



Effectiveness of iliac vein stenting combined with endovenous laser treatment of recurrent varicose veins associated with iliac vein compression

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Background: Iliac vein compression syndrome (IVCS) is an underlying cause of varicose vein (VV) recurrence after venous surgery. However, the management of recurrent varicose veins (RVVs) combined with IVCS has rarely been reported. This study aimed to investigate the outcomes of a one-stop procedure to correct outflow obstruction and superficial reflux for patients with RVVs and IVCS.

Methods: A retrospective analysis was conducted of 102 consecutive patients diagnosed with RVVs. Computed tomography venography (CTV) was performed to confirm IVCS. The cases were divided into 2 groups: the IRVVs group, including patients with RVVs and IVCS (n=48), and the RVVs group, including patients with RVVs only (n=54). The characteristics, vein reflux, and clinical, etiological, anatomical, and pathophysiological (CEAP) distribution were investigated. Then, the IRVVs group patients who underwent endovenous laser ablation (EVLA) (n=39) were divided into a further 2 groups: the EVLA + S group (n=19), who received EVLA and stenting of iliac vein, and the EVLA group (n=20), who received EVLA treatment alone. The great/small saphenous vein (GSV/SSV) trunk occlusion, VV recurrence, visual analogue scale (VAS), and venous clinical severity score (VCSS) were investigated.

Results: The prevalence rate of femoral vein reflux was 81.2% in IRVVs group and 50% in RVVs group (P<0.05). In the IRVVs group, 72.9% of patients manifested as CEAP clinical class >3, which was higher than that in RVVs group (48.1%) (P<0.05). The 12-month GSV/SSV occlusion rate in the EVLA + S and EVLA groups were 94.7% and 90.0%, respectively. Totals of 9 patients in EVLA + S group and 6 patients in EVLA group had active venous ulcers, and the ulcer healing time in EVLA + S group was significantly shorter (27.22±7.12 vs. 46.67±9.83 days, P<0.05). The reductions in the VAS and VCSS values between baseline, 1 month, and 12 months in the EVLA + S group were more obvious than those in EVLA group (P<0.05).

Conclusions: The one-stop combination treatment of iliac venous stenting and EVLA in patients with RVVs and IVCS is safe and effective and provides prominent symptom relief, improved quality of life, and a more satisfactory ulcer healing than EVLA alone.

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Keywords: Recurrent varicose veins (RVVs); iliac vein compression syndrome; May-Thurner syndrome; endovenous laser ablation; iliac venous stenting; one-stop combination treatment

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Introduction

Recurrent varicose veins (RVVs) of the lower extremities are a complex problem following varicose vein (VV) surgery, including high ligation (HL) and stripping, and endovenous interventions (1). RVVs have been reported to occur in 7–62% of cases (2–6). Many studies have been published on the classification and patterns of recurrence (7,8). However, RVVs remain a surgical challenge, partially due to a lack of understanding of the causative factors. Chronic venous hypertension is considered an important contributing factor to RVVs, which can result from reflux, obstruction, or both (9). Therefore, ablation alone of RVV-associated reflux veins without evaluation and treatment of the obstructive component may result in repeat recurrence (10).

Iliac vein compression syndrome (IVCS), also referred to as May-Thurner syndrome, is a clinical syndrome of unilateral lower extremity swelling and pain due to venous hypertension caused by an iliac artery compressing an overlying iliac vein (11,12). The venous hypertension caused by IVCS may be involved in the recurrence of VVs. It has been reported that IVCS is an independent etiologic factor for RVVs (13,14). Therefore, it is particularly important to evaluate and treat IVCS in patients with RVVs. In recent years, iliac vein stent placement has been considered an effective technique in IVCS treatment, with a good patency rate (15,16). Nevertheless, very few studies have reported on the incidence rate of IVCS in the RVVs population and one-stop treatment procedures to correct outflow obstruction and superficial reflux for patients with RVVs and IVCS.

