

Mid-term Results of a Novel Dedicated Venous Stent for the Treatment of Chronic Thoracic Central Vein Obstruction of Benign Aetiology

Guang Ming Tan ^{a,b}, Ken Wai Kin Chi ^a, Bryan Ping Yen Yan ^{a,c,*}

^a Division of Cardiology, Department of Medicine & Therapeutics, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong

^b Division of Cardiology, Massachusetts General Hospital, Boston, MA, USA

^c Department of Epidemiology and Preventive Medicine, School of Public Health, Monash University, Melbourne, Australia

WHAT THIS PAPER ADDS

Chronic thoracic central vein obstruction (TCVO) of benign aetiology with total occlusion can be treated safely and effectively by endovascular procedures. Multiple factors need to be taken into consideration when choosing the type of stent to be deployed. This study provides physicians with new clinical evidence of the long-term patency of a new dedicated venous stent in the treatment of TCVO.

Objectives: Endovascular treatment is indicated for the treatment of symptomatic thoracic central vein obstruction (TCVO) but is limited by high rates of restenosis and the need for re-intervention. The aim was to assess the safety and mid-term patency of a novel dedicated venous stent for the treatment of TCVO of benign aetiology.

Methods: This was a prospective single centre observational study of 20 patients (median age 65 years, 50% male) referred for the treatment of symptomatic chronic (>three months duration) TCVO between May 2016 and January 2018. Balloon angioplasty with implantation of a self expanding nitinol stent (Vici, Boston Scientific, Marlborough, MA, USA) was performed in all patients. Clinical records including demographics, aetiologies and types of TCVO, and procedural details were recorded. Patients were followed up clinically at one, six, and 12 months. Primary and assisted primary patency were reported.

Results: All 20 lesions were total occlusions, of which 55% ($n = 11$) were de novo, 10% ($n = 2$) peri-stent restenosis, and 35% ($n = 7$) in-stent re-occlusion. The aetiology of TCVO was predominantly (95%) because of multiple or prolonged central venous line insertion. The procedural success rate was 90% (18/20) with no procedural complications. The median follow up was 13.5 months. Primary patency was 100% at 6 months. One patient required re-intervention for stent in segment restenosis at 7 months. The assisted primary patency rate was 100% at 12 months.

Conclusion: Endovascular treatment of benign TCVO with the novel dedicated venous stent was safe and effective in relieving obstructive symptoms with excellent one year patency rates.

Keywords: Endovascular therapy, Venous stent, Thoracic central vein obstruction

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INTRODUCTION

The thoracic central veins (TCVs) include intrathoracic segments of the internal jugular (IJVs), subclavian (SCVs), brachiocephalic veins (BCVs), and superior vena cava (SVC).¹ TCV obstruction (TCVO) syndrome is defined as a pathophysiological venous luminal narrowing that impedes blood flow. Obstruction may be partial (i.e., stenosis) or complete (i.e., occlusion).¹ The most common cause of TCVO is

extrinsic compression by malignancy.² Venous wall thickening and fibrosis secondary to previous central venous catheter insertion for the purpose of dialysis or indwelling intracardiac devices are increasingly recognised as important causes of benign TCVO syndrome.^{3,4} Surgical reconstruction or bypass of TCVO may offer reasonable long-term patency but is associated with major peri-operative complications.^{5–8} Endovascular therapy with percutaneous transluminal angioplasty (PTA) with or without stenting has been proposed as an alternative to surgical repair with comparable short-term patency rates.^{7,8} However, the long-term results of PTA are limited by high rates of restenosis and the need for re-intervention.⁵ Currently, there are no stents dedicated for the treatment of TCVO.

* Corresponding author. Division of Cardiology, Department of Medicine & Therapeutics, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong SAR, China.

E-mail address: bryan.yan@cuhk.edu.hk (Bryan Ping Yen Yan).

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In this report, the aim was to assess the efficacy and safety of a novel nitinol self expanding stent (Vici, Boston Scientific, Marlborough, MA, USA), with an alternating open and close cell design (Fig. 1), which is designed specifically for venous intervention, for the treatment of TCVO of benign aetiology.

