Technique of stent sizing in patients with symptomatic chronic iliofemoral venous obstruction—the case for intravascular ultrasound-determined inflow channel luminal area-based stenting and associated long-term outcomes

Arjun Jayaraj, MD, David Thaggard, BS, *and* Michael Lucas, BS

ABSTRACT

Objective: Femoroiliocaval stenting has become the standard of care for patients with quality-of-life impairing chronic iliofemoral venous obstruction not responding to conservative measures. Although improvement after stenting has been noted in multiple large studies, sizing of stents has been subjective in nature with a general tendency to use smaller stents that would be required to relieve venous hypertension. This study evaluates the authors' technique of using the intravascular ultrasound (IVUS) inflow channel luminal area to guide stent sizing.

Methods: Patients who underwent femoroiliocaval stenting for quality-of-life impairing chronic iliofemoral venous obstruction and had failed conservative therapy from 2015 to 2021 were included in the study. Clinical outcomes including venous clinical severity score (VCSS), visual analog scale (VAS) pain score, and grade of swelling (GOS) were appraised before and after stenting. Also evaluated were quality of life (Chronic Venous Insufficiency Questionnaire-20 [CIVIQ-20] instrument) and stent outcomes including patencies and reinterventions. Comparisons were made between limbs that underwent placement of larger caliber stents (largest stent diameter >20 mm: >20 mm stent group) vs smaller caliber stents (largest stent diameter ≤20 mm: ≤20 mm stent group). *t* tests and analysis of variance were used to compare outcomes, whereas the Kaplan-Meier analysis was used to evaluate patencies with log rank used to compare the curves.

Results: A total of 300 patients (300 limbs) underwent stenting with a median age of 58 years. There was a preponderance of men (159 of 300), left laterality (176 of 300), and post-thrombotic syndrome (176 of 300). The median body mass index was 41. There were 120 limbs in the >20 mm stent group and 180 limbs in the ≤20 mm stent group. The median follow-up was 23 months. There was no significant difference in baseline VCSS, VAS pain score, or GOS between the two groups. However, there was a significant difference in IVUS-determined inflow channel luminal area between the two groups (228 mm^2 >20 mm stent group vs 176 mm^2 for ≤20 mm stent group [$P < .0001$]). After stenting there was a significant improvement in the VCSS, VAS pain score, and GOS at 6 weeks, 3, 6, 12, and 24 months ($P < .0001$) without any difference between the groups ($P > .05$). The CIVIQ-20 score also improved from 58 to 38 ($P < .0001$) for the entire cohort and for the two groups ($P < .0001$). Overall primary, primary-assisted, and secondary patencies at 60 months were 84%, 100%, and 100%, respectively. Reintervention rate was 10% without any difference between the groups.

Conclusions: Stent sizing using IVUS-determined inflow channel luminal area in patients undergoing stenting for quality-of-life impairing chronic iliofemoral venous obstruction resulted in a significant improvement in the VCSS, VAS pain score, GOS, and quality of life (CIVIQ-20) after stenting. Excellent stent patencies and low reintervention rates were also noted. IVUS-determined inflow channel luminal area represents an objective technique of stent sizing in comparison to the subjective techniques that currently exist. (J Vasc Surg Venous Lymphat Disord 2023;■:1-8.)

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

The last several years have witnessed the increasing utilization of venous stenting for the treatment of chronic iliofemoral venous obstruction (CIVO) in patients with quality-of-life impairing symptoms that have not responded to conservative therapy. The latter includes the use of compression stockings, leg elevation when feasible, regular exercise, and anticoagulation when appropriate. Several studies have demonstrated

From the RANE Center for Venous and Lymphatic Diseases, St. Dominic Hospital.

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Correspondence: Arjun Jayaraj, MD, The RANE Center, 971 Lakeland Dr, Ste #401, Jackson, MS 39216 (e-mail: jayaraj.arjun2015@gmail.com).