In this study, we summarized the venous disease characteristics of unilateral RVVs with and without IVCS. We also compared the outcomes of patients with RVVs and IVCS who underwent endovenous laser ablation (EVLA) alone and combination treatment (stenting and EVLA).

Methods

Patient selection

From May 2014 to May 2019, consecutive patients diagnosed with unilateral great saphenous vein (GSV)- or unilateral small saphenous vein (SSV)-derived RVVs were analyzed retrospectively. RVVs was defined as the presence of varices after interventional treatment (PREVAIT), irrespective of the cause and the previous intervention modality (1). The previous intervention modalities of the patients in the present study included HL and stripping, EVLA, and ultrasound-guided foam sclerotherapy (UGFS). All cases had undergone duplex ultrasound (DUS) to evaluate the truncal reflux in the GSV or SSV (17,18), and computed tomography venography (CTV) to estimate iliac vein compression including the left- or right-side. The patient selection process is shown in *Figure 1*. Physical examination was performed to classify the stage of chronic venous disease (CVD) according to the clinical, etiological, anatomical, and pathophysiological (CEAP) classification system (19). DUS was conducted in the upright position to map incompetent sources of venous reflux, including reflux of superficial and deep veins, which was defined as reverse flow with a duration of >0.5 seconds. Additional venography was recommended if IVCS was suspected using CTV. The patients were diagnosed with IVCS if their CTV results showed iliac vein filling defect or separation, stenosis >50% or occlusion, with visualization of collateral circulation (13). The degree of stenosis was calculated according to the previous study (stenosis = $100 - [100 \times D1/D2]$) (20), wherein D1 is the minimum diameter at the point of maximum compression and D2 is the minimum diameter at the common iliac vein caudal to the obstruction (*Figure 2*).

The exclusion criteria were as follows: RVVs not ipsilateral to the IVCS, inferior vena cava obstructive

