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Clinical Assessment of Endovascular Stenting Compared with Compression Therapy Alone in Post-thrombotic Patients with Iliofemoral Obstruction

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WHAT THIS PAPER ADDS

This study adds information regarding the effect of endovascular stenting of post-thrombotic patients with iliofemoral obstruction. Using the Villalta score, it appears that only patients with severe post-thrombotic syndrome benefit from endovascular procedures, indicating that perhaps this should be used in the selection criteria.

Objective: The study aimed to evaluate the clinical results of stent placement in post-thrombotic patients with iliofemoral obstruction compared with results in those treated with elastic compression stockings (ECS).

Methods: A retrospective analysis of post-thrombotic patients with iliofemoral obstruction was conducted in a single institution from January 2007 to December 2012. Duplex ultrasound and selective phlebography were performed in patients with chronic venous disease and previous deep venous thrombosis (DVT). Post-thrombotic syndrome (PTS) with iliofemoral vein obstruction (Villalta score $\geq$10) was diagnosed in 216 patients. Among these, 122 patients were treated by stent placement, and the remaining 94 patients were treated conservatively with 30–40 mmHg ECS therapy. Technical success, stent patency rates, and complications were recorded after the interventions. Results including Villalta score, pain, edema, ulcer, and popliteal vein reflux were assessed in both groups.

Results: Percutaneous iliofemoral venous stenting was successful in 116 of 122 patients (95.1%) without major complications. Follow up periods ranged from 3 to 58 months (median 21 months). Cumulative primary, assisted primary, and secondary stent patency rates at 3 years were 68.9%, 79.0%, and 91.6%, respectively. Among patients with severe PTS, the Villalta score decreased significantly with endotreatment, compared to the score of those treated by ECS therapy (16.12 $\pm$ 4.91 vs. 10.98 $\pm$ 5.89, $p < .01$). However, there was no significant score improvement between the two therapies in patients with moderate PTS (6.59 $\pm$ 2.37 vs. 5.75 $\pm$ 3.03, $p = .22$). There was a significantly higher 24 month recurrence free ulcer healing rate in the endotreatment groups (86.6% vs. 70.6%, $p < .01$). Both edema and pain improved significantly in the two groups. The popliteal vein reflux rate showed no significant change after endotreatment.

Conclusions: Endovascular treatment is a safe, effective, and feasible method to correct the iliofemoral obstruction of PTS. Only post-thrombotic patients with severe PTS as assessed by the Villalta score appear to benefit from the endovascular treatment.

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INTRODUCTION

The most frequent sequela that develops after deep venous thrombosis (DVT) is post-thrombotic syndrome (PTS), and it has a cumulative incidence of 20–50% within 2 years.[1,2] PTS has a wide range of symptoms and signs including heaviness, venous ectasia, edema, pain, hyperpigmentation, and, in severe cases, leg ulceration.[3,4] Despite anticoagulant therapy for treatment of acute DVT, there is still a high incidence of severe symptoms in patients with iliofemoral PTS.[5] Previously, the only surgical option in post-thrombotic patients with iliofemoral obstruction, who failed conservative treatment was venous bypass; however, this is a challenging procedure with poor long-term graft patency.[6]

Considering the poor results of venous grafts, endovascular treatment has been developed as an alternative in the treatment of post-thrombotic patients with iliofemoral vein obstruction.[7] Initial studies on its use have recently

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reported favorable technical success rates and mid-term clinical and stent outcomes, which indicate the value of endovascular therapy in treating PTS with iliofemoral obstruction.[8–11] In 2014, a scientific statement from the American Heart Association (AHA) mentioned that for severely symptomatic patients with post-thrombotic occlusion of their common femoral vein, iliac vein, and vena cava, combined operative and endovenous disobliteration may be considered.[12]

Most of the studies on stenting of PTS have shortcomings, for example small number of patients with short-term follow up and lack of control groups, such as compression therapy and medication.[13–15] Additionally, some of the published experience predates the development of objective reporting standards for the diagnosis and outcome assessment of PTS.[12]

The aim of this study was to assess the impact of endovascular treatment on the severity of PTS with iliofemoral obstruction, the ulcer healing rate, lower limb swelling and pain, as well as popliteal vein reflux when present. Patients treated with stocking compression therapy formed the control group.

