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Research Article

Safety And Efficacy Analysis of The Clottriever Catheter System in Acute and Subacute Iliofemoral Deep Vein Thrombosis Treatment

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Introduction

Deep Vein Thrombosis (DVT) is a major health-care problem with an incidence of 70-140 cases/100,000 person-year, associated with a substantial burden of illness [1-3]. Specifically, iliofemoral DVT (ifDVT) - defined as thrombus involving the iliac and/or common femoral veins with or without extension to the inferior vena cava, represents around one-quarter of all DVT cases with a distinctly increased post-thrombotic morbidity [4,5].

Over a 3-month follow-up period, patients with ifDVT show a 2.4-fold increased risk of recurrent venous thromboembolism (VTE) compared with less extensive DVT [6]; and, such patients have significantly increased severity of Post-Thrombotic Syndrome (PTS) over a follow-up period of 2-years in comparison with peripheral DVT cases (P<0.001) [7]. Clinical studies show that spontaneous recanalization of iliofemoral deep-vein segments is very poor with anticoagulation alone [8,9]; and, venous claudication, physiological abnormalities, venous ulcers, and impaired quality of life are commonly observed in ifDVT patients [9]. As such, this cohort represents unique features, to which special treatment-related considerations are required [5,9].

Over the last years, there is increasing evidence that early and comprehensive removal of thrombus in ifDVT patients is associated with improved outcomes, including decreased incidence of PTS and other debilitating long-term symptoms [10]; and, Percutaneous Mechanical Thrombectomy (PMT) was shown to be a highly effective method for the removal of clots.

A systematic review of a cumulative pool of 1170 patients performed by Wong *et al* [11], showed that compared to Catheter-Directed Thrombolysis (CTD), PMT offers a lower risk of PTS (1-year follow-up Villalta score 2.1 ± 3.0 in the PMT group an 5.1 ± 4.1 in the CDT group, P=0.03); and reduces bleeding complications (packed cells transfused 0.2 ± 0.3 units in the pharmaco-mechanical thrombectomy group and 1.2 ± 0.7 units in the CDT group, P<0.05). More recently, Lichtenberg and colleagues [12] performed a meta-analysis in patients with ifDVT, where PMT was associated with a higher cumulative 6-month primary patency and lower incidence of major bleeding compared to thrombolysis alone-

The ClotTriever System (Inari Medical Inc., Irvine, CA, USA) CE approved as well as approved by the US FDA in 2017, is a mechanical thrombectomy device consisting of an access sheath with expandable funnel and a thrombectomy catheter with a coring element and collapsible nitinol collection bag. The catheter is advanced over a wire beyond the thrombus, deployed, and pulled back toward the sheath, gathering the thrombus in a specific collection bag. The 6-month outcomes from the all-comer CLOUT registry – a prospective, multicenter study designed to evaluate safety and effectiveness of the ClotTriever System for the treatment of lower extremity DVT, demonstrated that in a range of thrombus chronicity there was favorable effectiveness, safety, and sustained clinical improvement in a pool of 250 treated patients [13]. In this study, no patients received thrombolytics and 99.6% were treated in a single session with a median thrombectomy time of 28 minutes. In the recent Maldonaldo *et al* [14] CLOUT registry sub-analysis, it was demonstrated that the extracted DVT thrombus may be more chronic than suggested by the patients' duration of symptoms; but, the ClotTriever was still effective removing acute, subacute, and chronic thrombus in a single-session procedure without the need for thrombolytics, particularly in patients contra-indicated for anticoagulation [14].

With this in mind, we performed a single-arm, single-center, non-randomized retrospective analysis to assess safety and efficacy of the ClotTriever System throughout a 6-month follow-up period in a group of symptomatic ifDVT patients treated at our clinic.

Patients and Methods

Ethical approval was obtained for this analysis by the ethics committee of the Ärztekammer Westfalen-Lippe and of the

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Westfälischen Wilhelms-Universität Müster, Münster, Germany. The study was also registered on ClinicalTrials (ClinicalTrials.gov Identifier: NCT05740410).

Patient Characteristics

For this retrospective analysis study, we included a total of 25 patients (> 18 years of age) with uni- and bilateral-ifDVT, which were admitted at the Vascular Center of Arnsberg Clinic, Arnsberg-Germany between June 2021 and May 2022. DVT was defined as acute thrombotic occlusion with an onset of pain < 14 days; and subacute DVT was defined with symptoms > 14 days. Eligible patients were identified through relevant clinical data, including baseline medical history, procedural data, and follow-up records at 1-month and 6-months' time points. Patients with previously stented treatment in the veins were excluded. Since this was a retrospective study, ethic commission approval was leveraged.

