

Research Article

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Simultaneous Thrombolysis and Venous Angioplasty in Acute Ilio-femoral Thrombosis after IVC filter Insertion and Novel Balloon Catheter Models

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Abstract

Four patients with extensive acute iliofemoral and popliteal vein thrombosis and partially extending into the inferior vena cava (IVC) with diffuse swelling of lower limb and gluteal region were studied. Initially, Gunther Tulip (Cook) IVC filter was placed in all patients. A 5F multipurpose catheter with side holes was placed in common iliac vein bifurcation and thrombolysis was done for 18 hours with diluted streptokinase infusion at 50,000 U/hr. Thereafter, a 5 mm × 4 cm peripheral balloon was advanced through the clots to mid or lower femoral vein level and thrombolysis was done for 18 hours with streptokinase infusion through the balloon's 035 wire port. The balloon was pulled back and multiple serial dilatations were done in all four procedures. Post procedure the venous channels were opened and were draining adequately. Limb edema subsided in 4 to 5 days and there were no bleeding or embolic complications in all patients. The first two patients are on follow up for 18 months, the third patient for 5 months, and the fourth patient for 2 weeks. Based on these observations, two novel balloon models for thrombolysis and to perform venous angioplasty simultaneously were developed. The piggyback model has a side lumen catheter with side holes attached to the shaft of the balloon catheter (5 mm width × 4 cm length). The side lumen terminates before the balloon. The horseshoe models made of polyethylene terephthalate have a 10 cm long and 4 mm wide compliant balloon with a double lumen catheter and multiple side ports till the balloon tip.

Keywords: Thromboembolism; Balloon catheters; Thrombolysis; Venous angioplasty

Introduction

Venous thromboembolism (VTE) is a common clinical problem and occurs in about 350 000 to 600 000 persons per year in the United States alone, of which approximately 50% are first episodes of deep vein thrombosis (DVT) [1]. In addition, 3 to 4 times as many cases occur asymptotically and are never detected [2]. Iliofemoral thrombosis is complicated commonly by pulmonary embolism and post thrombotic syndrome by swelling in the thighs and limb edema [3]. The commonly available treatment modalities are catheter directed thrombolysis [4-7], tere device that crushes clots [8-10], catheter directed suction devices and Angiojet [11-13]. We investigated the potential role of balloon directed thrombolysis as well as the safety and efficacy of such procedure.

Brief report

Four patients with extensive acute ilio-femoral and popliteal vein thrombosis and partially extending into the inferior vena-cava (IVC) with diffuse swelling of lower limb and gluteal region were studied. The first patient was a 29 yr old lady admitted with limb edema and pain consequent to an accidental fall and minor injury to thigh. The second patient who was a 48 yr old lady, stopped anticoagulation medications and presented with ilio-femoral thrombosis in the contralateral limb on follow-up. She discontinued warfarin and all allopathic medications and shifted to homeopathy medications, without taking medical advice. She also had an advanced squamous cell carcinoma of lung for which she is currently under treatment. The third patient was similar to the first patient on presentation. She was pregnant and delivered 6 months before developing this episode of DVT. The fourth patient presented 2 weeks postpartum after prolonged immobilization. Investigations for hyper-coagulation abnormalities were unremarkable in all four patients. Autoantibody tests, which include antinuclear antibodies, anti-cardiolipin antibodies and anti-Ds DNA antibodies, were not elevated.

Gunther Tulip (Cook) IVC filter was placed in all patients, initially after performing an IVC angiogram. A 5F multipurpose catheter with side holes was placed in common iliac vein bifurcation, and thrombolysis was done for 18 hours with streptokinase at 50,000 U/hr. Post thrombolysis IVC angiogram showed mild recanalization of left common iliac veins leaving a stump. On the next day, the left common iliac vein was cannulated through a 5F Torcon or 5F right Judkins catheter and a hydrophilic Terumo 035 J tipped wire was advanced through the clots. A 5 mm wide × 4 cm long peripheral balloon was advanced through the clots, and 18-hour thrombolysis with streptokinase was done at 50,000 U/hr through the port for 035 wire. The balloon was pulled back, and multiple serial dilatations were done in femoral, internal iliac and common iliac veins. In all patients, thrombolysis was started on the third day after the onset of symptoms. Venous angiograms were done through the balloons during the procedure. Figures 1 and 2 illustrate the procedures in a nutshell (Supplementary Video file).

Post-procedure the patients were started on anticoagulation and therapeutic INR was maintained between 2 to 3. Echocardiography, chestroentogram, electrocardiography and venous Doppler of the common iliac veins, femoral veins and IVC were done. All patients were discharged on the 7th day.