METHODS

Study group

After obtaining institutional review board approval, a retrospective review of the Shanghai Ninth People's Hospital database was completed between January 2007 and December 2012. All patients with chronic venous disease and previous DVT underwent duplex ultrasound (DUS). One experienced vascular technician performed the DUS using a Siemens ACUSON CV-70 scanner with a 3.5 or 5 MHz probe. Iliac, femoral, popliteal, and deep calf veins were evaluated in the longitudinal plane. The following criteria indicated post-thrombotic disease: vessel wall abnormalities (wall thickening, irregularities, reduced or occluded lumen) and flow in prominent collateral veins. Ascending phlebography (the injection of contrast medium into a dorsal foot vein) was selectively performed in patients whose iliac veins were difficult to visualize on DUS. To identify post-thrombotic patients with iliofemoral obstruction, transfemoral/popliteal venography was performed in cases with either: (1) visible pelvic collateral veins, ascending lumbar vein or stenosis/occlusion of the iliofemoral vein on phlebography, or (2) peak vein velocity ratio of >2.5 across the suspected iliofemoral vein obstruction or absence of blood flow on DUS.

All patients suffering from PTS with iliofemoral obstruction ($>50\%$ stenosis or occlusion on venography) and moderate/severe symptoms (Villalta score ≥ 10) were included in the present study and advised to undergo endovascular treatment. A proportion of patients declined endovascular treatment because of concerns with potential complications, while others could not afford the cost. In these cases, thigh high 30—40 mmHg elastic compression stockings (ECS) were applied for long-term treatment. These patients formed the control group. Popliteal vein reflux was also recorded in the two groups. Reflux was defined as flow retrograde to the direction of physiological flow, lasting for more than 0.5 seconds. Exclusion criteria included acute DVT less than 6 months prior to treatment; prior DVT thrombectomy or thrombolysis including failed stenting; mild symptoms (Villalta score <10); the presence of ulcers unrelated to venous disease; significant obstruction ($>50\%$ stenosis) of the femoral vein; post-thrombotic changes associated with the inferior vena cava; bilateral iliofemoral vein; popliteal vein and/or calf vein; as well as any contraindications to the use of ECS such as dermatitis or allergy; and an ankle brachial index of <0.9.

Procedure

Endovascular treatment was performed under local anesthesia. The common femoral vein was chosen as the preferred access in patients with involvement of the iliac vein only. In case of common femoral vein obstructive lesions, popliteal vein access was gained using the phlebography roadmap or with ultrasound guidance. After sheath insertion, a bolus of 80 U/kg of heparin was injected and supplemented as required to maintain an activated clotting time of >250 seconds. The technical details of cannulation and recanalization of iliofemoral obstruction have been outlined previously.[16] In brief, after successful access and heparinization, a straight 0.018 inch or 0.035 inch hydrophilic guide wire was directed through the iliofemoral vein obstruction under the guidance of a matched multipurpose catheter or angled tip catheter. Sometimes a wire loop technique was used to find the path of least resistance. Percutaneous transluminal angioplasty (PTA) was performed after successful cannulation of the iliofemoral lesion. Balloon catheters (EverCross; ev3 Endovascular, Inc.; ReeKross; ClearStream Technologies, Wexford, Ireland; PowerFlex P3; Cordis Corporation) with diameter of 4—16 mm and length of 60—220 mm were used for dilation. Elastic recoil after PTA was very common. As a result, self expanding stents (EverFlex; ev3 Endovascular, Inc.; LIFESTENT; BARD, Tempe, Arizona; WALLSTENT; Boston Scientific Corporation) with diameter of 10—16 mm and length of 60—150 mm were implanted to cover the entire lesion after PTA. The common femoral vein stent was deployed, usually below the inguinal ligament, to ensure adequate inflow in patients with recoil after common femoral vein PTA. Post-dilation was necessary because of the common phenomenon of recoil after stenting. Antero-posterior and oblique venography was performed after intervention to confirm the final results and identify any complications. All patients provided written informed consent before treatment.

The post-interventional treatment protocol included administration of 4100 I.U AXa/0.4 mL nadroparin (Fraxiparine, GlaxoSmithKline, Brentford, UK) every 12 hours while an inpatient and oral anticoagulation with warfarin (International Normalized Ratio of 2—3) for at least 6 months after discharge. No ECS was applied in the moderate PTS group as most moderate patients improved rapidly after stenting. Thigh high ECS (30—40 mmHg) were