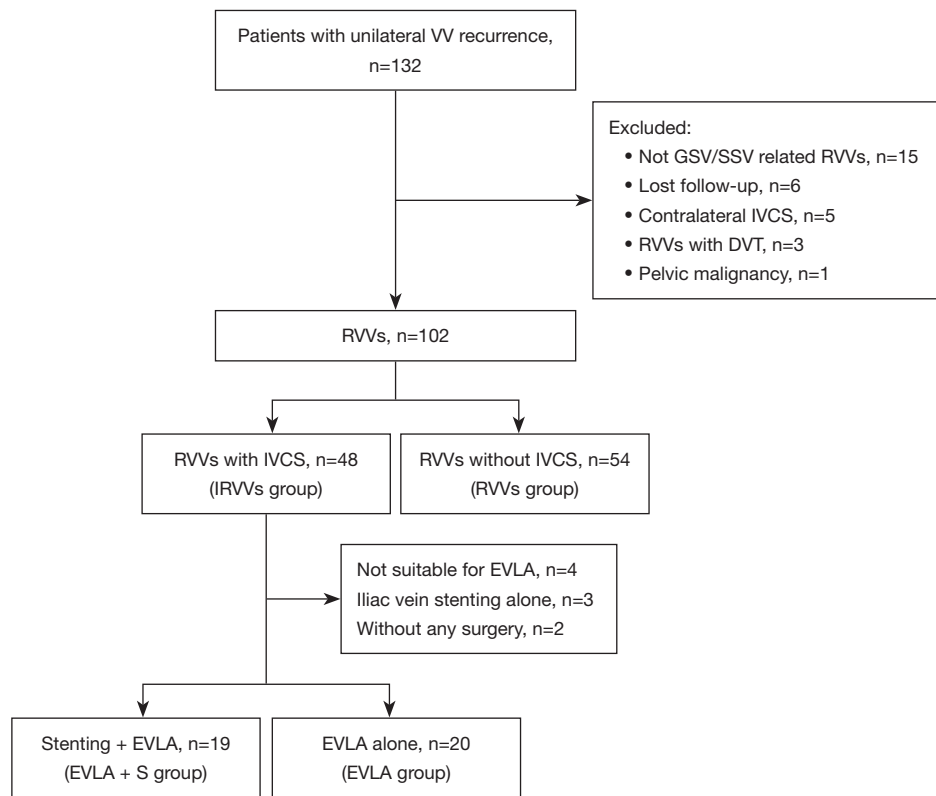


Figure 1 Flowchart of the study design. VV, varicose vein; GSV/SSV, great/small saphenous vein; IVCS, iliac vein compression syndrome; RVVs, recurrent varicose veins; DVT, deep vein thrombosis; EVLA, endovenous laser ablation.

disease, deep venous thrombosis, vascular malformation, superficial thrombophlebitis, pelvic malignancy, retroperitoneal fibrosis, poor general health condition, and anticoagulant or antiplatelet drug contraindication.

The choice of either EVLA treatment alone or the combination treatment of stenting and EVLA in the redo operation was determined by physician expertise and the possible benefits, risks, and costs of the treatment. All clinical data were collected and analyzed from the observational study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University, and informed consent was provided by all the patients.

Technique

Endovenous stenting procedures

The technical details of the balloon angioplasty and stent placement procedure have been described elsewhere (21-23). In brief, access to the common femoral veins was established

under local anesthesia, intraoperative 3-dimensional (3D) imaging was reconstructed depending on the venography (Philip Interventional Workspot; Philips, Amsterdam, The Netherlands), and then the stenosis of the iliac vein (>50%) and visualization of collateral circulation were used to determine stent placement. Before stenting, the balloon catheters (Boston Scientific, Marlborough, MA, USA) were used for dilation, and stenosis with a “waist” at the site of the lesions and other venographic findings (e.g., bull’s-eye sign) offered visual confirmation of the stenosis. After correction of iliac vein stenosis, the nitinol stent (SMART Control; Cordis, Miami, FL, USA) or Wallstent (Boston Scientific, Natick, MA, USA) with appropriate length and diameter was implanted across the lesion segment. Postoperative venography was performed to confirm the restoration of antegrade flow without refilling of the collateral veins.

Endovenous laser ablation procedures

After the endovenous stenting procedures, all patients underwent EVLA for GSV/SSV within 24 hours. The

