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ORIGINAL ARTICLE

Stent implantation for May–Thurner syndrome with acute deep venous thrombosis: acute and long-term results from the ATOMIC (AcTive stenting for May–Thurner Iliac Compression syndrome) registry

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Abstract

The outcomes of stent implantation in managing May–Thurner syndrome (MTS) are not well understood. To clarify the acute and long-term outcomes of stent implantation in patients with MTS having acute deep venous thrombosis (DVT), we retrospectively investigated consecutive 59 patients from 10 hospitals in Japan who were treated with stents for left iliac vein stenosis with acute DVT. Stents were considered successful if the stent was patent at discharge, which in turn was defined as patient success. The primary endpoint for the study was stent patency, and the secondary endpoint was recurrence of DVT and development of post-thrombotic syndrome (PTS) during follow-up. The patient success was achieved in 56 patients (95%). Clinical follow-up was conducted for 50 patients (89%) for a median duration of 40 months (range 8–165 months). Among them, 44 patients (79%) were followed up using imaging modalities. During this period, stent occlusion was revealed in four patients (9%), and one patient was successfully treated using balloon angioplasty. Primary and secondary patency rates were 84% at 19 months and 93% at 20 months, respectively. Recurrence of DVT was documented in 3 (8%) patients. PTS was evaluated from 36 patients. Three patients (8%) had PTS; however, none of the patients had severe PTS. This multicenter retrospective study of the use of stents for treating patients with MTS having acute DVT demonstrated good acute and long-term outcomes and long-term stent patency.

Keywords May–Thurner syndrome · Deep venous thrombosis · Venous intervention

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Introduction

In 1991, Okrent et al. reported the first case of stent implantation following catheter-directed thrombolysis (CDT) for May–Thurner syndrome (MTS) complicated with acute deep venous thrombosis (DVT) [1]. Since then, this treatment has emerged as an effective option to quickly relieve leg symptoms and reduce the risk of developing post-thrombotic syndrome (PTS) [2–6]. Although many studies demonstrating favorable clinical outcomes associated with stent implantation have been published, there are few clinical studies about stent implantation for MTS in Japan.

The aim of this study is to investigate the efficacy and safety of stent implantation for treating MTS with acute DVT in Japanese patients.

Methods

Study design and patient population

This is a multicenter, retrospective study conducted in association with 10 hospitals in Japan. All patients with had acute symptomatic DVT involving the left common iliac vein (LCIV) and underwent stent implantation in one of these hospitals were enrolled. There were no exclusion criteria except for patient's refusal.

Diagnosis of MTS

Severe LCIV compression by iliac artery was diagnosed as MTS using computed tomography (CT) or intravascular ultrasound (IVUS) images before stent implantation. Stent selection and implantation procedures were determined by the physicians.

Interventional procedures and anticoagulation therapy

An inferior vena cava (IVC) filter was utilized during thrombolysis. CDT was performed pre- or post-stent implantation using urokinase (UK) administration via a multi-side hole infusion catheter until thrombus was resolved and blood flow into the iliac vein was normal. After CDT, oral anti-coagulants were administered for at least 6 months. Procedural success was defined as successful stent implantation with residual diameter stenosis (DS) < 50% and without delayed venous flow at the stented site. Stents were considered successful if the stent was patent at discharge, which in turn was defined as patient success. IVC filter was retrieved when the risk of pulmonary embolism (PE) was diminished. Figure 1 shows a representative case of CDT and stent implantation for MTS with acute DVT.

Study end points

The primary end point was stent patency during follow-up. Stent patency was assessed by ultrasound (US), CT, or venography. The choice of imaging modality was entrusted to each physician. Stent patency was defined as DS < 50% for each modality. Primary patency was defined as uninterrupted vessel patency with no procedure performed on the treated segment, and secondary patency was defined as whenever maintenance of patency required a secondary intervention at the target lesion [7].

