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Deep Venous Stenting Improves Healing of Lower Extremity Venous Ulcers

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Publication Date
2022

DOI
10.1016/j.avsg.2021.05.026

Peer reviewed

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Clinical Research

Deep Venous Stenting Improves Healing of Lower Extremity Venous Ulcers

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Background: Long standing, recalcitrant venous ulcers fail to heal despite standard compression therapy and wound care. Stenting of central veins has been reported to assist in venous ulcer healing. This study reports outcomes of deep venous stenting for central venous obstruction in patients with recalcitrant venous ulcers at a single comprehensive wound care center.

Methods: A single center retrospective analysis was conducted of patients with CEAP (Clinical, Etiology, Anatomy, and Pathophysiology) 6 disease that had undergone deep venous stenting in addition to wound care and compression therapy. Intra-operative details, wound healing, and stent patency rates were recorded. Stent patency and intra-operative details were compared between the healed and unhealed groups.

Results: Between 2010 and 2019, 15 patients met inclusion criteria (mean age: 63 years old, 12 males). Pre-operative mean wound area was 14.1 cm2 with mean wound duration of 30 months. 93% of patients healed the ulcers at mean healing time of 10.6 months. Wound recurrence rate was 57% with mean recurrence time of 14.8 months. Ten patients presented with an inferior vena cava (IVC) filter, 4 in the healed group and 6 in the unhealed group. The common iliac vein was stented in all patients. Extension into the IVC was required in 4, the common femoral vein in 11, and femoral vein in 2 patients. The average stent length was 190cm. During the follow-up period, primary patency rates in healed patients (mean follow-up time: 19.2 months) was 83% and 59% in the unhealed group (mean follow-up time: 36.6 months); secondary patency rates were 83% and 89%, respectively.

Conclusions: In patients with recalcitrant venous ulcers with central venous obstruction, deep venous stenting resulted in a high rate of healing. However, a prolonged 10 month healing time was observed and despite high stent patency, wound recurrence rate was high.

INTRODUCTION

Chronic venous ulcers are a severe yet common manifestation of chronic venous insufficiency accounting for 70% of all ulcers of the lower extremity and affecting 20% of the 2.5 million patients with chronic venous insufficiency.[1] The mainstay of treatment of this disease includes aggressive and regular wound care, compression therapy, and treatment of superficial venous and perforator reflux.[1–4] Despite this multi-modal approach, approximately 32% of these patients do not heal by 36 months. A factor in refractory wounds may be an unaddressed obstructive component contributing to venous insufficiency.[5]

Declarations of interest: none

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Ann Vasc Surg 2022; 78: 239–246
https://doi.org/10.1016/j.avsg.2021.05.026

Manuscript received: December 7, 2020; manuscript revised: April 24, 2021; manuscript accepted: May 9, 2021; published online: 18 August 2021

Central venous stenting is a common therapy that can alleviate venous hypertension secondary to obstruction. Though most patients have a mixed (reflux and obstruction) pathophysiology of their venous disease, about one-third experience isolated central venous obstruction.[6] Addressing venous hypertension secondary to obstruction has been associated with improved healing rates.[7,8] This is well established and with low rates of morbidity.[9–11] Yet there continues to be a significant wound recurrence rate. In a recent multicenter retrospective view of patients with chronic venous ulcers, those that had undergone deep venous stenting and superficial venous ablation had a wound recurrence rate of 49% at 24 months.[12] Furthermore, there is no consensus among venous specialists, on the optimal treatment algorithm and the sequence of addressing the reflux and obstructive components of venous disease. The patient profile in which stenting will provide the most durable wound healing warrants further investigation.

The objectives of this study were to report wound healing outcomes in patients with recalcitrant venous ulcers and determine potential risk factors for failure to achieve durable wound healing after undergoing venous stenting. We hypothesize that deep venous stenting is associated with high wound healing rates.

MATERIAL AND METHODS

This study was approved by the Institutional Review Board and the University of California Los Angeles.

