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Early and Long-Term Outcomes of Venous Stent Implantation for Iliac Venous Stenosis After Catheter-Directed Thrombolysis for Acute Deep Vein Thrombosis

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Background: Although stent implantation is used worldwide for peripheral arterial disease, there is little data on the safety and long-term patency of stents implanted for venous disease.

Methods and Results: We studied 13 patients with 14 lesions (6 males, 7 females, mean age: 63.2±10.2 years) diagnosed with venous stenosis and who underwent venous stenting. We examined the location of the stenosis, safety of venous stenting, implantation success rate, and long-term stent patency rate. All patients were suffering from venous stenosis in the left common iliac vein because of iliac vein compression syndrome. No major complications occurred during stent implantation. Acute stent occlusion occurred in 1 patient, who was given additional thrombolytic therapy. Of the 13 patients, 10 underwent venography or contrast-enhanced computed tomography (CT) during mid-term follow-up (mean: 12.9±16.1 months), and only 1 stent was occluded, resulting in a patency rate of 90.0%. The latter patient decided to stop taking warfarin soon after stent implantation. Furthermore, 5 patients underwent contrast-enhanced CT to assess the long-term patency of their stents (mean: 79.6±31.2 months), and none was occluded.

Conclusions: Venous stents display a high long-term patency rate, and hence are a useful tool for treating iliac venous stenosis. (*Circ J* 20■■; ■■: ■■■■–■■■■)

Key Words: Deep vein thrombosis; Iliac vein compression syndrome; Venous stenosis; Venous stents

Treatments for deep vein thrombosis (DVT) aim to prevent thrombus extension, pulmonary thromboembolism, and the long-term complications of post-thrombotic syndrome including persistent leg pain, chronic leg swelling, hyperpigmentation, and skin ulceration. Early thrombolysis seems to be important for preserving venous valvular function. Although stent implantation is used to treat peripheral arterial obstruction or stenosis worldwide,[1,2] there is little data on the efficacy and long-term patency of stents that are implanted for venous disease. We perform catheter-directed thrombolysis for acute iliofemoral DVT, but we have often experienced recurrence soon after successful thrombolysis despite administration of anticoagulation therapy within the therapeutic range. Residual venous outflow obstruction or stenosis after clot lysis can lead to venous thrombus formation because of venous stasis and/or endothelial injury. The most common cause of outflow obstruction or stenosis is extrinsic compression of the iliac vein [eg, May-Thurner or Cockett's syndrome (in which the left common iliac vein is compressed between the right common iliac artery and the spine)]. We perform venous stent implantation in cases of severe stenosis associated with blood stagnation or symptomatic venous return disorders because of venous stenosis. In this study, we examined the short- and long-term efficacy and safety of venous stent implantation for iliac venous stenosis.

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Methods

Patient Selection and Evaluation

The subjects were 13 patients who continued to exhibit leg swelling and pain from severe venous stenosis or significant venous stasis, which was detected by venography through the

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Table 1. Patients Characteristics

Case no.	Age (years)	Sex	Risk factors	Location of DVT	Stenotic lesion	Cause
1	66	F	Orthopedic surgery	CIV-PV	Left CIV	IC
2	64	M	Protein S deficiency, left hemiplegia	CIV-PV	Left CIV	IC
3	72	M	None	EIV-PV	Left CIV	IC
4	51	F	Orthopedic surgery	CIV-PV	Left CIV	IC
5	71	F	Abdominal surgery	CIV-CFV	Left CIV	IC
6	70	F	Carcinoma of the breast	CIV-PV	Left CIV Left EIV	IC OT
7	43	M	Antithrombin deficiency, amyotrophic lateral sclerosis	CIV-PV	Left CIV	IC
8	65	M	Paralysis of the lower part of the body; postoperative gastric carcinoma	CIV-PV	Left CIV	IC
9	69	F	Carcinoma of the cervix (after radiotherapy)	EIV-PV	Left CIV	IC
10	75	M	Obesity	EIV-PV	Left CIV	IC
11	57	F	Orthopedic surgery	CIV-PV	Left CIV	IC
12	70	F	Lumbar compression fracture	CIV-PV	Left CIV	IC
13	48	M	Antipsychotic drug use; postoperative testicular tumor	EIV-SFV	Left CIV	IC

CFV, common femoral vein; CIV, common iliac vein; DVT, deep vein thrombosis; EIV, external iliac vein; IC, iliac compression; OT, organized thrombus; PTS, post-thrombotic syndrome; PV, popliteal vein; SFV,superficial femoral vein.

popliteal sheath, after catheter-directed thrombolytic therapy and/or rheolytic thrombectomy for acute DVT.

