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**Title**

Relationships between preventive activities, psychosocial factors and recurrence of venous leg ulcers: A prospective study.

**Short Title**

Preventive activities, psychosocial factors and recurrence of venous leg ulcers

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## **TITLE**

Relationships between preventive activities, psychosocial factors and recurrence of venous leg ulcers: A prospective study.

## **ABSTRACT**

**Aim:** To identify relationships between preventive activities, psychosocial factors and leg ulcer recurrence in patients with chronic venous leg ulcers.

**Background:** Chronic venous leg ulcers are slow to heal and frequently recur, resulting in years of suffering and intensive use of health care resources.

**Methods:** A prospective longitudinal study was undertaken with a sample of 80 patients with a venous leg ulcer recruited when their ulcer healed. Data were collected from 2006–2009 from medical records on demographics, medical history and ulcer history; and from self-report questionnaires on physical activity, nutrition, preventive activities and psychosocial measures. Follow-up data were collected via questionnaires every three months for 12 months after healing. Median time to recurrence was calculated using the Kaplan-Meier method. A Cox proportional-hazards regression model was used to adjust for potential confounders and determine effects of preventive strategies and psychosocial factors on recurrence.

**Results:** There were 35 recurrences in a sample of 80 participants. Median time to recurrence was 27 weeks. After adjustment for potential confounders, a Cox proportional hazards regression model found that at least an hour/day of leg elevation, six or more days/week in Class 2 (20–25mmHg) or 3 (30–40mmHg) compression hosiery, higher social support scale scores and higher General Self-Efficacy scores remained significantly associated ( $p < 0.05$ ) with a lower risk of

recurrence, while male gender and a history of DVT remained significant risk factors for recurrence.

**Conclusion:** Results indicate that leg elevation, compression hosiery, high levels of self-efficacy and strong social support will help prevent recurrence.

**Keywords**

chronic disease, venous leg ulcers, prevention, recurrence

## **SUMMARY STATEMENT**

### **What is already known about this topic**

- Approximately 1–2% of the adult population suffer from venous leg ulcers, which take months or years to heal, and after healing, up to 70% recur.
- Evidence on effective preventive strategies for recurrence is limited to use of compression hosiery and/or venous surgery; although many patients are not suitable for surgery and adherence to wearing compression hosiery is notoriously poor.
- Known risk factors for recurrence include venous factors, comorbidities and poor mobility, however little is known on relationships between recurrence, psychosocial factors and strategies for prevention of chronic leg ulcers.

### **What this paper adds**

- Low levels of social support and self efficacy were found to be significantly associated with a greater risk of recurring venous leg ulcers.
- After adjustment for demographic, medical and psychosocial factors, leg elevation and wearing compression hosiery are likely to prevent recurrence of venous leg ulcers.

### **Implications for practice and/or policy**

- Patients with chronic venous insufficiency should be encouraged to elevate their legs for at least an hour each day and wear Class 2 or 3 compression hosiery for 6 or 7 days/week.
- Health professionals caring for patients with chronic venous insufficiency should assess levels of social support and self efficacy and implement strategies to improve self efficacy and promote optimal social support.

## INTRODUCTION AND BACKGROUND

Chronic venous insufficiency (CVI) occurs as a result of defective valves or obstruction in the venous system, which can lead to venous hypertension, oedema, inflammatory changes to the skin and eventually venous leg ulcers (Brem *et al.* 2004, Nelson *et al.* 2006). It is estimated that 40 – 50% of the adult population suffer with chronic venous insufficiency (Abbade & Lastoria 2005) and 1 – 2% of the adult population progress to the most severe stage, venous ulceration (Briggs & Closs 2003). Venous leg ulcers often take months or years to heal and frequently recur, becoming a lifelong chronic condition with cycles of ulceration, healing and recurring ulceration. The impact of chronic leg ulcers has been well documented in the literature, with reports of reduced quality of life, pain, decreased mobility, reduced functional ability and social isolation (Chase *et al.* 2000, Persoon *et al.* 2004). In addition, there are significant costs to both the sufferers and to health care systems, including an estimated 2–3% of total health care expenditure in developed countries (Abbade & Lastoria 2005, Posnett & Franks 2008).

