Effect of body mass index on initial presentation and outcomes after stenting for quality of life–impairing chronic iliofemoral venous obstruction

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ABSTRACT

Objective: The incidence of obesity has been increasing, with recent data indicating that the age-adjusted mean body mass index (BMI) is close to 30 kg/m^2 in the United States. Prior studies have raised concerns for an increased incidence of chronic venous insufficiency in the obese population. We aimed to build on current knowledge by assessing the effects of BMI on the initial presentation and outcomes after intravascular ultrasound (IVUS) luminal area-guided stenting in patients presenting with quality of life (QOL)-impairing chronic iliofemoral venous obstruction (CIVO).

Methods: A retrospective analysis of contemporaneously entered electronic medical record data on 464 continuous patients (464 limbs) with initial iliofemoral stents (2014-2017) for QOL-impairing CIVO was performed. The characteristics evaluated and compared included the degree of iliofemoral compression, CEAP (clinical, etiologic, anatomic, pathophysiologic) clinical class, venous clinical severity score (VCSS), grade of swelling (GOS), visual analog scale (VAS) for pain score, ulcer healing, reflux (venous segmental disease score; venous filling index-90), calf pump function (ejection fraction; residual volume fraction), and quality of life (CIVIQ-20 [chronic lower limb venous insufficiency 20-item questionnaire]) for those with a BMI <30 kg/m^2 (group I) and a BMI ≥30 kg/m^2 (group II). Paired and unpaired *t* tests were used for comparisons of the clinical variables and a Kaplan-Meier analysis was used to evaluate stent patency.

Results: Of the 464 limbs in the study cohort, 122 were in group I and 342 in group II. The median BMI was 26.3 kg/m^2 (interquartile range, 19.6-29.9 kg/m^2) in group I and 38.9 kg/m^2 (interquartile range, 30.0-66.9 kg/m^2) in group II. The IVUS luminal area–determined degree of compression was higher in group I than in group II across the common iliac, external iliac, and common femoral segments ($P < .01$). The supine foot venous and femoral venous pressures were higher in group II than in group I ($P < .001$). The ejection fraction was higher (57.4% vs 45.6%; $P = .0008$) and residual volume fraction was lower (27.5% vs 40.5%; $P = .0008$) in group II than in group I. Although the baseline VCSS and GOS were lower in group I than in group II ($P < .05$), no differences were found in the VAS for pain scores or ulcer prevalence. The median follow-up was 22 months. At 24 months after stenting, improvement was found in the VCSS, GOS, and VAS for pain score in both groups. The CIVIQ-20 QOL score had improved from 58.1 to 18.8 in group I ($P = .0002$) and from 60 to 37.5 in group II ($P < .0001$). At 5 years, primary patency was 70% in group I and 73% in group II ($P = .6$) and primary assisted patency was 100% in both groups ($P = .99$) without a significant difference in the reintervention rate ($P = .5$).

Conclusions: Obese patients with CIVO-impairing QOL have a lesser degree of iliofemoral venous stenosis, more severe venous hypertension, and better calf pump function than their nonobese counterparts. After stenting, no differences were found in the clinical, stent patency, or QOL-related outcomes between the two groups. (J Vasc Surg Venous Lymphat Disord 2021;■:1-9.)

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

The incidence of obesity has been increasing for several years. This has led to an increased exploration of the effects of body mass index (BMI) on venous disease. van Rij et al[1] demonstrated that the CEAP (clinical, etiologic, anatomic, pathophysiologic) clinical class of venous disease is more advanced in obese patients than in nonobese patients with comparable anatomic patterns of venous competence. They also found that the obese had better calf pump function.[1] Danielsson et al[2] found a correlation of BMI with the clinical severity of reflux. They reported that being overweight was a separate risk factor for increased severity of skin changes in patients with chronic venous disease. From a hemodynamic standpoint, Willenberg et al[3] determined that the femoral vein diameter was increased and the peak and minimum femoral vein flow velocities and shear stress were decreased in obese individuals compared with nonobese individuals. They concluded that these findings place obese individuals at increased risk of venous thromboembolic events and chronic venous