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excellent outcomes with femoroiliocaval stenting.[1-4] However, the confirmation of diagnosis of CIVO and the determination of stent size(s) have continued to be a matter of subjective assessment. With regard to the former, the use of the 50% stenosis cutoff derived through "normal" vein dimensions below or above the "lesion" or on the contralateral side is fraught with problems. This is so because in venous stenosis, unlike arterial stenosis, there is a continuous rise in venous pressure with stenosis without a "critical stenosis" point.[5] In addition, the presence of multifocal lesions, long segment lesions, and contralateral disease makes the use of these comparators problematic.[5,6] The use of normal minimal luminal areas in the common femoral, external iliac, and common iliac veins and pursuing stenting when the luminal area is below these cutoffs in one or more segments in a patient with quality-of-life impairing symptoms not responding to conservative treatment helps overcome the first problem.[4,7] Regarding stent sizing, the authors have used the concept of intravascular ultrasound (IVUS)-determined inflow channel luminal area to determine the size of the caudal stent based on its physical properties and determined the size of the cranial stent by adding 2 mm to the diameter of the caudal stent. This study represents the outcomes after the utilization of this approach.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective analysis of prospectively collected data
- **Key Findings:** Stent sizing using intravascular ultrasound-determined inflow channel luminal area resulted in improvement in venous clinical severity score, visual analog scale pain score, grade of swelling, and quality of life (Chronic Venous Insufficiency Questionnaire-20) after stenting in patients with quality-of-life impairing chronic iliofemoral venous obstruction who had failed conservative therapy. Excellent stent patencies and low reintervention rates were noted on long-term follow-up.
- **Take Home Message:** Stent sizing based on intravascular ultrasound-determined inflow channel luminal area results in good clinical outcomes, stent patencies, and significantly improved quality of life. Interventionalists should not hesitate to use large caliber stents in the appropriate setting to ensure adequate relief of venous hypertension.

METHODS

Study design. This study is a single-center retrospective analysis of prospectively collected data from 2015 to 2021. Informed consent was obtained from patients for all tests and procedures. Franciscan Missionaries of Our Lady University institutional review board approval was obtained for dissemination of deidentified patient data.

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

Participants. Patients with symptomatic CIVO impairing their quality of life who failed conservative therapy and consequently underwent IVUS interrogation to confirm diagnosis and iliofemoral venous stenting were included in the study. Such symptoms/signs included swelling, pain, heaviness, tiredness, tightness, leg cramps, venous claudication, hyperpigmentation, lipodermatosclerosis, and/or venous leg ulcers. Those who underwent stenting after pharmacomechanical thrombectomy with/without thrombolysis for acute deep venous thrombosis or stenting after recanalization of chronic total occlusions were excluded. Patients who underwent additional stenting of the inferior vena cava were also excluded.

Intervention and follow-up. Criteria for confirmation of diagnosis of CIVO on IVUS (Visions PV.035 digital IVUS catheter; Philips) was a reduction in the normal minimal luminal areas of one or more segments including the common femoral, external iliac, or common iliac venous segments. These cutoffs were 125 mm^2 for the common femoral vein, 150 mm^2 for the external iliac vein, and 200 mm^2 for the common iliac vein. Any luminal area below these cutoffs was considered abnormal meriting stenting.[6,7] The technique of stenting, perioperative care, and follow-up have been described in previous publications.[4,8,9] In brief, access was attained under ultrasound guidance in the mid-thigh femoral vein and an 11F × 10 cm sheath placed. Venography was initially performed to determine flow characteristics followed by IVUS interrogation to confirm the diagnosis. The caudal stent size was determined by using the inflow channel luminal area considering the physical properties of the stent (Table I). The cranial stent was sized to a diameter 2 mm larger than the caudal stent. The angioplasty balloon was sized to the caudal stent. For example, if a 16 mm stent was used caudally, then a 16 mm Atlas Gold balloon (Becton, Dickinson and Company) was used. Predilation was then carried out with the balloon inflated to a pressure above nominal where equilibration occurs. Stenting was pursued using a composite stent configuration of a Wallstent body (Boston Scientific) and Z stent top (Cook Medical) or the Venovo stent (Becton, Dickinson and Company) making sure that all areas of disease were covered. Postdilation was performed using the same angioplasty balloon used for predilation or one size larger if the IVUS picked up inadequate expansion. A completion IVUS examination was performed to ensure adequacy of stenting and a completion venogram to determine final flow dynamics. Patients were typically discharged the same day.

