Catheter-Directed Therapy is Safe and Effective for the Management of Acute Inferior Vena Cava Thrombosis

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Background: The management of acute thrombosis of inferior vena cava (AT-IVC) has evolved to catheter-based therapies, the results of which remain uncertain. We report our institution's experience treating AT-IVC using endovascular methods.

Methods: A 10-year retrospective review of patients presenting with symptomatic IVC thrombosis between the years 2005 and 2014 was performed. Demographic data, treatment modalities, and outcomes were reviewed.

Results: Twenty-five patients (44% men) underwent treatment for acute (<2 weeks) symptomatic IVC thrombosis. Presenting symptoms included pain and limb swelling in 23 (92%), motor dysfunction in 16 (64%), sensory loss in 14 (56%), and pulmonary embolism (PE) in 2 (8%) patients. Phlegmasia cerulea dolens was present in 5 patients, a history of malignancy was identified in 7 patients, and 21 patients had an IVC filter at presentation (Trapease 12, G2X 3, Option 2, Eclipse 2, Meridian 2). Four patients had a documented hypercoagulable state, 21 patients underwent venous angioplasty, and 7 (28%) patients underwent venous stenting of the IVC or iliofemoral veins. Significant (>50% luminal gain) angiographic resolution of venous thrombus was achieved in all 25 patients. Twenty-one (84%) patients reported moderate-to-complete symptomatic improvement immediately after completion of the procedures. Two patients had a clinically symptomatic PE and 1 patient underwent an above-knee amputation secondary to venous gangrene. Other complications included 6 minor bleeding complications (2 local hematoma, 4 hematuria) all of which resolved spontaneously. There were 2 major bleeding complications (1 disseminated intravascular coagulation, 1 retroperitoneal hematoma).

Conclusions: Endovascular treatment of AT-IVC, regardless of etiology, is safe and effective with excellent short-term clinical results. An aggressive endovascular approach to treatment of AT-IVC is warranted even in the presence of a thrombosed vena cava filter.

INTRODUCTION

Acute thrombosis of the inferior vena cava (AT-IVC) is a potentially devastating problem for the patient. Left untreated, IVC thrombosis can lead to chronic venous stasis, postthrombotic syndrome (PTS), limb loss, pulmonary embolism (PE), or even death.[1,2] It is a challenging clinical entity. AT-IVC has a variety of treatment options, the results of which are ill defined. Previous treatment options include anticoagulation, systemic thrombolytic therapy, and open surgical thrombectomy. These modalities have been shown to be minimally effective with significant associated risks.[1,3]

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The long-term morbidity in patients with IVC thrombosis is largely unknown.[4] Most information has been extrapolated from studies regarding proximal deep vein thrombosis (DVT). A recent retrospective study showed that iliofemoral DVT is associated with significant postthrombotic morbidity if treated with anticoagulation alone.[5] Previous authors have reported that 90% of patients treated with anticoagulation alone will develop chronic venous insufficiency, 15% will develop venous ulcers, and 15% will show symptoms of venous claudication.[6]

Acute caval thrombosis is frequently associated with an underlying prothrombotic state such as previous episodes of DVT, intrinsic caval disease, or extrinsic compression from tumor.[7,8] Because of the increasing use of caval interruption devices (IVC filters), the number of cases of AT-IVC appears to be on the rise. Recent studies have demonstrated that up to 30% of these patients present with significant symptoms including bilateral lower extremity swelling and pain.[9,10]

Acute thrombosis of the IVC, in the presence of an IVC filter, may represent a de novo event or progressive filter occlusion because of interception of venous thromboembolic debris.[10] The presence or absence of an IVC filter is important as it will frequently impact on both the methods and the outcomes of treatment.

Regardless of the etiology, an aggressive approach toward patients with AT-IVC is warranted to prevent its devastating complications. We sought to examine the clinical outcomes of patients with AT-IVC treated using percutaneous methods of pharmacomechanical thrombectomy (PMT), catheter-directed thrombolysis (CDT), and adjunctive endovascular modalities.

