

# Monitoring patterns and quality of care for people diagnosed with venous leg ulcers: the argument for a national venous leg ulcer registry

Weller CD & Evans S

## ABSTRACT

Despite progress in the last two decades, chronic venous disease remains understudied and severely underestimated for its effect on public health. Venous leg ulcers (VLUs) are a common and costly problem worldwide. The burden of VLUs is expected to rise with an ageing population and the growing epidemic of diabetes and obesity, which coupled with chronic venous insufficiency (CVI) will reduce quality of life and increase health care costs. The main treatment for VLUs is a firm compression bandage to aid venous return. Variation in assessment, diagnosis and management of VLUs may mean delayed diagnosis, overuse of antibiotics and insufficient or inadequate use of compression therapy. Given the variation of care and the need to improve management of people with VLUs, there is an urgent need to develop and test clinical indicators to measure VLU outcomes. Significant variations predispose clinical practice that may not follow best practice guidelines. There is a need to monitor patterns and quality of care for people diagnosed with VLUs in Australia. The rationale for establishing a clinical quality registry is to improve quality and safety of care.

*Keywords: venous leg ulcers, quality of care, clinical registries.*

## BACKGROUND

Despite impressive progress in the last two decades, chronic venous disease remains understudied and severely underestimated for its effect on public health. People with chronic venous insufficiency (CVI) are prone to developing venous leg ulcers on lower limbs that can occur spontaneously or after minor trauma. Underlying CVI pathophysiology causes healing to be protracted and recurrence is

common<sup>1</sup>. Venous leg ulcers (VLUs) occur as a result of chronic venous insufficiency, which causes a functional disorder of the venous system in the lower limbs. This impairment, which has been shown to damage superficial, deep or perforator veins (or all three), can cause increased venous pressure. Chronic venous hypertension leads to an inflammatory response by leucocytes that cause cellular and tissue dysfunction in vascular changes, (manifested initially as varicose veins) and dermal changes such as oedema, hyperpigmentation, venous eczema, lipodermatosclerosis and ulceration<sup>2,3</sup>.

Venous leg ulcers are a common and costly problem worldwide<sup>4</sup>. In Australia an estimated 400,000 Australians suffer from chronic wounds, which in 2010 translated into costs of almost \$3 billion per year<sup>5</sup>. VLUs are a common chronic wound problem managed in many general practice, hospital outpatients and community settings with large variation in treatment and effectiveness<sup>6</sup>. People with CVI are prone to developing VLUs on ankles and lower legs. These ulcers are often painful and heavily exudating and due to underlying pathophysiology, healing is often protracted and ulcer recurrence common<sup>1</sup>. The natural history is a cycle of healing and recurrence<sup>7</sup> which has considerable impact on health, quality of life and socio-economic costs<sup>8</sup>.

The burden of VLUs is expected to rise with an ageing population and the growing epidemic of diabetes and obesity, which coupled with CVI will reduce quality of life and increase health care costs<sup>6</sup>. The main treatment for VLUs is a firm compression bandage to aid venous

**Dr Carolina D Weller\***

PhD

NHMRC Postdoctoral Research Fellow, Senior Research Fellow, Department of Epidemiology & Preventive Medicine, School of Public Health & Preventive Medicine, Level 6, The Alfred Centre, 99 Commercial Road, Melbourne VIC 3004

Email: carolina.weller@monash.edu

**Dr Sue Evans**

PhD

Head, Clinical Registry Unit, School of Public Health and Preventive Medicine, Monash University, Level 6 Alfred Centre, Melbourne 3004

\*Corresponding author

return<sup>9,10</sup>. Compression assists by reducing venous hypertension, enhancing venous return and reducing peripheral oedema<sup>11</sup>. Up to 70% of people with VLUs will experience ulcer recurrence after healing<sup>12</sup>. It has been reported that up to a third of affected individuals will experience more than 10 episodes of ulceration in a lifetime, which will further increase health care costs<sup>13,14</sup>.