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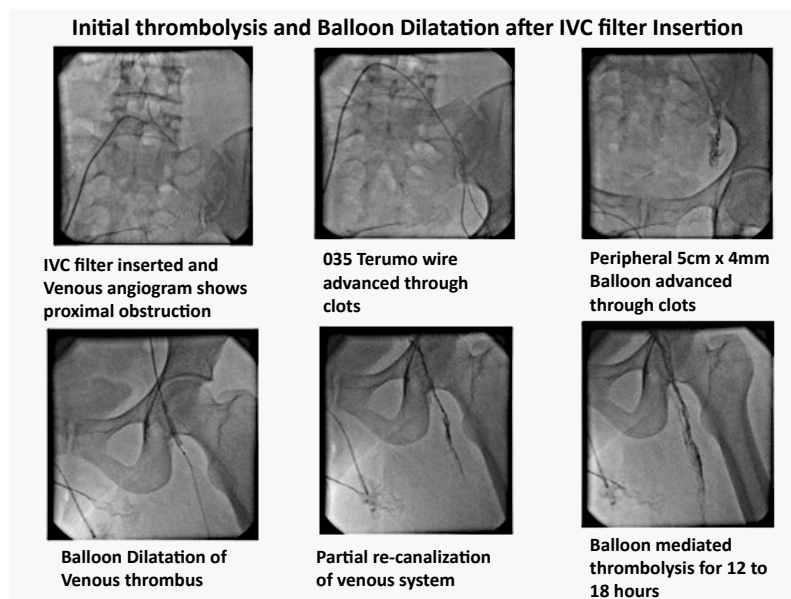


Figure 1: Demonstrates the procedure of IVC filter insertion, initial thrombolysis, insertion of 035 Terumo wire, advancement of balloon, balloon dilatation and balloon-mediated thrombolysis.

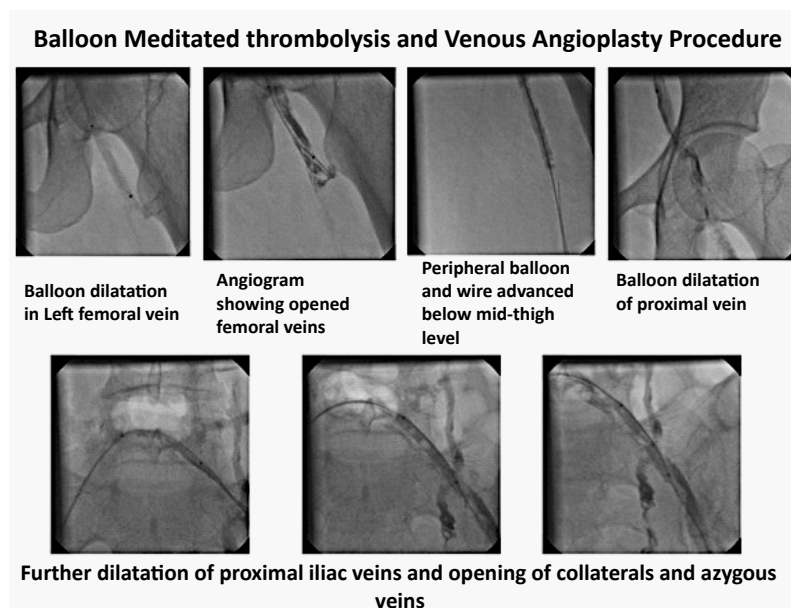


Figure 2: Demonstrates the procedure subsequently further venous angioplasty, balloon mediated thrombolysis and proximal dilatations and opening of collaterals.

Results

Post procedure the venous channels were opened and were draining adequately. There were only minimal residual clots in the venous system. Venous dissections or ruptures were not seen in these patients. Limb edema subsided and there were no bleeding or embolic complications. All patients are on oral anticoagulation and the first two patients are now on follow up for 18 months being asymptomatic at present. The third patient is on follow-up for 5 months and she

is clinically unremarkable. The fourth patient is on follow up for 2 weeks. Based on these interventions, two novel balloon models for thrombolysis and to perform venous angioplasty simultaneously in a single procedure, was developed. The first is a piggyback model which has a side port attached to the shaft of the balloon (4 cm length \times 5 mm width). The side port has side holes for 7 cm length, which could be custom-modified with further side holes using a needle if required. The other model is a horseshoe balloon catheter, which is a double lumen

