Comparison between a dedicated venous stent and standard composite Wallstent–Z stent approach to iliofemoral venous stenting: Intermediate-term outcomes

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ABSTRACT

Objective: Dedicated venous stents have not been used in the management of symptomatic chronic iliofemoral venous obstruction (CIVO) until recently. The Bard Venovo stent (Becton, Dickinson, and Co, Franklin Lakes, NJ) is one such stent noted to have an increased chronic outward force and radial resistive force compared with the Wallstent (Boston Scientific, Marlborough, MA). In the present study, we evaluated the outcomes following the use of the Bard Venovo stent vs a matched cohort of limbs that had undergone stenting with the Wallstent–Zenith (Z) stent (Cook Medical Inc, Bloomington, IN) composite configuration.

Methods: A review of contemporaneously entered electronic medical record data for 167 patients (167 limbs) with initial iliofemoral stents placed from 2019 to 2020 for quality of life (QOL)-impairing CIVO that had failed conservative therapy was performed. The visual analog scale for pain score (score, 0-10), grade of swelling (score, 0-4), venous clinical severity score (score, 0-27), and the 20-item chronic venous insufficiency quality of life questionnaire instrument for QOL were evaluated before and after intervention to assess the effects of stenting. A Kaplan-Meier analysis was used to examine primary, primary-assisted and secondary stent patency, and analysis of variance with repeated measures was used to compare clinical outcomes.

Results: A total of 167 limbs had undergone Bard Venovo stenting (56 men and 111 women). Their median age was 61 years. The laterality was right and left in 70 and 97 limbs, respectively. Post-thrombotic syndrome was seen in 84 limbs and nonthrombotic iliac vein lesions/May-Thurner syndrome in 83 limbs. At 6 months, the venous clinical severity score had improved from 7 to 4 in the limbs with a unilateral Venovo (UV) stent and from 5 to 4 in the composite Wallstent–Z stent group ($P = .9$). The grade of swelling had improved from 3 to 1 in the UV group and from 3 to 1 in the composite group ($P = .6$), and the visual analog scale for pain score had improved from 7 to 2 in the UV group and from 5 to 0 in the composite group ($P = .007$). At 12 months, ulcers had healed in 53% (8 of 15) of the UV group and 56% (5 of 9) of the composite group ($P = .7$). The global 20-item chronic venous insufficiency quality of life questionnaire scores had improved from 58 to 28 in the UV group and from 59 to 40 in the composite group ($P = .6$). The cumulative primary, primary-assisted, and secondary patency at 18 months was 81%, 97%, and 98% in the UV group and 87%, 98%, and 100% in the composite group, respectively ($P > .4$). No difference in the reintervention rates was noted between the two groups ($P = .5$).

Conclusions: For patients who had undergone stenting for QOL-impairing CIVO, the results with the Bard Venovo venous stent were comparable to those with the composite Wallstent–Z stent configuration for clinical outcomes, QOL improvement, and stent patency. Further study is, however, required to confirm this improvement in the long term. (J Vasc Surg Venous Lymphat Disord 2023;11:82-90.)

Keywords: Chronic venous insufficiency; Post thrombotic syndrome; May Thurner syndrome; Iliac vein obstruction; Venous stenting; Non thrombotic iliac vein lesion

The treatment of venous disease has changed dramatically over the years. Specifically, an endovascular approach has supplanted open surgery as the preferential treatment of patients presenting with symptomatic chronic iliofemoral venous obstruction (CIVO).[1-10] This approach, which originally began with the use of nondedicated stents, now has dedicated venous stents. Although multiple studies have investigated individual dedicated venous stents, a head-to-head comparison with nondedicated venous stents, which have been in use for more than two decades prior, has not been performed.[11-13] This is important because it will enable a

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side-by-side comparison of the effectiveness of the two stent configurations. Thus, we compared the Bard Venovo stent (Becton, Dickinson, and Company, Franklin Lakes, NJ) and the most recently used nondedicated venous stent configuration, the Wallstent—Zenith (Z) stent (Boston Scientific, Marlborough, MA; Cook Medical Inc, Bloomington, IN) combination. Thus, we evaluated the intermediate-term clinical, quality of life (QOL), and stent-related outcomes with the use of the Venovo stent vs those of a matched cohort treated with the composite Wallstent—Z stent configuration.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective analysis of prospectively collected data
- **Key Findings:** The use of the dedicated Bard Venovo venous stent (Becton, Dickinson, and Co, Franklin Lakes, NJ) for the treatment of quality of life (QOL) impairing chronic iliofemoral venous obstruction resulted in similar clinical, QOL, and stent outcomes as those for a matched cohort of patients who had undergone stenting with a composite Wallstent—Z (Boston Scientific, Marlborough, MA; Cook Medical Inc, Bloomington, IN) stent configuration.
- **Take Home Message:** Patients with QOL impairing chronic iliofemoral venous obstruction for whom conservative therapy has failed can expect good intermediate-term outcomes after correction of their obstruction using the Bard Venovo venous stent.