Study Design

This was a retrospective chart review of patients with CEAP (Clinical, Etiology, Anatomy, and Pathophysiology) 6 disease who had undergone iliofemoral venous stenting. The patients were identified by querying a prospective maintained database between 2010 and 2019. Then we reviewed each case manually to determine the patient's appropriateness for inclusion. The inclusion criteria were age greater than 18, stenting of the iliac and/or femoral venous segments, and presence of an active venous wound at the time of stenting in the ipsilateral limb. Both thrombotic and non-thrombotic etiologies were included in this study.

Data Variables

Demographic data and comorbidities were collected including presence of hypertension, diabetes mellitus, body mass index, hypercoagulability disorders, current or previous smoking history, and current use of antithrombotic therapy (at the time of stenting). Data documenting previous venous history included the presence of an inferior vena cava (IVC) filter, previous endovascular or open procedures addressing superficial venous reflux or perforator vein incompetence, and use of compression stockings. We collected details regarding the status of the patient's venous disease at the time of surgery including presence of superficial venous reflux, perforator vein incompetence, etiology of their venous disease (thrombotic versus non-thrombotic), wound area, and duration of wound prior to stenting. The presence of reflux was determined by venous duplex ultrasound in all cases. The wound area and duration were gathered from clinical notes as well as wound care clinic measurements when available. The intra-operative assessment of the venous segments (stenotic, occluded, or uninvolved) as well as details surrounding the stenting procedure were collected including stent endpoints, number and size of stents used, total stented length, and procedure time. These details were gathered from the operative record. The post-operative outcomes that were collected included achievement of post-operative wound healing as well as time to healing, recurrence and time to recurrence, use of compression, post-stenting reflux procedures, and stent patency. Primary and secondary stent patency was calculated. Primary patency is the time interval between the initial procedure and occlusion or any intervention intended to maintain patency. Secondary patency is the time between the initial procedure and occlusion or the end of follow-up, which includes interventions intended to maintain or re-establish patency.

Pre-operative Evaluation and Venous Stenting

The evaluation of patients prior to stenting was surgeon specific. In general, patients were initially assessed with venous duplex ultrasound to determine the presence of reflux disease and secondary signs of iliocaval obstruction. Given the chronic nature of the patient's wounds, most had cross-sectional imaging adequate enough to assess the central venous system at the time of presentation. If cross-sectional imaging was not available, the timing of central venous imaging was dependent upon surgeon preference. In general, superficial reflux disease was treated prior to specifically investigating the central venous system.

There were exceptions to this including in patients with phlebitis or when suspicion of central venous obstruction was high. For example, a patient with a chronic non-healing ulcer after multiple endovenous reflux procedures.

Patients suspected of venous obstruction based on cross-sectional imaging or ultrasound underwent venography with the intention of treating obstructive segments. All of the venous stenting procedures were done by Vascular surgeons. Ipsilateral venous access was obtained in the peripheral segment caudal to the anticipated stent landing zoned, usually in the groin (common femoral vein) or thigh (femoral vein). Intravascular ultrasound was conducted in addition to venography to verify the obstruction and its severity. Stenting was considered if there was a least a 50% stenosis. After crossing the lesion and prior to stenting, the lesion was treated with venoplasty with a high-pressure balloon. The stent size was chosen based upon the venous segment being stented and its expected normal size and less upon the sizes of the upper and lower landing zones. The landing zones were chosen to be in normal appearing venous segments. The stent was usually extended 1 to 2cm into the IVC if the proximal common iliac vein is involved. Stenting continued across the inguinal ligament if needed. Stents were continuous, even across multiple discrete diseased segments, to avoid short segments of unstented vein between stented segments. In all patients, the self-expanding Wallstent (Boston Scientific, Marlborough, Mass) was used in the iliocaval venous segments and either a Wallstent or self-expanding Protégé GPS (Medtronic, Minneapolis, MN) in the femoral venous segment. After stent deployment, the vein was post-dilated and inspected with intravascular ultrasound. Post-operatively, the patients were managed with at least a single anti-platelet therapy if not on an antithrombotic therapy in the pre-operative period. If they were, the same antithrombic therapy was continued post-operatively. Discharge typically occurred on post-operative day one, if pain was controlled. Wound care and compression were continued for all patients. Though patients were from a single institution, they were under the care of various surgeons. Therefore, the post-operative wound-care was not protocolized and dependent on provider preference.