Without active intervention, up to 70% of venous leg ulcers recur, often within three months of healing (Moffatt & Dorman 1995, McDaniel *et al.* 2002, Vowden & Vowden 2005). Despite the urgent need, evidence on effective preventive strategies is limited mainly to two interventions: the use of daily compression therapy for life (Nelson *et al.* 2000, Nelson *et al.* 2006); and/or venous surgery, particularly when superficial venous incompetence is involved (Gohel *et al.* 2007). Unfortunately, many patients with venous insufficiency are not suitable or willing to undergo surgery, due to age and multiple comorbidities (Warwick *et al.* 2007). Current advice provided to patients on prevention thus tends to concentrate on

conservative strategies to improve the impaired venous return, such as compression therapy, leg elevation, keeping mobile and exercise (Registered Nurses' Association of Ontario 2004, Royal College of Nursing 2006). Wearing compression hosiery, however, presents several problems itself as a prevention strategy, with reports of difficulties with application, comfort, appearance and cost (Anand *et al.* 2003, Flaherty 2005); and the lack of evidence for alternative strategies such as leg elevation and exercise creates difficulties in planning alternative preventive care. In addition, it is suggested that the low levels of adherence to compression therapy may be influenced by a variety of physical and psychosocial factors (Nelson 2005). Improved knowledge of the impact of these factors would facilitate the development of effective strategies for prevention.

A number of risk factors for recurrence have been identified, many related to the severity of venous disease e.g. a history of deep vein thrombosis (Franks *et al.* 1995, McDaniel *et al.* 2002), deep vein insufficiency (Barwell *et al.* 2004, Gohel *et al.* 2005), larger previous ulcer size (Franks *et al.* 1995, Vowden & Vowden 2005) and prolonged ulcer duration (Barwell *et al.* 2000, Gohel *et al.* 2005). Other risk factors include comorbidities such as rheumatoid arthritis and diabetes (Barwell *et al.* 2000, Ghauri *et al.* 2000), poor mobility or decreased ankle movement (Brooks *et al.* 2004, Nelson *et al.* 2006) and disadvantaged social groups (Callam *et al.* 1988). The diversity of these factors also point to a need for a multifaceted approach to prevention. Improved knowledge of the relationships between self-care activities, psychosocial factors and recurrence of venous leg ulcers would help facilitate this approach.

## **THE STUDY**

### **Aim**

The aim of this study was to determine relationships between psychosocial factors, activities to prevent recurrence and recurrence rates of venous leg ulcers.

### **Design**

A prospective longitudinal study was undertaken with participants who were diagnosed with a venous leg ulcer and recruited when their ulcer healed, then followed up for 12 months after healing.

### **Sample**

A convenience sample of 80 patients with a venous leg ulcer were recruited from leg ulcer clinics based in metropolitan hospitals or community-based clinics run by a district nursing service. This was a follow-up study of clients who had participated in research studies to evaluate the effect of different types of compression on healing rates in venous leg ulcers. There were no specific educational or self-management activities involved in the studies. Once clients were healed, they were discharged from the leg ulcer clinics.

All clients presenting at any of these clinics from 2006 to 2008 and fitting the inclusion and exclusion criteria were invited to participate in the original studies. Upon healing of their leg ulcer, patients were sent an information and consent package and invited to participate in the follow-up study via postal surveys. The option for telephone interviews was provided if preferred or the participant had



difficulties completing a written questionnaire.

#### *Inclusion Criteria*

- Clients with a previous leg ulcer diagnosed as venous
- Ankle Brachial Pressure Index greater than 0.8 and less than 1.3
- Ulcer completely healed (as defined by full epithelialisation maintained for at least two weeks)

#### *Exclusion Criteria*

- Clients unable to mobilise at all i.e. completely bed bound
- Clients who were unable to understand English
- Clients with a cognitive impairment

Cognitive impairment was diagnosed by the clinician assessing the client to determine whether they fitted the inclusion and exclusion criteria. A sample size calculation for survival analysis was undertaken as recommended by Collet (2003) which found a sample of approximately 100 participants would be required, using the following parameters: an estimated probability of recurrence of 0.5 at 12 months, 80% power; 95% significance level; able to detect significant clinical differences between groups based on results from previous work in this area (a 0.2 difference in proportions) and allowing for a 20% early drop-out rate.

#### **Data Collection**

Data were collected from June 2006 – June 2009. Data were collected at baseline (upon recruitment after healing), then at three, six, nine and twelve months after healing. Information gained from medical records included demographic

information (age, gender, marital status, income); health and medical history (height and weight, mobility, medications, comorbidities including diabetes, cardiac disease, hypertension, cerebrovascular disease, respiratory disease, osteoarthritis, rheumatoid arthritis and other autoimmune diseases); venous history and previous ulcer characteristics (size, duration and healing date of the recent venous ulcer, previous deep vein thrombosis (DVT), venous surgery, time since first ulcer, number of previous ulcers); follow-up care and treatment provided after healing (including prescribed compression hosiery details); and information on recurrences if they occurred.