METHODS

Study design. We performed a single-center, retrospective analysis of prospectively collected data from 2019 to 2020. All the patients had provided written informed consent for the procedure. The institutional review board approved the present study for the report of de-identified patient data.

Setting. The RANE Center is a tertiary center for the management of venous and lymphatic disorders.

Participants. Patients with QOL-impairing symptoms of CIVO for whom conservative therapy (ie, use of compression stockings, lifestyle modifications, exercise, antithrombotic agents, as indicated) had failed and who had subsequently undergone intravascular ultrasound (IVUS) for confirmation of the diagnosis and stenting formed the study cohort. The leg symptoms included swelling, pain, heaviness, tiredness, achiness, tightness, skin changes (including hyperpigmentation, lipodermatosclerosis), and venous ulcers. Patients who had undergone stenting after thrombolysis for acute deep vein thrombosis or stenting for chronic total occlusive lesions were excluded.

Stenting and follow-up. The diagnosis of iliofemoral venous obstruction using IVUS was determined by evaluation of the normal minimal luminal areas (125 mm^2 in the common femoral vein, 150 mm^2 in the external iliac vein, and 200 mm^2 in the common iliac vein).[14] These data were derived via use of the distribution curve of IVUS planimetry data, the Poiseuille equation, and the Young scaling rule. A luminal area less than these values in one or more segments of the iliofemoral vein was considered abnormal and merited stenting for symptomatic patients for whom conservative therapy had failed. The rationale for not using the 50% stenosis criterion was reported in a prior study.[15]

The procedure was typically performed with the patient under general anesthesia owing to the pain that occurs during angioplasty. Access was obtained with ultrasound guidance in the mid-thigh femoral vein or the popliteal vein, as dictated by inflow. After placement of an 11F $\times$ 10-cm sheath, venography was initially performed, followed by IVUS interrogation (Visions PV, 0.035-in. digital IVUS catheter; Philips, Amsterdam, Netherlands) for diagnosis confirmation. Predilation was typically performed using a 16- to 20-mm Atlas Gold angioplasty balloon (Becton, Dickinson and Co) inflated to a pressure greater than the nominal pressure at which equilibration occurs. Stenting was then pursued, covering all the areas of disease from the inflow with a normal luminal area to the outflow with a normal luminal area. The Bard Venovo stent sizes used varied from 14 to 20 mm according to the inflow. The Wallstent—Z stent sizes typically varied from 16 to 20 mm for the Wallstent and 25 to 30 mm for the Z stent. The criteria for stent sizing were reported in a previous study.[16] Extension into the inferior vena cava was ~2 to 3 mm for the Venovo stent, 1 to 2 mm for the Wallstent, and ≤20 mm for the Z stent. When multiple stents were used, the overlap was ~2 to 3 cm for both stent configurations to prevent shelving. Caudal stent extension into the common femoral vein was performed when the disease was multifocal or long segment in nature. Postdilation of the entire stent column was then accomplished, followed by completion IVUS and venography. The patients were typically discharged the same day unless pain or medical comorbidities required overnight observation.

Preoperative antithrombotic therapy consisted of prophylactic enoxaparin (30-40 mg subcutaneously) and bivalirudin (75 mg). Postoperatively, anticoagulation was continued for patients who had been taking anticoagulation agents preoperatively, those with thrombophilia, those whose interoperative findings were suggestive of possible stent complications in the absence of anticoagulation therapy (eg, severe post-thrombotic syndrome [PTS]), and those receiving hormonal therapy (eg, oral contraceptive pills, hormone replacement therapy). A direct oral anticoagulant was typically used when

anticoagulation was started after stenting. Additionally, aspirin 81 mg daily was continued lifelong if no contraindications were present.

After the intervention, every patient received a pair of compression wraps (20-30 mm Hg) with the recommendation for them to be worn regularly. Follow-up was in the form of duplex ultrasound and clinic visits at 3 weeks, 3 months, 6 months, and 12 months and annually thereafter, as long as the patients remained asymptomatic without evidence of stent malfunction. Closer follow-up was performed as indicated by the patient's clinical and stent status. Details of the technique of stenting, stent sizing, and perioperative management have been previously reported.[8,9,14,17-19]

Reintervention and contralateral intervention. Reintervention was performed for patients who had presented with QOL-impairing symptom recurrence. These patients underwent repeat IVUS interrogation and correction of the etiology of stent malfunction, which included in-stent restenosis (ISR), stent compression (SC), a combination of ISR and SC, and stent occlusion. The patients who had had persistent symptoms in the contralateral side at the 3-month mark after the initial intervention underwent IVUS for confirmation of the diagnosis and stenting of the contralateral side, as indicated. For the Bard Venovo stent, stenting was performed using a technique similar to that used for ipsilateral stenting. For the composite stent configuration, the Z-stent petals and struts were allowed to "flower" by cutting the cranial nylon suture after partially unsheathing the stent and resheathing it again. Such flowering enables easy interdigitation of the struts of Z stents on both sides without compromising outflow on either side. Details of this technique of composite iliac vein stenting have been previously reported.[18,20]

