



Venovo venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions – short-term results from the Arnsberg venous registry

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Abstract: *Background:* We sought to determine the patency and clinical symptom relief of the Venovo venous stent in the endovascular treatment of non-thrombotic (NIVL) or post-thrombotic venous obstruction (PTO) of the iliofemoral track over a period of 6 months. *Patients and methods:* A total of 80 patients (45 female, mean age 57 years) treated in 2016 and 2017 were included in the Arnsberg venous registry. Clinical improvement was determined by the revised venous clinical severity score (rVCSS) as well as the clinical, etiologic, anatomic and pathophysiologic (CEAP) score. Primary and secondary stent patency was evaluated using duplex ultrasound. *Results:* Overall 6-months patency rates were 98% for primary and 100% for secondary patency. For NIVL primary patency was 97%, whereas for PTO primary patency was 96%. Early stent re-occlusion occurred in 3 patients within 34, 59 and 156 days after intervention. Two of these patients were successfully treated by endovascular mechanical thrombectomy and stent in stent implantation. Clinical improvement with a gain of ≥ 2 rVCSS levels was observed in 51%. CEAP scores decreased from 4.3 to 2.7. *Conclusions:* In this first time report the novel Venovo venous stent showed adequate patency rates associated with reasonable clinical improvement and low device-related complications throughout a 6-months-follow-up in both NIVL and PTO.

Keywords: Chronic venous disease, stent, venous stenting, Venovo venous stent, post-thrombotic syndrome, compression syndrome

Introduction

Since more than two decades, ilio-femoral stent implantation has become the preferred treatment technique for chronic venous outflow obstruction. Previous systematic reviews have shown low complication rates (about 0–9%) and high technical success rates (up to 98%) for ilio-femoral stenting, showing better results in comparison to conventional therapy with compression therapy and anticoagulation alone [1, 2].

Originally, arterial stents were adapted for use in veins with reasonable outcome. However, as compared the arterial system, venous vessel stenting needs stents with larger diameter and higher radial force to serve its anatomical needs and to overcome underlying external compression [3, 4]. These observations advanced the development of

stents specially dedicated to vein anatomy. To date, there are eight different venous stents on the European market. Stuck et al. evaluated the sinus-Obliquus stent, demonstrating 6-months patency rates of 92% and 10-months patency rates of 83% [5]. De Wolf et al. reported 12-months primary patency rates of 92% for the sinus-Venous stent [6]. O’Sullivan et al. assessed patency rates of 85% at a median follow-up of 55 days for the Zilver Vena stent [7]. Own published data showed 12-months patency rates of about 92% for the Veniti Vici venous stents in the treatment of venous obstruction of the iliofemoral track [8].

So far, data for the novel Venovo venous stent are missing. The current analyses were performed to assess safety, clinical efficiency and short-term patency during an initial 6-months follow-up after self-expandable nitinol Venovo venous stent implantation in patients with non-

thrombotic iliac vein lesions (NIVL) and post-thrombotic iliac vein obstructions (PTO) in a single-arm, non-randomized registry.

Patients and methods

Patients' characteristics

Ethical approval was obtained by the ethics committee of the Ärztekammer Westfalen-Lippe and of the Westfälischen Wilhelms-Universität Münster, Münster, Germany (AZ 2017-382-f-S). From January 2016 to February 2017, a total of 80 patients receiving a Venovo venous stent at our institution and fulfilling the inclusion criteria of clinically significant chronic non-malignant obstruction of the iliofemoral venous segment as well as standardized baseline clinical evaluation were included in the registry. Baseline patients' characteristics including demographics and medical history are given in Table I.

Diagnosis of chronic venous obstruction was confirmed at the baseline visit using a combination of duplex scanning, computed tomography venography, magnetic reso-

nance venography, and duplex ultrasound. Ultrasound guidance was used to facilitate venous access in all cases, followed by digital subtraction angiography (DSA) to determine length of the lesion. DSA was supplemented by intravascular ultrasound (IVUS) in patients with NIVL. After stent deployment, correct placement and patency were evaluated by DSA and IVUS.

