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ORIGINAL ARTICLE

Randomized study of different approaches for catheter-directed thrombolysis for lower-extremity acute deep venous thrombosis

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KEYWORDS
catheter-directed thrombolysis;
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Background/Purpose: To investigate the feasibility, effectiveness, and complications of catheter-directed thrombolysis (CDT) using three different approaches for acute lower-extremity deep venous thrombosis (DVT).
Methods: A total of 106 patients with acute DVT were enrolled in this study. Forty-one patients received CDT through the small saphenous vein (Group A), 35 through the great saphenous vein (Group B), and 30 through the popliteal vein (Group C). Iliac vein balloon dilation and stenting was performed in 65 cases.
Results: The vascular approach route was not statistically related to limb edema reduction rates (Groups A, B, and C: 82.3 ± 7.6% vs. 81.6 ± 6.0% vs. 83.9 ± 6.1%), nor to thrombolysis rates (63.5 ± 7.7% vs. 66.9 ± 8.4% vs. 66.1 ± 2.7%). The procedure was significantly shorter for Groups B and C. No significant difference was found between Groups B and C. Most complications occurred in Group A. The complication rate in Group B was the lowest. Eighty-eight patients were followed up for 7–24 months. Of these, 78 were pain-free and without limb edema; six showed rethrombosis.
Conclusion: CDT is an effective method to manage acute DVT. Of the three routes tested, the small saphenous vein route was associated with more frequent complications. Great saphenous vein catheterization was more effective because of its lower complication rate.

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

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Introduction

Deep venous thrombosis (DVT) is commonly associated with vascular surgery, but there are very many other causes. Millions of patients are at risk of developing DVT, and it is estimated that > 250,000 new cases occur every year. Pulmonary embolus is the most serious complication of DVT, and > 50,000 patients die every year as a result of pulmonary embolus.[1] Even when DVT is diagnosed expeditiously, many patients are inadequately treated and experience a 20—50% recurrence rate. Furthermore, ~30% of patients who develop DVT experience life-long post-thrombotic syndrome.[2]

In addition to the acute risks of DVT, there are important long-term complications. Thrombus can cause valvular incompetence and luminal obstruction, which can ultimately lead to chronic deep venous insufficiency and chronic venous disease, such as chronic varicose ulceration, hyperpigmentation, pain, and edema, all of which represent a significant socioeconomic burden.[3] The main long-term goal of treatment for DVT is to prevent chronic deep venous insufficiency. Therefore, although the patency of the thrombolysed vein is of relevance, the venous valve function may be at least as important.

Thrombolytic agents may be delivered by systemic infusion, local-regional administration, or catheter-directed therapy. Systemic administration is associated with long infusion times, a high incidence of partial thrombolysis, and a significant rate of bleeding complications. In catheter-directed thrombolytic therapy (CDT), the tip of the catheter is placed inside the thrombus and the thrombolytic agent is administered directly therein. It is hoped that CDT preserves venous valves, thus restoring flow in the deep venous system and minimizing the long-term complications of DVT.[4] To date, the approaches for CDT reported in the literature include the right jugular vein, contralateral femoral vein, popliteal vein, great saphenous vein, and small saphenous vein. The popliteal vein is the choice in most procedures for catheterization; in our experience, however, this approach may not be possible in some patients. It is also important to review techniques to identify the safest and most effective approaches.

In this study, we reviewed the records of 106 patients admitted to our hospital with acute lower-extremity DVT who were treated with CDT using different access routes, including the small saphenous vein, great saphenous vein, and popliteal vein, between September 2011 and November 2013.

Methods

Ethics approval

This study was reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Soo Chow University, Suzhou, China (File No: 2011270).

Study groups

Between September 2011 and November 2013, 126 patients with extensive acute lower-extremity DVT were initially enrolled into this study and were randomized into three groups (Figure 1). Twenty patients were excluded from this study because of high blood pressure, thrombocytopenia, limb infection, or cardiac insufficiency, leaving 106 patients. Demographic information collected included age, sex, cause of DVT, duration of DVT before admission and which extremity was involved. Presenting symptoms included limb pain, phlegmasia, and edema. All patients were confirmed to have DVT by conventional venography before CDT, and only patients with extensive thrombosis including the femoropopliteal vein and iliac vein were recruited. All patients were randomly allocated to one of three groups. Randomization was determined sequentially, i.e., since the presentation of patients to the hospital is effectively random, procedures were allocated according to the previous allocation. Patient 1 received Procedure A, Patient 2 received Procedure B, Patient 3 received Procedure C, Patient 4 received Procedure A, etc. Groups A—C underwent catheterization via the small saphenous vein, the great saphenous vein and the popliteal vein, respectively. Of the 20 patients excluded from this study, there were one patient, seven patients, and 12 patients excluded from Groups A, B, and C, respectively. The group size was determined by the study duration, i.e. the study was planned to be carried out over 2 years, which meant that ~100 patients would be recruited during the period, based on previous experience of serious DVT incidence.

Prior to CDT, all patients were evaluated by the same member of the operation team to confirm their suitability for thrombolysis therapy. The inclusion criteria were: acute lower-extremity DVT (symptoms lasting < 14 days); extensive DVT (including iliac, femoral, and popliteal veins); age 15—75 years; thrombosis confirmed by anterograde venography using the dorsal vein; and informed signed consent by the patient to participate. The exclusion criteria were: contraindications to the use of anticoagulant drugs, thrombolytic drugs or intravenous contrast media; history of intracranial or internal hemorrhage in the previous 3 months; history of serious trauma or major operation in the preceding 4 weeks; pregnancy; high blood pressure (systolic blood pressure >180 mmHg, diastolic blood pressure >110 mmHg); and history of ipsilateral DVT.

Safety

For safety, the first procedure was to insert a retrievable filter into the inferior vena cava. If the temporary filter was free of thrombus, it was removed; otherwise, the filter was implanted permanently.

Catheter implantation

(1) Catheterization through the small saphenous vein: Patients were placed prone on the angiographic table, and a longitudinal incision of approximately 2 cm was made between the ipsilateral external malleolus and the Achilles tendon to expose the small saphenous vein. A 5F sheath was inserted, through which all subsequent catheter and wire exchanges were performed. Under the guidance of