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GuangMing Tan
Division of Cardiology, Department of Medicine & Therapeutics, Faculty of Medicine, The Chinese University of Hong Kong, tamgormin@hotmail.com

Madeleine G Yan
Hong Kong International School

Bryan PY Yan
Division of Cardiology, Department of Medicine & Therapeutics, Faculty of Medicine, The Chinese University of Hong Kong

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Procedural and Clinical Outcomes of Dedicated Venous Stents in Acute and Chronic Venous Obstruction: A Retrospective Single Center Study

Guang M. Tan [a,*], Madeleine G. Yan [b], Bryan P. Yan [a]

[a] Division of Cardiology, Department of Medicine & Therapeutics, Faculty of Medicine, The Chinese University of Hong Kong, China
[b] Hong Kong International School, China

Abstract

Background: **Endovenous angioplasty with stenting is an accepted treatment for patient with venous obstruction. Dedicated venous stents have been developed to improve the efficacy and safety of the venoplasty procedure. We report the procedural as well as clinical outcomes of these new generation stents in the treatment of acute and chronic venous obstruction.**

Method: **This is a single centre retrospective cohort study of patients who received venous stenting for either acute or chronic venous obstruction. Baseline demographics, procedural details, clinical outcomes including 30-day all-cause mortality, 90-day primary patency rate, and change in Villalta score were reported.**

Result: **41 patients with venous obstruction were included in this study. The mean Villalta score before the procedure was 13.8 ± 3.8. Extrinsic compression of the affected vein was found in 95.1% of cases. Procedural success was achieved in 97.6% of cases, with 2 ± 1 stents of mean diameter of 15.3 mm ± 1.9 mm and total stented length of 179.3 mm ± 85.3 mm used per case. There were no procedural complications. 90-day primary patency rate was 90.2%. The Villalta score decreased by 9.2 ± 0.7 to 4.6 ± 2.4 at 90 days.**

Conclusion: **Endovenous angioplasty with new generation of dedicated venous stents is a safe and effective treatment option for patients with acute and chronic venous obstruction.**

Keywords: Deep vein thrombosis, Post-thrombotic syndrome, Venous stent, Venoplasty

Introduction

Deep vein thrombosis (DVT) is a common presentation of venous disease [1]. Anticoagulation is the first line of treatment of DVT. However, almost half of patients with iliofemoral involvement will develop post-thrombotic syndrome (PTS) [2] which carries an enormous economic burden to both patients and the healthcare system [3,4]. Venoplasty with stents implantation is sometimes necessary to treat proximal DVT and PTS, especially in patients with concurrent venous compressive disorder. Dedicated self-expanding venous stents with larger diameter and higher radial strength have been developed for use in venoplasty. Separate reports of these dedicated venous stents have demonstrated favourable outcomes in the treatment of venous obstructive disorder [5–8]. However, reports of their efficacy in the real-world treatment of acute and chronic venous obstruction especially in Chinese population is lacking. We therefore aimed to report the procedural as well short-term clinical outcomes of these dedicated venous stents in the treatment of acute and chronic venous obstruction.

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* Corresponding author.
E-mail addresses: tamgormin@hotmail.com (G.M. Tan), bryan.yan@cuhk.edu.hk (B.P. Yan).

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Methods

This is a retrospective single centre study conducted at a tertiary teaching hospital in Hong Kong. Patients who have received venous stenting for either acute or chronic venous obstruction from June 2015 to June 2022 were identified. Their demographics, presenting clinical information such as Villalta score for PTS [9], and potential aetiology of venous obstruction identified by imaging including intravascular ultrasound (IVUS) were collected. Procedural details such as use of IVUS, stents type, numbers of stents, mean stent diameter and length were recorded. Patient were followed up clinically and by imaging at 90 days post-procedure.