Procedural characteristics

All patients received 5000 international units of heparin at the beginning of the procedure. Local anesthesia was used for patients with compression syndrome and general anesthesia for those with chronic obstructions or occlusions. The access site was chosen based upon the extent of the disease. In most cases, the femoral vein was used. Details on target vessel characteristics are given in Table II. After preprocedural imaging, the lesion was pre-dilated in all patients and the stent was implanted. If more than one stent was used, the stents were overlapped by at least 2 cm (Figure 1a and b). The stents were post-dilated to ensure complete expansion to the nominal stent diameter. Post-procedure anticoagulation was administered immediately following procedure completion. Patients were initially given low-molecular weight heparin, but were transitioned to vitamin K antagonists for long-term therapy. Anticoagulation was continued for a minimum of 6 months in NIVL patients and at least for 6–12 months for PTO patients. Patients with a history of ≥ 2 deep vein thromboses remained on anticoagulation indefinitely.

Table I. Basic characteristics including demographics, risk factors, comorbidities, CEAP score and clinical symptoms.

Category	Characteristic	Number	Percentage/ range
Demographics	age	57	19–89
	gender (female)	45	56 %
	NIVL	30	37 %
	PTS	50	63 %
Risk factors	smoking	13	16 %
	diabetes	11	14 %
	hypertension	40	50 %
	renal failure	6	8 %
Comorbidities	History of cancer	9	11 %
	History of previous stroke	3	3 %
	History of previous pulmonary embolism	8	10 %
	History of previous DVT	43	48 %
Symptoms	pain	79	98 %
	edema	62	78 %
	lipodermatosclerosis	41	51 %
	Venous ulceration	8	10 %
	compression stockings	68	85 %

NIVL: non-thrombotic iliac vein lesions; PTS: post-thrombotic syndrome; DVT: deep vein thrombosis; CEAP: clinical, etiologic, anatomic, pathophysiologic.

Stent characteristics

The Venovo venous stent system consists of a self-expandable nitinol stent with a dedicated unique flexible, fine tubular mesh prosthesis design for venous vessels, 6 markers at each end (3 nitinol, 3 tantalum), flared ends of 3 mm ensuring adequate wall apposition, deployed by a tri-axial dual speed thumbweel delivery system for slow or fast deployment [9]. Stent diameters of 10–20 mm (2 mm incre-

Table II. Overview of target vessel lesions.

Target vessel	Target limb per intervention		
	Both limbs	Right	Left
	n = 6 (8 %)	n = 18 (22 %)	n = 56 (70 %)
CIV	n = 3 (4 %)	n = 3 (4 %)	n = 30 (38 %)
CIV + EIV + CFV	n/a	n = 14 (17 %)	n = 18 (22 %)
EIV + CFV	n = 3 (4 %)	n = 1 (1 %)	n = 5 (6 %)
CFV	n/a	n/a	n = 3 (4 %)

CIV: common iliac vein; EIV: external iliac vein; CFV: common femoral vein.

