Treatment of Chronic Deep Vein Thrombosis Using Ultrasound Accelerated Catheter-directed Thrombolysis

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WHAT THIS PAPER ADDS

Few data are available concerning the feasibility, safety, and efficacy of ultrasound-accelerated, catheter-directed thrombolysis (UACDT) in "chronic" lower extremity deep vein thrombosis. Our study illustrates the beneficial role of UACDT using the EkoSonic system. Importantly, the study showed a higher treatment success rate with significant reduction in thrombolytic duration, thrombolytic dosage, and hemorrhagic complications. Additional clinical studies are necessary to validate the benefit and corroborate our results.

Objective: To evaluate the feasibility, efficacy and safety of ultrasound-accelerated catheter-directed thrombolysis (UACDT) in the delayed treatment of lower extremity deep venous thrombosis (DVT).

Design: Twelve patients with unilateral iliofemoral or femoropopliteal DVT (mean symptom duration 92 ± 44 days) were prospectively investigated.

Method: UACDT was performed using recombinant human tissue plasminogen activator delivered using the EKOS EkoSonic system. Stents were deployed if indicated by post-procedure venography. Follow-up comprised weekly duplex ultrasound for 1 month and monthly thereafter.

Results: Successful thrombolysis occurred in 11/12 limbs (92%; complete 6/12, partial 5/12) after a mean infusion time of 26 ± 7 hours. 2/12 patients required angioplasty and stent insertion. At a mean follow-up of 9 (6–15) months, 10/11 (91%) veins were patent whereas 1/11 re-occluded at 2 months (patient with protein-C deficiency). 2/11 limbs developed symptoms/signs of post-thrombotic syndrome and 3/11 had developed deep vein reflux (duplex ultrasound). 2/12 patients experienced peri-catheter bleeding but no major hemorrhage or symptomatic pulmonary embolism occurred.

Conclusions: This preliminary evidence suggests that UACDT may be a safe and effective option for the delayed treatment of lower limb DVT.

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INTRODUCTION

Deep venous thrombosis (DVT) of the lower extremity is recognized as a cause of both pulmonary embolism (PE) and the post-thrombotic syndrome (PTS).[1] Although anti-coagulation is currently considered the standard of care to prevent PE and recurrent DVT, it remains ineffective in removing thrombus burden and consequently does not prevent PTS, which can appear months to years after an acute DVT.[2]

A novel technique, ultrasound-accelerated catheter-directed thrombolysis (UACDT), has been developed to rapidly and completely lyse existing thrombus, thereby decreasing the potential risk of PTS.[3,4] The mechanism proposed is that this technique integrates high-frequency, low-intensity ultrasound (US) with standard catheter-directed thrombolysis (CDT) in order to accelerate clot dissolution, reducing treatment time, drug dosage, and the incidence of thrombolysis-related complications. US waves are known to increase permeability of biological structures including tissue, vessel walls, and thrombus. This increased permeability combined with the pressure gradient associated with an acoustic field is thought to facilitate delivery of therapeutic agents into, and past, older organized thrombus into regions where dissolvable clot remains.[5,6]

Several studies demonstrate evidence of safety and effectiveness in removing acute venous thrombosis using EKOS,[7–9] but limited data are available supporting its use for chronic DVT, particularly in patients with long-standing symptoms. Treatment of chronic DVT has long been a clinical problem as the thrombus has a tendency to adhere and organize after the acute stage. Therefore, the aim of this

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study is to examine the feasibility of using UACDT as a safe and effective option to treat patients with chronic DVT defined as having symptoms for greater than 28 days.

METHODS

Study patients

Between September 2009 and October 2011, 21 consecutive patients who had a first episode of proximal DVT were considered for this prospective study. Patients with chronic lower extremity DVT were eligible. The diagnosis of DVT was confirmed by duplex ultrasound (DUS) and venography. For this purpose, a Toshiba Xario SSA-660A series (Toshiba Medical System Corporation, Nasu-Tokyo, Japan) color Doppler ultrasound system was used with a 4.8—11 MHz (Toshiba PLT 704 AT) linear transducer. Proposed exclusion criteria included isolated infrapopliteal thrombosis, recurrent ipsilateral DVT, pre-existing leg ulcers, a short life expectancy or contraindications to anticoagulation, contrast media, and thrombolytic agents. Contraindications to thrombolytic agents were considered to be active internal bleeding, recent cerebrovascular accident, allergy to thrombolytic agents, recent major surgery, recent serious gastrointestinal bleeding, recent serious trauma or pregnancy. Computerized tomography angiography (CTA) was used to exclude subclinical pulmonary embolism, prior to the UACDT in all patients. Informed consent for participation in the study was obtained according to the guidelines of our institutional review board and the local ethics committee, which approved the study.