### EPIDEMIOLOGY AND BURDEN OF VLUs

The prevalence and costs of chronic VLUs in Australia are increasing. Age-related venous leg ulceration is the most common cause of lower limb wound in the western world, with prevalence estimated to be between 1.65% to 1.74%, and more common in adults aged 65 and older, a population expected to grow substantially in the next several decades<sup>15</sup>.

The Australian Diabetes, Obesity and Lifestyle study reports the prevalence of obesity among individuals with secondary level educational attainment is estimated to increase from 23% in 2000 to 44% in 2025. Among individuals with a degree qualification or higher, it will increase from 14% to 30%. Increasing levels of obesity over recent decades had expected to lead to an epidemic of diabetes and a subsequent reduction in life expectancy, but instead all-cause and cardiovascular-specific mortality rates have decreased steadily in most developed countries and life expectancy has increased<sup>16-18</sup>.

Estimated increase in life expectancy will mean more people will be living with VLUs by 2025. Adults over 70 years of age represent the fastest growing segment of the Australian population and retaining health, mobility and independence at this age has become a major goal of preventive medicine<sup>19-21</sup>.

### MANAGEMENT OF VLUs

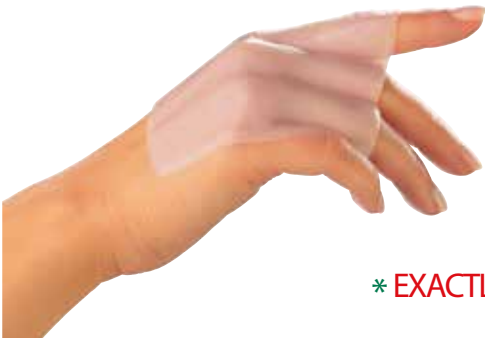
Evidence suggests VLUs heal more quickly with compression than without and that multi-component compression systems are more effective than single-layer compression<sup>22-25</sup>.

The main treatment for a VLU is a firm compression bandage to aid venous return<sup>9,10</sup>. It assists by reducing venous hypertension, enhancing venous return and reducing peripheral oedema<sup>11</sup>. When provided in a multidisciplinary clinic, compression has been shown to heal more than 50% of VLUs in 12 weeks<sup>26</sup> and another Australian study reported healing in up to 80% of VLU in 24 weeks<sup>27</sup>. Surgical removal of superficial and/or perforating veins or blocking incompetent veins by injecting an irritant solution (sclerotherapy) has been reported to aid VLU healing but not all patients are suitable for, or agree to venous surgery and surgery on deep veins is experimental and currently underevaluated<sup>11,28</sup>. One in three CVI-affected individuals experience more than 10 episodes of ulceration in a lifetime. This causes pain, poor quality of life (QoL) and increases health costs<sup>13,14,29</sup>.

When balance is everything....



Suprasorb® X



Professionals, like you, know the 1st PRINCIPLE of healing wounds is a MOIST environment

Modern technology brings significant development to moisture management, in EVERY part of the wound with Suprasorb® X

RELEASES AND ABSORBS MOISTURE, AS NECESSARY

- \* EXACTLY AS REQUIRED \* INDEPENDENTLY \* SIMULTANEOUSLY



Sentry Medical Pty Ltd 22 Peter Brock Drive, Eastern Creek NSW 2766 P: 1300 995 999 F: 1300 995 998 W: www.sentrymedical.com.au

Working in partnership with



There are many challenges to healing people with venous leg ulcers (Table 1) but this alone is not the main issue. There is an imperative to gain a better understanding of the disease process and natural history. Sweden has demonstrated increased promotion of evidence-based practice guidelines can impact on healing rates and ulcer recurrence<sup>30</sup>. Education of both frontline clinicians about the importance of VLU prevention as well as a public education campaign would go some way to improving the situation. However, changing health services to improve outcomes will require extensive infrastructure, costing time and money. It could be perceived as a major challenge to a large health care delivery system or it could be seen as an opportunity to make a major difference to improving quality care of people who suffer from CVI and active ulceration. Sweden has shown the way and demonstrated the improvement from a quality registry in leg ulcers in healing rates and improved QoL and also in economic terms. Management of people with a VLU has been found to be lacking due to treatment inconsistency<sup>27,31</sup> and limited patient adherence to compression therapy<sup>6,32</sup>. Individuals with a VLU will continue to experience more episodes of ulceration with recurrence rates estimated up to 80%<sup>33</sup> and most ulcers recurring within three months of healing<sup>7</sup>.