Data Analysis

All continuous variables are reported as mean ± standard error and categorical variables as frequencies (proportions). Variables were compared using univariate tests including chi-square tests for categorical variables and linear regression for continuous variables. Kaplan Meier analysis was used to describe stent patency. Given the small number of patients, multivariate analysis was not performed. The initial wound healing rate graphs were created by applying the local estimated scatterplot smoothing technique to normalized wound area per time scatterplots for each group. The wound area was normalized to the first known wound area in the 6 months prior to stenting. These scatterplots include data of the initial wound and do not include any recurrent wounds. All statistics were performed with R statistical package (Version 3.5.1, R Core Team, Vienna, Austria).[13]

RESULTS

Baseline Characteristics

During the study period, 15 patients (3 female, mean age: 62.7 years, age range: 33-89 years) with a lower extremity venous ulcer were treated with ipsilateral iliofemoral venous stenting (Table I). Six patients healed without recurrence (healed group) while 9 patients either did not heal or healed then recurred (unhealed group). The mean follow-up time was 19.2 ± 7.6 months for the healed group and 36.6 ± 8.2 months for the unhealed group. There were no significant differences in comorbidities between the two groups. Most of the patients in both groups were on antithrombotic therapy prior to stenting (5 patients in the healed group and 9 patients in the unhealed group).

Pre-operative Venous Status and Wound Characteristics

The vast majority of the study population had post-thrombotic disease with the exception of one patient (in the unhealed group) who had a non-thrombotic compressive syndrome (Table II). A majority of patients in both groups had an inferior vena cava filter in place prior to stenting. Although the rates of perforator incompetence were the same in both groups, the healed group had a lower rate of superficial venous reflux prior to stenting compared to the unhealed group. Nonetheless, a majority of patients (50% in the healed group and 56% in the unhealed group) had already undergone a previous venous procedure to address superficial venous reflux or perforator incompetence. The healed group had a pre-operative wound area that was 3 times that of the unhealed group. However, the unhealed group had their wounds 5 times as

Table I. Demographics and comorbidities in patient with chronic venous ulcers treated with deep venous stenting

Characteristics	Healed ($n = 6$)	Unhealed ($n = 9$)
Demographics		
Age (years)	64.2 ± 8.6	61.7 ± 4.2
Male Sex	3 (50%)	9 (100%)
Comorbidities		
Body Mass Index	30.8 ± 3.0	31.8 ± 2.0
Hypercoagulable Condition	2 (33%)	3 (33%)
Pre-operative Anticoagulation	4 (67%)	8 (89%)
Pre-operative Anti-platelet Therapy	2 (33%)	3 (33%)
Diabetes Mellitus	3 (50%)	3 (33%)
Hypertension	2 (33%)	3 (33%)
Positive Smoking History	3 (50%)	2 (22%)

Table II. Characterization of venous disease and venous wounds prior to deep venous stenting

Characteristics	Healed ($n = 6$)	Unhealed ($n = 9$)
Pre-operative Venous Status		
Post-Thrombotic Etiology	6 (100%)	8 (89%)
Inferior Vena Cava Filter in Place	4 (67%)	6 (67%)
Superficial Venous Reflux	1 (17%)	5 (56%)
Deep Venous Reflux	5 (83%)	6 (67%)
Perforator Incompetence	2 (33%)	2 (22%)
Previous Venous Reflux or Perforator Procedure	3 (50%)	5 (56%)
Wound Characteristics		
Wound Area (cm^2)	27.4 ± 14.9	9.1 ± 4.3
Duration of Wound Prior to Stenting (months)	8.6 ± 2.2	44 ± 17.3
Pre-operative Wound Infection	0 (0%)	2 (22%)
Compression Worn Pre-operatively	5 (83%)	6 (67%)

long as the healed group. Lastly, the healed group wore compression stockings in the pre-operative phase at higher rates than the unhealed group.

