# Percutaneous Mechanical Thromboectomy (PMT, AngiJet) for Treatment of Symptomatic Lower Extremity Deep Venous Thrombosis: Safety and Efficacy Study, Retrospective Study

***Ahmed El-Marakby, Ahmed Farghaly, Ahmed Gamal Eldin Fouad***
Vascular Surgery Department, Cairo University

## ABSTRACT

***Aim of Study:*** *We describe our vascular center experience in thromboectomy of extensive iliofemoral deep venous thrombosis by using PMT with or without thrombolytic agents in combination with venoplasty and stenting for underlying venous lesions at the same session.* ***Methodology:*** *Over 24 months 14 patients with extensive lower extremity DVT were treated with PMT with the AngioJet thromboectomy device in combination with lytic agent (tissue plasminogen activator or reteplase) added to the infusion in selected delayed cases. Venoplasty and venous stenting by using sinus venous stents (Optimed stent) were deployed in all cases with underlying venous stenosis in the same session of the intervention. The primary end point was angiographic evidence of restoration of venous patency at completion of the procedure. Complications, recurrent ipsilateral DVT, and improvement in clinical symptoms were evaluated.* ***Results:*** *Complete thrombus removal was obtained in 9 procedures (64%), and partial resolution in the remaining 5 procedures (36%). In the 5 procedures with partial resolution, rheolytic thromboectomy with thrombolysis carried out. Additional catheter-directed thrombolysis was done for 12 hours in three of these five cases. Occlusive lesions by external mass compression responsible for acute DVT were revealed in 2 patients (14%). Underlying venous stenosis was detected in 9 patients (64%) and balloon angioplasty alone without stenting was performed in one patient and the remaining 8 patients required stenting. 16 stents were deployed in these 8 patients (average two stents for the patient). Overall, immediate (<24 hours) improvement in clinical symptoms was noted in 14 patients (100%). There was only patient (1/14, 7%) suffered of generalized bleeding and retroperitoneal hematoma from the thrombolytic agent otherwise no major complications related to either PMT or the short duration of lytic agent infusion. 2 patients developed access sites minor hematoma, 5 patients developed haemoglobinuria & one patient developed severe bradycardia during the procedure. Only one patient had a recurrent thrombosis after thromboectomy by 7 months and was treated by anticoagulation.* ***Conclusions:*** *Percutaneous mechanical thromboectomy by using Angiojet machine is safe and effective method for thrombus removal in early cases with extensive iliofemoral DVT.*

***Key words:***

## INTRODUCTION

The incidence of deep vein thrombosis (DVT) is approximately 48 per 100,000 persons per year in large community-based studies, with an in-hospital case-fatality rate from complications of thromboembolism at 12%.[1] Venous thromboembolic disease, including both DVT and pulmonary embolism, is an underdiagnosed medical problem that results in high rates of significant patient morbidity and mortality. The most common late complication of DVT, post-thrombotic syndrome, is due to valve damage from chronic thrombus and intravascular scarring. This may occur months or years after DVT. Conventional therapy includes anticoagulation with either unfractionated heparin or low molecular weight heparin, followed by long-term therapy with oral warfarin sodium.[1,2] Anticoagulation therapies, and the current standard of care for DVT, only inhibits thrombus propagation and prophylaxis against pulmonary embolism. However, it neither prevents chronic post thrombotic complications nor removes existing thrombus.[2]

Endovascular management with percutaneous mechanical thromboectomy (PMT) is safe and effective in reducing thrombus burden.[2,3,4,5] However; experience with this therapy is limited. We hypothesize that an adjunctive measure to PMT, the addition of lytic agent, is safe and

effective, and enables rapid removal of thrombus and relief of symptoms from lower extremity DVT more quickly than does anticoagulation therapy alone in delayed cases. We present preliminary results of a new technique of PMT with possible adjuvant concomitant lytic therapy for treatment of venous thrombotic disease with primary venoplasty with stenting in the same session.

