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Role of Catheter Directed Thrombolytic Therapy in Acute Iliofemoral Deep Venous Thromboembolism

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ABSTRACT

Background: IlioFemoral Deep Venous Thromboembolism **(**DVT**)** accounts for around one-fourth of all instances of DVT . An endovascular treatment with minimally invasive procedures is catheter-directed thrombolysis CDT restoring venous patency, hastening the recovery of acute symptoms.

Objectives: to assess short term outcome of catheter directed thrombolytic **therapy** in acute ilioFemoral DVT treatment regarding improvement of clinical condition, assessment of benefits and hazards regarding utilizing CDT.

Methods: Clinically: evaluation of limb state tenderness, pain, edema during the hospitalized period. Radiologically: lower limb venous duplex to follow up the venous state and the time of thrombolytic therapy of the affected veins on admission and will be repeated after 1and 6 month Venography under C-arm after completion of recombinant tissue plasminogen activator (TPA) injection to follow up any residual part of DVT and assess vein patency after 2 days. Total 28 patients of acute (ilioFemoral DVT) was included in this study.

Results: This study showed that CDT is effective in treatment ilioFemoral DVT and giving better results than anticoagulant therapy. 92.6% of our patients had thrombus lysis while our bleeding complication rate of 17.9% with no mortality. Cases.

Conclusion: The early use of CDT immediately after onset of ilioFemoral DVT associated with satisfactory results in restoring normal venous patency and significant lowering post thrombotic complication

Keywords: *Iliofemoral deep venous thromboembolism DVT, catheter-directed thrombolysis CDT, recombinant tissue plasminogen activator TPA.*

1. INTRODUCTION

Deep vein thrombosis is a serious medical condition that can lead to various immediate consequences. Such as potentially fatal pulmonary emboli or phlegmasia cerulea dolens combined with venous gangrene that poses a hazard to one's limb. Conversely, chronic side effects include post-thrombotic syndrome and venous insufficiency, which have detrimental effects on long-term health and quality of life [1].

Up to 50% of cases of DVT are complicated by post-thrombotic syndrome (PTS), which usually results in incapacitating symptoms and a decreased quality of life [2]

Chronic symptoms of post-thrombotic syndrome (PTS) include stasis dermatitis, skin ulceration, persistent edema, and mild to moderate discomfort [3]

Anticoagulants therapy alone, the standard treatment for DVT of the lower extremities, has been shown to be inefficient in preventing recurrence. On the other hand, early endovascular intervention has been recommended for post-thrombotic syndrome to preserve valve function. [4]

A minimally invasive endovascular treatment is catheter-directed thrombolysis (CDT). At endovascular suit, a catheter is inserted directly into the thrombus site, where it is then slowly, over 24-48 hours, infused with a small dose of thrombolytic drug. Anticoagulant therapy takes longer time to restore venous patency than CDT, which imrove outcome of the treatment of acute symptoms [5]

In the case of acute DVT, (CDT) hss successful results in regaining venous patency and minimizing symptoms. Additionally, CDT is particularly helpful in preventing PTS. In actuality, the quantity of thrombus still present after CDT treatment is inversely associated to the likelihood of PTS. Patients appear to have a low risk of PTS if 90% or more of the thrombus is eliminated. Recurrent DVT risk percent is also decreased with CDT. [6]

Thrombolytic therapy is not without risk, including the potential for hemorrhagic bleeding that increases with lytic dose, complexity of treatment and high cost. [7]

Material and Methods

Patients: This is a retrospective and prospective clinical trial study was conducted on total 56 patients of acute ilio-femoral deep venous thromboembolism (DVT) at department of general surgery, unit of vascular surgery .Beni Suef University Hospital during the period from April 2022 to March 2024 to. This study was approved by the local research ethical committee in Beni-Suef university Hospital.

Approval No: FMBSUREC/10042022/Mohammed.