Operative Details

There were no significant differences between groups in the procedure time (healed 98.5 ± 19.7 minutes, unhealed 123.7 ± 21.4 minutes), number of stents used (healed 2.7 ± 0.6 stents, unhealed 2.9 ± 0.6 stents), and total length of stented venous segment (healed 195.0 ± 38.3 mm, unhealed 187.2 ± 41.1 mm). The stent sizes ranged from 12 to 24 mm (median size: 16 mm) in the unhealed and ranged from 12 to 18 mm (median size: 14 mm) in the healed group. Stent lengths ranged from 40 to 90 mm with a median length of 90 mm, for both groups. The iliac and femoral segments were most commonly stented. The stents crossed the inguinal ligament in most patients (Fig. 1). The common iliac vein was stented in all patients. Extension into the IVC was required in 4, the common femoral vein in 10, and femoral vein in 2 patients. There were no

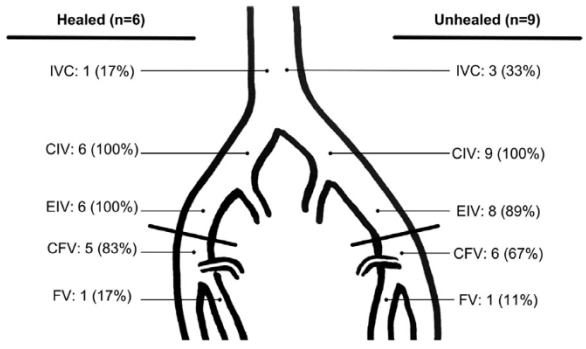

Fig. 1. The frequency (proportion) of patients with stenting per venous segment in the healed and unhealed patients where IVC, inferior vena cava; CIV, common iliac vein; EIV, external iliac vein; CFV, common femoral vein; FV, femoral vein.

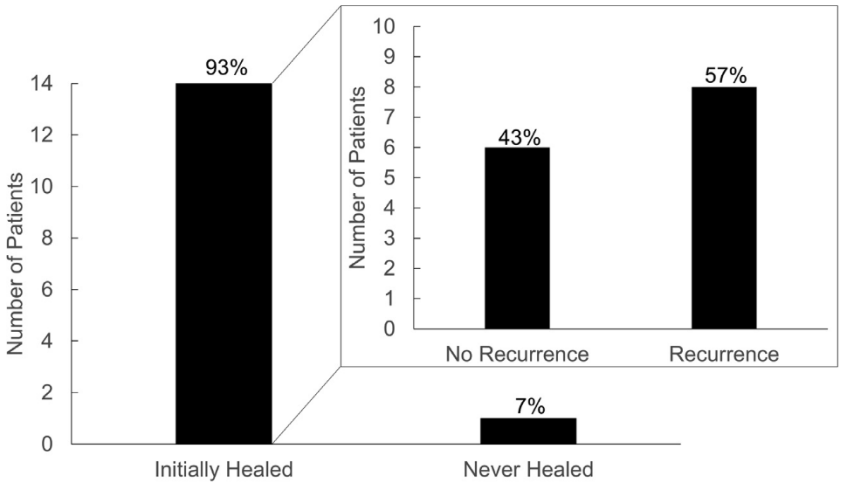

Fig. 2. The number of patients that initial healing of their venous ulcer after deep venous stenting. The chart in the insert shows the number of patients that had initial healing, but then developed wound recurrence in the same area as the initial wound.

significant differences in frequency of stenting the various venous segments.