METHODS

We retrospectively reviewed a prospectively maintained registry of all patients treated for AT-IVC between 2005 and 2014. AT-IVC was defined as IVC thrombosis within 2 weeks of onset of symptoms. Patients who were treated with PMT, CDT, venoplasty, and venous stents were identified. The records were reviewed for perioperative data, demographics, indications for treatment, DVT risk factors, and DVT location. Location was determined based on duplex ultrasound (DUS) imaging. The details of intervention including adjunctive measures were recorded. Clinical outcomes, periprocedural complications, follow-up DUS imaging findings, and follow-up clinical assessment were reviewed.

All patients determined to have AT-IVC underwent initial medical therapy, which consisted of aggressive anticoagulation with unfractionated heparin bolus (80 U/kg) followed by infusion therapy (18 U/kg) before intervention. All patients were initially treated with leg elevation, fluid resuscitation for 30 min to 3 hr depending on the urgency of intervention and correction of electrolyte imbalances before intervention. A hypercoagulable, hematologic workup was performed to identify an underlying prothrombotic state. The treating physician determined the timing and urgency of the intervention. Initial catheter-directed venography confirmed the diagnosis of AT-IVC in all patients.

Adjunctive procedures such as angioplasty and stent placement were recorded. All complications including bleeding, cardiac, pulmonary, and renal complications were identified. Bleeding complications were defined as major if they resulted in hemodynamic instability, large (>6 cm) hematoma, or in patients receiving multiple blood transfusions, and minor if resulted in puncture site bleeding, <6 cm hematoma, hematuria, and minor bleeding at a prior operative site. Cardiac complications were defined as documented acute myocardial infarction with enzyme elevation (troponins, creatine phosph okinase-MB isoenzyme) and electrocardiogram (EKG) changes. Pulmonary complications were defined as a documented PE on computed tomography pulmonary angiography or an intermediate-to-high probability ventilation-perfusion scintigraphy examination. Renal complications were defined as a doubling of baseline creatinine or need for hemodialysis.

After intervention, all patients were continued on medical therapy consisting of therapeutic anticoagulation with heparin (18 U/kg) or enoxaparin sodium (1 mg/kg every 12 hr) followed by oral anticoagulation therapy for a period of 6 months. Patients who had a prior episode of VTE were kept on lifelong anticoagulation. The international normalized ratio (INR) was maintained between a range of 2−3 in patients receiving warfarin. Antiplatelet therapy with aspirin 81 mg was added in patients undergoing venous stenting. Graduated compression stockings with 30−40 mm Hg of compression were prescribed to all patients. Patients were followed with venous duplex and clinical examination between 4.9 and 164.7 weeks after intervention.

TECHNIQUE

All patients were treated either in the operating room using portable imaging equipment (OEC 9800/9900; GE Medical Systems, Milwaukee, WI) or in a dedicated angiography suite using a fixed

imaging system (Siemens AG, Munich, Germany). Vena cava filters were not placed before attempting intervention. All patients were treated under conscious sedation and local anesthesia. Imaging of the access site was performed at the start of the procedure by DUS imaging, and access was obtained via the common femoral, popliteal, or internal jugular vein by ultrasound-guided puncture depending on physician preference. Popliteal access was performed when the common femoral veins were thrombosed. Venography was performed via a 6F sheath. The sheath was increased to 8F if the Trellis (Covidien, Mansfield, MA) thrombectomy device was used. Heparin anticoagulation was administered peripherally and was routinely dosed at 100 U/kg during the procedure. Activated clotting time (ACT) was checked intraoperatively, and additional bolus of heparin was administered to maintain therapeutic anticoagulation (ACT >200) during the procedure. Therapeutic levels (aPTT 60—90 sec) were maintained postoperatively with heparin drip administered through the procedural sheath.

