# Venous leg ulcer recurrence: deciphering long-term patient adherence to preventive treatments and activities

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#### **ABSTRACT**

To better understand long-term adherence to self-care activities to prevent the recurrence of venous leg ulcers (VLUs), participants (n=80) were recruited to a prospective longitudinal study after experiencing healing of a VLU. Data on demographics, health, psychosocial measures and adherence to prevention strategies (compression therapy, leg elevation and lower leg exercise) were collected every three months for one year after healing. Multivariable regression modelling was used to identify the factors that were independently associated with adherence.

Over the year, a significant decline in adherence to all three strategies was observed, predominantly between 6 and 12 months after healing (p<0.01). Several factors were associated with adherence to more than one preventive activity. Regular follow-up care and a history of multiple previous ulcers were related to improved adherence (p<0.05), while scoring at higher risk for depression and restricted mobility were related to decreasing adherence over time (p<0.05). Patients with osteoarthritis had significantly reduced adherence to compression hosiery (p=0.026). These results provide information to assist care providers plan strategies for prevention of recurrent VLUs; and suggest a need for regular follow-up care which addresses both the physical and mental health of this population.

Keywords: venous leg ulcer, prevention, recurrence, compression, adherence.

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#### INTRODUCTION

Around 60% to 70% of lower leg ulcers are venous in origin, developing as a result of chronic venous insufficiency from defective valves or obstruction in the venous system<sup>1</sup>. Chronic leg ulcers affect 1–3% of the population aged over 60 years and are associated with prolonged ill-health, pain, restricted mobility and decreased quality of life<sup>2,3</sup>. The ulcers often take months or years to heal and frequently recur, becoming a lifelong chronic condition<sup>4</sup>.

Although a considerable amount of time and resources are consumed during the processes of healing venous leg ulcers (VLUs)<sup>5</sup>, unfortunately, once healed, as many as 60% to 70% of patients suffer an ulcer recurrence<sup>6,7</sup>, with the majority recurring within 12 months of healing<sup>4,8</sup>. Evidence on effective strategies to prevent ulcer recurrence is limited. Treatments currently recommended include strategies to improve venous return and maintain general health — such as maintaining good skin condition, wearing compression garments, assessment for suitability for venous surgery, leg elevation, exercise, avoiding long periods standing or sitting and maintaining optimal nutrition<sup>9,10</sup>.

Compression therapy has been shown to be effective in preventing recurrence<sup>1</sup> and is thus the first-line preventive strategy recommended to patients with chronic VLUs<sup>10,11</sup>. However, problems with compression therapy as a lifelong prevention strategy are well documented, with many patients finding compression garments

uncomfortable, costly and difficult to apply<sup>12-14</sup>. Adherence rates are reported as ranging from 12%<sup>15</sup> to 52%<sup>16</sup> for wearing compression every or nearly every day. Consequently, while there is evidence that the use of compression hosiery is more effective than no compression in preventing recurrence, difficulties with patient adherence in wearing compression hosiery has limited generalisations from the findings of some of these studies<sup>17,18</sup>.

Recommendations such as elevation of the lower legs above the level of the heart and regular walking and ankle exercises to prevent recurrence are supported only by expert opinion<sup>9,10</sup>, as measures of activity, exercise or time spent with legs elevated are rarely reported in studies of ulcer recurrence. Because of the lack of evidence, advice on frequency and amount is variable and inconsistent, contributing to a lack of confidence and concordance in patients. However, physiological studies of calf muscle pump function following exercise in patients with venous insufficiency have found improved strength and calf muscle pump function<sup>19,20</sup>, and a study with 50 patients found significantly reduced recurrence in an intervention group who spent greater time with legs elevated than the control group<sup>21</sup>, suggesting these interventions may have potential value and there is a need for further investigation in this area.

