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Iliac venous stenting for outflow obstruction does not significantly change the quality of life of patients with severe chronic venous insufficiency

Alexander Shiferson, Edouard Aboian, Michael Shih, Qinghua Pu, Theresa Jacob and Robert Y Rhee

Abstract

Purpose: Percutaneous endovenous iliac stenting has emerged as a new modality in the treatment of advanced chronic venous insufficiency with outflow obstruction. However, the effect of this intervention on the quality of life remains unclear. We examined the impact of iliac venous stenting for outflow obstruction as compared to conservative medical management on the quality of life in severe chronic venous insufficiency patients.

Methods: Medical records of all patients with CEAP class 5 and 6 disease (N = 172) who underwent ilio-caval venography with intravascular ultrasonography (IVUS) at a single institution over a seven-year period, were reviewed for this case–control study. Quality of life evaluation was performed utilizing the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ-20) one year after the index procedure.

Results: Of the 172 severe chronic venous insufficiency patients, 109 were stented and 63 patients were treated medically based on their venography and IVUS results. The indication for stenting was confirmation of IVUS determined surface area or diameter outflow stenosis of greater than 50% within the common or external iliac venous systems. Eighty patients (47%) responded with completed CIVIQ-20 questionnaires for analysis. Of these, 47 were from the stented group and 33 from the non-stented group. At least moderate persistent pain or discomfort post-procedure was reported by 20 (43%) stented group patients and 19 (58%) non-stented group patients. Scores for all the other criteria in the CIVIQ-20 were similar between the groups. The mean total CIVIQ-20 score was 45.23 and 47.13, respectively, in stented group and non-stented group patients. ($p = 0.678$).

Conclusion: There was no significant difference in the quality of life reported by CEAP 5 and 6 patients who underwent iliac venous stenting versus those who were treated medically for presumed iliac outflow obstruction. Prospective studies are needed to determine the true value of iliac venous stenting based on IVUS criteria in the management advanced chronic venous insufficiency.

Keywords

Iliac venous stenting, chronic venous insufficiency, outflow obstruction, quality of life, CEAP 5 and 6

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Introduction

Chronic venous disease (CVD) is a relatively prevalent condition that can result in debilitating symptoms. Complications from CVD range from protuberant varicosities to more advanced presentations including dermal sclerosis, ambulatory venous hypertension, and recurrent ulcerations. Venous ulcers are seen in 1% of the adult population in the United States.[1] Advanced venous disease has a significant negative impact on quality of life (QOL) and the ability to engage in social and occupational activities. The disability resulting from venous ulcers leads to loss of productive work hours and may influence early retirement in up to 12.5% of workers.[2]

Department of Surgery, Division of Vascular Surgery, Maimonides Medical Center, Brooklyn, NY, USA

Corresponding author:
Robert Y Rhee, 4802 Tenth Ave, Brooklyn, NY 11219, USA.
Email: rrhee@maimonidesmed.org

The management of venous ulcers represents a formidable challenge to healthcare providers. It requires tireless commitment on the part of the physicians and healthcare staff and stringent patient compliance. The majority of venous ulcers will require prolonged therapy often lasting for more than a year.[3] Success in the treatment of chronic venous ulcers have been relatively poor, with delayed healing and ulcer recurrence hampering therapeutic efficacy. Current treatment modalities range from external compression therapy to endovenous or operative interventions.

Ilio-caval venous outflow obstruction may be associated with chronic venous disease.[4] Percutaneous endovenous stenting has emerged as a method of therapy for ilio-caval venous outflow obstruction within the last decade. Major improvements have been noted in pain and swelling of the extremity with and without ulcers.[5] However, the impact on QOL has not been well defined in the literature, especially in patients with advanced venous disease, namely those with Clinical-Etiology-Anatomy-Pathophysiology (CEAP) class 5 and 6 disease. Hence, we sought to evaluate the impact of venous outflow stenting on the QOL in patients with advanced venous disease. The study was aimed to assess QOL after iliac venous stenting for occlusive disease from the patient's perspective. It was not designed to evaluate the clinical effectiveness of the procedure.

The purpose of this study was to elucidate the quality of life in CEAP 5 and 6 patients who underwent iliac venous stenting versus those who were treated medically for presumed iliac outflow obstruction.

Methods

A retrospective review was performed of a prospectively maintained database of all endovenous procedures done at a single institution, a large community-based, independent academic medical center in the US, over a seven-year period (2006–2012). Outpatient information was included whenever possible. The study was approved by the Institutional Review Board. Patient consent was obtained for all patients who completed a Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ-20).

