomes compared with endovascular approaches. It remains valuable for patients who are not eligible for other interventional therapies. (J Vasc Surg: Venous and Lym Dis 2019;7:333-43.)

Keywords: Iliofemoral; Deep venous thrombosis; Surgery; Post-thrombotic syndrome

Inferior vena cava (IVC) thrombosis (IVCT) is an underrated but severe problem. The diagnosis is challenging, given the heterogeneous clinical symptoms. Isolated IVCT is extremely rare and frequently accompanied by a concomitant deep venous thrombosis (DVT). DVT of the limb has an annual incidence as high as 48 to 122 per 100,000.[1,2] Of these patients, 2.6% to 4% might suffer from IVCT, which significantly affects patients' long-term morbidity and mortality.[3-5] Notably, patients with congenital IVC abnormalities are at higher risk for development of an IVCT.[6-8]

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Author conflict of interest: none.

Additional material for this article may be found online at www.jvsvenous.org.

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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.

2213-333X

https://doi.org/10.1016/j.jvsv.2018.11.005

Patients who do not receive appropriate treatment have a 90% risk for development of a post-thrombotic syndrome (PTS) after IVCT, and up to 15% may develop severe PTS with chronic leg ulcers.[9] PTS severely impairs patients' health-related quality of life (HRQOL) and has immense economic impact on the health care system.[9]

Patients with IVCT often describe symptoms similar to those that occur with an isolated DVT, such as leg heaviness, pain, swelling, and cramping. Although symptoms can be nonspecific or clinically silent, timely diagnosis is crucial to prevent severe life-threatening complications, such as pulmonary embolism (PE) or clot migration into the renal veins.[10]

Compression duplex ultrasound (CDU) is the modality of choice to confirm the clinical suspicion of an IVCT; however, computed tomography (CT) or magnetic resonance imaging scans may be required. After the diagnosis is established, immediate effective anticoagulation and appropriate compression therapy are obligatory. Despite a growing number of minimally invasive treatment options that have become increasingly feasible and broadly available during the last decades, open surgical venous thrombectomy remains a potential alternative.[11]

Open surgical venous thrombectomy with formation of an arteriovenous fistula (AVF) to temporarily augment venous blood flow is challenging and risky as procedure-related factors, such as passing a catheter through the IVCT or IVCT manipulations, may lead to potentially fatal PE.[12] Open surgical venous thrombectomy typically ensures complete and visually verifiable clot removal while significantly reducing the risk for development of PTS at long term. However, modern approaches, such as catheter-directed thrombolysis (CDT), have been claimed to be equally efficient in restoring venous patency.[13,14]

This study retroactively investigated patient mortality, patency, and freedom from PTS after indirect transfemoral venous thrombectomy (iTFVT) and direct open venous thrombectomy (dOVT) with temporary AVF for IVCT. It further analyzes the risk for development of long-term PTS and evaluates patients' HRQOL.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Key Findings:** In a cohort of 152 patients who had open surgical thrombectomy for acute inferior vena cava thrombosis during a 32-year period, 5-year survival and secondary patency were 91% and 94%, respectively. Freedom from post-thrombotic syndrome after 25 years was 84%. Direct and indirect venous thrombectomy delivered similar outcomes.
- **Take Home Message:** Open surgical approaches may be considered for those patients with inferior vena cava thrombosis who are not candidates for endovascular treatment.

METHODS

Data collection. We reviewed our department's database and identified patients with IVCT starting from January 1, 1982, to December 31, 2013. Next, we included all patients who underwent open surgical venous thrombectomy as a first-line therapeutic approach. All relevant clinical information was extracted from archived medical records for patients' in-hospital stays and later outpatient department visits. The study was approved by the Ethic Committee of the Medical Faculty at the University Hospital Düsseldorf.

Surgery. CDU was used as first-line imaging to determine the extent of DVT and to aid in the diagnosis of an IVCT. Next, patients received a CT scan to confirm the diagnosis of IVCT, which was followed by recommendation of the appropriate direct or indirect surgical approach. On admission, patients received compression stockings along with intravenous administration of unfractionated heparin once the diagnosis was confirmed. Historically, once endovascular approaches had become a feasible alternative, patients were informed about the different therapeutic approaches. All cases were discussed among the senior surgeons of the department, considering severity of clinical symptoms and the patient's age. All cases underwent internal review, with consideration of the amount of IVC thrombus burden and lumen occlusion; the odds of successfully passing the IVCT with an occlusion catheter using a transfemoral approach followed by indirect thrombectomy were evaluated against the risk for PE. After thorough risk-benefit assessment, patients with disproportionate risk for thrombus mobilization with resultant PE (with use of iTFVT) were advised to undergo an open direct abdominal approach to improve the patient's safety. All patients gave their informed consent for the suggested surgical approaches. All procedures were performed by senior surgeons of the Department of Vascular and Endovascular Surgery at the University Hospital Düsseldorf. Patients received either iTFVT (n = 73) or dOVT (n = 35). In cases during which iTFVT or dOVT led to incomplete thrombus removal, both procedures were combined (n = 44; Supplementary Fig, online only).

iTFVT. All relevant veins were exposed using a longitudinal inguinal incision. Next, an entry-side segment in the femoral vein was identified, and a longitudinal venotomy was performed. The same approach was used on the contralateral side. Through the contralateral approach, an occlusion balloon catheter was advanced and placed proximal to the IVCT to prevent PE. Next, multiple venous thrombectomy maneuvers were performed on the thrombosed side using balloon catheters of increasing diameters to ensure complete thrombus removal (Fogarty maneuvers). To prevent PE, the positive end-expiratory pressure was temporarily raised to 15 mm Hg at the time of venous thrombectomy, and patients were kept in the supine anti-Trendelenburg position. Procedural success was confirmed by appropriate venous backflow. Thereafter, thrombectomy maneuvers were performed retrograde to remove the thrombus from the lower limb veins, guaranteeing appropriate backflow through the deep femoral vein. Manual compressions or Esmarch bandages were applied to augment complete clot removal. Sufficient backflow confirmed procedural success, and the venotomy was closed with running sutures. Before closure of the venotomy of the contralateral side, the occlusion balloon was used to perform a final Fogarty maneuver to remove mobilized residual thrombus (Supplementary Fig, *A*, online only).

dOVT through laparotomy. Briefly, median laparotomy was performed to open the abdominal cavity and to expose the IVC. Next, the proximal end of the thrombus was identified and the IVC was clamped. An entry-side segment was identified, and a longitudinal IVC venotomy was performed. The thrombus was carefully removed. Multiple retrograde venous thrombectomy maneuvers were performed as described before, augmented with manual compression or Esmarch bandages. Again, procedural success was confirmed by sufficient backflow. Finally, IVC venotomy and midline laparotomy closure was performed (Supplementary Fig, *B*, online only).