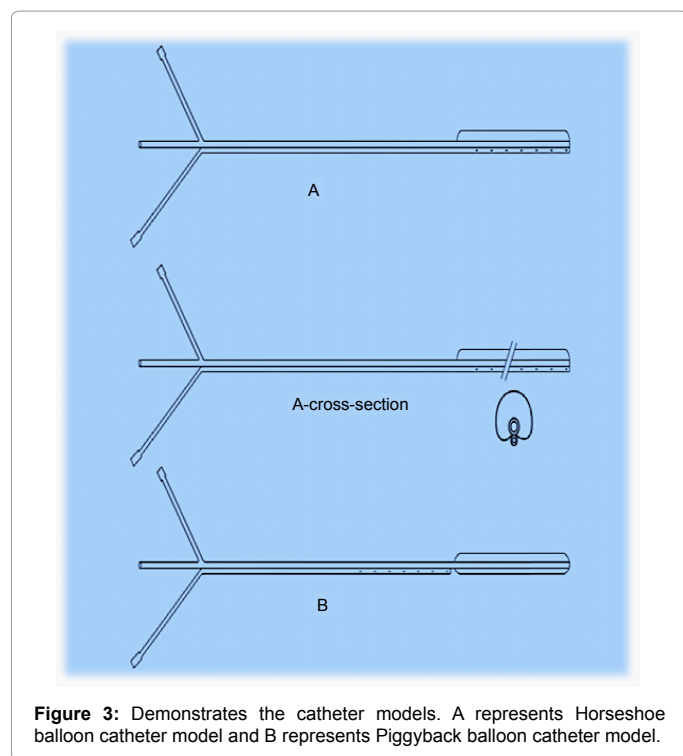


Figure 3: Demonstrates the catheter models. A represents Horseshoe balloon catheter model and B represents Piggyback balloon catheter model.

catheter model, and has a 10 to 14 cm long, and 4 mm wide compliant balloon with 0.75 mm diameter side port for thrombolysis till the balloon tip. This catheter on cross section gives a horseshoe appearance. The thrombolytic drugs could be delivered by using pressure injectors or intermittent hand injections for better controlled distribution of the drugs during the procedure. Figure 3 illustrates the models of these custom-made catheters. The horseshoe balloon catheters are made of polyethylene terephthalate (PET) polymer for better shape retention and piggyback balloon catheters were designed with nylon.

Discussion

The study outlines the potential for balloon directed thrombolysis as well as the safety of such procedure. The procedure is serial dilatation of the venous system and thrombolysis after insertion of venous filter. The effects were seen within 12 hours as evidenced by relief of thigh and pedal edema as well as relief of thigh and back pain. The limbs returned to near normal size in 4 to 5 days. The study outlines a novel method of treatment of DVT by direct thrombolysis through the balloon as well as venous angioplasty simultaneously. As the diameter of the balloon is moderate the chance of dissections in major venous systems is minimal. After multiple inflations, dissections were not observed in any of these patients. The balloons are 7F and 035 wire compatible and have excellent tracking ability. Venous angiograms during the procedure could be done efficiently using these balloons and side ports. These novel catheters are designed to have a dual purpose of thrombolysis and balloon venous angioplasty simultaneously. Also, these catheters can reduce procedural manipulations i.e. repeated exchange of catheters, wires and balloons to a large extent inside the venous system, which would be filled with profuse clots. Additionally, they can reduce procedure time. The horseshoe balloon catheters have a long balloon for efficient opening of the proximal veins and to reduce the number of balloon dilatations. It is interesting to note that after the procedures there were no clots trapped in the IVC filter as well as there

were no clinical features of pulmonary embolism. The observations demonstrate the relative safety of targeted thrombolysis by the absence of major or even minor bleeding complications.

Angiojet [11-13] (Medrad Interventional-Possis, Minneapolis, MN) and Trellis peripheral infusion system (Covidien-Bacchus, Santa Clara, CA) are the currently available FDA approved systems for treatment of deep venous thrombosis. The Trellis device [8-10] delivers thrombolytic drugs directly into the thrombus, and then spreads the drug within the clot using an oscillating wire.

Catheter directed thrombolysis [4-7] is a well-established treatment modality for this condition. Maceration and thrombectomy by maceration Helix thrombectomy device [14] and mechanical suction are other methods of treatment available for this condition.

Future Perspective

This is an observational study with four patients in whom catheter directed thrombolysis after IVC filter insertion was observed to be useful and safe. Further studies need to be performed with these novel catheters to demonstrate the potential clinical benefits.

Conclusion

Balloon mediated thrombolysis and venous angioplasty after IVC filter insertion is useful and novel balloon catheter models may be used in iliofemoral venous thrombosis.

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