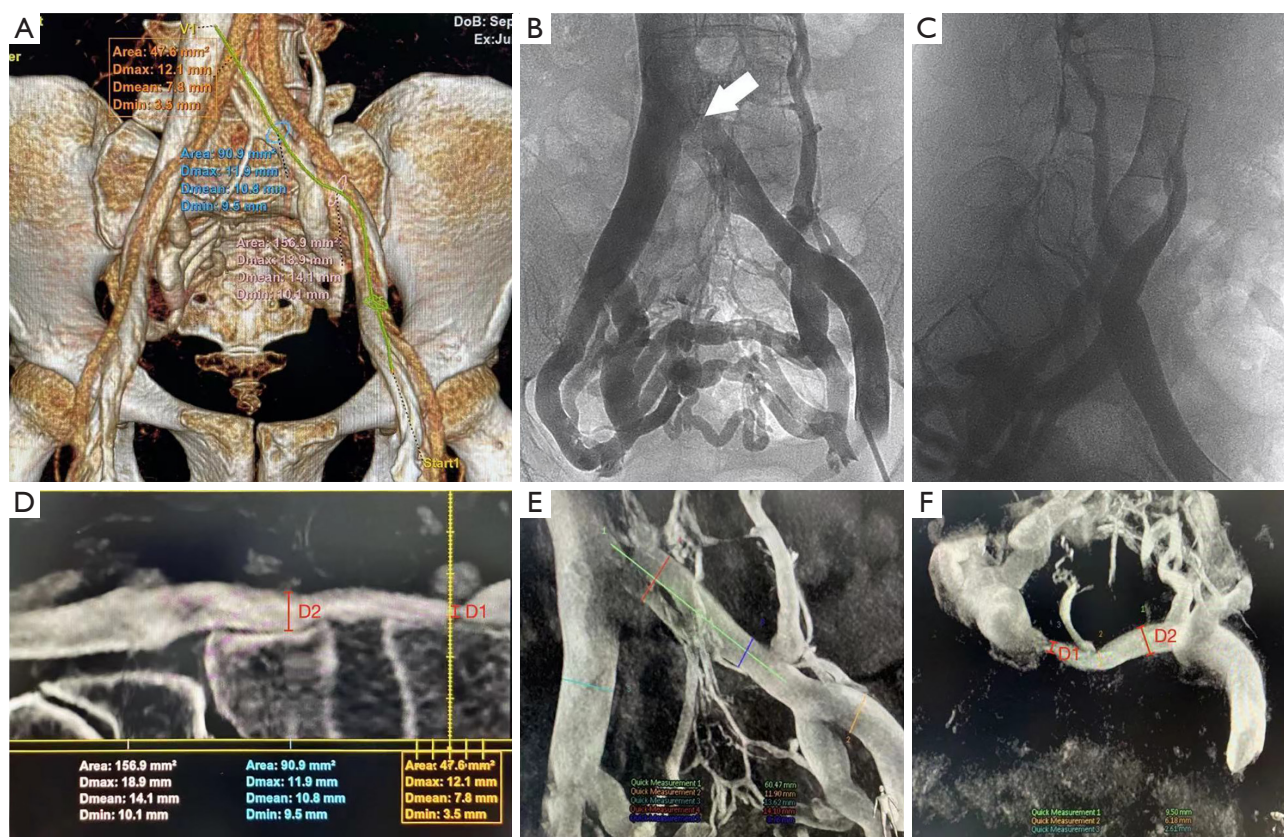


Figure 2 CTV and venographic images of a 53-year-old woman with IVCS. VR and centerline image reconstruction of iliac vein were performed (A,B). With the centerline image, the point of maximum iliac vein can be identified accurately. The degree of stenosis is determined by the following formula: $\text{Stenosis} = 100 - (100 \times D1/D2)$, where D1 is the minimum diameter at the point of maximum compression and D2 is the minimum diameter at the common iliac vein. Therefore, the degree of stenosis in this patient was calculated to be 63.2%. Intraoperative 3D venography was performed (C,E), the site of the maximum iliac vein compression by the iliac artery (white arrow) and plenty of pelvic collateral vessels were found. The iliac vein was reconstructed, and stenosis rate was calculated to be 72.5% (D,F). CTV, computed tomography venography; IVCS, iliac vein compression syndrome; VR, volume rendering.

procedures of GSV HL and EVLA were performed under laryngeal mask anesthesia and followed the standard treatment regimen described in the previous publications (24,25). A 2 cm incision in the groin was made to ligate the GSV trunk. The side branches were not ligated because the preoperative DUS evaluation showed that the reflux in the GSV trunk and VVs recurrence were not associated with the side branches. Next, access near the ankle was established using the Seldinger technique, and a laser fiber was inserted into the proximal GSV through the access. The GSV was then ablated using pulse mode at 12 W with an 810 nm diode laser (Lingyun, Hubei, China). The laser fiber was withdrawn at 1–3 mm/s, with an ablation time lasting 1–2 seconds. After completing the ablation in GSV, phlebectomy and sclerotherapy were used to treat the

branches of residual VVs.

The procedure of SSV ligation and EVLA followed the treatment regimen described in the previous publication (26). In brief, the location of the saphenopopliteal junction (SPJ) and the course of the SSV were marked on the skin with DUS. Then, in the prone position, a transverse incision was made in the popliteal fossa and the SSV was ligated and excised over a length of 2 cm. After the ligation, an SSV access was established at the mid-calf, and the remaining steps were same as for GSV EVLA.