Outcomes and Stent Patency

After stenting, 93% of patients had initial wound healing with a mean healing time of 10.6 ± 2.8 months (Fig. 2). However, 57% for these patients had recurrence at a mean time of 14.8 ± 5.2 months after stenting. When plotting wound area (of the initial wound) versus time centered around the stenting event, the trajectory of wound size after stenting can be seen. Stenting occurred when wounds were increasing in size (Fig. 3). Furthermore, the velocity of initial wound healing (slope of the wound area versus time plot) was constant in the healed group. In the unhealed group, there is an initial sharp improvement in wound size followed stagnation as seen by a gradual decrease in wound healing velocity. Post-operatively, there were 3 wound infections, 1 in the healed group and 2 in the unhealed group. Two patients in the healed group and 4 in the unhealed group underwent a reflux procedure in the post-operative period to address either superficial venous reflux or perforator incompetence. Although not routinely assessed, deep venous reflux in the post-operative period was investigated in only 5 patients, all of which had evidence of deep venous reflux. Four of these patients were in the unhealed group and 1 was in the healed group. All patients in both groups were compliant with compression stockings in the post-operative period. Primary patency rates were 83% in the healed group and 59% in the unhealed group, at the mean follow-up time (Fig. 4A). However, secondary patency rates were 83% in the healed and 89% in the unhealed groups (Fig. 4B). There were 3 stent occlusions. There was 1 in the healed group which occurred 2 months after initial stenting and healing occurred at 20 months without recurrence. There were 2 in the unhealed group, one occurring at 4 months after stenting and one occurring late at 37 months. The patient with occlusion at 4 months never healed their wound within the follow-up period. The patient with the late occlusion had initial wound healing at 3 months and recurrence at 30 months.

DISCUSSION

The treatment of chronic venous ulcers refractory to standard wound care and compression therapy is controversial as there continues to be a high rate of non-healing and recurrence.[12] In this patient population, there is a substantial number of patients with an obstructive component contributing to their venous disease. Addressing this component may provide wound healing, yet the effect of stenting on durable wound healing in this patient population is unclear. We present a single institution retrospective experience with deep venous stenting in patients with long standing recalcitrant venous ulcers.

In patients with an obstructive component, deep venous stenting can provide high rates of wound healing. In this small cohort, there was a high initial wound healing rate of 93% after venous stenting, which is comparable to published studies, albeit with different patient profiles.[14,15] In a cohort of 38 patients with chronic venous ulcers presented by George et al., median duration of wounds

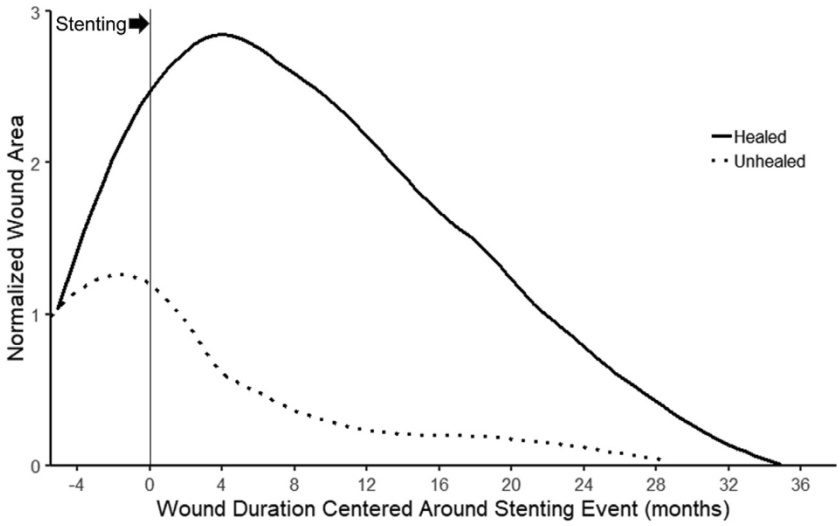

Fig. 3. Normalized wound area over time in patients with chronic venous ulcers that underwent deep venous stenting. Time is centered over the stenting event, which occurs at time 0. Wound area is normalized to the first known wound area in the 6 months prior to stenting. Only the initial wound is included. Initial wound healing rate in the healed group (initial wound healed without recurrence) was 13.0 ± 5.0 months while that in the unhealed group (initial wound healed never healed or healed but had recurrence) was 8.8 ± 3.2 months.