Whenever there was suspicion of residual thrombus by either approach, the procedures were combined successively within the same operation. To reduce the risk for development of recurrent thrombosis during the critical postoperative 3-month period, an inguinal AVF was established to augment blood flow after either procedure, on whichever side was affected by iliac vein thrombosis. Whenever possible, we used a distal side branch of the superficial femoral artery and established the AVF at the most distal possible location. Next, we confirmed pulsatile fistula flow using continuous-wave Doppler.

All patients received a CDU examination before discharge to confirm patent veins. CDU or CT scans were used to diagnose recurrent thrombosis after surgery whenever clinical symptoms occurred.

Patients were transferred to the Department of Hemostasis and Transfusion Medicine for anticoagulation management, where the individual risk for recurrent thrombosis was assessed, considering the original thrombus burden, presence of anticoagulation disorders, and general risk factors. Whereas patients in the 1990s were advised to undergo prolonged anticoagulation, this time frame was reduced to 12 months starting with the new millennium. Novel oral anticoagulant drugs began to replace warfarin starting around 2014, after safety concerns had been dispelled.

Follow-up. The AVF was ligated 3 months after primary surgery during a second in-hospital stay. During that in-hospital stay, all patients received a CDU examination together with a CT scan to exclude recurrent thrombosis before AVF ligation. Further follow-up CDU scans were suggested at 6 and 12 months after primary surgery in our outpatient department. Thereafter, patients were transferred to collaborating general practitioners for annual CDU follow-up.

Inclusion and exclusion criteria. Patients had to be at least 18 years old and diagnosed with IVCT using CT scans. All patients had to undergo a clinical examination and to give informed consent before operation. The exclusion criteria were as follows: pregnancy, prior DVT, prior endovascular therapy with a percutaneous inguinal approach on the affected leg, poor general condition, absent consent after the risk-benefit assessment, and impossibility of establishing an inguinal AVF because of access site inaccessibility at presurgery evaluation.

Detailed phlebologic follow-up examination (DPFE) and HRQOL. Contact information was available for 90 patients. These patients were contacted and invited to our outpatient department for a DPFE. Together with a written invitation, patients were mailed a 36-Item Short Form Health Survey (SF-36) questionnaire and asked to send it back. At examination, patients were assessed on the severity of PTS symptoms along with a detailed examination of lower limb veins for occlusion and reflux using CDU. We used the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification and Villalta score to objectively categorize patients according to PTS severity.

The self-assessment-based SF-36 questionnaires gathered during a 4-week period (second version) were used to score eight independent health domains (physical functioning, physical role functioning, bodily pain, general health perceptions, social role functioning, vitality, emotional role functioning, and mental health). Component summary scores (physical component summary and mental component summary) were calculated from independent health scores.

Statistical analysis. Categorical data are presented as frequency distribution with percentages, continuous data as mean ± standard errors of mean. The Kaplan-Meier estimator was used to estimate patency, survival, and PTS rates using the latest available clinical information. The log-rank (Mantel-Cox) test was used to test for significance between subgroups. We used logistic regression analysis or χ^2 testing with Yates continuity correction to identify the association between risk factors or coagulation disorders and PTS or mortality. Statistical analysis was performed using GraphPad Prism 7 (GraphPad Software Inc, La Jolla, Calif) and SPSS 25.0 software (IBM Corp, Armonk, NY). A *P* value <.05 was considered statistically significant.

RESULTS

Recruitment of patients and basic demographics. We identified 180 patients who underwent open surgical venous thrombectomy for IVCT from January 1, 1982, through December 31, 2013. Complete clinical data were available for 152 patients. There were 38 patients who accepted the invitation to attend a DPFE in the outpatient department and filed SF-36 questionnaires; another 10 SF-36 questionnaires were filed by mail (Fig 1). In our study cohort, we identified four patients (3%) who required stent implantation in the left iliac vein for diagnosed May-Thurner syndrome on initial CT scans. These four patients were lost to follow-up at 7, 35, 52, and 112 months, respectively. None of these patients needed revision surgery because of stent complications or occlusions.

The mean age was 42.3 ± 1.4 years for the study cohort (n = 152) and 42.9 ± 2.8 years for patients at the DPFE

