OPEN ACCESS

Clinics Surgery

Research Article

Article Information

Received date: Jan 02, 2019
Accepted date: Jan 26, 2019
Published date: Jan 30, 2019

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Keywords

Deep vein thrombosis; Villalta score; Clinical severity score

Mid–Term Result of Endovascular Intervention for Chronic Obstructive iliofemoral Deep Vein Thrombosis

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Abstract

Background: The purpose of this study was to propose an emerging endovascular technique and describe results of endovascaulr intervention in treating chronic iliofemoral deep vein thrombosis (DVT).

Methods: From January 2009 to October 2014, 37 patients with chronic obstructive iliofemoral DVTs received successful endovascular interventions. 34 patients with chronic iliofemoral DVT who received successful endovascular angioplasty plus stenting were included in this study. Perioperative and 36-month investigations included clinical severity score, Villalta score, levels of valvular incompetence, and the procedure outcome. The mean duration of the follow-up was 36.5 months.

Results: The overall success rate of endovascular technique was 91.9% (34 of 37 patients). Six- month, one - year, 2-year, 3-year primary patency and six- month and one - year assisted primary patency rates were 85.2% (29), 79.4% (27), 70.6% (24), 61.8% (21) and 82.4% (28), 73.5% (25), 64.7(22) and 58.8% (20), respectively. All patients with technical success had clinical improvement in clinical severity score (CEPA) and Villalta score. However, there are no significant change of levels of valvular incompetence. Three patients with active venous ulcers healed approximately three months after the procedure. No mortality, but minimal complications like ecchymosis and hematoma at puncture sites were found.

Conclusion: In the present study, endovascular intervention with balloon dilation plus stenting should be considered the treatment of choice for chronic obstructive iliofemaoral DVT because of a high technical success rate and a minimal complication.

Introduction

Deep vein thrombosis (DVT) is a potentially progressive disease with complex chronic sequelae. The most common late complication of DVT is postthrombotic syndrome, which results from sustained venous hypertension as a consequence of lasting venous obstruction and or valvular incompetence. Although long-term anticoagulant therapy and supplementary compressing stocking are the current standard of care for proximal DVT, they only inhibit thrombus propagation, prevent pulmonary embolism and temporally relive symptoms.

However, they neither avoid chronic postthrombotic complications nor remove existing thrombus. Bypass surgery (Palma bypass) [1] was the treatment of choice before the development of balloon angioplasty and stenting. Reports declare iliofemoral venous obstructions could

be corrected with this bypass surgery [2,3]. However, the majority of studies lack reliable follow-up results. Recently there has been great interest in the clinical use of endovascular management with pharmocomechanical thrombectomy, angioplasty and stenting. So far, there're few studies reporting the factors influencing the assisted patency after endovascular management in patients with obstructive iliofemoral DVT. This study was to assess the result of endovascular intervention with angioplasty plus stenting in treating obstructive iliofemoral deep vein thrombosis (DVT).

Material and Methods

The Institutional review board approval was obtained for this retrospective study, with waiver of informed consent (IRB No: 2011-10-014IC and 2012-04-011AC).

A retrospective review was carried out on 36 patients with chronic obstructive iliofemoral DVT with more than three months of symptom duration, in whom endovascular intervention was performed over a period of three years. The primary symptoms were limb swelling, discoloration, pain and venous claudication in all patients. Chronic DVT was diagnosed using duplex sonography, computed tomography (CT) venography or MRI.

Clinical symptoms were checked and recoded based on CEPA clinical classification, Villalta score and levels of valvular incompetence at 36 months [4,5].

In spite of the retrospective study, all patients were routinely followed and recorded according to the DVT protocol of our medical center before procedures. Thus, prospective medical data included blood pressure, pulse rate, body mass index (BMI), and blood profiles comprising Hemoglobin levels, platelet counts, PT & aPTT, fibrinogen levels, D-Dimer, protein C, S, antithrombin III, lupus anticoagulant and electrolytes etc.