prior to stenting was 36 months and only 8% had superficial reflux. After stenting, 51% were healed at 15 months.[16] In another study by Neglen et al, a patient cohort of 158 that had undergone a more heterogenous endovascular approach to venous ulcers (including stenting with or without superficial venous ablation) had an ulcer healing rate of 58% at 5 years.[17] However, this patient cohort included a large variety of venous disease and pre-operative wound characteristics were not reported. The high initial healing rates in our patient cohort expands the known profile of the patient that may benefit from stenting; our cohort was primarily composed of patients with large, long standing ulcers mostly of post-thrombotic etiology and existing superficial reflux.

Despite excellent initial healing rates, time to healing is prolonged in this patient cohort. The average wound healing rate in the patient cohort was 10.6 months with a mean size of 14.1 cm^2. This long healing time may be a consequence of size. A study by Raju et al, found that ulcer healing time was significantly associated with initial size of the ulcer; at 14 weeks, 81% of ulcers less than 500 mm^2 were healed while those greater than 500 mm^2 were not healed.[18] Furthermore, the use of compression increased after stenting in this group from 58% to 100%. Yet, the significance of using wound compression after endovascular venous interventions on wound healing rate and time is unknown. In the aforementioned study by Raju et al, with a large range of chronic venous disease, ulcer healing rate and time to heal were not significantly associated with use of compression stockings.[18] Contrarily, the ESCHAR trial showed that compression therapy alone led to healing rate of 65% at 2 years.[19] Regardless, compression stocking use may have been a marker of compliance with general wound care in our cohort. Therefore, an increase in compliance with compression may be associated with increased compliance in wound care. Despite high initial wound healing rates after a prolonged healing time, wound recurrence rate was high and was likely multifactorial.

Although this patient cohort is too small to draw strong conclusions about factors that contribute to wound recurrence, there are some important observations. Wound size did not seem to significantly affect healing rates as wounds were 3 times larger in the healed group. The effects of wound size may have been overshadowed by the effect of wound duration as the unhealed group had more chronic wounds, which may be associated with longer heal times and increased difficulty in achieving healing.[20] Secondly, stent patency was not different between the healed and unhealed groups and it is unclear whether long term patency significantly affects durable wound healing. While the stent patency rates are in line with published results, the rare occurrence of stent occlusion makes it difficult to associate it with wound recurrence.[14] Although recent