Self-report surveys were collected at baseline then every 3 months for twelve months from healing and included questions on:

- ulcer recurrences and time to recurrence (where recurrence was defined as a breakdown of skin over the same lower leg of the previous venous ulcer)
- level of physical activity and exercise, utilising the Yale Physical Activity Survey (YPAS) (Dipietro *et al.* 1993b). This survey consists of 36 items designed to assess physical activity levels in older adults during a typical week in the month prior to the survey. The YPAS has been validated with measures of weekly energy expenditure, hours spend sitting daily and oxygen consumption in early studies (Dipietro *et al.* 1993a); while later studies have found moderate to high validity and reliability, i.e. associations with YPAS, SF-36 and performance measures (Harada *et al.* 2001); criterion validity with comparisons to accelerometer data (Kolbe-Alexander *et al.* 2006); comparisons of YPAS energy expenditure to energy expenditure calculated from dietary intake (Campbell *et al.* 1997) and

moderate to high reliability tests (Dipietro *et al.* 1993a, Kolbe-Alexander *et al.* 2006).

- level, type and length of time in compression (i.e. how many days/week do they wear their compression hosiery);
- frequency and length of time of leg elevation above the level of the heart (i.e. how many days/week do they normally spend time with legs elevated and for how many minutes/day do they undertake this activity); and
- psychosocial factors, as measured with the Geriatric Depression Scale (Short Form) (GDS) (Sheikh & Yesavage 1986), Medical Outcomes Study (MOS) Social Support Scale (Sherbourne & Stewart 1991), and General Self-Efficacy Scale (GSE) (Schwarzer & Jerusalem 1993). These scales asked participants to record how they were feeling during the past week or at the time of completing the survey. The GDS was designed to be easily completed by older people in an outpatient setting. The short form 15-item scale avoids problems of fatigue and studies in varying settings have shown good reliability and high sensitivity (84%) and specificity (95%) among cognitively intact elderly people (Brink & Yesavage, 1982; McDowell & Newell, 1996). Internal consistency is reported at  $\alpha = 0.88 - 0.94$ , test-retest reliability 0.05 – 0.98 and inter-rater reliability of 0.85 (McDowell & Newell, 1996).

The MOS Social Support Survey (Sherbourne 1992) was designed for chronically ill patients and good evidence exists for its reliability and validity (McDowell & Newell 1996). Internal consistency is reported as being high ( $\alpha = 0.97$ ) with strong correlations (0.72 – 0.90) for item-scale correlations

(Sherbourne, 1992). The revised GSE scale consists of 10 items to determine confidence in ability to cope with challenging situations. Good reliability, stability, validity has been reported in a number of studies (Luszczynska *et al.* 2005a, Luszczynska *et al.* 2005b). GSE has been positively associated with optimism, self-regulation and self-esteem, and negatively associated with depression and anxiety across cultures (Luszczynska *et al.*, 2005a), while Leganger *et al.* (2000) reported satisfactory factor structure, internal consistency, construct validity and test-retest reliability.

The questions on recurrence and self-care activities were assessed for content validity by experts in the field and the survey was pilot tested with patients attending one of the clinics.

### **Ethical considerations**

Ethical approval for the study was obtained from the university, hospital and community health service organisations' Human Research Ethics Committees. All participants were provided with an information and consent package explaining the aims of the study, procedures involved and assurance of confidentiality of data. All participants gave written consent.

### **Data Analysis**

Data were analysed with SPSSv15 (SPSS Inc., Chicago IL). Descriptive analyses were undertaken for all variables. A survival analysis approach was taken to determine relationships between preventive activities, psychosocial factors and

recurrence. Survival analysis techniques examine the length of time to an event (in this case, ulcer recurrence) and can determine relationships between predictor variables and the time to recurrence (Tabachnick & Fidell 2007). It has been recommended that all studies assessing leg ulcer recurrence utilise survival rate analysis methods (Nelson *et al.* 2000). Median time to recurrence was calculated using the Kaplan-Meier method and log-rank test. A Cox proportional-hazards regression model was used to adjust for potential confounders and evaluate the influence of preventive activities and psychosocial factors on time to recurrence.

