Preventing venous leg ulcer recurrence: a review

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Abstract

Preventing venous leg ulcer recurrence is of prime importance to the individuals who live with these wounds and the health care providers participating in their care. Though the manifestation of these wounds is well understood, there are gaps in current understandings of how to prevent them. A survey of advanced clinical nurses in a Victorian home nursing service found a range of preventative practices employed and a subsequent review of the literature identified diverse approaches to the prevention of venous leg ulcer recurrence. The results from this survey and the accompanying review are of interest to multidisciplinary wound management practitioners who seek to promote best practice in this area of wound care.

Introduction

Managing venous leg ulcers presents challenges to the individuals who live with them and the healthcare providers participating in their care. Adding to the burden of every venous leg ulcer is the risk that it will recur after it has healed, an outcome which represents personal, social, financial and psychological costs to the individual and further economic burden to healthcare providers and the healthcare systems which support them.

Yet the manifestation of these wounds is well understood, there are gaps in current understandings of how to prevent them. For example, the most effective way to maintain skin integrity is unclear, how soon maintenance therapies should commence has not been established and the best way to ensure adherence to recommendations for successful maintenance has not been proven.

A survey of advanced clinical nurses undertaken in a Victorian home nursing service in 2007 found a range of practices employed for the management of clients post healing. The reality that domiciliary nurses frequently care for people

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with venous ulcers and are often charged with planning the post healing phase, established the imperative to identify best practice in post healing leg ulcer care. A review of the literature identified diverse approaches to the prevention of venous leg ulcers and recurrence. The recommendations arising from this review are of interest to a multidisciplinary wound management audience who are frequently charged with the care of people with venous ulcers but have ongoing frustration around ulcer recurrence and the associated implications.

Method

A database review of literature published during the last 10 years was commenced in June 2007 and included the Cumulative Index to Nursing and Allied Health Literature, Medline, The Joanna Briggs Institute database and the Cochrane Collaboration Database of Systematic Reviews. The local librarian undertook a double check of the search strategy and search terms – leg ulcer, venous ulcer, recurrence, healed, prevention, compression therapy, compression stockings and evidence-based practice. The Cochrane Collaboration revealed one systematic review of treatment of venous leg ulcers and one of prevention of recurrence of venous leg ulcers (both published more than 10 years ago). A World Wide Web based search was also undertaken. A repeat of the search strategy was conducted in February 2008.

Literature review results

Defining venous leg ulceration

The leg ulcer may be defined as a "loss of skin on the leg or foot which takes more than six weeks to heal" ¹. However, definitions differ and may for example exclude the foot and areas above the knee. Leg ulcers develop when there is an interference with normal healing processes; in the case of the

venous leg ulcer, the causative condition is chronic venous insufficiency ². There are also many other medical conditions which may be associated with and then complicate venous leg ulcers including diabetes, malignancy and connective tissue disorders ³. The lower leg ulcer is a common skin condition among aged persons who have multiple chronic health conditions but may also affect younger persons who do not.

Prevalence of venous leg ulcers

Leg ulcers are a sizable health concern. In a systematic review in 2003, global prevalence of leg ulceration was suggested to be 0.1-1.1% ⁴. In Australia, leg ulcers are estimated to affect up to 3.0 per thousand of our adult population ⁵. In a Victorian domiciliary nursing environment in 2004, over 3500 clients received care for leg ulceration ⁶ and in 2006/2007 the size of this group of clients had grown to nearly 5000 ⁷. Research from 10 years ago reported that leg ulcers were most commonly the result of venous disease ^{8,9}; a decade later this is still thought to be the case as large, more recent research has not been reported.

Available prevalence data is difficult to consolidate as existing studies lack methodological uniformity ¹⁰. Inconsistent definition of the venous ulcer and a lack of clinical or diagnostic validation of diagnosis have been identified as major limitations of current research ⁴. These shortcomings make it particularly difficult to compare research results and restrict the ability to combine studies for meta-analysis ¹¹. A further limitation is related to diagnostic reporting systems. Not all healthcare providers are required to utilise International Classification of Diseases reporting in Australia. This results in some care providers collecting diagnosis data and others not.

