Recurrence of chronic venous ulcers on the basis of clinical, etiologic, anatomic, and pathophysiologic criteria and air plethysmography

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Introduction: **Leg ulcers associated with chronic venous insufficiency (CVI) frequently recur after healing. The risk of recurrence has not been well defined for patients in different anatomic and hemodynamic groups. We reviewed the risk of ulcer recurrence on the basis of clinical, etiologic, anatomic, and pathophysiologic criteria and hemodynamic characteristics of the affected limb as assessed with air plethysmography (APG).**
Methods: **Ninety-nine limbs with class 6 CVI were assessed clinically and with standing duplex ultrasound scanning and APG for the definition of clinical, etiologic, anatomic, and pathophysiologic criteria. Leg ulcers were treated with high-pressure compression protocols. Surgical correction of venous abnormalities was offered to patients with appropriate conditions. After ulcer healing, the limbs were placed in compressive garments and followed at 6-month intervals for ulcer recurrence.**
Results: **The mean patient age was 54.3 years, and 46% of the patients were female. Corrective venous surgery was performed in 37 limbs. The mean follow-up time for all 99 limbs was 28 months. The ulcer recurrence rate with life table was 37% ± 6% at 3 years and 48% ± 10% at 5 years. The patients who underwent venous surgery had a significantly lower recurrence rate (27% ± 9% at 48 months) than did those patients who had not undergone surgery (67% ± 8% at 48 months; $P = .005$). The patients with deep venous insufficiency (DVI; n = 51) had significantly higher recurrence rates (66% ± 8% at 48 months) than did the patients without DVI (n = 48; 29% ± 9% at 48 months; $P = .006$). This difference was significant even after accounting for the effects of surgery ($P = .03$).The hazard ratio of ulcer recurrence increases by 14% for every unit increase in the venous filling index (VFI; $P = .001$). This remains significant even after accounting for the effects of surgery ($P = .001$). The combination of DVI and a VFI of more than 4 mL/s yields a risk of ulcer recurrence of 43% ± 9% at 1 year and 60% ± 10% at 2 years.**
Conclusion: **Leg ulcers associated with CVI have a high rate of recurrence. Ulcer recurrence is significantly increased in patients with DVI and in patients who do not have venous abnormalities corrected surgically. The VFI obtained from APG is useful in the prediction of increased risk for recurrence, particularly in association with anatomic data. (J Vasc Surg 2002;35:723-8.)**

Patients with chronic venous insufficiency (CVI) who have lower extremity ulceration develop have difficult conditions to treat even after ulcer healing because of the frequency of ulcer recurrence. The incidence rate of recurrent ulceration after wound healing with nonoperative techniques has been reported as 28% at 2 years,[1] 38% at 3 years,[2] and 57% at 2 years[3] in various studies. Unfortunately, many patients with recurring ulcers have multiple episodes and may have severe long-term limb dysfunction and occasionally amputation.

Numerous recent reports have investigated techniques to improve the rate of closure of leg ulcers, but there have been few studies that examine the risk factors related to ulcer recurrence. Most patients undergo treatment with compression hosiery after ulcer closure, but the rate of compliance with medical grade compression hosiery varied widely in reported studies.[3,4] Some patients are candidates for surgical correction of venous insufficiency, but these techniques may currently be underused because many patients are not referred for consideration for surgical correction. Prospective information is lacking that indicates that patients who undergo surgical correction of venous insufficiency can expect a reduced incidence rate of recurrent ulceration after surgery.

We have routinely followed patients with CVI for recurrence of healed leg ulcers. From the database established to track these patients, we present information that addresses the following questions: Which patients are at high risk for leg ulcer recurrence? Can we predict the risk of ulcer recurrence on the basis of anatomic or hemodynamic

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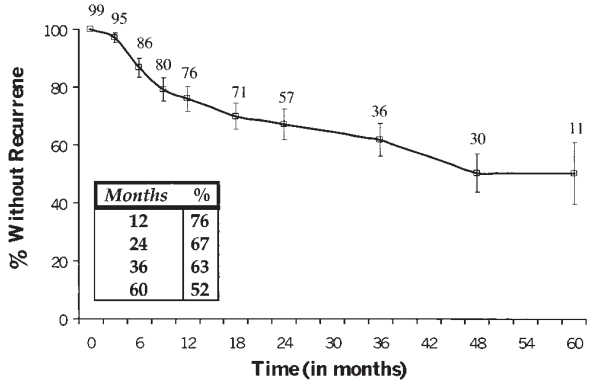

Fig 1. Percentage of all limbs free from ulcer recurrence over time with Kaplan-Meier method.

