ARTICLE TITLE

Predicting the likelihood of venous leg ulcer recurrence: the diagnostic accuracy of a newly developed risk assessment tool

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Keywords

recurrence, risk assessment, venous leg ulcers, validation

ABSTRACT

Aim: To validate a newly developed tool for predicting the risk of recurrence within twelve months of a venous leg ulcer healing.

Methods: Performance of the tool to predict recurrence within a twelve-month period was assessed using Area Under the Receiver Operating Characteristic Curve (AUC) analysis.

Design: Multi-site retrospective and prospective longitudinal studies were undertaken to validate a risk assessment tool for the recurrence of venous leg ulcers within 12 months.

Results: In the retrospective study (n=250), 55% of venous leg ulcers recurred within 12 months and the risk assessment total score had excellent discrimination and

goodness-of-fit with an AUC 0.83 (95% CI, 0.76-0.90, $p<0.001$). The prospective study (n=143) observed 50.4% (n=63) of venous leg ulcers recurred within 12 months of healing. Participants were classified using the risk assessment tool as being at low risk (28%), moderate risk (59%) and high risk (13%); the proportion of wounds recurring at 12 months was 15%, 61% and 67% for each group respectively. Validation results indicated good discrimination and goodness-of-fit with an AUC of 0.73 (95% CI, 0.64-0.82, $p<0.001$).

Conclusion Validation of this risk assessment tool for the recurrence of venous leg ulcers provides clinicians with a resource to identify high-risk patients and to guide decisions on adjunctive, tailored interventions to address the specific risk factors to decrease the risk of recurrence.

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Methods: Performance of the tool to predict recurrence within a twelve-month period was assessed using Area Under the Receiver Operating Characteristic Curve (AUC) analysis.

Design: Two studies, one a retrospective analysis of data from previous multisite studies; the other a multisite prospective longitudinal study, were undertaken to validate a risk assessment tool for the recurrence of venous leg ulcers within 12 months.

Results: In the retrospective study (n=250), 55% of venous leg ulcers recurred within 12 months and the risk assessment total score had excellent discrimination and goodness-of-fit with an AUC 0.83 (95% CI, 0.76-0.90, $p<0.001$). In the prospective study (n=143), 50.4% (n=63) of venous leg ulcers recurred within 12 months of healing. Participants were classified using the risk assessment tool as being at low risk (28%), moderate risk (59%) and high risk (13%); the proportion of wounds recurring at 12 months was 15%, 61% and 67% for each group respectively. Validation results

indicated good discrimination and goodness-of-fit with an AUC of 0.73 (95% CI, 0.64-0.82, $p<0.001$).

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INTRODUCTION

Chronic leg ulcers pose a considerable personal and financial burden for both patients and carers^{1,2}. Venous aetiology is the primary underlying factor in 70% of all chronic leg ulcers³ and 60-70% of these ulcers are reported to recur after healing^{3,4}. The highest rates of recurrence are within the first three months after healing^{5,6} while the majority recur within twelve months^{3,4}; a pattern of events often sustained over decades⁷. Twenty-eight per cent of patients will experience more than 10 episodes of venous leg ulceration in their lifetimes⁸.

Previously identified risk factors for recurrence predominantly relate to the severity of the underlying venous disease, i.e., history of deep vein thrombosis⁹⁻¹², lipodermatosclerosis¹³, deep vein insufficiency^{12,14-16}, larger ulcer size^{11,17,18}, number of previous ulcerations^{10,13}, and longer ulcer duration^{13-15,19}. Comorbidities such as rheumatoid arthritis, diabetes, cardiac disease, or low Body Mass Index (BMI) were associated with higher recurrence rates in a smaller number of studies²⁰⁻²³. There is conflicting evidence on poor mobility as a risk factor for recurrence. A large study by Barwell et al.²⁰ found no association between patient mobility scores and either healing or recurrence. However, patient mobility and/or restricted ankle movement were significantly related to recurrence rates in more recent studies by Sinabulya et al.²⁴, Brooks et al.²⁵, Vowden and Vowden¹⁷ and Nelson et al.¹³. Although few sociodemographic risk factors have been reported, male gender was associated with higher recurrence rates in two smaller studies^{14,26}.