Interventions

All procedures were performed according to the local standards of care, and according to the manufacturer's instructions. Access was achieved under local anesthesia, monitored conscious sedation, local anesthesia, or general anesthesia at the investigator's discretion. Periprocedural doses of unfractionated heparin (5,000 IE) were used in all patients.

Puncture was performed under ultrasound guidance. After venography, the lesion was traversed using a variety of guidewires. Once the guidewire is inserted beyond the clot, the ClotTriever sheath is positioned over the guidewire distal to the clot and the funnel is expanded for clot capture. The ClotTriever catheter is advanced through the sheath beyond the clot, where the nitinol coring element and collection bag are then deployed. Next, the coring element is retracted back towards the sheath, the thrombus is separated from the venous wall and captured in the collection bag. The side port can also be used for aspiration of remaining clot fragments in the sheath. Subsequently, a repeated venogram and intravascular ultrasound analysis was performed to ensure in-line flow, procedural success, and to exclude any target lesion complications.

For stent deployment, the lesion was further pre-prepared by dilatation using a high-pressure balloon to the nominal diameter of the stent along the entire length of the disease anatomical site. Only dedicated venous stents were deployed. The stents were post-dilated to ensure complete expansion of the stent. After stent deployment, another repeat venogram was performed to ensure patency, adequate adaptation to the wall and coverage of the entire lesion.

Study Endpoints and Follow-up

Procedural information including procedure time; approach; fluoroscopy time; contrast media; local or general anesthesia; location and length of occlusion; thrombectomy procedure data; removal of occlusion in blood vessels and restoration of blood flow; lesion preparation; post-stenting treatments (e.g., CDT therapy); and final % stenosis post-index procedure was recorded in all patients.

Furthermore, minor procedure-related Adverse Events (e.g., hematoma, puncture site-bleeding), Major Adverse Events (MAEs: death, any major amputation performed on the index limb or Clinically Driven Target Lesion Revascularization [CDTLR]), device malfunction, device-related complaints were also collected.

Primary patency was defined as freedom from ≥ 50% restenosis, as indicated by duplex ultrasound and doppler criteria. Post-procedure VCSS and CEAP scores were also recorded. Patients were evaluated clinically and by duplex ultrasound at 1-month, and 6-months follow-up time-points.

Statistical Analysis

Continuous variables were represented as median, standard deviation (SD) and range. Categorical data was presented as absolute number and percentage. Paired t-test and Wilcoxon tests were performed to analyze the statistical differences between baseline and the different follow-up time points with a 95% confidence interval.

Results

Detailed patients' characteristics are given in Table 1. In summary, a majority of the cohort was females (68%) with an average of 54 years of age.

Venous occlusion was diagnosed prior to treatment on Duplex Ultrasound Scanning (DUS), computed tomography venography or magnetic resonance venography. Occlusion was considered acute in

Table 1: Overview of patient's demographics, clinical conditions, and lesion characteristics at baseline.

		N (%) 25 (100%)
Total	Mean Age [Median range years]	54 [16-82]
	Female	17 (68%)
	Male	8 (32%)
Smoking Status	Current	2 (8%)
	No	1 (4%)
	Unknown	22 (88%)
Coronary Heart Disease	Yes	2 (8%)
	No	23 (92%)
Hypertension	Yes	10 (40%)
	No	15 (60%)
Oral contraceptive	Yes	6 (24%)
	No	18 (72%)
Diabetes mellitus	Yes (oral treatment)	3 (12%)
	No	22 (88%)
Malignancy	Yes	6 (24%)
	No	19 (76%)
Previous DVT (index lesion)	Yes	12 (48%)
	No	13 (52%)
Previous venous interventions (index lesion)	Yes	3 (12%)
	No	22 (88%)
Diagnosis	DVT	24 (96%)
	Sub-acute thrombosis	1 (4%)
Underlying lesion	May-Thurner syndrome	6 (27.3%)
	Conditions after surgery	3 (13.6%)
	Cancer (active/condition post)	6 (27.3%)
	Post-thrombotic alterations	11 (50%)
Clinical symptoms	Swelling	25 (100%)
	Pain	25 (100%)
	Lividity	7 (28%)
	Impalpable pulses	2 (8%)
	Feeling tension	18 (72%)
Side of occlusion	Left	18 (72%)
	Right	4 (16%)
	Both sides	3 (12%)

24 patients (96%), and sub-acute in 1 patient (4%). In 27.3 % of the patients, May-Thurner syndrome represented the underlying pathology. Cancer associated compression with consecutive thrombosis counted for 27.3% of the cases. In 50% of treated patients a post-thrombotic syndrome (i.e., post-thrombotic alterations of venous vessel wall) was already present at baseline (Table 1).

