Sharp wound debridement in the management of recalcitrant, locally infected chronic venous leg ulcers: A narrative review

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Abstract

Background: Sharp wound debridement has been identified as an essential component of biofilm-based wound care (BBWC) in the management of chronic wounds including chronic venous leg ulcers (CVLUs).

Aim: To evaluate the validity of available evidence regarding the role, safety and efficacy of sharp debridement in the management of recalcitrant, locally infected CVLUs.

Method: A literature search was conducted between August and September 2010. Evidence was sourced from the Cochrane Database of Systematic Reviews via Ovid, DARE, MEDLINE via OvidSP and CINAHL Plus. Search terms included "skin ulcer", "leg ulcer", "varicose ulcer", "wound pain", "wound infection", "biofilms", "debridement", "conservative sharp debridement". The search was restricted to adult, human subjects and articles published in English. The search was limited to articles published between 1999 and 2010.

Results: A Cochrane Systematic Review (protocol) was identified, with the review yet to be published on the effect of debridement on CVLU healing. Only three studies including a prospective, cohort study examining the effectiveness and feasibility of sharp debridement for CVLUs in the out-patient setting, a retrospective analysis of two randomised controlled trials (RCTs) examining the impact of serial sharp debridement on both CVLUs and diabetic foot ulcers (DFUs) and a report of four experimental models examining the effect of debridement on *in vitro*, *in vivo* and *in situ* (CVLUs) biofilms were identified.

Conclusion: Current high levels of evidence in the form of systematic reviews and large, well-designed RCTs are lacking at the time of this review. Ethical considerations in utilising RCTs to address clinical questions relating to debridement may have an impact on the design of future studies. Some low-level evidence exists, indicating sharp debridement may have an important role to play when undertaken as part of a multifaceted approach to the management of CVLU local infections (a biofilm), in combination with standard care. In this new and emerging science, it is proposed that a paradigm shift in current thinking will be required by both researchers and clinicians as urgently needed future research is planned and undertaken.

Keywords: varicose ulcer, wound infection, biofilms, debridement, conservative sharp debridement.

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Introduction

Chronic wounds (unhealed wounds at six to eight weeks) are a major cause of morbidity and mortality[1]. It is estimated that 1% of the population is directly affected by these costly and challenging non-healing wounds[2]. Chronic venous leg ulcers (CVLUs) are caused by incompetent or absent valves in the perforating, superficial or deep veins of the lower limb. It is thought that at least one in 100 individuals has some form of venous insufficiency, which can lead to chronic ambulatory

venous hypertension and ulceration[3]. Standard treatment for CVLUs includes graduated compression bandaging or hosiery, which is often regarded as 'first line' treatment to address the underlying pathology of chronic venous insufficiency[4]. Though regarded as an essential component of CVLU care, graduated compression should only be considered and implemented as part of a holistic, evidence-based management plan[5].

Chronic wounds, though differentiated by their underlying pathology and diagnosis – CVLU, pressure injury (PI) or neuropathic diabetic foot ulceration (DFU) – classically present with persistent non-viable tissue (NVT), bacterial and moisture imbalance, and may be slow or fail to heal. Wound-related pain (WRP) has also been identified as a common and distressing issue for those living with chronic wounds[6]. Looking beyond the macro appearance of chronic wounds, there are also many similarities on a cellular and biochemical level, including high levels of inflammatory cytokines and unrestricted protease activity which degrade growth factors and destroy the extracellular matrix. Cells essential for wound healing, including fibroblasts, become senescent and fail to function normally[1,7]. The concept of wound bed preparation (WBP) has aimed to address these imbalances and incorporates the assessment and management of local barriers to healing within the wound, while identifying and treating the underlying diagnosis, and managing the person's issues or concerns[8]. Yet even with this structured and holistic approach, some chronic wounds, including CVLUs, become recalcitrant and fail to respond to standard treatment.