All 13 patients underwent venous stent implantation between May 2000 and June 2008. The following information was obtained for each case: intravascular ultrasound (IVUS) scan findings; the number, size, and type of stents used; the stent implantation site; and whether thrombolysis or concurrent inferior vena cava (IVC) filter was used. In addition, complications that occurred after stent implantation, including recurrent venous thromboembolism, post-thrombotic syndrome, and stent fracturing, were recorded. The length of the follow-up period was determined by the timing of the last imaging examination of the stent.

Procedure

After implanting a retrievable IVC filter (Günther Tulip™ Vena Cava Filter Retrieval Set; Cook Medical, Bloomington, IN, USA) from the right internal jugular vein, we placed a sheath in the popliteal vein ipsilateral to the lesion and performed venography. In all patients, we performed catheter-directed thrombolysis (Fountain® Infusion System; Merit Medical, South Jordan, UT, USA). We also performed rheolytic thrombectomy in 4 of the patients,[3] using the 8 Fr Oasis Thrombectomy System (Boston Scientific, Natick, MA, USA) as the rheolytic device.

If patients had venous stasis because of severe stenosis after complete thrombolysis, we implanted a venous stent. We excluded young subjects aged less than 40 years because the long-term safety after venous stent implantation has not yet been established. Also, we excluded patients with a rich collateral through the pelvic venous plexus even if there was iliac vein compression syndrome. Furthermore, we excluded patients with a larger vessel diameter (>12 mm) than the size of available stents in Japan.

The length of the stent was chosen based on the length of the stenotic lesion on venography, and we chose the stent diameter based on measurements of venous diameter on IVUS. After the stent had been implanted, its expansion was confirmed by IVUS. Patients who exhibited inadequate stent expansion were treated with low-pressure balloon dilatation.

After stent implantation, we attempted to retrieve the IVC filter after cavography or contrast-enhanced computed tomography (CT) detected no thrombus trapped in the IVC filter.

During the procedure, all patients underwent full anticoagulation with unfractionated heparin through the side port of the introducer sheath. The heparin dose was adjusted to produce an activated partial thromboplastin time of twice the control value. After the procedure, all the patients were started on additional warfarin. The unfractionated heparin was discontinued after a therapeutic prothrombin time-international normalized ratio (PT-INR) had been obtained. The warfarin dose was adjusted to produce a PT-INR of 1.5–2.5.

Follow-up

Acute stent patency (within 2 weeks of stent implantation) and mid-term stent patency (approximately 1 year after stent implantation) were assessed with venography or contrast-enhanced CT; 3 patients were lost to mid-term follow-up, and we evaluated long-term stent patency (>3 years later) with contrast-enhanced CT in 5 patients.

We diagnosed post-thrombotic syndrome based on the CEAP classification.[4]

Results

The characteristics of the 13 patients (6 males, 7 females; mean age 63.2±10.2 years) enrolled in this study are shown in Table 1. During the same period, there were 74 cases of DVT for which catheter-directed thrombolysis was performed in our hospital, and the stent implantation rate was 17.6%. All patients were suffering from acute DVT or venous stenosis in the left common iliac vein because of iliac vein compression syndrome and continued to exhibit symptoms such as leg swelling and pain or venous stasis related to venous stenosis after thrombolytic therapy. One patient had stenotic lesions in both the left common iliac and external iliac vein. Thrombophilia, including protein S deficiency and antithrombin deficiency, was detected in 2 patients.