Treatment procedure

The procedures were performed in a hybrid vascular operating room. Patients were positioned prone and the popliteal vein was catheterized with a 6 F micro access set under DUS guidance using a 21 G needle and a 0.46 mm diameter guide wire after which ascending venography was performed. UACDT was performed using the EKOS EkoSonic Endovascular System (EKOS Corporation, Bothell, WA, USA).

A 5.4 F multi-lumen drug delivery catheter and matching US coaxial core wire are provided by the manufacturer with treatment zone lengths varying between 6 and 50 cm (Fig. 1). The drug delivery catheter was navigated over a 0.035 inch guide wire so that the treatment zone traversed the entire clot and the tip exited the thrombus. After final positioning, the guide wire was exchanged for a matching US core wire containing a series of US transducer elements (2.2 MHz, 0.45 W) distributed approximately 1.0 cm apart to evenly deliver US energy radially along the distal coaxial infusion zone. After priming the drug lumens of the catheter with sub-therapeutic unfractionated heparin (1,000 U/mL), continuous infusion of the thrombolytic agent was initiated through the side-holes along the treatment zone of the UACDT infusion catheter. A recombinant human tissue plasminogen activator (tPA), Alteplase (Actilyse, Boehringer Ingelheim GmbH, Germany), was given in a 5 mg bolus followed by an infusion at 0.02 mg/kg/hr during the

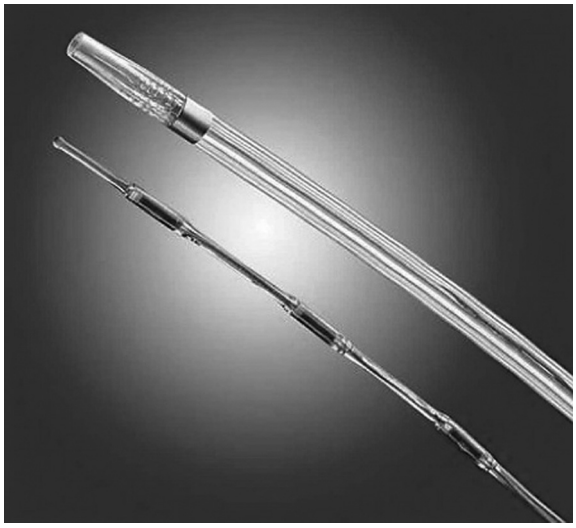

Figure 1. EKOS System, consisting of a multi-lumen infusion catheter with removable coaxial ultrasound core and a control unit, simultaneously delivers high-frequency, low-energy (2.2 MHz, 0.45 W) ultrasound energy and thrombolytic drug into the thrombus. Ultrasound exposure enhances the permeability of the thrombus to the lytic agent.

treatment. US energy was initiated via the core wire, simultaneously with the infusion of the tPA. The system control unit, which monitors temperature and power in the infusion zone via a series of thermocouples in the catheter, automatically adjusted power to optimize lysis of the treated segment.

Patients were followed up in the intensive care unit and continuously monitored to detect clinical signs and symptoms of complications such as pulmonary embolism or hemorrhage. Blood samples were taken every 12 hours for hematocrit, hemoglobin, partial thromboplastin time, fibrinogen, and platelet count to adjust the heparin dose and detect potential blood loss.

We made the decision of when to stop thrombolytic therapy based on each patient's disease and anatomy, graphical information displayed on the ultrasound system control unit and control venographies taken. We stopped UACDT when we transferred a patient to the angiography suite. Venography was performed before removing the introducer to determine whether there was recanalization of the treated vein. If we did not believe that recanalization of the target vessel was adequate at venography, we then reinserted the drug delivery catheter back into the target vessel and continued the UACDT for an additional 12 hours. If the patient had chronic DVT, if the length of occlusion was long or if the patient had a very large thrombus burden, we performed thrombolytic treatments for as long as 39 hours.

After thrombolysis, further adjunctive procedures consisting of PTA and stent placement were performed if there was an underlying iliac vein stenosis >50%.

Warfarin sodium was routinely started prior to hospital discharge and this was continued for at least 6 months, with the dose adjusted to maintain an international normalized ratio (INR) of 2.0—3.0. Adjuvant elastic compression therapy was recommended and encouraged for more than 1 year.

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