

Endovenous Therapy in Chronic Venous Insufficiency of the Lower Limbs Due To Iliocaval Obstruction

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ABSTRACT

Objective: This study was done to evaluate the efficacy of endovenous angioplasty & stenting as a primary choice for the management of chronic venous insufficiency due to iliocaval obstruction. **Methods:** This is a prospective study of post-thrombotic patients with iliofemoral obstruction was conducted at Ain Shams University and Health Insurance hospitals From March 2014 to November 2016. Duplexultrasound and CT venography were performed in PTS patients with chronic venous insufficiency. Post-thrombotic syndrome (PTS) with ilio-femoral vein obstruction (Villalta score >10) was diagnosed in 20 patients with percutaneous approach was performed in all patients. Patency rates and complications were analyzed by duplex ultrasound. Clinical outcome was scored by Venous Clinical Severity Score (VCSS), Villalta scale, and venous claudication rates. In addition, Venous Disability Score (VDS) has been used to score the functional outcome. **Results:** Percutaneous endo-venous recanalization was successful in 18 of 20 patients (90%) without major complications. mean age was (38.34±8.20) years, range (26-57), Male/Female ratio (3:1), Lt/Rt ratio (5.6:1), The mean duration of PTS symptoms was (28.75±15.14) months (range 6-75 months). Follow up period was 12 month. Cumulative primary, assisted primary patency rates at 1 year were 90%, and 100%, respectively. VCSS and Villalta scores were significantly improved at the last follow up. Venous disability scores demonstrated excellent functional recovery at 12 months follow up. Venous claudication totally subsided in 77.8% and ulcer healing achieved in 71.4% of patients at the end of follow up. **Conclusions:** Endo-venous therapy is a safe, effective, and feasible method to correct the ilio-femoral obstruction of PTS. It showed favorable short-term clinical and functional outcomes and showed patency rates comparable with previous studies.

INTRODUCTION

Approximately 20%–50% of cases of deep vein thrombosis (DVT) will develop post thrombotic syndrome (PTS) despite adequate anticoagulation. ⁽¹²⁾ Chronic iliac vein obstruction, which is the common outflow tract of the lower limb, may have severe clinical presentation because of poor collateral development. Only 20% to 30% of ilio-femoral DVT treated by anticoagulation alone completely recanalize. Five years later, the remaining obstruction results in venous claudication in 44% and venous ulcer in 15% of patients and 40% have limited ambulation. ⁽¹³⁾ several studies demonstrate hemodynamic impairment and decreased quality of life. ⁽²⁾

Spontaneous recanalization after DVT differs according to the affected anatomical venous segment. While recanalization occurs in up to 90% of the femoro-popliteal veins after one year, this is rarely the case (<5%) after ilio-femoral deep venous thrombosis ⁽⁸⁾.

Chronic venous insufficiency due to ilio-femoro-caval occlusion can cause disabling symptoms affecting the daily activities and reducing patients' quality of life. In the recent past, the most promising treatment consisted of painkiller, compression therapy, and anticoagulation; venous bypass was reserved only for severely affected cases. With the new era of minimally invasive Interventions by recanalization, percutaneous trans-luminal venoplasty, and stenting, treatment has been revolutionized. ⁽¹⁴⁾

Good results have been reported with the new era of minimally invasive interventions in both post-thrombotic syndrome (PTS) obstructions and May-Thurner syndrome. In previous literature decreased venous hypertension has been shown after interventional treatment. Most notably, this is the main factor in the relief of edema, pain relief, and ulcer healing. With this relatively new indication of endovenous stenting, a primary patency rate between 32% and 99% and a

secondary patency rate of 66% to 96% have been reported.⁽¹⁴⁾

The goal of this study was to assess the short-term patency and clinical outcome after recanalization and stenting of chronically occluded ilio-femoral venous segments among patients with chronic post-thrombotic venous occlusive disease.