Measurements. The metrics evaluated included the visual analog scale (VAS) for pain score, grade of swelling (GOS), and venous clinical severity score (VCSS). These were assessed before and after the intervention (before stenting and at every follow-up clinic visit). The VAS for pain score ranged from 0 for no pain to 10 for the most severe pain. The GOS (assessed objectively) was categorized as 0, no swelling; 1, pitting without obvious swelling; 2, visible ankle swelling; 3, gross swelling involving the leg up to the knee; and 4, gross swelling involving the entire leg, including the thigh. The VCSS was computed after subtracting 3 points for compression, for a range of 0 to 27. The QOL was appraised using the 20-item chronic venous insufficiency QOL questionnaire (CIVIQ-20), with a score of 100 indicating the worst possible QOL and a score of 0 indicating the best possible QOL.[21,22] All four domains (ie, pain, social, physical, and psychological) were considered individually, in addition to the generation of a global score. The composite chronic venous insufficiency score (CCVIS) was also calculated for each patient. The utility of the CCVIS has been evaluated previously.[15] The CCVIS combines the VCSS, VAS for pain score, and CIVIQ-20, with increased weight for the latter, because QOL forms the most important reason for intervention for venous disease. With the inclusion of the VAS for pain score, the VCSS for pain was removed (in addition to the 3 points removed for compression). The maximum combined score possible for CCVIS was, thus, 134 (range, 0-134, including 100 possible points for the CIVIQ-20, 24 possible points for the VCSS, and 10 possible points for the VAS for pain score). The last available response was used in the postoperative outcome analysis.

Subgroups and matching. The study cohort was divided into two subgroups. Subgroup 1 included the limbs with a unilateral Bard Venovo stent (hereafter referred to as unilateral Venovo [UV]; Supplementary Fig, *A*). Subgroup 2 included limbs in which both a Bard stent and a Wallstent were used in combination (Venovo–Wallstent; Supplementary Fig, *B*). The latter was used during the initial period of usage of the Venovo stents owing to concerns for stent fracture and potentially worse outcomes after extension across the inguinal ligament. Thus, the Wallstent was used to overcome this potential problem. Over time, we became comfortable using the Venovo stents across the inguinal ligament.

The UV subgroup was matched to a cohort that had undergone stenting using the composite stent (Wallstent–Z stent) configuration (subgroup 3; composite Wallstent–Z stent group) for comparison. The UV subgroup was also compared to the Venovo–Wallstent subgroup without matching. The matched variables included age, gender, laterality, CEAP (clinical, etiologic, anatomic, pathophysiologic) clinical class, body mass index, and pathology (ie, PTS, nonthrombotic iliac vein lesion), with matching performed using frequency matching. No significant differences among the variables were noted between the UV subgroup and the matched composite Wallstent–Z stent cohort ($P > .2$ for all variables).

Statistical analysis. Statistical analysis was performed using Prism GraphPad, version 6 (GraphPad Software, San Diego, CA) and SPSS statistics, version 24 (IBM Corp, Armonk, NY). Paired *t* tests were used to compare the outcomes within each subgroup before and after intervention (baseline vs 6, 12, and 24 months). For the VAS for pain score, any improvement in pain was graded as a binary outcome as either complete relief of pain (VAS score of 0 after intervention) or partial relief with improvement in the VAS score but not to 0. Unpaired *t* tests and χ^2 tests were used to compare the UV and unmatched Venovo–Wallstent subgroups. The UV

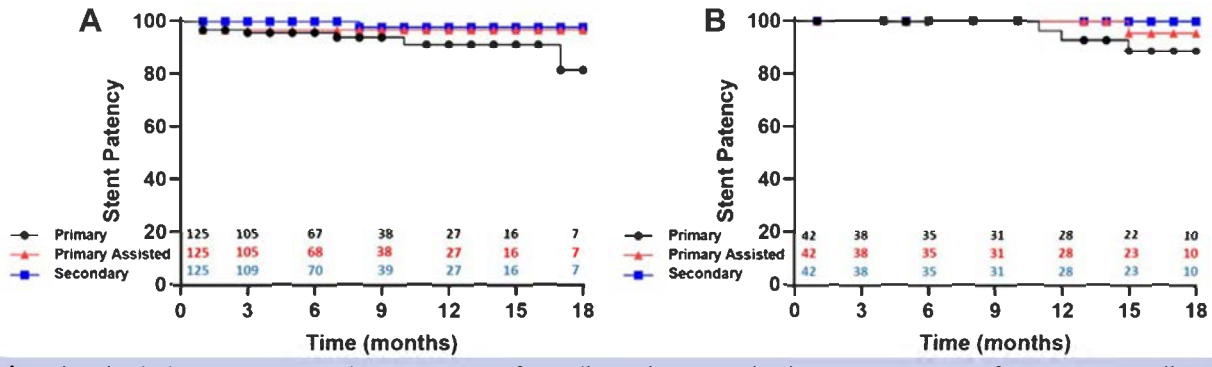

Fig. Plot depicting stent patencies. **A,** Patency for unilateral Venovo (UV) stent. **B,** Patency for Venovo–Wallstent combination.

subgroup was compared to the matched composite Wallstent–Z stent cohort via one-way analysis of variance with repeated measures, the Tukey test, and the McNemar χ^2 test. The primary, primary-assisted, and secondary stent patency and pain and swelling relief were assessed using the Kaplan-Meier method. $P \leq .05$ was considered significant.

