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Original Article

Iliofemoral stenting for chronic venous occlusive disease: Initial and mid-term outcomes in single institution

Tamer Khafagy [a], Samer Regal [a], Dalia Fahmy [b,*]

[a] Vascular Surgery Unit, Faculty of Micine, Mansoura University, Egypt
[b] Department of Diagnostic Radiology, Faculty of Micine, Mansoura University, Egypt

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ABSTRACT

Aim of the work: To evaluate and report the initial and midterm outcomes of endovascular venous stenting in cases suffering from chronic venous insufficiency due to iliac and common femoral vein obstruction.
Patients & methods: Patients with chronic venous insufficiency were referred to our institution during the period from January 2014 to October 2015. CT venography was performed to evaluate site and extent of proximal venous stenosis or obstruction. Then conventional venography and endovascular stenting were done. The patency of the stents was assessed at short and midterm follow-up examinations.
Results: CT venography revealed proximal iliac vein obstruction in 9 cases and common femoral vein obstruction in 3 cases. All were post-thrombotic. Technical success was 67% (8/12) with no immediate major complications. Follow-up CT venography done 1 month post-procedure revealed no restenosis. After one year 8 patients showed overall improvement of symptoms with decrease in lower limb edema, swelling and pain.
Conclusion: Stent implantation for symptomatic ilio-femoral venous obstruction is a safe and effective procedure to resolve venous disease symptoms. Despite the small number of patients, initial and mid-term outcome has been good.

1. Introduction

Chronic iliac and femoral vein occlusion or stenosis due to deep vein thrombosis or non-thrombotic conditions is an important cause of venous outflow obstruction and may lead to post-thrombotic syndrome and chronic venous insufficiency [1]. The resulting leg swelling, venous claudication, skin changes, and ulceration, have been linked to a significant deficit in quality of life [2,3].

However this anatomic obstruction is frequently overlooked, owing in part to diagnostic difficulty [4]. Treating these cases by conventional ways (as primary varicose veins) will exaggerate the symptoms as it eliminates the collateral pathway for venous hypertension. Because the clinical symptoms may be identical while the pathologic changes are vastly different, the clinical diagnosis is not a good predictor of the extent of venous damage [5].

Doppler ultrasound offers a high accuracy for the detection of lower limb deep venous thrombosis (DVT), but on the contrary pelvic veins are often inadequately visualized due to a limited acoustic window (e.g. due to bowel gas). Thus, CT-venography (CTV) has been propagated as an alternative test for the detection of DVT [6]. It also identifies other causes of non-thrombotic venous obstruction.

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* Corresponding author. Tel.: +20 96560054578.
E-mail address: daliamonir2525@gmail.com (D. Fahmy).

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Percutaneous venoplasty and stenting have become the preferred treatments for IVC and iliac vein obstruction, providing symptom relief and clinical improvement with encouraging early and intermediate outcomes [1,7].

The aim of this study was to evaluate and report the initial and mid-term outcomes of endovascular venous stenting in cases suffering from chronic venous insufficiency due to iliac and common femoral vein obstruction.

2. Patient and methods

This is a prospective study done after approval of the ethical committee and all patients signed an informed consent.

2.1. Case selection

- Patients with chronic venous insufficiency referred to our institution during the period from January 2014 to October 2015 to do endovascular procedure were included in this study.
- Criteria for selection included; patients suffering from chronic venous insufficiency presented with lower limb edema, venous claudications, leg ulcer or varicose veins that were unresponsive to other types of therapy (conservative treatment and surgery).
- Cases were excluded in the following situations; when Duplex examination showed acute DVT, when CT venography revealed no abnormality in the deep veins, when there is bleeding tendency and interventional procedures are contra-indicated.
- Etiology of the patient's venous obstruction was determined based on patient history, findings in the preoperative workup, and intraoperative data.

2.2. Clinical examination

- All patients were examined during standing and recumbent position, CEAP grading was used, and the presence of dermatitis, swelling, edema visible varicosities, or leg ulcer was assessed and recorded. Venous claudication which is defined as calf pain developed after 5 min of stepping test [8] was also assessed and recorded.
- Complete history taking as regards previous DVT, major operation with long duration of bed rest, exogenous hormone therapy, other co-morbidities and history of smoking.