The procedures were in accordance with the ethical standards of the responsible committee on human experimentation (Faculty of Medicine, Beni-Suef University) and with the Helsinki Declaration of 1975, as revised in 1983. All participants provided informed consent to participate in this study**. Inclusion criteria:** of the patients was based on the diagnosis of acute iliofemoral DVT , symptoms started within 2 weeks , age > 20 years old and unilateral lower limb DVT. **Exclusion criteria:** History of old DVT or recurrent DVT, Patients who have malignant tumor, Patients with haematological disorders, Females who are pregnant or lactating and Patients with renal impairment or chronic liver disease, uncontrolled hypertension.

Preoperative assessment: A total of 56 patients, aged between 20 and 58, were enlisted; 26 of them were female and 30 were male. Patients' ages, unique behaviors that are medically significant, medical histories, and family histories were among the demographic and medical information gathered. To determine the degree of thrombosis and the access point, a duplex scan of the affected limb's deep vein system was performed on each patient. Frequent laboratory tests were done, such as coagulation profile, kidney, liver, and complete blood counts. At the time of admission, patients received LMWH at a therapeutic dosage.

Technique

The patient was placed on the angiography table in the supine or prone position during the operation. A contralateral femoral vein puncture to implant a retrievable IVC filter following local anesthetic

As demonstrated in the (TORPEDO) study, IVC filter implantation during CDT decreased the incidence of iatrogenic pulmonary embolism (PE) eightfold (1.4% vs. 11.3%) [8].

The popliteal vein of affected limb was the site of the 6-F introducer sheath insertion. Every puncture was done per US guidance. The ipsilateral posterior tibial vein, ipsilateral GSV, and the ipsilateral or contralateral femoral vein were other potential puncture sites.

On venography, the thrombus's anatomy and expansion were then seen. Depending on the length of the thrombotic segments, an appropriate-length perfusion catheter was implanted with several side holes spanning 10–50 cm. Then, alteplase infusion guided by a catheter was created. An iliofemoral segment 5F multiple sidehole infusion catheter was placed.

Using the pulse spray approach, a first bolus (10–15 mg) of recombinant tissue plasminogen activator (Alteplase) was administered in the operating room while mobile c-arm imaging was being used.

The thrombolytic drug was administered until either venography revealed no further improvement or total lysis was attained. During the thrombolytic infusion, patients were kept bed-ridden and under close observation in the intensive care unit.

Depending on the equipment that was available and the degree of remaining stenosis, balloon dilatation with or without stenting was used to treat iliac vein stenosis that was discovered on completion venography at the conclusion of thrombolysis. Self-expandable wallstents were utilized in all cases.

Commonly used thrombolytic agents include recombinant tissue plasminogen activator (eg, alteplase). The standard dosage regimen for tissue plasminogen activator infusion is (0.01 mg/ kg/h). With maximum dose (2 mg/h) the patient was then transferred to the ICU and continuous infusion for 24 hours was initiated. Total dose of RTPA was 50 mg/24 hours.

Intraoperative venography was done after 24 hours. If there is residual thrombosis, the patient was maintained on alteplase for further 24 hours, with maximum total dose of alteplase being 100mg

During the procedure patients were maintained on unfractionated heparin administered through the sheath with aPTT 1.5 times normal. After the procedure, patients were maintained on LMWH. Patients who had stenting, also received clopidogril 75 mg/day. Anticoagulation and antiplatelets were continued for a minimum duration of 6 months postoperative

Endpoints included the thrombus burden in the iliac segment being cleared, the symptoms clearly improving, lysis occurring for 48 hours, complete lysis failing after the first 24 hours, a hemorrhage that threatened the patient's overall health, and the development of a pulmonary embolism.

Based on the quantity of remaining clot at the completion venogram compared with the pre-treatment venogram, the rate of clot lysis was assessed. A total thrombus score was determined prior to, during, and following CDT.

By summing the scores for the proximal and distal portions of the femoral vein, the popliteal vein, the common iliac vein, the external iliac vein, and the common femoral vein.

The degree of clot lysis at the conclusion of the process was used to determine the immediate effectiveness of CDT. By dividing the entire pre- and post-lysis thrombus grade by the prelysis grade, the lysis grade was determined. A grade III resulted in 100% lysis with no remaining clots, a grade II in 50%–99% lysis, and a grade I in less than 50% lysis. Lysis grades II and III (i.e., greater than 50%) were regarded as favorable results.