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insufficiency.[3] Arfvidsson et al[4] noted an increase in urinary bladder pressure and increased femoral venous pressure (FVP) in morbidly obese women compared with controls. They reported that increased intra-abdominal pressure (reflected by increased urinary bladder pressure) in morbidly obese patients caused increased FVP.[4] Padberg et al[5] reported that a higher CEAP clinical class correlated with an increased BMI. They also found that patients with a BMI >40 kg/m^2 had severe limb symptoms typical of chronic venous insufficiency (CVI), although more than two thirds did not have anatomic evidence of venous disease. These findings led them to conclude that obesity itself contributed to morbidity.[5] Raju et al[6] determined that although the mechanism of venous obstruction in obese patients presenting with CVI was substantially (89%) similar to that in the nonobese, compression of venous outflow and/or increased abdominal pressure could a factor in ~11%. They concluded that iliofemoral venous stenting was a satisfactory clinical option for obese patients with severe CVI manifestations.[6] Deol et al[7] explored the effects of BMI on patients undergoing superficial venous procedures. They found that a progressive increase in BMI negatively affected the CVD treatment outcomes as measured using the VCSS and CIVIQ-20.[7] Thus, we decided to evaluate the effects of patients' BMI on the initial presentation, clinical outcomes, hemodynamic outcomes, stent-related outcomes, and quality of life (QOL) in patients undergoing stenting for symptoms impairing their QOL secondary to chronic iliofemoral venous obstruction (CIVO).

METHODS

Study design. We performed a single-center, retrospective analysis of prospectively collected data for 4 years from 2014 to 2017. The St Dominic Hospital institutional review board approved the present study for the dissemination of de-identified patient data. All included patients had provided written informed consent for the procedure.

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

Participants. Patients with symptomatic CIVO-impairing QOL for whom conservative therapy had failed and who had consequently undergone intravascular ultrasound (IVUS) interrogation and iliofemoral venous stenting were included in the present study. Those who had undergone stenting after recanalization of chronic total occlusions or after thrombolysis for acute deep vein thrombosis were excluded. The participants were categorized according to their BMI into two groups: group I, BMI <30 kg/m^2; and group II, BMI ≥30 kg/m^2.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective analysis of prospectively collected data
- **Key Findings:** Obese patients with chronic iliofemoral venous obstruction impairing quality of life have a lesser degree of iliofemoral venous stenosis, more severe venous hypertension, and better calf pump function than their nonobese counterparts. After stenting, no differences were found in clinical, stent patency, or quality of life–related outcomes compared with nonobese patients.
- **Take Home Message:** Intravascular ultrasound interrogation and possible stenting should be offered to obese individuals presenting with quality of life–impairing symptoms from chronic iliofemoral venous obstruction for whom conservative therapy has failed, given the potential for improvement of exercise tolerance and consequent weight loss and enhancement of their quality of life.

Intervention and follow-up. Patients presenting with QOL-impairing symptoms of CVI, including pain, swelling, heaviness, tiredness, venous claudication, hyperpigmentation, lipodermatosclerosis, and/or venous leg ulcers, for whom conservative therapy had failed underwent IVUS interrogation for confirmation of CIVO and angioplasty or stenting after confirmation. The criteria for the diagnosis of CIVO on IVUS were abnormal findings for the minimal luminal areas. The normal luminal area is 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. A luminal area less than these cutoff points was considered abnormal, meriting stenting.[8,9] The technique of stenting, perioperative care, and follow-up protocols have been described previously.[10-12] In brief, access was obtained in the mid-thigh femoral vein or popliteal vein (depending on inflow) under ultrasound guidance and an 11F × 10-cm sheath placed. A venogram was initially performed to determine the flow characteristics, followed by IVUS interrogation to confirm the diagnosis. Predilation was performed using a 16- or 18-mm balloon, with the balloon inflated to a pressure greater than nominal such that equilibration occurred. Stenting was performed using a composite stent configuration of a Wallstent body (Boston Scientific, Waltham, Mass) and Z stent top (Cook Medical, Bloomington, Ind) to ensure that all areas of disease were covered. Post-dilation was performed using the same angioplasty balloon used for predilation. A completion IVUS interrogation to ensure the adequacy of stenting and completion venogram to determine final flow dynamics were then performed. Patients were typically monitored overnight after the procedure.

Prophylactic enoxaparin (30-40 mg subcutaneously based on weight) and bivalirudin 75 mg were given preoperatively. Postoperatively, therapeutic enoxaparin (1 mg/kg/dose every 12 hour) was continued until discharge the next day. Subsequently, aspirin 81 mg, cilostazol 50 mg twice daily, and therapeutic anticoagulation (direct oral anticoagulant or warfarin) were continued as long as no contraindications for their use were present. Anticoagulation was typically continued for 6 months unless the patient developed thrombophilia, was already receiving anticoagulation, or had developed stent-related complications that required reintervention. Aspirin 81 mg and cilostazol were continued lifelong. Additionally, all patients undergoing stenting were given a pair of compression stockings and compression wraps (both 20-30 mm Hg) to be worn regularly.