Due to the chronic nature of the venous disease that underpins venous leg ulceration, ongoing monitoring is essential after healing²⁷. The primary evidence-

based recommended prevention strategy is compression therapy²⁸. A systematic review concluded that use of compression hosiery lowered recurrence rates compared to no compression, and one study found high level compression hosiery lowered recurrence rates compared to moderate level hosiery, although adherence to high level compression was low.²⁹ Another strategy is surgery - episodes of recurrence have reduced in patients who undergo surgery for superficial venous reflux and/or perforator surgery in addition to wearing compression³⁰⁻³². However, surgery is not always an option for all patients, particularly in this population where patient age and co-morbidities frequently restrict suitability for surgery. Leg elevation is often recommended as a logical way to assist venous return, although only a few studies of low level evidence have found an association with reduced recurrence rates^{22,25,26}. For people with a history of multiple venous leg ulcers, the long term nature of these ulcers and the habitual recurrence leads to uncertainty³³, disappointment, hopelessness and worry that they may never be free of the condition³⁴.

Given existing demands on already stretched healthcare resources, the conscientious yet effective use of resources to prevent venous leg ulcer recurrences is required. The field of wound management presently lacks a validated means to identify those individuals at greatest risk of recurrence. At present, clinicians utilise their own expert judgement and previous experience in relation to whether they consider a patient's ulcer is likely to recur. A review of the literature has not identified any screening tools to assist clinicians to detect patients at high risk of recurrence after healing in order to guide appropriate prevention strategies. Yet, not only would the quality of life of patients be optimised by reducing venous leg ulcer recurrences, but estimates of 8% of cost savings to community nursing time would be achieved for every one month that the healed state was maintained³⁵.

A risk assessment tool has been developed to identify the risk of recurrence of venous leg ulcers within 12 months of healing³⁶. The tool items were based on data analysis from longitudinal studies of patients with venous leg ulcers, evidence in the literature and advice from an expert wound advisory group³⁶. The items included a history of previous leg ulcers, DVT, ulcer duration, a low BMI, whether the patient lived alone, level of activity, leg elevation, level and days/week wearing compression³⁶. Scoring and parameters of each item are described in Parker et al.³⁶.

The risk assessment tool is easy to use, includes a small number of items, does not require specialist assessment technology or skills³⁷; and could be used in time to generate a prediction of risk and guide clinical decision making³⁸. It is important that a tool uses items that are part of normal routine patient follow up and useful for all wound care health professionals. Previous reliability testing of the tool indicated high clinical relevance with the majority of ICC indices rated high (0.7-0.9) when compared between three raters ($p < 0.05$)³⁹. Given these encouraging results, validation of the recurrence risk assessment tool in venous leg ulcers was necessary to establish the tool's credentials for use in clinical care.

METHODS

Design

Two studies were undertaken to test validity: 1) a retrospective validation study and 2) a prospective longitudinal validation study to determine how accurately the risk assessment tool could identify patients at high risk of developing a venous leg ulcer recurrence within 12 months of healing.

Study 1

Participants

The data set used for retrospective validation was a combined database from three previous longitudinal studies which followed patients who had a newly healed venous leg ulcer between 2006 and 2011 and has previously been described by the authors¹⁰. The aim of the contributing studies was to identify factors associated with leg ulcer recurrence, and participants were recruited from community and hospital outpatient wound clinics. Inclusion criteria were patients with a recently healed leg ulcer of primarily venous aetiology, ABPI between 0.8 and 1.2, and who had cognitive capacity to provide consent¹⁰. Further details are available in Finlayson et al.¹⁰

Procedure and data measures

All participants in the contributing studies received a patient information and consent package and written consent was obtained. Ethical approval for the secondary analysis of data was obtained.

