Development of a UK cost analysis model for the various methods of debriding leg ulcers

KEY WORDS
- Chronic wounds
- Cost analysis
- Debridement
- Leg ulcers

Aims: In this study, an estimate of the costs of different debridement methods has been assessed using a cost analysis model. **Methods:** The methodology undertaken in this study combined the demographic and incidence data available on leg ulcers with all associated costs incurred in the debridement of wounds by differing methods. Excel spread sheets were developed incorporating costs associated with healthcare professional time, visit frequencies, dressings, compression bandages, ancillary materials and dispensing costs. Results: The use of hydrogels is relatively slow and, therefore, costlier (£806), but can be used as an adjunct to sharp or surgical debridement. The cost of sharp or surgical debridement, with the supervision of a multidisciplinary team approach and appropriate local topical anaesthesia using injected lidocaine (£166) or EMLA cream (£176) is the cheaper option, compared with other methods, for example, larval therapy (£795). Mechanical debridement is another option in community care but is also more expensive (£347). **Conclusions:** Further introduction and education in sharp/surgical debridement and anaesthetic techniques would shorten the time required to achieve a clean, leg ulcer, wound bed and improve healing rates. Early, effective and longer-lasting pain relief will lead to optimising wound bed preparation and could have potentially additional cost-saving benefits by reducing the overall healing time and the associated product and clinical resource usage costs.

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The term 'debridement' is derived from ancient French: 'desbrider' — to de-bridle. Early French military surgeons recognised that extensive and contaminated soft tissue limb injuries caused by gunshot/gunpowder wounds needed wide excision, rather like the "debridling" of a horse saddle, both to save lives, prevent infection, and allow such wounds to heal by secondary intention (Leaper and Harding, 2006). The term debridement is not derived from 'removal of wound debris'; although this concept of debridement could equally be applied to appropriate and complete cleansing at dressing changes of open chronic wounds, such as leg ulcers, which also heal by secondary intention (Leaper et al, 2011).

Necrotic or dead tissue mechanically prevents epithelialisation and contraction of open wounds acting as a barrier to facilitating the wound healing processes and does not allow the provision of an optimal moist wound environment (Enoch and Leaper, 2008; Leaper et al, 2012). If this material is not removed from a wound, a dysfunctional and disorganised acute inflammatory response results, which disrupts and delays the normal healing process (Leaper et al, 2012). All open wounds become contaminated by micro-organisms, which can rapidly progress to colonisation, develop into localised and systemic infection and become life-threatening (Gray et al, 2011; Leaper et al, 2015). Biofilm formation can also be part of this process of contamination and biofilms can become mature within 24–48 hours on the wound surface (Bianchi et al, 2016). Biofilms also contribute to an abnormal and excessive local inflammatory response by the promotion of an increased release of tissue-damaging oxygen-free radicals, nitric oxide, pro-inflammatory cytokines and metalloproteinases (Bianchi et al, 2016). Biofilms cannot be seen by the naked eye, and wound swabs taken from wounds may reveal no microbiological growth (Percival et al, 2016). However, biofilms are always present on the surface and deeper layers of open chronic wounds; molecular and staining techniques are required to confirm their presence and may reveal scores of microbial species in the wound (Schultz et al, 2017). For optimal healing of a chronic open wound, such as a venous ulcer, biofilm needs to be recognised as being present and removed, just as macroscopic necrotic tissue should be. At every wound dressing change, surface biofilm should at least be removed through the process of debridement — just as the unseen biofilm that causes plaque and gingivitis is preventatively brushed from teeth once or twice a day. Dressing changes without some form of debridement or wound surface manipulation may not represent best practice in wound care even in the presence of what appears to be a clean wound bed. The associated use of antiseptics at dressing changes, as a lavage, gel or impregnated dressing also helps to reduce the reformation of biofilm (Edmiston et al, 2015). This could add benefit to antibiotic stewardship programmes as biofilms and colonisation are prevented from progression to infection and the unnecessary need for antibiotics and the constant concern of antibiotic resistance (Malone et al, 2017; Roberts et al, 2017).

LOOKING AT COST-EFFECTIVENESS

To meet the objectives of limited financial resources in healthcare, which includes the management of chronic leg ulcer care, decisions on the need for and adequacy of debridement cannot be avoided. Cost modelling methods could help wound care decision makers in allocating these limited resources to maximise health benefits. For example, there can be confusion over unit purchase price of debridement products and the potential savings that could be made in nursing resources, consumables and bed days, if admission to hospital is required, which is critical for policy budgeting decisions.