2.3. Imaging

- All patients were evaluated first by Duplex scan during standing and recumbent position to assess the patency of external iliac, common femoral, superficial femoral and popliteal veins as well as assessment of incompetent valves in deep and superficial systems.
- CT venography was done for all patients included in this study to assess patency of the deep venous system. It was performed using a multi-detector CT scanner (Brilliance 64, Philips Healthcare, Best, The Netherlands). The parameters for CT venography were beam collimation, 64 × 0.625 mm; pitch 1:0.891; slice thickness 2 mm; and reconstruction interval, 1.25 mm. Images were obtained with the patient in the supine position. After 3.5 min, indirect CT venography is subsequently performed from above the iliac bifurcation to the ankle joint.

A total of 2.0 mL/kg of bodyweight of iohexol (Omnipaque 350; Amersham, Cork, Ireland) and then 30 mL saline bolus were injected with a flow rate of 3.5 mL/s.

Table 1
Demographic characters of patients included in this study.

Age	
Mean (range)	31 years (range, 12–43 years)
Sex	
Male	4
Female	8
Risk factors	
History of DVT	8
Obesity (BMI > 30)	4
Recent major operation	2 (caesarean section)
Exogenous hormone therapy	0
Other co-morbidities	
DM	3
Hypertension	2
Renal disease	1
Coronary artery disease	0
COPD	0
Autoimmune disease	0
Smoking	1

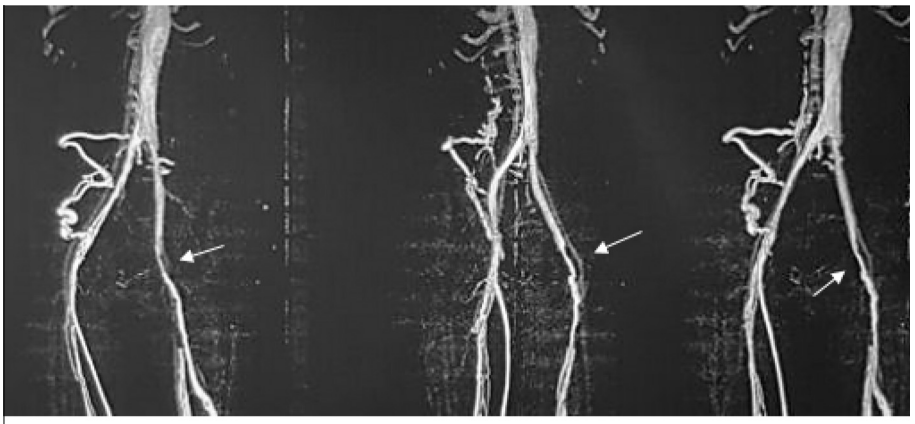
Table 2
Summary of clinical, pathological findings in 12 cases included in this study.

Clinical class	
0–1	0
2 (Varicose vein, pain)	1
3 (Venous edema)	6
4a (Dermatitis, hyperpigmentation)	3
4b (Lipodermatosclerosis, white scar)	0
5 (Healed ulcer)	0
6 (Active ulcer)	1
Venous claudications	4
Etiology	
Secondary (post-thrombotic)	12
Color coded Doppler sonography findings	
Acute DVT	0
Reflux	
Superficial system alone	0
Deep system alone	0
Superficial and deep system	8

Table 3
Demonstrate site of proximal venous obstruction in 12 cases.

	Right	Left
Common iliac	4	2
External iliac	3	2
Common femoral	1	2

NB: 2 cases showed stenotic segment involving common iliac vein and extending to external iliac veins.



A

B

Fig. 1. (A) (coronal volume rendering image of CT venography): showing severe stenosis at the distal left external iliac vein. (B, C, D & E) (conventional venography): A significant stenosis is noted in common iliac vein (black arrow) proximal to a stent [14 mm diameter/7 cm length expandella endovascular stent] (double black arrows) which has been inserted in external iliac vein during the same session (B), this stenotic segment was underestimated in CTV. It was followed by balloon dilatation (venoplasty) and stent insertion (16 mm diameter/7 cm length) in left common iliac vein (C & D). Finally conventional venography showed patent lumen after successful venoplasty and stenting (E).