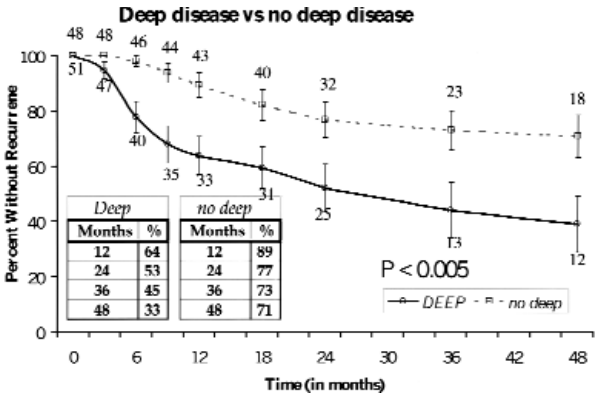

Fig 2. Freedom from ulcer recurrence in limbs with deep venous insufficiency as compared with limbs with superficial venous insufficiency.

Table I. Anatomy of venous insufficiency in all 123 limbs with standing reflux examination results

Anatomy	*No. of limbs*
Deep vein	33
Perforator vein	1
Superficial vein	32
Deep/perforator vein	8
Deep/superficial vein	21
Superficial/perforator vein	23
Deep/superficial/perforator vein	5
Total extremities	123

parameters? Does surgical treatment of CVI affect the incidence rate of ulcer recurrence?

METHODS

Between January 1992 and January 1999, 115 patients with 123 limbs affected with ulcers and duplex ultrasound scan evidence of venous insufficiency were identified at the University of North Carolina. In 99 extremities, both duplex scan examination and air plethysmography (APG) were performed and follow-up information was obtained more than 6 months after ulcer closure. Patients with morbid obesity and those who were unable to stand for testing were excluded from the study. Patient information, including age, sex, medical comorbidity, ulcer location, cause, duration, size, and type of treatment, was collected and maintained in a prospective database. For patients with bilateral disease, each limb was entered into the database and considered separately in all statistical evaluations.

Each patient underwent a complete three-part CVI evaluation by an experienced, registered vascular technologist. A lower extremity duplex ultrasound scan probe with a 5-MHz linear array B-mode ultrasound scan probe with a 3-MHz pulsed Doppler scan (Acuson 128 XP 10 color flow ultrasound scanner, Mountain View, Calif) comprised the initial study. This evaluation was performed with the patient in the supine position and 30 degrees of reverse Trendelenburg's position. Compression maneuvers and examination of flow patterns with augmentation allowed the identification of both acute or chronic venous obstruction and incompetent perforating veins. With commencement at the saphenofemoral junction, the deep, superficial, and perforating veins were assessed with Doppler scan flow patterns and B-mode imaging as previously described.[5]

Venous reflux in the deep and superficial venous systems was evaluated with a rapid inflation/deflation system (Hokanson E20 Rapid Cuff Inflator and AG101 Cuff Inflator Air Source, Issaquah, Wash) and duplex ultrasound scan while the patient stood. This evaluation allowed the measurement of valvular closure times, with a cutoff valve closure period of 0.5 seconds as the criterion for significant venous reflux.[6] Systematic interrogation of the common femoral, superficial femoral, popliteal, greater saphenous, and lesser saphenous veins was conducted.