From an antithrombotic standpoint, prophylactic enoxaparin (30-40 mg subcutaneously based on weight) and

Table I. Intravascular ultrasound (IVUS) inflow channel luminal area derived caudal/cranial Wallstent diameter(s)

Inflow channel IVUS luminal area, mm^2	Caudal Wallstent diameter, mm	Cranial Wallstent diameter, mm
<125	14	16
125-149	16	18
150-199	18	20
200-249	20	22
250-299	22	24
≥300	24	24

Adjustments have to be made for other venous stents based on their physical properties. Please refer to the text.

bivalirudin 75 mg were given preoperatively. On discharge, aspirin 81 mg was started provided there were no contraindications. Outpatient therapeutic anticoagulation in the form of a direct oral anticoagulant or warfarin was pursued in patients who were already on anticoagulation before the procedure, in those with a history of an unprovoked venous thromboembolic event, those with thrombophilia, in patients on hormonal therapy based on intraoperative findings (eg, severe post-thrombotic obstruction), and in patients who developed early severe in-stent restenosis (ISR) on duplex ultrasound (DUS) examination performed before discharge. The duration of such anticoagulation was usually long. In addition, all patients who underwent stenting were given a pair each of compression stockings and compression wraps (both 20-30 mm Hg) and were counseled to wear them regularly.

Follow-up was in the form of DUS examination starting on day 0 after the procedure before discharge, at 3 weeks, and subsequently at 3, 6, and 12 months after stenting. Concomitant clinic visits occurred starting at the 3-week mark and paralleled the DUS visits. Visits after the first year were typically yearly if patients remained without clinical recurrence and/or stent malfunction.[4,9-11]

Reintervention. Patients who developed recurrence of quality-of-life impairing symptoms not responding to conservative therapy underwent repeat IVUS interrogation and correction of the etiology of stent malfunction. Such malfunction varied from ISR to stent compression (SC) to a combination of ISR and SC to stent occlusion (SO). Diagnosis and management of stent malfunction have been described previously.[10,12,13]

Measurements. Clinical metrics evaluated included the venous clinical severity score (VCSS: 0-27 [30-3 for compression stockings]), grade of swelling (GOS) (0-4), visual analog scale pain score (VAS: 0-10), and the Chronic Venous Insufficiency Questionnaire-20 (CIVIQ-20) score. GOS was categorized as 0: no swelling; 1: pitting, nonobvious 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. Each of the scores was appraised at every clinic follow-up. Quality of life was assessed through the CIVIQ-20 instrument. A maximum score of 100 indicated the worst possible quality of life, whereas a score of 0 indicated the best possible quality of life.[14,15] The last available response from the patient was used in postoperative outcome analysis. Stent outcomes including patencies and reinterventions were also examined. In addition, comparisons were made between limbs that underwent the placement of larger caliber stents (largest stent diameter >20 mm) vs those in which smaller caliber stents (largest stent diameter ≤20 mm) were used.

Statistical analysis. Statistical analysis was performed using Prism version 8 (GraphPad)/SPSS statistics version 26 (IBM Corp). Paired and unpaired *t* tests in addition to analysis of variance were used to compare outcomes. The Kaplan-Meier analysis was used to assess stent patency after intervention with the log-rank test used to discriminate between different curves. Limb counts used for analysis are noted in the results where appropriate. Mean ± standard deviation was used to denote normally distributed variables, median ± interquartile range was used to denote non-normally distributed variables. A *P* value of ≤.05 was considered significant.