A recurrence of a venous leg ulcer was defined as a wound that had achieved 100% epithelialisation maintained for two weeks (i.e. healed), and that had recurred on the same leg of the recently healed venous leg ulcer and was diagnosed as predominantly venous in aetiology by the clinician in charge of care. Data collected for the contributing studies included demographic, general health, mobility, medical history, venous history, previous ulcer characteristics, treatments, preventive strategies, and psychosocial variables. These included data on all items forming the newly developed risk assessment tool, described in Parker et al.³⁶, i.e.,

- History of previous leg ulcers in this leg
- History of deep vein thrombosis in study ulcer leg
- Previous ulcer duration (weeks)
- Body Mass Index (BMI) < 22
- Whether the client lived alone

Preventive activities:

- Moving around on feet for at least 3 hours/day (i.e. walking, doing housework, shopping)
- Elevating legs for 30 minutes/day or more (above level of the heart)
- Wearing compression hosiery Class 2 or above (i.e. 20mmHg or higher) for at least 5 days/week

Using these measures collected at the time of healing (i.e. enrolment to the recurrence studies), the risk assessment tool sub-category scores (health/social history, and preventive activities) were calculated and summed to produce an overall risk assessment score ranging from 0 to 16, with 0 = low risk and 16 = highest risk. Risk of wound recurrence of participants was grouped into three equal groups according to the range of possible scores (i.e. low risk: < 6, moderate risk: 6 to 10 and high risk: ≥11). Follow up data were collected in the previous studies every 3 months for 12 months during clinic visits, home nursing visits, postal surveys or via telephone, on recurrence status. The 12 month recurrence data was used to validate the risk assessment tool.

Analysis

Data were analysed with the IBM SPSS Statistics for Windows (Version 21.0) software. A p value of below 0.05 was used for statistical significance. Risk assessment tool performance was evaluated in terms of discrimination (Area Under the Receiver Operating Characteristic (ROC) curve (AUC) and calibration (Hosmer-Lemeshow statistic). The AUC value has been widely used and is a fundamental tool for diagnostic test evaluation, indicating the overall discriminative ability of a model⁴⁰. The AUC is a good measure of how well a parameter can distinguish between two groups⁴¹ (e.g., those venous leg ulcers that recurred and those that did not recur by 12

months). Values range between 1.0 (perfect assessment of whether the venous leg ulcer will recur or not) and 0.5 (no indication as to whether the venous leg ulcer will recur or not). Thus, the nearer the AUC to 1, the better the risk assessment score is in its ability to detect whether a venous leg ulcer will recur within twelve months. The Hosmer-Lemeshow Goodness of Fit Test is widely used for the evaluation of risk-scoring models in medicine, developed using a wide range of sample sizes⁴², to test whether the predicted probabilities agree with the observed probabilities⁴³. The Hosmer-Lemeshow Goodness of Fit Test indicates a poor fit if the significance level is less than 0.05, so to support a model a significance value of larger than 0.05 is required⁴⁴.

Study 2

Procedure

All patients receiving wound care from ten hospital outpatient clinics, community clinics or domiciliary care sites across two states of Australia were approached to participate in this study if they had a newly healed venous leg ulcer (within 4 weeks of healing). These were similar sites to the retrospective study with the inclusion of domiciliary sites. All participants received a patient information and consent package in relation to the study, written consent was obtained and participants were assured that they could withdraw from the study at any time.

Participants

Sample size calculations indicated that a total of 195 participants were required for AUC curve analysis based on the following parameters: 195 patients (to obtain 55 positive cases and 55 negative cases): 90% power; 95% significance level; an

expected 40% recurrence rate, null hypothesis of area under the curve (AUC) 0.5, alternative hypothesis of AUC 0.75, and allowing for 30% dropout.

Inclusion Criteria:

- Participants with a healed leg ulcer of primarily venous aetiology as diagnosed by the clinician in charge of care
- Participants with an Ankle Brachial Pressure Index ≥ 0.8 and < 1.3

Exclusion Criteria:

- Participants whose recent leg ulcer was of non-venous aetiology (e.g. arterial, diabetic) as diagnosed by the clinician in charge of care
- Participants with a cognitive impairment

Data collection and measures

A recurrence of a venous leg ulcer was defined as a wound that had achieved 100% epithelialisation maintained for two weeks, and that had recurred on the same leg as the recently healed venous leg ulcer and was diagnosed as predominantly venous in aetiology by the clinician in charge of care. Data collected were guided by the initial development of the risk assessment tool for recurrence in venous leg ulcers³⁶.