The secondary end point was the recurrence of acute DVT and the occurrence of PTS during follow-up. Patient follow-up visits were conducted at outpatient clinics. PTS was assessed using the Villalta score calculated at the last visit to the cardiovascular physicians. According to five patient-rated venous symptoms and six clinician-rated signs, each item is rated as 0 (none), 1 (mild), 2 (moderate), 3 (severe), and summed to produce a total score. Total score < 5 was identified as no PTS, 5–9 as mild, 10–14 as moderate, and ≧ 15 or skin ulcer was identified as severe PTS [8].

Target lesion revascularization was defined as repeat intervention for stent restenosis or occlusion. Bleeding complications were classified using the bleeding academic

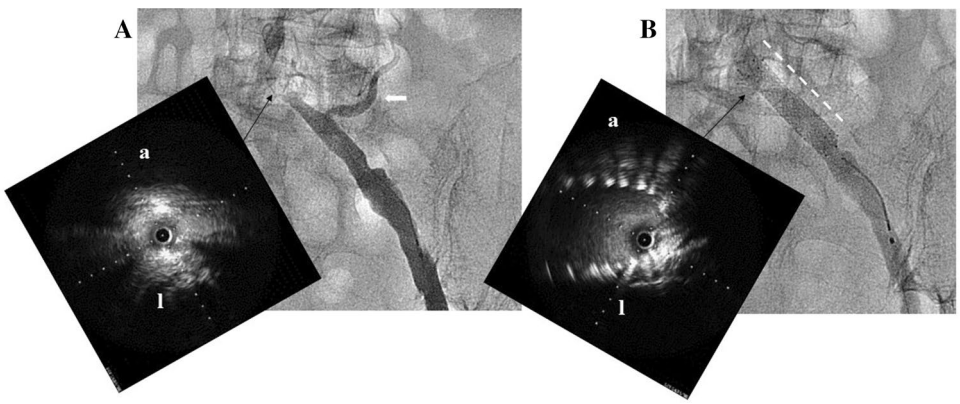

Fig. 1 Representative case of CDT and stent implantation for MTS with acute DVT. The patient was an 80-year-old female with swelling in the left leg for 3 days. Venography revealed venous thrombosis at the iliofemoral vein that extended below the knee. A 30-cm infusion catheter was inserted via the left popliteal vein and placed at the left iliac vein out flow tract. CDT was performed using UK doses of 60,000 IU administered four times per day. After 6 days, venography showed severe stenosis at the left iliac vein, although iliofemoral thrombus was resolved. IVUS revealed left iliac vein which was severely compressed by the right common iliac artery (a) and lumber vertebra (l) (**A**: white arrow indicates collateral channel). A SMART stent (10×40 mm) was implanted at the compression site. Stenosis was resolved as confirmed by IVUS and angiography (**B**: white dotted line indicates stented site). Two weeks after the procedure, the patient's leg swelling was seen to be resolved. Angiography showed that the thrombus was completely lysed with good venous flow into the stent

research consortium (BARC) criteria [9]. Major bleeding events were defined as type 3 or more.

Statistical analysis

Continuous variables are expressed as mean ± SD with either range or median. Values were reported as the numbers with a relative percentage. For continuous data, the groups were compared using the student's *t* test. Categorical variables were compared using the Chi-squared test. *P* values < 0.05 were considered statistically significant. StatView 5.0 (SAS Institute Inc, Cary, NC) was used for all statistical calculations.

Results

1. Patient lesion and procedural characteristics

From December 2000 to August 2014, consecutive 59 patients who received stent for MTS with acute DVT were enrolled. In this cohort, implantation has been performed since 2000, with more than half of implantations performed after 2011, reflecting the increasing rates of implantations (Fig. 2). Baseline patient and lesion characteristics are shown in Table 1. Sixty-six percent of the patients were females and the mean age of the patients was 68 years. In this study, immobilization state was the major risk factors for DVT, which was noted in 18 patients (31%). All patients had left iliac DVT, and in 41 patients (70%), DVT was extended to the popliteal vein. At baseline, 10 patients (17%) presented with symptomatic PE complication. Eight patients (14%) had recurrent thrombosis in the left iliac vein despite anticoagulation therapy at the first DVT event.

