CLINICAL STUDY

Aspiration Thrombectomy versus Conventional Catheter-Directed Thrombolysis as First-Line Treatment for Noniatrogenic Acute Lower Limb Ischemia

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ABSTRACT

Purpose: To examine the efficacy, safety, and procedural costs of percutaneous aspiration thrombectomy (PAT) as a first-line treatment for noniatrogenic acute lower limb ischemia (ALI) compared with conventional catheter-directed thrombolysis (CDT).

Materials and Methods: All patients who underwent endovascular intervention for ALI from January 2015 to August 2017 were included. Fifteen patients were treated with the use of primary PAT and 27 patients were treated with the use of primary CDT. The primary end point was complete thrombus clearance with improvement in Thrombolysis in Myocardial Infarction (TIMI) score. Adjunctive treatment for thrombus removal was considered to indicate technical failure. Treatment of underlying chronic disease was not considered to indicate technical failure. Procedural costs for each patient were calculated by itemizing all disposable equipment, facility overheads, and staff costs.

Results: Of the 15 primary PAT patients, technical success was achieved in 8 (53%); the remaining 7 (47%) required adjunctive CDT. Of the 27 primary CDT patients, technical success was achieved in 25 (89%); the remaining 2 (11%) required adjunctive PAT. There were 4 complications in the primary PAT group: 2 were procedure related and of a minor grade. There were 8 complications in the primary CDT group: All were procedure-related, including 2 major groin/retroperitoneal hemorrhage and 1 death from intracranial hemorrhage. Limb salvage was attained in all patients. There were no significant differences in average procedural costs per patient between the 2 groups.

Conclusions: First-line use of PAT for endovascular treatment of ALI can reduce the need for CDT, with no significant cost difference.

ABBREVIATIONS

ALI = acute lower limb ischemia, CDT = catheter-directed thrombolysis, PAT = percutaneous aspiration thrombectomy, TIMI = Thrombolysis in Myocardial Infarction

Acute limb ischemia (ALI) due to emboli or in situ thrombosis can be catastrophic with the sudden threat to limb viability (1). A variety of endovascular treatment options are available. Of these, conventional catheter-directed thrombolysis (CDT) is 1 of the most commonly used and well-established techniques. However, disadvantages of this

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technique include the need for multiple procedures, interval care in a higher-level nursing care unit, and risk of hemorrhage (2). The Penumbra aspiration thrombectomy device (Alameda, CA) is an endovascular device with a proven track record for treating embolic stroke. Larger catheter sizes, branded as Indigo, allow for more effective treatment in the peripheral vasculature. Previous studies of percutaneous aspiration thrombectomy (PAT), including those using the Indigo device, have typically included patients with both noniatrogenic and iatrogenic acute lower-limb ischemia (3–5). The latter group typically have shorter lengths of occlusion, where PAT performs better (5). In a number of these studies, PAT was used as an adjunct to CDT or other techniques rather than as a first-line treatment. The purpose of the present study was to examine the efficacy, safety, and procedural costs of PAT with the use of the Indigo device as a first-line treatment for noniatrogenic acute lower-limb ischemia compared with conventional CDT.

MATERIALS AND METHODS

Patients and Study Design

This was a retrospective study examining all patients who underwent endovascular treatment for noniatrogenic acute lower-limb ischemia at a tertiary referral center from January 2015 to August 2017. Patients were treated with PAT with the Indigo device and/or conventional CDT. This study was approved by the hospital's review board, with the need for informed consent waived owing to the retrospective nature of the study. Eligible cases were identified from a prospectively maintained audit database. Data were retrospectively gathered from electronic and paper records. There were 44 potentially eligible cases identified with 2 subsequently excluded because no endovascular treatment beyond initial diagnostic angiography was performed. Of the 42 included cases, 15 were treated with primary PAT and 27 with primary CDT. Demographics and comorbidities of these 42 patients are summarized in **Table 1**. Both groups were similar except for a higher prevalence of concomitant atrial fibrillation in the PAT group. A study flowchart is shown in the **Figure**.

Technical Details

Exact procedural details varied slightly on a case-by-case basis depending on operator and patient-related factors. All procedures were performed by 1 of 5 interventional radiologists or vascular surgeons with more than 10 years of experience. All operators were familiar with the use of PAT and conventional CDT for treating acute thromboembolic events in other vascular beds besides the lower limb arterial system examined in this study. The timing of treatment was dictated by clinical urgency. All Rutherford 1 and 2a patients received treatment within 24 hours of the decision to treat. All Rutherford 2b patients received treatment within 4 hours of the decision to treat. A standard technique was used to establish common femoral artery access under ultrasound guidance, perform baseline diagnostic angiography, and attempt to traverse the thrombus by a guidewire. If traversal was successful, the decision to treat with the use of either PAT or CDT was then determined by the operator.

Where conventional CDT was used as first-line treatment, 10 mg Alteplase recombinant tissue plasminogen activator (rt-PA) was injected via an end-hole or multi-sidehole thrombolysis catheter as a pulse-sprayed bolus to "lace" the thrombus, followed by an rt-PA infusion of 0.5 mg/h. Unfractionated heparin was infused through the sheath concurrently at 500 U/h. The rt-PA infusion was left unchanged provided there were no adverse events and fibrinogen levels remained at $\geq$1.5 g/L. The rate was halved if fibrinogen levels decreased to $<$1.5 g/L. Fibrinogen levels were monitored on a 6-hourly basis. Care was provided in a higher-level nursing care unit (1:2 nurse-to-patient ratio) for the duration of thrombolysis. Follow-up angiography was undertaken every 8–12 hours. In the absence of any contraindications, CDT was continued if thrombus load remained and discontinued when treatment was complete or in the event of an adverse event. CDT was not continued beyond 48 hours.

Where PAT was used as first-line treatment, the device instructions were followed. Aspiration catheter sizes used were as follows: 8-F in the iliac arteries and larger femoropopliteal arteries ($\geq$6 mm caliber), 6-F in smaller femoropopliteal arteries, and 3-F in the tibial arteries. Aspiration thrombectomy was continued until no further thrombus could be aspirated. If angiography showed further thrombus remaining, conventional CDT would be initiated in the manner described above.

Definitions and Outcome Measures

Acute lower-limb ischemia was defined as the onset of ischemic symptoms within 14 days of presentation. Vessel occlusion was confirmed before angiography by means of duplex ultrasonography or computerized tomographic angiography. The clinical severity of ischemia was classified by the Rutherford classification system for acute lower limb ischemia (6). Lesions were described by their proximal extent and by the number of arterial levels affected (supra-inguinal, infrainguinal/supragenicular, or infrainguinal/infragenicular).

Technical success of the primary procedure was defined as complete thrombus clearance accompanied by an improvement in Thrombolysis in Myocardial Infarction (TIMI) score of $\geq$1 to an absolute TIMI score of $\geq$2. Adjunctive treatment to achieve thrombus clearance was considered to indicate technical failure. Additional techniques (such as balloon angioplasty and/or stenting) to treat underlying chronic disease were recorded but not considered to indicate technical failure of the primary technique of thrombus clearance. TIMI scores were obtained at baseline, after clearance of thrombus, and at treatment completion (including balloon angioplasty or stenting for underlying chronic disease). TIMI scoring was evaluated by 2 readers