Thrombolysis problems that occurred during or soon after the CDT technique were among the safety results. If bleeding problems resulted in a drop in hemoglobin of at least 2 g/dL, needed transfusion of at least 2 U of packed red blood cells, were cerebral, retroperitoneal, or in a vital organ, or caused mortality, they were classified as significant bleeding complications. Examples of non-major bleeding that was clinically significant included spontaneous macroscopic hematuria, a visible big hematoma, and epistaxis intervention. The remaining bleedings were all classified as insignificant.

Follow up: Patients had clinical examinations for follow-up at one, three, and six-month intervals. After six months, PTS was identified using the Villalta scale, which assessed six physical signs—pretibial oedema, skin induration, hyperpigmentation, pain during calf compression, venous ectasia, and redness—as well as five patient-rated venous symptoms—pain, cramps, heaviness, paresthesia, and pruritus. A total score is calculated by adding the ratings of 0 (none), 1 (mild), 2 (moderate), and 3 (severe) for each sign or symptom.

Less than five points on the total score denotes no PTS, five to fourteen points indicate mild to moderate PTS, and fifteen points or more (or the presence of a venous ulcer) denote severe PTS. A lower limb venous duplex scan or CT pulmonary angiography was used to corroborate the reports of recurrent DVT or pulmonary embolism made during the follow-up visits.

Statistical Analysis

Results was expressed as means ± standard deviation of the means or number (%). Comparison between different parameters was performed using unpaired t test. Comparison between categorical data was performed using Chi square test. Statistical

Package for Social Sciences (SPSS) computer program (version 19 windows) was used for data analysis.

P value ≤0.05 was considered significant

RESULTS

During the study duration, 56patients (56 limbs) were recruited. the studied patients were from 30-58.0 years old with a mean of 41.64±8.11 years old. More than one half of them were males (53.6%).

Table (1) showed that the largest percentage of patients had an onset of symptoms for more than1 week (60.7%), with moderate severity (60.7%), and affected left side (64.3%).

		Frequency (n=56)	Percentage (%)
Onset of symptoms	**< 1 week**	22	39.3
	> 1 week	34	60.7
Severity of symptom	**Mild**	12	21.4
	Moderate	34	60.7
	Severe	10	17.9
Side of affection	**Right**	20	35.7
	Left	36	64.3

Table (2): Preoperative initial assessment of thrombus extension by duplex scanning of deep venous system of the affected limb.

Thrombus Extension	Frequency (n=56)	Percentage(%)
Common iliac vein to popliteal vein	**20**	**35.7**
Common iliac vein to Superficial fem. vein	**10**	**17.9**
External iliac vein to posterior tibial vein	**18**	**32.1**
External iliac vein to popliteal vein	**8**	**14.3**

Table (3): Operative findings of the studied patients

		Frequency (n=56)	Percentage(%)
Access site	**Popliteal vein**	36	64.3
	Posterior tibial vein	10	17.9
	Great saphenous vein	6	10.7
	Contralateral	4	7.1

	femoral		
ProcedureTime and Difficulty	**Mild**	10	17.9
	Moderate	34	60.7
	Difficult	12	21.4

Table (4): Thrombolysis results detected by venography and duplex postoperative

	Mean	**Standard Deviation**	**Minimum**	**Maximum**
Venography	75%	12%	50%	90%
Duplex scanning	**Frequency (n=56)**		**Percentage (%)**	
Grade I (less than 50% lysis)	4		7.2	
Grade II (50-99% lysis)	50		89.2	
Grade III (100% lysis)	2		3.6	

Table (5): Immediate outcome of the studied surgical technique CDT

		Frequency (n=56)	**Percentage (%)**
Outcome	Successful CDT*	48	85.7
	Completion Venoplasty with Stent	8	14.3
Improvement Of Symptoms	Mild	12	21.4
	Moderate	30	53.6
	Marked	14	25.0

Table (7): Long term outcome for the studied patients

		Frequency (n=56)	**Percentage (%)**
Post thrombotic syndrome (based on Villalta score)	**Absent (score less than 5)**	46	82.1
	Mild (score 5-10)	10	17.9

Table (6): Intraoperative complications for the studied patients.