Finally, venous hemodynamics were assessed with APG (ACI Medical, Inc, Sun Valley, Calif). The venous volume (VV) was measured initially, and reflux into the calf was determined with calculation of the venous filling index (VFI). Calf pump function was assessed with the measurement of the ejection fraction (EF) and the residual volume fraction (RVF), as previously described by Christopolous, Nicolaides, and Szendro.[7]

Many patients with acute leg ulcers had difficulty performing tiptoe maneuvers because of pain and reduced ankle mobility, which led to unreliable EF and RVF results. Although we were able to obtain VV and VFI in most patients, accurate EF and RVF were obtained in only 43 and 40 limbs, respectively.

Ulcers were treated with layered elastic compression techniques (Profore, Smith and Nephew, Inc, Hull, United Kingdom) or with Medicopaste boots (Graham-Field, Hauppauge, NY) and overlying compression layers until wound closure occurred. After healing, corrective

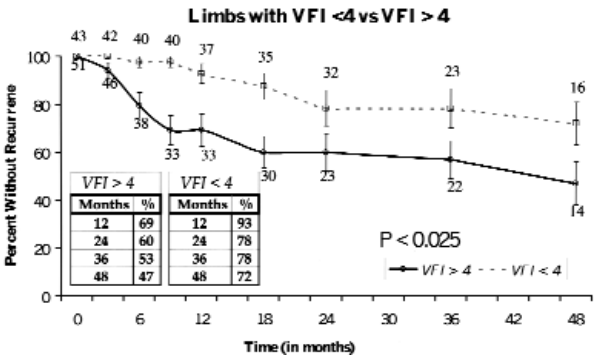

Fig 3. Freedom from ulcer recurrence with venous filling index *(VFI)* of more than 4 as compared with VFI of less than 4.

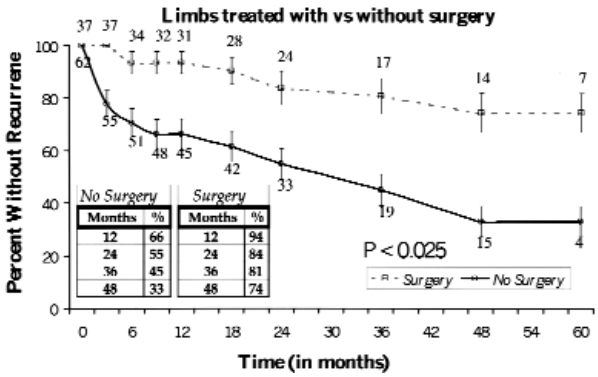

Fig 4. Freedom from ulcer recurrence in limbs after venous surgery as compared with limbs without venous surgery.

venous surgery was offered to patients on the basis of their anatomic abnormalities and their individual medical suitability for surgery. No randomization was performed, and surgical correction was on the basis of patient preference.

For patients with superficial insufficiency, saphenofemoral ligation was performed with stripping from groin to knee for greater saphenous incompetence and saphenopopliteal ligation was performed with stripping from knee to ankle for lesser saphenous incompetence. Patients with perforator incompetence underwent open ligation early in the series (n = 9) and subfascial endoscopic perforator division in the last 3 years (n = 6). Patients with deep venous insufficiency underwent treatment with valve transplantation from the axillary vein to the popliteal or superficial femoral vein. Four to 6 weeks after surgery, patients underwent repeat APG testing for the determination of the degree of hemodynamic correction from the procedure. The patients who underwent surgery received compression dressings after surgery until wound closure occurred.

After ulcer closure, all the patients underwent treatment with compression stockings, optimally 30-mm to 40-mm graded knee-high stockings. The patients who were unable to use compression hosiery because of physical limitations were offered CircAid leggings (CircAid Medical Products, Inc, San Diego, Calif). The patients were followed at a maximum of 6-month intervals for stocking replacement, reeducation, and limb examination. At these visits, the patients and family members were questioned to determine the level of compliance with limb compression. This was characterized as good compliance (use of compression >75% of the time), occasional compliance (25% to 75% of the time), or no compliance (<25% of the time). The clinical symptom scores were determined at follow-up visits as suggested by the American Venous Forum Ad Hoc Committee on Reporting Standards in Venous Disease.[8] Leg ulcer recurrence was defined as any new nontraumatic ulcer developing in the identified limb. Patient variables including age, sex, limb, clinical symptoms, etiologic classification, anatomic site of disease, APG parameters (VV, VFI, RVF, EF), compliance, and treatment with surgery were assessed for their association with recurrent ulceration.