Endpoints

The primary endpoints of this study was clinical symptoms, safety, and primary and assisted patency on 24-month follow-up. Patients were routinely restudied at intervals of 3 to 6 months by Doppler ultrasound after endovascular interventions. Clinical symptoms were checked and recoded based on Villalta score, and levels of valvular incompetence. If the Villalta score increases combined with abnormal Doppler findings including resistant flow and no compression of iliofemoral veins, another venography or CT venography will be arranged for assessment of patency.

Primary patency of the iliofemoroal vein was defined as compressible iliofemoral veins with flow, and no stenosis or a stenosis of less than 50% confirmed by last-imaging Doppler ultrasonography, and venography or CT venography at 36 months.

Assisted patency was defined as defined as, after patients received another percutaneous interventions to treat the previous and involved veins, compressible iliofemoral veins with flow, and no stenosis or a stenosis of less than 50% confirmed by last-imaging Doppler ultrasonography, and venography or CT venography at 36 months.

Safety was defined as the number of patients with major or minor bleeding, recurrent DVT and pulmonary embolism in 36-month follow-up.

Technique

Before the procedure, antithrombotic drugs were discontinued to obtain an INR < 1.5. At the beginning of the procedure, an intravenous bolus of unfractionated heparin (UFH) of 3000 U to obtain an ACT > 200 seconds.

In brief, percutaneous entry was obtained through the lesser saphenous vein (LSV) or the popliteal vein under ultrasound guidance. After the vein was punctured, the 5 or 6-F introducer sheath was inserted into the thrombosed vessel over a guide wire. Venograms were performed to evaluate the status of iliofemoral veins. The guide wire and catheter combinations were advanced step by step through the stenotic lesions, and the balloon angioplasty plus stent placement was followed. If the tough lesion was encountered, the low dose of urokinase solution was administered into the lesion for maceration of organized fibrosis, and endovascular intervention was followed subsequently.

Blood pressure, pulse and puncture site were checked four times daily. Hemoglobin, fibrinogen and platelet counts were monitored daily, and aPTT was examined twice daily.

Post-Procedure and Follow-up

A repeated venography was performed the next day to ensure venous patency.

Table 1: Demographic and Clinical characteristics of the study patients.

Characteristic	Number (%)
Patients	34
Age, mean ± SD years	66.2±14.5
Female Gender	17 (50)
Body mass index, mean ± SD	24.8±1.63
Lesion site (Left)	22(64.7)
malignancy	7(20.6)
Smoking	7(20.6)
Immobilization	2(5.9)
Thrombophilia	9(26.5)
Surgery	8(23.5)
Trauma	2(5.9%)
DM	9(26.5)
Anatomic distribution of obstructed venous segments	
CIV + EIV +CFV	19(55.9)
IVC + CIV	4(11.8)
CIV + EIV	6(17.6)
EIV+ CFV	7(20.6)

Trauma was defined as trauma that occurred 14 to 30 days before the onset of DVT. Surgery was defined as surgery experienced 30 to 90 days before the onset of DVT. The scope for a classification of immobilization was 4 to 30 days before the onset of DVT.

Thrombophilia was defined as documented biochemical hypercoagulable disorders, such as protein C or S deficiency and ant thrombin III, and lupus anticoagulant, etc. IVC, inferior vena cava vein CIV, common iliac vein EIV, external iliac vein CFV, common femoral vein.

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Table 2: Intervention, Clinical and venous outcomes at 36 months.

Characteristic	Number (%)
Technique success	34/37 (91.8)
Stent implantation	34
Endpoints	
Primary patency	
Six-month	29(85.3)
One-year	27(79.4)
Two-year	24(70.6)
Three-year	21(61.8)
Assisted patency	
Six-month	28(82.4)
One-year	25(73.5)
Two-year	22(64.7)
Three-year	20(58.8)
Valvular incompetence at 36 months, n (%)	
Reflux duration ≧ 0.5 second	22(64.7)
36-month PTS, n (%)	24(70.6)
36-month Villalta score, mean ± SD	5.32±2.03
Wound healing at 3 months	3(8.8)
Safety	
Ecchymosis or minimal bleeding	4(11.8)
Recurrent deep vein thrombosis	7(20.6)
Pulmonary embolism	3(8.8)

RD= Reflux duration; PTS= Postthrombotic syndrome.