Stents

The stent implantation sites were the left common iliac vein in 13 lesions and the left external iliac vein in 1 lesion. Easy Wallstents (Boston Scientific) were implanted into 7 patients, SMART stents (Cordis, Bridgewater, NJ, USA) were implant-

Table 2. Details of Stent and Implantation

Case no.	Stent	Diameter (mm)	Length (mm)	Predilatation	Post-dilatation	Additional thrombolytic therapy after stenting
1	Easy Wallstent	10	50	–	–	–
2	Easy Wallstent	12	50	+	–	–
3	Easy Wallstent	10	65	+	–	–
4	SMART	12	60	+	–	–
5	SMART	12	40	+	+	+
6	SMART	10	60	+	+	+
	SMART	10	40	+	–	+
7	Easy Wallstent	12	50	+	+	+
8	Easy Wallstent	10	65	+	+	+
9	Luminexx	10	100	+	–	–
10	Easy Wallstent	12	50	+	+	–
11	Easy Wallstent	12	30	+	+	–
12	SMART	10	40	+	+	–
13	SMART	10	40	+	+	–

Table 3. Follow-up Data

Case no.	Occlusion in acute phase	Occlusion in mid-term phase	Diagnostic method	Warfarin therapy (duration)	Recurrence of VTE	Prognosis
1	(–)	(–)	Venography	Discontinued (84 months)		Died of tongue cancer
2	(+)	(–)	Venography	Continuing	(–)	
3	(–)	Not examined	(–)	Discontinued (48 months)	(–)	
4	(–)	(–)	Venography	Discontinued (51 months)	(–)	
5	(–)	(–)	Venography	Discontinued (45 months)	(–)	
6	(–)	(–)	Venography	Continuing	(–)	
7	(–)	(–)	Enhanced CT	Continuing	(–)	
8	(–)	(–)	Venography	Continuing		Died of postoperative ileus
9	(–)	(+)	Enhanced CT	Discontinued (28 months)	(–)	
10	(–)	not examined	(–)	Discontinued (32 months)	(–)	
11	(–)	not examined	(–)	Discontinued (6 months)	(–)	
12	(–)	(–)	Enhanced CT	Continuing	(–)	
13	(–)	(–)	Enhanced CT	Continuing	(–)	

VTE, venous thromboembolism.

ed into 5 patients, and a Luminexx stent (Bard Medical, Covington, GA, USA) was implanted into 1 patient (Table 2). The mean stent diameter was 10.9±1.0 m, and the mean stent length was 52.9±17.2 mm.

Balloon Venoplasty for Pre- and Post-Stent Implantation Dilatation

All the patients underwent balloon venoplasty to induce venous dilatation prior to stent implantation. In addition, we performed balloon venoplasty for post-stent implantation dilatation in 8 patients. In addition, thrombolytic therapy for residual thrombi was administered after stent implantation in 5 patients. Of them, the residual thrombi were located outside of the stent in 4 patients, and within the stent in 1 patient (Table 3).

Acute Phase Results

Acute stent patency (within 2 weeks of stent implantation, mean follow-up period: 5.7±3.7 days) was assessed with venography (11 patients) or contrast-enhanced CT (2 patients). During the acute phase follow-up period, 1 patient suffered complete occlusion caused by a thrombus (Figure 1). Hence, the stent patency rate during the acute phase was 92.3% (Table 4).

Complications Related to Stent Implantation

No major complications occurred during stent implantation; 1 patient exhibited in-stent thrombosis immediately after stent implantation. There were no complications such as pulmonary thromboembolism, vascular injury, major bleeding, stent fracturing, or stent migration.

Retrieval of the IVC Filters

All the IVC filters that had been implanted in the patients with acute DVT were successfully retrieved after thrombolysis and stent implantation. No complications related to IVC filter implantation or retrieval occurred.

Mid-Term Follow-up

We administered warfarin-based anticoagulation therapy to all patients; 3 patients were lost to the mid-term follow-up; 1 patient suffered leg swelling because of a stent occlusion during the mid-term follow-up period (mean follow-up period: 12.9±16.1 months). Imaging studies (venography: 6 patients, contrast-enhanced CT: 4 patients) were performed for the remaining 10 patients to verify whether the stents were occluded, but stent occlusion was only detected in 1 patient. Thus, the stent patency rate for the mid-term phase was 90.0%.