Health care systems which are not designed to support long-term chronic disease management and preventive care are another barrier to consistent adherence to preventive strategies. Based on expert consensus, guidelines for care of patients with chronic VLUs from Australia and New Zealand<sup>9</sup>, the UK<sup>11</sup> and Canada<sup>10</sup> suggest prevention of recurrence of leg ulcers requires regular follow-up care, education on preventive measures and strategies to promote self-management of chronic venous insufficiency. However, authors from a number of countries and health care systems have described confusion over who owns responsibility of care and problems with poor communication and integration of health care services<sup>22,23</sup>. Most leg ulcer patients are treated in the community and access health care through a mixture of acute, general, specialist and community primary health care services, requiring complex communication and organisation to achieve continuity of care between services.

Strategies to prevent recurrence of VLUs are based on acceptance of the condition as a lifelong chronic disease, requiring permanent modifications to lifestyle. Adherence to self-care activities aimed at preventing recurrence is, therefore, reliant on understanding and agreement between patients and health professionals with the proposed prevention regimen. Difficulties in both these areas have been reported in patients with chronic leg ulcers. Patients have expressed concern that health professionals do not understand the difficulties associated with compression and the impact of their problems, leading to disempowerment and disagreement with treatment plans<sup>24</sup>.

Known influences on health-promoting behaviours and self-management of chronic disease in other chronic conditions include depression and self-efficacy<sup>25,26</sup>, social support<sup>27</sup> and male gender<sup>28</sup>. Many of these areas have not been well explored in samples of patients with chronic venous insufficiency. The presence of leg ulcers

has been significantly associated with being single and poorer levels of social support<sup>29</sup>, and a small study by Wissing *et al.*<sup>30</sup> noted that patients whose leg ulcers did not recur scored significantly higher on measures of social interaction than patients whose ulcers did not heal or recurred. Interestingly, Nelson<sup>31</sup> found that having a role as a care provider for another member of the household was one factor encouraging self-care activities for chronic leg ulcers.

A previous retrospective study by these authors found adherence to compression therapy was significantly associated with participants' knowledge of their condition, self-efficacy and depression<sup>32</sup>. The aim of this study was to analyse data from a prospective longitudinal study to identify the demographic, physical and psychosocial factors associated with long-term adherence to self-care strategies to prevent recurrence of VLUs. Specifically, we looked at long-term adherence to compression therapy, leg elevation and lower limb exercising.

#### **METHODS**

#### Design

A prospective longitudinal study was undertaken of patients diagnosed with a VLU who were recruited when their leg ulcer healed. Data were collected at baseline (within two weeks of healing), then follow-up data collected every three months for 12 months following the date of healing on demographics, health, physical activity, psychosocial measures, adherence to preventive strategies and ulcer recurrences.

#### Sample

All patients who had received care during 2006–2009 at a leg ulcer clinic based either at one of two metropolitan hospital outpatient services or within a community nursing organisation and who met the inclusion and exclusion criteria were invited to participate.

The inclusion criteria were all patients who had a previous VLU; with an Ankle-Brachial Pressure Index between 0.8 and 1.2; whose ulcer had completely healed, where healing was defined as full epithelialisation which was maintained for at least two weeks. Patients were excluded from the study if they were completely bed-bound and unable to mobilise; were unable to understand English; or who had a cognitive impairment as diagnosed by the clinician in charge of their care.

#### Data collection and measures

Data on demographics, general health, medical and venous history, and ulcer history and treatment were obtained from medical records. Participants were given a questionnaire to collect data on their level of physical activity; psychosocial measures (Geriatric Depression Scale — GDS<sup>33</sup>; MOS Social Support Survey<sup>34</sup>; General Self Efficacy Scale<sup>35</sup>); adherence to wearing compression (type, level, days/week wearing compression), leg elevation (how long, how often), ankle and calf exercise (how long, how often); and follow-up care and treatments. The questionnaires were completed on recruitment (healing), then at three, six, nine and 12 months after healing.

#### **Procedure**

Ethical approval for the study was obtained from the university and health services' Human Research Ethics Committees and all participants gave signed consent. All patients attending the identified leg ulcer clinics, diagnosed with a VLU and fitting the inclusion and exclusion criteria were eligible to participate in the study. Upon healing of their leg ulcer, all eligible patients were sent an information and consent package via post and invited to participate in the follow-up study. Participants were offered the opportunity to answer the survey via telephone or in person if preferred, or if disabilities made it difficult to fill in or return a postal survey. Two participants (2.5%) chose to answer the questionnaire via the telephone and one (1.2%) via email rather than filling out the form and posting it back, because of the convenience (n=2) or vision disabilities (n=1).