METHODS

From March 2014 to November 2016, 20 consecutive patients with chronic post thrombotic ilio-femoral venous occlusive disease were enrolled in our prospective clinical interventional study. This study was conducted at Ain Shams University and Health Insurance Hospitals. Our inclusion criteria were patients who presented with manifestations of chronic post thrombotic venous occlusive disease in the form of lower limb persistent swelling, pain, or ulcerations due to Ilio-femoral venous obstruction and/or Ilio-caval obstruction. Exclusion criteria were Patients with limited life expectancy to less than 5 years, such as severe chronic obstructive pulmonary disease, cardiac failure, and malignant disease, Patients with total infra renal IVC obstruction, recent acute DVT, Limbs with extensive obstructive femoro-popliteal venous lesions with poor inflow were also excluded.

Patients were clinically classified at enrollment according to the CEAP classification according to the Reporting Standards of Society of Vascular Surgery (SVS).⁽⁴⁾ The Venous Disability Score (VDS)⁽⁵⁾, the Venous Clinical Severity Score VCSS⁽⁶⁾ and the Villalta Scale⁽⁷⁾ were also used to assess and compare the clinical and functional outcome over the follow up period.

Our preoperative imaging protocol was by duplex ultrasound and ascending CT venography, which was performed with contrast injection through the superficial dorsal veins of the foot with a tourniquet, applied at mid-leg to direct the contrast medium the deep veins of the leg. We considered a case to be post thrombotic lesion if the patient had, a previous DVT diagnosed by duplex ultrasound and had subsequently been treated by anticoagulation; or findings on CT venography (ilio-femoral venous occlusion, stenosis or collaterals) denoting previous DVT. One of the pre requisites for our procedure was a CT venography evidence of a good adequate

access site for our sheath insertion that is either a patent superficial femoral vein in the upper or mid-thigh segment or a patent popliteal vein.

The procedure was performed under GA at an operative room with a mobile C-arm with vascular imaging capabilities. Vein access was done under duplex guidance either through a patent compressible femoral vein in upper or mid-thigh or through a patent compressible popliteal vein while the patient supine. An introducer 8Fr sheath was inserted percutaneously under duplex guidance then, intravenous administration of sodium heparin at a dose of 80 IU/Kg, then a venography was performed by injecting non-ionic contrast media (Ultravist®300, Bayer) diluted with 0.9% saline at a ratio of 1:1 through the sheath to get an overview of the pathologically stenosed or occluded venous segments and the collaterals around the occluded segments. An antero-posterior and oblique views were taken to get a clear idea of the intended pathway for the guide wire into the main iliac veins to avoid misleading pathways into surrounding collaterals. Traversing the pathologically affected venous segments was achieved by a hydrophilic angled tip guide wire 0.035 inch (Radiofocus® Glidewire® Terumo corporation, Japan) or a 0.018 inch steerable guide wire (V-18™, ControlWire™, Boston scientific corporation, USA) with the support of an angled tip angiographic catheter (BERN, Imager™, Boston scientific corporation, USA) or a straight support catheter (Rubicon™, Boston scientific corporation, USA). After traversing the occluded iliac venous segment, the angiographic catheter or the support catheter was used to perform a control venography to verify the true passage to the inferior vena cava (IVC) then guidewire exchange to a super stiff guide wire (Amplatz Super Stiff™ guide wire, Boston scientific corporation, USA). Balloon dilatation was attempted utilizing a high pressure 12mmx80mm balloon (Mustang™ Balloon Dilatation Catheter, Boston scientific corporation, USA) to the external iliac and common femoral veins, then a 14mmx40mm or a 16mmx40mm balloon (Advance® ATB PTA Dilatation Catheter, COOK® Medical incorporation, USA) was used to dilate the common iliac vein. Balloon inflation was kept for at least 3 minutes at the nominal inflation pressure. After balloon dilatation, another control venography was performed before

stenting to identify the confluence of the CIV with IVC proximally and to identify the confluence of the profunda vein with the CFV distally. Our stenting policy was to stent the entire pathological segment beginning proximally from inside the lower end of the IVC down to the EIV or even further down to the CFV above the profunda vein ostium liberally crossing the inguinal ligament in case where the common femoral vein is involved. Adequate overlap between the deployed stents was ensured to avoid foreshortening during post stent dilatation and to avoid having skipped non-stented pathological areas in the treated vein segment. For Vein stenting, we have used (WALLSTENT™ Endoprothesis, Boston scientific corporation,