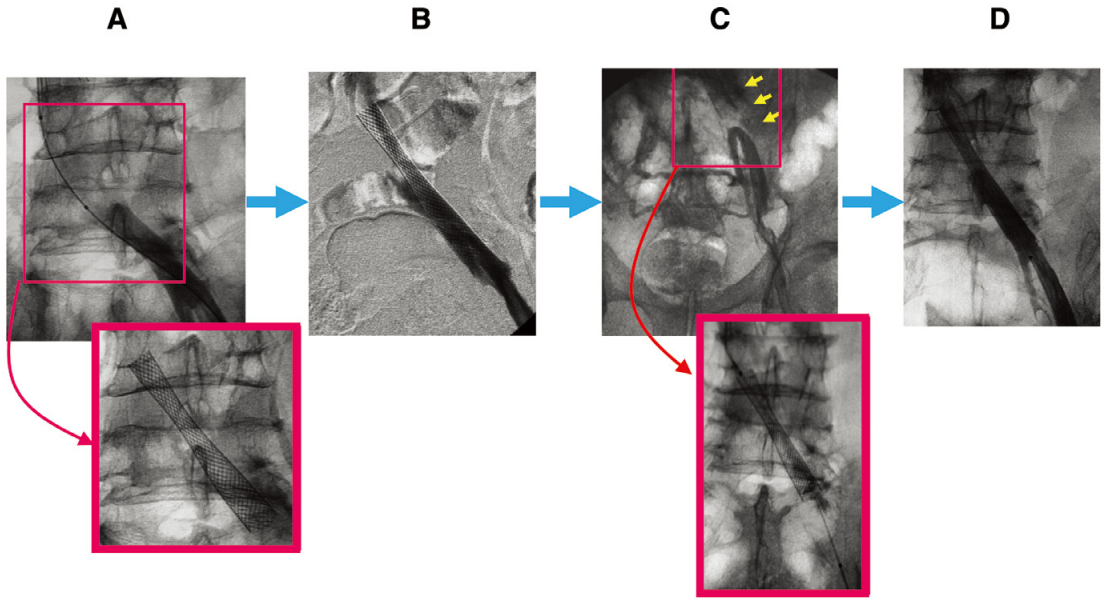

Figure 1. Stent occlusion during the acute phase (case 2). (**A**) Stent (Easy Wallstent, 12×50 mm) implanted after thrombolytic therapy. (**B**) After stent implantation. (**C**) At 2 days after stent implantation, catheter-directed thrombolytic therapy (Fountain infusion system, 5 Fr×10 cm) was initiated because of stent occlusion (yellow arrows). (**D**) Final imaging examination.

Table 4. Review of Venous Stenting Studies

Year	Author	n	Acute phase patency rate (%)	Chronic phase patency rate (%)	Follow-up (months)	Diagnostic method
1998	Binkert et al[13]	8	100	100	35	Venous US Venography
2000	Patel et al[14]	10	100	80	36	Venous US
2000	O'Sullivan et al[15]	35	93.6	93.6	12	Venous US
2001	Heijmen et al[16]	6	100	83	12	Venous US
2001	Hurst et al[17]	17	–	79	14~17	Venography Venous US
2002	Lamont et al[18]	15	93	87	16	Venous US
2005	Kwak et al[19]	22	96	95	24	Venous US
2006	Kim et al[20]	18	100	88	6	Venography
2008	Hartung et al[21]	29	89.7	78.9	63	Venous US
2012	Funatsu and Nakamura[22]	20	95	93.8	50	Venography Venous US
			mean: 96	mean: 88		
	Present study	13	92.3	90.0	79.9	Venography

Enhanced CT

Representative Case of Stent Occlusion

A 69-year-old woman (case no. 9) was admitted because of acute proximal DVT, and catheter-directed thrombolysis was initiated. After the clot had been dissolved, we implanted a stent (Luminexx, 10×100 mm) in a severe stenotic lesion in her left common iliac vein, which had been caused by iliac compression syndrome. After stent implantation, adequate stent expansion was confirmed by venography and IVUS. After discharge, the patient stopped taking warfarin of her own accord (10 days after stenting); however, her left leg subsequently began to swell. Complete obstruction from in-stent thrombosis was detected by CT at 1 month after stent implantation (**Figure 2**). Catheter-directed thrombolysis was not performed, but anticoagulation therapy was resumed, but despite long-term anticoagulation therapy, recanalization was not achieved. Finally, we ceased the anticoagulation therapy at 28 months according to the patient's wishes. After cessation of anticoagulation therapy, exacerbation of lower limb swelling has not been observed.

