

The effect of venoplasty and stent implantation in patients with chronic venous symptoms following deep vein thrombosis in iliofemoral segment

Seyed Masood Mousavi¹, Iraj Nazari¹, Hossain Minaee¹, Saman Ketabchian^{1,*}

¹Department of Surgery, Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Corresponding Author: Saman Ketabchian,

Department of Surgery, Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Email: sketabchian@gmail.com; Tel: +98 61 33337681; https://orcid.org/0000-0002-4905-4363

Abstract

Deep vein thrombosis (DVT) is a common vascular condition that affects 1 to 3 per 1,000 persons per year. Proximal thrombosis (including iliac arteries) is at higher risk for postthrombotic syndrome (PTS). Therefore, in the present study, we investigated the effect of venoplasty by stent placement in patients with chronic venous symptoms following DVT in the iliofemoral segment. In this cross-sectional study, patients with an age range of 20 to 70 years who presented with chronic symptoms of iliofemoral obstructive venous lesion following DVT were included in the study if satisfied. They were placed under local anesthesia with lidocaine and, if necessary, by venous sedation under lower extremity venography by catheter with popliteal vein surgery on the same side and placement of a sheet. Variables related to before the intervention and six months after the intervention were reviewed, recorded and analyzed. Among 24 patients participating in the study, 70.8% were male and 29.2% were female with a mean age of 51.42 ± 8.27 years. There was a significant difference in pain and wound condition before and 6 months after the intervention ($P < 0.001$). After the intervention, 58.3% of patients were in painless condition and the frequency of patients without wounds increased from 12.5% to 66.7%. Edema changes were not significant ($P = 0.29$). Stent implantation in patients with chronic venous symptoms following DVT in the iliofemoral segment reduces pain and wound healing and is an effective, usable and practical method.

Keywords: Deep Vein Thrombosis, Postthrombotic Syndrome, Stent

Introduction

Deep vein thrombosis (DVT) is a common vascular condition that affects 1 to 3 per 1,000 persons per year [1, 2]. In addition to the risk of recurrence, what threatens patients after DVT is the development of post-thrombotic syndrome (PTS). Approximately 20% -50% of patients with symptomatic DVT develop PTS within 2 years, despite adequate treatment [3-5]. PTS is an important cause of chronic disease and is associated with significant economic consequences for the patient and health services [6, 7]. Clinical features of PTS range from mild pain, occasional swelling, and venous ectasia to a very severe condition with chronic pain, incurable swelling, skin changes, and ultimately a leg ulcer [3-5]. Studies have shown that acute DVT

of the distal veins of the lower extremities has a relatively low rate of pulmonary embolism and PTS [8, 9]. However, acute DVT of proximal veins, including knee, femoral, and iliac veins, has more complications [9-13]. In general, proximal thrombosis, which involves the iliac arteries, is at higher risk for PTS [14, 15].

Until today, there is no specific treatment for PTS [16]. In studies, intravenous techniques have shown promising results in terms of safety and effectiveness [7, 15, 17-23]. However, few studies have examined the effect of angioplasty on the quality of life of PTS patients. Therefore, in the present study, we investigated the effect of venoplasty by stent placement in patients with chronic venous symptoms following DVT in the iliofemoral segment.

Materials and Methods

In this cross-sectional study, patients with an age range of 20 to 70 years that had chronic symptoms of iliofemoral obstructive venous lesion with an initial diagnosis of chronic venous insufficiency following DVT and without cardiopulmonary risk factors and diabetes were considered. They were referred to the Vascular Surgery Center of Ahvaz Golestan Hospital, from October 2018 to October 2020. Patients with symptoms of chronic venous insufficiency, such as swelling, pain or venous ulcers, and who underwent stenosis or obstruction of the iliofemoral venous segment, according to paraclinical studies, including Doppler ultrasound, were nominated for venography.