USA). The selection of stent diameter was achieved according to the discretion of the operator and was usually between 16-18mm in the CIV segment and 12-14mm in the CFV and EIV segment. The large diameter WALLSTENT necessitated that we changed the 8Fr sheath to a larger 10Fr sheath. The final step after stenting was post stent dilatation for 1 minute to ensure good stent to vein wall apposition and to prevent future stent migration. Completion venography was performed at the end of the procedure to visualize the treated segment and, to ensure free flow of contrast through the stented segment up to the IVC together with the disappearance of the collaterals and, to ensure that there are no residual significant stenotic areas (Fig 1).



Fig 1. (A) Pre and (B) post intervention venography showing free flow of contrast through the stented segment up to the IVC together with the disappearance of the collaterals

Immediately after the procedure the patient was kept on therapeutic low molecular weight heparin (Enoxaparin sodium) according to body weight at a dose of 1mg/Kg subcutaneous injection twice daily for at least 5 days with overlapping shift to oral vitamin K antagonists for a target International Normalization Ratio (INR) of 2.0 to 3.0 monitored at least once every month for 1 year.

Follow up was done post-procedure at 6 weeks, and every 3 months thereafter over the follow up period throughout the study by clinical evaluation according to the VCSS, Villalta scale, and Venous Disability Score (VDS). Duplex ultrasound examination was performed at each follow up visit looking for visible stenosis >50% of the flow lumen or localized increase in flow

velocities along the stented segment or abnormal waveform response to respiratory phasity.

CT venography was only requested in case of recurrence of symptoms with duplex findings suggesting restenosis during the follow up visits. Our primary end points were primary, assisted primary patency of the stented venous segment while the secondary end points were improvement in the VCSS, Villalta scale and Venous Disability Score (VDS) over the follow up period together with 30-day morbidity and mortality.

RESULTS

Data was obtained for 20 patients (20 limbs) who underwent stenting for post-thrombotic ilio-femoral venous occlusive disease during the study

period. Demographic and clinical features of the study group are shown in (Table 1). The group included 15(75%) males, with Mean age of 38.34 ± 8.20 years, range 26-57years). All 20 patients presented with unilateral lower limb Post-thrombotic manifestations. The left leg was the affected limb in 17 patients, with right to left ratio of (1:5.6). None of the 20 patients had a previous IVC filter placement. Seven patients had diabetes (35%), while four patients were hypertensive (20%) and two patients were IHD. The mean duration of post thrombotic symptoms was 28.75 ± 15.14 months, range (6-75) months.

Table 1. Demographic data

Characteristics	N (%)
Age	Mean 38.34 ± 8.20 years, range 26-57 years
Gender Male	15 (75%)
Female	5(25%)
Affected leg	
Right leg	3 (15%)
Left leg	17(85%)
Both	0
Ratio Rt:Lt	1:5.6
Duration of PTS symptoms	Mean 28.75 ± 15.14 months, range 6-75 months
Previous IVC filter placement	Zero
Diabetes	7(35%)
Hypertension	4(20%)
IHD	2(10%)

The baseline CEAP classification of the 20 patients was, four (20%) patients were C4 presenting with pigmentation and lipodermatosclerosis, nine (45%) patients were C5 presenting with healed venous ulcers, while seven (35%) patients were C6 presenting with active venous ulcers. Regarding the anatomical extent of the disease based upon CT venography, we had 13(65%) patients with common and external iliac vein involvement, while 7 (35%) patients had common, external iliac veins and common femoral vein involvement. Regarding the pathology, 17(85%) patients had obstruction only (Po) while 3(15%) patients had reflux and obstruction (Pr,o) (Table 2).