The clinical severity of diseased limbs was classified using the Venous Clinical Severity Score (VCSS) score and the Clinical, Etiologic, Anatomic and Pathophysiologic (CEAP) grading according to the reporting standards of the Society for Vascular Surgery (SVS) [15,16]. Table 1 shows an overview of the clinical stages found at baseline; and Table 2 details the target vessel location.

Table 2: Overview of target vessel lesions.

		N (%) 25 (100%)
Location of occlusion (vessel)	Right common iliac vein	3 (12%)
	Right external iliac vein	1 (4%)
	Right common femoral vein	4 (16%)
	Left common iliac vein	9 (36%)
	Left external iliac vein	11 (44%)
	Right complete pelvic veins	4 (16%)
	Left complete pelvic veins	7 (28%)
	Left popliteal vein	3 (12%)
	Venca cava inferior	2 (18%)
	Right deep femoral vein	1 (4%)
	Left superficialis femoral vein	2 (8%)
	Left femoral profunda vein	1 (4%)
	Right popliteal vein	2 (8%)
	Right femoral profunda vein	1 (4%)
Location of occlusion (vessel) by sub-group anallysis	Right iliac vein	7 (28%)
	Left iliac veins	21 (84%)
	Right femoral veins	2 (8%)
	Left femoral veins	4 (16%)
	Vena cava inferior	2 (8%)
Length of occlusion [mm]	Mean [SD]	253 [96]
	Median Range	110-500
Type of occlusion	Acute	22 (88%)
	Sub-acute	3 (12%)

Safety and Procedural Results

Different access site approaches were used; although, in 48% of the cases the left femoral vein was chosen (Table 3). In our cohort, 13F and 16F ClotTriever sheath sizes were used in 96% and 4% of the population, respectively (Table 3).

No MAEs occurred, and procedural success was attained in 100% of patients. No device-related complications or malfunction occurred during the procedures. The treatment duration ranged from 34 to 95 minutes, with a mean time of 65 min ± 20 min (Table 3). At the end of the procedure, SIR grade II lysis was achieved in all but one patient (n=24, 96%). In terms of hospital stay, the mean duration was 2 ± 2 days, with all patients reporting an improvement of the symptoms throughout the stay. No patients had to be admitted to the Intensive Care Unit (ICU). In terms of safety throughout the study, 15 patients reported Adverse Events (AEs) not related to the device nor the procedure (description in Table 4).

Table 3: Interventional details of the thrombectomy procedure.

		N (%) 25 (100%)
Access / Approach	Left popliteal vein	8 (32%)
	Right femoral vein	4 (16%)
	Left femoral vein	11 (44%)
	Right popliteal vein	2 (8%)
ClotTriever Catheter size	13F	24 (96%)
	16F	1 (4%)
Heparin	5000 IU	25 (100%)
Treatment time (min)	Mean [SD] Range	65 [20] 34-95
Fluoroscopy time (min)	Mean [SD] Range	14.5 [7.0] 6.5-37.7
Thrombolysis	No	25 (100%)
Pre ClotTriever PTA	Yes	3 (12%)
	No	22 (88%)
ClotTriever treated length (cm)	Mean [SD] Range	24 [7] 14-45
Post ClotTriever PTA	Yes	23 (92%)
SIR grade after ClotTriever	<50% thrombus removal	1 (4%)
	50-95% thrombus removal	24 (96%)
Number of implantade stents	Not applicable	3 (12%)
	0 stents	2 (8%)
	1 stent	5 (20%
	2 stents	14 (56%)
	4 stents	1 (4%)
Post Stent PTA	Not applicable	5 (20%)
	Yes	20 (80%)

Clinical Outcome

As represented in Table 4, at baseline 16% of the patients showed no Post-Thrombotic Syndrome (PTS, Villalta score < 5), 64% presented mild-PTS and moderate-PTS was seen in 20% of patients. At the 6-month follow-up, all but one patient showed no PTS (96%, n=24, p<0.001 *vs*. baseline). Graphic 1 represents the Villalta score changes over the course of time. At the 1-month follow-up appointment, values diminished from baseline of 7.5 ± 2.5 to 4.4 ± 2.6 (P<0.001); and, after 6-months, Villalta scores was 1.7 ± 1.4 (P<0.001).