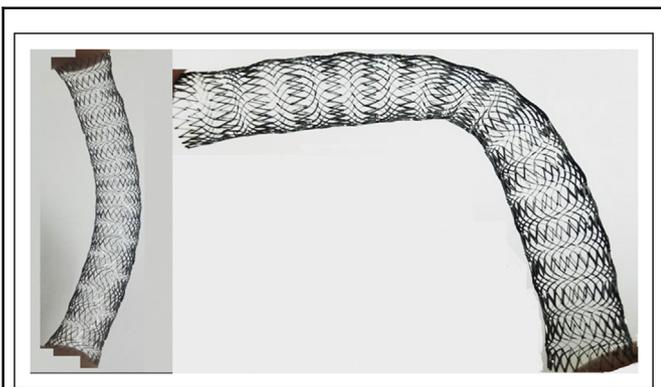


Figure 1. Vici stent (Boston Scientific) with alternating open and closed cell design.

METHODS

Study design

This was a prospective single centre observational study conducted in a tertiary referral hospital in Hong Kong from May 2016 to January 2018. Consecutive patients referred for the treatment of symptomatic benign TCVO syndrome were included in a registry. The diagnosis of TCVO was made by one of the following modalities: computed tomography (CT) venography, upper extremity duplex ultrasound, or invasive venography. All procedures were performed by two interventional cardiologists who specialised in vascular interventions. Clinical records including demographics, aetiology, and types of TCVO (according to the 2018 Society of Interventional Radiology [SIR] guideline;¹ Table 1); previous interventions, procedural details including access sites, equipment used, stent length and diameter, procedural outcomes, and complications were recorded. Patients were followed up clinically at one, six, and 12 months. Repeat intervention for restenosis was clinically driven by recurrent symptoms including upper extremity or facial swelling, or increase in venous pressure during haemodialysis. Primary end points of this study were primary and assisted patency rates, which were reported at one, six, and 12 month intervals. This study was approved by the Joint Chinese

Table 1. Comparison of Classifications of thoracic vein obstructions: Society of Interventional Radiology versus Stanford and Doty

SIR classification of TCVO pattern ¹	Stanford and Doty classification of SVCO ²⁵
<p>Type 1: both BCVs and the SVC are patent, but one IJV or SCV is obstructed</p> <p>Type 1A: unilateral IJV or SCV obstruction with patent ipsilateral BCV; patency of all other thoracic central venous anatomy is not known</p> <p>Type 1B: unilateral IJV or SCV obstruction with patent ipsilateral BCV; patency of contralateral thoracic central venous anatomy is not known</p> <p>Type 1C: unilateral IJV or SCV obstruction with known patency of the contralateral IJV, SCV, and BCV</p> <p>Type 1D: bilateral obstruction of IJVs, SCVs, or combined IJV and SCVs, with both BCVs patent</p>	<p>Type I: partial obstruction (up to 90% stenosis) of the superior vena cava with patency of the azygos vein</p>
<p>Type 2: any form of TCVO that causes unilateral BCV obstruction or ipsilateral obstruction of the IJV and SCV (equivalent to unilateral BCV obstruction)</p> <p>Type 2A: unilateral BCV obstruction with unknown condition of the contralateral side</p> <p>Type 2B: unilateral BCV obstruction with known patency of the contralateral side</p>	<p>Type II: near complete to complete obstruction (90–100%) of the superior vena cava with patency and antegrade flow through the azygos vein and into the right atrium</p>
<p>Type 3: both BCVs are obstructed, but flow to the right atrium passes through the SVC</p>	<p>Type III: near complete to complete obstruction (90–100%) of the superior vena cava with reversal of azygos blood flow</p>
<p>Type 4: SVC obstruction that prevents or impedes direct thoracic venous flow to the right atrium with any constellation of BCV, IJV, or SCV obstruction</p>	<p>Type IV: Complete obstruction of the superior vena cava and one or more of the major caval tributaries, including the azygos system</p>

BCV = brachiocephalic vein; IJV = internal jugular vein; SCV = subclavian vein; SVCO = superior vena cava obstruction; SIR = Society of Interventional Radiology; SVC = superior vena cava; TCVO = thoracic central vein obstruction.

University of Hong Kong — New Territories East Cluster Clinical Research Ethics Committee.