The thrombosed venous segment was traversed with a 0.035-in guide wire. Bilateral popliteal or common femoral vein access was obtained if the venous thrombus included both iliofemoral segments. The operative surgeon decided the use of each treatment modality at the time of the procedure based on the extent and location of the thrombus. If CDT was performed, a multiholed infusion catheter was used for intrathrombus infusion. The recombinant tissue plasminogen activator (rt-PA) infusion rate was set at a total of 1 mg/hr. Mechanical clot dissolution devices included AngioJet (Boston Scientific, Marlborough, MA) or Trellis Infusion Catheters (Covidien) introduced into the occluded segments. The AngioJet was used in power pulse mode with rt-PA infusion followed by thrombectomy mode after a 30-min dwell time. The Trellis catheter was used with a bolus dose of 2-mg rt-PA injected through the catheter and an additional 1 mg of rt-PA was infused every minute. After 10 min, the macerated thrombus was aspirated with a 30-cc syringe. The AngioJet and Trellis devices each used 10 mg of rt-PA for each treated segment. Successful thrombolysis was confirmed by repeated segmental venography, and a decision was made whether to continue with CDT in an intensive care setting if there was residual thrombus of >25% of the lumen. Patients requiring CDT were taken back to the operating room for repeat venography within 24 hr of the original procedure. Any significant stenosis or underlying chronic occlusion was treated with balloon angioplasty and stent placement (Wallstent, Boston Scientific; or Cordis Smart Stent; Johnson & Johnson, Warren, NJ). Stents were oversized by 10—15% based on the angiographic diameter of the treated vessel. A single stent localized to the stenotic area was used. The stent crossed the inguinal ligament and extended into the common femoral vein if needed. Multiple stents were used if there were multiple areas of stenosis. An overlap of 2 cm was maintained between the deployed stents.

Occluded IVC filters were traversed using a 0.035-in guide-wire. When a severely occluded IVC filter had extension of thrombus into both common iliac veins, bilateral wire access was obtained to perform dual-catheter PMT/CDT. This provided a more substantial flow lumen within the IVC and iliac veins. PMT (AngioJet/Trellis) was performed within the occluded filter based on thrombus burden and symptomatology. There was one patient with clot extending above the filter. An optional filter was placed from a jugular approach above the clot, before lysis was started. Venography was used to confirm that an adequate flow channel was present within the IVC after PMT. Further management of the remaining IVC thrombus was treated with CDT, PMT, or angioplasty depending on the chronicity of the thrombus, stability of the patient, and overall thrombus burden. Vena cava stent placement was not used to exclude the IVC filter from the IVC lumen. None of the IVC filters were removed after thrombolysis. Successful removal of the residual thrombus in the filters was confirmed radiographically with venography.

RESULTS

During the 10-year period, 25 patients with AT-IVC were treated with a multimodal endovascular approach. The demographics, risk factors, and presenting symptoms are shown on Table I. The patient mean age was 50.3 (range, 2—75) years. A history of malignancy was identified in 3 (12%) patients. All 25 (100%) patients had a prior history of DVT, of whom 5 patients were being treated with warfarin and had a subtherapeutic INR at presentation. All patients who were on warfarin therapy before presentation were being treated for prior history of DVT. A hypercoagulable panel consisting of antiphospholipid antibody, anticardiolipin antibody, factor V Leiden, factor II DNA analysis, antithrombin level, and protein C and S were sent on all patients. This workup was sent after initiation of heparin therapy in all patients. Only 3 (12%) patients had positive hypercoaguable studies (2 antiphospholipid and 1 anticardiolipin antibodies).

Table I. Patient demographics, risk factors, and presenting symptoms

Characteristic	*n*	%
Demographics		
Age (years)	50.3	
Male	11	44
Hx deep venous thrombosis	25	100
Coronary artery disease	15	60
Diabetes mellitus	7	28
Dyslipidemia	10	40
Risk factors		
Hx malignancy	7	28
Hypercoagulable state	4	16
Immobility	4	16
Hx pulmonary embolism	18	72
Recent surgery	3	12
Presenting symptoms		
Swelling	23	92
Pain	23	92
Motor dysfunction	16	64
Sensory loss	14	56
Pulmonary embolism	2	8
Phlegmasia cerulea dolans	5	20

Hx, history of.