Patients participated in the study after informed consent (Code of ethics: IR.AJUMS.HGOLESTAN.REC.1399.110). Demographic information of patients, medical history, family history and history of interventions, current status of lower extremity disease and its effect on daily activities and quality of life were recorded in the designed questionnaire. Also, a clinical examination was performed and the result of Doppler ultrasound of symptomatic iliofemoral veins was recorded in a questionnaire. Patients with inclusion criteria underwent local anesthesia with lidocaine and, if necessary, intravenous sedation under lower extremity venography by catheter with ipsilateral popliteal vein catheterization and placement of a sheath under ultrasound guidance with a water-soluble contrast agent. After administration of systemic anticoagulation (heparin 5000 units, intravenously) if significant stenosis or obstruction in the iliofemoral venous segment is identified and confirmed, high pressure balloon venoplasty with 14 to 18 mm caliber and implantable balloon expandable stent size 14 to 18 mm performed in the iliofemoral segment. In most cases, patients without any particular complication were discharged the day after the intervention with aspirin, clopidogrel and rivaroxaban and were advised to go to a vascular surgery clinic after three or six months. Variables related to before the intervention and six months after the intervention were reviewed, recorded and analyzed.

Results

Out of 24 patients participating in the study, 17 patients (70.8%) were male and 7 patients (29.2%) were female. Their mean age was 51.42 ± 8.27 years. Vein was patent in 20 patients (83.3%) and obstructed in 4 patients (16.7%). All patients had pain and edema and 21 patients (87.5%) had ulcers.

To evaluate the amount of pain, patients were divided into four groups: painless, low pain, moderate pain and severe pain. Before an intervention, the frequency of patients in these groups was 12.5%, 33.3%, 50% and 4.2%, respectively. After an intervention, it was 58.3%, 33.3%, 8.4% and 0, respectively ($P < 0.001$) (Table 1).

Patients were evaluated at four levels according to swelling: no edema, low edema, moderate edema and severe edema. Before an intervention, the frequency of patients in these four levels was 0, 8.3%, 58.3% and 33.4%, respectively. After intervention, it was 37.5%, 41.7%, 20/8 and 0, respectively. ($P = 0.29$) (Table 1).

For evaluating the wounds patients divided in three groups: no wounds, wounds less than 2 cm and wounds 2-6 cm. Before an intervention, their frequency was 12.5%, 50%, 37.5% and 0, respectively. After an intervention, it was 66.7%, 33.3%, 0 and 0, respectively ($P < 0.001$) (Table 1). By evaluating the satisfaction of patients participating in the study, it was found that 4 (16.6%), 7 (29.1%) and 13 (54.3%) patients had poor, moderate and good satisfaction rate, respectively.

Discussion

The pathophysiology of PTS, as the most important late complication of DVT, is venous hypertension which pathological components are the persistence of venous obstruction, or/and venous valvular reflux [9, 10, 24-27]. The overall results of DVT as a disorder of venous physiology are highly dependent on the anatomical position of the thrombosed venous segment [20, 28, 29]. In recent years, the therapies of acute DVT have become more widespread, but there is still much debate about the priority of treatment in terms of the lowest risk and the best prevention of complications [30]. PTS is still

Table 1. Frequency of variables studied in patients before the intervention and 6 months after the intervention

Variable		Before intervention	6 months after the intervention n(%)	P-Value
		n (%)		
Pain	No pain	3 (12.5%)	14 (58.3%)	<0.001
	Mild pain	8 (33.3%)	8 (33.3%)	
	Moderate pain	12 (50%)	2 (8.4%)	
	Sever pain	1 (4.2%)	0	
Wound	No wound	3 (12.5%)	16 (66.7%)	<0.001
	Wound smaller than 2 cm	12 (50%)	8 (33.3%)	
	Wound size 2-6 cm	9 (37.5%)	0	
Swelling	No edema	0	9 (37.5%)	0.000
	Mild edema	2 (8.3%)	10 (41.7%)	
	Moderate edema	14 (58.3%)	5 (20.8%)	
	Sever edema	8 (33.4%)	0	

a recurring complication in DVT and leads to significant complications, suffering, and high health costs [17]. Therefore, it is vital to study the treatment options for this complication.

