Evaluation of inferior vena cava filter placement during percutaneous endovenous intervention for proximal lower extremity deep venous thrombosis: a retrospective study

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Background
Anticoagulant therapy is still the prevalent treatment for venous thromboembolism. In the new era of percutaneous endovenous intervention, there is a progressive increase in the use of percutaneous endoluminal clot dissolution techniques such catheter-directed thrombolysis (CDT) and mechanical aspiration thrombectomy devices because of their short-term advantages. Prophylactic deployment of inferior vena cava (IVC) filter during percutaneous endovenous therapy for lower extremity deep venous thrombosis (DVT) is still a debatable issue.
Objectives
The aim of our study is to assess retrospectively the frequency of embolization and the need for deployment of a retrievable IVC filter during endovenous treatment of proximal lower extremity DVT using percutaneous CDT and AngioJet pharmacomechanical thrombectomy (PMT) techniques.
Settings and design
This was a retrospective study.
Patients and methods
Percutaneous endoluminal clot dissolution using either CDT or AngioJet PMT for proximal lower extremity DVT was performed on 56 patients (59 limbs) of 187 patients diagnosed with proximal acute/subacute DVT in the Vascular Surgery Department of the study hospitals. An IVC filter was deployed in 29 patients before or during the procedure.
Results
Of 56 patients who were treated for proximal DVT with clot debulking procedures, the IVC filter was prophylactically deployed in 26 (46.4%) patients. Trapped thrombus in the deployed filters as shown on venocavography was observed in 9/26 (34.6%) filters deployed prophylactically, with an overall rate of thrombus embolization during percutaneous endovenous thrombus dissolution techniques being 12/56 (21.4%) patients.
Conclusion
CDT could be performed safely and effectively without routine prophylactic IVC filter placement in the treatment of acute DVT. Selective filter placement may be considered in patients undergoing PMT or patients with more proximal thrombus patterns with multiple risk factors.

Keywords:
inferior vena cava filter, thrombolysis, venous thromboembolism

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Introduction

Deep vein thrombosis (DVT) at the lower extremity is associated with significant morbidity and mortality. DVT is well recognized as a cause of both short-term pulmonary embolism (PE) and long-term chronic venous insufficiency. Early treatment of DVT is therefore essential to prevent the risk of sudden death from acute PE and chronic venous insufficiency with its sequelae [1].

Conventional treatment of DVT consists of systemic anticoagulant with heparin followed by oral anticoagulation therapy. The role of anticoagulation therapy is to prevent complications such as PE, reduce the spread of thrombus, and reduce the risk of recurrent DVT. However, the anticoagulation does not have a direct thrombolytic effect and does not eliminate completely the formation of a new thrombus [2,3].

Recently, several percutaneous interventional treatment methods have been proposed, such as

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manual aspiration thrombectomy, catheter-directed thrombolysis (CDT), and pharmacomechanical thrombectomy (PMT), to be useful particularly for proximal DVT. Among these methods, aspiration thrombectomy is widely used by many physicians as a first-line therapy method. However, aspiration thrombectomy method is potentially associated with PE during thrombus manipulation [4,5].

Usage of CDT for the treatment of acute iliofemoral DVT can decrease the occurrence of postthrombotic syndrome; however, it carries the risk of developing significant hemorrhage [6]. AngioJet PMT is a newer system combining CDT and rheolytic mechanical thrombectomy and has demonstrated excellent protection and effectiveness. It also further decreases PTS and shows concomitant reduction in bleeding danger in contrast to CDT alone, because AngioJet has an additional mode – the 'power pulse' mode, which includes active spraying of lytic agent into the clot, allowing time to soften, and leading to more effectiveness when using rheolytic mode [7,8].

It is assumed that the mechanical stress applied to the clot by catheter-based clot dissolution procedures and the accelerated lytic process may increase the number and size of the showering emboli resulting in symptomatic or silent PE [9]. The theoretical risk of thrombolysis is iatrogenic PE, which is still relatively rare as a clinical sequela despite being documented in radiographic studies; therefore, the routine use of inferior vena cava (IVC) filters in patients undergoing CDT or PMT appears to be unjustified, and the selective use of such devices remains controversial [10,11].

Currently, there are few studies that evaluate IVC filter practice strategies directly during thrombolysis, with mixed results. The reported results are hindered by lack of control groups, no risk factor stratification or filter burden analysis, and associated clinical significance. The current guidelines do not recommend the routine use of filters for iliofemoral DVT during thrombolysis. However, they are based on a low level of evidence and have not resulted in a consistent approach in current clinical practice [12–14].

The objective of our study was to assess retrospectively the frequency of embolization and the need for the deployment of a retrievable IVC filter during endovenous treatment of proximal lower extremity DVT using percutaneous CDT and AngioJet PMT techniques.

Patients and methods

This was a retrospective study performed at Vascular Surgery Department, Zagazig University Hospitals, Egypt, and Intervention Radiology Department, Alnoor Specialist Hospital, Makkah, Saudi Arabia, after approval of the study protocol by the review board in the enrolled hospitals. Our database has been revised to identify and analyze all patients with proximal DVT who had been treated between January 2017 and June 2020. Of 187 patients who were diagnosed with proximal acute and subacute lower extremity DVT, 56 patients accepted to receive interventional debulking therapy (Fig. 1). The medical records have been retrospectively reviewed. Data collected included demography of the patients, risk factors for DVT, periprocedural data, periprocedural complications, lytic agent used, adjunctive interventions, and clinical outcomes. Informal consent was obtained from all patients following a full explanation of the risks and benefits of treatment.

All patients in our study were diagnosed with color Doppler ultrasonography for proximal DVT. Patients who accepted debulking therapy were investigated for proximal lung embolization documentation using computed tomography pulmonary angiogram before and after debulking therapy. Demographics of the patients are summarized in Table 1.