#### Data analysis

Data were analysed with IBM SPSS (Version 19.0, Armonk, NY). Descriptive statistics were calculated for all variables and repeated measures analysis of variance tests undertaken to identify factors associated with each outcome measure, that is, days/week wearing compression therapy; minutes/day leg elevation; and minutes/day of lower limb exercising. Multivariable repeated measures regression

modelling was used to control for potential confounders and identify the independent influence of variables on adherence to these three preventive strategies.

#### **RESULTS**

#### Sample characteristics

A sample of 80 participants was recruited, with an average age of 75 years (range 41–95 years). Just over half of the sample were female (58%), 52% were single or widowed, and 64% received an age or disability pension. The most frequent co-morbid conditions were hypertension (61%), osteoarthritis (41%) and cardiac disease (30%). The median duration of their recently healed VLU was 41 weeks (range 4–174), 36% of participants had experienced leg ulcers for longer than six years, and 24% of the sample had a history of a past deep vein thrombosis. Further details on health and demographic characteristics are reported in Finlayson *et al.*<sup>36</sup>. Almost half of the participants (44%) experienced an ulcer recurrence in the 12 months after healing, 21% (n=17) within the first three months of healing.

#### Adherence to strategies to prevent recurrence

Self-reported levels of adherence to compression therapy, leg elevation and lower limb exercising are shown in Table 1. There were significant



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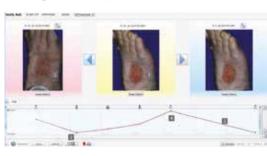








Table 1: Adherence to strategies to prevent ulcer recurrence in the first 12 months after healing

	Healed	Three months	Six months	Nine months	Twelve months
	Mean (SD)				
Days/week wearing compression hosiery	5.1 (2.53)	4.9 (2.75)	4.3 (2.93)	3.2 (2.99)	3.4 (2.93)
	Median (range)				
Minutes/day leg elevation	30.0 (0-120)	21.6 (0-120)	13.2 (0-120)	10.4 (0-105)	10.4 (0-120)
Minutes/day lower leg exercise	13.3 (0-60)	10.0 (0-120)	11.4 (0-120)	5.0 (0-90)	5.0 (0-60)

decreases in adherence to wearing compression (F=9.08, p<0.001), leg elevation (F=7.99, p<0.001), and lower leg exercising (F=4.07, p=0.010) over the 12 months after healing. When recruited (upon healing), 86% of participants also reported regular lower limb skin care (for example, moisturising and covering legs to protect them from trauma); however, this dropped to 14% by three months after healing and remained at this low level for the rest of the data collection points.

Repeated measures regression modelling was undertaken with factors potentially associated with adherence to the three strategies to prevent recurrence (in three separate models). Looking at adherence to wearing compression hosiery, a significant main effect of decreased adherence over time was maintained (F=4.53, p=0.006). Significant interaction effects were found between adherence to wearing compression hosiery and GDS scores (F=6.83, p<0.001); osteoarthritis (F=3.58, p=0.026); less than two follow-up visits/year for healed leg checks (F=2.83, p=0.043); and a history of more than one previous leg ulcer (F=2.92, p=0.04). Those who scored at higher risk for depression or had osteoarthritis were more likely to decrease the days/week wearing compression hosiery over time; while those who had a history of multiple previous leg ulcers, and those who attended a health service for at least two follow-up visits a year, were more likely to maintain their adherence to compression therapy over 12 months.

The regression model for adherence to regular leg elevation also found a significant main effect of decreased adherence over time (F=6.66, p=0.001). Significant interaction effects were found between decreasing time spent with legs elevated and higher GDS scores (F=5.03, p=0.004), less than two follow-up visits/year with a health professional (F=3.38, p=0.024), and deceased mobility, where decreased mobility was defined as requiring a physical aid to mobilise (F=3.24, p=0.045).