Data collected at baseline (at time of healing) for the risk assessment tool included:

Health, medical and social history:

- History of previous leg ulcers in this leg
- History of deep vein thrombosis in study ulcer leg
- Previous ulcer duration (weeks)
- Body Mass Index (BMI) < 22
- Client lived alone

Preventive activities:

- Moving around on feet for at least 3 hours/day (i.e. walking, doing housework, shopping)
- Elevating legs for 30 minutes/day or more (above level of the heart)
- Wearing compression hosiery Class 2 or above (i.e. 20mmHg or higher) for at least 5 days/week

These variables were collected by Registered Nurses with expertise and current wound care experience. The risk assessment tool's sub-category scores (health/social history, and preventive activities) were calculated from data collected at enrolment to the study (i.e. at the time of healing), and summed to produce an overall risk assessment score ranging from 0 to 16, with 0 = low risk and 16 = highest risk. Follow up data were collected every 3 months for 12 months on clinical variables and recurrence status during follow-up clinic visits or home nursing visits. The 12 month recurrence data were used to validate the risk assessment tool. Risk of wound recurrence of participants was grouped into three equal groups according to the range of possible scores (i.e. low risk: < 6, moderate risk: 6 to 10 and high risk: ≥11).

Analysis

Data were analysed with IBM SPSS Statistics for Windows (Version 21.0) software, using the same parameters as reported above. Area Under the Receiver Operating Characteristic (ROC) curve (AUC) and calibration (Hosmer-Lemeshow statistic) tests were utilised to evaluate the validity of the risk assessment tool.

ETHICAL CONSIDERATIONS

Ethical approval for these studies was obtained through Human Research Ethics Committees of the institutions involved. All participants received a patient information and consent package, and written consent was obtained. Participants

were assured that they could withdraw from the study at any time. If participants experienced physical pain or psychological distress at any point in the study process, the collection of data was ceased.

RESULTS

Study 1

Participant characteristics

The sample for retrospective analysis consisted of 250 participants; 55% (n=98) of venous leg ulcers recurred within twelve months, while 45% (n=81) did not. Full risk assessment tool data were only available on 156 participants due to differences in collection of data in the studies involved (i.e., one of the three studies did not collect BMI or previous ulceration data), thus 156 were included in the analysis. The model had excellent discrimination and goodness-of-fit in predicting recurrence of venous leg ulcers with an AUC of 0.83 (95% CI, 0.76-0.90, $p<0.001$) for the total risk assessment score. Thus, the model correctly discriminated between ulcers that did not recur as compared to those that did within 12 months, 83% of the time. The AUC results can be found in Table 1 and Figure 1.

Participants were grouped according to the total risk assessment score into three equal groups; low risk: < 6 ; moderate risk: 6 to 10; high risk: ≥ 11 (Table 2) and scores indicated that the higher the score the more likely a venous leg ulcer was to recur. At enrolment to the study (at the time of healing), 19% (n=30) of participants scored at low risk of recurrence, and of this group, 16.7% (5/30) subsequently experienced an ulcer recurrence in the following 12 months. Of the participants who scored at moderate risk of recurrence (46%, n=72) on healing, 54.2% (39/72) experienced a recurrence in the following 12 months. Of the participants who scored

at high risk of recurrence at the time of healing (35%, n=54), 85.2% (46/54) subsequently had an ulcer recurrence in the following 12 months. The Hosmer-Lemeshow Goodness of Fit Test showed the total risk assessment tool score to be acceptable [$\chi^2(7) = 6.29$, $p=0.51$].