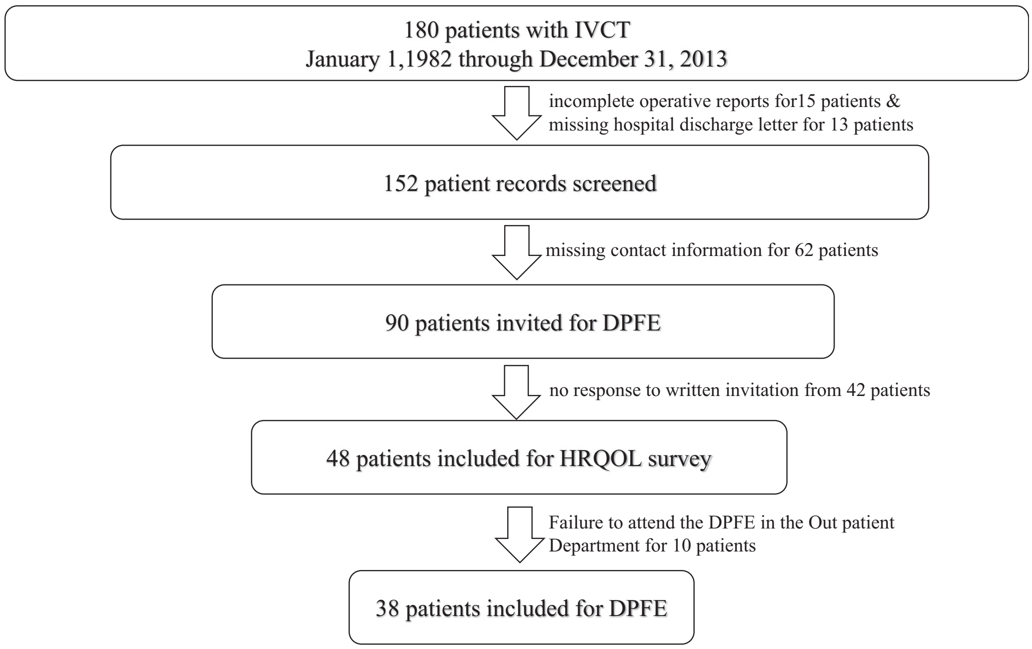

Fig 1. Patient recruitment and dropouts. We identified 180 patients with inferior vena cava thrombosis (*IVCT*) from January 1, 1982, through December 31, 2013, who underwent treatment at the University Hospital Düsseldorf. Of these, 90 patients were excluded because of incomplete clinical records; 90 patients were invited to attend a detailed phlebologic follow-up examination (*DPFE*) at the outpatient department. Patients also filed a 36-Item Short Form Health Survey (SF-36) questionnaire for assessment of health-related quality of life (*HRQOL*). Ultimately, 38 patients presented for the DPFE, and 48 patients returned the SF-36 questionnaire.

(n = 38). Mean follow-up time was 98.1 ± 8.5 months and 145.3 ± 15 at DPFE (143.5 ± 10.2 months for HRQOL). There was no sex preference. The left iliac-femoral veins were more frequently coaffected. The IVCT frequently extended to the lower extremity veins. Extension to the affected leg included 99.3% iliac, 77.63% femoral, and 33.55% popliteal veins. Logistic regression analysis revealed no association between risk factors and patient mortality or patency rates after open surgical venous thrombectomy. Patients received anticoagulation for a mean of 37.7 ± 6.1 months. Surgical subgroup-specific patient characteristics and risk factor distribution were similar to those of the total study cohort (Table I).

Mortality, patency, and freedom from PTS rates. Patient mortality, patency, and freedom from PTS rates were calculated using Kaplan-Meier estimation. During the follow-up period, 15 deaths occurred, none of them procedure related. Six patients died of a heart attack, three patients of lung cancer, two patients of colon cancer, three patients of pneumonia, and one patient of liver cirrhosis with visceral bleeding. Patients' 1- and 5-year survival rates were 93% ± 2% and 91% ± 3% after open surgical venous thrombectomy for IVCT (Fig 2, *A*). Subgroup-specific survival at 1 year (Fig 2, *B*) was as follows: iTFVT, 89% ± 4%; dOVT, 91% ± 5%; and combined, 100%. Subgroup-specific survival at 25 years (Fig 2, *B*) was as follows: iTFVT, 87% ± 5%; dOVT, 78% ± 9%; and combined, 100%. Patients' 1- and 5-year primary patency rates were 83% ± 3% and 80% ± 3%, and secondary 1- and 5-year patency rates were 96% ± 2% and 94% ± 2%, respectively (Fig 2, *C*). Subgroup-specific primary patency rates at 1 year (Fig 2, *D*) were as follows: iTFVT, 80% ± 4%; dOVT, 86% ± 6%; and combined, 83% ± 6%. Patients' 1- and 5-year freedom from PTS rates were both 100%, whereas 9 and 25 years later, they were 97% ± 2% and 84% ± 6%, respectively (Fig 2, *E*). Subgroup-specific 25-year freedom from PTS rates (Fig 2, *F*) were as follows: iTFVT, 96% ± 4%; dOVT, 90% ± 9%; and combined, 69% ± 12%.

Postsurgery complications. Overall postsurgery complications occurred in 46 of 152 (30%) patients. Complications were subclassified according to the Clavien-Dindo classification. Analyzing the complete patient cohort, the different surgical subgroups, and the patients who presented for DPFE, the distribution of complications was similar (Table II). Notably, there were no grade IVb complications (multiorgan dysfunction), whereas grade IIIb complications (requiring any sort of intervention needing general anesthesia) were most frequent. Screening the medical records, we identified 18 patients (~12%) who required blood transfusion. In detail, there were 8 hematomas (iTFVT, 2; dOVT, 4; combined operation, 2), 6 occluded AVFs (iTFVT, 2; dOVT, 1; combined operation, 3), 2 with impaired wound healing (dOVT, 1; combined

Table I. Patients' characteristics and risk factors

Characteristics	Total study cohort (N = 152)			Patients at DPFE (n = 38)
	iTFVT (n = 73)	dOVT (n = 35)	Combined (n = 44)	
Age, years		42.4 ± 1.4		42.9 ± 2.8
	44.8 ± 2.1	44.8 ± 3	36.5 ± 2.3	
Length of in-hospital stay, days	12.8 ± 1			10.4 ± 0.7
	12.1 ± 1.7	15.8 ± 2.3	11.8 ± 0.9	
Sex	M: 76/152 (50); F: 76/152 (50)			M: 19/38 (50) F: 19/38 (50)
	M: 33/73 (45.2) F: 40/73 (54.8)	M: 19/35 (54.3) F: 16/35 (45.7)	M: 24/44 (54.5) F: 20/44 (45.5)	
Concomitant PE before surgery		59/152 (38.8)		17/38 (44.7)
	22/73 (30.1)	14/35 (40)	23/44 (52.3)	
Concomitantly affected leg		r: 36/152 (23.7); l: 66/152 (43.4); b: 50/152 (32.9)		r: 9/38 (23.7) l: 20/38 (52.6) b: 9/38 (23.7)
	r: 19/73 (26) l: 38/73 (52) b: 16/73 (22)	r: 9/35 (25.7) l: 14/35 (40) b: 11/35 (31.4)	r: 8/44 (18.2) l: 13/44 (29.5) b: 23/44 (52.3)	
AVF		ss: 110/152 (72.4); bs: 42/152 (27.6)		ss: 27/38 (71.1) bs: 11/38 (28.9)
	ss: 62/73 (84.9) bs: 11/73 (15.1)	ss: 23/35 (65.7) bs: 12/35 (34.3)	ss: 25/44 (56.8) bs: 19/44 (43.2)	
Anticoagulation therapy, months		37.7 ± 6.1		48.2 ± 11.9
	69.4 ± 8.1	32.7 ± 11.6	50 ± 13.6	