Postoperative care

Patients were discharged on the first or second day after the procedure. Ambulatory activities were encouraged after treatment. Compression bandages were worn for at least 3

Table 1 Demographic characteristics, reflux distribution, and CEAP classification in RVVs

Variable	RVVs with IVCS (IRVVs, n=48)	RVVs without IVCS (RVVs, n=54)	P value
Left vs. right, RVVs limbs	32:16	32:22	0.44
Mean age (years)	59.04±8.40	59.25±8.13	0.90
Women vs. men	28:20	24:30	0.17
Hypertension	7 (14.6)	6 (11.1)	0.60
Heart disease	3 (6.3)	5 (9.3)	0.58
Diabetes	3 (6.3)	4 (7.7)	0.82
Smoking	9 (18.8)	12 (22.2)	0.67
Superficial reflux	48 (100.0)	54 (100.0)	1.0
Deep reflux	39 (81.2)	27 (50.0)	0.0013
Perforating reflux	12 (25.0)	14 (25.9)	0.92
CEAP C1-C3	13 (27.1)	28 (51.9)	
CEAP C4-C6	35 (72.9)	26 (48.1)	0.011

Data are presented as number (%) or mean ± standard deviation. RVVs, recurrent varicose veins; IVCS, Iliac vein compression syndrome; CEAP, clinical, etiological, anatomical, pathophysiological.

days, and a graduated compression stocking (23–32 mmHg) was worn at all times except when sleeping or showering for at least 3 months (27). The patients with iliac vein stent placement received oral anticoagulation therapy with rivaroxaban (Bayer AG, Leverkusen, Germany) or warfarin (Qilu Pharmaceutical, Shandong, China) for at least 6 months.

Clinical assessment and follow-up

Patients returned to the hospital for clinical assessment and physical examinations at 1 and 12 months after the procedure. DUS was used to evaluate vein reflux, GSV/SSV trunk occlusion, and residual veins, and CTV was performed to evaluate stent patency and restenosis during follow-up. Stent implantation success was defined as recanalization with antegrade flow and <30% residual stenosis after stent placement (18).

The pre- and post-procedural visual analogue scale (VAS) and venous clinical severity score (VCSS) were used to assess the clinical symptom improvements. Complications of iliac vein rupture, femoral vein injury, bleeding,

hematoma, wound infection, pulmonary thromboembolism (PE), deep vein thrombosis (DVT), paresthesia, superficial vein thrombosis, stent fracture, stent migration, and chronic pelvic pain were assessed and recorded by physicians. Effectiveness was evaluated by assessing ulceration healing and symptom reduction. Ulcer healing was defined as complete epithelialization (28). Successful ablation was defined as the absence of blood flow within the veins of ablation (29).

Statistical analysis

Individual data were displayed as the mean with range or as a percentage. Continuous data were compared using the Student's *t*-test and categorical data were compared using the χ^2 test. For all the data, $P < 0.05$ was considered significant. The software SPSS 25.0 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses.

Results

From May 2014 to May 2019, a total of 102 patients with RVVs were included in the present analysis. Of the 102 patients, 48 were diagnosed with IVCS by CTV, and 54 were not. All 102 RVVs were divided into 2 groups: the RVVs with IVCS group (IRVVs group) and the RVVs without IVCS group (RVVs group). The baseline data, including the demographics, CEAP classification, and incidence of deep vein reflux and perforating vein reflux, for the 2 groups, are listed in *Table 1*. No significant differences were present between the 2 groups in terms of demographics. However, of the patients in the IRVVs group, 81.2% ($n=39$) had femoral vein reflux, which was significantly higher than in RVVs group (50.0%, $n=27$, $P < 0.05$). In the IRVVs group, 72.9% ($n=35$) of patients manifested as CEAP clinical class >3, which was higher than that in the RVVs group (48.1%, $n=26$, $P < 0.05$). This result suggested that femoral vein reflux was more common in RVV patients when combined IVCS, and that the more severe the clinical symptoms of RVVs, the more likely they were to accompany IVCS.