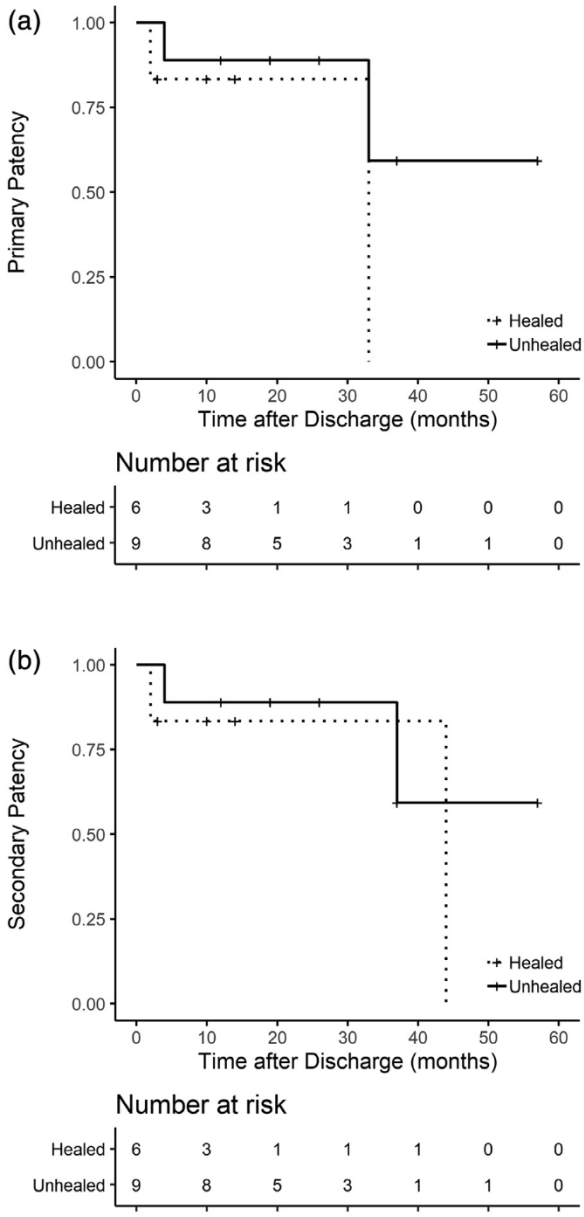

Fig 4. Primary patency (A) and secondary patency (B) of deep venous stents in patients that healed the chronic venous ulcers without recurrence and those that did not.

study of clinical outcomes after recanalization of occluded stents demonstrated a 40% wound healing rate at 17 months, it is unknown whether stent occlusion leads to wound recurrence.[21] The third observation of interest is the discrepancy between existing superficial reflux between the healed and unhealed group. This higher rates of reflux in the unhealed group highlights the controversy around the optimal sequence of treatment in this patient population. While the benefit of treating superficial reflux to reduce wound recurrence is well established, it is unclear whether this should be performed before, during, or after treatment of central venous obstruction. The long term results of the ESCHAR trial showed a significant reduction in wound recurrence from 56% to 31% with reflux treatment.[22] Contrarily, a retrospective study by Lawrence et al did not find a difference in healing or wound recurrence rates between patients that were only stented and those with stenting plus venous ablation.[12] However, the authors noted a large variation in criteria used to determine appropriateness for stenting. Furthermore, Raju et al have also found that despite the presence of severe reflux, 65-80% of wounds have durable long-term healing after stenting.[18,23] Our data supports that a multimodal approach may be necessary to heal a wound and prevent recurrence. Yet, the optimal sequence of deep venous stenting, superficial reflux, and perforator incompetence is unclear.

Limitations include retrospective nature of this study and its small cohort size. Selection bias may have been present as the unhealed wounds tend to be more chronic which may be marker for the complexity of the wound which was not captured in our data points. Furthermore, there may have been confounding factors that were not taken into account including quality of wound care. Though wound care was provided at the same clinic a single group of practitioners, wound care was not standardized. With a small number of patients, we could not draw definitive conclusions around the factors that contribute to durable wound healing as the study lack sufficient power to detect differences in the two groups. Furthermore, the small number of patients prohibited the use of more sophisticated statistical tools that may have detected differences between the groups.

CONCLUSION

In this small single-institution retrospective study of patients with large, long-standing venous ulcers with post-thrombotic etiology, deep venous stenting was associated with a high wound healing rate. Initial healing was prolonged. Despite excellent stent patency there was a high wound recurrence rate. Although the number of patients was small in this cohort, there is a suggestion that the presence of superficial venous reflux may be associated with wound recurrence. Yet, the optimal sequence of treatment for venous obstruction and reflux is unknown. Further studies regarding the optimal treatment algorithm specific to a patient's venous disease (etiology, pathophysiology, and clinical manifestation) are warranted.

ACKNOWLEDGMENTS

This work did not receive any specific grant from funding agencies.

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