## **Results**

Ninety-three clients attending the leg ulcer clinics fitted the inclusion criteria and were thus eligible and were invited to participate in the study. Eighty clients agreed to participate, giving a response rate of 86%. Of the clients who did not participate, ten were no longer able to be contacted on their previous address or phone details, one client had died and two clients did not wish to participate. Demographic, health, venous history and previous ulcer characteristics are shown in Table 1.

There were 35 recurrences in a sample of 80 participants (44%), with a total of 69 years person time follow-up. The median time to recurrence was 27 weeks. Twenty-one percent of participants (n=17) had recurred within three months of healing, 33% (n=26) had recurred by six months from healing, 39% (n=31) by nine months and 44% (n=35) by 12 months from healing.

### *Demographics, health and physical activity*

A greater proportion of men recurred (56%, n = 19) in comparison to women (35%, n = 16). Kaplan Meier survival curve analysis found median time to recurrence for men was 29 weeks, in comparison to 40 weeks for women (Log rank test  $\chi^2$  5.7, p = 0.017). With regard to venous history, participants who had a history of a previous DVT had a median time of 33 weeks to recurrence, while participants who had no history of a past DVT had a median time of 36 weeks (ns, p=0.26). Participants with a longer duration of the previous ulcer were significantly more likely to recur. Median time to recurrence for participants with a previous ulcer duration of less than 24 weeks was 39 weeks, in comparison to 27 weeks for participants with an ulcer duration of over 24 weeks (Log rank test  $\chi^2$  4.9, p = 0.027).

There were no significant associations between recurrence and age, comorbidities, previous ulcer area or venous surgery. The median BMI was quite high at 28 but was lower in participants who recurred (see Table 1). To enable Kaplan Meier survival curve analysis, BMI was grouped according to guidelines developed for older adults by the U.S. and Australian Nutrition Screening Initiative, with a BMI <22 considered underweight and a BMI >27 considered overweight (Lipski 1996). No relationship was found between recurrence and participants with a BMI >27, however, 80% (n=8) of participants with a BMI less than or equal to 22 recurred, compared to 39% (n=27) of participants with a BMI over 22. Kaplan Meier survival curve analysis found median time to recurrence for participants with a BMI less than or equal to 22 was 20 weeks, in comparison to 38 weeks for participants with a BMI over 22 (Log rank test  $\chi^2$  12.6, p < 0.001).

Median YPAS subscale scores are shown in Table 2. The median YPAS Total Activity Index, (calculated by multiplying the frequency of physical activities by duration by a weighting factor for each activity) was 27 (range 4 – 98), which is in the lowest quartile of possible scores, indicating overall low levels of physical activity. Higher scores on all YPAS summary indices were significantly associated with lower likelihood of recurrence. Kaplan Meier survival curve analysis found median time to recurrence for participants with the lowest quartile Total Activity Index scores was 22 weeks, in comparison to 32 weeks for those with scores in the second lowest quartile, 44 weeks for those in the second highest quartile and 49 weeks for those in the highest quartile (Log rank test  $\chi^2$  26.8,  $p < 0.001$ ).

#### *Self-care activities*

With regards to wearing compression hosiery, 15% ( $n = 12$ ) reported never wearing compression, 19% ( $n = 15$ ) reported wearing compression hosiery occasionally (1 to 5 days/week), and 63% ( $n = 50$ ) reported wearing compression hosiery for 6 or 7 days/week (see Table 2). Twelve percent ( $n = 9$ ) of participants wore Class 1 (14–19mmHg) hosiery, 75% ( $n = 56$ ) wore Class 2 (20–25mmHg) hosiery and 13% ( $n = 10$ ) wore Class 3 hosiery (30–40mmHg). Fifty percent of participants wearing no compression recurred, 60% of those wearing Class 1 hosiery recurred, 44% of those wearing Class 2, and 40% of participants wearing Class 3 hosiery. Kaplan Meier survival curve analysis found median time to recurrence for participants who wore Class 2 or 3 compression hosiery for 6 or 7 days/week was 43 weeks, in comparison to 29 weeks for participants who wore

compression hosiery for less than 6–7 days/week (Log rank test  $\chi^2$  13.2,  $p < 0.001$ ).

Thirty-six percent ( $n = 29$ ) of participants elevated their legs above the level of the heart for at least an hour/day, another 23% ( $n = 18$ ) elevated their legs for at least 30 minutes/day, 20% ( $n = 16$ ) elevated their legs occasionally and 21% ( $n = 17$ ) did not elevate their legs at all (see Table 2). Kaplan Meier survival curve analysis found median time to recurrence for participants who elevated their legs for an hour/day was 47 weeks, in comparison to 29 weeks for participants who did not elevate their legs for this length of time (Log rank test  $\chi^2$  16.9,  $p < 0.001$ ).