Table 2. Clinical presentation according to CEAP classification

CEAP classification	N (%)
C4	4(20%)
C5	9(45%)
C6	7(35%)
E (Etiology)	
- Post-thrombotic	20(100%)
A (Anatomy)	
- Common and external iliac vein only	13(65%)
- Common, external iliac, and common femoral vein	7(35%)
P (Pathology)	
- Occlusion (Po)	17(85%)
- Reflux and occlusion (Pr,o)	3(15%)

Primary vein access was achieved through the femoral vein in mid-thigh in 13 (65%) patients and through the popliteal vein in 7 (35%) patients.

Immediate technical success was achieved in 18 (90%) patients with remaining two technical failures out of the 20 patients (Table 3). Our technical failures were due to failure of crossing the chronically occluded femoral vein into the iliac veins, with either a preferential passage of the guidewire into large collaterals emerging just before the occlusive lesion in one case or due to sub-adventitial passage of the guidewire with the resultant perforation in the other case.

Perforation occurred in one out of the two failures and was self-limited and disappeared within minutes during the procedure without any undesired consequences (table 3).

Table 3. Immediate technical success, veins stented, and procedure related complications

	N(%)
Immediate technical success	18(90%)
Technical failure	2(10%)
Stenting common and external iliac veins	13(65%)
Stenting common, external iliac, and common femoral veins	5(25%)
Procedure related complications	1(5%)

Stenting of the common and external iliac veins after balloon dilatation was achieved in 13 patients, while extending our stents further down to involve the common femoral vein was needed in five patients. This makes 18 patients who had stents deployed in whom there was a technical success of the procedure after excluding the two technical failures (Tab 3). Procedure related complications such as access site hematomas, infection, arterio-venous fistulae, retroperitoneal bleeding, or contralateral iliac vein thrombosis was not encountered in any of our 20 patients apart from the one self-limited perforation mentioned earlier (Table 3).

Analysis of our clinical outcome was done by comparing the mean Villalta scale, the mean

VCSS and their significant parameters before and at six weeks, three months, six months, nine months and one year after the procedure. Paired "T test" was used to test our results against the Null hypothesis using a significance level of ≤ 0.05 .

All clinical outcome measurements improved at 12 months after recanalization. At final follow-up the Villalta score was (mean 10.10 ± 5.07 & median 9 range 6-30) versus (mean 23.65 ± 4.67 & median 23.5 range 15-33) at baseline respectively, $t = 15.53$, $p < 0.001^{**}$. (Tab 4). Similarly the VCSS dropped from (mean 18.85 ± 4.59 & median 17.5 range 13-27) at day 0 to (mean 8.95 ± 4.56 & median 7.5 range 6-26) at the latest follow up respectively, $t = 10.72$, $p < 0.001^{**}$ (Table 5).

Table 4. The Median, Mean & SD of Villalta scale throughout the follow up

	Villalta Score					Paired t-test	
	Range	Mean	±	SD	Median	T	P-value
Baseline	15 - 33	23.65	±	4.67	23.5		
6 wks	8 - 32	15.05	±	5.09	13.5	13.837	<0.001**
3 mon.	6 - 31	13.40	±	5.11	13	14.505	<0.001**
6 mon.	6 - 31	12.15	±	5.60	11	12.794	<0.001**
9 mon.	6 - 30	11.45	±	5.48	10	14.887	<0.001**
12 mon.	6 - 30	10.10	±	5.07	9	15.539	<0.001**

Table 5. The Median, Mean & SD of VCSS throughout the follow up

	VCSS Score					Paired t-test	
	Range	Mean	±	SD	Median	T	P-value
Baseline	13 - 27	18.85	±	4.59	17.5		
6wks	9 - 27	14.35	±	4.50	12	11.420	<0.001**
3mon	6 - 27	11.85	±	4.70	11	10.345	<0.001**
6mon	6 - 27	10.55	±	4.97	8.5	8.904	<0.001**
9mon	6 - 27	9.90	±	4.99	8	10.024	<0.001**
12mon	6 - 26	8.95	±	4.56	7.5	10.725	<0.001**