Definition of recurrence of leg ulcers

Defining recurrence of leg ulceration has not yet been approached in a standardised manner. Of two studies reviewed for a Cochrane Collaboration systematic review in 2000, one did not provide a definition of recurrence and the other defined recurrence as a break in the skin lasting for 6 weeks ¹². Factors not reported include whether or not the recurrent ulcer was in the same anatomical location as the previous one, and the time transpired between healing and re-wounding. In the absence of clear criteria, the accuracy of definition of recurrence may be questioned.

Rate of recurrence of venous leg ulcers

It is a common reality that, for many people, their venous leg ulcer will recur. Therefore, as venous leg ulcer management improves, it is logical to suggest that there are more healed persons at risk of recurrence. In the United Kingdom in 1985, it was reported that around 50% of venous leg ulcers were likely to recur (and within 3 months of healing) ¹³. In 1995 a comparison of several studies from different care settings in the United Kingdom found leg ulcer recurrence rates ranged from 22-69% ¹⁴. More recently, recurrence rates for venous ulcers were reported to range from 26-69% at 12 months ¹.

In another study reported in 2006, several pertinent findings were published – recurrence was found to be 70%, and the majority of recurrences occurred within 3 months of healing. Twenty eight percent experienced more than 10 episodes of ulceration and, among those who were noted to be noncompliant with compression stockings, all were noted to have had a recurrence within 36 months ¹¹. A variation in the length of time of monitoring after healing was noted across prevalence studies; the two Cochrane studies reported rates at 12-18 months ¹⁵ and 60 months ¹⁶, and another study considered as far as 7 years post healing ⁸.

Managing venous ulcer recurrence

Many of the management principles applied during the time the person is wounded are also integral to the success of the maintenance or post healing phase as venous hypertension persists and requires ongoing management. Graduated compression therapy is the gold standard in venous leg ulcer management 10 - it is usually graduated compression which is required after healing to prevent the ulcer from returning or a new area of ulceration developing. Invasive corrective therapies to address vein incompetence may also be considered 17. The ideal 'intervention' would identify risk and progress to strategies to prevent initial wounding. However, the challenge is to identify people who will likely ulcerate in the absence of overt signs of venous hypertension, and the clinical and cost effectiveness of such a risk screening programme and client implications have not been established.

In addition, the status of lower limb circulation is not static and may change during the time the individual requires maintenance therapy. Management of a limb post healing requires re-assessment of contributing factors that may generate risk of recurrence as well as assessment of barriers to adherence to maintenance therapies. Re-assessment of circulation needs to consider a range of clinical factors, including the measurement of ankle brachial pressure index (ABPI) ¹⁸.

Client knowledge and understanding of venous disease are important factors in the success of the maintenance phase ^{8,19}. There is a need for appreciation by the person that they have a lifetime condition and accompanying risk of recurrence post healing. Without this, the expectation that an individual will

both understand and contribute to a lifetime commitment to maintenance strategies is likely to be unrealistic ¹¹. Adequate education which sets expectations and prepares the person for what is required for self care is therefore imperative. It is logical that the earlier this commences, the better likelihood of the person taking ownership of their condition, acknowledging their responsibility to its management and promoting participation in their own care. Such strategy has not yet been evaluated.

Compression stockings, or what may also be referred to as maintenance stockings or hosiery, are the conservative intervention of choice for management of venous hypertension both in the absence of wounding and post healing of venous leg ulceration. These are material garments made from varying compositions of cotton, elastane, nylon and lycra. As is the case with compression bandaging, this therapy manages but does not change the underlying conditions which predispose the person to leg ulceration or recurrence. Compression stockings may be thigh length, below knee, tights or sock style and may be made to measure or purchased in standard sizing. Typically, there is a range of colours and the choice of an open or closed toe. These garments exert pressure which supports venous return ²⁰.

Compression stocking choice may be influenced by a range of factors such as the preference of the client and prescriber, cost and limb shape. Appropriate fitting and application is critical to ensure the stocking provides adequate compression and is worn safely, without risk of injury to the skin ²¹. Compression stockings are typically applied first thing in the morning upon getting out of bed (to avoid the development of any oedema prior to application) and removed upon retiring to bed at night.