Study 2

Participant characteristics

The prospective study recruited 143 participants between June 2012 and July 2015. Data on number of eligible patients and response rates were not available from two of the ten sites due to limited resources. However, at the remaining eight sites, 178 patients were treated with a venous leg ulcer which healed during the study recruitment period, and who fitted the inclusion criteria. Of these, 129 (72%) consented to participate and were enrolled in the study. The participants had a mean age of 72.66 years (SD 13.59). There was an equal representation of males (51%) and females (49%). Other demographic, ulcer and treatment characteristics of participants are shown in Table 3 and preventative activities are shown in Table 4. Fifty per cent (n=63) of participants experienced a venous leg ulcer recurrence within 12 months of healing. Rates of recurrence over the 12 months for both the retrospective and prospective studies are shown in Figure 3.

Of this sample of 143 participants, 26 were lost to follow-up due to missing data regarding wound recurrence (5 participants), missing data on one or more of the risk assessment tool fields (8 participants), withdrawal (2 participants), or inability to locate patient (11 participants). Therefore, the final analysis consisted of 117 participants.

The risk assessment scores of participants were again grouped into three groups: low risk (< 6); moderate risk (6 to 10) or high risk (≥ 11) (Table 5). In this study,

at enrolment (upon healing), 28% (n=33) of participants scored at low risk of recurrence, and of this group, 15.2% (5/33) subsequently experienced an ulcer recurrence in the following 12 months. Fifty-nine percent of participants scored at moderate risk of recurrence (n=69) on healing, and of these, 60.9% (42/69) experienced a recurrence in the following 12 months. Of the participants who scored at high risk of recurrence at the time of healing (13%, n=15), 66.7% (10/15) subsequently had an ulcer recurrence in the following 12 months. The model had good discrimination and goodness-of-fit in predicting the recurrence of venous leg ulcers within 12 months with an AUC of 0.73 (95% CI 0.64-0.82, $p<0.001$) for the total risk assessment score. The Hosmer-Lemeshow Goodness of Fit Test also showed the total risk assessment tool score to be an acceptable measure of recurrence within 12 months ($\chi^2(7) = 10.19$, $p=0.18$). AUC results for health, medical and social history, clinical examination and total risk assessment scores can be found in Table 6 and Figure 2.

DISCUSSION

After healing, the risk of recurrence of venous leg ulcers needs to remain a priority for all health professionals given the chronic nature of the underlying condition and high recurrence rates. The recurrence rates in these two studies were slightly lower (50-55%) compared to those in the literature of 60-70%^{3,4}, however were still high rates within a 12 month period after healing. Knowledge of the likelihood of recurrence within the next twelve months could contribute to improved outcomes for patients if used to shape communication about self-management between clinicians and patients. Additionally, the tool could inform a customised schedule of patient monitoring during the maintenance phase to ensure the judicious yet effective use of

healthcare resources, e.g. patients at high risk may be prioritised for early access to specialist expertise such as vascular physicians or compression therapy specialists. This study provides evidence to support the use of this risk assessment tool across a variety of clinical settings.

Development of this tool was based on evidence in the literature as described above, previous studies by the authors^{10,45,46}, and guidance from an expert panel, as described in Parker et al.³⁶. A risk assessment tool has an advantage over memorizing a list of known risk factors, by assigning scores appropriate to the strength of known predictors and providing a quick, easy to use total score indicating the level of risk of future ulcer recurrence of patients at the time of healing³⁶. The validity of any tool is an essential requirement in ensuring the clinical relevance of that tool. A loss of predictive ability in the prospective validation study, as compared to the validation based on the derivation database, (AUC 0.83 to AUC 0.73) was an expected finding⁴⁷; occurring in other validation studies of venous leg ulcer risk assessment (for delayed healing) tools^{48,49}. When looking at risk classification as low, moderate or high; the item with the largest change in predictive ability was for those classified as 'high risk', where 85% of patients scoring at high risk at the time of healing then recurred within 12 months in the retrospective study; however only 67% of those scoring at high risk subsequently recurred in the prospective study. This suggests that the lower boundary of the scores classified as 'high risk', (grouped as between 11–16), may need to be raised to 12 and over. However, as this result is only from one sample, additional studies in other countries and with different samples are needed to refine the cut-off scores for risk classification. Despite the drop, an AUC of 0.73 remained a good result. Furthermore, the samples included participants from multiple clinical settings, including home care,

specialist private, public and community domiciliary services, and as such, the tool has strong external validity and generalisability across a range of settings.