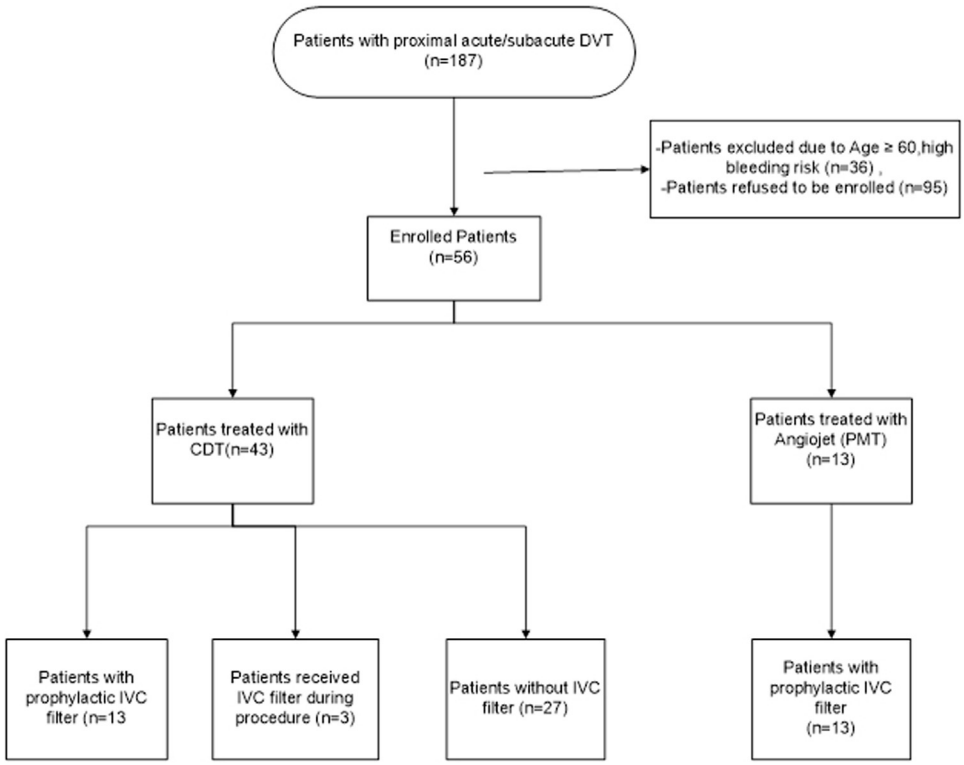
Patient selection

Patients with acute/subacute extensive proximal lower extremity DVT with symptoms duration of up to 3 weeks have been selected. Patients with thrombus located in the iliac vein with/without IVC extension, iliofemoral vein with/without IVC extension, and femoropopliteal segment were included. Patients who did not have a contraindication for local lytic therapy were offered CDT, whereas patients with relative contraindications such as previous major surgery and pregnancy or when rapid restoration of venous flow was crucial were treated with AngioJet PMT as an alternative option.

Risk factor evaluation

Specific risk factors for DVT included postoperative status, prior history of DVT, pregnancy and postpartum state, malignancy, hormonal therapy such as oral contraceptive pills, and inherited coagulation disorders. Our patients were screened for underlying thrombophilia including protein C deficiency, protein S deficiency, activated protein C resistance (Factor V Leiden), antithrombin deficiency,

Figure 1



Flow chart of the study.

lupus anticoagulant, cardiolipin antibodies, and prothrombin gene mutation. Permissive lesions such as iliac vein outflow obstruction were assessed by conventional venacavogram after debulking therapy in two different projections (Table 1).

Endovascular techniques

All procedures were done under local anesthesia. Fentanyl 25–50 μg intravenous or midazolam 3–10 mg intravenous was used as a conscious sedation if necessary. In patients operated on for CDT (Fig. 2), the decision for prophylactic IVC retrievable filter deployment was operator specific according to patients' risk factors and the thrombus pattern; it was deployed before starting local debulking therapy in 13 patients. Three patients received IVC filter during the procedure owing to symptomatic lung embolization. All filters were deployed through the contralateral femoral access or right jugular access with the patient initially in the supine position, or through the main procedure popliteal access while the patients were positioned in the prone position ultrasound guidance through 6–8 F sheath. Filters deployed in our patients were Denali retrievable vena cava filter (Bard Peripheral Vascular, Tempe, Arizona, USA) and Celect Platinum IVC filter (Cook Medical, Bloomington, Indiana, USA), with the patient initially in the supine position. After filter placement (through the contralateral femoral or right jugular access), the patients were positioned in the prone position, and access to the popliteal vein was obtained via a micropuncture needle with ultrasound guidance. Subsequently, a 6–8-F sheath was placed through which venography and intervention were carried out. A bolus of 5000 IU of heparin sodium was administered immediately through the sheath after confirming the diagnosis and the level of thrombus extension. A 0.035-inch hydrophilic guidewire (Terumo Corporation, Tokyo, Japan) was introduced, manipulated through the thrombus, and supported by a single-curved catheter, which were used to navigate through the thrombosed vein and extend beyond the diagnosed level of thrombus to confirm IVC patency. We used 5-F Fountain infusion system with an appropriate-length catheter 135 cm with infusion segment 50 cm was inserted (Merit Medical System Inc., South Jordan, Utah, USA). Once the infusion system was optimally positioned, catheter-directed infusion of tissue plasminogen activator (tPA) (Actilyse; Boehringer-Ingelheim, Ingelheim am Rhein, Germany) was then started at an infusion rate of 1–2 mg/h. According to the load of the thrombus. We used Actilyse powder containing concentrations of 50 mg of alteplase as an active ingredient. All patients were transferred to ICU to continue Actilyse infusion and received concomitant