In the IRVVs group, 39 patients underwent EVLA (EVLA alone or combination treatment with EVLA and stenting). The other 9 patients included 4 patients who were not suitable for EVLA for anatomical factors, 3 patients who underwent stent placement alone, and 2 patients who refused to receive any surgical treatment. All the 39 patients were divided into 2 groups: the stenting

Table 2 Operation details and outcomes in patients with RVVs and IVCS

Variable	Stenting + EVLA (EVLA + S, n=19)	EVLA (EVLA, n=20)	P value
Technical success	19 (100.0)	20 (100.0)	1.0
Treatment of trunk			
GSV HL + EVLA	16 (84.2)	15 (75.0)	
SSV HL + EVLA	3 (15.8)	5 (25.0)	0.48
Treatment of branch veins			
Phlebectomy	1 (5.3)	3(15.0)	0.33
Sclerotherapy	14 (73.7)	13(65.0)	0.57
Phlebectomy + sclerotherapy	4 (21.1)	4(20.0)	0.94
Number of VLU	9 (47.7)	6 (30.0)	0.28
VLU, days	27.22±7.12	46.67±9.83	0.0012
12 months	0 (0)	1 (5.0)	0.34
VV recurrence			
12 months	18 (94.7)	18 (90.0)	0.59
GSV/SSV occlusion			
12 months iliac stent patency	19 (100.0)	NA	NA
12 months iliac stent restenosis	1 (5.3)	NA	NA

Data are presented as number (%) or mean ± standard deviation. EVLA, endovenous laser ablation; HL, high ligation; GSV, great saphenous vein; SSV, small saphenous vein; VLU, venous leg ulcer; NA, not applicable.

and EVLA group (EVLA + S group, n=19) and the EVLA group (n=20), and the baseline data comparisons are shown in [Table S1](#). The success rate in both groups was 100%, and the operation details are listed in [Table 2](#). The 12-month GSV/SSV occlusion rate and the iliac stent patency rate in EVLA + S group were 94.7% and 100%, respectively. A single asymptomatic GSV trunk occlusion failure, and 1 asymptomatic iliac stent restenosis were found, and no VV recurrence was found in this study. In the EVLA group, the 12-month GSV/SSV occlusion rate was 90%, and 1 case free from GSV occlusion showed VV recurrence. Meanwhile, 15 patients manifested as active venous leg ulcers (VLUs), and the VLUs healing time in EVLA + S group was significantly shorter than that in EVLA group (27.22±7.12 vs. 46.67±9.83 days, $P<0.05$).

The only reported acute adverse event was bleeding

Table 3 VAS and VCSS scores at baseline and follow-up

Variable	Stenting + EVLA (EVLA + S, n=19)	EVLA (EVLA, n=20)	P value
VAS			
Preoperative values	3.89±1.15	3.95±1.28	0.089
1 month	0.84±0.60	1.80±1.01	0.0035 ^a
12 months	0.26±0.45	1.15±1.35	0.027 ^a
VCSS			
Preoperative values	13.68±5.72	12.75±4.33	0.057
1 month	7.21±3.26	8.15±2.48	0.033 ^b
12 months	3.15±2.09	5.25±3.13	0.020 ^b

Data are presented as mean ± standard deviation. ^a, comparisons of VAS value reductions between EVLA + S group and EVLA group (reductions represent 1-month postoperative values subtract preoperative values, and 12-month postoperative values subtract preoperative values, respectively). ^b, comparisons of VCSS value reductions between EVLA + S group and EVLA group. EVLA, endovenous laser ablation; VCSS, venous clinical severity score; VAS, visual analogue scale.