The CEAP classification, previously published as the reporting standard of International Society of Cardiovascular Surgeons (ISCVS)/Society of Vascular Surgeons (SVS), was used to assess the severity of venous disease at the time of presentation.[6] This study utilized the CEAP classification because of its reproducibility and acceptability in the vascular literature. It is not possible to obtain Villalta score or the Venous Clinical Severity Score (VCSS) from retrospective data. The study was conducted based on chart review of patients with a thorough clinical history, physical exam, and diagnostic venous ultrasound. The etiology of the symptoms was venous in origin in all patients and CEAP classified accordingly. All CVI patients of CEAP clinical class 5 and 6, who underwent ascending ilio-caval venography and intravascular ultrasound (IVUS) were identified for analysis. Data collected included patient demographic information as well as operative details.

Ultrasound-guided access was used to gain entry into the distal common femoral vein ipsilateral to the side of the ulcer. A hydrophilic wire was passed and positioned in the inferior vena cava. Ascending venograms in the anterio-posterior and lateral projections were performed. IVUS of the outflow tract was performed on each patient. Cross-sectional diameter measurements of the stenosis were obtained by IVUS and compared to the measurements of the normal vein adjacent to the stenosis. The indication for stent placement was a diameter or surface area reduction of at least 50% as measured by IVUS. Wallstents (Boston Scientific, Natick, MA) sized based on the IVUS measurements were used in all stented veins. The cross-sectional diameter and surface area were measured by IVUS before and after the procedure. All patients were placed on antiplatelet therapy with Clopidogrel for three months, unless they were on anticoagulation therapy for other medical reasons.

Based on absence or presence of iliac stenosis requiring iliac stenting, patients were divided into two groups: cases, the stented group (SG) and controls, the non-stented group (NSG). The QOL evaluation was performed with the validated CIVIQ-20.[7] The description and validation of this questionnaire in assessing QOL in CVI has been previously reported.[7,8] The questionnaire was mailed directly to all patients following the procedure. Patients who did not return the questionnaire were contacted by phone by an investigator and asked to answer questions on the CIVIQ questionnaire.

All patients who underwent bilateral procedures were excluded from the study cohort. Questionnaires that contained more than three missing answers were also excluded from analysis. All patients with active venous ulcers were treated with multilayer compression therapy and local wound care in the clinic on a weekly basis until complete ulcer healing was achieved. Patients with healed venous ulcers were encouraged to continue compression therapy with gradual compression stockings.

The data were analyzed using the t-test for continuous variables. The individual data are given as median with range or mean with SD. Results are reported using p values and either effect or odds ratio for continuous

and categorical variables, respectively. A p-value of less than 0.05 was considered significant.

Results

One hundred and seventy-two venograms were performed in 172 patients. The mean age of patients was 61 years. The mean age was 59 years and 63 years, respectively, in SG and NSG. There were 42 males and 38 females. Forty-five procedures in the analyzed cohort were performed on the left iliac vein. Iliac vein outflow stenosis was identified in 109 patients. It was treated with iliac vein stenting using a self-expanding stainless steel stent. The remaining 63 patients were treated medically with compression therapy.

CIVIQ-20 questionnaire was mailed to all 172 patients post-treatment. There was at least one-year interval between procedure date and QOL assessment with CIVIQ-20 questionnaire. Only one patient expired during study period from an unrelated medical problem. Eighty patients (47%) responded with completed CIVIQ-20 questionnaires for analysis. Nineteen additional patients were reached but returned incomplete questionnaires or refused to participate. This is a retrospective study which specifically was designed to assess quality of life (QOL) at least one year after the index intervention. All effort was made to include as many long-term patients as possible but in our experience, if a patient did not experience improvement in the QOL after one year, the changes thereafter were negligible. The small sample size was the direct result of a 47% return of the QOL evaluations. This QOL return average was on par with the literature.

Of the 80 patients who responded, there were 47 patients were from SG, with 24 of them belonging to CEAP 5 and 23 to CEAP 6 categories. Of the 33 patients medically treated (NSG), 23 were CEAP 5 and 10 belonged to CEAP 6. Twenty SG patients (43%) and 19 (58%) NSG patients report having had at least moderate persistent pain or discomfort post-procedure. Similarly, 20 SG (43%) and 19 (58%) NSG patients reported limitations in their daily work. The mean total CIVIQ-20 score SG was 45.23 and in the NSG was 47.13. ($p = 0.678$). The summary of all four QOL categories is reported in Table 1.

Table 1. QOL characteristics of patients who underwent iliac venous stenting versus those treated conservatively.