Although participants were asked how often and for how long they undertook ankle or lower limb exercises, around three-quarters of the sample (70%,  $n = 56$ ) reported exercising less than once a week, and of the participants who exercised more than once/week, the average time spent on ankle exercises was less than ten minutes. It was decided therefore that the YPAS Total Activity Index would remain as a more accurate measure of activity to include in further analysis, as the scale is calculated from the frequency and duration of time spent doing vigorous activity, leisurely walking, moving on feet, standing or sitting.

### *Psychosocial factors*

Psychosocial measures were found to be significantly associated with the risk of recurrence. Approximately a third of participants (34%,  $n = 27$ ) scored as 'at-risk' of depression (i.e. scores of 5 or above) on the short form Geriatric Depression scale (see Table 2). Kaplan Meier survival curve analysis found median time to



recurrence for participants who scored as at-risk of depression was 31 weeks, in comparison to 39 weeks for participants who scored below 5 (Log rank test  $\chi^2$  6.1,  $p = 0.042$ ). Median time to recurrence for participants with General Self-Efficacy scale scores in the lowest tertile was 12 weeks, in comparison to 21 weeks for middle tertile and 48 weeks for the upper tertile (Log rank test  $\chi^2$  94.7,  $p < 0.001$ ); while median time to recurrence according to MOS Social Support Scale scores from the lowest quartile to the highest was 13 weeks, 22 weeks, 47 weeks and 49 weeks respectively (Log rank test  $\chi^2$  78.3,  $p < 0.001$ ).

#### *Cox regression model*

As the YPAS summary indices were significantly correlated and there was a risk of collinearity, only the YPAS Total Activity Index variable was entered in the model. In addition, BMI was not included in the model due to the small numbers of participants who had a BMI under 22. All remaining variables associated with recurrence ( $p < 0.05$ ), or identified in the literature as having a significant effect on recurrence, were entered simultaneously into a Cox proportional hazards regression model using recurrence as the dependent variable. After mutual adjustment for all variables, the regression model found gender, previous DVT, leg elevation, six or more days/week in Class 2 or 3 compression hosiery, social support scale scores and General Self-Efficacy scores remained significantly associated ( $p < 0.05$ ) with recurrence (see Table 3).

This model found participants who elevated their legs for an hour/day were 16 times (95% CI 2.6 – 77) less likely to recur than participants who did not elevate their legs for an hour a day. Participants who wore Class 2 or 3 compression

hosiery at least six days/week were 2.6 times less likely to recur (95% CI 1.2–5.6). Both the General Self-Efficacy scale scores and Social Support Scale scores were inversely associated with recurrence. In comparison to General Self-Efficacy scale (range = 30) scores in the lowest tertile, those scoring in the middle tertile were 2.4 times (95% CI 1.04 – 5.9,  $p = 0.042$ ) less likely to recur, while those scoring in the upper tertile were 13.2 times (95% CI 2.1 – 89.9,  $p = 0.009$ ) less likely to recur (see Table 2). Social Support Scale scores in the two highest quartiles were 12.9 times (95% CI 1.2 – 100,  $p = 0.035$ ) and 4.3 (95% CI 1.05 – 17.2,  $p = 0.043$ ) times less likely to recur than those in the lowest quartile, while there was no significant difference between the second lowest quartile and the lowest (hazard ratio 1.04, 95% CI 0.44 – 2.51,  $p = 0.914$ ). The likelihood of recurrence in participants with a history of previous DVT were 2.75 times higher (95% CI 1.12 – 6.69) than participants who had not suffered a previous DVT, while males were 3.2 times (95% CI 1.29 – 8.33) more likely to suffer a recurrence than females.

## **Discussion**

In this study, significant relationships were found between recurrence of venous leg ulcers, the preventive activities of leg elevation and compression hosiery, and the psychosocial factors self-efficacy and social support, as well as gender and a history of a past DVT. Previous studies have found similar results on the effectiveness of compression hosiery for prevention (Nelson *et al.* 2000, Nelson *et al.* 2006), however, there is little evidence in the literature on leg elevation as a preventive strategy, or on the relationships between self-efficacy, social support and recurring leg ulcers.