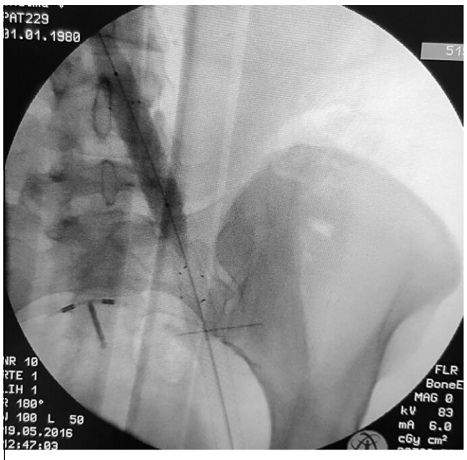
– Significant stenosis was defined as at least 50% narrowing of iliac or common femoral veins. Obstruction was identified by non-opacification of the lumen of the vein.

2.4. Lab tests

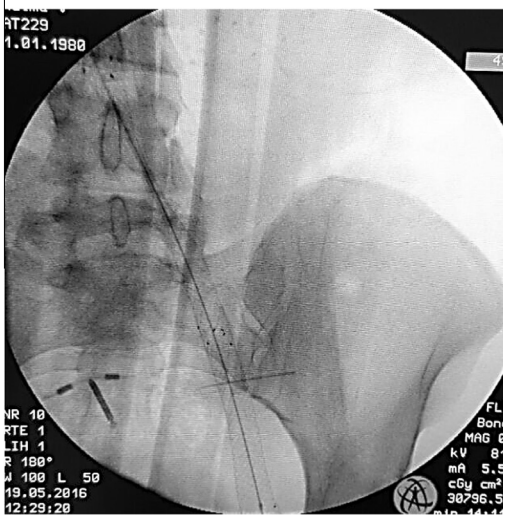
– Routine tests were done for all patients including CBC with platelet count, serum creatinine, blood urea, serum bilirubin, SGOT, SGPT, INR, fasting blood sugar.
– All patients were checked for coagulation disorders (Factor V Leiden deficiency, Antithrombin III deficiency, Protein S or Protein C deficiency, Anti-cardiolipin antibodies, Lupus anticoagulant).
– Prothrombin time (PT) and activated partial thromboplastin time (APTT) if the patient is on anticoagulation.
– ECG and cardiac ECHO if needed.

2.5. Interventional procedure

– The procedure was performed under spinal anesthesia to avoid pain and discomfort often associated with iliac vein balloon dilatation.
– Ultrasound guided puncture of ipsilateral popliteal (prone position) or superficial femoral vein (supine position). Then the occluded or stenotic vein is passed by a Terumo guidewire which was further advanced into the inferior vena cava (IVC).
– Venography was done by injecting 10 cc contrast material, then the degree and extent of stenosis were evaluated in antro-posterior and lateral views.
– Pre-dilatation of vein using 6–14 mm balloons and post-dilatation using 10–14 mm balloons were done



C



D

E

Fig. 1 (*continued*)

before and after placement of 4–9 cm self expandable stents (diameter ranging 8–16 mm).

- Dilatation (venoplasty) and stent placement were done. No pressure gradient was measured. Size of stents was based on the vessel in which it was deployed.
- A post-venoplasty venogram of each patient revealed a widely patent stent and good contrast material flows through the stent up to the inferior vena cava without filling of the cross pelvic collaterals.
- Intravenous (IV) heparin (5000 IU) was given during the procedure.
- The patients were discharged the same day or on the first postoperative day.
- Anticoagulant treatment with warfarin targeting INR in the range of 2–3 with bridging of low molecular weight heparin was prescribed for 6 months and high above knee-class II compression stoking was recommended for 1 year.