[n=1 (5.3%)] in the EVLA + S group; this was not reported in the EVLA only group ($P=0.31$). There were no acute complications of iliac vein rupture, femoral vein injury, hematoma, wound infection, or DVT/PE in either group. Delayed complications, including superficial vein thrombosis [EVLA + S vs. EVLA only: 3 (15.8%) vs. 3 (15.0%), $P=0.95$], was not significantly different across the patient groups. There was also no reporting of paresthesia in either patient group. Pertaining to the EVLA + S patients, there was one incidence of chronic pelvic pain [n=1 (5.3%)], but no incidence of strength fracture or stent migration during the follow-up ([Table S2](#)).

The preoperative VAS and VCSS scores in the EVLA + S and EVLA groups showed no significant difference ($P>0.05$). The VAS and VCSS scores reductions in the EVLA + S group were more obvious than those in the EVLA group at the 1- and 12-month follow-ups ($P<0.05$) ([Table 3](#)).

Discussion

RVVs are a complicated disease caused by several etiological factors, and the recurrence rate is expected to increase with a longer duration of follow-up (4). Due to the lack of prospective studies, the weight of each factor has not yet been demonstrated. Recently, IVCS was reported as

an independent risk factor for RVVs, and as many as 55% (41/74) of patients with IVCS were found among RVV patients (13). The underlying reason may be that IVCS leads to chronic venous hypertension, which in turn leads to recanalization, vascularization, and disease progression. In this study, the incidence of ipsilateral IVCS in RVVs was 47% (31% in left side and 16% in right side), which is consistent with the aforementioned report. Thus, IVCS should not be overlooked in RVV patients regardless of the previous intervention modality and pathophysiology of VV recurrence. In addition, it was shown that significantly more IVCS was found in C4 to C6 RVV patients than in C1 to C3 patients, which suggested that RVVs with severe clinical symptoms were more likely to be relevant to IVCS. Although we could not conclude whether there is a causal relationship between IVCS and RVVs, we propose that patients with VV recurrence after different kinds of surgery for superficial reflux should undergo venous CT angiography or CTV to exclude IVCS, especially in the C4 to C6 populations.

DUS is the most commonly used diagnostic method for RVVs, but its diagnostic value in IVCS is limited by body habitus, bowel gas, and technical expertise. The visualization of the common iliac vein by DUS has been estimated to be only 47% (30). In contrast, CTV provides a more comprehensive diagnosis of IVCS, which can help determine the optimal treatment approach. Despite being an invasive procedure, CTV was performed on all RVVs cases in our center to achieve a more accurate diagnosis of IVCS. Nevertheless, DUS is the best noninvasive tool to accurately detect vein reflux, and a common femoral vein reflux duration of >2.5 seconds is the optimal cutoff point for predicting >50% iliac vein stenosis (31). In this study, femoral vein reflux was found in as many as 64.7% (66/102) of patients, which is more frequent in RVVs and IVCS patients. This suggests that femoral vein reflux may manifest subsequent to IVCS. Unfortunately, we did not perform further correlation analysis between reflux time and IVCS due to the small sample size. Axial femoral vein reflux may be an important cause of treatment failure in VVs, as its nontreatment usually leads to sustained global reflux of the hindlimb (9,32,33). However, deep vein valvular surgery is not widely applied due to uncertain outcomes. The latest study from Raju *et al.* found that the prevalence and severity of ipsilateral vein reflux will improve in most limbs after iliac vein stenting during long-term follow-up (34). The underlying cause may be that the post-stent remittance in the venous pressure reduces the blood flow

load on the valve. Although the hemodynamic differences between IVCS and femoral vein reflux remain unclear, it can be concluded that the occurrence of femoral vein reflux in some RVV patients might be potentially related to IVCS and that the relief of iliac vein obstruction could benefit RVV patients.