There has been substantial research which considers the efficacy of compression stockings in the maintenance of people with healed leg ulcers. Notable early research originates from the Riverside Community Leg Ulcer Project, set up as part of a preventative programme for patients with healed ulcers; this incorporated a district-wide leg ulcer service developed within the vascular service of an acute care hospital in the United Kingdom ¹⁴. A randomised trial was undertaken within this project in 1994 to consider the recurrence rate of persons with healed leg ulcers (normal ABPI) when wearing one of two compression stockings both reported to deliver 23mmHg compression at the ankle. Three-monthly visits were attended for 18 months, during which time participants were assessed and re-measured for new stockings. The incidence of recurrence at 18 months was







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similar (and not significantly different) for both groups (24% and 33%), with those unable to wear the prescribed stockings reported to have considerably higher recurrence rates than those adhering to the randomised treatment ¹⁴. This research did not include a control group.

The Cochrane Collaboration systematic review *Compression* for preventing recurrence of venous leg ulcers, undertaken in 2000, found that only two studies met their inclusion criteria ¹². In the first, a community based study in 1995, 166 participants were randomised to one of two compression stockings reported to deliver 23mmHg (Class 2). Recurrence rates were 21% and 34% at 18 months, with no statistically significant difference detected ¹⁵. The second study included in the systematic review was hospital based, with 300 participants randomised to either 18-24mmHg or 25-32mmHg (Class 2 or Class 3 respectively) compression stockings.

In the trial, more than one third of the participants were found to be non-compliant with the intervention, mostly participants who had been randomised to the higher compression treatment. Intention to treat analysis found recurrence rates at 60 months were 39% and 32% respectively, also not statistically significant ¹⁶. Efficacy subset analysis was not reported. The review concluded that there is no rigorous evidence to suggest that compression stockings effectively prevent or delay recurrence of venous leg ulcers and that a limitation of available research is that there is "a lack of evidence of benefit, rather than evidence of lack of benefit" ¹².

The implications for practice noted in the review are therefore based on circumstantial rather than empirical evidence that poor adherence to compression stocking use is associated with high recurrence rates. A limitation of the studies is that they did not employ a control group. It is noted, however, that it would be unethical to now undertake randomised controlled trials which allocated participants to no compression treatment. Therefore it remains unclear as to whether high or moderate levels of compression are better. What is known and accepted is that compliance with compression stockings appears to be poorer with higher compression levels and that the person should wear the highest level of compression they can tolerate and manage ¹².

Exactly when is the best time to commence compression stockings for maintenance post healing has also not been specifically addressed in the literature or in any published guidelines. It is generally accepted that it takes several months or more to increase the tensile strength of a newly healed wound and, even then, only around 80% of normal strength is likely to be regained ²². However, the question that remains unanswered is, in the absence of oedema, when is it time to cease bandaging and commence maintenance stockings?

Stocking aids or donners may be used to assist with application and removal of compression stockings. When the person is applying their own stocking, these appliances may reduce physical exertion, which is of benefit to those with limited strength, poor manual dexterity, poor hip flexion or inability to reach the feet. For the professional care giver, stocking aids may reduce the physical effort required during application and removal and prevent associated injury, an important factor for consideration when deciding how to protect the occupational health and safety of the relevant workforce and the informal care giver. A small exploratory study undertaken in 2005 identified a range of factors which affect the suitability of hosiery aids, including the type of hosiery worn and limitations of the user. It was recommended that further research is required to identify which aid or donner best suits the individual or individual characteristics 23.

A range of additional interventions are beneficial in maintaining skin integrity during the maintenance phase. An effective skin care programme which promotes normal skin pH is valuable, and using soap substitutes or cleansing agents may be advantageous. Dry, rough skin is more likely to be breached than supple skin, therefore skin moisturisers should be used regularly ²⁴. For very dry and scaly skin, such as is frequently the case in limbs compromised by varicose eczema, an oil or emollient-based moisturiser is more effective than a cream or lotion. Radiant heat will dry the skin, therefore individuals prone to leg ulceration should refrain from sitting too close to heat sources ²⁵. Movement, exercise and elevation contribute the same positive benefit as they do during active ulceration.

Less conservative measures which may be employed during the maintenance phase include medical and surgical interventions; these are also considerations during the wounded phase. However, surgical options such as perforating vein surgery ¹⁷, though emphasised in wound management literature, may be less appropriate for the older person with co-morbidities. This may explain why this intervention appears to be less common in the elderly.