As represented in Graphic 2, VCSS at baseline was 6.6 ± 1.6, which after 1-month decreased to 4.8 ± 1.1 (P<0.001); and, at the 6-month follow-up appointment reached 3.3 ± 1.6 (P<0.001). VCSS grade<6 was attained cumulative in 57.2% of the patients, with 28.6% achieving VCSS<3 at this time after 6-months.

In relation to CEAP scores, at baseline patients had a mean score of 3.1 ± 0.3, which improved to 2.7 ± 0.9 and 1.7 ± 0.9 at 1-month and 6-month follow-up time points, respectively (*vs*. baseline P<0.05, Graphic 3). As such, at baseline CEAP score of grade <3 was achieved in 92% of the cohort. After 6-months, 68% and 5% achieved CEAP<2 and CEAP<1, respectively (Wilcoxon test result: p<0.001 *vs*. baseline). Full patency was achieved in 88% of the patients.

All patients reported improvement of symptoms after 6 months, with 36% of the cohort (n=9) reporting no PTS.

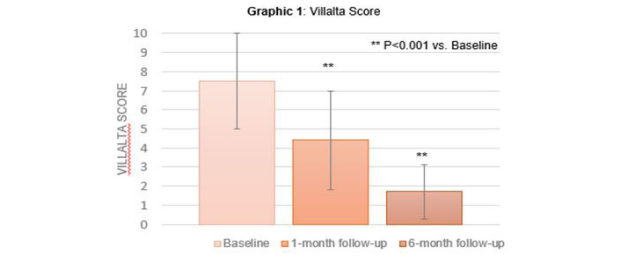
Table 4: Clinical Results: primary and secondary endpoints, safety. SD: Standard Deviation.

		N (%) 25 (100%)
Technical success		25 (100)
Technical success: Based on location of occlusion	Right iliac veins	7 (28%)
	Left iliac veins	21 (84%0
	Right femoral veins	2 (8%)
	Left femoral veins	4 (16%)
	Vena cava inferior	2 (8%)

		Mean	SD	Locations (N)
Final stenosis, visual assessment (%, mean) depending on location	Right iliac veins	22	6	7
	Left iliac veins	19	15	21
	Right femoral veins	25	7	2
	Left femoral veins	35	30	4
	Vena cava inferior	13	4	2

Villalta Score	**Baseline**	**1-month follow-up**	**6-month follow-up**
No PTS (score < 5)	4 (16%)	9 (52.9%)	24 (96%)
Mild PTS (score 5-9)	16 (64%)	8 (47.1%)	1 (4%)
Moderate PTS (score 10-14)	5 (20%)	0 (0%)	0 (0%)
Mean [SD]	7.5 [2.5]	4.4 [2.6]	1.7 [1.4]

Not-device related Adverse Events (AES)	**N (%)** only patients with AEs
In-stent restenosis target vessel	1 (6.7%)
Pulmonary embolism	1 (6.7%)
Post-interventional hematoma	1 (6.7%)
Re-thrombosis	1 (6.7%)



Villalta Score: paired t-test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	7.5 [2.5]	4.4 [2.6]	1.7 [1.4]

Paired t-test:
Baseline vs. 1 month FU: t=4.46, df=16, P<0.001
Baseline vs. 6 month FU: t=10.47, df=24, P<0.001

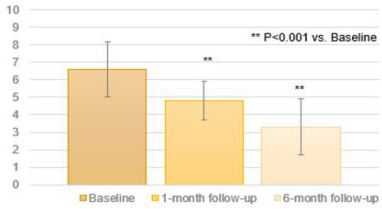
Villalta Score: Wilcoxon test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	8.3 [2.4]	4.4 [2.6]	1.6 [1.3]

Wilcxon test:
Baseline vs. 1 month FU: Z= -3.24, P=0.001
Baseline vs. 6 month FU: Z= -4.38, P<0.001

Figure 1: Villalta score (mean ± Standard Deviation) over the course of time.