Table 1: Challenges to healing

Patient factors	Comorbidities e.g. diabetes, obesity Socioeconomic Adherence to compression therapy
Wound factors	Ulcer size and duration Wound bed condition
Resource factors	Access to right care at the right time Reimbursement variability Cost of compression
Health care related factors	Clinical knowledge and skill variation Treatment by numerous practitioners No standardisation of venous diagnosis No standardisation of definitive treatment No national standard to monitor patterns and quality of care to measure outcomes

## VARIATION IN MANAGEMENT OF VLUs

Variation in assessment, diagnosis and management of VLUs may mean delayed diagnosis, overuse of antibiotics and insufficient or inadequate use of compression therapy<sup>31,34</sup>. Clinician knowledge of best practice has been reported as lacking, and compression application has been shown to be varied and at times omitted if the Ankle-Brachial Pressure Index (ABPI) is unknown or is not able to be measured in the clinical setting<sup>24,25</sup>.

Studies in Denmark and Ireland found that only about half of patients with leg ulcers had undergone investigations to determine aetiology<sup>35</sup> and only 40% of patients with VLUs had been treated with compression. In Scandinavia, researchers reported that clinical setting; diagnosis and treatment of VLUs can vary considerably from

patient to patient<sup>36</sup>. An audit in England in 2005 found that 26% of leg and foot wounds had no definite diagnosis<sup>37</sup>. Without a definitive diagnosis, the true prevalence of venous disease is unknown and by extension the burden on the health system and society is not documented in Australia. In addition, it has been reported that nurses who manage people with VLUs demonstrate a lack of understanding about the key concepts underlying compression therapy<sup>31,38,39</sup>.

Best practice VLU guidelines are available to help guide clinical practice<sup>6,40,41</sup> although uptake of these guidelines is inconsistent<sup>25</sup>. Given the variation of care and the need to improve management of people with VLUs, there is an urgent need to develop and test clinical indicators to measure VLU outcomes. Significant variations predispose clinical practice that may not follow best practice guidelines. There is a need to monitor patterns and quality of care for people diagnosed with VLUs in Australia.

## WHY ESTABLISH A NATIONAL VLU REGISTRY?

Clinical quality registries systematically collect health-related information on individuals who are: (a) treated with a particular surgical procedure, device or drug (for example, joint replacement); (b) diagnosed with a particular illness (for example, stroke); or (c) managed by a specific health care resource (for example, treated in an intensive care unit)<sup>42</sup>.

Information in clinical quality registries is captured on an ongoing basis from a defined population. The standardised set of information may be extracted from existing databases such as pathology, radiology or administrative systems, or it may need to be purposefully collected from medical records or directly from clinical staff using data-collection forms. The data are pooled at a central location, typically in a government, academic or research institute, and analysed to provide information about processes or outcomes of care.

The principal rationale for establishing a clinical quality registry is to improve quality and safety of care. Feedback is provided to participating health care settings and clinical staff to enable them to benchmark the outcomes of their treatment or their patterns of practice (after risk adjustment) to other Australian and international units<sup>42</sup>.

The value of clinical registries as cost-effective tools has been explored and reported<sup>43</sup>. Larsson *et al.* analysed data from 13 disease registries in Australia, Denmark, Sweden, the United Kingdom and the United States and concluded that making health outcome data transparent to both the practitioners and the public can result in considerable cost savings to the health system. They found that for every dollar invested in registries, the return in terms of reduced direct health care costs could be as high as one hundredfold<sup>43</sup>.