Follow-up included duplex ultrasound on day 1, 2 and 4 weeks, and 3, 6, and 12 months after stenting. Clinic visits began at 6 weeks postoperatively and paralleled the duplex ultrasound visits. Examinations after the first year were typically annually as long as the patients remained asymptomatic without evidence of clinical recurrence and/or stent dysfunction.[10,12-14]

Reintervention. The patients who developed recurrence of their initial QOL-impairing symptoms underwent IVUS interrogation and consequent correction of the etiology of stent malfunction. The latter varied from in-stent restenosis (ISR) to stent compression (SC) to a combination of ISR and SC to stent occlusion. The technique of correction of stent malfunction has been described previously.[13,15,16]

Measurements. The clinical parameters appraised included the venous clinical severity score (VCSS; 0-27 [3-30 for compression stockings]), visual analog scale (VAS) for pain score (0-10), grade of swelling (GOS; 0-4), and CIVIQ-20 score. The GOS was categorized as 0, no swelling; 1, pitting, no 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. All the scores were appraised at every clinic follow-up visit. QOL was evaluated using the CIVIQ-20. A maximum score of 100 indicated the worst possible QOL and a score of 0, the best possible QOL.[17,18] The last available response was used in the postoperative outcome analysis.

Initial IVUS interrogation was used to help determine the baseline iliofemoral compression in the two groups, and the completion IVUS was used to assess the relief of such compression after stenting. These metrics were compared at baseline and after stenting between the two groups. The Gaussian distribution of the baseline common and external iliac vein luminal areas for the two groups was plotted.

The foot venous pressure was evaluated in a dorsal foot vein with the patient in the supine position. The femoral venous pressure was ascertained in the common femoral vein by insertion of a 5F sheath in the supine position. Air plethysmography was performed as described by Christopoulos et al,[19] and the venous filling index (VFI-90), ejection fraction (EF), and residual volume fraction (RVF) were computed. The venous segmental disease score (VSDS) was used to categorize venous reflux in the two groups.[20] Although the hemodynamic parameters were ascertained in both limbs, only the index limb (undergoing stenting) was used in the analysis.

Statistical analysis. Statistical analysis was performed using Prism, version 8 (GraphPad, San Diego, Calif) or SPSS statistics, version 26 (IBM Corp, Armonk, NY). The BMI <30 kg/m^2 (group I) and BMI ≥ 30 kg/m^2 (group II) groups were compared at baseline and after stenting using unpaired or paired *t* tests. The limb count used for analysis is reported when appropriate. The mean $\pm$ standard deviation was used for normally distributed variables and the median and interquartile range (IQR) for non-normally distributed variables. The Kaplan-Meier analysis was used to assess stent patency after intervention, with log-rank test used to discriminate between curves. $P \leq .05$ was considered statistically significant.

RESULTS

Of the 464 limbs in the study cohort, 122 were in group I and 342 in group II. No significant differences were found in the median age, gender, nonthrombotic iliac vein lesion or post-thrombotic syndrome between the two groups. The median BMI was 26.3 kg/m^2 (IQR, 19.6-29.9 kg/m^2) in group I and 38.9 kg/m^2 (IQR, 30.0-66.9 kg/m^2) in group II. The baseline characteristics, including CEAP clinical class, are listed in Table I. No statistically significant difference was found in the proportion of each CEAP clinical class between the two groups, except for C0 and C2, which included a total of five limbs. Patients with CEAP clinical class 0 and 2 underwent intervention secondary to disabling venous claudication (leg pain or tightness that developed with ambulation and/or exercise). A statistically significant increase was present in group II compared with group I in the prevalence of diabetes mellitus (25% vs 11%; $P = .001$), obstructive sleep apnea (13% vs 2%; $P < .0005$), and hypertension (61% vs 37%; $P < .0001$). The median follow-up was 22 months.

Baseline clinical characteristics. A statistically significant difference was present in the baseline VCSS (median, 5 [IQR, 4-6.5] in group I; median, 6 [IQR, 4.8-8] in group II; $P = .0008$) and GOS (median, 2 [IQR, 1-3] in group I; median, 3 [IQR, 1-3] in group II; $P < .0001$), without a significant difference in the median VAS for pain score (median, 4 [IQR, 1-7] in group I; median, 5 [IQR, 2-8] in group II; $P = .4$).