RESULTS

A total of 300 limbs (300 patients) underwent stenting. The median age for the cohort was 58 years. There were slightly more males than females in the study (159:141). Left laterality was more common (176:124). There was a preponderance of limbs with post-thrombotic syndrome compared with nonthrombotic iliac vein lesions (167:126). The median body mass index was 41. Breakdown of the baseline characteristics including the Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) clinical class is considered in Table II. Five limbs C0-2 underwent intervention for venous claudication that impaired their quality of life in spite of optimal conservative therapy. A total of 120 limbs had at least one wall stent larger than 20 mm in diameter, and 180 had all wall stents less than 20 mm in diameter. Of the 300 limbs, 40 (13%) received one stent, 65 (22%) received two stents, 140 (47%) received three stents, 44 (14%) received four stents, and 11 (4%) received five stents. The median follow-up was 23 months.

Baseline characteristics

There was a statistically significant difference in the IVUS inflow channel luminal area between the two groups. The median luminal area was 228 mm^2 in the >20 mm stent group (n = 115) vs 176 mm^2 in the ≤20 mm stent group (n = 171) ($P < .0001$). With regard to the baseline clinical characteristics, there was no statistically significant difference between the VCSS (8 [>20 mm stent group] vs 7 [≤20 mm stent group], $P = .17$), GOS (3 [>20 mm stent group] vs 3 [≤20 mm stent group], $P = .78$), or VAS pain score (8 [>20 mm stent group] vs 8 [≤20 mm stent group], $P = .31$).

Table II. Baseline characteristics of the entire cohort (300 patients/300 limbs) broken down into the >20 mm stent and ≤20 mm stent groups

Variable	>20 mm stent (n =120)	≤20 mm stent (n = 180)	*P*
Age, median (range)	58 (25-84)	59 (11-85)	.8162
Male, No. (%)	71 (59)	95 (53)	.3065
Laterality left, No. (%)	70 (58)	106 (59)	.8634
NIVL:PTS	51:69	81:98	.7330
BMI, median (range)	43 (21-63)	40 (21-73)	.1549
CEAP clinical class, No. (%)			
C 0-2	1 (1)	4 (2)	.4996
C 3	12 (10)	24 (13)	.4308
C 4	82 (68)	117 (65)	.5911
C 5	10 (8)	17 (9)	.7625
C 6	15 (13)	18 (10)	.4203

BMI, Body mass index; *CEAP*, Clinical, Etiological, Anatomical, and Pathophysiological; *NIVL*, nonthrombotic iliac vein lesion; *PTS*, post-thrombotic syndrome.

Clinical outcomes

Outcomes after stenting for the entire cohort for the VCSS, GOS, and VAS pain score with the number of limbs (n) available for analysis are depicted in Table III. Comparisons across the groups at different time points are provided in Table IV.

Venous clinical severity score. For the entire cohort, the VCSS improved from 8 to 5 ($P < .0001$) at 3 months, remained at 5 at 6 months ($P < .0001$), improved further to 4 at 12 months ($P < .0001$), and remained at 4 at 24 months ($P < .0001$). In the >20 mm stent group, the VCSS improved after stenting from 8 to 5 at 3 months ($P < .0001$) and remained at 5 at 6 months ($P < .0001$) before further improving to 4 at 12 months ($P < .0001$) and mildly worsening to 5 at 24 months ($P < .0001$). For the ≤20 mm stent group, the VCSS improved from 8 to 4 at 3 months ($P < .0001$) and increased to 5 at 6 months ($P < .0001$) before coming down to 4 at 12 months ($P < .0001$) and remaining at 4 at 24 months ($P < .0001$). There was no significant difference between the groups at any of the follow-up time points.

Grade of swelling. For the entire cohort, the GOS improved from 3 to 1 ($P < .0001$) at 3 months and remained at 1 at 6 months ($P < .0001$), 12 months ($P < .0001$), and 24 months ($P < .0001$). In the >20 mm stent group, the GOS improved after stenting from 3 to 1 ($P < .0001$) at 3 months and remained at 1 at 6 months ($P < .0001$), 12 months ($P < .0001$), and 24 months ($P < .0001$). For the ≤20 mm stent group, the GOS improved 3 to 1 ($P < .0001$) at 3 months, but increased to 2 at 6 months ($P < .0001$) and remained at 2 at 12 months ($P < .0001$) before decreasing to 1 again at 24 months ($P < .0001$). A statistically significant difference was not found between the two groups at the various time points.