Intervention technique

Balloon angioplasty and stenting were performed according to guidelines.⁹ Initial venous access was obtained via the right common femoral vein (CFV) using a 9F 65 cm guiding sheath. Additional access was obtained via the deep veins in the ipsilateral upper extremity or the IJVs if the distal target vessel could not be visualised or when retrograde recanalisation failed. In patients with a functioning arteriovenous fistula, additional antegrade venous access was obtained at the venous limb. Contrast central venography using digital subtraction angiography was performed. A 0.035 cm hydrophilic wire (Advantage, Terumo Medical, Somerset, NJ, USA) with a support catheter was used as the initial wire to cross the lesion. If unsuccessful, wire escalation to 0.018 chronic total occlusion (CTO) wires (Treasure or Astato, Asahi Intecc Co. Ltd., Aichi, Japan; Victory, Boston Scientific Corporation, Marlborough, MA, USA; or Connect, Abbott, IL, USA) with increasing tip loads were chosen. After successful wire crossing, PTA was performed using a high pressure non-compliant balloon (Conquest or Atlas, BARD Medical, Tempe, AZ, USA). Sequential upsizing of the balloon was performed to achieve adequate lesion preparation. The Vici stent (Boston Scientific; Fig. 1) of sufficient length to ensure coverage of at least 10 mm beyond both ends of the occluded segment, and of appropriate diameter (1–2 mm above the maximum pre-dilatation balloon size) was selected. All stents were deployed in the distal to proximal direction via CFV access. Post dilatation of the stent was performed in all cases using a non-compliant balloon (Atlas, BARD Medical, Tempe, AZ, USA) at high pressure, with balloon size matching the diameter of the stent. All patients were given aspirin 100 mg and clopidogrel 75 mg daily for one month after stent deployment and then lifelong aspirin 100 mg daily.

Definitions

Benign chronic TCVO syndrome was defined as venous obstruction because of non-malignant blockage of blood flow through the BCV and/or SVC into the right atrium for more than one month. Procedural failure was defined as the inability to cross the occluded segment, inability to satisfactorily dilate the lesion, >30% residual stenosis, or failure to deploy the stent in the intended position. Procedural complications were defined using the SIR standards.¹⁰ Primary patency was defined as a patent central vein without recurrent stenosis or the need for repeat intervention within the central veins. Assisted primary patency was defined as a patent central vein that required repeat intervention to maintain patency.¹¹

Statistics

Kaplan–Meier survival curves were used to estimate the primary and assisted primary patency. The date of the first

intervention was defined as Time 0. The dates when a repeated intervention was performed to maintain assisted primary patency and the date when a further attempt to establish patency was abandoned were counted as an event towards primary patency and assisted primary patency respectively. Owing to the small size and low event rate of this study, regression analysis of the predictors for loss of primary patency was not performed. Data analysis was performed using STATA version 15 software (College Station, TX, USA).

RESULTS

Twenty patients were treated for benign TCVO syndrome during the study period. The median follow up was 13.5 months (interquartile range [IQR] 19.1 months). The median age was 65 (IQR 22.5) with 50% male. The most common aetiology of TCVO was previous multiple or prolonged central venous catheter insertion (95%). Most of the patients (70%) presented with haemodialysis dysfunction and 30% with upper limb or head and neck swelling. Approximately half (45%) of the lesions were re-occluded lesions after previous interventions and all 20 lesions (100%) were complete occlusion with SIR type II occlusion being the most common (Tables 2 and 3, Fig. 2).

Technical success was achieved in 18 cases (90%), and there were no procedure related complications. Failure of wire crossing was the primary cause of procedural failure in

Table 2. Demographic information on 20 included patients with thoracic central vein obstruction

Characteristic	n (%) or median (IQR)
Age, years	66 (49–69)
Male/Female	10/10 (50/50)
Diabetes mellitus	6 (30)
ESRF	19 (95)
Aetiology: central line/pacemaker	19/1 (95/5)
Symptom: Failed HD/Facial Swelling	14/6 (70/30)
De novo lesions	11 (55)
Previous TCVO intervention	9 (45)
Peri-stent re-occlusion	2 (10)
In stent re-occlusion	7 (35)
Follow up, median months (IQR)	13.5 (1.3–20.4)

ESRF = end stage renal failure; HD = haemodialysis; SVC = superior vena cava; TCVO = thoracic central vein obstruction; IQR = interquartile range.

Table 3. Distribution of TCVO types among 20 included patients

SIR Classification		Stanford Classification	
Type	n (%)	Type	n (%)
Type 1	2 (10)	Type I	–
Type 2	15 (75)	Type II	–
Type 3	1 (5)	Type III	2 (10)
Type 4	2 (10)	Type IV	18 (90)

SIR = Society of Interventional Radiology; TCVO = thoracic central vein obstruction.