The 12 month recurrence rate (44%) in this sample is similar to levels reported previously in the literature in patient groups without controlled interventions (Ghuri *et al.* 2000, Vandongen & Stacey 2000, Fassiadis *et al.* 2002). Moffatt and Dorman (1995) and Vowden and Vowden (2005) found that the highest rates of recurrence were within three months of healing, and likewise nearly half of those who recurred in this study did so within the first three months of healing. With regard to medical history and comorbidities, although Barwell *et al.* (2000) and Ghauri *et al.* (2000) found relationships between recurrence and rheumatoid arthritis or diabetes, no significant associations were found in this study. This may be a result of small numbers of participants involved with these conditions in this sample. However, in agreement with previous reports (Franks *et al.* 1995, Barwell *et al.* 2000, McDaniel *et al.* 2002, Gohel *et al.* 2005), ulcer duration and history of a previous DVT were found to be significantly associated with time to recurrence. Interestingly, although ulcer duration was found to be significant at the bivariate level, the variable was not significant after adjusting for other factors in the multivariable regression model, whilst a history of a past DVT was not significant at the bivariate level, but was identified as a significant factor in the adjusted multivariable model.

Also in agreement with previous studies (Brooks *et al.* 2004, Vowden & Vowden 2005, Nelson *et al.* 2006) were the initial relationships found with recurrence and poor levels of mobility, although the relationship was not statistically significant within the adjusted multivariable model. Reduced mobility has been measured by a variety of methods in the literature and there are conflicting results on its impact

(Barwell *et al.* 2000, Nelson *et al.* 2006). However, the results from this study in combination with previous reports (Brooks *et al.* 2004, Nelson *et al.* 2006, Finlayson *et al.* 2009) suggest there is likely to be a positive relationship between increased levels of physical activity and prevention of recurrence.

Male gender was unexpectedly identified as a significant risk factor in this sample. To explain this variation, the data were checked for any differences in demographics, risk factors, psychosocial variables or self-care activities according to gender. Although there were no significant differences found between gender with most of these variables, only 6% (n = 2) of the men had undergone previous venous surgery, in comparison to 28% (n = 12) of the women ( $\chi^2 = 5.9$ ,  $p = 0.015$ ). However, when this variable was added to the multivariable model, previous venous surgery lost significance while gender remained a significant risk factor. In addition, it was found that 41% of the men were self-supporting (e.g. received a salary, in comparison to those who received an age or disability pension), while only 22% (n = 9) of the women were self supporting ( $\chi^2 = 2.9$ ,  $p = 0.08$ ). It was also noted that many of the male participants who were employed had sedentary occupations (e.g. taxi drivers, truck drivers) and it may be that physical and time constraints for those male participants still in the workforce impacted on self-care activities and risk factors for recurrence.

Poor nutrition and a high BMI have been suggested to delay healing in venous leg ulcers (Taylor *et al.* 2002, Iglesias *et al.* 2004, Meaume *et al.* 2005) and a small study by Wissing, Ek and Unosson (2001) found patients with recurrent ulcers had decreased Mini-Nutritional Assessment scores over time. Although only small

numbers were involved, a relationship between a low BMI and higher risk of recurrence was found at the bivariate level, suggesting further research may be valuable in this area.

### *Self-care activities*

Previous evidence on the use of compression therapy to prevent recurrence has shown its effectiveness (Nelson *et al.* 2000, Vandongen & Stacey 2000, Nelson *et al.* 2006) and results from this study support those findings. This study found no difference in the risk of recurrence between participants wearing Class 2 or Class 3 hosiery, however, there were only small numbers wearing Class 3 hosiery (n = 10). There was no significant difference in risk of recurrence between participants not wearing any compression and participants wearing Class 1 hosiery, however, again only small numbers (n = 7) of participants wore Class 1 hosiery. Only 66% of participants reported wearing compression hosiery regularly in this first year after healing – confirming many reports in the literature on poor rates of adherence with compression (Anand *et al.* 2003, Flaherty 2005, Seppanen 2007); and the need to identify physical and psychosocial factors which may influence adherence to compression therapy (Nelson 2005).

Levels of adherence to leg elevation are not reported as frequently as those of wearing compression hosiery. One study (Seppanen 2007) found around 28% of participants elevated their leg several times/day, while in this study 36% of participants reported elevating their legs for at least an hour/day. Elevation of the affected legs above the level of the heart is recommended to prevent recurrence in many best practice guidelines for caring for patients with venous leg ulcers (Arrol

*et al.* 1999, Stacey *et al.* 2002, Royal College of Nursing 2006), although reviews in 1998 (Peters) and 2000 (Nelson) noted that this strategy was supported only by expert opinion. However, more recent studies by Brooks *et al.* (2004) and Finlayson *et al.* (2009) have found significantly reduced recurrence in participants who spend longer amounts of time with legs elevated, suggesting this activity is beneficial for prevention.