Table 1 Baseline patient and lesion characteristics

	N = 59
Female	39 (66%)
Age, years	68 ± 14 (range 29–88)
Onset to admission (days)	6.6 ± 9.1 (median 4; range 1–62)
Risk factor	
Immobilization	18 (31%)
Current smoking	8 (14%)
Cancer	6 (10%)
Steroid use	4 (7%)
Coagulation abnormality	3 (5%)
DVT distribution	
Involved IVCs	6 (10%)
Left iliac vein	59 (100%)
Involved femoral vein	50 (85%)
Involved popliteal vein	41 (70%)
Right side DVT	0
Symptomatic PE	10 (17%)
Recurrence of left iliac DVT	8 (14%)

DVT deep venous thrombosis, *PE* pulmonary embolism

Table 2 shows the characteristics of the stent implantation procedures. Temporary or retrievable IVC filters were used in 58 patients (98%). CDT was performed in 50 patients (85%). Remaining nine patients were treated by systemic UK administration. The mean duration of thrombolysis was 5 days, and the mean total amount of UK was 2,090,000 international units (IU). For the stenting procedure, ipsilateral common femoral vein was accessed in 58% of the

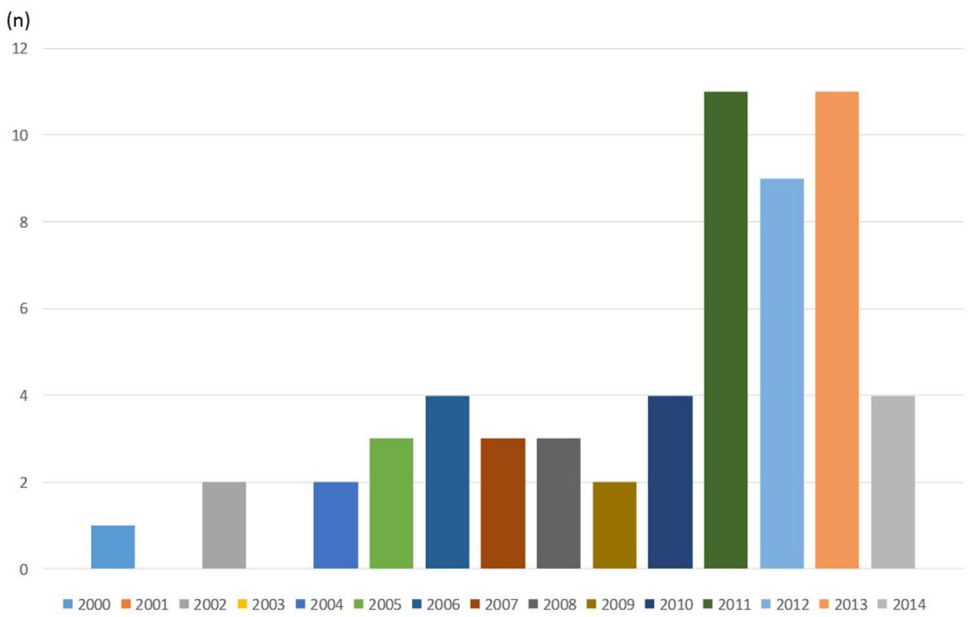

Fig. 2 Transition graph of the number of enrolled patients treated each year

Table 2 Procedural characteristics

	N = 59
IVC filter	58 (98%)
Aspiration	24 (41%)
CDT	50 (85%)
Duration of thrombolysis	5.1 ± 3.7 days
Total amount of urokinase	$209 \times 10^4 \pm 135 \times 10^4$ IU
Approach site	
Left CFV/left Pop.V/left SV	34 (58%)/23 (39%)/2 (3%)
IVUS use	39 (66%)
Total stent number	71 stents
Self-expandable stent	51 (72%)
LUMINEXX	26
SMART	10
EPIC	8
WALL	7
Balloon expandable	20 (28%)
PALMAZ	16
Express LD	4
Stent size	9.9 ± 1.8 mm (range 6–14 mm)
Total length	69 ± 34 mm (range 16.8–157 mm)
Post balloon	9.0 ± 1.5 mm (range 6–14 mm)