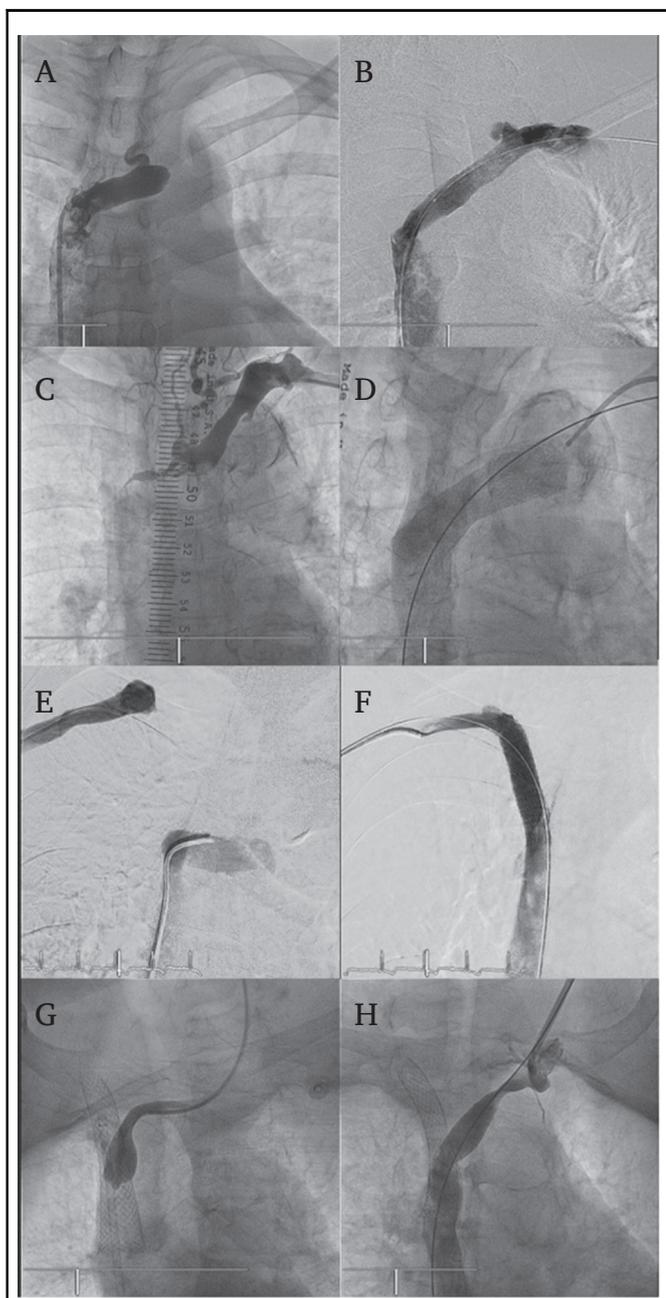


Figure 2. Representative cases. (A) Total occlusion of left subclavian vein (Type 1), and (B) after stent placement. (C) Total occlusion of left brachiocephalic vein (Type 2), and (D) after stent placement. (E) Total occlusion of right brachiocephalic vein (Type 2), and (F) after stent placement. (G) Total occlusion of previous superior vena cava stent (Type 4), and (H) after stent placed across previous stent.

two cases. Bi-directional wire crossing of the lesion was required in most cases. In 55% of the cases, wire escalation was required. For the majority the distal stent landing site was in the BCV (83.3%) and all the stents were deployed in the intended position with no foreshortening or migration. Procedural details are summarised in Table 4.

All successful cases experienced significant symptom relief (defined as resolution of upper limb or facial swelling, or the ability to resume adequate haemodialysis) within 72 h of the procedure. Re-attempt intervention was arranged for

Table 4. Procedural details in 20 patients undergoing TCVO-stenting

Parameter	n(%) or median (range)
Procedural success	18/20 (90)
Procedural complication	0
Single/bidirectional access	2/18 (10/90)
Crossing: initial wire/CTO wire	9/11 (45/55)
Stent diameter in mm	16 (12–16)
Stent length in mm	60 (60–120)
<i>Number of stents</i>	
1	16 (88.9)
2	2 (11.1)
<i>Stent proximal landing zone</i>	
SVC	16 (88.9)
BCV	2 (11.1)
<i>Stent distal landing zone</i>	
SVC	1 (5.6)
BCV	15 (83.3)
SCV	2 (11.1)
Intended stent positioning	18/18 (100)

CTO = chronic total occlusion; BCV = brachiocephalic vein; SCV = subclavian vein; SVC = superior vena cava; TCVO = thoracic central vein obstruction.

the two failed cases but both patients declined. There were two adverse events within 30 days, but neither was related to the TCVO intervention. One patient died on Day 20 from severe sepsis and the other was admitted on Day 16 for acute pulmonary oedema.

