CLINICAL STUDY

Technical Results of Vacuum-Assisted Thrombectomy for Arterial Clot Removal in Patients with Acute Limb Ischemia

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ABSTRACT

Purpose: To assess the efficacy and safety of a vacuum-assisted thrombectomy (VAT) catheter system for treating patients with acute limb ischemia (ALI).

Materials and Methods: A retrospective study evaluated VAT systems (Penumbra, Alameda, California) in a consecutive series of 30 patients with ALI. ALI was defined as clinical symptoms within 2 weeks of presentation. The primary endpoint was improvement in blood flow across a lesion by improvement in Thrombolysis in Myocardial Infarction (TIMI) score that was adapted to peripheral arteries. Concomitant balloon angioplasty or stent placement in addition to VAT was considered a complementary treatment. Additional thrombectomy treatments, such as thrombolysis and mechanical thrombectomy, were considered technical failures. Target lesions were grouped anatomically into above-the-knee (ATK) or below-the-knee (BTK) lesions.

Results: In 30 patients, 33 lesions (ATK, n = 13; BTK, n = 20) were treated. No complications were attributed to the VAT systems. The primary endpoint was obtained in 24/33 (72.7%) lesions (BTK, 17/20 [85.0%]; ATK, 7/13 [53.9%]; $P = .050$ by χ^2 test). TIMI scores were similar at baseline but differed after VAT between the ATK and BTK groups ($P < .025$ by t test). ATK lesions required more concomitant angioplasty or stent placement, or both ($P < .015$ by χ^2 test).

Conclusions: VAT is a safe, technically successful short-term therapeutic option for thrombus removal in patients with ALI.

ABBREVIATIONS

ATK = above-the-knee, ALI = acute limb ischemia, BTK = below-the-knee, TIMI = Thrombolysis in Myocardial Infarction, VAT = vacuum-assisted thrombectomy

Acute limb ischemia (ALI) is characterized as the sudden (< 14 d) presentation of ischemia and is typically associated with acute thrombus. Various endovascular treatment options are available when managing patients presenting with ALI that are aimed at reestablishing arterial blood flow and thrombus treatment (1–8). These options include intraarterial thrombolysis with or without ultrasound assistance (4,5) as well as various thrombectomy devices (1). Intraarterial thrombolytic infusion therapy is often performed as two procedures occurring between a catheter-based infusion lasting ≥ 12 hours. During the intraarterial lysis, the patient is usually observed in a higher care nursing unit. These procedures not only are time-consuming and resource-consuming but also are associated with the risk of bleeding. Some thrombolytic techniques can be used as a single-setting procedure, but these procedures still are associated with the risk of bleeding as well as a risk of distal embolization. The advantages of thrombectomy devices include the immediate reestablishment of blood flow without the use of thrombolytics, reducing the risk of bleeding and potentially reducing costs (7). Vacuum-

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assisted thrombectomy (VAT) is a catheter-based thrombectomy system that does not use intraarterial thrombolytics. The purpose of this study is to report the short-term technical success of a consecutive series of patients with ALI in whom VAT was performed for arterial thrombus removal to reestablish blood flow in the lower extremities.

MATERIALS AND METHODS

Patients and Study Design

This was a retrospective study to report the success of VAT in patients treated for ALI. A consecutive series of 30 patients (mean age, 70.7 y ± 15.1) treated with VAT at a tertiary referral center between July 2014 and May 2015 was evaluated. The study was approved by the hospital institutional review board before data collection and analysis and was subsequently performed in accordance with the Health Insurance Portability and Accountability Act and the Declaration of Helsinki (9). Based on the retrospective nature of the study, the need for informed consent was waived.

VAT Devices

The VAT systems (Penumbra, Inc, Alameda, California) used consisted of four components: a catheter, a separator wire, reinforced tubing, and an aspiration pump. The catheters are tapered and do not collapse during maintained suction. The study involved the use of several catheter types, including some primarily designed for cerebrovascular arteries, which are referred to as the Penumbra System (Penumbra, Inc), and others primarily designed for peripheral arteries, which are referred to as the Indigo System (Penumbra, Inc). The main difference between these systems is the catheter diameter (French size), as the main principles and components of the VAT systems are the same. A separator wire (size matched to the catheter used) can be used if deemed necessary by the operator. The purpose of the separator wire is to help break up thrombus at the catheter tip and prevent occlusion of the catheter, aiding in aspiration of thrombus. The tubing attaches the catheter to the vacuum pump and has a valve switch to turn the system on and off. The tubing is maximized to the catheter diameter used and reinforced to prevent collapse during application of the suction. The pump is a portable device that provides continuous negative pressure for suction.