Early reporting of any concern with skin integrity is important. The Royal College of Nursing in the United Kingdom suggests immediate referral is essential if recurrence presents and the more quickly a person receives multi layer compression bandaging after the recurrence, the shorter the time to healing ²⁶. However, sufficient understanding of the importance of accessing healthcare early to avoid the implications of long term ulceration must be established – this has implications for self management education during the healing phase.

Setting of care

Leg ulcer management is usually provided by community based services or through outpatient settings within the acute care system. Frequently, care is provided by domiciliary nursing care providers in consultation with general practitioners. The general practitioner is the most frequent referrer of lower leg ulcer clients to Victoria's largest home nursing organisation; this organisation provides more wound care than any other type of care, the majority of visits being to clients with lower leg ulcers 6. There is a strong case for community based care for persons living at home requiring leg ulcer management, especially for those with limited ability to access other services. Home based nursing care has significant advantages over in-patient care which is known to be a more costly and less effective alternative ²⁷. People with uncomplicated leg ulcers should rarely require or utilise inpatient facilities on account of their ulcer.

It is important to note that there is a growing body of evidence that demonstrates the benefits and efficiencies of alternative models of community nursing care; this may also include clinics. A recent randomised controlled trial undertaken in Canada compared the effectiveness and efficiency of providing nursing care in a clinic model as compared to

nursing care in the home setting. The clinic care was found to be as effective as the home based care, visit times were found to be shorter (with travel time for the home visiting nurse the major factor contributing to the time difference) and less staff were required to service the clinic model clients. Furthermore, client satisfaction was greater in the clinic group and, overall, healthcare costs were higher in the at-home group 28.

Models of care utilising nurse clinics which are specifically targeted to wound management also demonstrate promise 29-32. In Australia, it is suggested that nurse led wound clinics can be a valuable adjunct to domiciliary nursing services 33. More specifically, models of nurse led clinics which target leg ulcer clients, such as the Leg Ulcer Club first developed by Lindsay, have demonstrated improved healing 34 and cost effectiveness 35.

Given the proven benefits of clinic based care, it is not surprising that successful management of the maintenance phase has also found favour in this setting. Nurse led 'healed' leg ulcer clinics are reported to be effective in reducing the recurrence of ulceration 20, 29, 36 and have demonstrated cost effectiveness in terms of staffing requirements 37. Leg ulcer clinics that prevent recurrence for just 1 month are suggested to save up to 8% of home nursing time and associated costs 38. Focus group research and interviews undertaken with participants



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of a community based monthly support group in the United Kingdom for persons with healed leg ulcers supported these positive findings³⁹.

Whilst clinic models are noted to have significant advantages, there are also limitations and barriers to the successful implementation of this model of care. Clinics require planning, resourcing, staffing and evaluation ⁴⁰. Clinics need to be placed in appropriate locations, and be convenient and accessible to clients. There may be an added challenge for the domiciliary care provider whose clients know and expect care provided in the home setting.

Clinician survey results

Ten clinical nurse consultants practising within a Victorian based home nursing organisation were invited to participate in a short survey in October 2007 which considered the use of compression stockings for the management of healed leg ulcers. Eight consultants chose to participate in the survey. The aim of the survey was to ascertain the practices and clinical opinions of advanced practising wound management nurses to complement planning for an upcoming research project at the same site which considers best practice management of healed leg ulcers.

Clinicians were asked to provide written responses to five questions, three of which related to stockings for maintenance for clients who had had venous leg ulcers. Data were collated and themes generated. The relevant questions asked in the survey were:

- 1. When prescribing maintenance hosiery for venous leg ulcers, what do you choose? Please note the class, the mmHg range and any other factors of interest.
- 2. Do you have a favourite brand? Type? Style? Fabric? Composition?
- 3. What stocking donners do you favour? Why?

With regard to compression hosiery for prevention of venous ulcer recurrence (Question 1), a range of levels of compression were applied from 15-20mmHg to 30-40mmHg. One clinician reported applying Class 1 hosiery when client difficulties were present, another chose Class 2 at all times, and another only ever chose Class 3 hosiery. However, most often clinicians tended to apply hosiery within the Class 2 range, including 20-30mmHg and 25-32mmHg, and considered client dexterity to be an important factor in the decisions relating to level of compression. Several respondents noted that they wanted to apply more compression but felt that client factors, including physical restrictions and ability to tolerate compression, prevented this approach.