2.6. Follow-up

- Scheduled follow-up was done in the outpatient clinic at 4 weeks, 3 months, 6 months and annually thereafter.
- Patient's symptoms (pain, venous claudications, heaviness, paresthesia, and pruritus) and signs (pretibial edema, skin induration, hyperpigmentation, redness, venous ectasia, and ulcer) were recorded.
- Post-procedure CT venography was done 1 month after the procedure and repeated if there is any clinical suspicion of recurrent venous obstruction. Abdominal plain film was done every 6 months to assess whether the stent had migrated.

We assessed the effectiveness of the treatment by evaluating the relief of limb pain and edema and the healing of ulceration and absence of recurrence.

2.7. Statistical analysis

Individual data are given as range with mean ± SD, unless otherwise indicated.

3. Results

Twelve patients with iliac and/or common femoral vein stenosis/occlusion were included in this study. They were 8 females and 4 males with the mean age of 31 years (range, 12–43 years). Demographic data and medical history are shown in Table 1.

The clinical score (CEAP) was class 2 in 1 class 3 (edema) in 6 patients, class 4a (pigmentation or eczema) in 3, class 5 (healed venous ulcer) in 0, and class 6 (active venous ulcer) in 1. Four cases had venous claudications. All cases were thrombotic, and no cases of external compression or May Turner were encountered. Also according to Laboratory tests there was no case of thrombophilia. Color coded Doppler sonography showed reflux in deep and superficial venous systems in 8 cases. These data are shown in (Table 2).

All cases suffered from single limb disease. The anatomical distribution of obstruction (as determined by CT venography and conventional venography done during