In the present study, we concluded that after stent implantation in patients with chronic venous symptoms, the amount of pain was significantly different than before the intervention ($P < 0.001$). After the intervention, 58.3% of patients were in painless condition and the number of patients with severe pain decreased from 4.2% to 0. Also, Razavi et al. reported that implanting a stent to treat iliofemoral venous obstruction lead to relief pain rate from 69 to 82% [20]. In a study by Falcoz et al., it was reported that three months after stent implantation in the iliofemoral vein, the amount of pain was significantly reduced and in 42.9% of patients the pain completely improved [31]. The study of Moini et al. Also showed that in PTS patients, stenting reduced pain significantly [32]. Therefore, stenting in the

iliofemoral vein of patients with a history of DVT reduces pain.

Another finding of this study is a significant difference in wound condition before and after the intervention ($P < 0.001$). So that after stent implantation, the frequency of patients without wounds increased from 12.5% to 66.7%. The frequency of patients with wounds larger than 2 cm decreased from 37.5% to 0. In the meta-analysis, wound healing was estimated 71 to 81% [20]. Therefore, stent placement has a significant role in improving the condition of the wound.

In our study, the rate of edema before and after the intervention was significantly different ($P = 0.00$). By comparing conditions of patients after the intervention compared to before, it was observed that a number of patients after the intervention were without edema (37.5% vs. 0). Also, after the intervention, the number of patients with severe edema reached 0. Most of them experienced low and

moderate edema. However, Moeini and colleagues reported a significant reduction in edema [32]. In another study, the results showed that edema was significantly reduced during the quarter after stenting and in 33.3% of patients, edema completely improved [31]. The meta-analysis also showed that implantation of a stent to treat iliofemoral venous occlusion improved 64 to 68% of the edema [20].

In the present study, the patients' satisfaction rate survey showed that 54.3% of them had good satisfaction. Also, the study by Falcoz et al. showed that endovascular stent placement for iliofemoral obstructive venous lesions after thrombosis had a significant effect on improving patients' quality of life. This method also had a high rate of clinical success and safety [31]. A study by Kurklinsky et al. confirmed the safety of this method [19]. Other studies have confirmed its safety and effectiveness [32-34]. Therefore, based on the results of the study and also by considering the endovascular approach with venous angioplasty and stenting in comparison with conventional surgical treatments to a fully accepted treatment option in chronic venous obstruction with a high rate of technical success, minimal complications and There has been a very short hospital stay [15, 35-37], stent placement in patients with chronic venous symptoms following DVT in the iliofemoral segment is an effective, usable and practical method.

Acknowledgments

This study was resulted from thesis of vascular surgery fellowship. It was supported by the Vice Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical Sciences (project number: U-99293)..

Author contribution

All authors contributed equally in all parts of article and approving the final version of the manuscript before submission

Conflict of Interest

Authors declare no conflicts of interest.

Ethical declaration

There was no ethical declaration.

Funding source

There was no source of funding.