Other registries have demonstrated that monitoring activity improves compliance with quality indicators. The American Heart Association and the American Stroke Association have supported development of registries to monitor compliance with guidelines in patients suffering stroke, heart disease, heart failure and cardiac arrest<sup>44</sup>. The stroke registry has reported a ninefold improvement in compliance with

guidelines and a highly significant improvement in equality of care over the six-year period it covers. The four registries have among them produced more than 200 published articles in peer-reviewed journals. They have identified areas of concern; driven improvement in measurement, guidelines and implementation strategies; reduced inequalities; and determined the safety and effectiveness of therapies applied in routine practice.

The expansion of clinical registries is a development common to most advanced health care systems. Sweden was one of the first to develop a coordinated approach for establishing clinical registries. More than 70 registers have been established in Sweden to monitor the quality of care<sup>45</sup>. While each registry operates as an independent database, they all use common operating principles. In the UK there are more than 50 clinical registries (<http://www.hqip.org.uk/assets/Core-Team/Directory-of-Clinical-Databases-and-Registers-JANUARY-2014.pdf>). More recently the US has recognised the importance of clinical registries, stating “Clinical registries provide the optimal foundation upon which to base many important elements of US health reform”<sup>46</sup>.

A VLU registry can identify where variation exists in the management of venous ulcers, and will quantify the human and economic impact of that variation. It will monitor whether evidence-based practice is being delivered and the effectiveness of strategies to improve practice. Quality indicators fed back to health care institutions will, among other things, examine the extent to which healing time and recurrence varies according to patient and health service-related factors.

In the United States a wound registry collects three quality indicators specifically to monitor the quality of VLU care: (1) whether adequate compression has been provided at each visit; (2) healing or closure rates; and (3) whether a plan of care has been developed for ulcers not achieving 30% closure at four weeks. (The US Wound Registry 2014 at <http://www.uswoundregistry.com/Specifications.aspx>).

Given the recent Australian study highlighting deficits in knowledge of appropriate VLU assessment and when to refer patients with non-healing ulcers for specialist review, quality indicators monitoring whether ABPI is used and referral practice may also be appropriate quality indicators<sup>31</sup>.

In Australia, our poor understanding of key concepts of best practice treatment, inadequate understanding of the extent of clinical care delivered, and lack of economic evaluation identifying the impact on the health system and society as a whole, leaves an information vacuum for policy decision-makers when allocating resources. Through improved capacity to measure, a VLU registry will help us monitor and ultimately improve quality of care.