Undertaking regular calf muscle and ankle exercise was the activity least adhered to in this study. In the repeated measures regression model, a significant main effect of decreased time spent in exercise over time was maintained (F=3.96, p=0.023); however, the only factors found significantly related to decreasing exercise time over 12 months were decreased mobility (F=4.09, p=0.021) and the absence of a history of multiple previous leg ulcers (F=4.50, p=0.013).

#### **DISCUSSION**

Knowing the extensive costs and suffering associated with unhealed VLUs<sup>3,5</sup> and the high rates of ulcer recurrence in this population<sup>6,7</sup>, a greater emphasis on prevention of recurrence of VLUs is vital. The aim of this study was to identify any demographic, physical and/or psychosocial factors associated with long-term adherence to self-care strategies to prevent recurrence of VLUs, to obtain information which may guide effective plans for self-management of chronic venous insufficiency.

As expected, adherence to all three of the preventive strategies investigated in this study — wearing compression hosiery, leg elevation, and lower limb exercise — decreased over time, and levels of adherence to all strategies were well below recommendations, particularly after the first six months after healing. The findings on wearing compression are consistent with the literature on adherence to wearing compression garments<sup>15,16</sup> and reinforce the need to address some of the problems associated with compression hosiery. Levels of leg elevation and daily lower limb exercises are rarely reported in studies of ulcer recurrence<sup>37</sup>, although an earlier study also found low levels of uptake of these activities, with 44% of 122 participants regularly elevating their legs for at least 30 minutes/day, and only 35% reporting any lower leg exercises<sup>4</sup>.

An increased risk of depression was significantly associated with decreased adherence to both wearing compression hosiery and leg elevation over time. Although few studies have been done on self-management of chronic venous insufficiency to prevent ulcer recurrence, chronic disease management in other conditions is well researched and depression is a known influence on health-promoting and self-management behaviours<sup>25,26</sup>. Surprisingly, there were no relationships found with adherence to preventive activities and self-efficacy or social support, despite the links noted in the literature between increased prevalence of leg ulcers and poorer levels of social support were significantly correlated with the GDS scores (r=-0.38 and -0.42 respectively); however, when controlling for all variables in the regression models, only the GDS remained significantly associated with adherence.

Physical restrictions, whether the need to use an aid to walk, or the presence of osteoarthritis, were significantly associated with decreased adherence to all three preventive activities. The strength and dexterity required to don and remove compression hosiery has been previously reported as a barrier for their use, as many adults with VLUs are older, with multiple co-morbidities<sup>13</sup>. However, there are conflicting results on this topic reported in the literature; as large studies by Jull et al. 16 and Raju et al. 15 found this was not a significant influence on wearing compression. In this study sample, physical restrictions impacted on all three preventive activities (all of which require physical exertion or flexibility). This area could be investigated further in future studies, for example, to determine easy and effective strategies or programs for calf and ankle exercises for patients with physical disabilities. In addition, increased importance needs to be placed on gaining access to appropriate applicators and remover devices for compression hosiery, systems enabling easy application, and practical education for patients and their carers in their use.

Regular follow-up health service visits after healing (two or more per year, that is, at least six-monthly) were found to be associated with improved adherence to wearing compression hosiery and leg elevation. However, it is recognised that many health care systems do not support services for preventive care or management of peripheral vascular disease, despite evidence-based guidelines recommending regular follow-up care and patient education and support9. Health services for chronic leg ulcers are typically structured for provision of acute wound care, and there are many reports of difficulties of integration and coordination of chronic disease management services within health services designed for acute care<sup>22,23</sup>. In this sample, it appeared that patients learned through experience, as a history of more than one previous VLU was associated with improved adherence to compression therapy and lower leg exercises. This information suggests that health professionals may need to reinforce and/or repeat education on preventive strategies after each ulcer episode — an activity which would be facilitated through regular follow-up visits.

Results from this study provide important information for health professionals, patients and carers on areas to consider when developing a plan for prevention of recurrence of VLUs; and suggest there is a need for regular follow-up care with a focus on addressing individual physical and mental health needs, and improving self-management skills.

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