Risk factors	Total study cohort (N = 152)					Patients at DPFE (n = 38)
				Log regression		
	iTFVT (n = 73)	dOVT (n = 35)	Combined (n = 44)	Mortality	Patency	
Obesity		19/152 (12.5)				6/38 (15.8)
	8/73 (11)	4/35 (11.4)	7/44 (15.9)	.92	.39	
Immobilization		97/152 (63.8)				23/38 (60.5)
	48/73 (65.8)	21/35 (60)	28/44 (63.6)	.75	.43	
Smoking		30/152 (19.7)				10/38 (26.3)
	16/73 (21.9)	4/35 (11.4)	10/44 (22.7)	.51	.17	
Carcinoma		23/152 (15.1)				3/38 (7.9)
	11/73 (15.1)	7/35 (20)	5/44 (11.4)	.58	.41	

AVF, Arteriovenous fistula; *b,* both; *bs,* both sides; *dOVT,* direct open venous thrombectomy; *DPFE,* detailed phlebologic follow-up examination; *iTFVT,* indirect transfemoral venous thrombectomy; *l,* left; *PE,* pulmonary embolism; *r,* right; *ss,* single side.
Patients' basic characteristics are presented for the total study cohort, the surgical subgroups, and the DPFE cohort separately. Arteriovenous fistula was constructed on the side of iliac vein thrombosis. A logistic regression analysis (Hosmer-Lemeshow test) was applied to analyze whether risk factors for inferior vena cava thrombosis (total, n = 152) are associated with patient mortality, patency, or post-thrombotic syndrome rate. Data are presented as mean ± standard error of the mean or frequency distribution (%).

operation, 1), 1 intestinal obstruction (combined operation), 1 peritonitis (dOVT), and 36 recurrent thromboses (iTFVT, 20; dOVT, 6; combined operation, 10).

Applying CDU and CT scans, 36 patients with recurrent thromboses were identified. In detail, we observed 33 recurrent iliac vein thromboses. Of these, 23 recurrent thromboses also affected the femoral veins and 6 the popliteal veins. Whereas there were no isolated recurrent thromboses in the femoral or popliteal veins, four isolated recurrent IVCTs were observed. In accordance with extension of the proximal recurrent thrombosis in the IVC, 19 iTFVTs and eight dOVTs were performed as repeated operations. Nine of the recurrent thrombosis patients showed limited extension and mild clinical symptoms and underwent conservative management. A second additional recurrent thrombosis after repeated surgery occurred in 11 patients. For these, four iTFVTs and one dOVT were performed as second repeated operations, whereas six patients underwent conservative management.