Also at the final follow up, the pain had disappeared in seven patients (35%), became mild in twelve patients (60%) and still severe in one patient (5%) in whom the procedure failed. So the rate of patients with severe pain fell from 80% to 5%, and 35% remains pain free at the end of follow up. In addition, the Pretibial edema had disappeared in five patients (25%), became mild in fourteen patients (70%) and still severe in one patient (5%) in whom the procedure failed. So

gross swelling fell from 80% to 5%, and 25% remains edema free at the end of the study. At the final follow up five patients experienced ulcer healing (71.4%) out of the seven patients presented with ulcers. Seven of the nine (77.8%) patients who presented with venous claudication reported no such symptoms at final follow-up $p = 0.003^*$.

To further assess postoperative functional outcome, the Venous Disability Score (VDS)

which is a part of a disease-specific quality-of-life measurement tool, was calculated. Comparison between the VDS before and at twelve months after the procedure was done using Chi-square. Venous disability scores demonstrated excellent functional recovery at twelve months follow up. Seventeen (85%) of the eighteen patients, in whom the procedure was technically successful, were able to perform their baseline activities without requiring compression therapy or leg elevation, VDS score 1, and One (5%)

patient was able to carry out usual activities only with compression and/or limb elevation VDS score 2. The remaining two (10%) patients had VDS score 3, they were Unable to carry out usual activities even with compression and/or limb elevation. In one of them the procedure was initially technically failed, and the other was the patient that had in-stent restenosis at nine months follow up. These changes in the VDS were statistically highly significant, $P < 0.001^{**}$ (Fig 2).

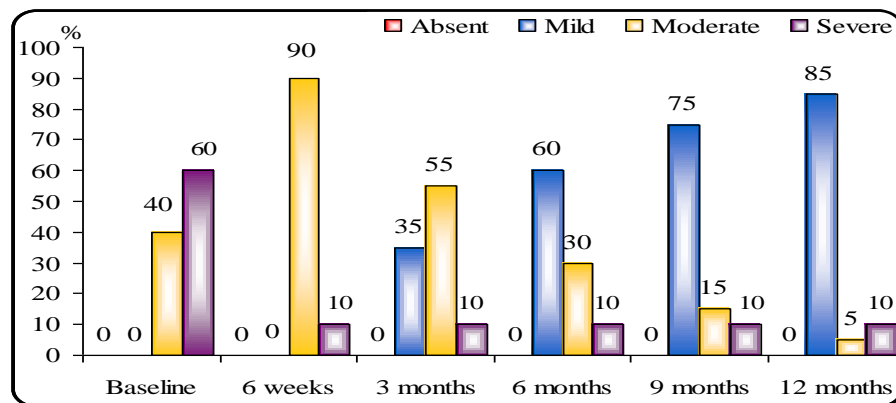


Fig 2. The Venous Disability Score (VDS) before then at 12 months after the procedure

Follow-up duplex performed on these patients revealed patent stents after initial stent placement in all eighteen technically successful limbs at 6 weeks follow up, however there was one patient who had $>60\%$ in-stent stenosis at 6 months, and another patient had $>80\%$ in-stent stenosis at 9 months. Those duplex findings of in-stent stenosis were accompanied by a deterioration of clinical and functional outcomes in these two patients at these follow up time points as evidenced by a rise in the Villalta, VCSS, and the VDS scores. Those two patients had a re-intervention to maintain the patency of these stents and to restore the clinical and functional outcome. The re-intervention in those two patients was in the form of balloon dilatation only, which yielded an immediate satisfactory angiographic result. The first showed improvement of both clinical and functional outcome over the rest of the follow up period, whereas, the second showed mild improvement of

the clinical but not the functional outcome over the rest of the follow up period.

Notably, these two events of in-stent stenosis occurred in patients who had stents extending from the common iliac veins down to involve the common femoral vein. The second patient was presented by active ulcer, which had healed at 6 months, and recurrence occurred at 9 months, and still active until the end of follow up due to the in-stent stenosis, and poor patient compliance that had occurred.