RESULTS

A total of 167 limbs (167 patients) had undergone stenting using the Bard Venovo stent; 125 with Venovo stents only and 42 with a Venovo–Wallstent combination. Their median age was 61 years (interquartile range, 23-88 years). The cohort included 111 women (66%) and 56 men (34%). The laterality was the right limb for 70 patients (42%) and the left limb for 97 patients (58%). PTS was the recorded etiology for 84 limbs (50%), and nonthrombotic iliac vein lesions were noted in 83 limbs (50%). The CEAP clinical class included C3 for 26 (16%), C4 for 105 (63%), C5 for 17 (10%), and C6 for 19 (11%). The median follow-up was 7 months (interquartile range, 1-22 months).

Of the 167 limbs that had undergone stenting with a Venovo stent, 101 had received one stent, 65 had received two stents, and 1 had received three stents at the initial stenting. The stent sizes are listed in Supplementary Table I for both Venovo stent subgroups. For the limbs for which more than one stent had been used at the initial stenting, the stent length was determined by the total stent column length.

During stenting, 14 patients (14 limbs) had undergone simultaneous endovenous laser ablation for saphenous reflux. The great saphenous vein was ablated in all 14 limbs, and the small saphenous vein was also ablated in 2 limbs. No other secondary procedures were performed at the initial stenting.

The demographic information, CEAP clinical class, and comorbidity data for each subgroup and the matched composite Wallstent–Z stent cohort are listed in Table I.

Clinical outcomes

The comparative outcomes for the VCSS, GOS, VAS for pain score, and numbers of limbs available for analysis at each follow-up point are provided in Table II. The limbs available for comparison in each group at the different follow-up points are listed in Table III.

Venous clinical severity score. In the UV group, the VCSS had improved from 7 to 4 at 3 months ($P < .0001$) but had remained the same at 6 months ($P < .0001$). At 12 months, the VCSS had further improved to 3 ($P < .0001$). In the Venovo–Wallstent group, the VCSS had had similar improvement (from 7 to 4; $P < .0001$) at 3 and 6 months but had remained unchanged at 12 months ($P < .0001$). In the composite Wallstent–Z stent group, the VCSS had improved from 5 to 4 at 3 months ($P < .0001$) and had remained at a score of 4 at 6 months ($P < .0001$). At 12 months, the VCSS had decreased to 3 ($P < .0001$).

Grade of swelling. In the UV group, the GOS had improved from 3 to 1 at 3 months ($P < .0001$) and had remained unchanged at 6 months ($P < .0001$) and 12 months ($P < .0001$). In the Venovo–Wallstent group, the GOS had had similar improvement at 3, 6, and 12 months (from 3 to 1; $P < .0001$). In the composite Wallstent–Z stent group, the GOS had improved from 3 to 1 at 3 months ($P < .0001$) and had remained unchanged at 6 months ($P < .0001$) and 12 months ($P < .0001$).

VAS for pain score. In the UV group, the VAS for pain score had improved from 7 to 2 at 3 months ($P < .0001$) and had remained unchanged at 6 months ($P < .0001$). At 12 months, the VAS for pain score had increased to 4 ($P = .0004$). In the Venovo–Wallstent group, the VAS for pain score had decreased from 8 to 4 at 3 months ($P < .02$) and had decreased to 2 at 6 months ($P < .0001$). However, the VAS score for pain had increased to 6 at 12 months ($P < .002$). In the composite Wallstent–Z stent group, the VAS for pain score had improved from 5 to 0 at 3 months ($P < .0001$) and had remained unchanged at 6 months ($P < .0001$) and 12 months ($P < .0003$).

Table I. Demographics of each subgroup

Demographics	Unilateral Venovo (n = 125)	Matched composite (n = 125)	Venovo-Wallstent[a] (n = 42)
Left laterality	72 (58)	75 (60; *P* = .7)	25 (60)
Female gender	79 (63)	83 (66; *P* = .6)	32 (76)
Age, years	60 (28-88)	58 (18-84; *P* = .5)	61 (23-81)
Median BMI, kg/m^2	35.7	36.0 (*P* = .8)	35.3
NIVL	71 (57)	60 (48; *P* = .2)	13 (31)
PTS	54 (43)	65 (52; *P* = .2)	29 (69)
CEAP class			
3	21 (17)	31 (25; *P* = .1)	5 (12)
4	79 (63)	79 (63; *P* = .9)	26 (62)
5	10 (8)	6 (5; *P* = .3)	7 (17)
6	15 (12)	9 (7; *P* = .2)	4 (10)

BMI, Body mass index; *CEAP,* clinical, etiologic, anatomic, pathophysiologic; *NIVL,* nonthrombotic iliac vein lesion; *PTS,* post-thrombotic syndrome.
Data presented as number (%), median (range).
[a]The Venovo-Wallstent subgroup did not have a matched cohort.