Venous intervention procedure

All procedures were performed under local anaesthesia. Access sites were chosen based on on-table ultrasound to be 1 segment distal to the most distal obstruction. For example, if the most distal obstruction was identified to be at the femoral vein, the access site would be obtained at the ipsilateral popliteal vein. Additional access site would be obtained if needed based on the operator's discretion. 9Fr sheath was used for all the cases. A hydrophilic 0.035 wire (Advantage Glidewire; Terumo Medical, Tokyo, Japan) was used as the work-horse wire for crossing, and its position at the proximal true lumen was confirmed by either venography or IVUS (Vision PV, Volcano Inc.; Rancho Cordova, CA, USA). Once wire crossing was achieved, balloon pre-dilatation would be performed. Adjuvant thrombectomy would be used in selected cases in the presence of acute thrombosis at operator's discretion. Venous stenting would be carried out after satisfactory pre-dilatation. The size and the total length of stents required would be determined either by IVUS or by angiography. The diameter of stent would be chosen to be 1 size above the size required. For example, if the diameter of the target segment was measured to be 14 mm, a 16 mm stent would be used. The total length of the stents required would be chosen to be 20 mm more than the length required, with 10 mm added to the proximal and the distal ends. For example, if the total length required was measured to be 100 mm, a 120 mm stent would be used. After venous stent implantation, post-dilatation would be performed using balloon approximating to the vessels size. Dedicated venous stents from 4 different manufacturers (*Zilver Vena*; Cook, Dublin, Ireland. *Vici*; Boston Scientific, Marlborough, MA, USA; *Venovo*; Bard Inc, Tempe, AZ, USA. *Abre*; Medtronic, Minneapolis, MN, USA.) were used by random rotations. An illustrative case example of the procedure is shown in Fig. 1. All patients were required to be initiated on pre-procedural anticoagulation, which was recommended to be continued for a minimum of 6 months post-procedure.

Outcomes definition

Procedural success was defined as successful implantation of the venous stents with <30% residual stenosis as identified on either IVUS or venography.

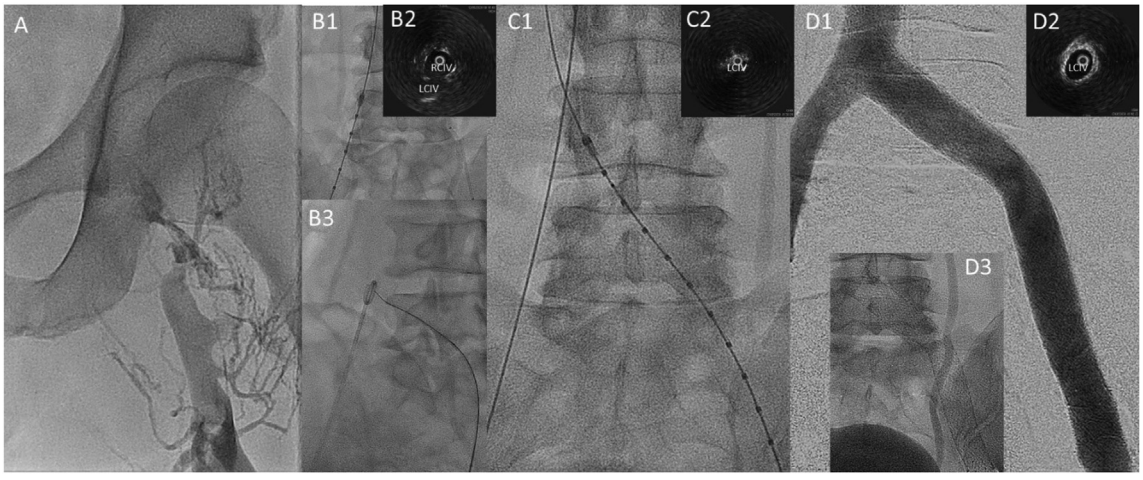

Fig. 1. Case example of Endovenous stenting for chronic LCIV occlusion. A: baseline venography showing occlusion of common femoral vein. B1: IVUS interrogation from contralateral RCIV to mark the position of LCIV (B2); B3: pigtail from contralateral RCIV positioned at level marked by IVUS for puncturing. C1: IVUS from ipsilateral LCIV for confirming true lumen and for confirming compression aetiology (C2). D1: Final venography after stent (D3) implantation with IVUS showing good stent expansion against compression. IVUS = intravascular ultrasound, LCIV = left common iliac vein, RCIV = right common iliac vein.

Procedural complications were defined using Society of Interventional Radiology standards [10]. The primary efficacy endpoint is the 90-day primary patency which is defined as a patent vein without recurrent stenosis or the need for repeat intervention within the veins. The secondary efficacy endpoints are the procedural success rate, and changes in Villalta scores at 3 months. The primary safety endpoint is the occurrence of procedural related complications and 30-day all-cause mortality.