## METHODOLOGY

Patients who underwent PMT by using AngioJet machine over 24 months (from October 2012 – October 2014) were identified at our vascular department, were retrospectively reviewed. Data collected included patient demographics, DVT risk factors, periprocedural data, lytic agent used, adjunctive venoplasty interventions, and clinical outcomes. All patients were admitted to the vascular surgery department after identification of a lower extremity DVT at duplex ultrasound scanning. Patients chosen for intervention had symptoms of edema and with or without incapacitating pain with extensive iliofemoral DVT either extending to popliteal vein or not. During this period 14 patients with thrombotic events were identified who had undergone PMT with possible adjunctive lytic therapy in selected delayed cases in whom mechanical thromboectomy as a solo treatment failed in resolution of the thrombus. In the delayed cases, the incidence of thrombotic occlusion was more than two weeks from the onset. Venoplasty and direct venous stenting by using self-expandable venous stents (sinus venous stents) were inserted in cases that showed underlying stenosis or compression by an external mass.

Mean patient age was 41 ± 3 years (range, 23-68 years). For the purpose of this study, the age of the thrombus is defined as the time from diagnosis with duplex ultrasound scanning to PMT intervention, and was 12 days (range, 2-21 days). Because thrombus age was calculated from the initial diagnostic duplex ultrasound scan, thrombus was present for variable amounts of time. Chronic thrombus is considered if it is more than 2 weeks duration and potentially contributed to decreased success in some patients and in whom the lytic agents were added to improve the patency.

Pre-intervention and post-intervention venograms were obtained and graded for degree of thrombus reduction. Thrombus removal was scored as “complete” if the dictated procedure report and the venogram demonstrated no residual thrombus after the procedure. “Partial thrombus removal” defined those procedures in which any amount of thrombus remained after the intervention was completed. We chose not to further separate the amount of remaining thrombus into this group because this type of measurement from venographic imaging is operator-dependent and subject to bias.

Angiojet thromboectomy system with possible rheolytic technique

The Angiojet rheolytic thromboectomy system consists of 3 components, including a single-use catheter, a single-use pump set, and a pump drive unit. This system is approved for peripheral arterial use by the US Food and Drug administration. The 6F catheter is available in working lengths of 60, 100, or 120 cm. The catheter is introduced through a percutaneous approach (6F sheath), and operates over a 0.035-inch guide wire. The catheter design consists of a lumen that supplies pressurized saline solution to the distal catheter tip, and a second lumen incorporating the first lumen, guide wire, and particulate debris removed from thrombus. The drive unit or pump generates pressure up to about 10,000 psi (350-450 km/hr.) of pulsatile saline solution flow, which exits the catheter tip through multiple retrograde-directed jets. These high-velocity jets create a localized low-pressure zone (Bernoulli Effect), which leads to thrombus maceration and aspiration. The jets also provide the driving force for evacuation of thrombus particulate debris through the catheter. The catheter design also produces radially directed low-velocity fluid recirculation to dislodge thrombus from the vessel wall and direct thrombus to the catheter tip for evacuation. The Angiojet system works in an isovolumetric manner; the saline solution infusion flow rate (60 mL/min is equal to the evacuation rate of thrombus particulate debris. The duration of the mechanical thromboectomy was in average 300 seconds with maximum time allowed to be 600 seconds in delayed chronic thrombotic occlusion.

In this study a thrombolytic agent was recombinant tissue plasminogen activator (Alteplase). The dosing range used 2-4 units in 50

mL saline solution. In addition, we were concern for potential pulmonary embolism during the procedure; vena cava filter was placed in all patients except two cases. The filters were inserted via contralateral femoral vein in supine position before starting PMT. Although no guidelines for mandatory insertion of the filter before the thromboectomy but in our practice we preferred routine insertions of IVC filters to avoid occurrence of the pulmonary embolism. In two patients, no filters were deployed, one had diagnosed with congenital absence of IVC and the other one had CRF with SVC complete occlusion associated with one lower limb had permicath for dialysis and the other lower limb that suffered of extensive thrombosis, already had femoro-femoral AVG for dialysis.