Table II. Comparative outcomes for venous clinical severity score (VCSS), grade of swelling (GOS), and visual analog scale (VAS) for pain score

Comparison	Unilateral Venovo	Matched composite	*P* value	Unilateral Venovo	Venovo-Wallstent	*P* value
VCSS						
Before stenting	7 (5-9; n = 125)	5 (4-7.8; n = 125)	.0006	7 (5-9; n = 125)	7 (6-9; n = 42)	.7
3 Months	4 (3-6; n = 119)	4 (3-5; n = 104)	.6	4 (3-6; n = 116)	4 (3-6; n = 42)	.9
6 Months	4 (2-6; n = 106)	4 (2-5; n = 95)	.9	4 (2-6; n = 105)	4 (3-6.3; n = 38)	.7
12 Months	3 (3-5; n = 37)	3 (2-5; n = 77)	.9	3 (3-5; n = 36)	4 (2-5; n = 31)	.9
GOS						
Before stenting	3 (2-3; n = 125)	3 (1-3; n = 124)	.3	3 (2-3; n = 125)	3 (3-3; n = 42)	.9
3 Months	1 (0-3; n = 116)	1 (1-3; n = 104)	.9	1 (0-3; n = 116)	1 (0.8-3; n = 42)	.4
6 Months	1 (0-2; n = 105	1 (0.8-3; n = 95)	.6	1 (0-2; n = 105)	1 (0-3; n = 38)	.4
12 Months	1 (0-1.8; n = 36)	1 (1-2.5; n = 77	.8	1 (0-1.8; n = 36)	1 (0-2; n = 31)	.9
VAS score for pain						
Before stenting	7 (5-9; n = 114)	5 (1-8; n = 99)	.0003	7 (5-9; n = 114)	8 (6-9.3; n = 34)	.3
3 Months	2 (0-5; n = 72)	0 (0-3; n = 98)	.2	2 (0-5; n = 72)	4 (0.3-6.8; n = 16)	.2
6 Months	2 (0-6; n = 98)	0 (0-2; n = 90)	.007	2 (0-6; n = 98)	2 (0-6.5; n = 29)	.5
12 Months	4 (0-5; n = 37)	0 (0-4; n = 74)	.2	4 (0-5; n = 37)	6 (1-7.8; n = 24)	.06

Data presented as median (interquartile range) and number of limbs available for analysis at each follow-up point.

Table III. Comparison of limbs available in each group at different follow-up points

Follow-up point, months	Unilateral Venovo (n = 125)	Matched composite Wallstent–Z stent (n = 125)	*P* value
3	119 (95)	104 (83)	.003
6	106 (85)	95 (76)	.07
12	37 (30)	77 (62)	<.0001

Data presented as number (%).

Relief of combined symptoms. Complete relief of pain and/or swelling was noted in 81 of 123 limbs (66%) in the UV group and 26 of 41 limbs (63%) in the Venovo–Wallstent group. Partial relief of pain and/or swelling was observed in 33 of 123 limbs (27%) in the UV group and 15 of 41 limbs (37%) in the Venovo–Wallstent group. Compared with the UV group, the composite Wallstent–Z stent group had experienced complete relief of pain and/or swelling in 56% of limbs (*P* = .2) and partial relief in 27% of limbs (*P* = .9). No differences were

Table IV. Comparison of relief from pain and/or swelling between unilateral Venovo (UV) and composite Wallstent–Z stent groups and UV and Venovo–Wallstent groups

Relief	UV (n = 125)	Matched composite (n = 125)	*P* value	UV (n = 125)	Wallstent–Venovo (n = 42)	*P* value
Complete pain and/or swelling	81 (66)	66 (56)	.2	81 (66)	26 (63)	.7
Partial pain and/or swelling	33 (27)	32 (27)	.9	33 (27)	15 (37)	.2
Complete pain	57 (53)	58 (74)	.004	57 (53)	14 (44)	.3
Partial pain	35 (32)	12 (15)	.02	35 (32)	17 (53)	.02
Complete swelling	51 (43)	29 (26)	.02	51 (43)	21 (55)	.2
Partial swelling	46 (39)	43 (39)	.9	46 (39)	14 (37)	.8
No pain or swelling	9 (7)	20 (17)	.2	9 (7)	0 (0)	.08

Table V. Comparisons of stent patency at 18 months between unilateral Venovo (UV) and composite stent groups and UV and Venovo–Wallstent groups

Patency	UV (n = 125)	Matched composite (n = 125)	*P* value	UV (n = 125)	Wallstent–Venovo (n = 42)	*P* value
Primary	81	87	.4	81	89	.2
Primary assisted	97	98	.9	97	96	.8
Secondary	98	100	.8	98	100	.4

found in complete ($P = .7$) or partial ($P = .2$) pain and/or swelling relief between the UV and Venovo–Wallstent groups. The pain and swelling relief comparisons are presented in more detail in Table IV.