Providing a valid and reliable tool for measuring the risk for recurrence of venous leg ulcers will enable clinicians to intervene early according to the patient's individual level of risk and assist health professionals to be more confident in recognising the necessity for interventions to prevent venous leg ulcers in patients who have healed. This tool is not resource intensive and provides a quick and easy way to identify those at high risk of recurrence of a venous leg ulcer. Questions use plain language with simple responses and can be applied in an inexpensive manner in a variety of clinical settings.

The tool may facilitate decisions with respect to ongoing care of the patient, when to review, or referrals that may be necessary to improve the recurrence rates. For example, following identification of a patient as high-risk, a plan to address the individual risk factors identified by the tool for that patient could be developed and implemented, including close monitoring of progress. The presence of risk factors indicating more severe venous disease may prompt referral to specialist vascular centres and/or allied health specialists e.g. exercise physiologists for tailored programs to improve calf muscle exercise and venous return. Patients a low BMI may benefit from referral to a dietician, while those living alone may need referral for additional support services to assist them with treatments or attending health services for follow-up care. Similarly, high risk scores resulting from poor involvement in preventive activities such as wearing compression, lower limb exercise, and leg elevation suggest the need for a multidisciplinary approach to long term management of chronic venous insufficiency; in addition to innovative models of care which promote patient education, peer support, and self-management skills. Knowledge of being at higher risk may help

increase motivation for adherence to preventive self-management activities. Widespread use of the tool and sharing of level of risk may also help lower the likelihood of conflicting advice that is often reported by patients as having been received from health professionals⁵⁰. Instruments to assess the risk of recurrence of these wounds could help to enhance communication among clinicians by defining a common language and standardising assessment characteristics⁵¹. When paired with adequate instruction, clear documentation and guidelines for use, such an instrument will enable even a novice wound care health professional to complete an accurate assessment.

Limitations

The risk factors included were limited to those assessed in the derivation study, literature and expert opinion. There may be other factors that have not been investigated well such as ankle range of motion or venous disease characteristics, that may be identified and provide a more reliable scoring system. Recurrence over a period of time longer than 12 months was not assessed.

Although the study did not reach the required sample size of 195 participants, we still achieved a large sample with good results. Conservative figures of 40% recurrence and 30% loss to follow-up were used in the pre-study calculation, while the study actually had an 18% loss to follow-up. Calculations undertaken with current software demonstrate that a sample of 106 participants is adequate to provide 90% power, indicating both studies had a sufficient sample size.

This study provides evidence to support the use of the risk assessment tool for use in all settings, however further prospective testing will continue to evaluate individual variables to determine individual variable influence on the final outcome which could guide future education and lead to lower levels of recurrence in future by targeting specific variables. There are also a high number of participants in the

moderate risk groups (retrospective study 46% and prospective study 59%) and further investigation should occur of the groupings.

CONCLUSION

This study confirmed that the tool for recurrence, with components of past history of ulceration, living alone, level of activity, leg elevation, and type and amount of compression therapy use, is a valid measure of the risk of recurrence within 12 months after healing of venous leg ulcers.

Venous leg ulcer management and prevention is a priority for all health professionals working in wound care. Early availability of information on the risk of recurrence within 12 months could contribute to improved outcomes for patients and health care systems. This study provides evidence to support the validity of this risk assessment tool in home, community clinic, and hospital outpatient settings.