PMT technique for treatment of DVT

All PMT procedures were performed in a fully equipped operating room with capability for endovascular intervention. IVC filters were inserted routinely in supine position via femoral approach in supine position as described before except in two cases. Than the patients were placed in a prone position, and the ipsilateral popliteal vein was cannulated under ultrasound guidance either the popliteal vein was thrombosed or not. Only one case in which cross over technique by puncture the contralateral common femoral vein was done. After the initial ascending venogram was obtained, the Angiojet catheter was advanced over a guide wire and through the thrombosed vein segment. Two trials of mechanical thromboectomy were done alone. If still the thrombus was not resolved, at this point adjunctive thrombolytic agent was added to the infusion solution. One slow pass during withdrawal of the catheter was made to lace the thrombus with lytic agent and aspirate loose thrombus fragments. The design of the catheter enables thrombus fragmentation and rapid evacuation through the effluent lumen. This sequence may be repeated in the event that significant residual thrombus is seen on subsequent venograms. If still the thrombus persists for dissolution, a long thrombolytic catheter inserted into the sheath and its tip to be at the iliofemoral segment and thrombolytic agents infused for 12 hours at the ICU. After average 12 hours infusion, the patients returned back to the Endovascular Theater for completion venogram and possible venoplasty with stenting. In the case that needed venous stenting, the 6F sheath was replaced by another 10F one and in all these cases the sinus venous (Optimed) stents were used.

## RESULTS

Over 24 months in 14 patients were treated with this technique. Success, defined as complete thrombus removal, was achieved in 9/14 treated limbs (64%). The remaining 5 limbs (36%) demonstrated varying degrees of partial thrombus extraction. These 5 limbs required thrombolytic infusion during the thromboectomy. Three of them required prolonged infusion over 12 hours with thrombolytic catheter inserted at the iliofemoral segment and these patients returned back to Endovascular Theater for another session of PMT in the next day for complete resolution of the thrombus.

Identified risk factors and co-morbidity in these patients are listed in **Tables I, II & III**. All limbs had significant iliofemoral thrombus burden, and 6 limbs had thrombus extended to the femoropopliteal segment. Pulmonary embolism was detected either by CT angio or ventilation perfusion scan before the intervention in 4 patients. In 9 limbs (64%) anatomic lesions in the thrombosed vein were revealed after PMT. These lesions were thought to contribute to development of DVT. In these 9 limbs, combined angioplasty and stent placement was performed after PMT, for definitive treatment of underlying stenosis **(Fig 1, Fig 2, Fig 3, and Fig 4)**. In the 3 limbs in which initial PMT with adjunctive lysis failed, catheter-directed thrombolysis was continued on average for an additional 12 hours. This additional thrombolytic therapy dramatically improved thrombus removal in 2 patients and one remaining was not completely resolved. Post intervention, either subcutaneous low molecular weight heparin or intravenous unfractionated heparin was continued in all patients. Patients were subsequently given oral warfarin sodium, the duration of which was at the discretion of the primary care physician. Clopidogrel was added for three months in whom the venous stents were inserted. In 12 patients inferior vena cava filters were placed before PMT. Filters were placed at the discretion of the surgeon as prophylaxis against pulmonary embolism that might occur during the procedure. One of these 2 cases in whom IVC filters were not inserted, showed

congenital absence of IVC and another case was CRF with in the same limb in which DVT developed, a loop femoro-femoral AVG was created for dialysis. No patient experienced clinical evidence of pulmonary embolism during and post intervention.