Statistical methods

Continuous numeric variables were reported as mean and standard deviation for parametric distribution and median (interquartile range (IQR)) for non-parametric distribution. Categorical variables were reported as absolute number and percent, unless stated otherwise. The relations of stent diameter and length with the use of IVUS were analysed using the Student's t test. Multivariate Cox regression analysis was used to determine independent predictors of primary patency and change of Villalta scores. P value of <0.05 was considered statistically significant for all analyses. Data analysis was performed using STATA version 15 software (College Station, TX, USA).

Results

41 patients with median age of 60 (IQR 51–69) were included in the analysis. 63.4% of them had PTS with a mean Villalta score of 13.8 ± 3.8 indicating moderate to severe PTS. Most of the lesions (82.9%) were left-sided, and extrinsic compression was identified in the majority (95.1%) of the lesions. The patient's demographic and clinical characteristics were summarized in Table 1.

Procedural success was achieved in almost all the cases (97.6%). The only case where procedure was considered unsuccessful was due to suboptimal inflow from distal femoral vein which was considered too small to be amendable by stenting. The average stent diameter was 15.3 mm ± 1.9 mm and the mean total stent length was 179.3 mm ± 85.3 mm. The mean numbers of stent used per case were 2 ± 1. IVUS was used in 70.7% of the cases. The use of IVUS was significantly associated with longer total stent length (difference = 76.7 mm ± 27.0 mm, p = 0.007) but not with larger stent diameter (difference = 0.6 mm ± 0.7 mm, p = 0.37). The procedural details were summarized in Table 2.

There were no procedural complications, nor 30-day all-cause mortality. 90-day primary patency rate was 90.2%. The number of stents used was the only variable significantly associated with the primary endpoint (coefficient index 0.36 ± 0.15, p = 0.029) on regression analysis. All of the patients with PTS experienced symptoms improvement with an average Villalta score of 4.6 ± 2.4 on 90-day follow-up. The difference between pre and post-procedure Villalta score was 9.2 ± 0.7 (p < 0.01) (Fig. 2). Age (coefficient index 0.14 ± 0.05, p < 0.01) and history of smoking (coefficient index 5.63 ± 2.06, p = 0.017)

Table 1. Patient demographics and clinical characteristics

	Frequency (percentage) if not specified
Age	Median 60 (IQR 51–69)
Male sex	18 (43.9%)
Smoker	8 (19.5%)
Current malignancy	5 (12.2%)
History of thrombophilia	5 (12.2%)
History of VTE	29 (70.7%)
PTS at presentation	26 (63.4%)
Laterality	
• Left	34 (82.9%)
• Bilateral	5 (12.2%)
Most proximal segment involved	
• IVC	5 (12.2%)
• Iliac	35 (85.4%)
• Femoral	1 (2.4%)
Most distal segment involved	
• Iliac	12 (29.3%)
• Femoral	18 (43.9%)
• Popliteal	10 (34.4%)
• Tibial	1 (2.4%)
Presenting Villalta score	Mean 13.8 ± SD 3.8
Presence of venous ulcer	1 (2.4%)
Extrinsic compression as identified by imaging	39 (95.1%)

IVC: inferior vena cava; PTS: post-thrombotic syndrome; SD: standard deviation; VTE: venous thromboembolism.

Table 2. Procedural and stents details

	Mean ± standard deviation, or frequency (percentage)
Single access site	32/41 cases (78.5%)
Procedural time (minutes)	110 ± 56
Use of IVUS	29/41 (70.7%)
Number of stents used	2 ± 1
Total stented length (mm)	179.3 ± 85.3
Average stent diameter (mm)	15.3 ± 1.9
Stent brand	
• Zilver Vena	2/41 (4.9%)
• Vici	10/41 (24.4%)
• Venovo	13/41 (31.7%)
• Abre	16/41 (39.0%)
Procedural success rate	40/41 (97.6%)

IVUS: intravascular ultrasound; Zilver Vena; Cook, Dublin, Ireland. *Vici*; Boston Scientific, Marlborough, MA, USA; *Venovo*; Bard Inc, Tempe, AZ, USA. *Abre*; Medtronic, Minneapolis, MN, USA.