In response to Question 2, different stockings were favoured for a range of reasons. Stocking material and the interface with the skin were considered important and a range of factors were noted to make some stockings easier to apply than others. For example:

The contact side of the [brand] garment is a cotton mix and seems to irritate the skin less... seem to be more suitable for those clients who have some venous eczema on board.

The [brand] can also be good as the lycra does seem to make them easier to apply.

Specifications of 'off the shelf' stockings, including foot and calf size, were considered to be important factors. Cost was also noted as a factor by several clinicians:

I actually prefer [brand]... yet cost can be prohibitive.

There was considerable opinion on stocking donners (Question 3), with a range of different types employed including metal frame donners, material donners and plastic (tubular) donners. The material donner was most favoured by staff as one they would use themselves when applying clients' stockings and favoured when considering the needs of informal caregivers who may attend this task:

Definitely the [material donner].... just works well for me and I find it hard to pull stockings over a frame. The clients I see who need assistance with their stockings often need some one to apply them and I think the [material donner] is best for this.

Great for [staff] and carers to use.

When considering the situation where the client applies their own stocking, client characteristics were most frequently noted to have an impact on the suitability of stocking donner. Physical factors were reported to play a role:

My favourite donners are the [brand] frame for those without hip flexion, a plastic bag or the silk slip and the [material donner] for staff.

Am trying at present the new [plastic tubular donner]... It is much easier than all the others I have trialled. All the others are too difficult for clients to get down and manipulate.

Cognitive factors were also noted to affect the client's ability to use a donner:

I find the [material donner] good but they have to be able to reach their toes with no loss [sic] (short term memory loss) so they can learn the steps involved to use.

An alternative opinion is noted below, suggesting there is rarely benefit when using any donner with the client who is unable to apply a compression stocking:

I find that if a client cannot apply stockings themselves, it is rare they can also manipulate donners!

In summary, the clinical opinion of most respondents is that higher levels of compression are desirable, however, not always realisable. This suggests current practice is consistent with what is suggested by the relevant systematic review. A number of barriers exist to the successful application of compression stockings, with and without the assistance of the donner – these mostly relate to the physical or cognitive abilities of the client. Material, sizing and cost were factors which influenced which brand of stocking was selected. A range of donners are employed for use. For the nurse and informal carer, the material donner was favoured; for the clients' self use, a range of donners have been employed to suit a range of client situations.

Limitations of this survey include that it was brief, considered only a small number of responses and can only be generalised to a domiciliary nursing environment and client population. However, it is encouraging that the results 'fit' with current understanding in this area of health promotion. The survey results highlight that concern exists among nurses as to the person's ability to participate in their own care. The results of this survey suggest another larger, more comprehensive and more widely distributed survey is warranted.

Discussion

Leg ulcers are a significant health problem and present a considerable cost to the individual and the healthcare provider. Venous leg ulcers are wounds that frequently recur. Despite some understanding of how recurrence may be prevented, current knowledge and understanding has failed to bridge the gap between what should happen and what is happening. Both unmoved prevalence rates and an ageing population suggest venous leg ulcers and their recurrence will be a persistent healthcare concern. Combating the issues associated with successful management of venous hypertension has been shown to be a challenge of some significance to the wound management community.

Research method has proven to be a major limitation in the available evidence pertaining to leg ulcers and recurrence. Lack of definition or poor definition of ulceration and recurrence are noted as factors for attention. The impact these limitations have had on the rigor of available research must be considered when reviewing the evidence. Further, as risk of recurrence usually spans the individual's lifetime, research studies which do not track outcomes for the long-term are unable to provide a truly accurate account of the problem (although it is noted that in the longer-term, passive attrition is an unavoidable limitation). To ensure an accurate and clear profile of this health concern, methodological clarity must be gained and must be a focus of future research in this area.