The primary patency rates at one, six, and 12 months were 100%, 100%, and 94.4%, respectively; the assisted primary patency rate at 12 months was 100% (Fig. 3). One patient was found to have elevated venous pressure during dialysis. Repeated intervention for distal stent in segment restenosis with implantation of an additional venous stent to maintain TCV patency was performed for her. Another patient had recurrence of symptoms at 13 months and underwent balloon angioplasty for in stent restenosis to maintain TCV patency.

DISCUSSION

Stents are routinely used to prevent acute elastic recoil and improve primary patency during angioplasty procedures. While no study has directly compared balloon angioplasty with stenting in TCVO, a retrospective cohort study in the paediatric population demonstrated that stenting significantly reduced the incidence of re-intervention when compared with balloon angioplasty alone.¹² However, in another retrospective cohort study of patients with haemodialysis, stenting did not confer additional benefit in terms of primary patency when compared with primary balloon angioplasty.¹³ The requirements for venous stents are different from those of arterial stents. A dedicated venous stent needs to have high radial force to make up for the relative lack of muscle layers in the vein, yet it needs to be flexible to adapt to the tortuous venous anatomy.¹⁴ Different types of stents have been used for the treatment of TCVO and several dedicated venous stents are available on the market. The Elgiloy (cobalt, chromium, nickel alloy)

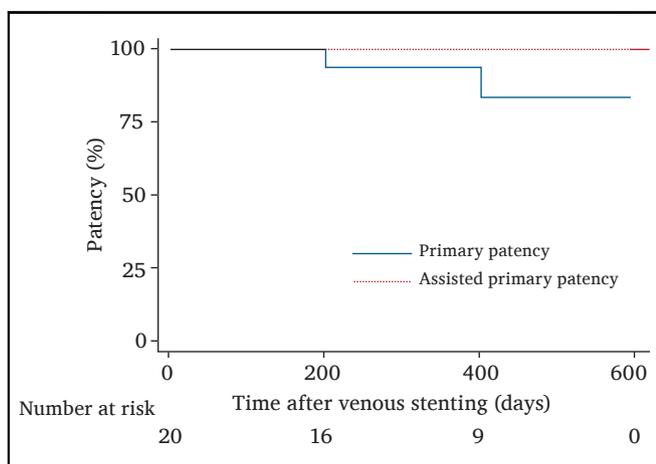


Figure 3. Kaplan Meier estimates of primary and assisted primary patency.

based Wallstent (Boston Scientific) is the most reported stent used in the treatment of TCVO, but its use is limited by a high tendency for stent shortening and migration during deployment.¹⁵ This is probably related to the non-uniform distribution of radial force of the Wallstent with both ends being weaker. As a result, it tends to be “squeezed” away from a hard and fibrotic lesion. The use of dedicated venous stents such as the Zilver Vena (Cook Medical) has been reported but only one set of results is available.¹⁶ The results of previous studies using various types of stent for the treatment of TCVO are summarised in Table 5.

The dedicated venous stent used in this study is a nitinol based stent that has been studied in the treatment of peripheral venous obstruction.¹⁴ It has a unique alternating closed cell and a bridging open cell design (Fig. 1). The closed cell segment provides high crush resistance of 0.19–0.71 N/cm at 90–60% diameter in laboratory testing,²⁴

while the open cell segment provides the necessary flexibility to navigate through tortuous venous anatomy. This appears to be the first report of its use in the treatment of benign chronic TCVO. In this study, the safety and mid-term efficacy of this new venous stent was demonstrated to be at least similar to if not better than previous series. Although a similarly high assisted primary patency rate has been shown (80–100%) across various studies, this new venous stent was shown to have a high primary patency rate. Unlike patients with malignant SVC syndrome whose survival is limited by their underlying disease, freedom from additional intervention to maintain patency in patients with benign TCVO syndrome may confer better long-term quality of life.