**Table I:** Patients Demographic Features and Comorbidities

| *Patients* | *Age* | *Gender* | *Smoking* | *Renal impairment* | *Diabetes* | *Hypertension* | *IHD* |
|---|---|---|---|---|---|---|---|
| **1** | 38 | F | ---- | ---- | ----- | -------- | --- |
| **2** | 34 | F | ----- | ------ | --- | ---- | -- |
| **3** | 43 | M | ----- | ++++ | ---- | ++++ | -- |
| **4** | 42 | F | ----- | ----- | ---- | ----- | -- |
| **5** | 29 | F | ----- | ++++ | ---- | ---- | +++ |
| **6** | 40 | M | +++ | ----- | ----- | ----- | - |
| **7** | 36 | M | ---- | CRF | ----- | ----- | -- |
| **8** | 28 | F | --- | --- | ---- | ----- | - |
| **9** | 68 | F | ---- | ---- | ---- | +++ | - |
| **10** | 23 | F | ---- | +++ | ---- | ----- | - |
| **11** | 44 | M | +++ | +++ | + | + | +++ |
| **12** | 61 | F | ---- | ----- | + | + | +++ |
| **13** | 32 | M | ----- | ---- | - | - | - |
| **14** | 56 | M | ---- | ---- | -- | + | - |

**Table II:** Patients Comorbidities

| ***Patients*** | *Associated cancer* | *Autoimmune disease* | *Hypercoagulable status* |
|---|---|---|---|
| **1** | ------- | SLE | -------- |
| **2** | ---- | ---- | PT C deficiency |
| **3** | Lymphoma | ----- | ------ |
| **4** | ---- | ----- | PT C &S deficiency |
| **5** | Uterine mass | ----- | ------ |
| **6** | ---- | ----- | ------ |
| **7** | ------ | ------ | Anti-thrombin 3 deficiency |
| **8** | ------ | ------ | ----- |
| **9** | ----- | RA | ----- |
| **10** | ---- | SLE | ---- |
| **11** | ---- | ----- | ------ |
| **12** | ----- | ------ | ------- |
| **13** | ---- | ------- | PT C deficiency |
| **14** | ------ | ------- | ----- |

**Table III:** Obstetric And Contraception History

| *Patients* | *Contraceptive pills* | *Current abortions or pregnancy* |
|---|---|---|
| **1** | +++ | +++ |
| **2** | +++ | ----- |
| **3** | ---- | ---- |
| **4** | ++ | ---- |
| **5** | --- | ---- |
| **6** | ---- | ---- |
| **7** | ---- | ----- |
| **8** | +++ | ---- |
| **9** | --- | --- |
| **10** | +++ | +++ |
| **11** | ---- | ---- |
| **12** | ----- | ---- |
| **13** | ---- | --- |
| **14** | ---- | ---- |