Long-Term Follow-up

The mean follow-up after stent implantation was 79.9±29.8 months (range 28–117 months). During follow-up, 2 patients died of tongue cancer and postoperative ileus, respectively. No deaths because of venous thromboembolism occurred. We list the long-term outcomes of anticoagulation therapy in **Table 3**. At the time of the last follow-up examination, 7 patients had

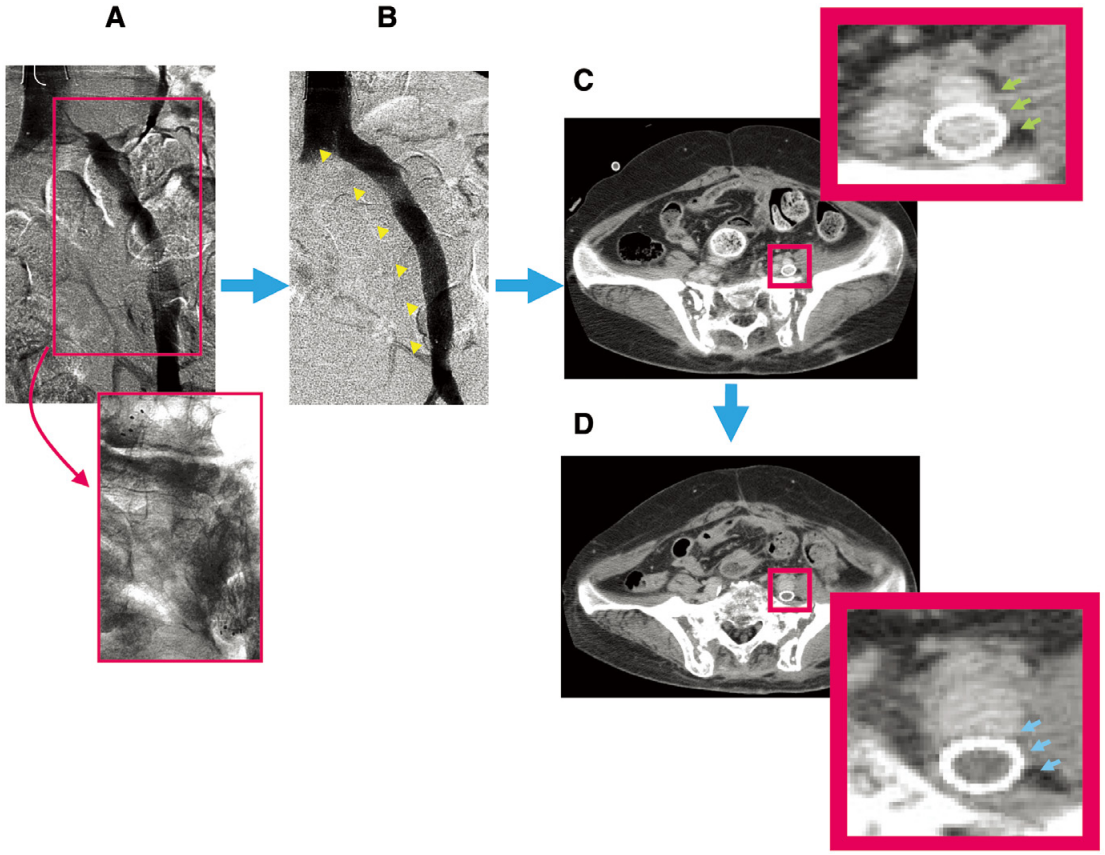

Figure 2. Stent occlusion during the mid-term phase (case 9). (**A**) Stent (Luminexx, 10×100 mm) implanted after thrombolytic therapy. (**B**) After stent implantation (yellow arrowheads indicate the stent). (**C**) Contrast-enhanced CT (4 days after stent implantation; green arrows show stent patency). (**D**) Contrast-enhanced CT (1 month after stent implantation; blue arrows show stent occlusion).

stopped taking anticoagulants, and 6 patients were continuing to receive anticoagulation therapy. The mean duration of anticoagulant therapy in the patients who ceased treatment was 42.0±24.1 months. None of the surviving patients who had ceased anticoagulation therapy developed recurrent venous thromboembolism. Contrast-enhanced CT was performed to examine the long-term stent patency in 5 patients (including 2 patients who had discontinued anticoagulation therapy; mean duration of stent implantation: 79.6±31.2 months). Good stent patency was observed in all 5 patients, and none of the stents had fractured.

Only 1 patient had leg swelling according to the CEAP classification (C3), but post-thrombotic syndrome was not observed in any other patient (CEAP classification: C0).