Statistical methods. Recurrence rates and survival rate curves were calculated with the Kaplan-Meier method.[9] Univariate Cox proportional hazards models were used for the determination of whether each covariate was significantly associated with time to ulcer recurrence.[10] Multivariate Cox proportional hazards models were used for the determination of which covariates were significantly associated with time to ulcer recurrence after accounting for the effects of surgery. The following covariates were considered in this model: age; sex; side (left/right); deep, superficial, or perforator venous insufficiency; VV; VFI; and compliance with compression hose.

All the statistical tests were two-sided, and the type I error probability was set to .05. Hazard ratios (with 95% confidence intervals [CI]) were used to summarize the results. All the analyses were performed with the SAS System software (V8.0, SAS Institute, Cary, NC).

RESULTS

The mean patient age for the entire study population was 54.3 years, with a range from 28 to 82 years. Forty-six percent of the patients were female, and 57% of the ulcers affected the left leg. Mean ulcer size at presentation was 18.6 ± 24.9 cm^2, and the time to healing ranged from 21 to 495 days (mean, 100.1 days). The clinical, etiologic, anatomic, and pathophysiologic classification was as follows: clinical: by definition, all included limbs had active ulceration (class 6); etiologic: 64% of the patients had primary CVI and 36% were classified as secondary CVI; anatomic: the distribution of anatomic abnormalities identified with standing reflux examination results is detailed in Table I; pathophysiologic: the pathophysiology identified was reflux in 94% of the limbs, obstruction in 4% of the limbs, and both in 2% of the limbs.

The mean APG values are displayed in Table II. For the limbs that underwent surgical correction, preoperative and postoperative APG means are given. For the limbs that were not treated surgically, the APG mean values are listed separately. In 36 limbs, venous surgical procedures

Table II. Mean air plethysmography values measured for limbs treated with surgery as compared with limbs without surgery

	Surgical limbs		
	Before surgery	*After surgery*	*Limbs without surgery*
VV (mL)	154	138	125
VFI (mL/s)	6.74	4.45	5.34
EF	56%	61%	57%
RVF	48%	41%	47%

VV, Venous volume (mL); *VFI,* venous filling index (mL/s); *EF,* ejection fraction; *RVF,* residual volume fraction.

Table III. Venous procedures performed

Surgery type	*No. of procedures*
Autologous vein transplant	6
Vein transplant with GSV stripping	1
GSV stripping	12
LSV stripping	1
GSV and LSV stripping	2
GSV stripping and perforator	12
Perforators	2
Total procedures	36

GSV, Greater saphenous vein; *LSV,* lesser saphenous vein.

were performed as listed in Table III. Length of follow-up period, beginning at the time of ulcer closure, for all 99 limbs averaged 28 months, with 82% of patients followed for longer than 12 months.

At the latest follow-up examination, 61.2% of the patients were classified as being compliant with compression hosiery, 19.4% were classified as occasionally compliant, and 19.4% were not compliant. The mean clinical symptom score at the time of latest follow-up examination was 7.75. The incidence rate of ulcer recurrence with life table (Fig 1) was 37% ± 6.4% at 3 years and 48% ± 10.1% at 5 years. The incidence rates of ulcer recurrence in various groups are presented in Table IV. The factors noted previously were evaluated for their association with ulcer recurrence. With univariate analysis, age, sex, limb, presence of hyperpigmentation or lipodermatosclerosis, EF, and RVF were not associated with an increased risk of recurrence. Poor compliance with compression hosiery appeared to be associated with an increased risk of recurrence, but the *P* value was .07, which did not reach the .05 level of significance. The following factors were univariately associated with a reduced risk of ulcer recurrence: absence of pain ($P = .007$), absence of edema ($P = .02$), absence of deep venous disease ($P = .006$), lower VV ($P = .05$), lower VFI ($P = .001$), and performance of venous surgery ($P = .005$).