IVC inferior vena cava, *CDT* catheter directed thrombolysis, *CFV* common femoral vein, *Pop.V* popliteal vein, *SV* saphenous vein, *IVUS* intravascular ultrasound

Table 3 Acute results and in-hospital outcomes

	N = 59
Procedural success	59 (100%)
Removal IVC filter	50/58 (85%)
Mean duration of hospitalization	21 ± 14 days (median 17)
All death	0
Symptomatic PE	0
Subacute stent occlusion	6 (10%)
Successful revascularization	3/6
Patent success	56 (95%)
Bleeding complication (BARC ≧ type 3)	6 (10%)
Medication at discharge	
Warfarin	53 (90%)
DOAC	5 (9%)
Antiplatelet drugs only	1 (1%)

Patient success indicates that stent is patent at discharge

BARC Bleeding Academic Research Consortium, *DOAC* direct oral anticoagulant, other abbreviations as in Tables 1 and 2

patients and ipsilateral popliteal vein was accessed in 39% patients. Twenty of the earlier cases were implanted with balloon expandable stent; recently, self-expandable stent was used in almost all the cases. The mean stent diameter was 9.9 mm, the total stent length was 69 mm, and the final balloon size was 9.0 mm.

2. Acute results and in-hospital outcomes (Table 3)

Stent implantation was successful in all cases (100%). There were no deaths or symptomatic PEs during hospitalization. IVC filters could be removed in 50 (85%) patients after median 9 days (range 1–118 days) of stent implantation. As an anticoagulation therapy, 53 patients received warfarin and five patients received factor Xa inhibitor after CDT and stent implantation. Fifteen patients received antiplatelet agents, including aspirin and clopidogrel. Bleeding complications during hospitalization were documented in 6 (10%) patients. Four of them suffered intra-muscular hemorrhage, including iliopsoas hemorrhage. Two bleeding complication events occurred during CDT procedures and the remaining four bleeding complication events occurred while anticoagulation therapy was being administered.

Subacute stent occlusion was identified in six patients. Possible causes of stent occlusion include the following: in two patients, anticoagulation therapy was discontinued because of bleeding complications; in two patients, there was insufficient flow into the stented site from the femoral vein; in one patient, there was insufficient lesion coverage by the first stent; and in one patient, there was embolization by a distal floating thrombus into the stented segment. Among these subacute stent thrombosis cases, 3 cases were successfully reopened by repeat intervention during hospitalization. Thus, the patient success was achieved in 56 patients (95%) (Fig. 3).

3. Long-term clinical outcomes

Among the 56 successful cases, 50 cases were clinically followed up (follow-up rate was 89%) (Fig. 3). Table 4 shows the long-term results. During a median duration of 40 months of follow-up, six patients died. Recurrence of acute DVT was documented in three patients. One patient had iliofemoral thrombosis because of stent occlusion. Two patients suffered SFV thrombosis after discontinuation of warfarization; these two patients had autoimmune disease as a risk of DVT. Patency of the stents in the patients with SFV was confirmed by US and CT. Bleeding complication ≧ BARC type 3 occurred in only one patient, and was caused by a gastric ulcer after 28 months of warfarization.