The new SIR classification of TCVO patterns was used for the evaluation of all the lesions in this study. This new classification is more relevant to endovascular intervention than the Stanford and Doty venographic classification of SVC obstruction²⁵ used in previous studies which was more appropriate for surgical planning and identification of graftable veins. Moreover, the Stanford classification only categorises SVC obstruction, but did not include other TCVs such as the BCVs and the SCVs (Table 1).

Although direct comparison with previous studies that used the Stanford classification is not possible, all patients in this study had complete TCVO occlusion which was similar to Type III and Type IV SVC obstruction under the Stanford classification. Totally occluded lesions are generally under represented or even excluded in most studies as they are considered unsuitable for endovascular intervention.⁸ In this study, it was demonstrated that high success rates with endovascular treatment can be achieved with a clearly defined algorithm of access planning and wire selection. The 12 month outcomes of endovascular treatment of these complex lesions in the current series were similar to simpler lesions (Stanford Type I and II) in previous series (Table 5).

Table 5. Summary of studies on SVC stent for the treatment of benign SVC syndrome

Study, year	Type of stents	Type III and IV lesions ^a	Patients (n)	Outcome (patency rates)
Haddad ¹⁷ 2018	Various types	32%	47	Primary patency: 80% at one year
Breault ¹⁸ 2017	Various types	52%	44	Primary and assisted primary patency: 80% and 100% at one year
Fu ¹⁹ 2014	Various types	66%	6	Primary and assisted primary patency: 50% and 100% at two years
Rizvi ⁸ 2008	Various types	46%	32	Primary and assisted primary patency: 70% and 96% at one year, 44%, and 96% at three years
Bakken ¹³ 2007	Wallstent	–	26	Primary and assisted primary patency: 76% and 84% at one year, 21%, and 46% at two years
Sheikh ²⁰ 2005	Various types	–	19	Primary and assisted primary patency: 79% and 93% at two years
Bornak ²¹ 2003	Wallstent	77%	9	Primary and assisted primary patency: 67% and 100% at one year
Verstandig ¹⁵ 2003	Wallstent	–	10	Primary and assisted primary patency: 25% and 75% at one year, 0%, and 57% at two years
Haage ²² 1999	Wallstent	13%	50	Primary and assisted primary patency: 56% and 97% at one year, 28%, and 89% at two years
Mickley ²³ 1997	Wallstent	–	14	Primary and assisted primary patency: 70% and 100% at one year, 50%, and 85% at two years

SVC = superior vena cava.

^a Stanford & Doty Classification of SVC obstruction.²⁵

The results suggest that endovascular stenting can be a viable alternative in the treatment of these challenging lesions. A large proportion of the patients included in this study had re-occlusion after previous TCV intervention and 35% had in stent re-occlusion (Fig. 2). The efficacy of this new venous stent in maintaining patency in this complex subset of patients suggests its superiority over older generation metallic stents. However, this needs to be investigated further in a head to head comparison trial.

This study was limited by the relatively small number of patients, short duration of follow up, and lack of a comparative arm with a different treatment modality. Furthermore, being a single centre study, the reproducibility of the results might be affected. Only a handful of patients received imaging follow up. The recurrence of symptoms was used as the primary indicator for recurrent stenosis. Although a milder degree of recurrent stenosis might be missed, as sometimes symptoms may not be apparent until complete re-occlusion occurs due to the presence of extensive collaterals, the clinical symptoms were more meaningful parameters as they were the reason that prompted interventions in the first place. Last but not the least, standardised reporting of symptoms such as the Kishi scores²⁶ or the SIR reporting standards¹ were not used in the follow up as patients were followed up by their referring physicians instead of vascular specialists.

CONCLUSION

Endovascular treatment of benign chronic TCVO by balloon angioplasty and stenting is safe and effective in relieving obstructive symptoms. The new dedicated venous stent was equally effective in the treatment of de novo and in stent re-stenotic TCVO with excellent one year patency rates.

CONFLICT OF INTEREST

None.

FUNDING

None.