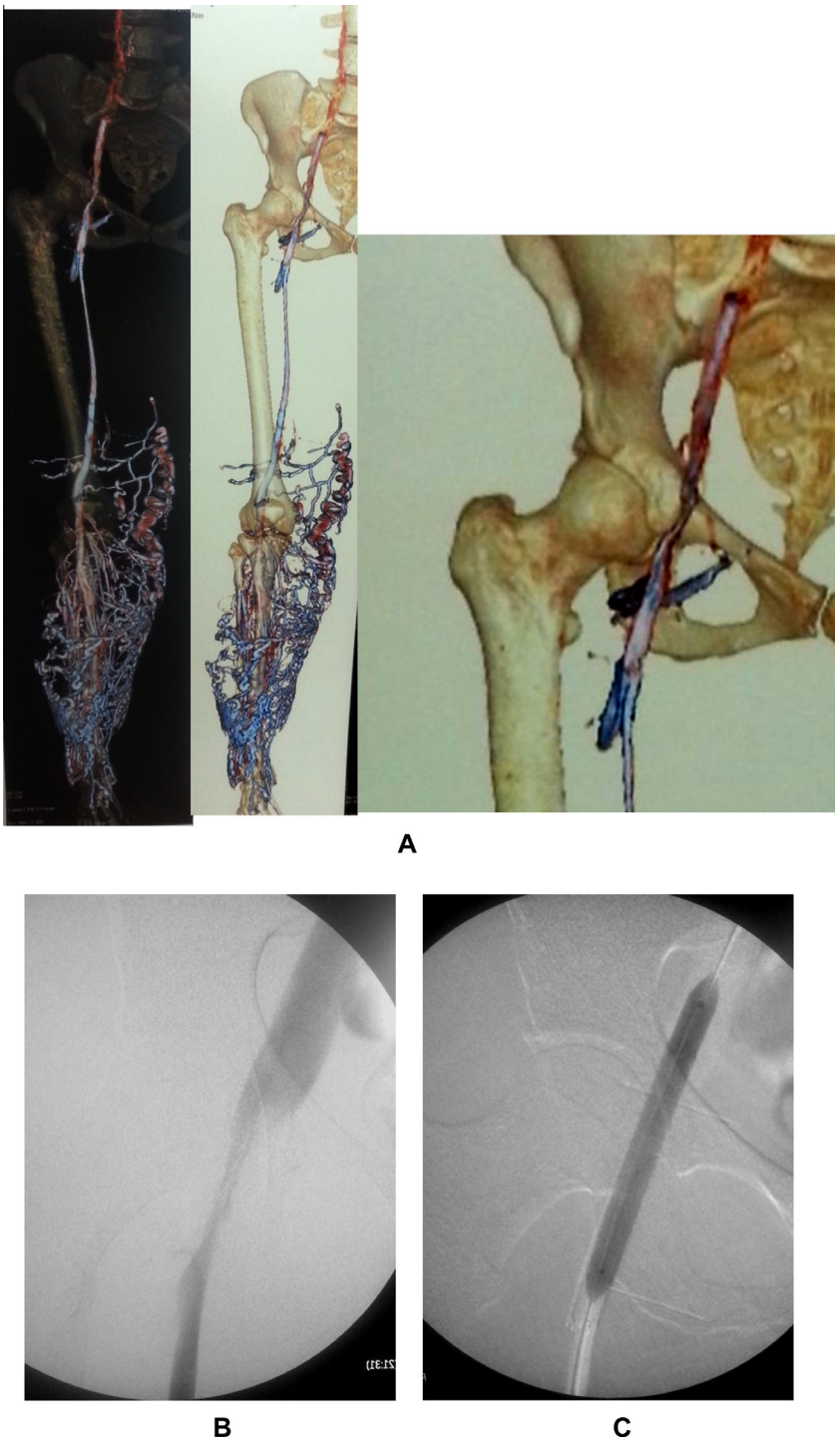
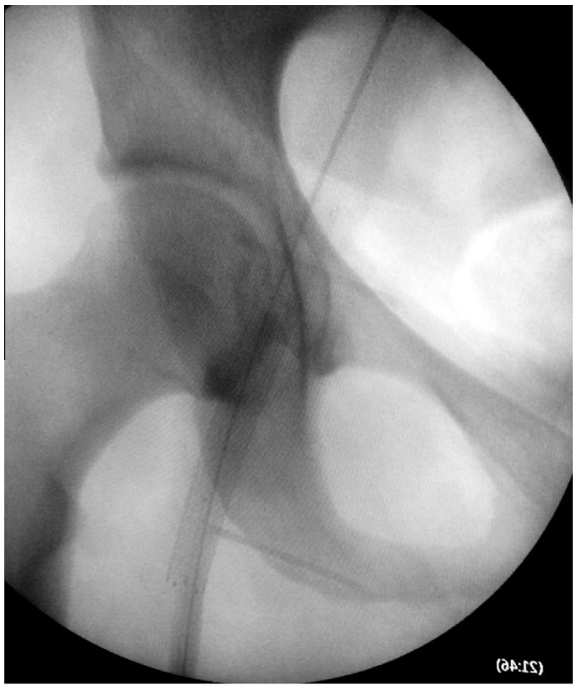