Visual analog scale pain score. For the entire cohort, the VAS pain scores improved from 8 to 3 at 3 months ($P < .0001$), remained at 3 at 6 months ($P < .0001$), and increased to 4 at 12 months ($P < .0001$) before declining to 2 at 24 months ($P < .0001$). In the >20 mm stent group, the VAS pain scores improved after stenting from 8 to 4 at 3 months ($P < .0001$), further decreasing to 3 at 6 months ($P < .0001$). The VAS pain score increased to 4 at 12 months ($P < .0001$) before decreasing to 2 at 24 months ($P < .0001$). For the ≤20 mm stent group, the VAS pain score improved from 8 to 2 at 3 months ($P < .0001$), increased to 3 at 6 months ($P < .0001$), and remained at 3 at 12 months ($P < .0001$) before declining to 2 again at 24 months ($P < .0001$). Here again no significant difference was noted between the two groups at follow-up intervals.

Ulcer healing. Healing of leg ulcers for the entire cohort was 67% (22 of 33), and ulcer recurrence was 18% (4 of 22) over the course of follow-up. When comparing the groups, stents >20 mm had a healing rate of 60% (9 of 15), whereas stents ≤20 mm had a healing rate of 72% (13 of 18) ($P = .5$). Recurrence of leg ulcer was 0% (0 of 9) in stents >20 mm and 31% (4 of 13) in stents ≤20 mm ($P = .07$).

Back pain. Back pain has often been thought to be a concern with the use of larger caliber stents. On analysis, in the >20 mm stent group, severe back pain was present after surgery in only 5 of 120 (4%) patients. Of these 5 patients, only 3 (of 120, 2.5%) required the prescription of narcotics or oral steroids for additional relief.

Quality of life

For the entire cohort, the global CIVIQ-20 scores improved from 58 to 38 ($P < .0001$). The global CIVIQ-20 score improved from 61 to 36 ($P < .0001$) in the >20 mm stent group, whereas it improved from 54 to 38 ($P < .0001$) in the ≤20 mm stent group. There was no significant difference between the pre- and poststenting CIVIQ-20 scores of the two groups.

Table III. Clinical and quality of life outcomes before and after stenting for the entire cohort

Follow-up after intervention	Variable	No.	Prestenting (median)	Poststenting (median)	*P*
3 months	VCSS	236	7	5	<.0001
	GOS	236	3	1	<.0001
	VAS	188	8	3	<.0001
6 months	VCSS	189	8	5	<.0001
	GOS	192	3	1	<.0001
	VAS	175	8	3	<.0001
12 months	VCSS	186	7	4	<.0001
	GOS	189	3	1	<.0001
	VAS	160	8	3	<.0001
24 months	VCSS	138	7	4	<.0001
	GOS	138	3	1	<.0001
	VAS	125	8	2	<.0001
QOL		146	58	38	<.0001

GOS, Grade of swelling; *QOL*, quality of life; *VAS*, visual analog scale; *VCSS*, venous clinical severity score.

Stent outcomes

Patency. Overall primary, primary-assisted, and secondary patencies at 60 months were 84%, 100%, and 100%, respectively. Patencies for the whole cohort can be seen in Fig 1. For the >20 mm stent group, primary patency was 90%, whereas both primary-assisted patency and secondary patency were 100%. In the ≤20 mm stent group, primary patency was 80%, primary-assisted patency was 100%, and secondary patency was 100%. Fig 2 compares patencies between the two groups. Log-rank comparison of stent patencies between the two groups was nonsignificant ($P = .29$).

Reintervention. Reintervention of the initial surgery occurred in 10% (34 of 311) of the entire cohort. In the >20 mm stent group, reinterventions were needed in 7% (8 of 120), whereas the ≤20 mm stent group required reinterventions in 12% (22 of 180) of the patients. Of the reinterventions in the >20 mm stent group, 4 (50%) were for ISR and 3 (38%) were for SO. Reinterventions for the ≤20 mm stent group consisted of 9 (41%) for ISR, 1 (5%) for SC, 7 (32%) for a combination of ISR and SC, and 3 (14%) for SO. Comparison between the two groups showed no statistical difference.