Regarding ulcers, 14 limbs (11%) in group I had venous leg ulcers compared with 26 (8%) in group II ($P = .3$). From a QOL standpoint, no statistically significant

Table I. Comparison of baseline characteristics between groups

Characteristic	Total (n = 464)	Group I (BMI <30 kg/m^2; n = 122)	Group II (BMI ≥30 kg/m^2; n = 342)	*P* value
Left side	288 (62)	70 (57)	218 (64)	.2
Female sex	320 (69)	90 (74)	230 (67)	.2
Median age, years	59	61	59	.6
NIVL/MTS	96 (21)	20 (16)	76 (22)	.2
PTS	368 (79)	102 (84)	266 (78)	.2
Diabetes	100 (22)	13 (11)	87 (25)	.001
Sleep apnea	47 (10)	3 (2)	44 (13)	.0005
Hypertension	252 (55)	45 (37)	207 (61)	<.0001
CAD	9 (2)	1 (1)	8 (2)	.5
CHF	14 (3)	2 (2)	12 (4)	.3
CEAP class				
0	3 (1)	2 (2)	1 (0)	.01
1	0 (0)	0 (0)	0 (0)	.9
2	2 (0)	2 (2)	0 (0)	.01
3	135 (29)	36 (30)	99 (29)	.8
4	256 (55)	65 (53)	191 (56)	.6
5	21 (5)	3 (2)	18 (5)	.2
6	47 (10)	14 (11)	33 (10)	.8

BMI, Body mass index; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *CEAP,* clinical, etiologic, anatomic, pathophysiologic; *MTS,* May-Thurner syndrome; *NIVL,* nonthrombotic iliac vein lesion; *PTS,* post-thrombotic syndrome.
Data presented as number (%), unless noted otherwise.

difference was found in the baseline CIVIQ-20 scores between the two groups (group I: score, 58.1; group II: score, 60; $P = .22$).

Hemodynamic parameters. The FVP was higher in group II (15.6 mm Hg) than in group I (11.8 mm Hg; $P < .0001$). After stenting, the FVP had improved in both groups, with a decrease to 10 mm Hg in group I ($P = .009$) and to 13.6 mm Hg in group II ($P = .0005$). A significant difference remained in the supine FVP after stenting between the two groups (group I, 10 mm Hg; vs group II, 13.6 mm Hg; $P = .0001$).

The baseline supine femoral vein pressure in group I was 5.8 mm Hg vs 8.5 mm Hg in group II ($P = .001$). The calf pump characteristics, including the VFI-90, EF, and RVF, for both groups before and after stenting are listed in Table II.

At baseline, group I had a mean VSDS of 1.5 compared with 0.7 in group II ($P < .0001$). Data were available for 94 limbs in group I and 279 limbs in group II for analysis.

Table II. Calf pump characteristics

Metric	Group I (BMI <30 kg/m^2)		Group II (BMI ≥30 kg/m^2)		*P* value (group I vs II)
	Value	*P* value	Value	*P* value	
VFI-90		.4 (n = 90 limbs)		.4 (n = 247 limbs)	
Before stenting	0.98		1.6		.1
After stenting	0.9		1.4		.4
EF, %		.3 (n = 72 limbs)		.3 (n = 185 limbs)	
Before stenting	45.6		57.4		.0008
After stenting	44.7		57.3		<.0001
RVF, %		0.1 (n = 71 limbs)		.07 (n = 179 limbs)	
Before stenting	40.5		27.5		.0008
After stenting	43		29		<.0001

BMI, Body mass index; *EF,* ejection fraction; *RVF,* residual volume fraction; *VFI-90,* venous filling index.

Table III. Median IVUS luminal areas of common iliac, external iliac, and common femoral veins in groups I and II before and after stenting

Segment	Group I (BMI <30 kg/m^2) Area, mm^2	Group I (BMI <30 kg/m^2) *P* value	Group II (BMI ≥30 kg/m2) Area, mm^2	Group II (BMI ≥30 kg/m2) *P* value	*P* value (group I vs group II)
CIV		<.0001 (n = 98)		<.0001 (n = 270)	
Before stenting	94		122		<.0001
After stenting	201		207		.005
EIV		<.0001 (n = 103)		<.0001 (n = 273)	
Before stenting	98		116		.0004
After stenting	172		177		.3
CFV		<.0001 (n = 101)		<.0001 (n = 265)	
Before stenting	96		115		<.0001
After stenting	161		162		.08

BMI, Body mass index; *CFV,* common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein.

IVUS-determined venous compression. At baseline, the degree of compression was higher in group I than in group II in the common iliac vein (group I, 53%; group II, 39%; $P < .0001$), external iliac vein (group I, 35%; group II, 23%; $P < .0004$), and common femoral vein (group I, 24%; group II, 8%; $P < .0001$) segments. The luminal areas of the common iliac vein, external iliac vein, and common femoral vein in both groups before and after stenting are listed in Table III. The Gaussian distributions for the common and external iliac vein luminal areas for the two groups are shown in the Supplementary Fig (online only).