Most limbs that were treated surgically had superficial or superficial and perforator disease. Multivariate analysis was performed for the determination of which factors were associated with a reduced risk of ulcer recurrence after accounting for the effects of surgery. These results indicated that the absence of deep venous disease, lower VV, lower VFI, and absence of recurrent pain were each significant determinants of reduced ulcer recurrence after accounting for the effects of surgery (Table V).

Recurrence rates with life table results for patients with and without deep venous disease are illustrated in Fig 2. After adjusting for surgery, the hazard of ulcer recurrence was 2.4 (95% CI, 1.1 to 5.3) times higher in patients with deep venous insufficiency than in those patients with healthy deep veins. Also accounting for surgery, each mL/s increase in VFI translates to a 17% increase (95% CI, 6% to 28%) in the risk of ulcer recurrence. Recurrence for patients with VFI of more than 4 mL/s as compared with those patients with VFI of less than 4 mL/s is represented in Fig 3. Note that the hazard of ulcer recurrence was 3.4 (95% CI, 1.5 to 8.1) times higher in patients who did not undergo venous surgery, and these recurrence rates are detailed in Fig 4. The combination of deep venous insufficiency and a VFI of more than 4.0 mL/s was associated with a particularly high incidence rate of recurrence: 43% ± 9.1% at 1 year and 60% ± 9.8% at 2 years.

DISCUSSION

The treatment of lower extremity wounds associated with CVI has focused for centuries on various techniques of limb compression. Venous ulcers have been reported to heal reliably with these techniques, although the time of healing is often quite prolonged. The time to wound closure depends largely on ulcer size, but three large studies reported similar data, with 70% to 80% of ulcers healed after 6 months of compression therapy.[2-4] A major focus has been to reduce the time to healing with techniques such as subfascial endoscopic perforator division and cultured human tissue equivalents.[11,12]

Erickson et al[3] reported that 56% of healed ulcers recurred during the follow-up period, at a mean time of 10.4 months. Poor compliance with compression hosiery was associated with an increased risk of ulcer recurrence, but photoplethysmography-derived refill time did not correlate with the risk of ulcer recurrence. Mayberry et al[4] from the University of Oregon reported a 27% rate of recurrence at 2 years, with all patients who were noncompliant with compression hosiery having ulcer recurrence. In two studies of perforator ligation with the open[13] or the endoscopic[11] technique, the incidence rate of recurrence was

Table IV. Number of recurrent leg ulcers in studied groups

Variable	*Patient total*	*Ulcer recurrence*
Study group	99	35
Evidence of deep venous disease	51	25
No evidence of deep venous disease	48	10
VFI >4 seconds	51	23
VFI <4 seconds	43	9
No surgical intervention	62	27
Surgical intervention	36	8

VFI, Venous filling index (mL/s).

Table V. Effects of each covariate on ulcer recurrence after accounting for surgery

Variable	*No. extremities*	P *value*	*Hazard ratio*	*95% CI*
Age	99	.08	0.98	0.96 – 1.00
Male sex	99	.18	1.61	0.81 – 3.21
Right side	99	.79	1.10	0.55 – 2.18
Deep venous insufficiency	99	.03	2.43	1.11 – 5.31
Superficial venous insufficiency	99	.27	0.68	0.34 – 1.35
Perforator insufficiency	99	.08	0.43	0.17 – 1.11
VV	87	.02	1.01	1.00 – 1.02
VFI	87	.001	1.17	1.06 – 1.28
EF	43	.81	1.00	0.97 – 1.03
RVF	40	.28	1.02	0.99 – 1.04
Compliance with compression hosiery	96	.31	0.68	0.33 – 1.43
Pain	96	.02	2.38	1.12 – 5.04
Edema	96	.11	1.93	0.87 – 4.29

CI, Confidence interval; *VV,* venous volume; *VFI,* venous filling index; *EF,* ejection fraction; *RVF,* residual volume fraction.

markedly increased by associated deep venous insufficiency. In the long-term follow-up period after deep venous valve reconstruction, Masuda and Kistner[14] reported that 50% of ulcers recurred, but many of these patients had periods of 5 to 10 years with no ulceration, a marked improvement from their preoperative ulcer frequency. Again, patients with postthrombotic syndrome fared more poorly than those with primary valvular incompetence.