Ulcer healing. The healing of leg ulcers at 12 months was noted in 8 of 15 (53%) in the UV group and 5 of 9 (56%) in the composite Wallstent–Z stent group ($P = .7$). Neither group had experienced ulcer recurrence within 12 months after stenting. No ulcers were present in the Venovo–Wallstent group at intervention.

Quality of life. The median global CIVIQ-20 score had improved from 58 to 28 ($P < .0001$) in the UV group and from 60 to 36 in the Venovo–Wallstent group ($P = .3$). The individual domain scores are presented in Supplementary Table II (online only). The median global CIVIQ-20 score in the composite Wallstent–Z stent group had improved from 59 to 40 ($P < .0001$). No significant difference was found in the CIVIQ-20 scores between the two groups ($P = .6$; Supplementary Table II, online only). The median CCVIS had improved from 71 to 29 in the UV group ($P < .0001$) and from 69 to 46 in the Venovo–Wallstent group ($P = .06$). The median CCVIS had improved from 73 to 43 in the composite Wallstent–Z stent group ($P < .0001$) without a significant difference compared with the UV group ($P = .3$).

Stent outcomes

Patency. For the UV group, the primary, primary-assisted and secondary patency at 18 months was 81%, 97%, and 98%, respectively. For the Venovo–Wallstent group, the primary patency, primary-assisted, and secondary patency at 18 months was 89%, 96%, and 100%, respectively (Fig, *A* and *B*). Compared with the UV group, the matched composite Wallstent–Z stent group had had primary, primary-assisted, and secondary patency of 87% ($P = .4$), 98% ($P = .9$), and 100% ($P = .8$), respectively. The patency comparisons are provided in more detail in Table V.

Reintervention. Reintervention, which was pursued secondary to symptom recurrence impairing QOL, was required for 8 of 125 limbs (6%) in the UV group and 3 of 42 limbs (7%) in the Venovo–Wallstent group. Of these 11 reinterventions, 5 (3%) were for ISR, 3 (2%) for ISR plus SC, and 3 (2%) for stent occlusion. Of the three occlusions, one had occurred within the first 30 days in the UV group. The reinterventions for the composite Wallstent–Z stent group included two (2%) for occlusion, six (5%) for ISR, and six (5%) for ISR and SC. No significant differences were found in the reintervention rates between the UV group (6%) and composite Wallstent–Z stent group (11%; $P = .5$).

Contralateral intervention. Contralateral limb intervention was required for nine limbs (4.9%) after initial ipsilateral stenting in the entire Venovo cohort (UV subgroup and Venovo–Wallstent subgroup) because of a lack of improvement or delayed worsening. The median interval between initial stenting and contralateral stenting was 3 months. For the composite Wallstent–Z stent group (n = 125), six limbs (4.8%) had undergone contralateral stenting because of a lack of improvement or delayed worsening. The median interval to contralateral stent placement was 4.5 months. No cases of contralateral deep vein thrombosis had occurred in either group.

Procedure-related complications. One patient had required transfusion of blood products to treat procedure-related hemorrhage. Anticoagulation therapy had had to be stopped or altered for four patients. Of these four patients, three had developed access site hematomas (one had required surgical evacuation and two had resolved spontaneously). One patient had experienced gastrointestinal bleeding that had resolved spontaneously with the cessation of anticoagulation therapy. Of the patients whose anticoagulation therapy was stopped, one had required reintervention for recurrent symptoms due to ISR at 15 months after initial stent placement. No other major adverse events, including death, had occurred. These procedure-related complications were similar to those recorded for the composite Wallstent–Z stent group.

DISCUSSION

Venous stenting has been the first line of treatment for patients presenting with QOL-impairing CIVO not responsive to conservative therapy for many years now. In the United States, the past few years have witnessed the introduction of dedicated venous stents for the treatment of CIVO. Although these dedicated venous stents have been the subject of many trials, none of these trials had included a control group or matched cohort.[12,13,23] In the present study, we attempted to address this gap by comparing our experience with the use of a dedicated venous stent (Bard Venovo) to a matched cohort of patients who had undergone stenting with a standard composite Wallstent–Z stent approach.

Clinical improvement after stenting. We found significant improvement in the clinical parameters in both groups, the UV and composite Wallstent–Z stent group, at various follow-up points, including at the 12-month mark. Although no significant differences were found between the two groups at 6 and 12 months in the VCSSs and GOS, a significant difference was found in the VAS for pain score at 6 months. This likely resulted from the higher VAS for pain score in the UV stent cohort at baseline (VAS for pain score, 7) than in the composite Wallstent–Z stent group (VAS for pain score, 5; $P = .0003$).