Clinical outcomes. Improvement occurred in the VCSS, GOS, and VAS for pain score in both groups after stenting (Table IV). The availability of the follow-up data is presented in Tables V and VI. After stenting, the ulcer healing rate was 86% (12 of 14) in group I and 85% (22 of 26) in group II ($P = .9$). No significant difference was found in the ulcer recurrence rates between the two groups (group I, n = 1; group II, n = 2; $P = .9$). Improvement was noted in the CIVIQ-20 scores in both groups after stenting. The group I score changed to 18.8 ($P = .0002$) and the group II score changed to 37.5 ($P < .0001$) without a statistically significant difference between the two groups ($P = .11$).

Stent-related outcomes. Stenting was performed across all three segments, common femoral vein, external iliac vein, and common iliac vein in all limbs in both groups, except for seven limbs in group I and three limbs in group II ($P = .7$), which had no stent placed in the common femoral vein. At 60 months after stenting, primary patency was 70% in group I and 73% in group II ($P = .6$), and the primary assisted patency was 100%

Table IV. Comparison of *VCSS*, *GOS*, and *VAS* for pain score for both groups before and after stenting

Metric	Group I (BMI <30 kg/m^2; n = 122) Median score	Group I (BMI <30 kg/m^2; n = 122) *P* value (before vs after)	Group II (BMI ≥30 kg/m^2; n = 342) Median score	Group II (BMI ≥30 kg/m^2; n = 342) *P* value (before vs after)	*P* value (group I vs II)
VCSS					
Before stenting	5	NA	6	NA	.0008
12 Months after stenting	3	<.0001	4	<.0001	.005
24 Months after stenting	4	<.0001	4	<.0001	.005
GOS					
Before stenting	2	NA	3	NA	<.0001
12 Months after stenting	1	<.0001	1	<.0001	.0004
24 Months after stenting	1	<.0001	1	<.0001	.004
VAS score					
Before stenting	3	NA	5	NA	.4
12 Months after stenting	0	.003	1	<.0001	.4
24 Months after stenting	2	0.07	2	<.0001	.4

BMI, Body mass index; *GOS,* grade of swelling; *NA,* not applicable; *VAS,* visual analog scale; *VCSS,* venous clinical severity score.

Table V. Comparison of limb count available for analysis at each follow-up point between the two groups

Follow-up time, months	Group I (BMI <30 kg/m^2; n = 122)	Group II (BMI ≥30 kg/m^2; n = 342)	*P* value
3	55 (45)	163 (48)	.6
6	57 (47)	154 (45)	.7
12	69 (57)	174 (51)	.3
24	62 (51)	113 (33)	.0005

BMI, Body mass index.
Data presented as number (%).

in both groups ($P = .99$; Fig *A* and *B*). Secondary patency at 18 months (because the standard error was >10% beyond 18 months) was 100% in both groups ($P = .99$; Fig *C*).

Group I required 43 reinterventions and group II required 88 reinterventions, without a statistically significant difference between the groups ($P = .5$). Four limbs in group I and three in group II required more than one reintervention. The median time to reintervention was 11 months for group I and 10 months for group II.

Table VI. Limbs available for analysis at 24 months in each group across demographic, clinical, and hemodynamic parameters

24 Months of follow-up	Group I (BMI <30 kg/m^2; n = 62)	Group II (BMI ≥30 kg/m^2; n = 113)	*P* value
Left laterality, %	60	69	.2
Female sex, %	79	78	.9
Median age, years	59	59	.9
NIVL/MTS, %	16	19	.6
PTS, %	84	81	.6
CEAP class, %			
C0	2	0	.1
C1	0	0	.9
C2	3	0	.06
C3	35	28	.3
C4	47	58	.2
C5	2	7	.2
C6	11	7	.4
Median FVP, mm Hg	5	8	.01
Median SFP, mm Hg	10	15	<.0001
Median VFI-90	1.0	1.5	.1
Median EF, %	46	61	.01
Median RVF, %	41	28	.05

BMI, Body mass index; *CEAP,* clinical, etiologic, anatomic, pathophysiologic; *EF,* ejection fraction; *FVP,* femoral venous pressure (supine); *MTS,* May-Thurner syndrome; *NIVL,* nonthrombotic iliac vein lesion; *PTS,* post-thrombotic syndrome; *RVF,* residual volume fraction; *SFP,* supine foot venous pressure; *VFI-90,* venous filling index.

The reinterventions were for ISR in 12 limbs (10%) in group I and 29 limbs (8%) in group II ($P = .6$). No reinterventions were for SC in group I compared with one (<1%) in group II ($P = .5$). Reintervention was required for ISR plus SC in 11 limbs (9%) in group I and 30 limbs (9%) in group II ($P = .9$). Stent occlusion occurred in three limbs (2%) in group I and four limbs (1%) in group II ($P = .3$).