Regarding the two technical failures, one of them shows no improvement, but the other shows satisfactory improvement with elastic stocking throughout the follow up. Primary, and assisted primary patency rates as defined by the reporting standards of the ISCVS/SVS, were calculated using chi-square. Our primary patency rate was 90% at 12 months, while our assisted primary patency rate was 100% at 12 months. (Fig 3)

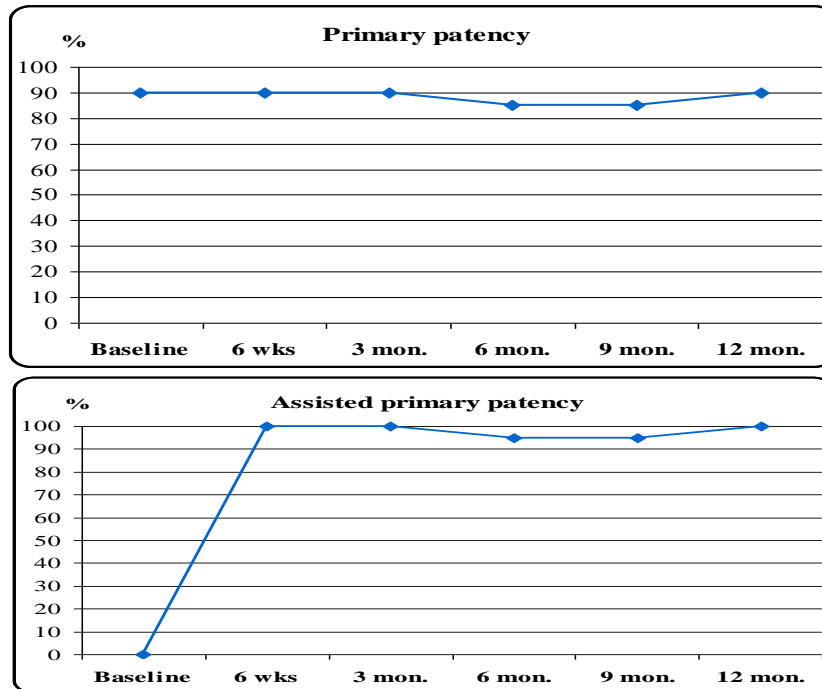


Fig 3. Primary & Assisted primary patency throughout the follow up

DISCUSSION

The long-term sequelae of ilio-femoral thrombosis manifesting as post-thrombotic syndrome are associated with significant ongoing disability and detrimental effects on quality of life.⁽¹⁾

Over the previous decade, endovascular treatment options including angioplasty and stenting have been incorporated into treatment paradigms, especially in the setting of underlying untreated iliac vein stenosis. Although numerous previous reports have primarily focused on the technical success and durability of endovascular intervention,⁽³⁾ few have addressed functional outcomes in these otherwise relatively young, healthy, active patients.

Although prior reports have demonstrated symptomatic improvement in both pain and edema, such studies have rarely examined short-term disability as measured by one's performing activities of daily living as measured by the Venous Disability Score (VDS). The Venous Disability Score (VDS) is a modification of the original CEAP disability score. It is intended to correlate the patients' symptoms to their daily

usual activities. This previously validated venous disability index has been used to quantify degree of disability referable to a patient's venous disease burden reflecting their ability to perform activities of daily living with or without compression and/or elevation.⁽⁵⁾

In our study, Venous Disability Scores demonstrated excellent functional recovery at twelve months follow up. 85% of patients were able to perform their baseline activities without requiring compression therapy or leg elevation, VDS score 1, and 5% of patients was able to carry out usual activities only with compression and/or limb elevation VDS score 2. Highlighting that the vast majority of patients undergoing treatment will derive a sustained functional benefit. By comparison, only 10% of the patients were unable to perform their usual activities despite using compression support.