DISCUSSION

Although iliofemoral venous stenting has become the standard of care for patients with symptomatic CIVO, one aspect of stenting that merits further clarification is the technique of stent sizing. Generally, the method even in high-volume practices has been to make a subjective assessment of the stent size required for the patient. This may or may not result in the appropriate stent size with inherent consequences. In this study, the authors present an objective technique to size stents based on the IVUS inflow channel luminal area. The improvement in clinical, quality of life, and stent-related metrics supports the utilization of this technique.

Basis for IVUS inflow channel luminal area-based stenting. The inflow channel luminal area is the narrowest luminal area of the native vein just below the anticipated caudal end of the stent. This location is determined by careful IVUS interrogation after access is obtained in the mid-thigh femoral vein. Given the increase in the stent size required in the common iliac vein compared with the common femoral vein to conform to normal anatomy, a 2 mm increase in the cranial stent compared with the caudal stent is necessary. Given that the normal luminal area in the common femoral vein is 125 mm^2 corresponding to approximately 12.6 mm diameter, the stent size in the common femoral vein should not be below this. Given the physical properties of the Wallstent, a 14 mm stent would be the smallest that one would be able to use in the common femoral vein. The corresponding common iliac stent would be 16 mm. Considering the physical properties of the different dedicated venous stents, the Cook Zilver Vena (Cook Medical) would be sized just like the Wallstent.[16] The Venovo (Becton, Dickinson and Company) or Abre (Medtronic) stents would be sized one size smaller compared with the Wallstent. The latter concept is likely to be true for the Sinus Venous, Sinus XL Flex, and Sinus Obliquus (Optimed) stents as well given their physical properties, although they are not yet available in the United States.[16] Given that the normal minimal luminal diameters of the common femoral, external iliac, and common iliac veins are 12 mm, 14 mm, and 16 mm, respectively, stents (irrespective of physical properties) should have these minimum diameters in the corresponding segments to avoid iatrogenic stenosis and residual/persistent venous hypertension.[7]

Table IV. Comparison of pre- and poststenting clinical and quality of life outcomes for the two groups (>20 mm stent group and ≤20 mm stent group)

Unpaired *t*-test of group outcomes					
Outcome	**Group**	**Follow-up, months**	**No.**	**Median**	***P***
VCSS	Stents >20 mm	Prestenting	119	8	.1657
	Stents ≤20 mm		175	8	
	Stents >20 mm	3	94	5	.1680
	Stents ≤20 mm		145	4	
	Stents >20 mm	6	71	5	.5975
	Stents ≤20 mm		123	5	
	Stents >20 mm	12	60	4	.2299
	Stents ≤20 mm		118	4	
	Stents >20 mm	24	46	5	.8142
	Stents ≤20 mm		93	4	
GOS	Stents >20 mm	Prestenting	120	3	.7779
	Stents ≤20 mm		178	3	
	Stents >20 mm	3	92	1	.8283
	Stents ≤20 mm		145	1	
	Stents >20 mm	6	71	1	.1137
	Stents ≤20 mm		122	2	
	Stents >20 mm	12	71	1	.4538
	Stents ≤20 mm		119	2	
	Stents >20 mm	24	46	1	.8762
	Stents ≤20 mm		93	1	
VAS	Stents >20 mm	Prestenting	101	8	.4635
	Stents ≤20 mm		164	8	
	Stents >20 mm	3	77	4	.1366
	Stents ≤20 mm		128	2	
	Stents >20 mm	6	72	4	.3402
	Stents ≤20 mm		124	3	
	Stents >20 mm	12	64	4	.0925
	Stents ≤20 mm		110	3	
	Stents >20 mm	24	44	2	.9297
	Stents ≤20 mm		86	2	
QOL	Stents >20 mm	Prestenting	77	59	.3441
	Stents ≤20 mm		86	54	
	Stents >20 mm	Poststenting	90	36	.6673
	Stents ≤20 mm		148	38	

GOS, Grade of swelling; *QOL*, quality of life; *VAS*, visual analog scale; *VCSS*, venous clinical severity score.