To our knowledge, there has been no evaluation of the incidence rate of venous ulcer recurrence on the basis of APG data. In this study, we found that there was again a high incidence rate of ulcer recurrence after closure: 48% at 5 years. The factors found to increase the risk of recurrence were the recurrence of pain, presence of deep venous disease, an increased VV, an increased VFI, and the lack of surgical treatment of CVI.

The recurrence of pain is a typical symptom of ulcer recurrence, so this finding was expected. Although edema recurrence was significantly associated with recurrence in univariate analysis results, it was no longer significant after accounting for the effects of surgery.

The finding that deep venous insufficiency was associated with increased ulcer recurrence is not surprising because most patients with postthrombotic syndrome were in the group with deep venous insufficiency. Clearly, a larger number of patients with superficial or superficial and perforator disease underwent venous surgery, but the presence of deep venous disease was still an independent predictor of recurrence despite the performance of surgery. In this group, two thirds of patients had recurrent ulceration within 4 years of ulcer closure.

Abnormally elevated VV and VFI were associated with an increased rate of ulcer recurrence, which suggests that these parameters might be used before surgery to aid in the selection of patients who would benefit from surgical reconstruction. Even within a given anatomic group, the use of the VFI may be beneficial. A patient with deep venous insufficiency and a VFI of more than 4 mL/s has a 43% chance of recurrent ulceration at 1 year and of 60% at 2 years. It is reasonable to recommend that these patients undergo evaluation for venous reconstruction if they are surgical candidates. Conversely, if the patient has a VFI of less than 4 mL/s, the deep venous reflux is probably less severe and the patient may not benefit from venous reconstruction. Also, in patients with both deep and superficial disease, correction of superficial reflux may result in improvement in some patients, particularly those without postphlebitic changes.[15] The VFI after superficial surgery can indicate whether the patient is likely to have a reduced risk of recurrence without the necessity of further surgery.[16]

Although EF and RVF were not significantly associated with ulcer recurrence, this might be the result of insufficient numbers because many patients could not complete these maneuvers. The population of patients studied was comprised of a significant number of debili-

tated patients with acute painful leg ulcers. This condition occasionally resulted in a limited ability to stand without assistance, which prohibited forceful tiptoe maneuvers. Back et al[17] reported a significantly limited ankle range of motion in patients with venous leg ulcers, associated with a decrease in EF and an increase in RVF.

Patients who were not candidates or who elected to forego venous surgery had a 3.4 times higher rate of ulcer recurrence. This is not conclusive proof that surgical procedures reduce the risk of ulcer recurrence because this was not a prospective randomized trial. However, it does support the continued use of surgical techniques to eliminate venous reflux in selected patients, particularly in those who have had ulcer recurrence while undergoing compression therapy or in those who are unable to comply with compression stocking use.

The lack of a strong correlation between compliance with compression hosiery and recurrent ulceration does not agree with previous studies on venous ulcer recurrence.[3,4] The reduction in recurrence rate was relatively small, so our sample size may have been inadequate to determine significance. We calculate that, given the reduction in risk observed for compression hose use, 749 observations would be necessary to adequately determine significance. Another factor is that the assessment of patient compliance depends largely on truthful admission of noncompliance, and we suspect that some patients with recurrence did not admit their noncompliance as a causative factor.

In conclusion, in this study of patients with CVI and ulceration, we found a high incidence rate of recurrence, nearly 50% at 4 years of follow-up examination. The risk of recurrence is significantly increased in patients with deep venous insufficiency and abnormally elevated VFI measured with APG and in patients who did not undergo corrective venous surgery. The use of anatomic and hemodynamic data may help select those patients who are at high risk of recurrence and are more likely to fail conservative nonoperative treatment.

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