CLINICAL STUDY

Utility of a Power Aspiration–Based Extraction Technique as an Initial and Secondary Approach in the Treatment of Peripheral Arterial Thromboembolism: Results of the Multicenter PRISM Trial

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ABSTRACT

Purpose: To investigate the safety and initial efficacy of XTRACT, a power aspiration–based extraction technique for treatment of peripheral arterial thromboembolism with the use of the Penumbra/Indigo system.

Materials and Methods: A total of 79 patients were enrolled: 39 (49.4%) underwent XTRACT as the initial therapy and 40 (50.6%) underwent XTRACT after failed catheter-directed thrombolysis or other mechanical intervention or for removal of distal emboli that occurred during an intervention. Occlusion locations were as follows: 36.7% (n = 29) in the profunda, common, or superficial femoral artery; 35.4% (n = 28) in the popliteal artery; 15.2% (n = 12) in the tibial artery; 7.6% (n = 6) in the peroneal artery; and the remainder in the common iliac (n = 1), external iliac (n = 1), sciatic (n = 1), and brachial (n = 1) arteries.

Results: Complete or near-complete revascularization (Thrombolysis In Myocardial Infarction [TIMI] grade 2/3 flow) was achieved in 87.2% of patients (68 of 78) immediately after the XTRACT procedure and before any other intervention. Successful revascularization was achieved in 79.5% of patients (31 of 39) as an initial treatment and in 92.5% (37 of 40) as salvage or secondary therapy. After additional adjunctive endovascular interventions, TIMI grade 2/3 flow was achieved in 96.2% of patients (76 of 79). Complete thrombus removal and restoration of normal flow (TIMI grade 3) was achieved in 77.2% of patients (61 of 79) after all endovascular treatment was completed. No patients required surgical revascularization. No device-related adverse events occurred.

Conclusions: XTRACT was safe and effective for revascularization of acute or subacute peripheral arterial occlusions as a primary therapy or as a secondary therapy after other endovascular techniques had failed.

ABBREVIATIONS

ALI = acute lower-extremity ischemia, CDT = catheter-directed thrombolysis, IQR = interquartile range, OD = outer diameter, PAT = percutaneous aspiration thrombectomy, PMT = pharmacomechanical thrombectomy, TIMI = Thrombolysis In Myocardial Infarction

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Acute lower-extremity ischemia (ALI) comprises approximately 20% of the in-hospital peripheral vascular workload and is associated with high in-hospital amputation rates of 10%–30%, 1-year mortality rates of 15%–20%, and low amputation-free survival rates of 50%–65% (1). Although catheter-directed thrombolysis (CDT) is associated with a lower morbidity rate and is as effective as surgery for stage I and IIa ALI (2,3), it takes substantial time to be effective. According to the Inter-Society Consensus for the Management of Peripheral Arterial Disease II guidelines (4), surgery is the recommended approach for more critical stage IIb and early stage III disease.

Surgical management of arterial thromboembolism, often with the use of balloon embolectomy, has been associated with incomplete revascularization, considerable morbidity, and rare serious complications (4,5). Percutaneous aspiration thrombectomy (PAT) with the use of sheaths and catheters has been used as an alternative to surgical balloon embolectomy since at least 1985 (6). In the setting of acute embolic arterial occlusions, high success rates of more than 85% have been reported with PAT (7). In other series, or in more difficult clinical situations associated with ALI, variable results have been reported with high technical failure rates (6,8). For example, Oğuzkurt et al (8) reported only a 36% success rate in subacute thrombus, with a vessel injury rate of 15%.

The Penumbra/Indigo system (Penumbra, Alameda, California) is designed for aspiration thromboembolectomy with Food and Drug Administration–cleared Indigo catheters available from 3 F to 8 F in size (**Fig 1**). The size-matched "separator" allows the catheter to be cleared of occlusive material without catheter removal from the area of thrombus. It has a pump-driven vacuum for consistent aspiration, which, unlike syringes, allows for single-operator or "hands-free" operation. Previous studies have validated the ability of the Penumbra system to access the cerebral arteries and to safely recanalize sites of large vessel occlusion, often in settings with tortuosity (9). This system could broaden the application of aspiration thromboembolectomy while potentially lowering the incidences of vessel injury, hemolysis, and distal embolization reported with other approaches (10).

The purpose of the present study (PRISM [A Retrospective Analysis of Technical Success Using the Penumbra and Indigo Systems for Mechanical Thrombectomy in the Periphery] Trial; *ClinicalTrials.gov* ID code NCT02085551) was to determine the initial safety and technical effectiveness of the Penumbra/Indigo system in performing XTRACT (a power aspiration-based extraction technique) for mechanical clot extraction in a broad patient population including those with ALI secondary to thromboembolism, those with acute distal emboli that occurred during endovascular interventions, and those in whom other forms of clot removal or dissolution (e.g., CDT) had failed.

MATERIALS AND METHODS

PRISM was a single-arm, multicenter, retrospective analysis of patients in whom the XTRACT technique was performed with the Penumbra/Indigo system ("study device"). Data on a consecutive series of patients who had undergone reperfusion with the study device were collected and analyzed retrospectively according to a protocol that was approved by the institutional review board at each of the study sites. The study began collecting procedural data on patients treated with the Penumbra system (indicated for the neurovascular system) until the Indigo system became available. The Indigo system is cleared by the US Food and Drug Administration for reperfusion of occlusions in peripheral arterial and venous systems and was released in 2014. Catheter sizes and designs of the peripheral system are very similar to the catheters designed for the cerebral circulation. The peripheral catheters are built with fewer transition zones. There is no difference in aspiration proficiency for equivalent catheter sizes. In addition, the 8-F catheters are exclusive to the peripheral Indigo system.

Initially, 52 patients were treated with the Penumbra system. Beginning in 2014, another 27 patients were treated with the Indigo system. Data on all patients were pooled for analysis. Seven patients treated with the 8-F catheters were also analyzed separately to assess potential benefit of the larger catheter size.

Patient Selection and Technique

A total of 79 patients who presented to one of five sites in the US with peripheral arterial occlusion and were treated with the study device were enrolled in the study. Numbers of patients enrolled by site were 24, 19, 18, 13, and 5 patients. Patients included those with acute limb ischemia, previous attempted CDT that had failed, attempted mechanical thrombus removal with a different device that had failed, and distal iatrogenic emboli secondary to previous endovascular interventions. Patients were not excluded based on the severity of their comorbidities or limited life expectancy. Patients were only excluded from the study in the event of participation in another clinical investigation that might confound the results of the present study. All patients treated at the five centers with the use of the study device during the trial period, other than those in other clinical trials, were enrolled.

The median age of the patients was 69 years (interquartile range [IQR], 60–78 y; range, 34–95 y). Baseline characteristics are detailed in **Tables 1** and **2**. Regarding vessel locations, 36.7% of occlusions (n = 29) were in the common, profunda, or superficial femoral arteries, 35.4% (n = 28) in the popliteal, 15.2% (n = 12) in the tibial, and 7.6% (n = 6) in the peroneal arteries. Common iliac (n = 1), external iliac (n = 1), sciatic (n = 1), and brachial (n = 1) arterial occlusions were also treated.

For access, retrograde femoral, antegrade femoral, and brachial access sites were all used. Treatment of thrombi and emboli was performed completely at the operator's discretion. Operators were all experienced interventionalists with > 5 years of experience. At the two institutions with training programs, attending physicians performed the procedures with trainees in all cases.