A New Method for Aggressive Management of Deep Vein Thrombosis: Retrospective Study of the Power Pulse Technique

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Failure to treat deep vein thrombosis (DVT) is associated with significant morbidity and mortality. Anticoagulation, although effective at preventing clot progression, is not able to prevent postthrombotic syndrome. Catheter-directed thrombolysis is a more aggressive alternative, with some small studies suggesting a better long-term outcome, but the associated risks are significant, and the treatment can require 2–3 days in a monitored setting. This report describes the power pulse technique, in which mechanical thrombectomy is combined with thrombolytic agents to maximize the effectiveness of the treatment and reduce the need for prolonged infusion and its associated risks. A 24-patient retrospective study showed complete thrombus removal (>90%) in 12 patients, substantial thrombus removal (50%–90%) in seven patients, and partial thrombus removal (<50%) in five patients. All 24 patients had resolution of presenting symptoms. Only two patients required blood transfusion, and one patient experienced temporary nephropathy.

ALTHOUGH anticoagulation is effective in the treatment of deep vein thrombosis (DVT), it does not prevent postthrombotic syndrome (PTS), the long-term negative side effect of venous damage that consists of pain, swelling, discoloration, and leg ulcers (1). Catheter-directed thrombolysis (CDT) with urokinase or tissue plasminogen activator is a more aggressive alternative and has been reported to be associated with better long-term outcomes, but the use of thrombolytic agents increases the risk of bleeding, and CDT can be a prolonged procedure that requires 2–3 days in a monitored setting (2).

The use of mechanical thrombectomy devices alone or as an adjunct to CDT helps to minimize the risks of thrombolysis and maximize the effectiveness of the treatment; however, as mechanical thrombectomy is currently performed, prolonged lysis may still be necessary. Herein, we describe a new procedure known as the power pulse technique and present a multicenter retrospective study of 24 patients treated for iliofemoral DVT. The power pulse technique is a pharmacomechanical therapy in which the blood clot is bathed in the lytic agent before it is evacuated. Early aggressive therapy with the power pulse technique can be completed within 2–4 hours, and this retrospective review shows it to be equally efficacious and less time-consuming compared with other published techniques, with fewer return trips to the angiography suite. The purpose of this study was to evaluate the safety and efficacy of this method as a viable option for the aggressive management of DVT.

MATERIALS AND METHODS

Study Patients

Between March 2003 and October 2004, 24 patients from six academic and community-based sites with documented acute (<14 days) or subacute (>14 days) iliofemoral and/or inferior vena cava (IVC) DVT were treated with the power pulse technique. Patients were identified from a registry maintained by the departments of vascular and interventional radiology at the participating institutions. All identified patients were included in the study. The investigation was approved by the institutional review boards of each of the participating medical centers.

The study included 16 men and eight women (Table 1). Informed consent was obtained from each patient after discussion of risks and benefits

Table 1
Patient Demographics (N = 24)

Demographic Category	Value
Sex	
Male	16
Female	8
Mean age ± SD, range (y)	43 (16–86)
IVC filter use	
None	5
Preexisting	9
Second retrievable filter placed and removed	1
Filter placed before Power Pulse treatment	8
Filter placed after Power Pulse treatment	1
Mean procedure time, range (h)	3.25 (1.75–6.5)

associated with thrombolysis of DVT and the off-label use of mechanical thrombectomy devices. The age range of those treated was 16–86 years (mean age, 43 y). All 24 patients had severe leg swelling, and three patients presented with phlegmasia cerulea dolens. Twenty patients had acute DVT, and four had subacute DVT. All 24 patients had thrombosis of at least one iliac vein. Fifteen of the patients had extension into the IVC, and nine patients had involvement of the popliteal or infrapopliteal vessels. Ten patients had preexisting IVC filters, and nine had undergone placement of filters before the procedure. IVC filters were not present in five cases. One patient had a filter placed after the intervention. One of the patients with a preexisting filter had a second retrievable filter placed that was removed after the procedure was concluded. Four patients had medical histories that excluded them from typical venous lysis procedures, including one patient each with gastrointestinal bleeding and postpartum bleeding and two with recent surgical procedures.