It has been proposed that chronic inflammation or a hyper-inflammatory state exhibited in recalcitrant chronic wounds may be caused by surface-associated bacterial populations (a biofilm) and that this localised "chronic infection"[9], may be an unrecognised barrier to healing, contributing to the development and perpetuation of chronicity in wounds[1,10-13]. It is also postulated that this state of "sub-clinical" or "quiet" infection may be best classed as a biofilm or biofilm phenotype infection and should be regarded as a clinical reality versus an academic concept[14,15]. Biofilms are formed when planktonic phenotype bacteria (both anaerobic and aerobic) attach to the wound surface and colonise into highly organised structures encased in a protective outer coating (extracellular polysaccharide matrix – ECM – or extracellular polymeric substance – EPS)[2,11,16-18]. Within the biofilm, the phenotype of the bacteria changes, making the organisms highly resistant to both systemic and local

antimicrobial agents along with the host's immune response, when compared to planktonic organisms. Calls have been made to better understand the impact of biofilms on chronic wounds so as to identify appropriate interventions to modify and manage the local infection[19].

Wound debridement has been defined as "... the removal of devitalised or infected tissue, fibrin, or foreign material from a wound ('debris')" and includes a variety of modalities including surgical, sharp, mechanical, autolytic, biosurgical and enzymatic[20]. Debridement is an accepted and utilised tool used to address local barriers to wound healing[6,21-23]. The challenge for today's health care professional is that, to date, there is little published evidence available to indicate which form of debridement should be used where and when, and if or how it improves chronic wound healing[11,24].

Sharp debridement, sometimes referred to as conservative sharp wound debridement (CSWD), can be performed at the bedside by trained health care professionals using surgical instruments, including scalpel, scissors and curette[20]. Though considered less aggressive than surgical debridement, it has been reported to be a safe and effective method to debride chronic wounds, when pain minimisation and topical management strategies (for example, topical EMLA®) were implemented[22].

It has been postulated that sharp debridement not only removes NVT and debris from the wound surface, but that mature biofilms are physically disrupted and/or removed during the procedure. The concept of biofilm-based wound care (BBWC) has emphasised the importance of serial sharp debridement in providing a "therapeutic window" of opportunity[11] to introduce multifaceted, targeted interventions (which may include antibiotics, antiseptic dressings and antibiofilm agents) to physically remove, attack and suppress the biofilm during its reconstruction phase, when most vulnerable and susceptible[12,13,18].

Method

In August and September 2010, a literature search was undertaken utilising EBM Reviews – Cochrane Database of Systematic Reviews via Ovid, DARE and MEDLINE via OvidSP, CINAHL Plus. Database search strategies (where applicable) included the use of key terms and words based on search concepts, MeSH terms, subheadings in the MeSH tree (using explode or focus commands), boolean logic, and truncation to address possible word variations. Search terms included "skin ulcer", "leg ulcer", "varicose ulcer", "wound pain", "wound infection", "biofilms", "debridement", "conservative sharp debridement". Selection criteria included studies evaluating sharp debridement of CVLU and measuring clinical outcomes of healing, incidence of local infection (biofilm) and pain reduction. Limitations were applied to include only adult human studies and English publications. The search period was limited to the last decade, 1999–2010.

Results

Cochrane Systematic Review (protocol)

An intervention protocol for a Cochrane Systematic Review is currently being undertaken[4] and aims to determine the effects of different debriding methods on the rate of debridement and wound healing in venous leg ulcers. The researchers have proposed that the underlying pathogenic abnormalities of chronic wounds cause a build-up of NVT and that regular debridement is required to remove the necrotic burden and stimulate healing. Complications of failing to debride chronic wounds are listed as slower healing, protein loss, risk of osteomyelitis, generalised infection and sepsis. The protocol acknowledges existing Cochrane Systematic Reviews which examine the effect of debridement on healing in DFUs and the effect of different methods of debridement on the rate of debridement and healing of surgical wounds. Both reviews reported a lack of large, high-quality published randomised controlled trials (RCTs) evaluating or comparing methods of debridement to guide clinical decision-making. It is of note that no reference is made in this protocol to the terms biofilm, chronic infection or local infection.

Controlled prospective cohort study

The evaluation of sharp debridement on the progression of recalcitrant CVLUs and the feasibility to undertake the procedure in an out-patient setting, were the aims of a concurrent prospective cohort study[25]. Fifty-five persons with non-healing diagnosed CVLUs were placed into two groups:

(1) Study group – NVT with no granulation wound (n=28). Intervention was one-off, sharp debridement with curette with standard care.
(2) Control – no NVT, granulation (minimum 15–20%) (n=27). Standard care only.