As suggested in this review, there is a considerable amount of evidence to guide clinical practice; however, it is a challenge to systematically identify and effectively engage individuals most at risk of recurrence. The literature supports the institution of compression stockings for individuals with healed venous leg ulcers; however, it highlights that adherence to high compression levels delivered by this therapy is variable and may have a significant impact on recurrence rates. The effect of adjunct interventions are considered to be favourable; however, these are largely unmeasured in regard to impact on adherence to recommendations and ultimately leg ulcer recurrence. It is with regard to these factors, optimal compression and promotion of adherence to maintenance compression, that potential exists to undertake investigation and contribute to and consolidate the evidence. To date, practice guidelines are lacking and, whilst best practice has been suggested, it has not yet been realised.

Wound dressing products may not be easily afforded by people with chronic wounds, and people with venous leg ulcers may be particularly unfortunate in this respect. Wounds of other aetiologies which heal result in the cessation of the financial burden associated with products for the wound. However, the person who suffers with venous leg ulceration faces a life-long financial commitment to paying for maintenance stockings (or dressing and compression products if the wound recurs). Wound dressing products and compression hosiery are not provided free to people receiving domiciliary nursing care (and this also often applies to clients receiving care from other providers) in Victoria. Australian wound management organisations and individual care providers continue to advocate for the provision of funding for products and it is timely to consider compression stockings within this initiative. An evaluation of the provision of funded compression hosiery should be pursued.

Given that maintenance therapy is typically a life-long commitment for the person with a healed venous ulcer, it is surprising that there was very little reference to this issue in the literature. The justification for providing in-home monitoring of skin integrity by community nursing services is yet to be proven. Unfortunately, age and morbidity tends to create a dependence on formal or informal care providers which may increase over the person's lifetime. Care provided in a clinic setting may be clinically advantageous and cost effective; however, it may not be accessible to all people with leg ulcers. Client and organisational barriers and enablers to clinic based care should be evaluated.

The Australian government Department of Heath and Ageing has suggested a national approach to chronic disease prevention and management and has strategic policy and a chronic disease strategy in place for a range of service improvements associated with major health concerns including heart, stroke and vascular disease ⁴¹. As expected, the Victorian government policy vision statements mirror these recommendations and emphasise that community based healthcare is the most sustainable way to deliver services ⁴². A 10 year focus on prevention and early intervention, improved convenience, accessibility, quality and efficiency sees the issue of leg ulceration and recurrence well targeted for improvement in the current healthcare climate. In light of the composite of unique knowledge and understanding yet diversity of practice within domiciliary nursing organisations, it is timely to consider areas for improvement in the care and outcomes for persons with venous disease who are receiving care at home and elsewhere in the community.

Recommendations

Consideration of the literature presented suggests there is room for clinical improvement and support for research initiatives which may include evaluation of innovative, alternative service delivery models to promote successful maintenance of healed venous leg ulcers.

Clinical recommendations

- Development of practice guidelines for the management of healed venous leg ulcers.
- Development of nursing education to support best practice interventions.
- Development of client education programmes to promote ownership of their chronic health condition and participation in care.
- Consideration of alternative service delivery models and cost-benefit analyses of same.

Research recommendations

- Rigorous prevalence and incidence studies undertaken across a range of care settings and environments which establish clinically validated point prevalence of leg ulcers and recurrence.
- Rigorous trials of compression stocking interventions for prevention of venous leg ulcer recurrence.
- Evaluation of the impact of client education on adherence to maintenance care planning and recurrence.
- Comparison of outcomes for persons who receive funding for compression stockings compared to those who do not.

Service delivery model recommendations

 Evaluation of a recall and review programme for persons who receive formal care for leg ulceration. • Evaluation of out-of-home community based nursing models in an Australian context.

Conclusion

People suffering from venous leg ulceration require therapies to promote healing and afterwards to promote maintenance of skin integrity and avoid recurrence. It is acknowledged that not all persons will remain healed; however, the potential for improvement in outcomes for this group of healthcare consumers is evident. A programme that accurately ascertains the extent of the problem of ulcer recurrence and identifies and tests a range of preventative interventions is overdue. Action on the recommendations made in this paper will go some way to informing practices associated with management of leg ulceration within and beyond the domiciliary nursing environment. The potential outcomes may positively affect the health and wellbeing of individuals with leg ulcers in any setting, cared for by any provider, formal or otherwise. Whilst the issue of lower leg ulcer recurrence perhaps lacks the glamour of more 'topical' wound management issues, its refinement nonetheless has enormous potential for improvements to the sufferers' wellbeing and the care provider and funding bodies' budgets.

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