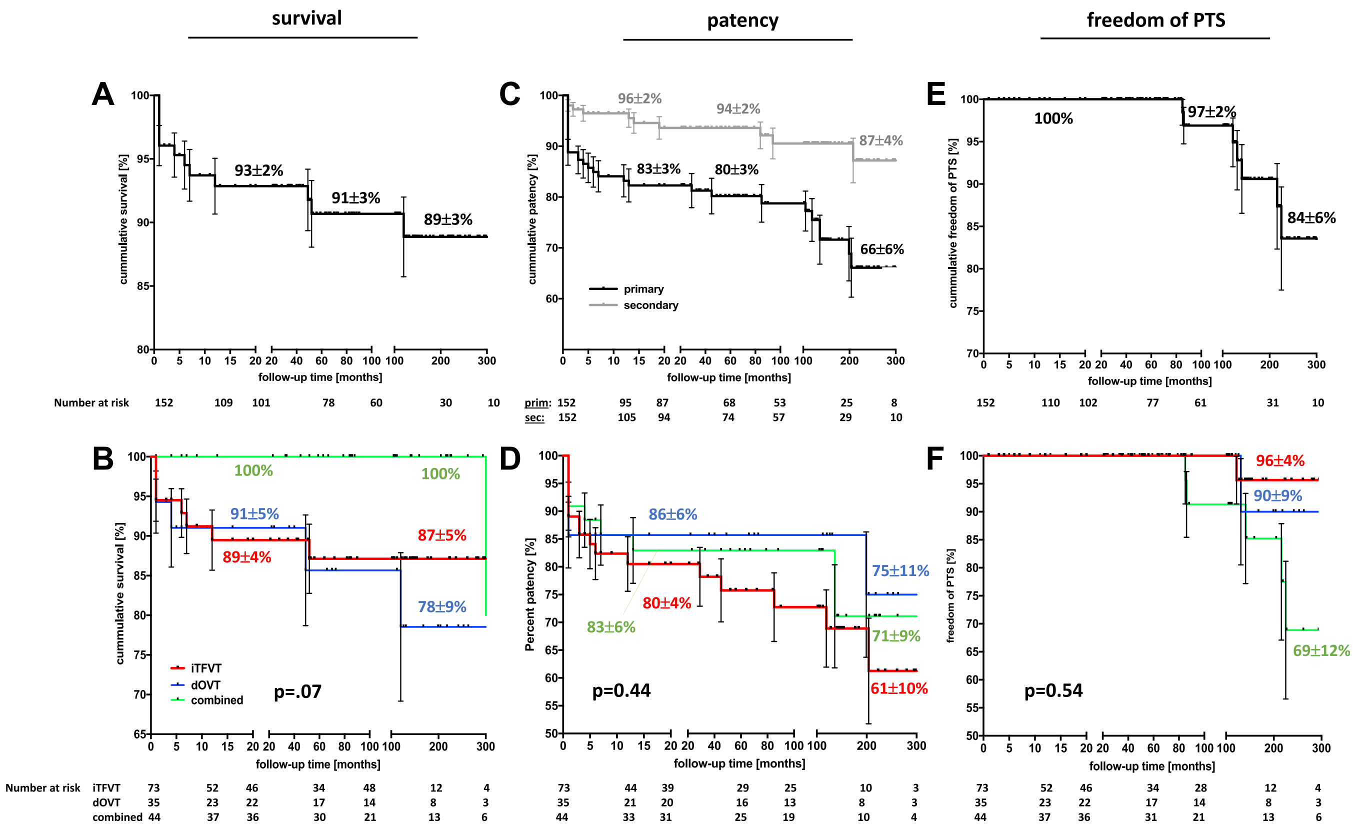

Fig 2. Kaplan-Meier estimator for patient follow-up outcomes. Data are ±standard error of the mean. Post-thrombotic syndrome (*PTS*) was defined inconsistently during the study period. For patients who attended the detailed phlebologic follow-up examination (DPFE; n = 38), a Villalta score of ≥5 was considered PTS. For the remaining patients (n = 114), PTS needed to be mentioned in the list of diagnoses of the latest archived medical records of collaborating general practitioners or of the outpatient department. **A,** Kaplan-Meier estimator for patient survival. Patients' 1-, 5-, and 25-year survival rates are presented. **B,** Subgroup-specific Kaplan-Meier estimator for patient survival. Patients' 1- and 25-year survival rates are presented for each subgroup. *dOVT,* Direct open venous thrombectomy; *iTFVT,* indirect transfemoral venous thrombectomy. **C,** Kaplan-Meier estimator for primary and secondary patency rates for inferior vena cava thrombosis (IVCT). Recurrent thrombosis after primary surgery was diagnosed using compression duplex ultrasound (CDU) or computed tomography (CT) scans. Patency rates at 1 year, 5 years, and 25 years are presented. **D,** Subgroup-specific Kaplan-Meier estimator for primary patency rates. Patients' 1- and 25-year primary patency rates are presented for each subgroup. **E,** Kaplan-Meier estimator for freedom from PTS. The 1-, 5-, and 25-year freedom from PTS rates are presented. **F,** Subgroup-specific Kaplan-Meier estimator for freedom from PTS. Patients' 25-year freedom from PTS rates are presented for each subgroup. **A, C,** and **E:** n = 152. **B, D,** and **F:** n = 73 for iTFVT, n = 35 for dOVT, n = 44 for combined procedures; log-rank (Mantel-Cox) test was applied. No significant differences were found between subgroups. *P* values are shown.

DPFE. Patients were invited to attend a DPFE at the outpatient department. Along with the invitation, patients were asked to file an SF-36 questionnaire.

We received 48 questionnaires, resulting in a 53% return rate (48/90) of mailed questionnaires and 27% (48/180) for the entire patient cohort. Patients with IVCT who underwent open surgical venous thrombectomy considered their physical and social functioning worse than did the German normative control group. Nevertheless, there was no difference for the mental and physical component summary scores between cohorts (Table III).

There were 38 patients (38/180 [21%]) who presented for a DPFE. The mean follow-up time at clinical examination for this subgroup of patients was 145.3 ± 15 months. All of these patients were screened for coagulation disorders. Antithrombin III deficiency (3/38 [7.9%]) was the most common coagulation disorder. We could not identify an association between coagulation disorders and follow-up patency or PTS (Table IV).

At clinical examination, patients received detailed assessment of lower limb veins for reflux and occlusion (Supplementary Table, online only). Next, patients were classified on the basis of their clinical symptoms according to the Villalta score and CEAP clinical classes. Using the Villalta score, 10 of 38 (26%) patients received a score of ≥5. When the CEAP clinical classes were used, 15 patients (15/38 [39%]) were subclassified for classes ≥C3 (Table V).

Table II. Postsurgery complications according to the Clavien-Dindo classification

	Total study cohort (N = 152)			
Grade	iTFVT (n = 73)	dOVT (n = 35)	Combined (n = 44)	Patients at DPFE (n = 38)
0		106/152 (69.7)		25/38 (65.8)
	55/73 (75.3)	22/35 (62.9)	30/44 (68.2)	
I		8/152 (5.3)		4/38 (10.5)
	4/73 (5.5)	3/35 (8.6)	1/44 (2.3)	
II		10/152 (6.6)		3/38 (7.9)
	3/73 (4.1)	2/35 (5.7)	(5/44 11.4)	
IIIa		2/152 (1.3)		0/38 (0)
	0/73 (0)	0/35 (0)	2/44 (4.5)	
IIIb		20/152 (13.2)		6/38 (15.8)
	7/73 (9.6)	6/35 (17.1)	6/44 (13.6)	
IVa		1/152 (0.7)		0/38 (0)
	1/73 (1.4)	0/35 (0)	0/44 (0)	
IVb		0/152 (0)		0/38 (0)
	0/73 (0)	0/35 (0)	0/44 (0)	
V		5/152 (3.3)		0/38 (0)
	3/73 (4.1)	2/35 (5.7)	0/44 (0)	

dOVT, Direct open venous thrombectomy; *DPFE,* detailed phlebologic follow-up examination; *iTFVT,* indirect transfemoral venous thrombectomy. Data are presented as frequency distribution (%). Distribution of complications was similar between surgical subgroups.

DISCUSSION

This single-center study reports clinical patient outcomes after iTFVT and dOVT for IVCT during a 25-year follow-up period. We included 152 patients, with 38 patients presenting for a DPFE with assessment of PTS symptoms. As noted before, patient survival was satisfactory, and patency rates were similar to those of modern endovascular interventional approaches. Applying the Villalta score, freedom from PTS after 25 years was 84% using Kaplan-Meier estimation and 26.3% after 12 years using detailed phlebologic examination.