Complications	Frequency (n=56)	Percentage (%)
Absent	46	82.1
Minor bleeding	8	14.3
Major bleeding	2	3.6

this study revealed that the incidence of PTS was significantly higher among patients with onset of symptoms more than 1 week (100.0%) and mild improvement of symptoms postoperative (80.0%), (p values < 0.05).

2. DISCUSSION

A randomized trial [9] found that patients treated with recombinant tissue plasminogen activator (rt-PA) exhibited higher than 50% clot lysis in 89.2% of cases, compared to 0% of patients receiving anticoagulation alone. Additionally, individuals treated with rt-PA tended to have lower PTS if lysis was successful.

The study showed that thrombolytic drugs can produce superior clinical outcomes when administered via catheter-directed method as opposed to systemic administration

In the current study, we used the alteplase infusion protocol which is the maximal dose per the available literature (10–15 mg bolus followed by infusion at rate 1.5–2 mg/hr not to exceed 50 mg rtPA in 24 hours). This is distinct from the actilyse continuous infusion dose utilized in the CaVenT and ATTRACT studies, which was 0.01 mg/kg/hr not to exceed 1.0 mg/hr. [10]

56 limbs received CDT for 48 hrs (mean duration of CDT was 2 days). This duration is shorter than that used in the CaVenT trial (2.4 days), but the incidence of PTS at 6 months in CaVenT is more than ours (30.3% and 18% respectively) [11]

In contrast to the 88.8% of patients in the CaVenT research, 92.6% of our patients experienced thrombus lysis more than 50% [11]

Our bleeding complication rate of 17.9%; for example, the CaVenT study's bleeding complication rate was 9%. This is because bleeding events without clinical relevance were eliminated. The larger dosage of thrombolytic agent may be to blame for this. In the ATTRACT and CaVenT investigations, no information was shown regarding the effect of access site on incidence of access site bleeding. [11]

About 3% of CDT-treated individuals experienced significant bleeding in contrast to our study (3.6 %), but none experienced long-lasting effects. Although the CDT patients, particularly those with a patent venous system, experienced a somewhat bigger change in health-related QOL from baseline to 6 months [12]

No patient of ours had a score of 10 or a venous ulcer. There are no published data regarding the Villalta score for CaVenT trial patients at 6 months; however, in the ATTRACT research, 18% of patients who had CDT/PMT experienced severe PTS (Villalta score 10 or any score with venous ulcer) . The fact that we employed the maximal dosage of actilyse (2 mg/hr) may potentially have had an impact on this result. Thus, rather than the length of symptoms, the dose of thrombolytic drug employed may be more important. [13]

In the ATTRACT trial, there were no deaths at 10 days, 2 recurrent VTE in 10 days, 1 fatal PE at 6 months, and 2 recurrent VTE in 10 days. In our trial, there were no fatalities, post-lysis PE, or recurrent VTE.[10]

PTS occurred less frequently in individuals receiving thrombolytic therapy [n=849 (8.3%)] while in our study mild PTS symptoms 6 months post operative in 5 cases about 17.9%.[14]

Rethrombosis was also less common in patients on thrombolytics (n=849, 2.4% vs. n=460, 39%).but in this study rethrombosis didn't occur. [15]

3. CONCLUSION

The use of thrombolytic therapy offers many advantages over the standard treatment of DVT by reducing the proportion of patients with chronic disabling leg symptoms (from PTS)

Author contributions:

Mohammad Hussien: data analysis and writing. Ahmed Soliman: data analysis and writing. Khaled Ahmed Shawky: supervision. Osama Sameh Mohammed: data collection, writing. Ayman Refaat Abdelhassib: supervision. Abdulaziz Zienulabeden Algaby: data collection. Ibrahim Sayed Abdelaziz: data collection. Mohamed Hassan Abdelmawla: data analysis. All authors revise and approve the final manuscript

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