4. Stent patency rates during follow-up (Table 4)

Forty-four lesions were examined by angiography, CT, or US during follow-up (follow-up rate, 79%; median duration, 21 months; range 1–117 months). Three stents that had been occluded once during hospitalization were

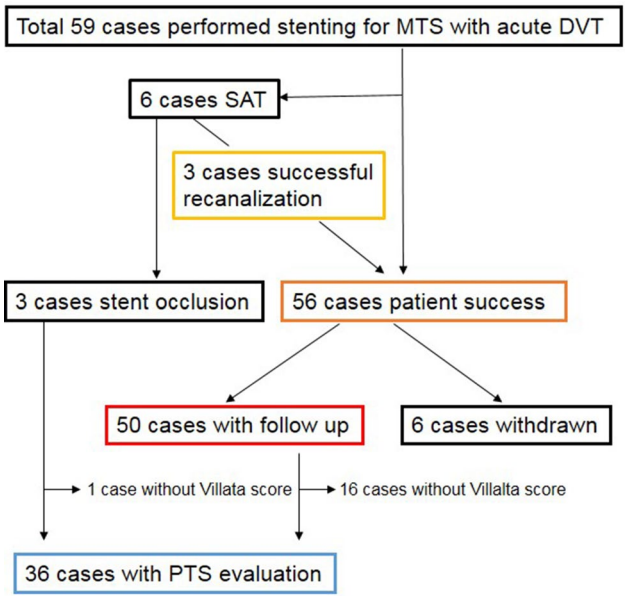

Fig. 3 Patient flow chart. *MTS* May–Thurner syndrome, *DVT* deep venous thrombosis, *PTS* post-thrombotic syndrome

Table 4 Long-term clinical and imaging results

	$N=50$
Follow-up duration	Median 40 (range 8–165) months
All death	6 (12%)
Malignancy	3 (6%)
Sudden death	2 (4%)
Respiratory disease	1 (2%)
DVT recurrent	3 (8%)
Bleeding event (BARC ≧ type 3)	1 (2%)
Evaluation of stent patency	$N=44$ (79%)
Follow-up duration	Median 21 (range 1–117) months
Stent occlusion (acute phase)	3 (7%)
Stent occlusion (chronic phase)	4 (9%)
Successful repeat intervention	4 (9%)
Primary patency	37 (84% at 19 months)
Secondary patency	41 (93% at 20 months)

Abbreviations as in Tables 1 and 3. Acute phase indicates during hospitalization, and chronic phase indicates after discharge

successfully reconstructed in the acute phase and remained open during follow-up. Four stents were found to be occluded after 6, 13, 19, and 21 months, respectively, even though all patients were on anticoagulation therapy. Figure 4 shows stent patency across all patients during the follow-up period. One case was reopened for repeat intervention. Primary patency and secondary patency rates were 84% at 19 months and 93% at 20 months, respectively.

5. Post-thrombotic syndrome evaluation

PTS was analyzed using the Villalta scores obtained from 36 patients (Fig. 3). Thirty-four of these patients are from the group of patient success cases with adequate follow-up data ($N=50$) and two patients are from the group of unsuccessful patients with adequate follow-up data ($N=3$) obtained at median 43 months (range 13–165). The mean Villalta score was 1.3 ± 1.8. Thirty-three patients in the study showed no signs of PTS. Three patients (8%) presented with mild PTS. There were no patients with moderate and severe PTS. We classified the 36 patients into the following three groups: group A, patients with confirmed patent stents (27 patients); group B, patients with patient success but no follow-up imaging diagnosis (6 patients); and group C, patients with stent occlusion (3 patients). The Villalta scores in group C were significantly higher than that in group A (3.7 ± 2.1 and 1.0 ± 1.6, respectively; $P=0.012$) (Fig. 5). When the prevalence of PTS (defined as Villalta score ≧ 5) was compared between the three groups, no statistical difference was observed between them (4, 17, and 33% in groups A, B, and C, respectively).