Table 3: Clinical outcomes before recanalization and at 36 months.

Test	preoperative	postoperative	P value
Clinical severity score	2.91±0.75	2.03±0.72	**<0.001**
C3	0	8(23.5)	
C4	11 (32.4)	17(50)	
C5	15 (44.1)	9(26.5)	
C6	8 (23.5)	0	
Reflux duration ≧ 0.5 second	25(73.5)	22(64.7)	0.375
PTS, n (%)	34(100)	24(70.6)	0.002
Villalta score, mean ± SD	11.9±3.25	5.32±2.03	<0.001

RD= Reflux duration; PTS= Postthrombotic syndrome.

All patients were regularly followed up by clinical examination at 1 week, 3 months, 6 months, 9 months, 12 months, 24 months, and 36 months thereafter. All patients should receive Coumadin of at least six months, life-long Clopidogrel (75 mg/day) and Pntoxifylline (800mg/day). Elastic bandage or thigh-high graduated elastic compression stockings were applied on all patients, and ambulation was also initiated as soon as possible.

Statistical analysis

Continuous and categorical variables were analyzed by paired nonparametric Wilcoxon signed rank test. McNemar's test was used to analyze paired nominal data. A value of P<.05 was considered significant. All Statistical analyses were performed using statistical analysis software (SPSS).

Results

A retrospective review was carried out on 37 patients with chronic iliofemoral DVT with more than 3 months of symptom duration, in whom endovascular intervention was performed between January 2009 and October 2014. There were 17 females and 17 males successfully treated with endovascular angioplasty plus stent, and the mean age was 66.2±14.5 years (37-86 years).

According to the CEAP classification, all patients had unilateral symptoms like pain, swelling and venous claudicaiton, and the obstructed lesions were located on the left side in 22(64.7%) patients. The clinical severity score in CEAP was C4 in 11 cases, C5 in 15, and C6 in eight. The etiology was post-thrombotic in all patients, and the pathophysiology was of outflow obstruction in all patients. Patient demographics, comorbidities and distribution of obstructed venous segments were completely listed in Table 1. Intervention, Clinical and venous outcomes at 36 months was showed in Table 2.

The overall success rate of endovascular technique was 91.8% (34 of 37 patients). The average duration of clinical follow-up was 36.5 months (range, 36- 45.5). Six- month, one - year, 2-year, 3-year primary patency and six- month and one - year assisted primary patency rates were 85.3% (29), 79.4% (27), 70.6% (24), 61.8% (21) and 82.4% (28), 73.5% (25), 64.7 (22) and 58.8% (20), respectively. At the 36-month follow-up, recurrent DVT was found in 7 (20.6%) patients, and pulmonary embolism was noticed in 3 (8.8) patients. None of the patients died, but minimal complications, such as ecchymosis and hematoma at puncture sites, were noted in four patients. Three patients with active venous ulcers healed approximately 3 months after the procedure. Clinical outcomes before recanalization and at 36 months were listed in Table 3.

Post-thrombotic syndrome (PTS) were significantly different before and after intervention (P=0.002). The mean Villalta scores before and after intervention were 11.9±3.25 and 5.32±2.03 (P<0•0 01), whereas there're insignificant difference in valvular incompetence (P=0.375) (Table 3).

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Discussion

This study assessed the efficacy and safety of endovascular treatment in patients with chronic and iliofemoral obstructive DVT. This study showed the 36-month primary patency was independently correlated with DVT duration, recurrent DVT and treatment method. Besides, chronic iliofemoral DVT of one-month duration has usually a more unstable and organized thrombus and thus has potential thrombus embolization and recoil while manipulating, and poor prognosis. The results of this study can provide physicians with evidence to manage obstructive iliofemoral DVT, and prevent intervention failure and preserve venous function early using stent placement.

Chronic DVT with obstructive iliofemoral venous lesions is still a challenging disease. Before the advent of novel oral anticoagulant and pharmacomechanical thrombetomy, patients with acute iliofemoral DVT were prescribed with traditional anticoagulant and thigh-high graduated elastic compression stockings. Published literatures have established that 49-60% of patients develop PTS within 2 years after initial treatment of proximal DVT [6-7].