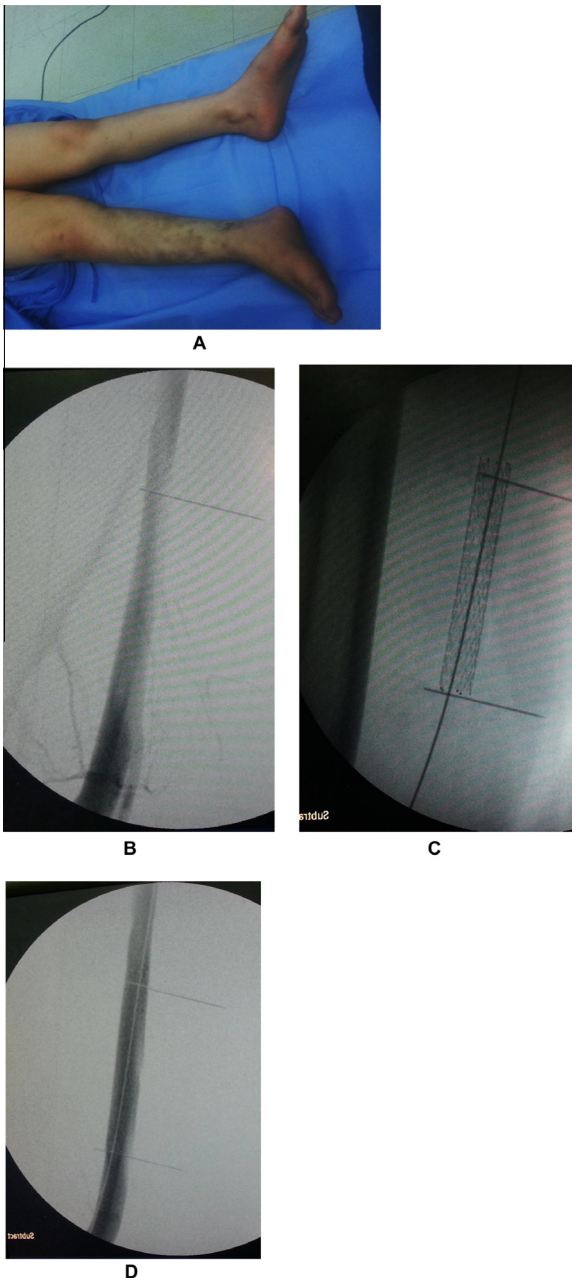
Fig. 2. (A) (coronal volume rendering image of CT venography): significant stenosis of the right common femoral vein, associated with extensive tortuous varicosities of the veins of the distal thigh and leg. (B, C & D) (conventional venography): Significant stenosis of right CFV is noted (B), followed by balloon dilatation [venoplasty] (C) and insertion of (10 mm diameter/6 cm length) expandella endovascular stent (D).

venoplasty) is shown in (Table 3). In all cases; findings in CTV and venography were identical. However in one case CTV and initial venography underestimated the length of stenotic lesion which involved the left common iliac vein as well as the left external iliac vein and required insertion of 2 stents (Fig. 1).



D

Fig. 2 (*continued*)



A

B C

D

Fig. 3. (A) showed right lower limb pigmentation. (B, C & D) (conventional venography): significant stenosis is noted at the right common femoral vein (B). Successful stenting (8 mm diameter/6 cm length expandella endovascular stent) was done (C) followed by venography showing complete re-canalization and opacification of the lumen of the common femoral vein (D).

Successful venoplasty and stenting were done for 8 patients (67%) as shown in [Figs. 1–3]. Technical failure in four cases was due to long segment of mixed thrombosis and fibrosis with subsequent failure of passage of the wire. These cases were referred for conventional treatment by elastic stockings and venotonics.

No major early complications were observed (no death, pulmonary embolism or contrast induced nephropathy). There was no stent migration or fracture. However local hematoma at site of incision developed in 3 cases and was treated successfully by local compression and bandage.

Follow-up CT venography was done 1 month after procedure in 8 cases; all stents were patent, no restenosis was noted (as shown in Fig. 4).

The mean follow-up time was 12 months (range, 8–22 months). Six patients (73%) had total or almost total symptom relief at follow-up (Table 4). Two patients still suffered from light PTS; however, all reported that stenting had improved their symptoms considerably.

Primary patency rate of the inserted stents after one year was 100%.

4. Discussion

Post-thrombotic syndrome (PTS) is a chronic complication of deep venous thrombosis that leads to considerable pain and suffering to patients [9]. It is characterized by chronic, persistent pain, swelling, and even venous ulcers in severe cases [10,11].

A subgroup of patients may also develop severe thigh pain with strenuous exercise which is referred to as venous claudication [12]. It was first reported by Cockett et al. [8] who claimed its occurrence only in patients with a chronic obstruction involving the iliofemoral venous segment. Although it is not included in the CEAP classification, we believe that this complaint is of high clinical importance as it may be a clue to proximal venous obstruction. In