The second principle is to ensure that larger stent sizes are used when appropriate. An individual with an IVUS inflow channel luminal area of 275 mm^2 merits a caudal Wallstent of 22 mm diameter. A 16 mm or 18 mm stent will not suffice and result in residual venous hypertension and persistent or recurrent symptoms. Although individuals requiring stents of such caliber are far less common than those requiring stents 20 mm or smaller, this is an important concept that needs to be borne in mind. This aspect is supported by the finding that limbs with large inflow channel luminal areas (requiring stents >20 mm) had at baseline VCSS, VAS pain score, and grade of swelling that were not statistically different from those with smaller inflow channel luminal areas (requiring stents ≤20 mm). There was no difference in the distribution of the CEAP clinical class at baseline either. After stenting both groups had a significant improvement in these clinical metrics without a significant difference between the groups. The absence of a significant difference between the two groups applied to stent patencies and reintervention rates as well. Another advantage of IVUS inflow channel luminal

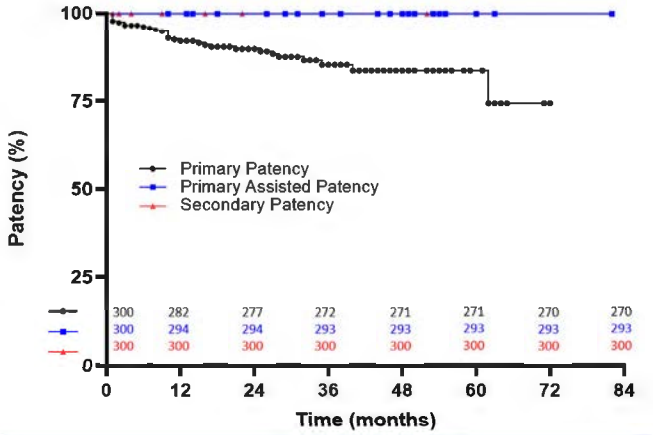

Fig 1. Plot demonstrating primary, primary-assisted, and secondary stent patencies for the entire cohort (standard error of the mean was <10%).

area-based stenting besides adequate correction of venous hypertension is that appropriately sized stents are unlikely to migrate given good apposition to the vein wall. A point that needs to be made here relates to the indispensability of IVUS for both diagnosis and treatment of CIVO.[17-19]

Also, as noted previously, it is important to bear in mind that the concept of critical stenosis used in arterial stenosis does not apply to veins given the continuous rise in venous pressure with stenosis. So, there really is no role for treatment based on a set degree of iliofemoral venous stenosis.[6] In addition, the development of symptoms depends on the ability of the superficial venous system, venous collaterals, and lymphatic system to compensate. So, someone could have a 70% iliofemoral venous stenosis and severe symptoms, whereas another patient could have the same degree of stenosis and remain asymptomatic. When a patient develops symptoms/signs in the setting of iliofemoral venous

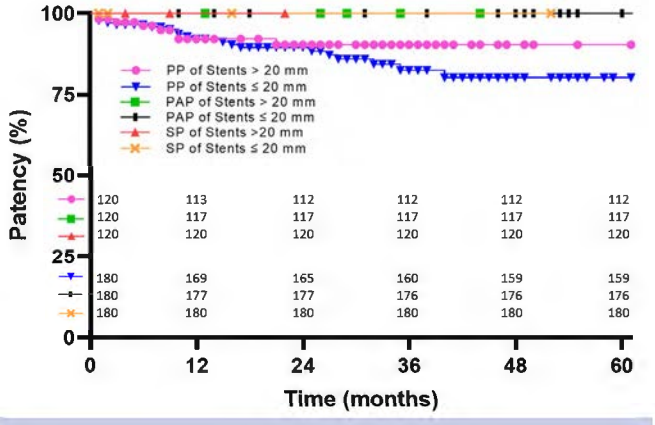

Fig 2. Plot demonstrating primary (*PP*), primary-assisted (*PAP*), and secondary stent (*SP*) patencies for the two groups (>20 mm stent and ≤20 mm stent) (standard error of the mean was <10%).

obstruction, it means that the compensatory mechanisms have been overwhelmed. Such symptoms can respond to conservative therapy including the use of compression stockings, leg elevation when feasible, regular exercise as tolerated, and anticoagulation when appropriate. This should be the first line of treatment in patients with C3 disease, in those with venous hypertension syndrome, or in patients with venous claudication. When conservative therapy does not work or when the patient develops evidence of tissue damage (C4-6 disease) correction of the obstruction is warranted.