References

1. Guanella R, Ducruet T, Johri M, Miron MJ, Roussin A, Desmarais S, et al. Economic burden and cost determinants of deep vein thrombosis during 2 years following diagnosis: a prospective evaluation. *J Thromb Haemost.* 2011; 9(12):2397-405.
2. Kahn SR, Comerota AJ, Cushman M, Evans NS, Ginsberg JS, Goldenberg NA, et al. The postthrombotic syndrome: evidence-based prevention, diagnosis, and treatment strategies: a scientific statement from the American Heart Association. *Circulation.* 2014; 130(18):1636-61.
3. Bernardi E, Prandoni P. The post-thrombotic syndrome. *Curr Opin Pulm Med.* 2000; 6(4):335-42.
4. Kahn SR, Ginsberg JS. The post-thrombotic syndrome: current knowledge, controversies, and directions for future research. *Blood Rev.* 2002; 16(3):155-65.
5. Saarinen J, Kallio T, Lehto M, Hiltunen S, Sisto T. The occurrence of the post-thrombotic changes after an acute deep venous thrombosis. A prospective two-year follow-up study. *J Cardiovasc Surg (Torino).* 2000; 41(3):441-6.
6. Kahn SR, Ginsberg JS. Relationship between deep venous thrombosis and the postthrombotic syndrome. *Arch Intern Med.* 2004; 164(1):17-26.
7. Prandoni P, Kahn SR. Post-thrombotic syndrome: prevalence, prognostication and need for progress. *Br J Haematol.* 2009; 145(3):286-95.
8. Douketis JD, Crowther MA, Foster GA, Ginsberg JS. Does the location of thrombosis determine the risk of disease recurrence in patients with proximal deep vein thrombosis? *Am J Med.* 2001; 110(7):515-9.
9. Meissner MH, Eklof B, Smith PC, Dalsing MC, DePalma RG, Glociczki P, et al. Secondary chronic venous disorders. *J Vasc Surg.* 2007; 46 Suppl S:68s-83s.
10. Augustinos P, Ouriel K. Invasive approaches to treatment of venous thromboembolism. *Circulation.* 2004; 110(9 Suppl 1):I27-34.
11. Kamphausen M, Barbera L, Mumme A, Marpe B, Grossefeld M, Ascitto G, et al. [Clinical and functional results after transfemoral thrombectomy for iliofemoral deep venous thrombosis: a 5-year-follow-up]. *Zentralbl Chir.* 2005; 130(5):454-61; discussion 61-2.
12. Markel A. Origin and natural history of deep vein thrombosis of the legs. *Semin Vasc Med.* 2005; 5(1):65-74.
13. Monreal M, Barba R, Tolosa C, Tiberio G, Todolí J, Samperiz AL. Deep vein thrombosis and pulmonary embolism: the same disease? *Pathophysiol Haemost Thromb.* 2006; 35(1-2):133-5.
14. Bergan JJ. A major step forward in the treatment of venous occlusion. *J Endovasc Ther.* 2000; 7(2):92-3.
15. Neglén P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. *J Vasc Surg.* 2007; 46(5):979-90.

