Pharmacomechanical Thrombectomy of Acute Deep Vein Thrombosis with the Trellis-8 Isolated Thrombolysis Catheter

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PURPOSE: To evaluate the performance of the Trellis-8 isolated thrombolysis catheter during single-session pharmacomechanical thrombectomy (PMT) combined with low-dose thrombolysis with tissue plasminogen activator (TPA) in the treatment of patients with acute deep vein thrombosis (DVT) and multiple comorbidities.

MATERIALS AND METHODS: Retrospective analysis was performed of 19 consecutive patients with acute above-knee DVT treated by PMT with the Trellis device followed by venous angioplasty and stent placement. Isolated thrombolysis with low-dose TPA was used with all patients. Concurrent therapies included retrievable inferior vena cava filter insertion ($n = 4$). The primary endpoint was restoration of rapid inline venous flow; the secondary endpoint was thrombus clearance.

RESULTS: Restoration of rapid inline venous flow was achieved in all cases; thrombus removal was less than 50% in one case (4%), 50%–95% in 18 cases (82%), and at least 95% in three cases (14%). The median administered dose of TPA was 13.4 mg per patient. The mean treatment time was 91 minutes per limb (range, 61–129 min), with a mean of 21 minutes per thrombosed segment (range, 8–31 min). There were no major complications. Primary patency rate of the treated venous segments at 2 days was 86% ($n = 19$) and the primary assisted patency rate was 100% at 30 days. Two patients died of advanced malignancy at 17 and 24 days.

CONCLUSIONS: The Trellis system was an effective method for the treatment of acute DVT. Based on the present data, the Trellis system could prove to be a safe and feasible single-session PMT method for the treatment of acute DVT in a broader patient population and warrants further investigation in a large-scale study.

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Abbreviations: CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, IVC = inferior vena cava, PMT = pharmacomechanical thrombectomy, TPA = tissue plasminogen activator

CONSEQUENCES of deep vein thrombosis (DVT) include pulmonary embolism and venous insufficiency (1–3). Early thrombolysis is attractive because it offers early resolution of acute symptoms and may decrease the risks of valvular insufficiency and postthrombotic syndrome (4,5). Early thrombolysis also has been shown to improve patients' quality of life (6).

During the past decade, considerable interest has developed in the treatment of DVT with catheter-directed thrombolysis (CDT) as an alternative to more standard, conservative regimes involving anticoagulation (7–13). This has important implications for cost containment, patient safety, and bed use in the future treatment of this condition. However, thrombolytic therapy has inherent risks of hemorrhage and is therefore contraindicated in some instances per guidelines from the National Institutes of Health (3). In addition, the average treatment duration for CDT is 40 hours (8). This prolonged therapy typically requires access to a monitored bed, multiple trips to the interventional radiology suite to assess progress, prolonged bed rest, patient discomfort and confinement, and multiple laboratory evaluations including fibrinogen and activated partial thromboplastin time.

More recently, several studies have described the use of mechanical thrombectomy to treat venous thrombosis. Most of these treatments have been

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based on initial overnight CDT (4,5,14, 15), with mean infusion times of 23 hours (range, 16–37 h), followed by mechanical thrombectomy. A number of small studies describe the use of mechanical thrombectomy alone in patients with contraindications to thrombolysis (16,17).

The purpose of this study was to evaluate the performance of the Trellis-8 isolated thrombolysis catheter (Bacchus Vascular, Santa Clara, Calif) during single-session pharmacomechanical thrombectomy (PMT) in a group of patients with acute DVT and multiple comorbidities.

MATERIALS AND METHODS

Recruitment Method

Referring physicians were informed of the availability of the Trellis-8 catheter for single-session PMT and were asked to consider offering it to their patients with above-knee DVT. The majority of patients originated from the oncology department of University College Hospital in Galway, Ireland, an academic tertiary care institution; the interventional radiologist who would perform the procedures had a close working relationship with the oncology department.

Inclusion and Exclusion Criteria

Patients included in this study had acute DVT (≤2 weeks) involving veins of the lower extremity from the distal femoral vein (above the knee) to the inferior vena cava (IVC). Patients were excluded who had chronic DVT (>2 weeks) or below-knee DVT or were allergic to iodinated contrast medium.