Table II. Previous inferior vena cava filter and extent of thrombosis

Type of previous IVC filter	*n*	%
Trapease[a]	12	57
GX2[b]	3	14
Option[c]	2	10
Eclipse[b]	2	10
Meridian[b]	2	10
Total	21	84
Extent of thrombosis		
IVC	1	4
IVC, iliac	7	28
IVC, iliac, femoral	17	68

[a]Cordis (Warren, NJ).
[b]CR Bard (Tempe, AZ).
[c]Rex Medical (Conshohocken, PA).

Twenty-one patients had an inferior vena cava filter at presentation. Most of these filters were Trapease (Cordis, Warren, NJ) IVC filters. A full list of filter type is presented in Table II. A previous history of thrombophilia was seen in 3 patients.

All patients had symptoms starting within 2 weeks of the initiation of therapy. Phlegmasia cerulea dolens (PCD) was the presenting clinical indication in 5 of the 25 (20%) patients. Of the 5 patients who presented with PCD, all 5 (100%) had a previous IVC filter. Limb swelling and pain were present in 23 (92%) patients. Motor dysfunction was present in 16 (64%) patients, and sensory loss was present in 14 (56%) patients. All patients underwent DUS imaging preoperatively.

All 25 patients underwent successful endovascular management of AT-IVC. Twenty-two (88%) patients received both CDT and PMT, whereas 3 (12%) patients had CDT alone. No patient had PMT alone. Sixteen patients (64%) underwent bilateral catheter placement for thrombolysis. The Trellis device was used in 7 (28%), the Angiovac in 1 (4%) and the AngioJet device was used in 21 (84%) patients either alone or in combination with another PMT device. The position of the previously placed IVC filters at the level of the renal veins was confirmed with the initial angiogram in all 21 cases.

Eight patients (32%) suffered bleeding complications (Table III). There were 6 minor bleeding complications and 2 major bleeding complications requiring blood transfusion. None required operative intervention for bleeding. Six (24%) patients developed transient contrast-induced nephropathy, none of whom required hemodialysis, and all resolved during their hospital stay. One patient who presented with phlegmasia underwent an above-knee amputation (AKA) secondary to progression of venous gangrene after rethrombosis of the iliofemoral venous segment despite revascularization of the IVC. This same patient progressed to multisystem organ failure and death. One (4%) patient with a thrombosed IVC filter had a clinically symptomatic PE immediately after the completion of PMT.

Significant (>50% luminal gain) angiographic resolution of venous thrombus was achieved in all 25 patients. Twenty-three (92%) patients reported moderate-to-complete symptomatic improvement immediately after completion of the procedure. Eighteen (72%) patients were monitored long term with venous duplex of the entire IVC and iliac venous segment and serial physical examinations (Table IV). Median follow-up was 54.3 weeks (range, 4.9–164.7 weeks). On the last follow-up, 12 (67%) patients had a patent IVC and the iliofemoral segment on duplex with no evidence of recurrent DVT. Six (33%) patients were observed to have chronic DVT within the iliofemoral venous system (Table V). Symptomatic improvement was noted in all patients, and complete resolution of symptoms was seen in 16 (89%) patients.

DISCUSSION

Present therapies for the treatment of AT-IVC have ranged from conservative treatment with heparin

Table III. Postoperative complications

Complication	*n*	%
Minor		
Site hematoma	2	8
Hematuria	4	16
Major		
DIC	1	4
Retroperitoneal hematoma	1	4
Fasciotomy	2	8
Major amputation	1	4
Pulmonary embolism	2	8
Death	1	4

DIC, disseminated intravascular coagulopathy.