These patients with later development of chronic DVT, have also been treated with conservative measures such as thigh-high graduated elastic compression stockings, intermittent compression devices, and long-term anticoagulation. Until the 1990s, endovascular re-canalization of obstructed iliofemoral venous lesions or establishment of surgical bypass (Palma bypass) were considered to reconstruct the antegrade flow through the iliac venous system and improve patients' symptoms. Although several reports on the crossover-bypass technique claim durable symptomatic relief [8,9], the advantages of endovascular treatment over surgical bypass reconstruction was remarkable and included the small magnitude of intervention, minimal complications, reliable diagnostic venography, and effective management of obstruction lesions. In spite of the high technical success reaching 91.8 %., this endovascular procedure had certain technical limitations. For example, in patients with chronic iliofemoral venous obstruction and severe edema of the lower extremities, access site may be difficult. Consequently, for each patient treatment planning, vascular surgeons required as much information as possible, and in our study, MRI or CTV revealed the severity, extent and cause of central venous obstruction, as well as thrombus burden. With this information, it was possible to select patient candidates for endovascular intervention and determine the most suitable venous access route for the procedure.

The underlying pathophysiology of venous diseases was also different from arterial diseases, and the elastic recoil was characteristic of venous lesions. Therefore, endovascualr skills in management of venous obstructed diseases were obviously different from those in arterial diseases, but a bit similar to thrombosed autogenous arteriovenous fistulas. If it's unsuccessful by passing a catheter beyond the obstruction, the low dose of urokinase solution was administered into the lesion for maceration of organized thrombus followed by pre-dilation with 3-5 mm balloon. The guide wire and catheter combinations could be nearly successfully advanced step by step through the obstructed lesions. Subsequent balloon dilatation and stent implantation can be performed safely.

In this study, endovascular interventions were successfully undergone in 32 patients with iliofemoral venous obstruction. Primary and assisted one-year patency was 85.3% (29) and 82.4 % (28), respectively. These results are consistent with those of published series reported primary one-year patency and secondary patency to be 50% -85 % and 90%, respectively [10-12]. Our satisfactory result was attributable to that all patients should receive long-term Coumadin, life-long Clopidogrel and Pntoxifylline, wear elastic bandage or thigh-high graduated elastic compression stockings, and initiate ambulation as soon as possible.

Therefore, all patients with technical success had clinical improvement in swelling, venous claudication, clinical severity score and Villalta score (Table 3).

Decousus et al. have demonstrated that there's a significant decrease in the incidence of pulmonary embolism (PE) compared with anticoagulation alone (1.1% vs. 4.8%, p=0.03) at 8 to 12 days of follow-up [13]. At the same time, an inferior vena caval filter is associated with significantly more recurrent DVT than anticoagulation alone (20.8% vs. 11.6%, p = 0.02) [12,13]. In the present study, all patients experienced chronic obstructive DVT treated with anticoagulation before and after the procedure. Therefore, retrievable inferior vena cava filter was not routinely used to prevent fatal pulmonary embolism. As yet, no PM and related mortality were noted. If necessary, implanted filters could be expected to take out after approximate three to six months [14,15].

In addition, one major concern was recurrent DVT and PE. Our results showed recurrent DVT was found in 7 (20.6%) patients, and pulmonary embolism was noticed in 3 (8.8%) patients at the 36-month follow-up. In the subgroup analysis, our findings showed that most of patients developed recurrent DVT was attributable to risk factors related to lupus anticoagulant, protein C or S, malignancy and orthopedic surgery compatible to published literature [16,17]. This study suggested most of recurrent DVTs could happen anytime during 36-month follow-up.

This study has some recognized limitations, including the small number of patients, its retrospective nature, and the relatively mid-term follow-up period. Therefore, we need to present a prospective control study with a large sample size.

In conclusion, our mid-term results suggest that endovascular intervention with balloon dilation plus stenting is a minimally invasive and effective treatment for chronic DVT with obstructive iliofemoral veins. On account of a high technical success rate and a minimal complication, endovascular intervention with balloon dilation plus stenting appear to be better than surgical treatment and should be considered the treatment of choice for chronic obstructive iliofemoral DVT.

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