The Power Pulse Technique

The power pulse technique has been previously described for use in peripheral arterial and portal venous occlusion (3,4). The technique is described here as a method to aggressively treat DVT.

The power pulse technique requires an AngioJet rheolytic thrombectomy system (Possis Medical, Minneapolis, MN). It consists of an Xpeedior catheter (0.035-inch guide wire compatible),

a pump set, and a drive unit (**Fig 1**). In the usual thrombectomy mode, the pump set and drive unit produce a high-velocity saline solution jet that is directed backward from the tip of the device to outflow channels to produce a zone of low pressure (−1 atm) at the catheter tip. The low-pressure environment causes fragmentation and aspiration of the clot through the effluent lumen.

Ultrasound (US) guidance was used during vascular access. The ipsilateral popliteal vein was punctured while the patient was prone, or, if the common femoral vein was confirmed patent by US, common femoral vein puncture was performed with the patient in a supine position. A 4-F or 5-F micropuncture set was typically used for initial access. After diagnostic venography was performed, the 4-F micropuncture catheter was exchanged for a 6-F sheath. A 0.035-inch guide wire was then used to cross the thrombus and advanced into the IVC. The 6-F Xpeedior catheter was advanced over the 0.035-inch guide wire into the thrombus. The AngioJet was set up in the usual fashion but with the return port closed on the catheter with a stopcock. Closure of the return port of the AngioJet catheter enabled a powerful spray of diluted lytic agent (10-20 mg of alteplase [Genentech, South San Francisco, CA] or 250,000–500,000 U of urokinase [Abbott Laboratories, North Chicago, IL] in 50–100 mL of saline solution depending on the length of thrombus being treated) to be injected in an antegrade and retrograde direction with each 0.6-mL pulse of the AngioJet catheter at 1-mm increments throughout the length of

the clot. When the entire dose was administered, the lytic agent was allowed to bathe and soften the clot for 20–45 minutes. The AngioJet catheter was reintroduced with its return port open. With outflow restored, the AngioJet device was used in its usual thrombectomy mode to further disrupt and evacuate thrombus. Repeat venography was performed to assess extent of thrombus removal. Additional AngioJet thrombectomy was then performed in areas of residual clot.

At the time of the procedure, the interventionalist performed adjunctive measures as indicated, which included CDT if there was residual clot and balloon angioplasty and/or stent placement. When CDT was used, the total duration of thrombolysis and amount of thrombolytic agent used were recorded. Some of the patients had preexisting IVC filters at the time of the procedure. At the discretion of the interventionalist, some other patients without preexisting filters had a filter placed. Systemic heparin was also administered during and/or after the procedure.

Pre- and postprocedural laboratory values were also recorded for all patients. These values included hemoglobin and hematocrit, blood urea nitrogen, and creatinine levels, and activated partial thromboplastin time. After the procedure, patients were cared for in a standard inpatient ward or an intensive care or "step-down" unit, depending on whether CDT was administered. Patients were discharged with an oral anticoagulation regimen for at least 6 months.