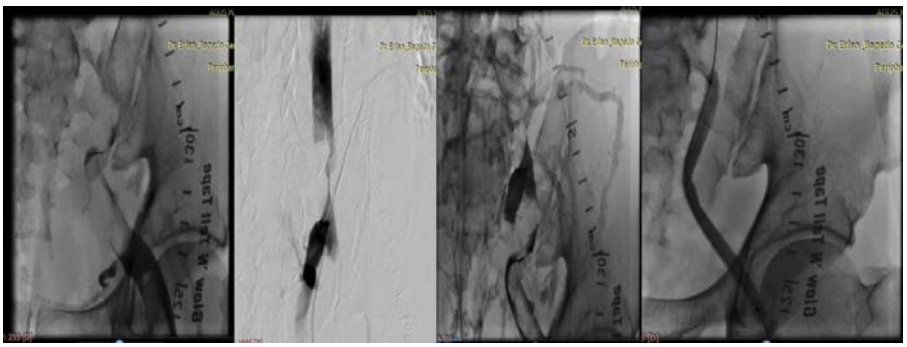

Fig. 1

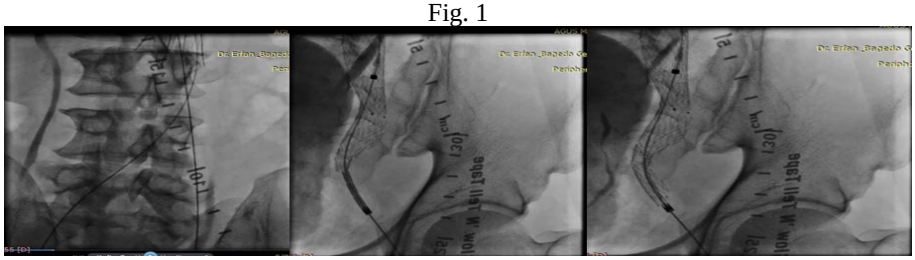

Fig. 2

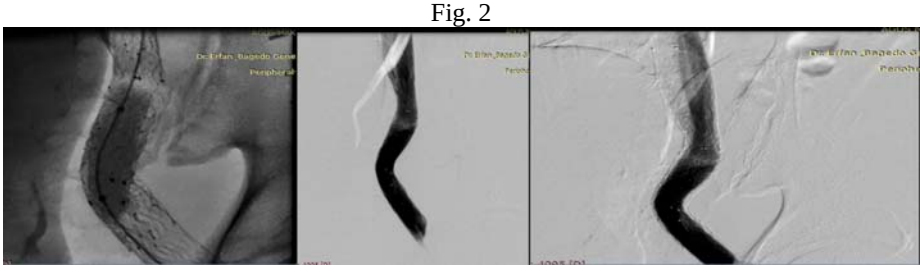

Fig. 3

**Figures 1, 2 & 3:** Initial ascending venograms demonstrate thrombotic occlusion of common iliac & femoral veins, stenosis in the common iliac vein. Venogram obtained after Pharmacomechanical thromboectomy with AngioJet catheter & iliac & femoral stenting with complete resolution of the thrombus.