### *Psychosocial factors*

As well as a direct effect on the immune system and normal healing processes, psychosocial factors may have an indirect effect on recurrence by impacting on self care activities to prevent recurrence. Depression, stress and anxiety have been associated with delayed healing in acute wounds (Cole-King & Harding 2001, Doering *et al.* 2005, McGuire *et al.* 2006) and the presence of leg ulcers has been significantly associated with being single and poorer levels of social support (Moffatt *et al.* 2006). However, in general there is little information available on the relationships between psychosocial factors and recurrence of chronic leg ulcers. In this study depression did not remain significantly associated with the risk of recurrence in the adjusted multivariable regression model, however, the significant relationship found between social support and recurrence supports findings reported by Wissing *et al.* (2001), who found higher measures of social interaction in patients whose ulcers did not recur; and Heinen *et al.* (2007), who suggested social support influenced the level of physical activity undertaken. Self management of other chronic conditions has also been demonstrated to be influenced by social support (Sousa *et al.* 2004, Jeon & Kim 2006).

In addition, a significant relationship between self-efficacy and recurrence was identified in this study. Levels of self-efficacy are rarely reported in leg ulcer patients; although close relationships between self-efficacy and health promoting activities have been reported in studies of self management programs for other chronic conditions (Brody *et al.* 2006, Buszewicz *et al.* 2006, Jeon & Kim 2006). This area needs further research in future studies on prevention of chronic venous leg ulcers.

### *Strengths and Limitations*

Data were unavailable on the type or degree of venous insufficiency, which may also influence recurrence. Small numbers in some variable categories (i.e. BMI <22, some comorbidities) limit the reliability of those results. Measures of physical activity, psychosocial scales and self-care activities were obtained from self-report questionnaires, with the possibility of response bias. However, study strengths include prospective measurement of a broad range of demographic, medical, psychosocial and preventive activity variables, which enabled use of a multivariable model to determine the individual relative contributions of each of these variables. Limited quantitative information on the impact of psychosocial variables on recurrence is available in the current research evidence and this study contributes some preliminary information to the area.

### **Conclusions**

In conclusion, this study identifies a number of areas which could be targeted for further investigation and included in a multifaceted prevention plan for patients with chronic venous insufficiency. There has been an absence of studies examining both physiological and psychosocial influences on recurrence of venous leg ulcers and findings from this study highlight the importance of chronic disease self care behaviours and psychosocial factors in this area. Importantly, most of the factors found to be significantly associated with the risk of recurrence in this study, e.g. self efficacy, leg elevation, compression therapy and social support, are amenable to interventions. It is recommended that health professionals caring for this population consider a holistic long term management program encompassing strategies to improve self efficacy and facilitate preventive self care activities. Additional multisite prospective studies with larger samples and longer follow-up time are recommended to examine the broad range of factors associated with recurrence, along with experimental studies on interventions to prevent recurrence.

### **Conflicts of Interest**

No conflict of interest has been declared by the authors.



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**Table 1.****Demographic, health, venous history and previous ulcer characteristics**

	Recurred (n = 35) n (%)	No recurrence (n = 45) n (%)	Total sample (n = 80) n (%)
<b>Gender *</b>			
Male	19 (56%)	15 (35%)	34 (42%)
Female	16 (45%)	30 (67%)	46 (58%)
<b>Marital status</b>			
Married	17 (49%)	20 (48%)	37 (48%)
Single	7 (20%)	4 (9%)	11 (14%)
Widowed	11 (31%)	18 (43%)	29 (38%)
<b>Income</b>			
Aged pension	18 (53%)	24 (57%)	42 (55%)
Disability pension	4 (12%)	3 (7%)	7 (9%)
Employed or self-funded retiree	12 (35%)	14 (33%)	26 (34%)
Lived alone	13 (37%)	23 (51%)	36 (45%)
Osteoarthritis	14 (41%)	18 (40%)	32 (41%)
Rheumatoid arthritis	5 (15%)	6 (13%)	11 (14%)
Hypertension	12 (35%)	26 (58%)	48 (61%)
Diabetes	6 (17%)	5 (11%)	11 (14%)
Cardiac disease	8 (24%)	16 (36%)	24 (30%)