Table IV. Follow-up—length, outcomes, and symptomatic relief

Length of follow-up (weeks)	
Mean	54.3
Minimum	4.9
Maximum	164.7
Outcomes of follow-up, *n* (%)	
Expired	1 (4)
Lost	6 (24)
Follow-up	18 (72)
Relief of symptoms at follow-up, *n* (%)	
Partial	2 (8)
Complete	16 (64)

products to surgical thrombectomy to endovascular management. Although somewhat effective, the morbidity associated with open venous thrombectomy has fueled an interest in percutaneous venous thrombectomy procedures. Presently, catheter-based treatment modalities have emerged as an important option in the treatment of these patients and may be considered as first-line therapy for the treatment of AT-IVC.

Successful thrombolysis maintains venous valve function and clears luminal obstruction. These 2 factors are associated with the most severe cases of postthrombotic morbidity.[11] Pharmacomechanical options have included CDT in combination with mechanical thrombus debulking therapies. This combination therapy has the distinct advantage of rapid clot dissolution while minimizing thrombolytic drug requirement.

Several case reports describe successful use of either the Trellis or AngioJet with or without adjunctive balloon angioplasty of the iliocaval segment for thrombosis.[12–14] Determining which PMT device is better at removal of thrombus burden was evaluated by Murphy et al., who compared 33 patients undergoing PMT for iliofemoral DVT using

Table V. Ultrasound findings at follow-up

Finding	*n*	%
Acute DVT	0	0
Chronic DVT	6	33
IVC	0	0
EIV	1	17
CFV	5	83
Negative	12	67

EIV, external iliac vein; CFV, common femoral vein.

the AngioJet or Trellis device. Using quantitative assessment of the diameters of the involved venous segments and intravascular ultrasound (IVUS), they concluded that greater clot lysis was seen with the AngioJet system. However, both devices resulted in clinically significant thrombus lysis.[15]

Based on our series, it appears that the use of these devices in extensive AT-IVC is safe and effective. The incidence of our early and late postoperative serious complications (bleeding, PE, venous gangrene) was 32%. This compared favorably with other studies. The one patient who suffered a postprocedural PE may have benefited from a temporary suprarenal filter, but we do not routinely place them and cannot predict who will have a postprocedural PE. Even with the use of PMT, we did not find any intraoperative PE; therefore, we do not advocate the routine use of filter placement during lytic therapy. Postoperatively, sensory loss was observed to persist in 3 patients (17%), and motor dysfunction had resolved in all. The number of patients who presented with PCD likely explains this result.

Case reports have documented the successful use of CDT alone in IVC occlusion. The use of CDT in the case of iliocaval thrombosis causing phlegmasia and prolonged lysis with urokinase has been reported to successfully restore venous patency with good short-term and midterm clinical benefit.[16,17] As our experience developed, we used bilateral CDT in patients with AT-IVC associated with bilateral common iliac vein thrombus. We maintained the same total dose of lytic therapy by reducing the individual catheter infusion by half. Establishing a second flow lumen within the occluded IVC may provide more area for the thrombolytic agent to act on the thrombus.

In our experience, most patients (84%) presenting with AT-IVC had a previously placed IVC filter. The insertion of IVC filters has increased over the last several years, with the rate of prophylactic IVC filter placement increasing at a significantly higher rate than filter placement for associated DVT or PE.[18] Corriere et al. have described 4 cases of vena cava thrombosis after IVC filter placement in 189

patients. The incidence of filter thrombosis differed according to the specific filter device they deployed. In their series, all observed vena cava thromboses were associated with patients who received opposed biconical filter designs.[19] The rate of IVC thrombosis from these biconical designed devices range from 6% to 28%.[9,20–22] The Trapease device was the most commonly thrombosed filter (57%) seen in our review.

Recanalization of the thrombosed IVC did not appear to be related of the type of filter encountered. Success in recanalization is likely a function of the acuity of the thrombus encountered. The high rate of IVC filter thrombus seen in our patient population should be considered when placing an IVC filter in patients with greater risk of developing AT-IVC. Furthermore, early filter retrieval when feasible should be practiced to avoid the increased incidence of AT-IVC in patients with filters.