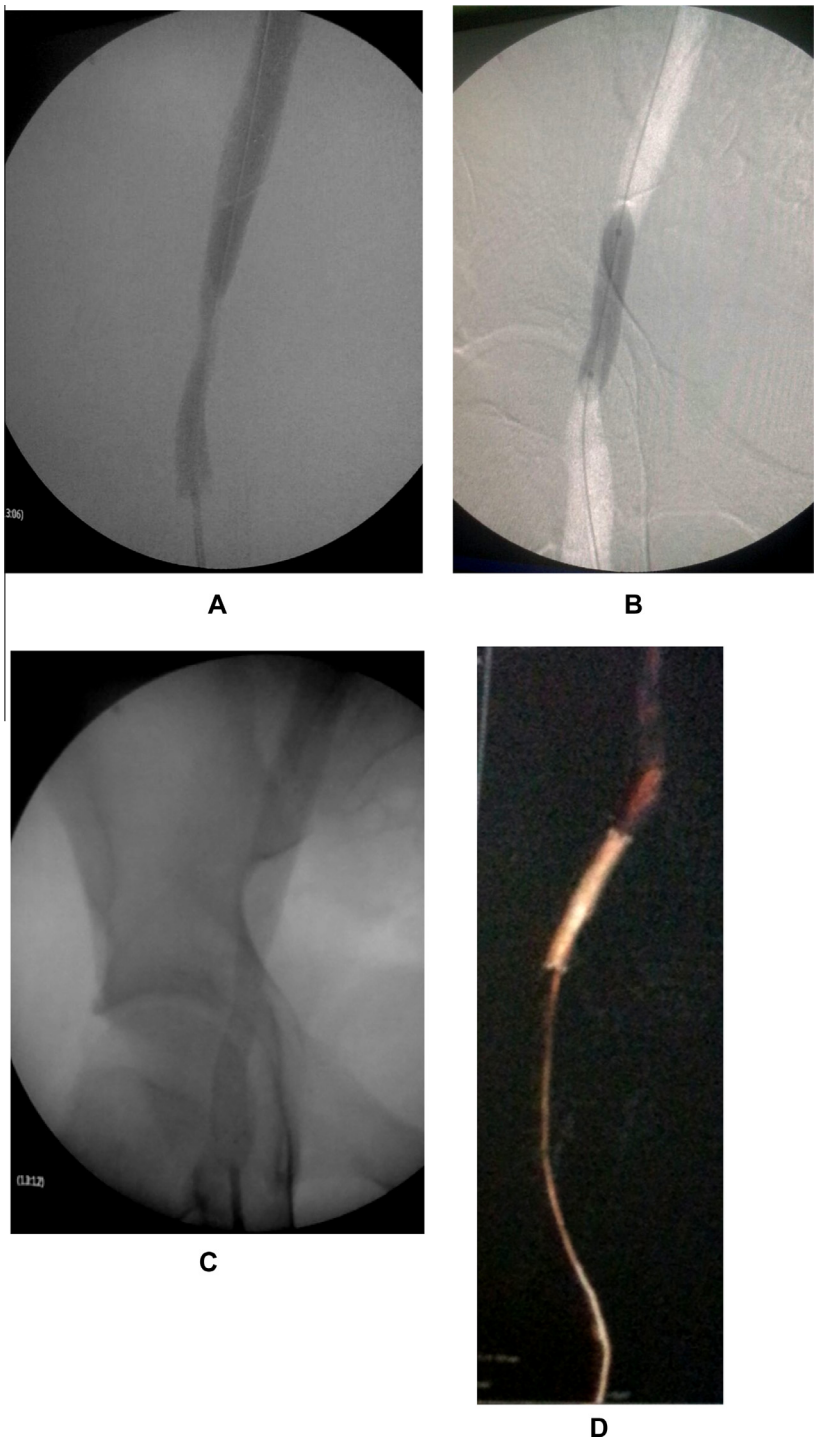


Fig. 4. (A, B & C) (conventional venography of the right lower limb): significant stenosis is noted at the right external iliac vein (A). Successful dilatation of stenotic segment (B) and insertion of (10 mm diameter/7 cm length expandella endovascular stent) were done with subsequent patent lumen (C). Follow-up CT venography done 1 month after venoplasty and revealed patent stent (D).

the current study we encountered 4 cases suffering from venous claudications.

Risk factors to develop PTS include location of the DVT and DVT recurrence, gender (1.5 times greater risk for women), obesity, and genetic factors (thrombophilia) [13,14]. Only 20% of iliac veins will recanalize on anticoagulation treatment alone after an iliofemoral DVT leading to PTS for a considerable number of patients [15]. In this study all cases had iliofemoral DVT, 67% of cases were females and 33% had morbid obesity.