DISCUSSION

The increasing levels of obesity have resulted in an increased focus on the venous problems associated with the condition. The reported data have suggested that obese individuals will tend to have worse CVI than their nonobese counterparts.[1,2,5] The presence of other comorbidities further impairs vein function. Although exercise represents an avenue for individuals to lose weight, its use becomes difficult for obese patients with CIVO owing to their difficulty in mobilizing secondary to the lower extremity CVI symptoms. Although bariatric surgery represents an option for weight loss for obese individuals, it should not be considered a panacea, given the significant peri- and postoperative issues that can arise. Additionally, such surgery only represents one component of the multifaceted approach required to lose weight in the setting of bariatric surgery. Exercise represents another facet but is difficult for individuals to engage in owing to the lower extremity CVI symptoms.

It has been reported that obesity by itself is a pathologic contributor to iliofemoral venous compression.[5,6] Although conceivable, our study found a lesser degree of compression across all three segments, common femoral, external iliac, and common iliac veins, in the obese cohort compared with the nonobese group. The degree of compression was determined according to the IVUS luminal areas, with abnormal considered those areas less than the normal minimal luminal area for each vein segment. The utility of using the normal minimal luminal criteria instead of assessing stenosis by comparing the stenotic vein segment with the normal vein proximally or distally or the normal opposite side lies in the prevalence of multifocal and long segment lesions and bilateral disease, and the consequent error associated with such measurements. The Gaussian distribution of the common and external iliac vein luminal areas for the two groups is shown in the

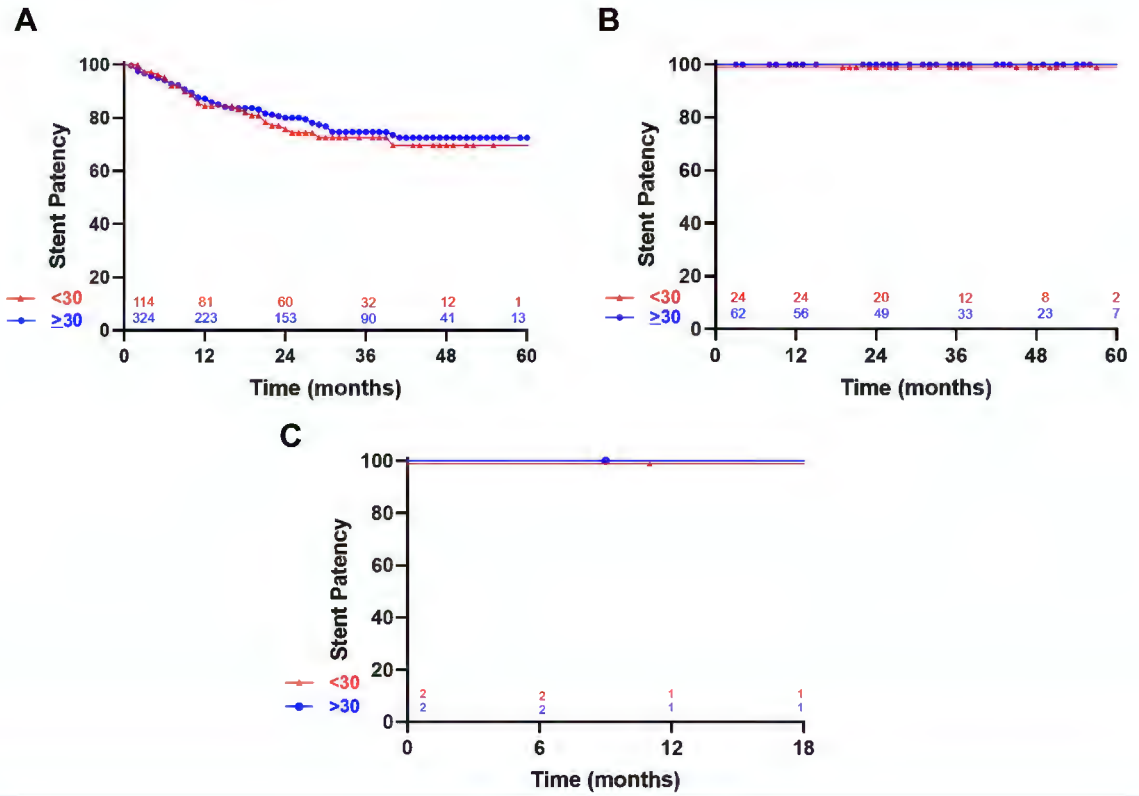

Fig. A, Plot demonstrating primary stent patency (standard error of the mean, <10%). **B,** Plot demonstrating primary assisted stent patency (standard error of the mean, <10%). **C,** Plot demonstrating secondary stent patency (standard error of the mean, <10%).