Successful clearance of thrombus with good clinical results is more challenging in patients with AT-IVC complicated with an IVC filter. Vedantham et al. have demonstrated good venographic and clinical results when treating patients with a thrombosed filter. In that series, 9 of these patients received CDT and 66% of these patients received adjunctive PMT. The authors concluded that endovascular recanalization of the occluded IVC is feasible and reasonably safe in their experience. However, in most cases, CDT alone did not produce complete thrombolysis within the IVC.[23] Neglen et al. have documented successful stenting chronically obstructed IVC filters using stainless steel stents. These authors used IVUS to guide venoplasty and stent placement by identifying the degree of perivenous fibrosis and constriction. A thicker layer of echogenic material around the vein suggested significant postphlebitic fibrosis, and a high pressure balloon was used to dilate these areas and size stents.[24] We advocate the use of IVUS when available to determine the degree of residual stenosis.

In our series, there was no need for IVC filter stenting because of the acuity of the thrombus and adequate patency seen on completion venogram after PMT/CDT treatment. Our technique of combining PMT with selective CDT yielded very good angiographic and clinical results. After iliac vein stenting, we maintained patients on aspirin 81 mg as that is our practice for bare metal stents. In our experience, we have not witnessed a significant increase in stent thrombosis when using a single antiplatelet agent.

Patients who presented with PCD and were taken for PMT and CDT after resuscitation had a poorer outcome despite achieving IVC patency in a timely fashion. The 1 patient who presented with PCD subsequently required an AKA and ultimately expired secondary to multisystem organ failure illustrates the severity of this end-stage process in AT-IVC. These findings are comparable to previous case reports.[17,25,26] This subgroup of AT-IVC patients may present beyond the limits of what can be achieved by any catheter-based procedure, and the key to achieving favorable outcomes may revolve around early recognition of the disease process.

One major limitation of this study was its retrospective, chart review nature. Unfortunately, we do not have long-term follow-up data as of yet, but our 54-week follow-up findings are promising. Other researchers have shown similar mid- to long-term results. Ren et al.[27] found patent IVC after caval thrombolysis in 40 patients with Budd—Chiari syndrome at a mean follow-up of 29.08 ± 15.02 mo. Patient symptoms improved during the postprocedure period, providing a good indicator for establishing clinical success in this patient population. Another limitation of the study was the lack of use of intravascular ultrasound (IVUS) to assess the degree of lysis and to evaluate for residual stenosis. This occurred because the technology was not available to the surgeon at the time of procedure. A major limitation of this review was the inconsistency in checking for hypercoagulable states. Because this was a retrospective review, protocols were not in place to perform a hypercoagulability workup. Because patients were already on either warfarin therapy or started on heparin infusion by the time a hypercoagulable panel was sent, many results such as antithrombin level and protein C and S would be inaccurate. Performing the hypercoagulable workup can help to identify underlying prothrombotic states, but protocols should be in place to avoid ordering studies that will not yield usable results. Such protocols should deal with timing of blood draws and initiation of anticoagulation. The lack of uniformity in treatment of AT-IVC makes it difficult to fully compare therapeutic modalities, but this echoes the need for good randomized prospective data. The ATTRACT (Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter Directed Thrombolysis) randomized trial is currently underway to examine the outcomes of patients with acute symptomatic DVT undergoing conventional therapeutic anticoagulation versus pharmacomechanical catheter-directed lysis in addition to therapeutic anticoagulation.[28] The results of this trial may help establish guidelines for treating AT-IVC along with DVT of the lower extremity. Further research is needed to determine which type of endovascular modality will provide the best outcome for patients with AT-IVC.

CONCLUSIONS

Endovascular treatment of AT-IVC seems to be the safest and most effective treatment available with acceptable short-term clinical results. An aggressive endovascular approach to treatment of AT-IVC is warranted even in the presence of a thrombosed caval filter. The presence of phlegmasia seems to portend a poor prognosis despite aggressive management.

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