## REFERENCES

1. Donnelly R & London N, eds. *ABC of arterial and venous disease*. 2nd ed. Chichester, UK; Hoboken, NJ: Wiley-Blackwell/BMJ; 2009.
2. Bergan JJ & Shortell CK, eds. *Venous Ulcers*. Elsevier Academic Press; 2007.
3. Bergan JJ, Schmid-Schonbein GW, Coleridge Smith PD, Nicolaidis AN, Boisseau MR & Eklof B. *Chronic venous disease*. *Minerva Cardioangiolog* 2007; 55:459–76.
4. Weller C, Ademi Z, Makarounas-Kirchmann K & Stoelwinder J. Economic evaluation of compression therapy in venous leg ulcer randomised controlled trials: A systematic review. *Wound Practice & Research* 2012; 20:21.
5. Australian and New Zealand clinical practice guideline for prevention and management of venous leg ulcers. Australia: Cambridge Publishing; 2011.
6. Weller C & Evans S. Venous leg ulcer management in general practice — practice nurses and evidence-based guidelines. *Aust Fam Physician* 2012; 41:331–7.
7. Moffatt C, Martin R & Smithdale R. *Leg Ulcer Management*. Oxford: Blackwell Publishing; 2007.
8. Gottrup F, Apelqvist J & Price P. Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care* 2010; 19:237–68.
9. Grey JE, Harding KG & Enoch S. Venous and arterial leg ulcers. *BMJ* 2006; 332:347–50.
10. Iglesias C, Nelson EA, Cullum NA & Torgerson DJ. VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. *Health Technol Assess* 2004; 8:iii:1–105.
11. Weller C. Compression improves healing of venous leg ulcers compared to no compression, with differences between different compression systems. *Evid Based Nurs* 2013; 16:94.
12. Weller CD, Evans SM, Staples MP, Aldons P & McNeil JJ. Randomized clinical trial of three-layer tubular bandaging system for venous leg ulcers. *Wound Repair Regen* 2012; 20:822–9.
13. Price PE & Harding KG. Acute and chronic wounds: differences in self-reported health-related quality of life. *J Wound Care* 2000; 9:93–5.
14. Van Hecke A, Grypdonck M & Defloor T. A review of why patients with leg ulcers do not adhere to treatment. *J Clin Nurs* 2009; 18:337–49.
15. Passman MA, Elias S, Gloviczki M *et al*. Non-medical initiatives to decrease venous ulcers prevalence. *J Vasc Surg* 2010; 52:29S–36S.
16. Walls HL, Backholer K, Proietto J & McNeil JJ. Obesity and trends in life expectancy. *J Obes* 2012; 107989.
17. Backholer K, Wong E, Freak-Poli R, Walls HL & Peeters A. Increasing body weight and risk of limitations in activities of daily living: a systematic review and meta-analysis. *Obes Rev* 2012; 13:456–68.
18. Backholer K, Mannan HR, Magliano DJ *et al*. Projected socioeconomic disparities in the prevalence of obesity among Australian adults. *Aust N Z J Public Health* 2012; 36:557–63.
19. Diabetes prevalence in Australia: an assessment of national data sources. Australian Institute of Health and Welfare, Canberra: AIHW 2009; Diabetes series no. 12.
20. Australian Institute of Health and Welfare. Diabetes prevalence in Australia: an assessment of national data sources. In: AIHW, ed. Canberra: 2009.
21. Economic implications of an ageing Australia: Productivity Commission research report. Canberra; 2005.
22. O'Meara S, Cullum N, Nelson EA & Dumville JC. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2012; 11:CD000265.
23. O'Meara S, Cullum NA & Nelson EA. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2009; CD000265.
24. Weller CD. Compression improves healing of venous leg ulcers compared with no compression, with differences between different compression systems. *Evid Based Nurs* 2013.
25. Weller C. Evidence and clinical decision-making In: Flanagan M, ed. *Wound healing and skin integrity: principles and practice*. Chichester, West Sussex, UK; Oxford, UK; Ames, Iowa, USA: John Wiley & Sons, Ltd; 2013, xiii, 298 pages.
26. Weller CD, Evans SM, Staples MP, Aldons P & McNeil JJ. Randomized clinical trial of three-layer tubular bandaging system for venous leg ulcers. *Wound Repair Regen* 2012.