Table 1 Demographics and general characteristics

Study groups	*n* (%) (*N*=56 patients)
Age (years)	
Mean±SD	35.4±6.52
Sex	
Male	19 (33.9)
Female	37 (66.1)
Clinical presentation	
Pain	7 (12.5)
Edema	25 (44.7)
Pain and edema	20 (35.7)
Phlegmasia cerulea dolens	4 (7.1)
Pulmonary embolism at admission	2 (3.5)
Bilateral lower limb DVT	3 (5.4)
Thrombus location	
Iliac vein	14 (25.0)
Iliac without IVC extension	10 (17.9)
Iliac with IVC extension	4 (7.1)
Iliofemoral vein	33 (58.9)
Iliofemoral without IVC extension	29 (51.8)
Iliofemoral with IVC extension	4 (7.1)
Femoropopliteal vein	9 (16.1)
Risk factors	
Patients with absent risk factors	13 (23.2)
Patients with risk factors	43 (76.8)
Strong risk factors	5 (8.9)
Moderate risk factors	25 (44.6)
Weak risk factors	6 (10.7)
Combined risk factors	7 (12.6)
Risk factor classification	
Strong risk factors	
Major surgery	5/43 (11.6)
Moderate risk factors	
Thrombophilia	7/43 (16.3)
Hormonal therapy	9/43 (20.9)
Pregnancy	3/43 (7.0)
Postcesarean section	10/43 (23.3)
Previous DVT	8/43 (18.6)
Malignancy	6/43 (14.0)
Family history	3/43 (7.0)
Weak risk factors	
Immobilization	6/43 (14.0)
Iliac vein outflow obstruction	16 (28.6)

DVT, deep venous thrombosis; IVC, inferior vena cava.

5000 IU heparin flush through the side port of the access sheath every 6 h during the procedure. Thrombus resolution was assessed every 24 h by use of an ultrasound that evaluated compressibility and flow pattern. In patients with isolated iliac vein thrombosis, 24-h infusion of lytic therapy was sufficient to achieve recanalization. At 48 h, completion venogram was performed after full dose of thrombolysis to evaluate the recanalization of the thrombosed iliofemoral segment. When total recanalization with rapid contrast flow was regained without residual thrombus in different venous segment, the procedure was terminated. If the angiographic results were unsatisfactory (<50% of clot lysis), thrombolytic therapy was extended for no more than 72 h, to avoid bleeding complications.

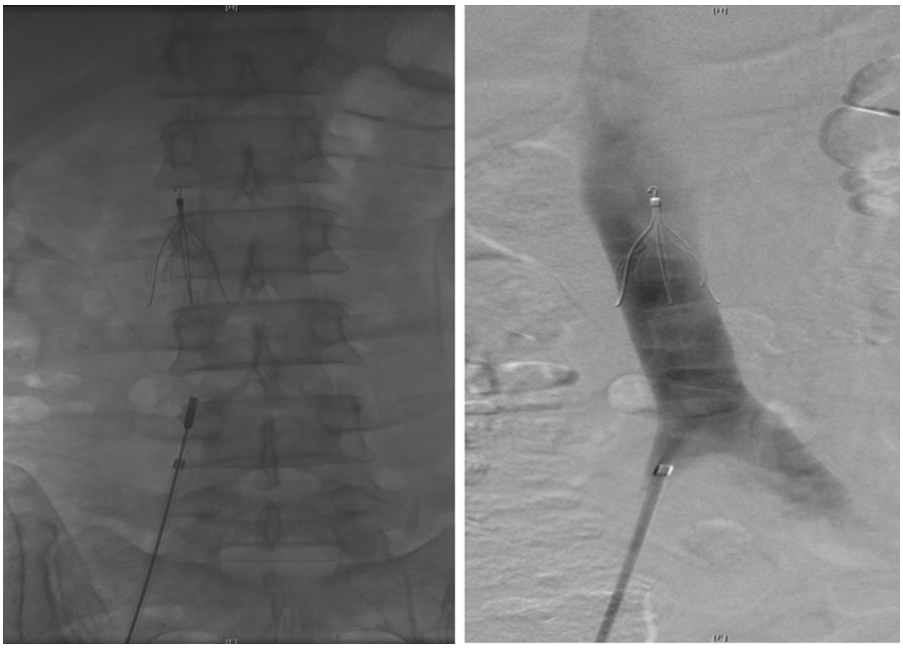
In 13 patients operated upon for AngioJet PMT (Fig. 3), prophylactic IVC filter was routinely deployed as before. Subsequently, a 6-F Solent Omni and 8 F Zelante DVT AngioJet catheter (Boston Scientific Corporation, Global Park, Heredia, Costa Rica) was advanced for PMT through the popliteal vein using an eluent consisting of 10-mg tPA) in 500-ml normal saline solution. We used 470 ml of 10-mg tPA (Actilyse; Boehringer-Ingelheim) in 500-ml normal saline solution with the Zelante DVT catheter. After thrombus ablation was complete, the suspected underlying chronic obstructions and residual thromboses were stented after assessment in two different projections and after a balloon inflation test.

Filter thrombus load was assessed by the completion venacavogram. Contrast-filling defects within the filter were interpreted as emboli. Filter thrombus load was classified based on the ratio of the maximum transverse length of the thrombus trapped in relation to IVC diameter into two grades [grade I (≤50%) or II (>50%)] [1]. Anticoagulation with unfractionated or low-molecular-weight heparin was resumed as soon as possible after sheath removal, usually within 2 h. For long-term therapy, oral anticoagulation with warfarin or other novel oral anticoagulants [direct factor Xa inhibitors (apixaban and rivaroxaban)] were prescribed based on the guidelines of DVT therapy. Filter retrieval was performed in some patients who had no evidence of filter thrombus or after filter thrombus lysis by 12 h extended lytic therapy at another session before hospital discharge. Other patients were arranged for filter retrieval during the follow-up period (Fig. 4).