Discussion

Venous stenosis can lead to blood flow stagnation and cause DVT.[5] Also, the administration of anticoagulation therapy alone in patients with poor collateral vessels can lead to leg swelling, pain, and skin ulcers because of venous stenosis.[6] Therefore, it is important to treat stenotic lesions in such patients.

In recent years, the use of catheter interventions for vascular disease has spread rapidly in conjunction with the development of catheter devices. In addition, catheter-directed thrombolysis is being increasingly used to treat DVT and venous disease.[7] Stent implantation for venous stenosis is a catheter intervention for venous disease and is considered to be an effective treatment for venous stagnation. In our hospital, venous stents are implanted in patients with venous stasis because of severe stenosis after complete thrombolysis. On the other hand, we exclude young subjects or with a rich collateral through the pelvic venous plexus.

All patients in the present series were suffering from left common iliac vein stenosis. The left common iliac vein is often compressed (iliac compression syndrome) because it runs behind the right iliac artery, and in some patients there is a pelvic venous spur in this region. As a result, the left leg is prone to venous stagnation and DVT.[8]

To treat the patients with DVT, we placed a sheath in the popliteal vein ipsilateral to the lesion and performed stent implantation. After stent implantation, stent expansion was confirmed by IVUS. The 6 patients who exhibited inadequate stent expansion were treated with additional low-pressure balloon dilatation. Vascular injury, bleeding, infection, and pulmonary embolism were absent as complications, but 1 patient suffered in-stent thrombosis just after stent implantation. In that patient, venous stenosis and a thrombus developed in the distal part of the lesion, probably because of in-stent thrombus formation. Catheter-directed thrombolysis was highly effective, but venous stenosis remained in the distal portion of the lesion.

Blood flow stagnation was also observed at this site, and so an additional stent was implanted. After treatment, no recurrence developed during the chronic phase of the patient's condition.

Only 1 patient developed stent obstruction in the acute phase and that patient did not undergo balloon dilatation after stent implantation. Angiography performed just after stent implantation suggested that the stent might not have been large enough. Therefore, it was considered that blood flow stagnation led to the formation of a thrombus. The patient's blood flow was restored by catheter-directed thrombolysis, and no recurrence was observed.

IVC filters are often required in cases of acute DVT treated with a catheter intervention.[9] In this study, we implanted retrievable IVC filters in all patients. After completion of the catheter intervention, the IVC filters can be retrieved. However, implantation of a permanent IVC filter increases the risk of recurrent DVT,[10,11] so IVC filters should only be implanted during the catheter intervention. In this study, all of the IVC filters were successfully retrieved.

Of the 10 patients in whom we were able to assess stent patency during the mid-term follow-up phase, occlusion was only observed in 1 patient. After discharge, the latter patient decided to stop warfarin therapy (10 days after stenting). In all other cases in which anticoagulation was continued, the stents remained patent. According to the guideline,[12] anticoagulation therapy for venous thromboembolism is necessary for at least 3 months. We maintain that a longer duration of anticoagulation is necessary for venous stents. However, there is no evidence for the duration of anticoagulation for the venous stent. Among our cases, 6 patients with no persistent risk factors of venous thromboembolism discontinued anticoagulation therapy after a mean of 42 months and none had a recurrence of DVT. Although a shorter duration may be adequate, further prospective studies are needed to confirm the optimal duration of anticoagulation therapy for venous stents.

Table 4 summarizes the findings of some previous reports on stent implantation for venous stenosis.[13–22] All these studies report high patency rates during the acute and chronic phases. In most of them, chronic patency was assessed using venous ultrasound, but because the veins in the pelvis are difficult to observe on ultrasound,[23] stent patency was inferred from assessments of peripheral blood flow. In contrast, we have high confidence in our results, as stent patency was assessed by angiography in the current study. In the present study, the acute phase patency rate was 92.3%, and the mid-term patency rate was 90.0%. Also, long-term stent patency was assessed by contrast-enhanced CT in 5 patients and in all of them the stents exhibited good patency, and there were no fractured stents. Thus, stent implantation is considered to be an appropriate treatment for venous stenosis.

Conclusions

In conclusion, venous stent implantation for iliac venous stenosis is associated with a high long-term patency rate and is an effective and safe therapy.

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