Reduction in mean surface area (MSA) from baseline and reduction MSA between groups, along with the number of wounds healed were the outcome measures at –4 weeks, 0 week (sharp debridement) and +4, +8 and +20 weeks. Two patients were lost to follow-up in the study group and two measurements not recorded at +20 weeks for the control group. The author reported a significant reduction in mean surface area in the debridement group at +4 weeks (p=0.002) and + 20 weeks (p=0.008). Fewer infections were reported in the study cohort and five patients healed in each group during the study period. The researchers concluded that sharp debridement, when combined with standard treatment, stimulated healing and the procedure was safe and well tolerated.

The cohort design provides a valuable, yet weaker level of evidence than RCT due to non-randomisation, which may increase the risk of bias and reduce internal validity. Selection, performance, risk attrition and detection bias were identified and limited reporting of the individual MSAs, restricted the reader from further analysis of findings. More wounds did heal in the study group closer to the debridement, but over time the same number of wounds healed in both groups (relative risk reduction (RRR) 3% and numbers needed to treat (NNT)=143 for 20 weeks for one wound to heal). Of interest, further analysis of the infection data provided revealed that the RR (relative risk) for infection was .83, the absolute risk reduction (ARR) 6%, RRR 17% and the NNT was 16 persons for 20 weeks.

Pain severity scores at baseline and over time were not reported and the study protocol stipulated that the sensitive wound edges should be avoided during debridement (EMLA® cream was not routinely used during the procedure – only when necessary). These clinical considerations along with patient-important outcomes require further investigation in future research.

Retrospective study of RCTs

The impact of serial sharp debridement on the wound healing of CVLUs and DFUs has been reported[26]. A retrospective analysis was undertaken of two separate, controlled, prospective, randomised trials of 366 CVLUs and 310 DFUs over a 12-week period. Study protocols saw both wounds reviewed every week, DFU wounds debrided every week (necrotic or hyperkeratosis) with instructional videos provided for clinicians. The CVLU wounds were debrided only if deemed necessary by the clinician, and no instruction of debridement was provided.

Wound tracings were measured using digital planimetry – and wound healing, for each study ulcer, used median percentage of baseline wound area (week 0) healed per week. Surface area reduction was also calculated to measure the percentage difference in area between visits and debridement. It was reported that both wound types that received serial debridement had greater maximum

The percentage healed from baseline versus less frequent debridement, but the findings for both groups was not significant; DFU 95% versus 81% (p=0.077) and CVLU 84%

versus 78% (p=0.079). In further analysis using Kaplan–Meier probability plots, it was demonstrated that time to healing was significantly shorter when VLUs were serially debrided (p=0.044). The authors concluded that 'more is better' and that more frequent debridement is associated with improved healing outcomes.

Retrospective analysis of RCT findings – post hoc analysis – provides a weaker level of evidence again due to potential for bias[26]. No baseline data information of the two patient groups are provided, thus the validity of the research is in question due to contributing confounders and the potential implications of co-interventions due to non-standard protocols. As identified by the author, the RCT studies reviewed were never designed to measure debridement, thus this study should not be used to provide evidence of a causal relationship – just that of an association between frequent debridement and improved wound healing may exist in the management of lower leg ulcerations.

Experimental non-comparative

A recent series of experimental studies (*in vitro/in vivo/in situ*) has been reported in one publication and explored the hypothesis that newly formed (immature) biofilms are more susceptible to antimicrobial treatments[11]. Four different models were designed and undertaken by four independent biofilm research laboratories including a (1) drip-flow biofilm model with hydro-debridement, (2) a porcine skin punch biopsy model, (3) a mouse chronic wound model (4) and a clinical longitudinal debridement study of three patients with CVLUs. Using both recognised and new experimental models, bacteria was allowed to develop on the four different surfaces, they were then removed and the biofilms response to antibiotic exposure was monitored and measured over time.