We also used the Villalta scale, which is designed to monitor clinical outcome by symptoms and signs, which showed a significant improvement both early at one month and late at 12 months of follow up. The Villalta scale consists of six clinician-rated physical signs and five patient-rated venous symptoms, of which each are rated on a four-point scale (0= none, 1 =

mild, 2 = moderate, 3=severe). Points are summed to produce a total score (range 0-33). Subjects are classified as having post-thrombotic syndrome if the score is ≥ 5 or if a venous ulcer is present in a leg with previous DVT. The Villalta scale was used in several studies to diagnose post thrombotic syndrome (PTS). Score ≥ 5 confirming the diagnosis of PTS, and a score >14 denoting severe PTS. The Villalta scale has also been used as a continuous measurement for longer term follow up to grade the severity of the condition and to assess the effectiveness of treatments.⁽⁷⁾

In our study, the villalta scale showed significant improvement at the latest follow up, and this was comparable with *Yin et al., 2015* who conducted a study to evaluate the clinical results of stent placement in post-thrombotic patients with ilio-femoral obstruction compared with results in those treated with elastic compression stockings (ECS) in 216 patients. They reported improvement in the endovascular group median villalta scale from 22, range (11-33) to 8, range (2-18) post-stenting⁽¹⁰⁾. Also, our results are comparable with *Ruihua et al., 2017* who conducted a retrospective study to evaluate the technical aspects and early clinical results of combined stent placement for the management of postthrombotic syndrome chronic total occlusions (CTOs) of the ilio-femoral veins in 81 consecutive patients. Villalta scores were significantly improved from 21.5 before the procedure to 11.0 after the procedure ($P < 0.01$) during a median follow-up of 19 months⁽¹²⁾.

We also used the venous clinical severity score, which is designed to monitor clinical outcome and, assess the severity of chronic venous disease by symptoms and signs. The VCSS identifies 9 clinical characteristics of chronic venous disease that are graded from 0 to 3 (absent, mild, moderate, severe) with specific criteria to avoid overlap or arbitrary scoring⁽⁶⁾.

In our study, the VCSS was significantly improved at the final follow up. Our results are comparable with *Rosales et al., 2010* who conducted a study to determine the mid-term patency and the clinical outcome after stenting of chronic occluded ilio-femoral venous segments. The clinical improvement recorded by using the VCSS score was statistically significant ($p = 0.0001$) At Two-years follow up. 27 patients were C3, 25 of them were successfully recanalized and their pre-VCSS were 9 range (5-

12) and 7 patients were C6 and their pre-VCSS were 21 range (18-29). Post intervention the VCSS fell to 1 range (0-11) for the C3 group and to 7 range (6-14) for the C6 group respectively⁽⁸⁾. Also, our results are comparable with *Rossi F.H, et al., 2017* who conducted a study to compare medical and endovascular treatment results in symptomatic chronic venous disease patients with significant IVO documented by (IVUS) in 207 CVD patients. At 6 months' followup, The Venous Clinical Severity Score dropped from a median of 18.5 to 11 after stenting and from 15 to 14 with medical treatment ($P < .001$)⁽⁹⁾.

In our study, the rate of patients with severe pain fell from 80% to 5%, and 35% remains pain free at the final follow up. In addition, gross swelling fell from 80% to 5%, and 25% remains edema free at the end of the study. This was discordant with *Neglen, et al., 2007* who documented long-term clinical and hemodynamic outcomes in a cohort of 870 patients with chronic venous obstruction and, they reported severe leg pain and leg swelling decreased from 54% and 44% pre-stent to 11% and 18% post-stent, respectively. At 5 years, cumulative rates of complete relief of pain and swelling were 62% and 32%, respectively⁽¹³⁾. In 2015, *Raju S*, reported Clinical relief of pain ranged from 86% to 94% and for swelling ranged from 66% to 89% in a review of worldwide iliac and IVC stent series⁽¹¹⁾. *Yin et al., 2015* reported significant improvement in both edema and pain in the two groups after the corresponding treatment. Moreover, this probably because of the small study sample and, the short follow up duration in our study⁽¹⁰⁾.