27. Edwards H, Finlayson K, Courtney M, Graves N, Gibb M & Parker C. Health service pathways for patients with chronic leg ulcers: identifying effective pathways for facilitation of evidence-based wound care. *BMC Health Serv Res* 2013; 13:86.
28. Schulz KF & Grimes DA. Multiplicity in randomised trials I: endpoints and treatments. *Lancet* 2005; 365:1591–5.
29. Hjort A & Gottrup F. Cost of wound treatment to increase significantly in Denmark over the next decade. *J Wound Care* 2010; 19:173–84.
30. Öien RF & Forssell HW. Ulcer healing time and antibiotic treatment before and after the introduction of the Registry of Ulcer Treatment: an improvement project in a national quality registry in Sweden. *BMJ open* 2013; 3:e003091.
31. Weller C & Evans S. Venous leg ulcer management in general practice — practice nurses and evidence-based guidelines. *Aust Fam Physician* 2012; 41:331–7.
32. Weller CD, Buchbinder R & Johnston RV. Interventions for helping people adhere to compression treatments for venous leg ulceration. *Cochrane Database Syst Rev* 2013; 9:CD008378.
33. Abbade LP & Lastoria S. Venous ulcer: epidemiology, pathophysiology, diagnosis and treatment. *Int J Dermatol* 2005; 44:449–56.
34. Moffatt C, Kommala D, Dourdin N & Choe Y. Venous leg ulcers: patient concordance with compression therapy and its impact on healing and prevention of recurrence. *Int Wound J* 2009; 6:386–93.
35. O'Brien JE, Grace PA, Perry IJ & Burke PE. Prevalence and aetiology of leg ulcers in Ireland. *Ir J Med Sci* 2000; 169:110–2.
36. Kjaer ML, Mainz J, Soerensen LT, Karlsmark T & Gottrup F. Clinical quality indicators of venous leg ulcers: development, feasibility, and reliability. *Ostomy Wound Manage* 2005; 51:64–6, 8–72, 4.
37. Drew P, Posnett J, Rusling L & Wound Care Audit T. The cost of wound care for a local population in England. *Int Wound J* 2007; 4:149–55.
38. Barrett S, Cassidy I & Graham MM. National survey of Irish community nurses leg ulcer management practices and knowledge. *J Wound Care* 2009; 18:181–2, 4, 6 passim.
39. Annells M, O'Neill J & Flowers C. Compression bandaging for venous leg ulcers: the essentialness of a willing patient. *J Clin Nurs* 2008; 17:350–9.
40. Scottish Intercollegiate Guidelines Network (SIGN) 120 — National clinical guidelines for management of chronic venous leg ulcers. NHS Quality Improvement Scotland; SIGN 2010.
41. Ulcer and Wound management Expert Group. Therapeutic Guidelines: ulcer and wound management Melbourne Therapeutic Guidelines Limited; 2012.
42. McNeil JJ, Evans SM, Johnson NP & Cameron PA. Clinical-quality registries: their role in quality improvement. *Med J Aust* 2010; 192:244–5.
43. Larrson S, Lawyer P, Garelick G, Lindahl B & Lundstrom M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. *Health Affairs* 2012; DOI: 10.1377/hlthaff.2011.0762.
44. Ellrodt AG, Fonarow GC, Schwamm LH *et al.* Synthesizing lessons learned from get with the guidelines: the value of disease-based registries in improving quality and outcomes. *Circulation*; 2013 128:2447–60.
45. Sweden. E. Handbook for Establishing Quality Registries. Sweden; 2005.
46. Jain SH, Conway PH & Berwick DM. A public-private strategy to advance the use of clinical registries. *Anesthesiology* 2012; 117:227–9.

## In the battle against biofilms, IODOSORB<sup>◊</sup> gets the job done.



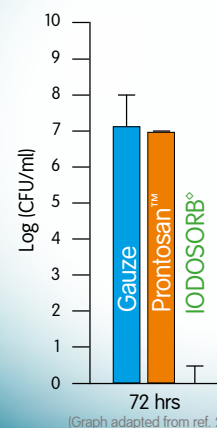
- Following debridement, biofilms can return in as little as 3 days without active intervention.<sup>1</sup>
- In a recent study, IODOSORB<sup>◊</sup> was the only topical dressing capable of completely killing biofilm bacteria.<sup>2</sup>
- The significantly improved efficacy provided by IODOSORB<sup>◊</sup> may be attributed to the CADEXOMER iodine formulation which results in a sustained release that maintains iodine availability.<sup>2</sup>

IODOSORB<sup>◊</sup> – powered by CADEXOMER.

Indicated for the treatment and healing of chronic ulcers.

Australia: T 13 13 60 [www.smith-nephew.com.au/healthcare](http://www.smith-nephew.com.au/healthcare)  
New Zealand: T 0800 807 663 [www.smith-nephew.com/nz](http://www.smith-nephew.com/nz)

Bacterial biofilm detected after 72hrs<sup>2</sup>



References 1. Wolcott RD, et al. Biofilm maturity studies indicate sharp debridement opens a time-dependent therapeutic window. *J Wound Care* 2010; 19: 320–328.  
2. Phillips PL, et al. Antimicrobial dressing efficacy against mature *Pseudomonas aeruginosa* biofilm on porcine skin explants. *Int Wound J* 2013; doi:10.1111/iwj.12142.

© Smith & Nephew. Trademark of Smith & Nephew SNT1042 (10/13)