Statistical analysis

All data were collected, tabulated, and statistically analyzed using SPSS 22.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as the mean±SD, and qualitative data were expressed as absolute frequencies (number) and relative frequencies (percentage). Independent samples Student's *t* test was used to compare between two groups of normally distributed variables. Percent of categorical variables were compared using χ^2 test when appropriate. All tests were two sided. *P* value less than 0.05 was considered statistically significant, and *P* value more than or equal to 0.05 was considered statistically insignificant.

Figure 2



A 38 years old female with left femoropopliteal DVT (supine position) prepared for CDT. Venography shows Celect IVC filter insertion immediately before the procedure. CDT, catheter-directed thrombolysis; DVT, deep venous thrombosis; IVC, inferior vena cava.

Results

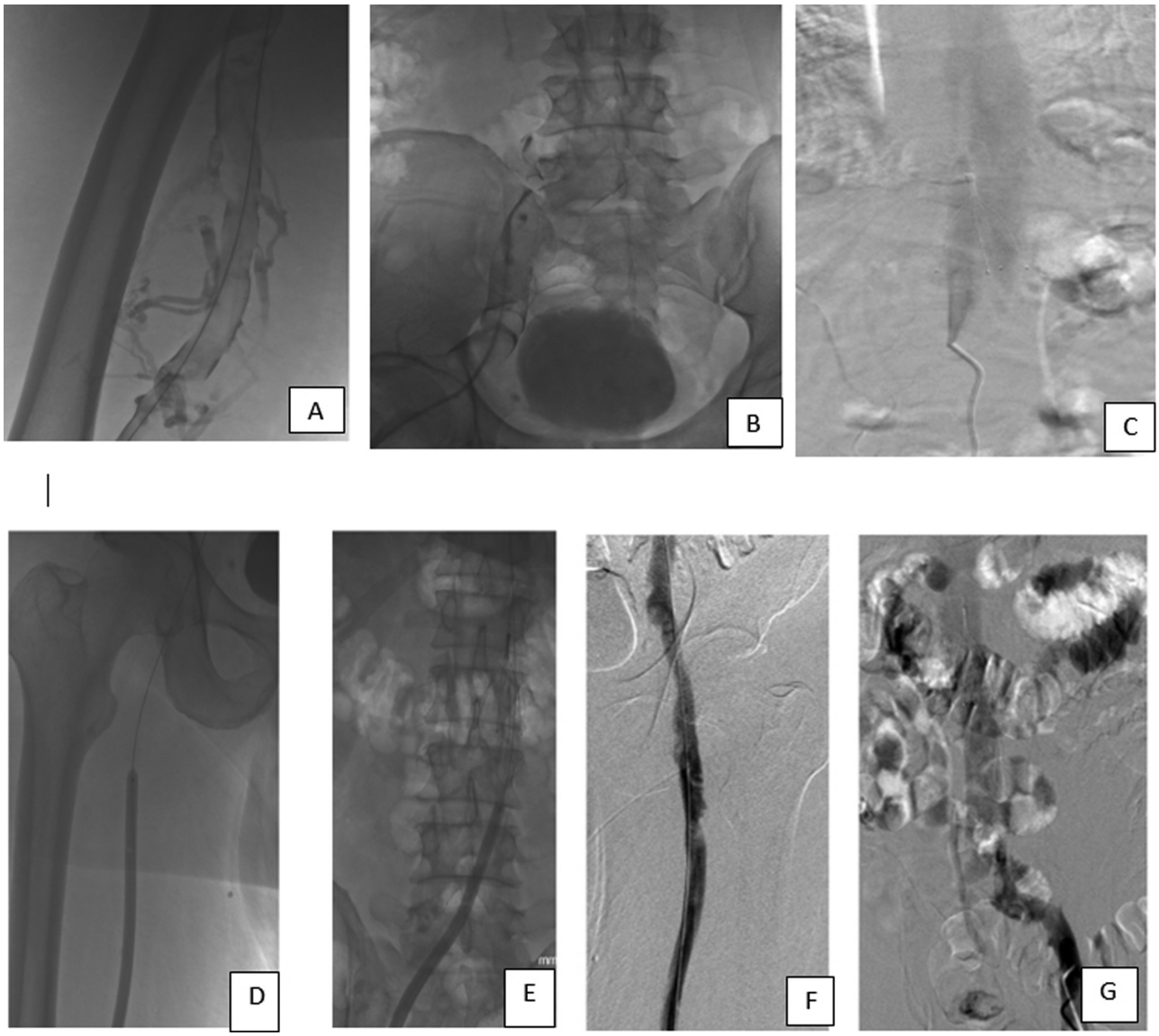
Our retrospective analysis of 56 patients who underwent percutaneous endovenous thromboablation for extensive lower extremity DVT using CDT and PMT with/without prophylactic vena cava filtration shows that 37 (66.1%) patients were women and 19 (33.9%) were men, with mean±SD age of 35.4±6.52 years. Unilateral lower extremity DVT was seen in 53 (94.6%) patients and bilateral lower extremity DVT in three (5.4%) patients. Complaints were in the form of edema in 25 (44.7%) patients, pain and edema in 20 (35.7%) patients, pain in seven (12.5%) patients, and phlegmasia cerulea dolens in four (7.1%) patients. Two of the studied patients had showering PE (3.5%) before the initiation of endovenous therapy. Thrombus was located in iliac vein in 14 (25.0%) patients, iliofemoral venous segment in 33 (58.9%) patients, IVC was involved in eight (14.3%) patients, and femoropopliteal venous segment was included in nine (16.1%) patients. A total of 43 (76.8%) patients had risk factors for DVT as summarized in Table 1.