Although procedural details varied slightly on a case-by-case basis depending on the operator and clinical presentation, the standard technique for using the VAT systems was followed. Arterial access was established from the contralateral common femoral artery with placement of a 45-cm 6-F sheath (Destination; Terumo Medical Corporation, Somerset, New Jersey). A sheath with a removable valve is recommended to avoid shearing any attached thrombus when the catheter is removed through the sheath valve.

After diagnostic angiography established the lesion location (Fig 1), the patient was anticoagulated using unfractionated heparin or bivalirudin. All lesions were treated using the 3MAX (n = 4 lesions), CAT5 (n = 15 lesions), 5MAX (n = 13 lesions), or 6-F Neuron (n = 1 lesion) catheters (Penumbra, Inc). The catheter size was selected to approximate the size of the treatment vessel. In larger vessels, such as the common femoral artery and

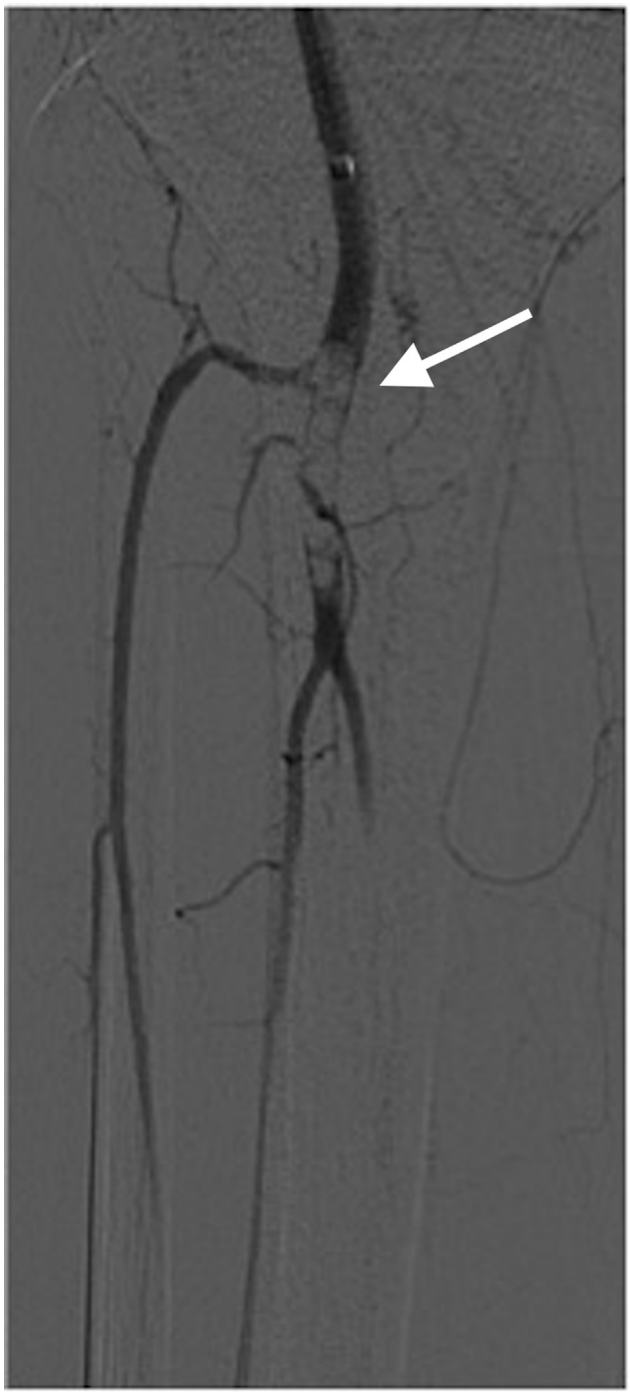

Figure 1. An arterial thrombus obstructing blood flow in the tibioperoneal trunk (arrow) at baseline.