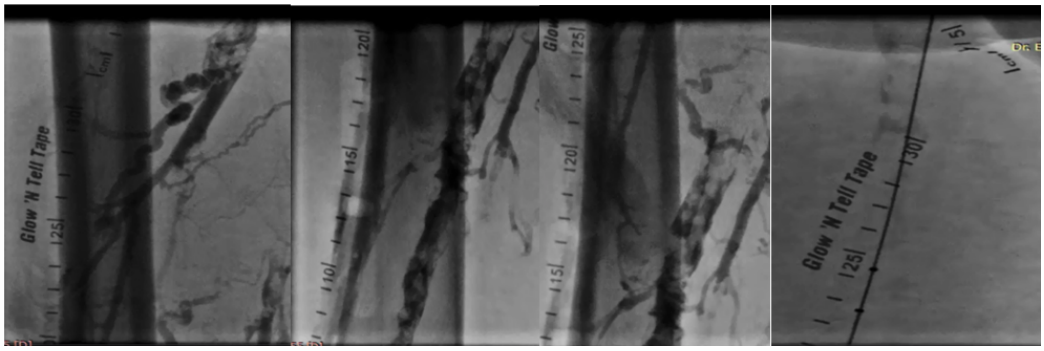


Fig. 5

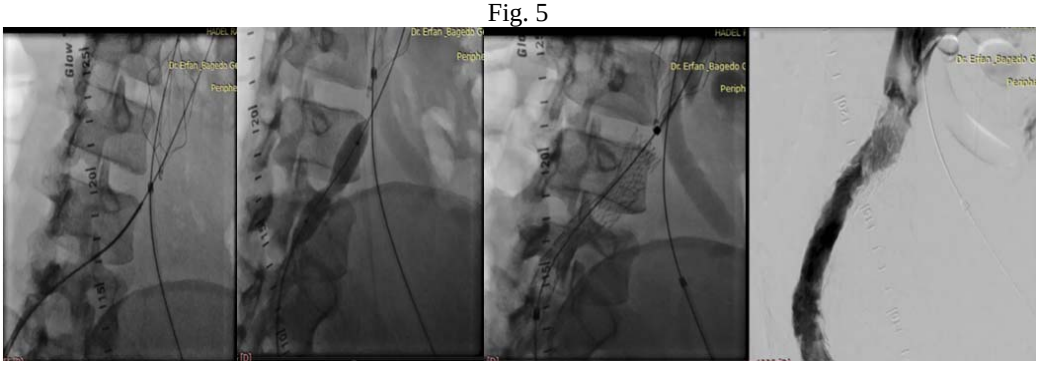

Fig. 6

**Figures 5 & 6** showed ascending venogram with complete thrombotic occlusion of iliofemoral & femoropopliteal veins, AngioJet catheter during thromboectomy, kissing wires at both iliac veins with IVC filter placement, venous stenting & post stenting venogram showed partial resolution.

Significant clinical improvement was seen in all limbs (100%), as marked by a decrease in pain or swelling of the affected extremity within 24 hours of treatment. This subjective clinical data was further stratified, on the basis of medical record documentation of patient well-being, as dramatic improvement (6 limbs), moderate improvement (5 limbs), or mild improvement (3 limbs). Three patients required intensive care for average 2 days. There were 2 access site hematomas and 1 retroperitoneal hematoma; however, no surgical interventions or blood transfusions were required for these hemorrhagic complications. Five patients developed haemoglobinuria (from hemolysis) that resolved within 48 hours. One case developed bradycardia that required stopping the procedure. There were no in-hospital deaths.

Follow-up averaged 6.2 ± 0.3 months (range, 2-24 months). There were no deaths during this time. Subsequent imaging was incomplete, and was performed in only 7 patients, including the 2 patients with recurrent DVT who underwent medical treatment. No meaningful data could be elucidated from follow-up imaging; thus no documentation of venous patency or preservation of valve function was collected in this review.