Required aid to mobilise	8 (24%)	16 (36%)	24 (30%)
At risk of nutritional deficiency on			
MNA-SF <sup>†</sup> scale	16 (46%)	14 (31%)	30 (38%)
Body Mass Index ≤ 22*	8 (23%)	2 ( 4%)	10 (13%)
Varicose veins	18 (53%)	28 (64%)	46 (59%)
Past DVT <sup>‡</sup>	10 (29%)	9 (20%)	19 (24%)
Past venous surgery	6 (18%)	8 (19%)	14 (18%)
Time since first ulcer: 1–2 years	15 (43%)	20 (44%)	35 (44%)
3–5 years	6 (17%)	10 (22%)	16 (20%)
6–10 years	6 (17%)	7 (16%)	13 (16%)
>10 years	8 (23%)	8 (18%)	16 (20%)
		Median (range)	
Ulcer duration (weeks)*	35 (4–174)	27 (5–133)	29 (4–174)
Ulcer area (cm <sup>2</sup> )	4.5 (1-21)	3.0 (1-62)	4.0 (1–62)
Age	73 (41–84)	75 (46–95)	75 (41–95)

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\**P* < 0.05 difference between those who recurred and those who did not recur

† Mini-Nutritional Assessment – Short Form

‡ Deep Vein Thrombosis

**Table 2. Yale Physical Activity Survey (YPAS) subscales, preventive activities and psychosocial scale scores.**

	Recurred	No recurrence	All subjects
	<i>Median (range)</i>	<i>Median (range)</i>	<i>Median (range)</i>
YPAS			
†Total Time Index*	14.0 (0–119)	22.0 (1.8–109)	17.0 (0–119)
††Energy Expenditure*	2562 (0–21480)	4353 (277–20499)	3097 (0–21480)
†††Total Activity Index**	23.0 (4–98)	34.0 (4–90)	27.0 (4–98)
	<i>Number (%)</i>	<i>Number (%)</i>	<i>Number (%)</i>
compression hosiery			
≥6 days/week*	17 (34%)	33 (73%)	50 (63%)
Leg elevation	8 (23%)	21 (47%)	29 (36%)
≥1 hour/day**			
‡GDS score ≥5 *	17 (49%)	10 (22%)	27 (34%)
	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>Mean (SD)</i>
‡†MOS Social Support**	54.8 (11.5)	78.9 (10.2)	66.9 (17.3)
§General Self-Efficacy**	22.1 (2.4)	35.1 (2.1)	30.3 (5.4)

\* $P < 0.05$  difference between those who recurred and those who didn't recur.

\*\* $P < 0.005$  difference between those who recurred and those who didn't recur.

† Total Time index = sum of hours for all physical activities per week

†† Energy Expenditure Index = sum of time of each activity x intensity [kcal/min]

††† Total Activity Index = frequency x duration x weighting factor for activities

(possible range 0–137)

‡Geriatric Depression Scale Short Form - range 0–15, where higher scores indicate greater levels of depression

‡‡ Medical Outcomes Study (MOS) Social Support Index - scale from 0–100, where higher scores indicate more support

§General Self-Efficacy - scale from 10–40, where higher scores indicate greater levels of perceived self-efficacy

**Table 3.****Risk of ulcer recurrence - Cox proportional hazards regression model**

	$\beta$	Hazard Ratio	95% CI	p
Gender (male, referent=female)	1.18	3.23	1.29–8.33	0.012
Previous DVT*	1.01	2.75	1.12-6.69	0.026
Ulcer duration >24 weeks	0.76	2.13	0.79–6.36	0.175
YPAS Total Activity Index				
scores 0 – 20		referent group		
21 – 30	-0.37	0.69	0.30–1.58	0.382
31 – 40	-0.62	0.54	0.14–2.05	0.363
41 – 100	-1.63	0.20	0.04–1.02	0.053
Leg elevation ( $\geq 1$ hour/day)	-2.86	0.06	0.01–0.39	0.004
Compression ( $\geq 6$ days/week)	-0.96	0.38	0.18–0.83	0.015
General Self-efficacy Scale				
scores 0 – 10		referent group		
11 – 20	-0.90	0.41	0.17-0.96	0.042
21 – 30	-2.58	0.08	0.01-0.54	0.009
MOS Social Support Scale				
scores 0 – 25		referent group		
26 – 50	0.05	1.05	0.44-2.51	0.914
51 – 75	-1.45	0.24	0.06-0.96	0.043
76 – 100	-2.56	0.08	0.01-0.83	0.035

\* Deep Vein Thrombosis