To date, there is no specific recommendation for the duration of long-term anticoagulation for IVCT. It is well established that a recurrent thrombosis is a significant risk factor for development of PTS. The Recurrent Venous thromboembolism Risk Stratification Evaluation (REVERSE) study has demonstrated the importance of therapeutic anticoagulation in reducing the long-term

Table III. The 36-Item Short Form Health Survey (SF-36) scores for patients at detailed phlebologic follow-up (DPFE)

	Physical functioning	Role physical	Bodily pain	General health perceptions	Energy/ vitality	Social functioning	Role emotional	Mental health	Physical component score	Mental component score
IVCT										
Mean score	74.1	79.5	71.9	62.3	58.1	80.5	83.3	72.8	46.7	48.1
SEM	4.0	5.0	4.2	3.0	2.9	3.2	4.5	2.7	5.0	1.7
German normative data										
Mean score	83.6	80.3	77.2	66.0	61.8	87.7	87.7	72.8	49.3	49.4
Difference in means	9.5	0.8	5.3	3.7	3.7	7.2	4.4	0	2.6	1.3
Analysis										
Levene test	0.16	0.97	0.84	0.77	0.42	<.05	0.11	0.31	0.78	0.13
P value, *t*-test	<.05[a]	.84	.21	.22	.22	<.05[a]	.34	.99	.58	.66

IVCT, Inferior vena cava thrombosis; *SEM,* standard error of the mean.
Eight domain scores of the SF-36 and two summary scales (physical component and mental component) are presented for patients after indirect transfemoral or direct open venous thrombectomy with temporary arteriovenous fistula for IVCT. Physical and social functioning scores were significantly lower vs German normative data, whereas there was no difference for the physical and mental component summary scores. Data were analyzed for homogeneity of variances (Levene test), and Student or Welch *t*-test was applied accordingly.
[a] $P < .05$ IVCT vs German normative data.

Table IV. Coagulation disorders of patients at detailed phlebologic follow-up (DPFE; N = 38)

	Frequency distribution	%	*P* value	
			Association with patency	Association with PTS
APC resistance	2/38	5.3	.78	.11
Prothrombin mutation	1/38	2.6	.74	.59
Antithrombin III deficiency	3/38	7.9	.55	.69
MTHFR mutation	1/38	2.6	.74	.59
Antiphospholipid antibody	0/38	0	–	–
Protein C deficiency	2/38	5.3	.53	.97
Protein S deficiency	2/38	5.3	.78	.97
Factor VII deficiency	0/38	0	–	–
Factor V Leiden thrombophilia	2/38	5.3	.78	.97
Elevated factor VIII level	0/38	0	–	–
Hyperfibrinogenemia	2/38	5.3	.78	.97
Homocysteinemia	0/38	0	–	–

APC, Activated protein C; *PTS*, post-thrombotic syndrome.
At clinical follow-up examination, patients were screened for coagulation disorders. The χ^2 test with Yates continuity correction was used to determine the association of anticoagulation disorders with patency or PTS in the long term.

incidence of PTS.[15,16] The American College of Chest Physicians suggests anticoagulation for 3 to 6 months for provoked proximal DVT and up to 12 months for unprovoked proximal DVT.[16] Notably, prolonged anticoagulation in the early years of the study may have caused a clinical advantage for this subgroup of patients, generating less recurrent thrombosis and increased patency, thus potentially biasing outcomes.

In the case of IVCT, the authors believe that there is a higher risk for recurrent thrombosis compared with proximal DVT patients, given the large amount of structurally damaged post-thrombotic vein wall area. In this study, we found that our cohort received anticoagulation for a mean of 37.7 ± 6.1 months. Considering this and in line with current guidelines, the authors advise that anticoagulation should be administrated for at least 12 months, in particular after open surgical venous thrombectomy, which can cause additional damage to vein valves.[16] Thereafter, patients might benefit from interdisciplinary management to further optimize the duration of anticoagulation, thereby minimizing the risk for development of PTS.

During the last two decades, there has been a scientific debate about the benefits and complications of IVC filters in this context. Interestingly, placement rates are 25 times lower in Europe than in the United States, reflecting a considerable difference in expertise.[12] Considering procedure-, postprocedure-, and retrieval-related complications, such as tilted implantation or incomplete filter opening, filter migration and thrombosis, and IVC injury during retrieval, our department intentionally decided not to use retrievable IVC filters for iTFVT.[17] Instead, placement of a temporary occlusion balloon above the renal veins combined with a temporary elevation of positive end-expiratory pressure and a supine anti-Trendelenburg position was used to prevent PE. Conspicuously, the study's procedure-related PE rate was as low as 2.6%, suggesting the effectiveness of this approach.

Previous studies have already evaluated surgical thrombus removal and systemic thrombolysis and proved both approaches to be effective in preventing PTS.[18-21] Considering available surgical approaches, the majority of authors focus on minimally invasive iliofemoral methods, in which a Fogarty catheter is advanced

Table V. Villalta score and Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) classification results at the detailed phlebologic follow-up (DPFE; N = 38)

	Frequency distribution	%
Villalta score		
None (≤5)	28/38	73.7
Mild disease (5-9)	4/38	10.5
Moderate disease (10-14)	4/38	10.5
Severe disease (≥15)	2/38	5.3
CEAP class		
C0	11/38	29
C1	7/38	18.4
C2	5/38	13.2
C3	7/38	18.4
C4a	5/38	13.2
C4b	1/38	2.6
C5	2/38	5.3
C6	0/38	0

At clinical examination, patients were categorized and scored according to the CEAP classification and the Villalta score based on clinical findings.

through an inguinal venotomy to remove the thrombus. In the case of extensive IVCT, this approach bears elevated risks of incomplete thrombus removal and should be performed only after placement of an occlusion catheter proximal to the IVCT through the contralateral side before Fogarty maneuvers. In contrast, dOVT is much more invasive. Both procedures should always be combined with a temporary AVF.[22,23] In this study, either procedure or both procedures were performed on the basis of the extension of the IVCT. Interestingly, we did not find a difference between the surgical approaches in terms of survival, patency, or freedom from PTS rates. Consequently, we conclude that whenever physicians decide to treat an IVCT using open surgical approaches and the burden of IVCT allows either procedure, surgeons should decide on the basis of their personal preference and skill set as clinical outcomes appear similar.