Data Collection

Medical records, radiology reports, procedural data, and venograms were reviewed for all patients in the study. The extent and cause of DVT, endovascular treatment modalities used, procedural time, total thrombolytic agent dose, venographic and clinical success, complications, and other data were recorded in detailed case report forms. Complications were classified as major or minor according to the Society of Interventional Radiology reporting standards. Specifically, intracranial bleeding or bleeding resulting in death, transfusion, surgery, or cessation of thrombolytic therapy was
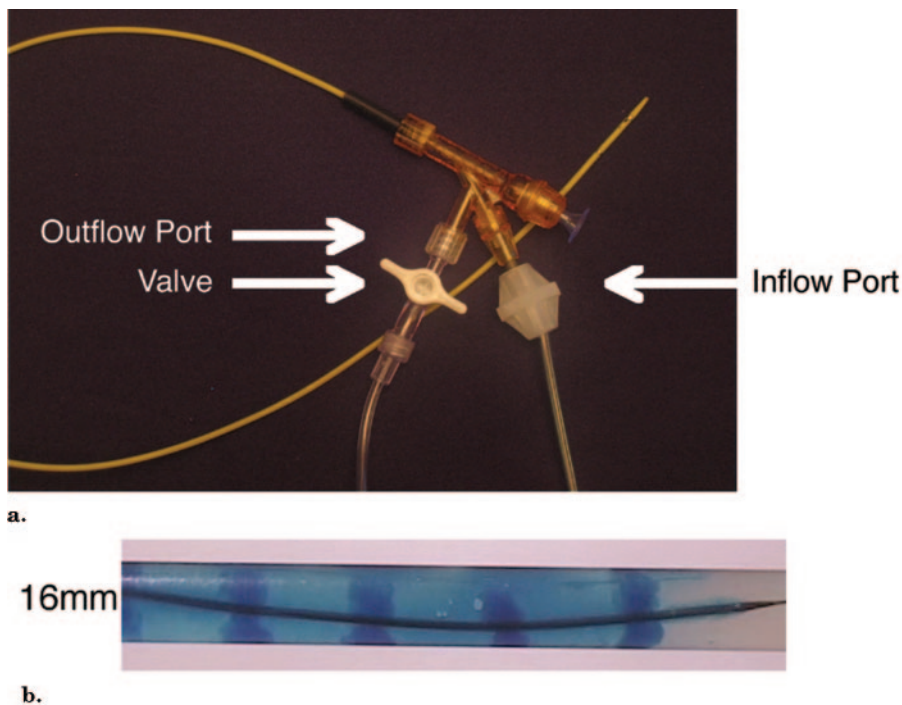
Figure 1. Illustration of the power pulse technique. In the usual thrombectomy mode, the Xpeedior catheter (0.035-inch guide wire–compatible) **(a)** has inflow and outflow ports that are connected to a separate pump and drive unit that produces the low-pressure environment that causes fragmentation and aspiration of the clot. In the power pulse technique, the valve on the outflow port is initially closed, and thrombolytic agent is infused into the clot **(b)**. Then, after the lytic agent is allowed to bathe the clot for 20–45 minutes, the valve on the outflow port is opened, and the thrombolytic agent and the now-softer thrombus are aspirated.

classified as major bleeding. Nephropathy was defined by a postprocedural increase in serum creatinine level of 20% or greater.

All pre- and postprocedural venograms were evaluated for evidence of thrombus removal by an expert interventional radiologist. Thrombus removal was graded as complete (>90% of thrombus), substantial (50%–90%), or partial (<50%). Early clinical success was assessed in each treated limb and was defined as the presence of technical success in conjunction with considerable improvement in lower-extremity swelling that lasted at least 3 days or until hospital discharge. Follow-up data were obtained from return visits or by telephone contact with the patient.

RESULTS

At least partial technical success with the power pulse technique was achieved in all 24 patients. Complete removal of thrombus was achieved in 12 of 24 cases (50%), substantial removal was achieved in seven cases (29%), and partial success was achieved in five cases (21%). Fifteen of the 24 patients (63%) had angioplasty for underlying venous lesions, and nine of these patients also had stents placed in an iliac vein. Sixteen procedures were completed (ie, clot removed and angioplasty/stent placement) in a single visit to the angiography suite, with a mean procedure time of 3.25 hours and procedure times ranging from 1.75 to 6.5 hours. In all 24 cases, there was clinical and venographic improvement after completion of the intervention (**Figs 2, 3**).