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Table 1: Recurrent venous leg ulcers within 12 months

AUC Results of retrospective analysis of subscales and total risk assessment score

(n=156)

	AUC	SE	p	95% CI
Health, Medical and Social History	0.674	0.044	<0.001	0.589-0.760
Clinical Examination	0.795	0.036	<0.001	0.723-0.866
Total Score	0.826	0.035	<0.001	0.758-0.895

Figure 1: Retrospective analysis: ROC Curve for subscales and total risk assessment score

Table 2: Recurrence within 12 months of venous leg ulcers by total risk assessment score: Retrospective validation sample (n=156)

Total risk assessment score	n, % not recurred	n, % recurred
< 6 (low risk)	25 (83.3%)	5 (16.7%)
6-10 (moderate risk)	33 (45.8%)	39 (54.2%)
≥ 11 (high risk)	8 (14.8%)	46 (85.2%)

Table 3: General demographic and Health Descriptive Variables (Prospective Study: n=143)

Demographic & health information		n (%)
Age (Mean $\pm$ SD)	72.66 $\pm$ 13.59	
BMI (Mean $\pm$ SD)	32.39 $\pm$ 10.14	
*BMI <22		16 (11%)
Wound duration of recently healed ulcer (weeks) (Median (Range))	23.5 (1-182)	
*Wound duration $\geq$ 52 weeks		29 (20%)
Gender	Female	73 (51%)
	Male	70 (49%)
Income	Age Pension	84 (59.2%)
	Current unemployed	19 (13.4%)
	Self-funded retiree	13 (9.2%)
	Disability pension	12 (8.5%)
	Dept of Veterans Affairs pension	11 (7.7%)
	Unemployment benefit	3 (2.1%)
*Social functioning	Live alone	63 (44.1%)
Comorbidities	Hypertension	94 (65.7%)
	Osteoarthritis	79 (55.6%)
	Heart disease	65 (45.5%)
	Chronic pulmonary disease	33 (23.2%)
	Diabetes	31 (21.7%)
	Cancer	23 (16.2%)
	CVA	22 (15.4%)
	Hypercholesterolemia/Hyperlipidemia	21 (14.8%)
	Autoimmune disease	16 (11.3%)
	Rheumatoid arthritis	12 (8.5%)
	Hypothyroidism	9 (6.3%)
	Gout	6 (4.2%)
	>3 medical conditions	90 (62.9%)
Venous history in study leg	Varicose veins	102 (73.9%)
	Surgery or trauma	63 (45.7%)
	Venous surgery	26 (18.6%)
	*DVT	25 (17.6%)
	*>1 previous ulcer	95 (66.4%)
Other	Walking aid	67 (47.5%)
	Smokers	13 (9.2%)

* Items which were part of the risk assessment tool

Table 4: General Preventative Activities (Prospective Study: n=143)

*Wearing compression hosiery Class	Yes	89 (65%)
2 or above for at least 5 days/week	No	48 (35%)
Moisturising	At least once/day	75 (62.5%)
	Less than once/day	45 (37.5%)
*Moving around on feet for at least 3	Yes	85 (60.3%)
hours/day	No	56 (39.7%)
*Elevating legs (above level of heart)	Yes	57 (41%)
for 30 minutes or more/day	No	82 (59%)
Ankle / leg exercises (>10min)	No	39 (37.1%)
	Once or less/week	4 (3.8%)
	2-3 times/week	18 (17.1%)
	Nearly every day	22 (21%)
	At least once/day	22 (21%)

* Items which were part of the risk assessment tool

Table 5: Recurrence within 12 months of venous leg ulcers by total risk assessment score: Prospective validation sample (n=117)

	n, % not recurred	n, % recurred
< 6 (low risk)	28 (84.8%)	5 (15.2%)
6-10 (moderate risk)	27 (39.1%)	42 (60.9%)
≥ 11 (high risk)	5 (33.3%)	10 (66.7%)

Table 6: Recurrence venous leg ulcers within 12 months: AUC Results of prospective analysis of subscales and total risk assessment score (n=117)

	AUC	SE	p	95% CI
Health, medical and social history	0.69	0.05	<0.001	0.60-0.79
Preventive Activities	0.62	0.05	0.03	0.52-0.72
Total risk assessment score	0.73	0.05	<0.001	0.64-0.82

Figure 2: Prospective validation Sample – AUC Results for the sub-scores and total risk assessment score

Figure 3: Ulcer recurrence rates over 12 months in retrospective and prospective studies