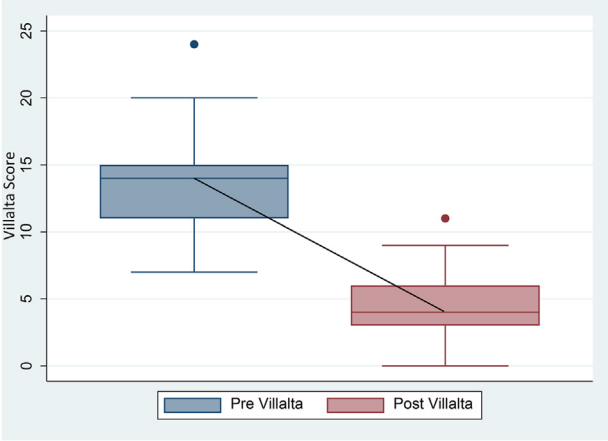

Fig. 2. Villalta Score before and 90 days post intervention.

Table 3. Results from 90-day follow-up

Primary patency rate	37/41 (90.2%)
90-day Villalta score	4.6 ± 2.4
Change of Villalta score from baseline	−9.2 (95% CI 7.8–10.5, $p < 0.05$)

CI: confidence interval; SD: standard deviation.

were the only two variables associated with the post-procedural Villalta sore change. These endpoints were summarized in Table 3.

Discussion

Previous generation of venous stents was associated with risk of stent migration and shortening [11]. New generation dedicated venous stents have undergone significant improvements in their design to overcome the challenges in venous intervention. New generations venous stents were more flexible and deliverable in tortuous venous anatomy and confer higher radial force and crush resistance to withstand the external compression. These stents have been shown, separately, to have good safety and efficacy in the treatment of venous obstructive disease [5–8]. In our series, stents from 4 manufacturers displayed similar procedural safety as well as 90-day primary patency rate. The results from our study re-affirms the device as well as procedural related safety of these new generation of dedicated stents in a real-world clinical setting. This should reassure interventionalist the safety of using these new devices.

Most of the lesions in our studies were left-sided, and compression was demonstrated in majority of the cases. This echoes the finding from previous IVUS study which showed that venous compression is an under-appreciated aetiology of venous obstruction [12], and reinforces the need for stents with high radial force and crush resistance to withstand external compression. Previous studies have shown that under-estimation of vessel diameter with angiography is common as compared with IVUS [13]. In our study, stent diameter although numerically larger than reported in Asian population [14,15], was not significantly influenced by IVUS use. This might be due to relative consistency in iliac vein diameter across the population. In our study, the length of stents was significantly influenced by the use of IVUS. This might be due to the 'normal-to-normal' segment selection based on IVUS as opposed to angiographic guidance. It is still unknown whether this strategy of stent selection will translate into clinical significance as there is no relationship shown between the primary patency rate and the change of Villalta score with IVUS use in this study.

Significant improvement in symptoms and Villalta score was demonstrated in our cohort. This is similar to studies of old and new generation of venous stents [5–8,16]. Such a significant symptomatic improvement can be especially beneficial to patients with moderate to severe PTS, which impart enormous economic benefits on the patients as well as the healthcare system. Moreover, these benefits appear to be universal with all stent platforms as no difference was shown to be associated with different stent manufacturers. With more than 90% primary patency rate and excellent safety profiles, such treatments should be offered to patients with clinical indications and suitable anatomy.

Limitations

There were several limitations in our study. Firstly, this was a retrospective single-centre study with a small number of patients thus limiting the generalisability of the results. Secondly, patients were not randomized to the stent types, making direct comparison of the efficacy and safety of stents difficult. Last but not the least, the follow-up duration was short. Longer term follow-up study should be considered to evaluate the performance of these stents.

Conclusions

Venous compression is a common aetiology in acute and chronic venous obstruction for which endovenous stenting is an effective treatment option that offers favourable short-term primary patency rate and significant improvement of symptoms in patients with PTS, with excellent safety profile.

Funding

None declared.

Conflict of interest

The authors have no conflict of interest to disclose.

Ethical information

This study was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee.

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