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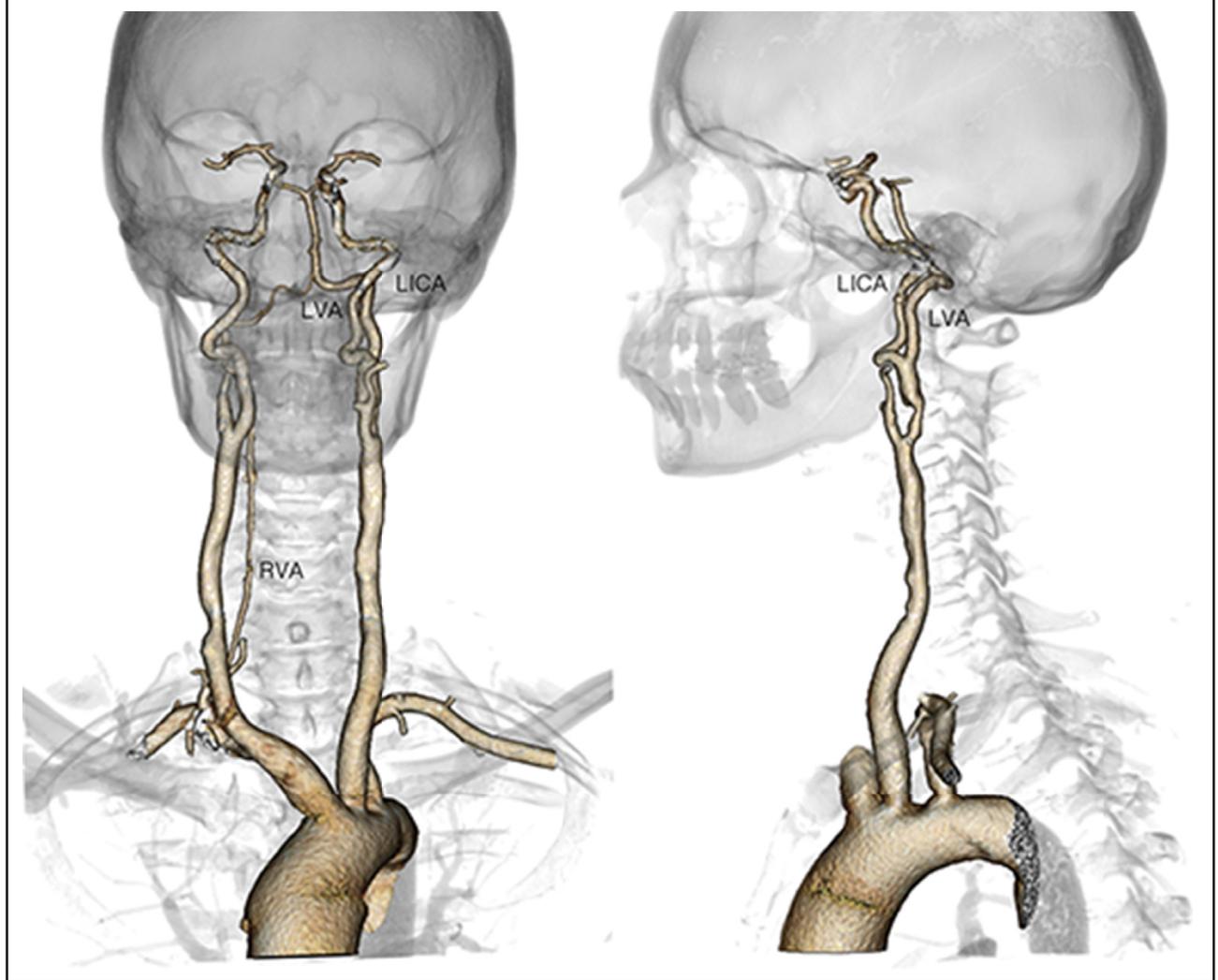
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COUP D'OEIL

Atypical Carotid Origin of the Vertebral Artery

Maria Katsarou, Luca Bertoglio *

Scientific Institute H. San Raffaele, Chair of Vascular Surgery, Vita Salute San Raffaele University, Milan, Italy



A 52 year old hypertensive woman (a smoker with systemic lupus erythematosus) was diagnosed with left internal carotid artery (ICA) stenosis after a transient ischaemic attack. Computed tomography angiography revealed an atypical origin of the left vertebral artery (VA) directly from the extracranial portion of the ICA and the course of the left VA that passed postero-medially to join the right VA to form the basilar artery. Anatomical variants of the VA origin are frequent (5%) but its origin from the ICA is quite rare. Successful standard left carotid endarterectomy with patch closure was performed without the need for a shunt.

* Corresponding author. Division of Vascular Surgery, IRCCS H. San Raffaele, Via Olgettina, 60, 20132 Milan, Italy.

E-mail address: bertoglio.luca@hsr.it (Luca Bertoglio).

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