Regarding the extent of the resolution of the baseline symptoms, complete relief of pain and/or swelling was noted in 66% of the limbs in the UV group vs 56% of the limbs in the matched composite Wallstent–Z stent group ($P = .2$). The occurrence of complete pain relief was better in the composite Wallstent–Z stent group (74%) than in the UV group (53%; $P = .004$). However, complete relief of swelling was better in the UV group (43%) than in the composite Wallstent–Z stent group (26%; $P = .02$). The differences in pain relief likely resulted from the higher proportion of patients in the UV group with pain compared with the composite Wallstent–Z stent group. Because the complete relief of pain will usually be seen in a constant proportion of limbs (~60% of limbs) after stenting, a difference in the proportion of limbs with pain at baseline will continue after stenting.[18] When complete and partial relief of pain was considered, no difference was between the two groups (Table IV). The VERNACULAR study (Bard the Venovo venous stent study for treatment of iliofemoral occlusive disease), a multicenter study assessing the safety and patency of the Venovo stent, had included 170 limbs (no control group) that had undergone stenting and noted an improvement in the VCSS for pain of 1.7 ($P < .001$) at 12 months and an improvement of 1.8 (95% confidence interval, 1.7-2) from baseline to 36 months (n = 128).[12] These results are indicative of a lack of improvement after 12 months. The total VCSS and swelling alone were not assessed in the VERNACULAR study; thus, it is difficult to compare their results with those from the present study, in which the overall VCSS improvement was 4 at 12 months.

We found no difference between the UV and Venovo–Wallstent groups regarding complete or partial relief of pain and/or swelling. However, the occurrence of complete or partial relief of pain was better in the Venovo–Wallstent group than in the UV group. Although we did not investigate the occurrence of stent fracture in the different Bard Venovo stent groups. However, stent fracture, even if present, did not appear to affect the stent or QOL outcomes. The VERNACULAR study did not report any stent fractures or migration during 36 months of follow-up. Regarding ulcer healing, we found no differences in ulcer healing or recurrence between the UV and composite Wallstent–Z stent groups. Ulcer occurrence and healing were not considered in the VERNACULAR study.

QOL comparison. Significant improvement ($P < .0001$) was noted across all four CIVIQ-20 domains (pain, social, physical, psychological) and in the global score for the UV group (from 58 to 28). These outcomes were similar to those found in the Venovo–Wallstent group (from 60 to 36; $P = .4$) and composite Wallstent–Z stent group (from 59 to 40; $P = .3$). The VERNACULAR study noted an improvement in the CIVIQ-20 score from 49.6 to 33.6 ($P < .001$) at 12 months and to 31.3 (95% confidence interval, 13.5-20.1) at 36 months (n = 128). These improvements are similar to those from the present study. We found a 42-point improvement in the CCVIS in the UV group (from 71 to 29) after stenting compared with a 30-point improvement in the composite Wallstent–Z group (from 73 to 43; $P = .3$) and 23-point improvement in the Venovo–Wallstent group (from 69 to 43; $P = .06$). These results indicate that the QOL improvement noted with the use of the Bard Venovo stent is similar to that noted with the use of a composite Wallstent–Z stent configuration.

Stent patency and reintervention. At 18 months, no differences in stent patency were noted between the UV and composite Wallstent—Z stent groups. The primary, primary-assisted, and secondary stent patency was 81%, 97%, and 98% for the UV group and 87%, 98%, and 100% for the composite Wallstent—Z stent group, respectively ($P > .4$). When considering the need for reintervention within 18 months, the UV group had required 8 reinterventions (6%) and the composite Wallstent—Z stent group had required 14 reinterventions (11%; $P = .5$). No significant differences were found between individual reasons for intervention between the two groups. The primary patency at 12 and 36 months in the VERNACULAR study was 88.6% and 84%, respectively (n = 128). A comparison between the VERNACULAR study and the present study would be difficult given the follow-up points involved. The primary patency in the VERNACULAR study appeared to be somewhat better than that in our study. However, it should be remembered that the present study represents real world data. Primary-assisted and secondary patency and reintervention data were not reported in the VERNACULAR study.

Contralateral intervention. Contralateral limb intervention was required for nine limbs (4.9%) in the UV group and six limbs (4.8%) in the composite Wallstent—Z stent group, similar to the previously reported rates of contralateral stent placement with a composite Wallstent—Z stent and well below that reported with the isolated use of Wallstents (~13%).[18,24] The median interval to contralateral stent placement after ipsilateral stent placement was also similar, at 3 months vs 4.5 months. The low rate of contralateral intervention and the absence of contralateral iliofemoral venous thrombosis are both relevant aspects resulting in the superiority of the Venovo stent compared with use of the Wallstent alone and on par with the use of a composite Wallstent—Z stent.