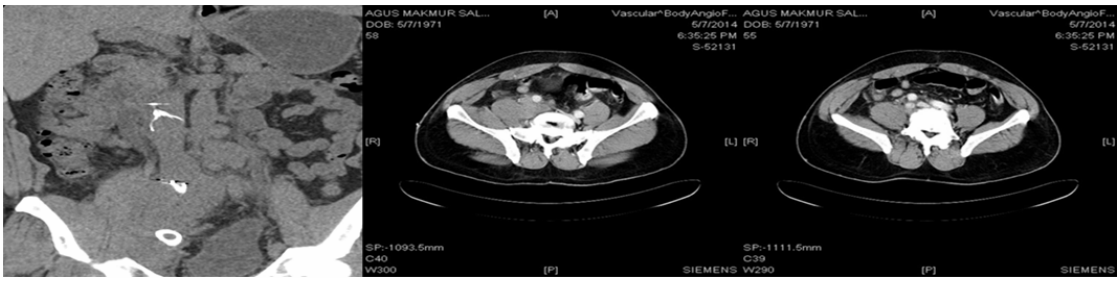

Fig. 7

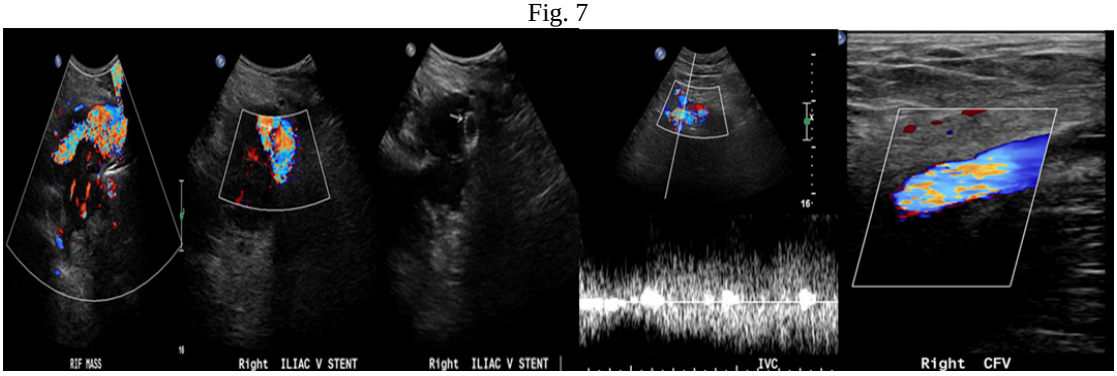


Fig. 8

**Figure 7** showed CT venogram with complete iliofemoral thrombosis with mass compression. **Figure 8** showed duplex examination post intervention with complete resolution of veins with no residual thrombosis & iliac stent in place compressed by lymphoma mass.

## DISCUSSION

Venous valvular reflux is the dominant cause of chronic venous insufficiency, with valvular incompetence directly resulting from DVT.[6] Techniques to preserve venous valves and restore venous patency should, in theory, decrease venous hypertension, reducing the incidence and degree of post thrombotic symptoms. The ability of interventions such as anticoagulation therapy, thrombolytic therapy, and surgical or endovascular thromboectomy to restore venous patency, remove obstruction, and ultimately decrease the incidence and severity of reflux in a diseased extremity can be used to return patients to their normal way of life. However, no therapeutic options or interventions to date have demonstrated superiority over anticoagulation therapy. Consequently, anticoagulation remains the standard of care while new methods are being evaluated. [6, 7]

It is hypothesized that rapid relief of thrombus burden by directly extracting thrombus surgically or with lytic therapy, or a combination of the 2 methods, should decrease the risk for pulmonary embolism and post thrombotic syndrome resulting in manifestations of chronic venous insufficiency. As a result of the hemorrhagic complications associated with catheter-directed thrombolysis, PMT has emerged as a useful option for treatment of acute DVT. Various thromboectomy catheters with different mechanisms of clot removal are commercially available; full discussion of each of these catheters is beyond the scope of this article. The catheters fall into 1 of 2 categories for clot extraction mechanism: micro fragmentation or thrombo-aspiration (Venturi effect). Several PMT catheters may be used in combination with adjunctive thrombolytic agents for more complete and rapid thrombus removal. The combination of therapies enables lower mean dosage and duration of lytic infusion. Reducing the dosage or time for complete thrombolysis should translate into reduced morbidity (fewer hemorrhagic complications) and cost savings. Furthermore, underlying anatomic lesions that precipitated the thrombotic event may be unmasked with PMT, with or without adjunctive lysis. Venous stenoses can be treated after thromboectomy at the same

setting, as evidenced in 64% of our cases, resulting in more efficient patient care.[6, 7, 8]

Several authors have evaluated multiple PMT catheters in the treatment of DVT. However, to date there are no prospective, randomized trial data available or large-scale clinical series. The AngioJet thromboectomy device has no direct contact with the vessel wall, thus causing only minimal endothelial denudation.[7]

Because thrombus removal is not produced by the actual mechanical force of the infusion solution, but by an indirectly created negative pressure zone, risk for luminal endothelial damage is minimal. By maintaining the structural integrity of the native venous endothelium, viability and the anti-thrombotic activities of the intact endothelium are preserved. Nonetheless, prolonged contact time between thrombus and endothelium increases endothelial damage.[8]

In a retrospective review of the management of DVT, Kasirajan et al demonstrated the efficacy of the AngioJet PMT system in thrombus removal, venous patency restoration, and relief of symptoms. In that study, more than 90% thrombus clearance with PMT alone was achieved in only 4 patients (23.5%). Adjunctive thrombolytic agents were used after unsatisfactory PMT in 9 of 17 patients with a lesser amount of clot extracted with the PMT catheter. Improvement in clinical symptoms was noted in 82% of patients over 11-month follow-up. [4]