It is widely believed that percutaneous iliac vein stenting as an effective treatment option for IVCS has satisfactory long-term patency and clinical outcomes (35). Nevertheless, the treatment sequence of iliac vein stenting and VV surgery remains controversial. One-stop treatment with a combination of iliac vein stenting and EVLA for IVCS and VV patients was reported successively, and the 1-year outcomes were satisfactory (22,23). Recently, Han *et al.* (36) reported that reflux times and ulcer healing times were lower in the EVLA combined with stenting angioplasty procedure than in the EVLA procedure or EVLA combined with balloon angioplasty procedure at 12 months. The symptom recurrence in EVLA combined with stenting angioplasty procedure was significantly higher than in the other 2 procedures. However, some other studies have indicated that ablation of superficial venous reflux is safe for VV patients with concurrent iliac venous obstruction (37,38). Some other studies have reported that iliac vein stenting alone was sufficient to relieve symptoms in most patients with outflow obstruction and lower extremity CVD (24,39). In our center, one-stop treatment is the preferred procedure, as multiple interventions may have a greater chance of achieving better and sustained symptom relief. In addition, the advantages of one-stop treatment may be more obvious when RVV patients are combined with IVCS.

To date, only very few studies have reported simultaneous surgical treatment for patients with RVVs and IVCS. Kong *et al.* reported a small sample size with 6 case studies and showed the safety and efficacy of simultaneous surgical therapy (10). In the current study, the one-stop combination treatment with iliac venous stenting and EVLA was first compared with EVLA treatment alone in RVVs and IVCS patients. Our results showed that the 12-month stent patency was 100% with a stent restenosis rate of 5.26% in the EVLA + S group, similar to the results in previous studies (23,40). The 12-month GSV/SSV occlusion rates were 94.7% and 90.0% in the EVLA + S and EVLA groups, respectively ($P>0.05$). Thereinto, 1 case in group EVLA manifested as clinical VV recurrence. As we know, VLUs are caused by a complicated cascade of events, triggered by venous hypertension resulting from venous reflux, venous obstruction, or both (41). In this study, 9 patients in the

EVLA + S group and 6 patients in the EVLA group had active VLU (CEAP C6), and the ulcer healing time in the EVLA + S group (27.22 ± 7.12 days) was significantly shorter than that in the EVLA (46.67 ± 9.83 days), which is similar to the report of Yang *et al.* (42). This suggests that both venous reflux and obstruction should be treated to treat RVV-related VLUs, as the recommendation of current guidelines for VLUs (43). Moreover, 3 patients experienced superficial vein thrombosis due to sclerotherapy, and only 1 case of puncture site bleeding and 1 case of nonsustainable pelvic pain were found during hospitalization and early follow-up, respectively. The VAS and VCSS values were used to evaluate the outcome postoperatively, which were found to be significantly more reduced in the 1-stage procedure than in the EVLA or stenting procedure at 1 month and 12 months post-surgery. These findings are close to those of previous reports about VVs and IVCS (32). Overall, these results suggest the effectiveness and safety of a one-stop combination treatment for patients with RVVs and IVCS.

The shortcomings of this study included the following: the relatively small size, short-term follow-up, and nonrandomized design could not provide a higher level of evidence. The retrospective design of the study also precludes establishing causality between IVCS and RVV. Due to the lack of some information about the initial surgery, we could not provide baseline comparisons of the other risk factors associated with recurrence, which may lead to bias in the results. Due to the high cost, we did not routinely use intravascular ultrasound examinations to assess iliac venous lesion. Combined use of HL during EVLA in RVVs is controversial and lack of evidence-based guidelines.

Conclusions

RVVs may be associated with IVCS, particularly in CEAP C4 to C6 patients. Femoral vein reflux is more likely to occur in RVVs accompanied by IVCS. The combination treatment of iliac vein stenting and RVV ablation is safe and effective for patients with unilateral RVVs and IVCS.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://qims.amegroups.com/article/view/10.21037/qims-22-1280/coif>).

The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University, and informed consent was provided by all the patients.

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