Of the enrolled patients, 16 (28.6%) were found after completion venogram to have iliac vein outflow obstructive lesion. A total of 43 (76.8%) patients were operated upon for CDT, whereas 13 (23.2%) patients were operated upon for AngioJet PMT. In our study, 29 retrievable IVC filters were successfully deployed in 29 (51.8%) patients. Preprocedural prophylactic deployment was done in 26 (46.4%), comprising 13 (50.0%) filters in CDT patients, and 13 (50.0%) filters in PMT patients, whereas three (5.4%) patients received IVC filter during the procedure owing to symptomatic PE.

In CDT patients, the mean duration of thrombolytic therapy was 43.54±12.0 h, complete recanalization was achieved in six (10.7%) patients with isolated iliac vein thrombosis after 24 h of thrombolysis, 34 (60.7%) patients after 48 h of thrombolysis, and three (5.4%) patients requiring extended therapy for 72 h due to extensive residual thrombus and to allow IVC filter thrombus lysis after repositioning of the catheter. In PMT patients, complete recanalization was achieved in eight (14.3%) patients with a single-session therapy, and five (8.9%) patients required additional thrombolytic drug infusion for 12 h. Technical success in restoring the venous flow on the final venogram was achieved in all 56 patients. Adjunctive iliac vein stenting was performed in 21 (37.5%) patients, comprising 16 (28.6%) patients due to iliac vein outflow obstructive lesion and five (8.9%) patients due to residual iliac vein thrombus (Table 2).

There was no mortality related to the procedure. Three patients had died at follow-up: two patients due to cancer and one patient died 6 months after procedure because of filter-related IVC penetration with subsequent focal periaortic inflammatory changes and focal weakness of the aortic wall leading to

Figure 3



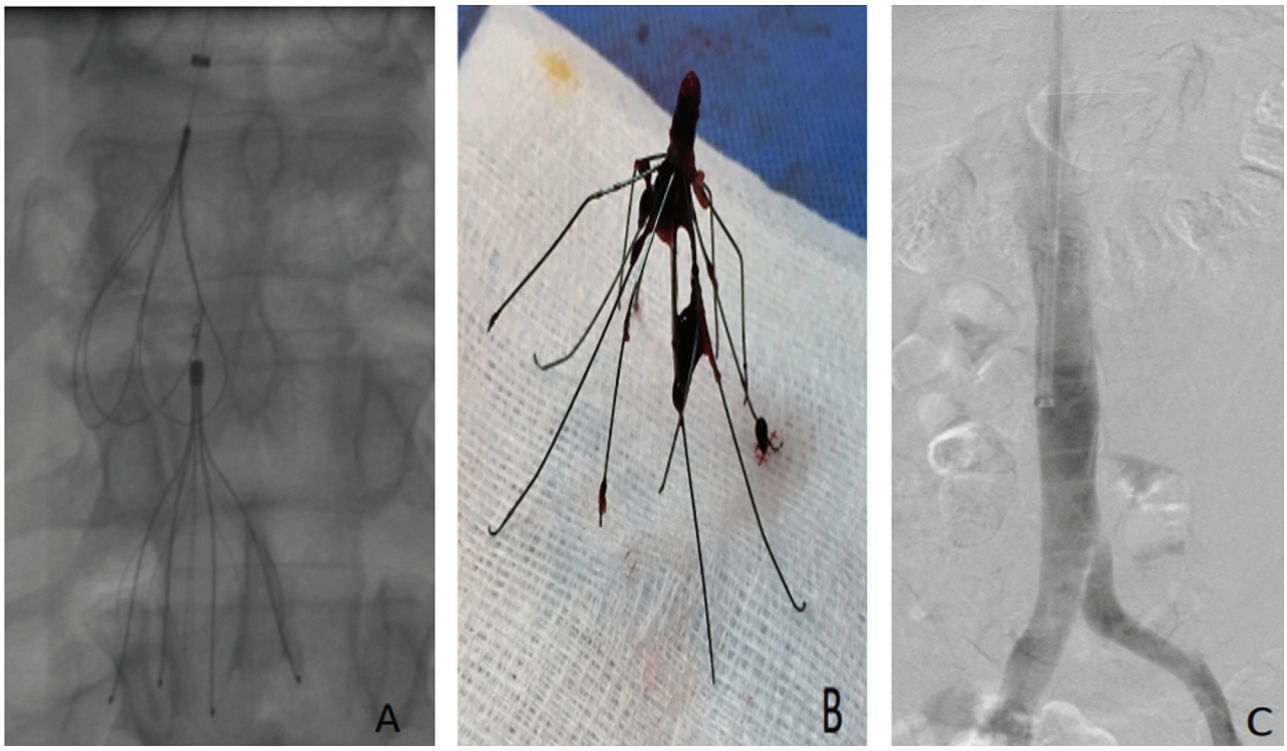
A 40 years old male with left iliofemoropopliteal DVT (prone position). (A, B) venography shows irregular filling defect of the deep venous system up to IVC. (C) Confirmed patency of IVC and shows IVC filter that was inserted immediately before the procedure. (D, E) shows AngioJet thromboectomy catheter (Zelante). (F, G) completion venography confirmed patency of the deep venous system (Note that the patient was turned supine). DVT, deep venous thrombosis; IVC, inferior vena cava.

aortic aneurysm (Fig. 5). Complications occurred in nine (16.1%) patients; three (5.4%) patients had procedure-related PE (Fig. 6), and all of them received IVC filter during the procedure owing to symptomatic PE. Five (8.9%) patients had access site hematoma: three of them related to the main procedure access site, and two related to filter deployment access sit, and one patient had filter related IVC penetration.