Supplementary Fig (online only), which depicts the negation of the baseline luminal area difference after stenting. Although obese individuals had a lesser degree of stenosis than their nonobese counterparts, such stenosis still met the criteria for treatment as defined by the normal minimal luminal areas. Additionally, both the supine FVP and the supine femoral venous pressure were significantly more elevated in the obese cohort than in the nonobese cohort, suggesting more severe venous hypertension in the obese group. Thus, although the obese group had a lesser degree of venous stenosis, they appeared to have more severe venous hypertension. The likely reason for this paradox is because the volume pressure relationship in veins is not linear such that a given degree of iliofemoral venous stenosis will result in a set degree of venous hypertension. According to Katz et al,[21] this relationship can be depicted as a sigmoid curve, with significantly greater increases in pressure for smaller increases in venous volume toward the right of the curve. This part of the curve is more easily reached in the presence of iliofemoral obstruction secondary to increased venous volumes in the lower extremities or loss of compliance due to vein wall damage (eg, post-thrombotic syndrome), or both. This highlights the problem with using a fixed degree of stenosis to determine the need for intervention because the degree of stenosis required to generate venous hypertension and consequent manifestation of CVI varies from individual to individual. Patients presenting with QOL-impairing symptoms of CIVO for whom conservative therapy has failed merit IVUS interrogation and correction of stenosis once identified, irrespective of their BMI. The relationship between venous pressure and limb volume is parabolic, with the concavity toward the Y axis such that small changes in venous pressure will result in greater increases in limb volume.[22] This would explain the increased swelling in the obese cohort compared with the nonobese group, given the higher supine FVP and femoral venous pressure in the former group. This increased swelling in the obese group contributed to their higher VCSS, because no significant difference was found in the VAS for pain score between the groups at baseline. Another finding of importance was that the QOL at baseline for the obese patients with CIVO was not different from that of their nonobese counterparts.

Unlike some prior studies, we did not find an increase in the CEAP clinical class with an increasing BMI. Additionally, no significant difference was found in ulcer prevalence between the two groups. Although the nonobese group had a higher VSDS (1.5) than the obese group (0.7), the scores were low for both groups. The lack of

venous reflux as a significant contributor to disease in either group was supported by the low, nonsignificant VFI-90 (obese, 1.6; nonobese, 0.98; $P = .13$).

The results from our study support the findings from van Rij et al,[1] with the obese group having better calf pump function than the nonobese group, as evidenced by the better calf pump EF and RVF. This finding likely resulted from the more well-developed calf musculature in the obese group owing to the additional weight load bearing. This difference remained after stenting, without a significant improvement in the EF and RVF from baseline in either group.

Outcomes after stenting. After stenting, a statistically significant improvement in the VCSS was seen in both groups at 12 and 24 months. Although a difference remained between the groups at these points, the difference was small. This finding also applied to the GOS. Regarding the VAS for pain score, we found no significant differences between the groups at baseline or after stenting. Edema appeared to be a more defining feature in the obese cohort than was pain. No significant differences were found in the rates of ulcer healing or recurrence between the two groups. Although obese individuals had a higher VCSS and GOS than the nonobese group, after stenting, these differences were mitigated, supporting the role of correction of iliofemoral venous stenosis in obese individuals with QOL-impairing symptoms. QOL, as reflected by CIVIQ-20 scores, also improved in both groups after stenting. Similar to baseline, no significant differences were found in the CIVIQ-20 scores between the two groups after stenting, suggesting that correction of stenosis improves QOL, irrespective of the BMI. Stent patency was also not affected by the BMI, as evidenced by the excellent primary, primary assisted, and secondary patency rates in both groups. The reintervention rates and pathology requiring reintervention were also not different between the two groups.

Obese patients presenting with QOL-impairing symptoms of CIVO for whom conservative therapy has failed merit IVUS interrogation and correction of their obstruction once the stenosis has been confirmed. Good clinical and stent-related outcomes with improvement in QOL can be expected after stenting. This improvement in QOL could lead to increased functionality and enhanced exercise tolerance by the mitigation of exercise-limiting CVI symptoms, potentially leading to weight loss. Further study is, however, required to quantify these benefits.

Study limitations. The retrospective nature of the present study represented a shortcoming. Additionally, although sample size was increased for the obese cohort, both groups were matched for age, gender, and pathology (PTS/nonthrombotic iliac vein lesion). We also had a loss of patients to follow-up after stenting, although this was only significant between the two groups at the 24-month follow-up point. These deficiencies would be difficult to counter and likely have a bearing on the results of our study.