Study Group Characteristics

From January to July 2005, 19 consecutive patients with acute above-knee DVT (nine men, 10 women; age range, 4–72 years; mean age, 45 y) were treated for acute DVT affecting the IVC, the iliofemoral venous system, or the femoral vein in the thigh. A single operator performed the treatment with the patients in standard inpatient hospital beds. Neither intensive care nor high dependency unit beds were required. The time between the development of symptoms and the initiation of interventional procedures ranged from 1 day to 14 days (mean, 9 d). The symptoms were swelling of the leg (n = 22; 100%) and pain (n = 17; 77%). As a result of involvement of the IVC, three patients had symptomatic limbs bilaterally. Four patients had clinical phlegmasia cerulea dolens (20%). Three other patients (16%) had skin blisters. No patient had frank venous gangrene. Four patients (21%) had recently proven pulmonary thromboembolism (one was symptomatic and three were asymptomatic and diagnosed on contrast medium–enhanced computed tomography [CT]) and had an IVC filter placed before the onset of therapy. The diagnosis of acute DVT was based on duration and a combination of compression US (n = 16), digital subtraction venography (n = 2), and contrast medium–enhanced CT/magnetic resonance imaging (n = 4).

Risk Factors and Predisposing Conditions.—All patients were hospitalized at the time of diagnosis and subsequent treatment. Fourteen of the 19 patients (73%) had a previously diagnosed malignancy. Four patients (21%) had a hereditary coagulation abnormality. Two patients (10%) had recent trauma leading to immobility. One patient (5%) had sepsis with retained products of conception after an intrauterine death at 26 weeks. Only one patient (5%) had recently undergone surgery (for an ankle fracture treated 8 days earlier) and one had no known risk factors. One patient (5%) had received a femoral vein dialysis catheter. Several patients had more than one risk factor. Therefore, the main risk factor in our group for development of DVT was malignancy.

Major Comorbidities.—Two patients were subject to bleeding risks: one patient had a hemorrhagic brain tumor and one patient had gastrointestinal bleeding within 3 months before the study. This is why the primary endpoint of the study was restoration of rapid inline venous flow.

Previous or Concomitant Treatment.—Therapies before intervention consisted of bed rest with leg elevation, low-pressure thigh-high stockings, and standard anticoagulation to therapeutic levels (ie, warfarin or low molecular weight heparin). All patients were receiving oral or intravenous anticoagulation at the time of referral, and this therapy had failed in eight of 19 patients (52%).

After a detailed discussion of the risks and benefits of and alternatives to the procedure, informed consent was obtained from each patient and a copy was placed in the chart. Institutional review board approval was neither sought nor required; all products used were commercially available at the time of the study.

Treatment Description

PMT with the Trellis device involves the following: puncturing a nonthrombosed vein distally, performing diagnostic venography, working proximally, aiming for rapid clot clearance in a single setting, and then treating any underlying stenoses. Ultrasound (US)-guided venous access was used in every case. Access was attained via the popliteal vein (n = 16; 73%) or femoral vein (n = 6, 27%).

The Trellis-8 peripheral infusion system is an 8-F, percutaneous, 0.035-inch-diameter, over-the-wire device consisting of two balloons (occlusion diameter range of 5–16 mm). These balloons are separated by 15 cm or 30 cm, and the area between the balloons has multiple holes for drug infusion (**Fig 1**). The guide wire (typically an Amplatz wire; Cook, Bloomington, Ind) was removed from the central channel of the device, followed by the insertion of a sinusoidal-shaped nitinol wire connected to a motor drive. The two portions were locked together with a Luer-Lok system. We inflated the balloons to occlude the vessel so the treatment area was essentially isolated from the remainder of the circulation (**Fig 1**). We then administered diluted thrombolytic agent through the infusion port of the device. This pharmacomechanical combination enables focused treatment of thrombus within a targeted vessel. In our study, tissue plasminogen activator (TPA; Genentech, South San Francisco, Calif) was used. Depending on the length between the two balloons (15 cm or 30 cm), a slightly increased concentration of TPA was administered (3 mg or 5 mg TPA diluted to 6 mL with normal saline solution, respectively).

We infused the combined TPA/saline solution mix into the patient in aliquots of 1 mL every minute while the sinusoidal wire was rotated at 3000 rpm. Every minute, the contact point of the wire was shifted in a longitudi-