Proximal embolization was recognized in 12 (21.4%) patients during revision of venacavograms and postprocedure pulmonary computed tomography pulmonary angiogram; nine (75.0%) patients underwent preoperative IVC filter placement, whereas the remaining three (25.0%) were without the IVC filter, and they had symptomatic PE during the procedure necessitating filter placement. Filter thrombus load was classified as grade I and grade II, based on the ratio of the maximum transverse length of the thrombus trapped in relation to IVC diameter; five (55.6%) of the nine patients with embolization had grade I, whereas four (44.4%) patients had grade II.

Proximal embolization to IVC filter or to lung was analyzed in relation to patients' characteristics and details of the procedure. These are summarized in Tables 3 and 4. Proximal embolization was found to be more frequent in proximal lesions with caval extension (P=0.048) and patients with concomitant

Figure 4



Filter retrieval procedure. (A) Snaring. (B) The filter was removed with little thrombus burden. (C) Cavography after filter retrieval confirmed patency of the iliac veins as well.

PE at admission (P=0.044). No proximal embolization occurred in patients with absent risk factors (P=0.037). Malignancy as a risk factor has been associated with increased proximal embolization (P=0.019). Proximal embolization was less frequent in patients who underwent iliac vein stenting due to iliac vein outflow obstruction because of lower thrombus loading, narrowing of the vessel diameter, and irregular endoluminal surface (with consequent higher resistance to free flow of debris), which may have reduced the embolization risk; however, it was statistically insignificant (P=0.164).

Subanalysis of patients showed no significant differences in other patient-related and procedure-related factors, such as age, sex, use of thrombolytic catheter or PMT devices, or time for thrombolysis. There was no PE breakthrough (defined as new PE occurring after IVC filter placement) seen in any of the patients; 17 (58.6%) filters were successfully retrieved, whereas four (13.8%) filters failed to be retrieved owing to penetration of the IVC wall (Fig. 5) causing aortic aneurysm (one patient), filter tilting (one patient), and identified thrombus within the filter (two patients), and the remaining filters in eight (27.6) patients were lost during follow-up. Macroscopic thrombi were detected in four (23.5%) filters of the 17 filters removed.

Discussion

PE caused by DVT is associated with high mortality and morbidity, making the prevention of VTE is one of the national hospital inpatient quality measures. Anticoagulation is considered the standard therapy for venous thromboembolism; however, anticoagulation may be ineffective or associated with an increased risk of bleeding in selected group of patients [10].

Percutaneous interventional therapy is used in an increased manner as a powerful tool for the treatment of DVT. One of the major concerns and premonitions related to the use of mechanical aspiration thrombectomy and to a lesser extent with CDT in patients with extensive lower extremity DVTs is the development of PE during percutaneous therapy [15].

The use of IVC filters as an adjunct procedure to CDT/PMT remains controversial and not well established owing to lack of the data from controlled studies. However, there has been little debate on the necessity of filter deployment during DVT therapy using percutaneous endovascular procedures other than CDT [16].

Many times, we have heard from many people about how they never put an IVC filter during thrombolysis,

Table 2 Procedure characteristics

Procedure details	*n* (%) (*N*=56 patients)
Procedure	
CDT	43 (76.8)
PMT	13 (23.2)
Access site	
Main procedure access	
Single access	27 (48.2)
Double access	26 (46.4)
Dual access	3 (5.4)
Filter deployment access	
Contralateral femoral vein access	13 (44.8)
Transjugular access	16 (55.2)
Popliteal access	3 (10.4)
Filter deployment	29 (51.8)
Prophylactic	26 (46.4)
During the procedure	3 (5.4)
Retrieved filters	17/29 (58.6)
Nonretrieved filter	12/29 (41.4)
Failed retrieval	4/29 (13.8)
Patient lost during follow-up	8/29 (27.6)
Procedure duration	
CDT	
24 h duration	6 (10.7)
48 h duration	34 (60.7)
72 h duration	3 (5.4)
PMT	
Single-session therapy (average 40 min)	8 (14.3)
Single-session with extended 12 h lytic therapy	5 (8.9)
Iliac vein stenting	21/56 (37.5)
Due to iliac vein outflow obstruction	16 (28.6)
Due to residual iliac vein thrombus	5 (8.9)
Complications	9/56 (16.1)
Procedure-related PE	3 (5.4)
Symptomatic	3 (5.4)
Asymptomatic	0
Puncture site bleeding	5 (8.9)
Procedure site access	3 (5.4)
Filter site access	2 (3.4)
Specific filter complications (IVC penetration)	1 (1.8)

CDT, catheter-directed thrombolysis; IVC, inferior vena cava; PE, pulmonary embolism; PMT, pharmacomechanical thrombectomy.

whereas others have insisted on routine use before every case. As a result of this conflict of opinion and practice, our study findings show that the overall incidence of proximal embolization among the 56 treated patients was 21.4%. Patients with retrievable filter deployment were 51.8% of patients; 34.6% of retrievable IVC filters placed before CDT±PMT showed evidence of proximal showering with variable grades of filter thrombus load and 10% of patients without IVC filter developed proximal embolization during CDT in the form of symptomatic PE necessitating filter placement. This figure is more than the 11% rate of venographic evidence of thromboembolism trapped by IVC filters in the TORPEDO study [17]. Kölbel *et al.* [18] have shown that almost 45% of retrievable IVC filters placed before CDT±PMCT for proximal DVT showed a visible thrombus in the filter, whereas Jiang *et al.* [19] reported the incidence of IVC filter thrombus of patients with acute proximal DVT during CDT was 4.2% which was much lower than that of the study by Kölbel and colleagues. Our results were higher than those of Jiang and colleagues, which may be owing to the large sample of the patients included in their study.