Discussion

The aim of PMT is to accelerate thrombus maceration and removal, effectively decreasing the residual thrombus burden [12]. Furthermore, PMT reduces or totally avoids the need for thrombolytics, which leads to an immediate decrease of the bleeding risk and no need for ICU monitoring of the patients treated. This retrospective study of a cohort of patients treated at our clinical for ifDVT with a novel PMT device - the ClotTriever catheter system, confirms that PMT has the power and



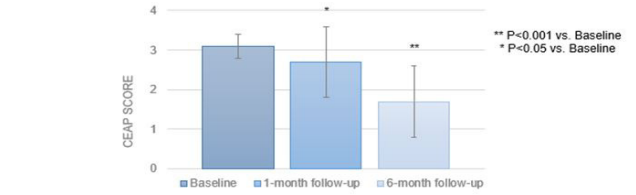
VCSS: paired t-test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	6.6 [1.6]	4.8 [1.1]	3.3 [1.6]

Paired t-test:
Baseline vs. 1 month FU: t=6.15, df=17, P<0.001
Baseline vs. 6 month FU: t=10.47, df=24, P<0.001

VCSS: Wilcoxon test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	7.1 [1.4]	4.8 [1.1]	3.2 [1.5]

Wilcxon test:
Baseline vs. 1 month FU: Z= -3.32, P=0.001
Baseline vs. 6 month FU: Z= -4.39, P<0.001

Figure 2: Venous Clinical Severity Score (VCSS, mean ± Standard Deviation) over the course of time.



CEAP: paired t-test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	3.1 [0.3]	2.7 [0.9]	1.7 [0.9]

Paired t-test:
Baseline vs. 1 month FU: t=2.13, df=16, P=0.049
Baseline vs. 6 month FU: t=7.14, df=24, P<0.001

CEAP: Wilcoxon test	Baseline	1-month follow-up	6-month follow-up
Mean [SD]	3.1 [0.3]	2.7 [0.9]	1.8 [0.9]

Wilcxon test:
Baseline vs. 1 month FU: Z= -3.32, P=0.001
Baseline vs. 6 month FU: Z= -4.39, P<0.001

Figure 3: Clinical, etiologic, anatomic, and pathophysiologic (CEAP) score over the course of time.

flexibility to remove thrombus and restore in-flow safely and effectively in ifDVT cases.

No thrombolytics were needed in any of our patients; and, in a single session, there was complete clot evacuation without the need to repeat interventions. Most of the patients reported an improvement of DVT symptomology like leg heaviness, pain, cramping swelling and discomfort already during the short hospital stay, leading to a prompt hospital discharge. No MAEs occurred, and procedural success was attained in 100% of patients. At the end of the procedure, SIR grade II lysis was achieved in all but one patient (n=24, 96%). At baseline, 16% of the patients showed no PTS (Villalta score < 5); and, at the 6-month follow-up, all but one patient showed no PTS. VCSS grade < 6 was attained cumulative in 57.2% of the patients, with 28.6% achieving VCSS < 3 after 6-months. Furthermore, at this time-point 68% and 5% achieved CEAP < 2 and CEAP < 1, respectively; and full patency was achieved in 88% of the patients. Our data shows the advantage of early restoration of venous patency by reducing the risk of port-thrombotic complications.

As stated in the review by Chan and colleagues (10) and corroborate by our study, the major benefits of the ClotTriever system are the complete evasion of ICU stays, avoidance of lytic therapy, the ability to treat DVTs in a single session and quicker patient recovery. The device was safe and effective removing large volumes of lower extremity acute thrombus. As such, for patients where thrombolysis is contra-indicated, the ClotTriever catheter system is an effective solution for resolution of DVT-illness burden.

The results of our study further confirm the results obtained in the CLOUT registry [13,14], and validate the significant and sustained

improvements observed in clinical outcomes after 1- and 6-months, with effective reduction of VCSS, CEAP and Villalta scores. Furthermore, in terms of health-economics there is a cost-effectiveness to this procedure - by reducing the hospital stay and decreasing the need for ICU. The body of evidence suggests that for patients with ifDVT, a ClotTriever strategy for thrombus removal offers an effective and safe solution.

Limitations

This was a single-group retrospective analysis of a cohort of patients previously treated at our clinic with a limited follow-up time point of 6 months. Further studies are warranted to determine long-term outcomes. Additionally, some data was missing (e.g., only 17 patients had 1-month follow-up data), which could not be collected. Furthermore, this cohort of patients was included to study the specific safety and procedural outcomes of the ClotTriever ifDVT treatment, without a randomized control group – as such, there is an inherent selection-bias of the study group.

Conclusions

The ClotTriever thrombectomy system was safe and effective in our ifDVT cohort of patients outside a randomized clinical trial. This minimally invasive mechanical thrombectomy device promises to become a next-generation device for thrombus removal in DVT.

Author Statements

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