As Comerota et al[24] correlated PTS development to residual thrombus burden, complete thrombus removal seems vital for patients' long-term benefit. Intraoperative venography may help establish whether this has occurred after intervention. However, that planar imaging technique is prone to missing residual thrombus. Given that recent advances in CT imaging have reduced the radiation dose, it seems plausible to suggest routine CT scans after surgical venous thrombectomy to establish irrefutable results, although this was not done in the study.

Modern, less invasive approaches have gained prominence within the last decades, such as CDT, pharmacomechanical CDT (PCDT), and pharmacomechanical thrombectomy. In comparing CDT and PCDT with anticoagulation alone, both approaches are thought to be effective in preventing PTS long term when used for iliofemoral DVT.[25,26] However, Alkhouli et al[27] reported a considerably elevated risk for PE (12.1% vs 7.8%), intracranial hemorrhage (1.6% vs 0.2%), and acute renal failure (13.9% vs 9.4%) when using CDT for treatment of IVCT. In addition, patients treated with CDT require continuous clinical bleeding observation by medical professionals combined with prolonged intensive care unit stay, which leads to the patient's discomfort.[12] Regardless of the invasiveness of iTFVT and dOVT, severe complications (Clavien-Dindo grade ≥IIIa) are uncommon,[12] acting in favor of these procedures. Despite in-hospital stays lasting as long as 13 days on average for open surgical venous thrombectomy, specific material-related cost-intensive endovascular approaches are still more expensive on final analysis.[12]

Besides major procedure-related complications, patency rates should also be taken into consideration in deciding on the best therapeutic approach. Our study reports a survival rate of 91%, with primary and secondary patency rates of 80% and 94% at 5 years after surgery. A study by Ye et al[28] cited 3-year primary and secondary patency rates of 63% and 83% using PCDT for IVCT. Moreover, comparing the outcome of our study with others, open surgical venous thrombectomy for iliofemoral DVT has been suggested to have a 3-year patency rate of 86%.[29] Patency rates for iTFVT and dOVT are comparable to previously reported outcomes using similar surgical procedures and are slightly better compared with patency rates using endovascular approaches such as CDT.

In summary, endovenous therapy bears significant risk of recurrent thrombosis and incomplete clot removal. Considering the presented data, the authors believe that lessons learned from endovenous approaches may act as an impetus for re-establishing open surgical venous thrombectomy.

The most severe long-term complication for patients is the development of relevant PTS, with venous ulceration at worst. PTS dramatically impairs the patient's quality of life. Notably, this study provides the longest follow-up period of analyzing surgical approaches for IVCT to date by covering >25 years. As such, it is important to diagnose PTS on the basis of objective scores. As the CEAP classification does not have an agreed-on cutoff, the Subcommittee on Control of Anticoagulation of the International Society on Thrombosis and Hemostasis suggests routine use of the Villalta score for establishing an appropriate diagnosis and that the score should be considered the "gold standard."[30,31] This study found a 25-year freedom from PTS of 84% (PTS rate of 16%) using Kaplan-Meier estimations and a PTS rate of 26.3% for patients who attended the DPFE at a mean follow-up of 12 years. Using the Villalta score, frequently used endovascular approaches found PTS rates of 13% after 26 months for PCDT and 41% for CDT in patients with IVCT or proximal DVT.[28,32] Considering these results, iTFVT and dOVT might improve the risk for development of clinically relevant PTS long term compared with modern endovascular techniques.

Nevertheless, it is certainly the case that patients might prefer endovascular minimally invasive approaches as these procedures cause less access site tissue damage and have been shown to reduce the risk of significant blood loss.[33] This is in line with our study, as we report a considerable blood transfusion rate of ∼12%. Equipment availability for low-invasiveness procedures, along with interventionalists' expertise, is gradually expanding. For this reason, it is likely that patient outcomes will improve for these techniques in the near future. However, evidence proving the superiority of endovascular techniques regarding patient outcomes is not yet available.

The acceptance and relevance of any therapy always depend on patient satisfaction. Therefore, the patient's HRQOL would seem of utmost interest. Our study suggests that open surgical approaches for IVCT affect patients' physical and social functioning, whereas overall mental health and physical health seem similar to those found in German normative data when the SF-36 questionnaire is used. In general, patient-based quality of life measures correlate with physicians' objective assessments of clinical PTS symptoms.[4] Broholm et al[34] demonstrated that venous reflux and occluded veins are the main contributors favoring impaired HRQOL for patients with iliofemoral DVT. The fear of social stigmatization due to visible ulcerations, along with widespread disease-specific knowledge about long-term complications, might explain impaired social functioning in our patient collective.

This study has major limitations. The retrospective design potentially biased reported outcomes. Only patients with valid contact information were available for objective data acquisition and Villalta scoring, thus limiting the power of the study. Furthermore, the majority of patients were enrolled early in the study, which might have resulted in a significant selection bias due to shifts in patients' age and comorbidities. Reported PTS rates might also be biased as objective criteria to diagnose PTS were not applied consistently during the study period. Exact Villalta score calculation based on objective clinical symptoms could be obtained only for patients attending the DPFE, whereas the remaining patients were screened for PTS on the basis of their latest archived medical records. In addition, our reported results might incorporate a timing bias, meaning that patient scoring and record analysis were performed at a given time point, although patients might have suffered from PTS symptoms at some prior time point. Our conclusions may also be somewhat compromised, given that only 21% of the entire patient cohort was available for a DPFE, and only 27% filed an SF-36 questionnaire, even though basic characteristics were similar between the entire study cohort and patients at DPFE.

CONCLUSIONS

Open surgical venous thrombectomy delivers satisfactory patient outcomes regarding patency and long-term PTS. Even though patients' preferences might favor endovascular interventional therapies, open surgery remains an option for patients who either reject or are ineligible for these approaches. In particular, emergency situations with fulminant PE might still require the skill set and knowledge of a trained surgeon capable of performing indirect or direct surgical approaches for the most beneficial patient outcomes.