Discussion

Previous studies on CDT and stenting for MTS showed < 90% initial success rate and approximately 80% primary patency rate during 12–63 months of follow-up [2–4, 6]. Matsuda et al. reported an initial success rate of 92% and a 90% patency rate after 80 months in 13 patients who received stent implantations for MTS with acute DVT [10]. We also reported that the restenosis rate after iliac vein stenting was 6% at median 19 months in 20 patients [11]. These results demonstrate the effectiveness of CDT and stent implantation for MTS with acute DVT. However, interventional treatment for venous disease has not been established. The number of patients with DVT was smaller than that of patients with other cardiovascular diseases, such as acute myocardial infarction or peripheral artery disease; thus, we examined a small cohort in single center, which could be a limitation of this study, and our clinical results should be validated in a larger cohort. Hence, we conducted this multicenter study to confirm the efficacy of stents in treating MTS with acute DVT. To our knowledge, this study contains the largest number of Japanese patients who underwent stent implantation for MTS with acute DVT.

The main purpose of DVT treatment is to obtain immediate relief from symptoms and to prevent recurrence of thrombosis. However, if iliac venous compression at LCIV exists, the patient has a high risk of rethrombosis. Mickley et al. reported that 73% of the patients with untreated venous stenosis after CDT had iliac vein rethrombosis despite

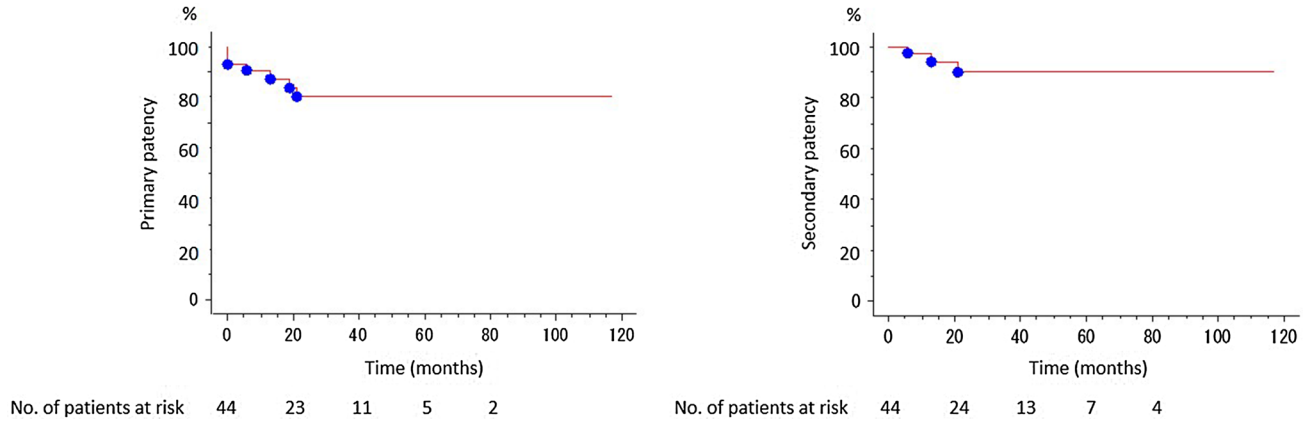

Fig. 4 Kaplan–Meier curve of primary (left) and secondary (right) patency of the implanted stent during follow-up. Patients at risk are reported at the bottom

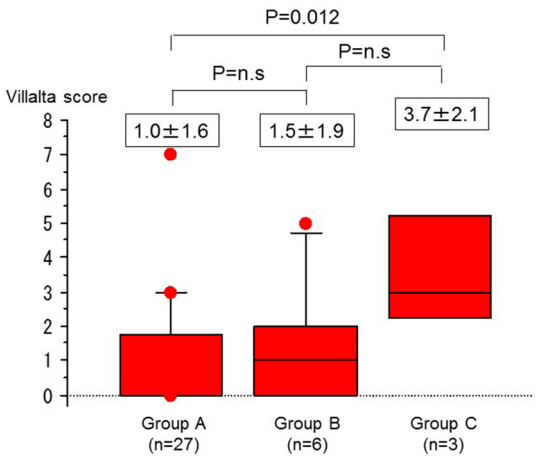

Fig. 5 Comparison of the Villalta scores between the three groups. Group A included patients with confirmed patent stents (27 patients). Group B included patients with patient success at discharge but no follow-up imaging diagnosis (6 patients). Group C included patients with stent occlusion (3 patients)

adequate anticoagulation therapy [2]. In the study cohort, eight patients (14%) had recurrent thrombosis after successful recanalization using CDT and subsequent anticoagulation at the first DVT event. Therefore, it is important to keep the left iliac vein open at the compression site.