However, our results and the results of Jiang and colleagues were lower than those of Kölbel and colleagues; this could be explained by (a) Kölbel's series, which included only iliocaval DVT, whereas the femoropopliteal vein, iliofemoral vein, and iliac/iliocaval vein DVTs were all included in our study, and (b) the continuous pumping of thrombolytic drug through the catheter for 48 h and the ascending venography was performed every 2 days, which may underestimate the true incidence of filter embolization owing to continuous lysis of the small-size filter thrombus before detection.

PE had occurred in only two (0.9%) of 214 patients who received CDT for DVT in the lower extremity without IVC filter placement, according to Bjarnason *et al.* [20] and in only six (1.3%) of 473 patients, as reported by Mewissen *et al* [21].

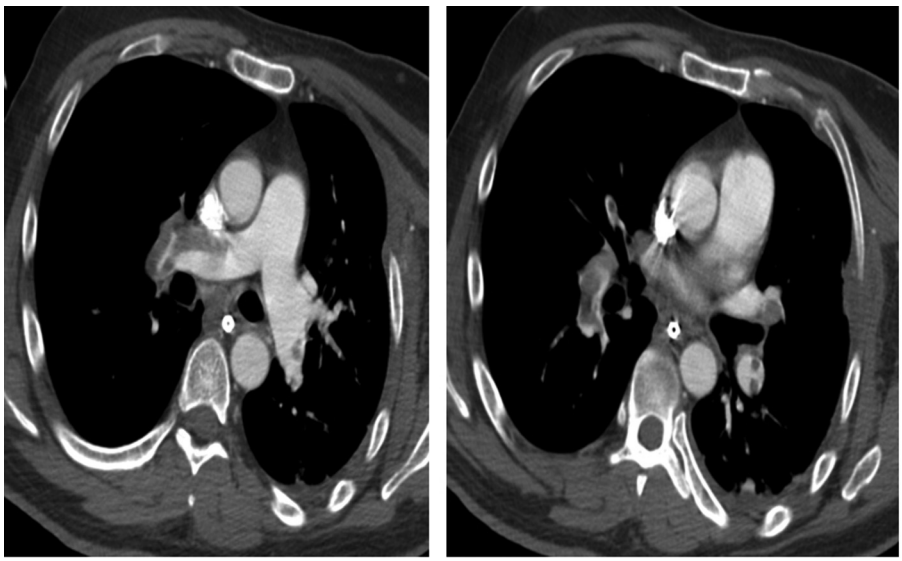
IVC filter implantation to lower thromboembolic risk in percutaneous endovascular intervention trial published by the Arizona Heart and Vascular Institute randomized 141 patients undergoing percutaneous endovascular intervention for acute extensive DVT to receive a prophylactic IVC filter, divided into two groups (filter group, 70 patients) that receive IVC filter and control group (71 patients) that did not receive IVC filter, showed an eightfold increase in symptomatic iatrogenic PE in those patients who did not receive a filter. However, no increased mortality was observed in patients without a filter, and all PEs were in the groups undergoing pharmacomechanical techniques; no PE developed in patients undergoing CDT alone [4].

Yamagami *et al.* [22] concluded that prophylactic placement of an IVC filter was efficient in the prevention of PE in lower extremity DVT during endovascular therapy owing to the high rate of thrombi trapped in IVC filters. Endovascular removal of thrombus was performed following insertion of IVC

Figure 5

Complications of IVC filter: Penetration of IVC with subsequent focal periaortic inflammatory changes (arrow in A) and small aortic aneurysm (arrow in B). Also note extensive IVC thrombosis below the filter. (C) Cavogram shows extravascular invasion. IVC, inferior vena cava.

Figure 6



A 41 years old female operated with CDT for extensive iliofemoral DVT with caval extension. The patient developed intraprocedural PE which diagnosed with CTPA necessitating IVC filter insertion. CTPA shows bilateral pulmonary artery embolism. CDT, catheter-directed thrombolysis; CTPA, computed tomography pulmonary angiogram; DVT, deep venous thrombosis; IVC, inferior vena cava; PE, pulmonary embolism.

Table 3 Patient characteristics in relation to proximal embolization

Study groups	Proximal embolization [*n* (%)]		Test	*P* value
	Yes (12 patients)	No (44 patients)		
Age (years)				
Mean±SD	37.47±5.82	33.76±4.53	1.76	0.091
Sex				
Male	5 (41.7)	14 (31.8)	0.094	0.765
Female	7 (58.3)	30 (68.2)		
Clinical presentation				
Pain	0	7 (15.9)	0.97	0.324
Edema	7 (58.4)	18 (40.9)	0.561	0.454
Pain and edema	4 (34.3)	16 (36.4)	0.038	0.846
Phlegmasia cerulea dolens	1 (1.3)	3 (6.8)	0.033	0.856
Pulmonary embolism at admission	2 (16.7)	0	3.65	0.044*
Level of DVT				
Iliac vein	3 (25.0)	7 (15.9)	0.092	0.761
Iliocaval vein	4 (33.3)	4 (9.1)	1.94	0.048*
Iliofemoral with caval extension	5 (41.7)	24 (54.5)	0.217	0.641
Femoropopliteal vein	0	9 (20.5)	1.6	0.205
Risk factors				
Patients with absent risk factors	0	13 (29.5)	3.1	0.037*
Patients with risk factors				
Strong risk factors	2 (16.7)	3 (6.8)	0.24	0.624
Moderate risk factors	5 (41.7)	20 (45.5)	0.055	0.815
Weak risk factors	1 (8.3)	5 (11.4)	0.09	0.736
Combined risk factors	4 (33.3)	3 (6.8)	2.44	0.117
Risk factor classification				
Strong risk factors				
Major surgery	2 (16.7)	3 (6.8)	0.24	0.624
Moderate risk factors				
Thrombophilia	2 (16.7)	5 (11.4)	0.24	0.622
Hormonal therapy	3 (25)	6 (13.6)	0.25	0.612
Pregnancy	1 (8.3)	2 (4.5)	0.27	0.605
Postcesarean section	2 (16.7)	8 (18.2)	0.015	0.903
Previous DVT	3 (25)	5 (11.4)	0.535	0.464
Malignancy	4 (33.3)	2 (4.5)	5.34	0.019*
Family history	0	3 (6.8)	0.148	0.700
Weak risk factors				
Immobilization	2 (16.7)	4 (9.0)	0.051	0.821
Iliac vein outflow obstruction	1 (8.3)	15 (34.0)	1.63	0.164