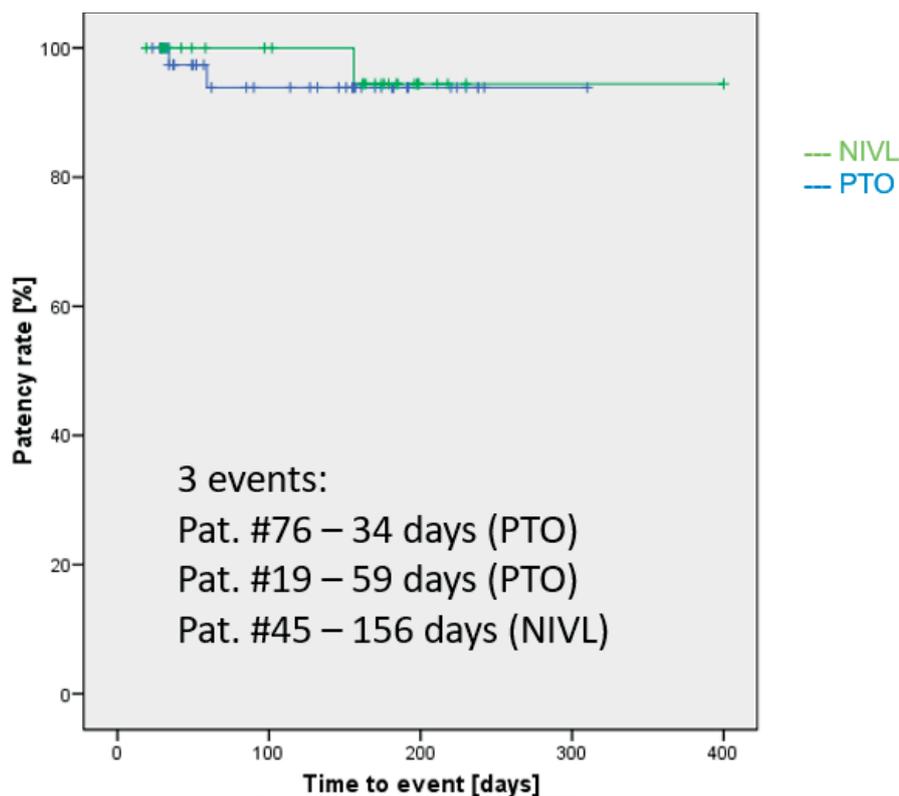


Figure 2. Comparison of Kaplan-Meier analysis of overall patency between patients with NIVL (non-thrombotic iliac vein lesions) versus patients diagnosed as PTO (post-thrombotic obstruction) treated with the Venovo venous stent.

Table III. Overview of procedure-related complications.

Adverse events	Number	Percentage
Access-site complications	4	5%
Hematoma	3	4%
Infection	1	1%
Early stent re-occlusion (within 3 days)	3	4%
Stent migration	0	0%
Clinically significant pulmonary embolism	0	0%
Venous rupture	0	0%
Blood transfusion	2	3%

Clinical presentation

The mean rVCSS at the baseline visit was 9.6 (range 5–14). Mean rVCSS scores lowered to 5 (range 1–14) at FU1 and 4 (range 1–7) at FU2. (Table IV). Especially, venous claudication and persistent swelling improved during follow-up. Together, 51% of the patients showed substantial clinical improvement reflected by a reduction of rVCSS of ≥ 2 . The mean C-class of CEAP score at baseline was 3.5. It lowered to up to 2.6 at FU1, showing a slight increase to 2.7 at FU2 (Table V). There were 10 patients with active ulcers prior to the stenting procedure. At 6-months-follow-up, 8 of the ulcers had healed until FU2.

Discussion

Chronic venous obstruction is a condition caused by intraluminal or extraluminal obstruction of the vein. Whereas in most cases, an intraluminal obstruction is related to a previous DVT between 15–50% of patients with a history of ilio-femoral DVT will develop a post thrombotic syndrome. The best-known external iliac vein compression syndrome is the May-Thurner syndrome, which generally describes a significant compression of the left common iliac vein between the lumbar vertebral column and the right common iliac artery. Several studies have shown that rates of post thrombotic syndrome lower if compression therapy is used [12–14].

During the last years and with the development of special venous stent design, endovascular ilio-femoral venous stenting represents a safe treatment option for chronic venous obstruction showing mortality and morbidity rates of $<1\%$ [1–3, 15]. First data are available on the sinus-Obliquus stent, the sinus-Venous stent, the Zilver vena stent as well as the Veniti Vici venous stent in the treatment of iliofemoral venous obstruction [5–8]. The current study assessed the safety and effectiveness of the Venovo venous stent for treating chronic post-thrombotic and non-thrombotic venous obstruction. As to our data, the Venovo venous stent exhibits acceptable patency rates compared to other dedicated venous stents and a similar low rate of early stent occlusion as summarized elsewhere [16]. There was no inferiority in the treatment of PTO as compared to patency in NIVL patients as previ-

Table IV. Overview of improvement of the rVCSS (mean values and range) score between baseline and follow-up.