AUTHOR CONTRIBUTIONS

Conception and design: MW, KA, HS, MD
Analysis and interpretation: MW, CD, KA, JM, WI, NE, JS
Data collection: MW, CD, KA, YMJ
Writing the article: MW, CD, NE, JS
Critical revision of the article: MW, CD, KA, YMJ, JM, WI, JS, HS, MD
Final approval of the article: MW, CD, KA, YMJ, JM, WI, NE, JS, HS, MD
Statistical analysis: MW, CD, YMJ, WI, MD
Obtained funding: Not applicable
Overall responsibility: MW

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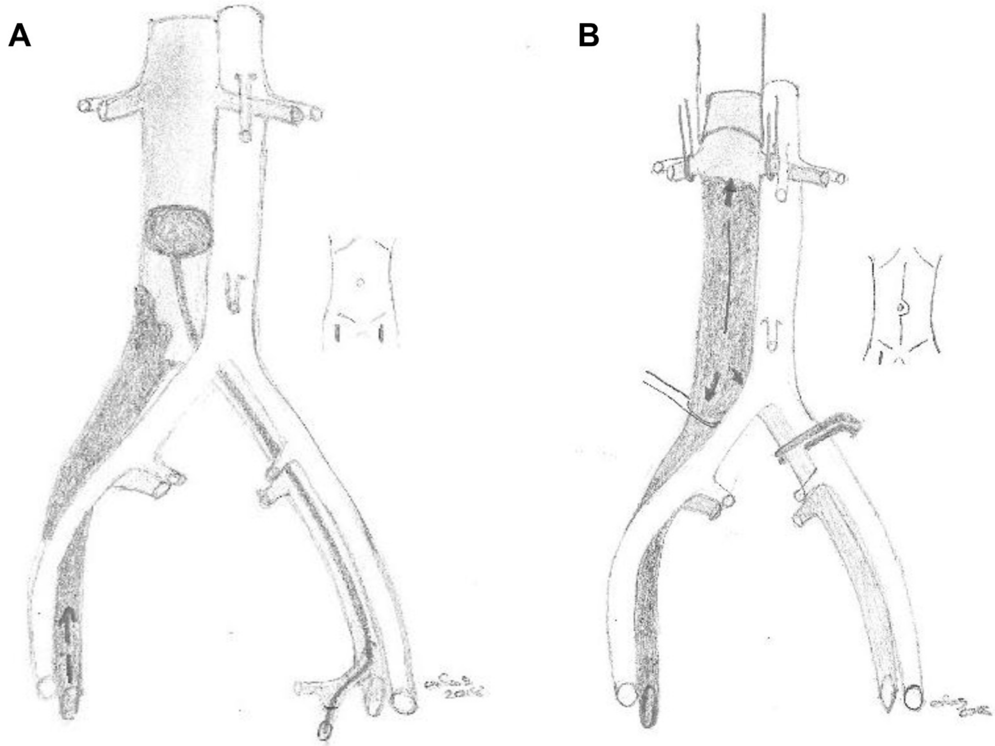
Submitted Aug 1, 2018; accepted Nov 7, 2018.

Additional material for this article may be found online at www.jvsvenous.org.



Supplementary Fig (online only). Surgical approaches. **A,** Indirect transfemoral venous thrombectomy (iTFVT). Inferior vena cava thrombosis (IVCT) with deep venous thrombosis (DVT) of the right iliac and femoral veins. Bilateral inguinal incision with exposure of all relevant structures including femoral artery and veins. An occlusion balloon is advanced over the left inguinal approach and placed proximal to the thrombus in the inferior vena cava (IVC). Thereafter, Fogarty maneuvers (*arrows*) are performed for complete thrombus removal. The final thrombectomy maneuver is performed with the occlusion balloon over the left inguinal approach to completely remove residual and mobilized thrombus. **B,** Direct open venous thrombectomy (dOVT). Extensive thrombus burden with extension of the IVCT to the renal vein level. Median laparotomy is performed to expose the aorta and the IVC. Temporary vessel loops are used to control venous backflow over the renal veins, the IVC, and the thrombosed common iliac vein. The contralateral common iliac vein is clamped. Direct thrombectomy is performed using venotomy of the IVC, followed by retrograde Fogarty maneuvers (*arrows*). Additional inguinal incision on the thrombosed side or additional abdominal incision combining dOVT and iTFVT was necessary for 44 patients (conversion rate from iTFVT to dOVT, n = 35 patients; dOVT to iTFVT, n = 9 patients). An arteriovenous fistula (AVF) was established for both procedures to augment blood flow on the sides of the thrombosed iliac veins during a period of 3 months.

Supplementary Table (online only). Compression duplex ultrasound (CDU) for patients at detailed phlebologic follow-up (DPFE; N = 38)

	Affected leg (reflux/total)	Contralateral leg (reflux/total)	Affected leg (occlusion/total)	Contralateral leg (occlusion/total)
Common femoral vein and iliac veins (iliofemoral trunk)	7/38 (18.4)	2/38 (5.3)	5/38 (13.2)	3/38 (7.9)
Femoral vein	2/38 (5.3)	1/38 (2.6)	1/38 (2.6)	3/38 (7.9)
Deep femoral vein	0/38 (0)	0/38 (0)	0/38 (0)	0/38 (0)
Popliteal vein	4/38 (10.5)	3/38 (7.9)	1/38 (2.6)	1/38 (2.6)
Posterior tibial vein	0/38 (0)	0/38 (0)	0/38 (0)	0/38 (0)
Anterior tibial vein	0/38 (0)	0/38 (0)	0/38 (0)	0/38 (0)
Fibular vein	0/38 (0)	0/38 (0)	0/38 (0)	0/38 (0)
Great saphenous vein	10/38 (26.3)	8/38 (21.1)	0/38 (0)	0/38 (0)
Small saphenous vein	2/38 (5.3)	0/38 (0)	0/38 (0)	0/38 (0)

Data are presented as frequency distribution (%).