CIVIQ category	Stented group	Non-stented group	p
Leg pain (0–5) Q1–4	9.38 ± 4.37	9.70 ± 4.17	0.74
Physical activity (0–5) Q5–7, 9	9.84 ± 5.05	10.93 ± 5.41	0.36
Psychological activity (0–5) Q12–20	18.69 ± 9.03	20.07 ± 9.15	0.51
Social activity (0–5) Q8, 10, 11	7.69 ± 4.09	7.63 ± 4.23	0.95

CIVIQ: Chronic Venous Insufficiency Quality of Life Questionnaire.

Discussion

Advanced stages of CVI have a significant impact on QOL and ability to engage in social and occupational activities.[9–11] The disease process rarely poses an immediate threat to the limb or to the life of the patient. Therefore, the ultimate goal of therapy in CVI is to improve QOL. In our study, we compared two similar groups of patients with advanced venous disease treated for presumed iliac venous outflow obstruction and evaluated their QOL at least one year following the intervention. The goal was only to evaluate the QOL following an ubiquitous vascular procedure which may or may not have true benefit in the long term.

Neglén et al. reported improvement in QOL in all four problem categories of the CIVIQ.[5] The C5 and C6 category comprised only 22% of patients with majority in C3 category. Our patients had more advanced disease with more significant QOL impact. We only included those patients with C5 and C6 disease. One would expect a more robust improvement in QOL metrics following iliac stenting in this particular group of patients. However, in our cohort, we noted a moderate degree of persistent pain in 43% of the patients, which is much higher than 26% reported by Neglén et al. In another study by the same group, 73% of patients were found to be pain free at four years, which is in contrast to our findings.[12] According to published literature, only half of CEAP 6 cohort healed with stenting.[13,14] This may explain persistent pain in patients whose ulcers did not heal.

There are some limitations to this study. First, our cohort was derived from a retrospective evaluation of patients that were treated for presumed iliac venous obstruction. As a result, we were unable to directly compare each individual patient before and after the procedure. In addition, we could not directly document changes in early postoperative period. Nevertheless, by sending questionnaire at least one year after the procedure, we felt we could assess a long-term QOL impact in two similar groups. Second, given the limitations of our clinical follow-up, we did not have correlating stent patency data. The study simply compared those patients with similar CEAP classifications based on whether they achieved an improved QOL, from the patient's perspective. The paper did not have an aim to evaluate stent patency as these data have been published previously. Moreover, it has been reported that iliac venous stents have excellent patency, with primary

patency of 83% at four years.[12] Therefore, we would expect that majority of stents remained patent in our cohort during the study period. Third, our dataset mostly captured inpatient procedures and makes office-based procedures difficult to monitor. Even though, all patients with evidence of axial reflux in great saphenous vein on duplex ultrasound subsequently underwent endovenous ablation procedures, the details could not be captured accurately. Fourth, the purpose of this paper was to look at primary stented patients versus medical treatment only. No patients who had secondary interventions were included. Therefore, the effect of concomitant great saphenous vein ablation on QOL, if any, could not be accurately ascertained.

There are no previous studies that actually reviewed the QOL of these patients post procedure. Many previous studies have evaluated patency and ulcer healing, but we have not found a direct link between clinical outcomes (such as patency) and patient satisfaction in this group of patients.

Conclusion

There was no significant long-term difference in the reported QOL in patients with C5 and C6 venous insufficiency who underwent iliac venous stenting, in comparison to those who were treated medically. We believe that the vascular clinician should be armed with these data in order to fully inform patients regarding the true symptom alleviation efficacy of iliac venous stenting. Additional clinical correlations are needed with regard to stent patency and endovenous ablation procedures. Prospective studies are warranted to determine the true value of iliac venous stenting based on IVUS criteria in the management of patients with advanced CVI.

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Authors' contributions

AS and RR conceived and designed the study. AS, EA, TJ and RR were involved in data acquisition, analysis, and interpretation; TJ took part in the statistical analysis; AS drafted the manuscript with inputs from MS, QP and RR; All authors were involved in the critical revision of the manuscript for important intellectual content and approved the final manuscript.

Declaration of conflicting interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Robert Y Rhee is a consultant for Boston Scientific Corp. outside the submitted work.

Ethical approval

This work was completed in compliance with federal, state and institutional regulations as well as confidentiality standards. This study was approved by the Maimonides Institutional Review Board/Research Committee. Study number – 12/07/XA02-MMC.

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Guarantor

RR.

ORCID iDs

Alexander Shiferson https://orcid.org/0000-0002-5915-8991

Theresa Jacob https://orcid.org/0000-0002-2654-5071

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