	Pre-stent	1 month	6 months	p-value (pre-stent to 6 months FU)
All limbs (n = 80) ^a	9.6 (5–14)	5 (1–14)	4 (1–7)	<0.001 to pre-stent
PTO (n = 50) ^b	8.5 (5–20)	5 (1–14)	4 (1–14)	0.001 to pre-stent
NIVL (n = 30) ^c	8 (4–21)	5 (2–13)	4 (2–8)	<0.001 to pre-stent

rVCSS: revised venous clinical severity score; PTO: postthrombotic obstruction; NIVL: non-thrombotic iliac vein lesion.

^a All limbs (80 limbs in 80 patients) had pre-stent rVCSS scores. Eighty limbs had scores available at 1 and 6 months.

^b of 50 PTO patients, 46 had rVCSS scores at 1 month and 44 at 6 months.

^c of 30 NIVL patients, 28 had rVCSS scores at 1 month and 24 at 6 months.

Table V. Overview of improvement of the clinical symptoms (C-class) based on CEAP (clinical, etiologic, anatomic, pathophysiologic) score between baseline and follow-up.

	Pre-stent	1 month	6 months	p-value (pre-stent to 6 months FU)
All limbs (n = 80) ^a	3.5 (2.6–4.2)	2.6 (1.6–3.6)	2.7 (1.8–3.6)	<0.001
PTO (n = 50) ^b	4.6 (3.2–6.3)	3.2 (1.8–4.2)	2.8 (1.6–3.4)	<0.001
NIVL (n = 30) ^c	3.2 (2.7–3.5)	2.2 (1.3–2.8)	2.1 (1.1–2.4)	<0.001

PTO: postthrombotic obstruction; NIVL: non-thrombotic iliac vein lesion.

^a All limbs (80 limbs in 80 patients) had pre-stent CEAP scores. Eighty limbs had scores available at 1 and 6 months.

^b of 50 PTO patients, 46 had CEAP scores at 1 month and 44 at 6 months.

^c of 30 NIVL patients, 28 had CEAP scores at 1 month and 24 at 6 months.

ously described [17]. Simultaneously, there was a profound increase in clinical symptoms, reflected by a drop of the rVCSS dropped from 9.6 to 4 and of the CEAP score from 4.3 to 2.7 after 6 months. Patients felt substantially better, especially showing an improvement of venous claudication and ulceration. Thereby, the complication rate was low, equals the rate of other venous stent studies and raises no concerns [1, 2].

Even though these preliminary results are promising, longer studies are needed to confirm the initial results of the Venovo venous stent patency presented in this article.

Limitations

This study is limited by the short-term analysis for clinical follow-up. We also did not include more established clinical venous scores for baseline and follow-up analysis, including the Villalta score. The main criticism of the Villalta score in the literature appears to be its use of subjective measures. To that end, we propose that use of a venous disease-specific quality-of-life questionnaire in combination with the Villalta score may help standardize the subjective criteria and should be the gold standard for the diagnosis and classification of post-thrombotic syndrome in the future. However, the main thrust of this paper is to assess the safety and patency rate of the stent in the short-term, not the clinical impact.

Conclusions

The Venovo venous stent turns out to be associated with satisfactory patency rates and profound symptomatic improvement through a 6-months-follow-up in the treatment of non-thrombotic or post-thrombotic iliac vein lesions, at the same time exhibiting minimal device-related adverse events. At this early stage for analysis, with only short-term outcome data of the novel venous stents, a valid comparison between these stents is not advisable as the patient cohorts and clinical outcome measurements differ significantly in between the studies.

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Manuscript submitted: 23.08.2018

Accepted after revision: 08.10.2018

Published online: 19.11.2018

Conflicts of interests: MKWL and RDG received speaker honoraria from BARD, the manufacturer of the Venovo venous stent.

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