Previous studies have reported that CDT is more effective in reducing thrombus and bleeding complications than systematic thrombolysis [12, 13]. However, these findings may not be applicable to Japanese patients because UK doses used in the previous studies were significantly higher than the doses used in daily practice in Japan. A UK dose of approximately three million IU per day was used in the previous studies for CDT treatment. In this study, CDT was performed using approximately 0.4 million IU of UK per day. Even though the exact dose of UK required for CDT treatment of Japanese patients with DVT was not clear [14], we believe approximately 0.4 million IU per day is an appropriate dose.

We generally performed CDT before stent implantation to clarify residual stenosis and maintain adequate inflow into the iliac vein. However, six of fifty cases received CDT after stent implantation due to the presence of residual thrombus. Although the iliac vein was successfully aspirated before stent implantation in these six cases, longer stents were required than those used in other cases (87 ± 24 vs. 67 ± 35 mm, respectively) to ensure residual thrombus is covered by the stent. Therefore, placing stents at compressed sites after reducing thrombus by CDT is recommended.

Retrievable IVC filters are occasionally indicated to prevent PE during CDT for iliocaval DVT [15]. However, PE is not rare. In a large scale observational study where IVC filters were used in 35% of patients, Bashir et al. reported that the incidence of PE during CDT for lower extremity proximal deep vein thrombosis was 17.9% [16]. In this study, we used IVC filters in 98% of cases and there were no complications due to PE during hospitalization. We believe that retrievable IVC filters should be used until completion of the catheter intervention and then should be retrieved once the risk of PE has been minimized.

Bleeding complications must be monitored not only during CDT, but also during the anticoagulation phase. Four of the six cases with BARC type 3 bleeding complications in the hospital occurred several days after the CDT procedure. Furthermore, stent thrombosis occurred in two of these patients because of discontinuation of anticoagulation therapy. Recanalization of the stent could not be achieved in these patients.

In this study, PTS developed in only 8% of the 36 patients with Villalta scores obtained after 43 months of follow-up. PTS occurred at a lower frequency in the present study than that observed in other large randomized trials that examined the efficacy of pharmacomechanical thrombolysis for acute DVT. In the ATTRACT Trial, the 47% of the patients developed PTS during 6 and 24 months follow-up in pharmacomechanical thrombolysis group [17]. Similarly, in the CaVent trial, 43% of patients undergoing pharmacomechanical thrombolysis developed PTS after 5 years of follow-up [18]. However, these two trials included patients not only with MTS but also with DVT caused by other reasons. Stent implantation was performed in 28 and 17% of patients in each of the studies, respectively.

This multicenter, retrospective study examined the acute and long-term efficacy of stenting for Japanese patients with MTS having acute DVT. High success rates in the acute phase and high patency rates for the stent in the long-term phase were observed. The Villalta scores were observed to be significantly lower in patients with patent stents than in those without patent stents.

Study limitations

This was a retrospective study of patients who underwent CDT and stent implantation in 10 different hospitals. Therefore, diagnosis of MTS, indications and strategies for CDT, and implantation of stents were performed differently each of these hospitals. Moreover, no comparison of outcomes between MTS patients with and without stent implantation was studied. Further investigation should be conducted to assess whether CDT and stent implantation can improve the outcome of MTS patients with acute DVT.

Conclusion

This multicenter retrospective study of stenting to treat MTS with acute DVT in Japanese patients strongly suggests that stents are safe and effective, demonstrating good long-term stent patency and clinical results.

Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required. The study protocol was reviewed and approved by the institutional review boards and ethics committee of each participating hospital, and posted for eligible patients.

Conflict of interest The authors declare that they have no conflict of interest.

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