In our study, at the final follow up five patients experienced ulcer healing (71.4%) out of the seven patients presented with ulcers. This was comparable with *Ruihua et al., 2017*, who found that, Active ulcers were present in 33 limbs, and the cumulative recurrence-free ulcer-healing rate was 81% at follow-up⁽¹²⁾. In addition, *Rosales A et al., 2010* reported healing of four of the seven ulcers presented in their patients⁽⁸⁾. In 2015, *Raju S* reported 58% to 89% of venous ulcers healed in a review of worldwide iliac and IVC stent series⁽¹¹⁾. *Yin et al., 2015* reported significantly higher 24 month recurrence free ulcer healing rate in the endo-treatment groups (86.6% vs. 70.6%, $p < .01$)⁽¹⁰⁾. In 2007, *Neglen et al* reported 58% ulcer healing⁽¹³⁾.

In our study, Seven (77.8%) of the nine patients who presented with venous claudication reported no such symptoms at final follow-up $p = 0.003^*$. This was comparable with *van Vuuren, et al., 2017* who conducted a study to assess mid-term clinical outcomes and patency rates in a large cohort after percutaneous and hybrid interventions in 425 lower extremities in 369 patients were treated. At 60 months, venous claudication subsided in 90%, 82%, and 83%, in the IVCS, P-PTS group, H-PTS group, respectively⁽¹⁴⁾. In addition *Rosales et al., 2010* reported that, venous claudication resolved in those successfully recanalized⁽⁸⁾.

Regarding technical success and durability of the procedure, as measured by patency rates, our study documents good short-term overall patency after endovenous treatment. Our primary patency was 90%, with associated assisted primary patency rates of 100% at 12 months. Loss of primary patency, when it did occur, was observed in the early post-intervention period, with excellent assisted primary patency rates. Thus, aggressive re-intervention for early in-stent stenosis in this patient population may be beneficial, leading to a sustained clinical benefit for the patients.

Our technical results are comparable with other previous studies. In *2017 Ruihua W, et al.*, reported primary, primary assisted, and secondary cumulative stent patency rates, 81.5%, 91.4%, and 93.8%, respectively at 2-years⁽¹²⁾. In addition, *Rossi F.H, et al., 2017* reported primary, assisted primary, and secondary patency rates, 92%, 96%, and 100%, respectively (median, follow up, 11.8 month)⁽⁹⁾. Moreover, in *2017, van Vuuren, et al.*, reported, primary patency, assisted primary patency, and secondary patency rates, 90%, 100%, and 100% for IVCS, and 64%, 81%, and 89% for the P-PTS group, respectively. At 60 months. The H-PTS group, showed patency rates of 37%, 62%, and 72%, respectively, at 36 month⁽¹⁴⁾. Although additional reports also highlight the technical success of aggressive therapy in patients for both acute and chronic indications, few have measured functional outcomes in both acute and chronic settings. Accordingly, our study attempts to better define the functional outcomes following ilio-femoral venous stenting.

This study has an intrinsic limitation of being modest in size, No long-term follow up, various

anatomical lesions (ilio-caval & bilateral lesions) were not represented in this study. Another important issue that needs to be evaluated in our study is the applicability of extending venous stents below the inguinal ligament to involve the common femoral vein. Yet it still considered one of the very few series to date documenting post-intervention functional outcomes. Despite these limitations, this series does successfully document good durability and functional improvement in a real-world experience at a tertiary care center. So, randomized studies with larger patient population followed by long term follow up including various anatomical lesions using different techniques is recommended.

In conclusion, this study successfully demonstrates a durable 1-year primary, and assisted primary patencies among patients treated for chronic post-thrombotic ilio-femoral venous occlusive disease. Furthermore, those patients derived sustained symptomatic relief and significant improvement in their venous disability scores, with the majority of patients able to resume their activities of daily living. Therefore, aggressive endovascular therapy in patients with chronic post-thrombotic ilio-femoral venous occlusive disease provides durable patency as well as significant clinical improvement. Those patients, many of whom are young, can anticipate an excellent functional recovery with a high likelihood of returning to work.

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