16. Kolbach DN, Sandbrink MW, Hamulyak K, Neumann HA, Prins MH. Non-pharmaceutical measures for prevention of post-thrombotic syndrome. *Cochrane Database Syst Rev.* 2004; (1):Cd004174.
17. Ashrani AA, Heit JA. Incidence and cost burden of post-thrombotic syndrome. *J Thromb Thrombolysis.* 2009; 28(4):465-76.
18. Enden T, Haig Y, Kløw NE, Slagsvold CE, Sandvik L, Ghanima W, et al. Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial. *Lancet.* 2012; 379(9810):31-8.
19. Kurkclinsky AK, Bjarnason H, Friese JL, Wysokinski WE, McBane RD, Misselt A, et al. Outcomes of venoplasty with stent placement for chronic thrombosis of the iliac and femoral veins: single-center experience. *J Vasc Interv Radiol.* 2012; 23(8):1009-15.
20. Razavi MK, Jaff MR, Miller LE. Safety and Effectiveness of Stent Placement for Iliofemoral Venous Outflow Obstruction: Systematic Review and Meta-Analysis. *Circ Cardiovasc Interv.* 2015; 8(10):e002772.
21. Sarici IS, Yanar F, Agcaoglu O, Ucar A, Poyanli A, Cakir S, et al. Our early experience with iliofemoral vein stenting in patients with post-thrombotic syndrome. *Phlebology.* 2014; 29(5):298-303.
22. Titus JM, Moise MA, Bena J, Lyden SP, Clair DG. Iliofemoral stenting for venous occlusive disease. *J Vasc Surg.* 2011; 53(3):706-12.
23. Ye K, Lu X, Jiang M, Yang X, Li W, Huang Y, et al. Technical details and clinical outcomes of transpopliteal venous stent placement for postthrombotic chronic total occlusion of the iliofemoral vein. *J Vasc Interv Radiol.* 2014; 25(6):925-32.
24. Agnelli G. Current issues in anticoagulation. *Pathophysiol Haemost Thromb.* 2005; 34 Suppl 1:2-9.
25. Comerota AJ, Gravett MH. Iliofemoral venous thrombosis. *J Vasc Surg.* 2007; 46(5):1065-76.
26. Heit JA. The epidemiology of venous thromboembolism in the community: implications for prevention and management. *J Thromb Thrombolysis.* 2006; 21(1):23-9.
27. Murphy KD. Mechanical thrombectomy for DVT. *Tech Vasc Interv Radiol.* 2004; 7(2):79-85.
28. Singh H, Masuda EM. Comparing short-term outcomes of femoral-popliteal and iliofemoral deep venous thrombosis: early lysis and development of reflux. *Ann Vasc Surg.* 2005; 19(1):74-9.
29. Yamaki T, Nozaki M. Patterns of venous insufficiency after an acute deep vein thrombosis. *J Am Coll Surg.* 2005; 201(2):231-8.
30. Serrao A, Merli M, Lucani B, Aprile F, Fiori L, Gioia S, et al. Outcomes of long-term anticoagulant treatment for the secondary prophylaxis of splanchnic venous thrombosis. *Eur J Clin Invest.* 2021; 51(1):e13356.
31. Falcoz MT, Falvo N, Aho-Glélé S, Demaistre E, Galland C, Favelier S, et al. Endovascular stent placement for chronic post-thrombotic symptomatic ilio-femoral venous obstructive lesions: a single-center study of safety, efficacy and quality-of-life improvement. *Quant Imaging Med Surg.* 2016; 6(4):342-52.
32. Moini M, Zafarghandi MR, Taghavi M, Salimi J, Tadayon B, Mohammad Sadat SA, et al. Venoplasty and stenting in post-thrombotic syndrome and non-thrombotic iliac vein lesion. *Minim Invasive Ther Allied Technol.* 2020; 29(1):35-41.
33. Guillen K, Falvo N, Nakai M, Chevallier O, Aho-Glélé S, Galland C, et al. Endovascular stenting for chronic femoro-iliac venous obstructive disease: Clinical efficacy and short-term outcomes. *Diagn Interv Imaging.* 2020; 101(1):15-23.
34. van Vuuren T, de Wolf MAF, Arnoldussen C, Kurstjens RLM, van Laanen JHH, Jalaie H, et al. Editor's Choice - Reconstruction of the femoro-ilio-caval outflow by percutaneous and hybrid interventions in symptomatic deep venous obstruction. *Eur J Vasc Endovasc Surg.* 2017; 54(4):495-503.
35. Hartung O, Otero A, Boufi M, De Caridi G, Barthelemy P, Juhan C, et al. Mid-term results of endovascular treatment for symptomatic chronic nonmalignant ilio-caval venous occlusive disease. *J Vasc Surg.* 2005; 42(6):1138-44; discussion 44.
36. Schwarzbach MH, Schumacher H, Böckler D, Fürstenberger S, Thomas F, Seelos R, et al. Surgical thrombectomy followed by intraoperative endovascular reconstruction for symptomatic ilio-femoral venous thrombosis. *Eur J Vasc Endovasc Surg.* 2005; 29(1):58-66.
37. Nicolaidis AN, Allegra C, Bergan J, Bradbury A, Cairols M, Carpentier P, et al. Management of chronic venous disorders of the lower limbs: guidelines according to scientific evidence. *Int Angiol.* 2008; 27(1):1-59.