Table 4
Follow-up findings in 8 patients 12 months post-stent placement.

Clinical class	
0–1	6
2 (Varicose vein, pain)	1
3 (Venous edema)	0
4a (Dermatitis, hyperpigmentation)	0
4b (Lipodermatosclerosis, white scar)	0
5 (Healed ulcer)	1
6 (Active ulcer)	0
Venous claudications	0
Complications	
Death	0
Pulmonary embolism	0
Recurrent DVT	0
Stent migration	0

Other causes of iliofemoral vein obstruction include the iliac compression syndrome that was described by May and Thurner [16] and by Cockett [8]. It is an anatomically variable condition of the left common iliac vein with outflow obstruction caused by the right common iliac artery compression against the lower lumbar vertebrae [17]. Unfortunately as we had very small study population, no such case was included in this study.

The diagnosis of PTS relies on clinical signs and symptoms as well as radiologic assessment of morphologic venous outflow obstruction [4]. Over the years, Duplex ultrasound was considered the first line evaluation of venous system because of its wide availability, portability and cost-effectiveness. It allows correct evaluation of patency of the deep system of lower limbs as well as the presence of reflux. However ultrasonography has lower sensitivity above the inguinal plane [18]. On the other hand CT venography is useful for a fast, comprehensive evaluation of the vascular system [19]. It helps in predicting endovascular potential difficulties by analyzing the morphologic features [20].

We believe that both modalities are complementary to each other especially in cases of post-thrombotic syndrome. In the current study pre-procedure Duplex ultrasound was done for all patients to assess patency and valve competence of the deep venous system of the lower limb, followed by CT venography to evaluate the iliac veins and IVC. In all cases findings in CT venography were identical to conventional venography except for one case where length of stenotic segment was underestimated in CT venography and initial venography before stent insertion. Residual stenosis was detected in subsequent venography followed by venoplasty and insertion of another more proximal stent. Intravascular ultrasound (IVUS) would have overcome such difficulty as it provides accurate and valuable on vascular size and morphology [21]. It considered by other researchers [22] the definitive diagnostic test of ilio-femoral venous obstruction and is essential for guiding stent insertion. Unfortunately IVUS is not available in our institution.

No specific criteria of when to perform venoplasty and stenting of an obstructive lesion exist in the literature [23]. In our institution this procedure is recommended for cases suffering from chronic venous obstruction or secondary varicose veins who are not responsive to conventional treatment. However owing to financial causes this technique is not widespread.

Technical success in the current study was 67%. Failure of cannulation was encountered in 4 cases due to long segment of extensive thrombosis and fibrosis. However there were no major immediate post-procedure or late complications. Only 2 cases had access site hematoma which was managed successfully by compression and bandage. Follow-up CT venography after 1 month revealed patent stents with no restenosis or thrombosis. After 12 months 67% of patients were free from symptoms while the remaining 2 showed significant improvement. Several studies have reported similar results that show stenting to be safe, with high patency rates, low rate of in-stent restenosis, and little need for re-intervention [9,23–28].

The primary patency rate in this study was 100%, which is comparable to rates reported in previous studies [23,28,29]. Patency rate mainly depends on the number of lesions needing recanalization, and if the common femoral vein is involved in the obstructive lesion [30].

Both safety and efficacy of the venoplasty and stenting are high, and the clinical results are excellent, reducing PTS symptoms and hence the health costs in most of the patients. However, only dedicated centers perform the endovascular procedures in selected patients. Patients with iliofemoral venous obstruction and moderate to severe PTS symptoms should, in our opinion, be offered venoplasty and stenting.

This study is limited by small number of cases. Larger scale studies are recommended.

5. Conclusion

Stent implantation for symptomatic ilio-femoral venous obstruction is a safe and effective procedure to resolve venous disease symptoms. Despite the small number of patients, initial and mid-term outcome has been good.

Conflict of interest

None declared

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