No large randomized control studies have been published looking at mechanical thromboectomy in DVT. An analysis by Karthikesalingam et al (2011) on 16 retrospective case series on the use of mechanical thromboectomy in DVT, with a total of 481 patients, looked at its efficacy. They found successful thrombolysis (>50% lysis) in 83-100% of patients. Bleeding complications requiring transfusion were seen in 7.5%. Symptomatic PE was seen in <1%. No procedure related deaths or strokes were seen. Of the studies that did look at mid-term follow up, 75-98% of patients demonstrated significant improvement of symptoms and similar improvement in radiological findings. [9, 13]

PMT with added lytic agents restores venous patency in the operating room or intervention suite, obviating the need for intensive care unit stays or multiple transfers for repeat venography. Furthermore, lower total dosage and decreased infusion time of thrombolytic agents were used than with catheter-directed thrombolysis alone. This synergistic treatment method resulted in lower overall cost and reduction in hemorrhagic complications in this limited study. [10, 11]

To date, the largest DVT thrombolytic database is the venous registry (Mewissen 1999), which is a prospective registry of patients with a DVT who underwent CDT with urokinase.473 patients were enrolled with 287 patients followed up at 1 year. 83% of patients had thrombolysis >50%. There was also a strong relationship between early thrombus removal and 1-year patency (primary patency rate of 60%). Major bleeding complications occurred in 11%, most often at the puncture site. 1% of patients developed a PE. Two patients (<1%) died (one from PE and one from intracranial hemorrhage). Grunwald and Hofmann (2004) retrospectively analyzed 74 patients who underwent CDT for DVT and compared Urokinase, Alteplase and Reteplase. They found that there was no statistical difference between infusion times, success rates and complication rates between the three agents. However, they did find that the new recombinant agents are significantly less expensive than Urokinase in the United States. No RCTs have been published looking at CDT in acute DVT. However, currently the TORPEDO trial is underway which is a large scale RCT looking at the efficacy of CDT vs anticoagulation in treatment of DVT. Mid-term results show that CDT is superior to anticoagulation therapy alone in the prevention of recurrence of DVT, reduction in PTS, and reduction of hospital stays .Similarly the ATTRACT Trial is currently underway looking at the efficacy of CDT. [15, 16, 17]

In this preliminary study inferior vena cava filters were placed at the discretion of the treating surgeon. Retrievable inferior vena cava filters are efficacious in preventing pulmonary embolus and in trapping embolus. However, controversy remains as to use of filters as a prophylactic intervention.[8, 9, 10]

We have seen no associated complications, such as insertion site thrombosis, filter migration, or vena cava injury. In addition, the removable filters were successfully retrieved. The window for removal, however, has been short (2 weeks), but newer filters are available that allow a longer time frame for placement. [9, 10, 12]

Moreover, adjunctive endovascular techniques, such as balloon angioplasty with or without stent placement, were successfully performed in the same setting of PMT. There are limitations to our study. This report is a retrospective observational analysis of patients who underwent treatment with a new technique for venous thrombus extraction. Randomization or direct comparisons between mechanical thromboectomy with lysis to mechanical thromboectomy alone were not part of this limited preliminary study. Although we are encouraged by the excellent outcomes presented, we cannot be absolutely certain that the lytic agent conferred additional benefit to PMT. The need for inferior vena cava filters and adjunctive therapy such as angioplasty were at the discretion of the surgeons performing the individual procedures. Routine follow-up duplex ultrasound scanning was not performed to assess venous patency and valve function or to document recurrent thrombotic events. [18, 19, 20]

## CONCLUSIONS

PMT with the AngioJet thromboectomy catheter with or without concomitant thrombolysis is a new use of existing technologies that should promote more rapid and complete thrombus extraction over standard therapy (anticoagulation). Only long-term prospective randomized studies comparing mechanical thromboectomy with or without thrombolysis with standard anticoagulation therapy will provide definitive data to support our supposition. Venoplasty and stenting as a primary intervention for the underlying venous stenosis markedly improves the patency and the outcome.

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