Eight patients (33%) received adjunctive CDT to improve the final outcome. In all eight, lysis was completed in less than 24 hours with only a single additional visit to the angiography suite. As seen in **Table 2**, only two of 13 patients with primary DVT (15%) required adjunctive CDT, whereas six

of 11 patients with recurrent DVT (55%) required this therapy. Of patients with subacute symptoms of DVT (>14 days), two of four (50%) required adjunctive thrombolysis. This additional treatment was used in only six of 20 patients (30%) with acute symptoms (<14 days). CDT was also required in a greater proportion of patients in whom the clot was not allowed to bathe in lytic agent for more than 30 minutes (40% vs 22%).

Complications related to the power pulse technique included six cases of 5% or greater decrease in hematocrit (25%), with two patients requiring transfusions. Seven patients experienced hemoglobinuria or myoglobinuria, which is a common occurrence with the use of the AngioJet device. One patient experienced nephropathy, which resolved. Several patients experienced shaking chills of unknown cause, which resolved spontaneously. Surgical fasciotomy was required to treat compartment syndrome in one patient after the procedure. There were no other major or minor complications resulting from treatment with the power pulse technique.

Follow-up after a minimum of 1 month (average, 5.3 mo) was obtained in 21 of the 24 patients. Of these 21, only two patients experienced recurrent symptoms, and one of these was successfully treated a second time with the power pulse technique.

DISCUSSION

The incidence of DVT is as high as 1–2 per 1,000 persons per year. DVT and pulmonary embolism cause an estimated 250,000–600,000 hospitalizations per year in the United States and result in more than 100,000 deaths (5–7). Although pulmonary embolism is the most feared consequence of DVT, other more chronic effects are more common and contribute to significant morbidity. Ninety percent of patients with DVT experience chronic venous insufficiency, and many will experience chronic limb edema, pain, skin hyperpigmentation, venous claudication, and venous stasis ulcers years after diagnosis (8). This constellation of symptoms is called PTS. Venous occlusion and damage to the valves of the femoral and popliteal veins has been implicated as the cause of PTS (9).

a.   **b.**   **c.**

Figure 2. Case study 1 of a 52 year-old man with an IVC filter (Simon nitinol) placed for DVT several years earlier, who presented with bilateral lower-extremity swelling. The patient reported that he had noticed the problem only the day before. Duplex imaging evaluation demonstrated bilateral occluded iliac veins but patent femoral veins. Venography via the right CFV demonstrated that the iliac veins were patent, but the flow through them was very slow and the IVC was thrombosed at the level of the filter **(a,b)**. The power pulse technique was performed. The IVC thrombus, including the region of the filter, was laced with 10 mg of alteplase in 50 mL of normal saline solution. After 30 minutes, the AngioJet device was passed through these same areas. The postprocedural venogram demonstrated brisk flow **(c)**. Follow-up at 11 months showed the patient to be asymptomatic with normal extremities.

The usual therapy for DVT centers on anticoagulation. Initial treatment involves intravenous or subcutaneous anticoagulation with unfractionated heparin or low-molecular-weight heparin, and then oral anticoagulation therapy is initiated with warfarin at a dosage titrated to achieve a target International Normalized Ratio of 2.0–3.0. This protocol effectively inhibits the thrombotic process and allows for at least partial clearance of existing thrombus by endogenous plasmin (10–15). Current guidelines recommend the continuation of warfarin therapy for 3–6 months depending on the cause of DVT. In cases of recurrent venous thromboembolic disease and in patients with hypercoagulable disorders or other permanent risk factors, lifelong anticoagulation may be indicated (16).

Although anticoagulation is effective in preventing recurrence of DVT, it does not prevent the future development of PTS, which may occur years after the original thrombotic event. This is especially true of iliofemoral and IVC thrombosis, in which there is a higher incidence of acute and late morbidity even with proper oral anticoagulation (17).