Overall, after stenting using the dedicated Bard Venovo stent, significant clinical improvement was realized, as indicated by improvements in the VCSS, GOS, and VAS for pain score, which were similar to those recorded for the matched Wallstent—Z stent cohort. Although no differences were found in the incidence of complete relief of pain and/or swelling, pain seemed to improve better with the composite Wallstent—Z stent and swelling seemed to improve better with the Bard Venovo stent. From a QOL or stent patency standpoint, including reintervention, no differences were found between the dedicated Bard Venovo stent and the nondedicated Wallstent—Z stent configuration. Long-term follow-up is required to determine whether these results will be maintained over time.

Study limitations. The limitations of the present study included its retrospective nature and loss of patients to follow-up. One of the reasons for the latter was the COVID-19 (coronavirus disease 2019) pandemic. Although the groups were matched according to a variety of demographic and clinical parameters, they were not perfectly matched across VCSS, GOS, and VAS for pain score owing to the inherent independent nature of these clinical scores. The short- to intermediate-term nature of the data also confined the scope of the present study. However, the strength of our study was in the use of a matched cohort treated with the composite Wallstent—Z stent configuration for comparison.

CONCLUSIONS

For patients requiring stenting for QOL-impairing CIVO, the Bard Venovo venous stent had results comparable to those with the composite Wallstent—Z stent configuration in the clinical outcomes, QOL improvement, and stent patency. Further study is, however, required to confirm this improvement in the long term.

AUTHOR CONTRIBUTIONS

Conception and design: AJ
Analysis and interpretation: TP, AJ, SR
Data collection: TP, AJ
Writing the article: TP, AJ
Critical revision of the article: TP, AJ, SR
Final approval of the article: TP, AJ, SR
Statistical analysis: TP
Obtained funding: Not applicable
Overall responsibility: AJ

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Supplementary Table I (online only). Description of stent sizes used in Venovo stent subgroups

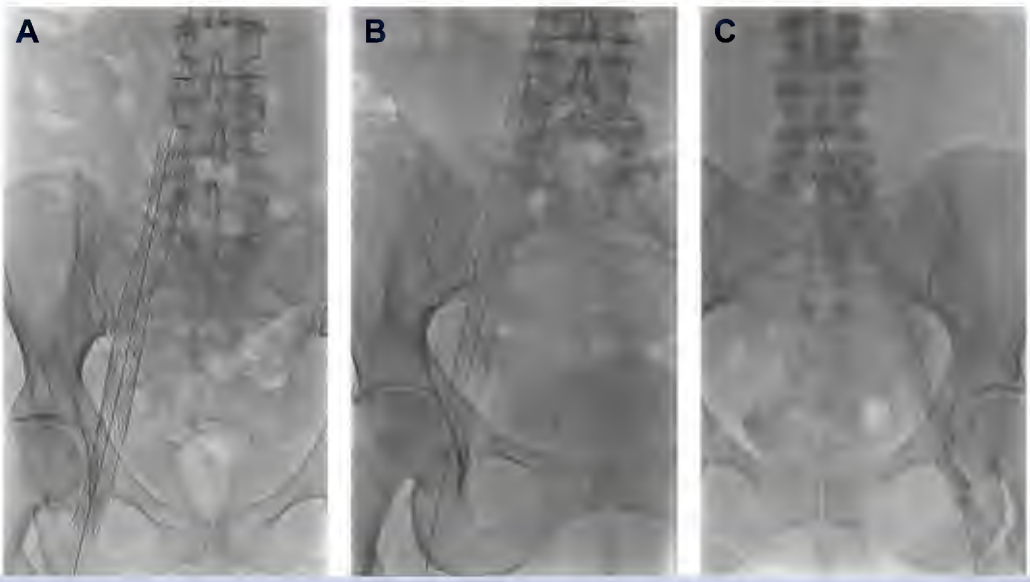
Variable	Unilateral Venovo (n = 125)	Venovo–Wallstent (n = 42)
Stents, No.	1 (1-2)	2 (2-3)
Length, mm	160 (80-210)	180 (150-240)
Diameter, mm	18 (14-20)	18 (14-20)

Data presented as median (interquartile range).

Supplementary Table II (online only). Comparison of stent patency between unilateral Venovo (UV) and composite stent groups and UV and Venovo–Wallstent groups

	UV (n = 59)			Venovo–Wallstent (n = 16)		
CIVIQ-20 domain	Pre-stent score	Post-stent score	*P* value	Pre-stent score	Post-stent score	*P* value
Pain	65	45	<.0001	68	58	.08
Social	53	33	<.0001	57	40	.04
Physical	70	45	<.0001	75	50	.03
Psychological	67	42	<.0001	67	56	.2
Global	58	28	<.0001	60	36	.08

CIVIQ-20, 20-Item chronic venous insufficiency QOL questionnaire.



Supplementary Fig (online only). A, Unilateral Bard Venovo stent. **B,** Venovo–Wallstent combination. **C,** Composite stent (Wallstent–Z stent) configuration.