It is also important to not forget that unlike arterial disease, the goal of treatment of venous disease is to improve quality of life and not preserve limb or life. Correction of iliofemoral venous obstruction not responding to conservative therapy is vital to get these patients back to being functional members of the society. In this regard, it is imperative that quality of life be assessed with a validated instrument. Although the authors have used the CIVIQ-20 instrument for this paper, they have previously proposed a composite chronic venous insufficiency score (CCVIS) that pools the VAS pain score, VCSS, and the CIVIQ-20 scores to help determine a baseline score that would be predictive of significant improvement. This score was computed using 0 to 10 points for the VAS pain score, 0 to 24 points for the VCSS (30-6 [removed for compression stockings and pain score]), and 0 to 100 for the CIVIQ-20, giving a maximum score of 134. The 3 points for pain were removed from VCSS to prevent duplication of pain scores from VCSS and VAS pain scores. The authors found that after stenting, for a 30-point improvement, the CCVIS baseline score would have to be at least 84.5 or higher, for a 40-point improvement, the CCVIS baseline score would have to be 86.9 or higher, whereas for a 50-point improvement, the CCVIS baseline score would have to be 105.3 or higher.[6] Further work is necessary in this regard.

Impact of stenting on clinical parameters and quality of life. After stenting there was an improvement in the VCSS, VAS pain score, and GOS in the entire cohort that was statistically significant. When assessed as individual groups, both the >20 mm stent group and the ≤20 mm stent group had a significant improvement in the VCSS, VAS pain score, and GOS after stenting without a difference between the groups. This represents an important finding and supports the concept of individualizing the stent sizing using the IVUS-determined inflow channel luminal area to determine the stent size. This is further supported by quality of life that was assessed through the CIVIQ-20 instrument. Here, again not only was there a significant improvement in the entire cohort after stenting (58 improved to 38; $P < .0001$), there was also a significant improvement in both groups (>20 mm

stent group: 61 improved to 36; $P < .0001$ and ≤20 mm stent group: 54 improved to 38; $P < .0001$).

Stent outcomes after inflow-based stenting. Patencies in the entire cohort included a primary patency of 84% and primary-assisted and secondary patencies of 100% each. There was no difference in the primary, primary-assisted, or secondary patencies between the two groups. A primary patency of 84% at 5 years is favorable compared with other large published series.[1,4] Reintervention rate for the entire cohort was lower than comparable studies at 10% without a significant difference between the groups.

Limitations. Limitations include the retrospective nature of the study and relatively small sample size. There is also the problem of loss to follow-up, all of which has an impact on the results of the study. These, however, represent deficiencies of studies of this nature and are difficult to counter. In addition, the GOS assessment although simple to perform and performed by expert clinicians is subjective bringing with it some risk of observer bias. The uniqueness of the study lies in the fact that it puts forth and evaluates an objective criterion for sizing stents in patients undergoing stenting for CIVO and reports good results on long-term follow-up.

CONCLUSIONS

Stent sizing using the IVUS-determined inflow channel luminal area in patients undergoing stenting for symptomatic CIVO resulted in a significant improvement in the VCSS, VAS pain score, GOS, and quality of life (CIVIQ-20) after stenting. Excellent stent patencies and low reintervention rates were also noted. The IVUS-determined inflow channel luminal area represents an objective technique of stent sizing in comparison with the subjective techniques that currently exist. Further corroboration is warranted.

AUTHOR CONTRIBUTIONS

Conception and design: AJ
Analysis and interpretation: AJ, DT
Data collection: DT, ML
Writing the article: AJ, DT, ML
Critical revision of the article: AJ
Final approval of the article: AJ, DT, ML
Statistical analysis: DT, ML
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