Prevention of PTS requires prompt removal of the thrombus from the vein. To achieve this, CDT was proposed as a means to gain the benefits of thrombolytic therapy while minimizing the potential systemic side effects by focusing delivery of the agent directly to the thrombus. A prospective multicenter registry, the National Venous Thrombolysis Registry, was

Figure 3. Case study 2 of a 48-year-old man with protein S deficiency, multiple DVTs, and four previous pulmonary emboli, who presented with persistent lower-extremity and scrotal swelling **(a)**. The patient received 72 hours of CDT, and a stent was placed in the left common iliac vein. Forty-eight hours after therapy was discontinued, duplex imaging evaluation demonstrated the femoral veins to be patent, but the iliac veins were occluded. Venography via the femoral vein confirmed thrombosis of the iliac veins and IVC **(b)**. The power pulse technique was performed. The left iliac vein and IVC thrombi were laced with 500,000 U of urokinase. After 45 minutes, the AngioJet device was passed across the same regions. The previously placed left common iliac stent was extended into the IVC with an 18-mm × 60-mm Wallstent **(c)**. The procedure was then performed on the right iliac vein. Postprocedural venography demonstrated marked improvement in clot burden and flow. However, there was residual clot in a previously placed IVC filter that was partially limiting flow **(d)**. A Berenstein catheter was advanced to the level of the residual thrombus, and an infusion of urokinase was begun at 40,000 U/h overnight. Repeat venography the next morning showed brisk flow throughout the iliac veins, the IVC, and the IVC filter **(e)**. The patient's lower-extremity and scrotal swelling returned to normal in 72 hours **(f)**. At discharge, the patient had decreased lower-extremity and scrotal edema and decreased pain and was given a warfarin regimen. Four-month follow-up showed the patient to be asymptomatic with normal extremities.

established to collect and analyze data for a large number of patients with lower-extremity DVT treated with CDT (18). In this study of 287 patients, long-term patency was dependent on two factors: the degree of initial lysis and whether stents had been placed. At 12 months, 79% of limbs with initially complete lysis remained patent, compared with only 32% of limbs with an initial lysis of less than 50%. Of limbs treated with stents, 74% were

Table 2
Characteristics of Adjunctive CDT

Characteristic	Total Patients	Patients Treated with Adjunctive CDT
DVT symptom chronicity	24	8
Acute	20	6 (30)
Subacute	4	2 (50)
Occurrence of DVT		
Primary	13	2 (15)
Recurrence	11	6 (55)
Wait time after lytic infusion		
<20 minutes	15	6 (40)
>30 minutes	9	2 (22)

Note.—Values in parentheses are percentages.

patent at 1 year compared with 33% of limbs that did not receive stents. In addition, in a study reported by Comerota et al (19), patients treated with thrombolysis assessed by an 80-item quality of life questionnaire reported improved overall physical function and fewer postthrombotic symptoms than did patients treated with only anticoagulation.

Despite these findings, there are significant barriers to the widespread use of CDT. These include the associated bleeding risks and the intense effort required for CDT. In the National Multicenter Venous Registry, major bleeding complications requiring transfusion were found in 11% of cases, and an additional 16% of patients had minor bleeding complications. Additionally, CDT requires multiple visits to the angiography suite and long infusion times that may be difficult for a patient to endure. It also requires observation in a monitored setting such as an intensive care or step-down unit.

In an effort to produce more rapid lysis and reduce visits to the angiography suite, PMT has evolved as an alternative or adjunct to CDT for the treatment of DVT. The AngioJet rheolytic thrombectomy system is approved for native vessels, specifically for use in infrainguinal peripheral arteries.

A study examining the efficacy of the AngioJet device (20) found that mechanical thrombectomy alone achieved greater than 90% thrombus removal in 24% of patients with DVT and 50%–90% removal in 35% of patients. However, after CDT was used as an adjunct in the remaining patients

without contraindications, the overall clinical success rate was 82%. This and other studies have demonstrated that, although mechanical thrombectomy may be an effective alternative to CDT, the combination of both therapies is even more powerful (21,22).