CONCLUSIONS

Obese patients with CIVO-impairing QOL had a lesser degree of iliofemoral venous stenosis, more severe venous hypertension, more limb edema, and better calf pump function than their nonobese counterparts. After stenting, we found no differences in the clinical, stent patency, or QOL-related outcomes. IVUS interrogation and possible stenting should be offered to obese individuals presenting with QOL-impairing CIVO symptoms for whom conservative therapy has failed, given the potential for improvement of exercise tolerance and consequent weight loss and enhancement of QOL.

AUTHOR CONTRIBUTIONS

Conception and design: AJ
Analysis and interpretation: AJ, TP, SR
Data collection: AJ, TP
Writing the article: AJ, TP
Critical revision of the article: AJ, SR
Final approval of the article: AJ, TP, SR
Statistical analysis: TP
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Overall responsibility: AJ

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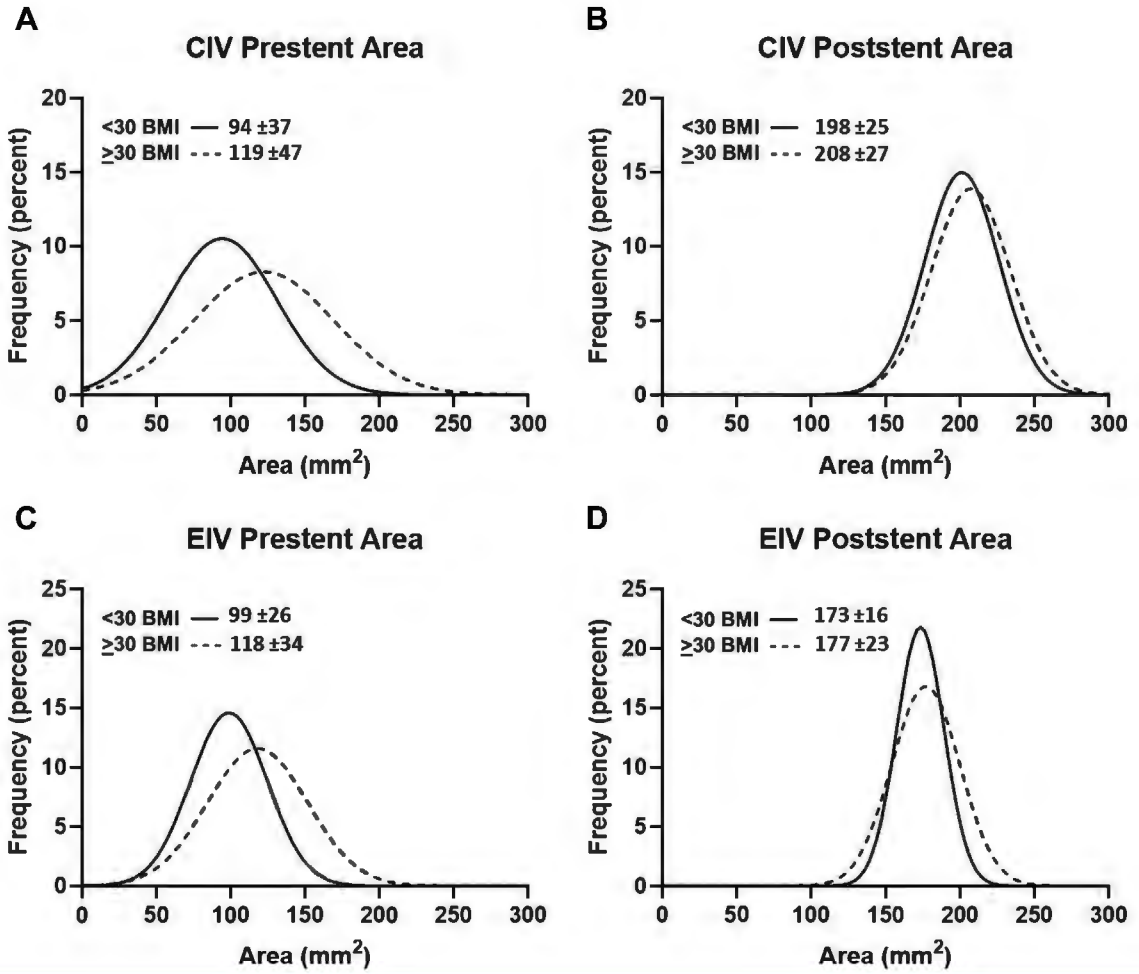

Supplementary Fig (online only). Gaussian distribution of common iliac vein (*CIV*) and external iliac vein (*EIV*) intravascular ultrasound (IVUS) luminal areas for group I (nonobese patients, body mass index [*BMI*] <30 kg/m^2) and group II (obese patients, BMI ≥30 kg/m^2) before and after stenting. Data presented as mean ± standard deviation.