Each model reported that within the first 24 hours of biofilm development, the immature biofilm was susceptible to antimicrobial therapy, but that after 48 hours the biofilm can reach maturity and be highly resistant to antibiotic therapy. The author concluded that their hypothesis was valid and that BBWC should include serial debridement to continually remove and disrupt the mature biofilm and expose a less mature, vulnerable biofilm to antimicrobial therapy while it is in recovery phase.

Though identified that the studies were small in number (replications), the power of the conclusions were strengthened by the four different sites and models reporting the same conclusions.

Discussion

Chronic wounds including CVLU are characterised by non-viable tissue, persistent inflammation and/or infection, moisture imbalance and non-advancing wound edges. For the last decade, an emphasis has been placed on the importance of addressing these local barriers to healing[6,8,27,28], in conjunction with defining diagnosis (for example, ambulatory venous hypertension, vasculitis), addressing contributing factors (for example, malnutrition, smoking, pain) and focusing on the person's concerns and issues, all essential components of management. Biofilm infections, previously unknown and unrecognised, may provide the common 'thread' as to why some chronic wounds have failed to heal despite standard care[15].

These recent changes in our understanding of bacterial phenotype and proposed subsequent local infection (biofilm) in recalcitrant wounds, raises many questions regarding the common use of systemic and/or topical antibiotics and antimicrobial dressings in the absence of sharp debridement, and may provide an insight into the challenges faced when managing non-healing wounds which respond briefly to therapies, to then only deteriorate again. This has been described as "undulating exacerbations" – a waxing and waning[29].

The concept of initial and maintenance debridement was first described over a decade ago[30], yet its initial preface was not biofilm-based, but to address persistent and recurrent NVT including slough, which is now hypothesised to be a potential marker of the complex biofilm environment[14]. Serial sharp debridement may not only remove the physical barrier of NVT, which, in turn, reduces inflammation, but may play an integral role in disrupting, suppressing and weakening mature biofilms, contributing to its vulnerability and making it more susceptible to both multifaceted therapies and the host's immune cells[13].

This review of the literature has clearly demonstrated that we are just beginning to understand the importance and relevance of sharp debridement in chronic wound care. To date, small, weaker designed research is all that is available to guide and inform practice relating to VLUs. The three studies reviewed have alluded that 'one-off' sharp debridement of CVLU containing NVT appeared clinically to improve the rate of MSA reduction and reduce infections when compared to standard care, yet more frequent debridement, for wound beds with or without NVT, used in association with biocides, may also improve clinical outcomes, a conclusion which should be examined in future research. In the recently published *Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers*[5], health care professions (HCPs) are guided to address NVT and

infected tissue or debris, as part of WBP and to consider other debridement methods (other than enzymatic), to prepare the ulcer bed for healing (Consensus-based recommendation).

Future research

What we have learned from available evidence is that future research will need to examine a variety of debridement methods, explore the impact and consequences of debridement frequency and stratify the patient populations (based on wound type, duration and wound bed appearance). Future studies should be considered which examine the safety and efficacy of multimodal BBWC, reporting on the impact of serial CSWD, along with other debridement modalities including surgical, dressings, biotherapy, mechanical (including low-frequency ultrasound debridement – LFUD) and stratified antimicrobial dressings.

The ethical considerations for undertaking RCTs in this patient population presents a clinical challenge to researchers, and the implications of utilising this design for future research is debatable and has previously been discussed[25].

There is a dearth of evidence to support the minimisation of WRP associated with biofilm infection, an area of research in dire need of recognition. Pain characteristics including quality and quantity should be included in future studies and could examine the hypothesis that effective serial debridement of both the wound bed and edge under local anaesthetic – EMLA® (as part of BBWC), may reduce both background and persistent WRP associated with chronic wounds, by addressing local infection and thus inflammation.

Conclusion

We are currently at a turning point in clinical practice, which will require a paradigm shift in the thinking of both researchers and clinicians, as future studies are designed and much needed guidelines (based on best available evidence) are produced.

Ensuring that the right type of debridement is provided for the right person, by the right HCP, at the right time, in the right way, in the right setting, and with the right equipment and resources, is our challenge for today and into the future.

Ensuring that serial sharp debridement is provided for the right person, by the right HCP, at the right time, in the right setting, with the right equipment and resources, is our challenge today and in the future.

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