The power pulse method is a further modification of pharmacomechanical therapy. In this procedure, thrombolytic agents are infused directly into the thrombus via the AngioJet catheter. After the thrombolytic agent is given the opportunity to bathe the thrombus, the AngioJet is used in the usual manner to evacuate the clot. When the clot is removed, venous lesions predisposing to thrombus formation are treated as part of the intervention with angioplasty or stent implantation as needed.

In our retrospective study, all 24 patients treated with power pulse technique and adjunctive measures had resolution of symptoms. The intervention took an average of 3.25 hours and required a second trip to the angiography suite only if CDT was performed. For 19 of the 21 patients with follow-up data available, there was no recurrence of symptoms for a mean of 5.3 months.

In the power pulse technique, immediately after the elimination of venous clot, the interventionalist has the opportunity to identify culprit venous stenoses that can be treated with angioplasty and stent implantation. In our case series, 15 patients were able to benefit from venous angioplasty, including nine who also received stents in an iliac vein.

In the power pulse technique, thrombolytic agents are infused di-

rectly into the clot and are later evacuated along with the clot. Because the infusion is performed in an area of venous circulation with low flow, there is minimal concern about systemic distribution of the thrombolytic agent. In our case series, six patients had a hematocrit decrease of greater than 5%, with only two patients (8%) requiring transfusions. In the other six patients, bleeding secondary to the use thrombolytic agents was not always the clear cause of the hematocrit decrease. Aspiration of blood and hemolysis can cause a significant hematocrit decrease and can result in hemoglobinuria or myoglobinuria, as was seen in seven patients in this series. Nephropathy caused by hemoglobinuria or contrast agents can occur but is likely transient, and no irreversible renal insufficiency was seen in this study population.

Unlike previously described pharmacomechanical therapies, the power pulse technique does not necessarily require CDT before or after the intervention. In 16 of our patients, CDT was avoided completely, with excellent outcomes. Further analysis of the eight patients who required adjunctive CDT may demonstrate how the need for CDT can be limited in future interventions. In patients in whom the clot was allowed to bathe in lytic agent for a longer time (>30 min), adjunctive CDT was necessary less often. This probably reflects the ability of the lytic agent to penetrate deeper and make more of the clot amenable to aspiration and evacuation. Similarly, in patients with subacute DVT or recurrent DVT, in whom there was likely more organized thrombus, adjunctive CDT was required more often. However, it is important in this series to note that even patients who required adjunctive CDT required it for less than 24 hours, which reflects an improvement over CDT alone or over previously described combinations of CDT and pharmacomechanical therapy.

CONCLUSION

From this case series, we find that the power pulse technique is a rapid and effective means to treat extensive DVT, thereby possibly reducing the long-term sequelae of chronic DVT. Because anticoagulation alone does not remove thrombus immediately,

and CDT can require multiple trips to the angiography suite and long stays in monitored settings, pharmacomechanical therapy with the power pulse technique is preferred to relieve patients' symptoms and improve their overall quality of life. Our retrospective study confirms that this technique shortens procedure time and produces rapid thrombus removal, resulting in clinical and venographic improvement with fewer complications and less intensive patient monitoring than in some series examining CDT alone.

This study was limited in that it was a retrospective study of patients from several institutions that dealt with a procedure performed without a standardized protocol. Additionally, the lack of long-term follow-up limits our ability to draw conclusions about the long-term efficacy of the technique and its impact on PTS. However, the encouraging results of this small study warrant further investigation of this new strategy for the treatment of DVT in the form of randomized prospective trials to compare the power pulse technique with typical CDT and standard anticoagulation therapy. Until that happens, we encourage practitioners to use this technique and contribute to the increasing pool of data regarding this therapy by reporting their results.

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