Categorical variables expressed as *n* (%) (χ^2 test); continuous quantitative variables expressed as mean±SD (independent Student *t* test). DVT, deep venous thrombosis. **P* value less than 0.05 is significant.

filter in 37 sessions, and 20 (54.1%) patients with thrombi trapped in the filter were reported [22]. Noguchi *et al*. [23] concluded that temporary IVC filters were safe and useful for the treatment of acute proximal DVT, especially in patients requiring aggressive removal of thrombus such as in PMT.

The analysis of our patient-related and procedure-related factors showed that the absence of risk factors for DVT was a predictor for safe procedure, whereas the presence of risk factors was associated with proximal embolization. A higher number of patients with embolization was expected in PMT; however, 58.3% of patients who had undergone PMT showed proximal showering to the routinely placed retrievable filter, which was not statistically significant from CDT (*P*=0.186).Chung *et al*. [24] reported selective deployment of IVC filters in cases of thrombus extension to the IVC in the absence of venous stenosis of the common iliac vein in a computed tomography scan. None of their patients undergoing aspiration thrombectomy with or without IVC filter insertion experienced symptoms suggesting PE [24].

Of 16 patients with iliac vein outflow obstruction, only one (6.3%) patient had proximal embolization despite the remaining 15 (93.7%) patients associated with the most proximal DVT pattern and seven of them had more than one risk factors, so iliac vein obstructive lesions appear to be protective against proximal

Table 4 Procedure details in relation to proximal embolization

Procedure details	Proximal embolization [*n* (%)]		Test	*P* value
	Yes (12 patients)	No (44 patients)		
Procedure				
CDT	5 (41.7)	38 (86.4)	1.74	0.186
PMT	7 (58.3)	6 (13.6)		
Preprocedural CTPA evidence of PE	2 (16.7)	0	3.53	0.044*
Postprocedural CTPA evidence of proximal lung showering	3 (25.0)	0	7.21	0.007*
Filter deployment				
Prophylactic	9 (75.0)	17 (38.6)	3.65	0.05
During the procedure	3 (25.0)	0	7.21	0.007*
Procedure duration				
CDT				
24 h duration	1 (8.3)	5 (11.4)	0.09	0.936
48 h duration	2 (16.7)	32 (72.6)	3.45	0.06
72 h duration	2(16.7)	1 (2.3)	1.53	0.215
PMT				
Single-session therapy (average 40 min)	3 (25.0)	5 (11.4)	0.535	0.646
Single-session with extended 12 h lytic therapy	4 (33.3)	1 (2.3)	0.045	0.832
Iliac vein stenting				
Due to iliac vein outflow obstruction	1 (8.3)	15 (34.0)	1.63	0.164

CDT, catheter-directed thrombolysis; CTPA, computed tomography pulmonary angiogram; PE, pulmonary embolism; PMT, pharmacomechanical thrombectomy. Categorical variables expressed as *n* (%)(χ^2 test); continuous quantitative variables expressed as mean±SD (independent Student *t* test). *P* value less than 0.05 is significant.

embolization but still statistically insignificant (*P*=0.164).

Based on the results of this study, four of the nine filters with thrombus load (grade II) were lysed with CDT and 17 filters were successfully retrieved. The suitability for filter retrieval of the IVC filter containing thrombus is not well established. The manufacturers of the most type of filters recommend avoiding retrieval if the thrombus is more than 25% of the filter volume. Deferring filter removal may be unavoidable because some patients with IVC filter thrombus were missed during the follow-up period, making filter retrieval more difficult [25,26].

Consequently, routine placement of IVC filters is not recommended. However, they should be considered in certain high-risk patients after assessment with an adequate protocol or patients with PE undergoing thrombus debulking therapy and should be of temporary type that allows rapid removal after restoration of the venous flow. This adds more costs (especially with retrievable filters) to the already expensive procedure.

Limitation and recommendation

Our study was conducted in a retrospective manner. Moreover, the limitations included the following: no randomization for patient selection, the patient sample was small, and coincidence was considered as a reason of our findings. A prospective randomized study is needed to overcome these limitations, and further studies are generally needed for corroboration of the results presented here for the development of a standard treatment protocol and endovascular treatment technique.

Conclusion

The routine placement of IVC filters is not recommended. However, they should be considered in certain high-risk patients after assessment with an appropriate protocol or patients with PE undergoing thrombus debulking therapy especially when using mechanical aspiration thrombectomy devices. CDT could be performed safely and effectively without routine prophylactic IVC filter placement in the treatment of acute DVT. However, further studies are needed for the establishment of a standard protocol for the placement of prophylactic of IVC filter during percutaneous endovenous intervention for proximal lower extremity DVT.

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Conflicts of interest

There are no conflicts of interest.

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