There are three main drivers that determine the level of resources used in wound care, which should be considered to make leg ulcer management more efficient (Lindholm and Searle, 2018). These are:

- The time it takes to heal a wound. Longer duration means increased nursing and dressing costs and an increased risk of complications
- The frequency of dressing changes, where a higher frequency means increased dressing and nursing costs
- The incidence of complications, particularly infection. Complications may lead to hospital admission, the need for surgical intervention, an extended period of treatment or increased use of other resources.

If any of these cost drivers can be reduced without detrimental impact on outcomes, then an improvement in efficiency could be delivered. It is logical that earlier intervention, through optimising the frequency and quality of debridement procedures, could result in improved patient outcomes, such as faster healing times and lower treatment costs (Wilcox et al, 2013), thereby, allowing savings to be utilised in other initiatives.

Debridement is a key process of wound bed preparation or in "the global management of the wound to accelerate endogenous healing, or to facilitate the effectiveness of other therapeutic measures" in wound care (Falanga, 2002). Wounds with debridement intervals of 1 week or less heal significantly more quickly (Wilcox et al, 2013). There are several debridement techniques currently available: autolytic, enzymatic, irrigation and negative pressure therapy, mechanical, surgical (sharp), and biosurgical (Bekara et al, 2018; Gethin et al, 2015). Although the cost of treating and healing venous ulcers has been well documented (Guest et al, 2018), the cost associated with various methods of debridement of venous ulcers has not. The costs vary considerably depending on the method used and time to achieve a clean wound bed. This has the potential to contribute substantially to the total cost of managing a wound in order to achieve a successful outcome. In this study, costs associated with this essential, early and first-line intervention associated with the main types of debridement have been identified utilising a simple cost analysis model. With procedures, such as sharp and surgical debridement, adequate pain management is a key part of the process. Estimates of cost-effectiveness, utilising local anaesthetics, together with the chosen

Table 1. Healthcare professional costs per visit and total pharmaceutical and device dispensing costs associated with each method of debridement		
Type of debridement	**Cost for healthcare professional visit**	**Total cost of dispensing fees per visit**
Autolytic	District nurse £67	£5 Medical Device
Mechanical	District nurse £67	£5 Medical Device
Sharp	GP £88, Practice nurse £47	£23.25 (pharmaceutical plus medical device)
Larval	District nurse £67	£47.75 (pharmaceutical plus medical device)

Table 2. Summary of costs of debridement for each debridement method with assumptions made in terms of frequency of nurse/GP visits and dressing changes during each procedure			
Method of debridement	**Number of visits required to debride**	**Frequency of dressing change**	**Total cost of debridement (£)**
Sharp no pain relief	2	Twice weekly	303.31
Sharp with Lidocaine	1	Weekly	166.75
Sharp with EMLA	1	Weekly	176.58
Autolytic	10	Twice weekly	806.90
Mechanical	4	Twice weekly	347.16
Larval	4	Twice weekly (Two applications of larvae)	795.31

debridement tool, have also been assessed. It is this aspect of sharp and surgical debridement that needs attention to make it suitable for all clinicians involved in leg ulcer management.

METHODOLOGY UTILISED IN MODEL DEVELOPMENT

The cost to the NHS associated with the debridement of venous leg ulcers is difficult to determine. The costs are compartmentalised and met from numerous different departmental and operational budgets, which is often overlooked when determining the total impact of a procedure to the health system as a whole. The methodology undertaken in this study combined the demographic and incidence data available on leg ulcers with all associated costs incurred by the NHS in the debridement of patients' wounds, including consumables, associated prescription charges, dispensing fees and staff time. The model captures expenditure on dressings and other medical device items associated with good clinical practice in performing the various methods of wound debridement, together with associated dressing changes, including dressing packs, cover dressings, compression bandages, saline solution, sterile gloves and the cost of sharps bins when required.

The cost of healthcare professionals' time is a key driver of the overall cost of care and is the most expensive component of leg ulcer management (Lindholm and Searle, 2018). However, the model excludes travel time and associated charges as it is impossible to determine accurate values for each episode of care provided. The information on product costs used to populate the model was taken from the current Drug Tariff (December, 2018), which details the real cost to the NHS of all consumables and the NHS Supply Chain Catalogue, where every-day consumables would most likely be supplied through the NHS stores and logistics network. Other information on personnel and total visit costs were taken from data published by the Personal Social Service Research Unit report entitled Unit Costs of Health and Social Care (Curtis and Burns, 2015). In terms of estimating the number of home or GP surgery visits required to achieve debridement, literature searches were made followed by discussions with healthcare professionals to reach a general consensus on what was considered reasonable practice. Healthcare professional costs, dispensing fees, number of visits required to debride and frequency of dressing changes are highlighted in *Table 1* and *Table 2.*

Table 3. Total number of leg ulcers in the UK that require debridement and related cost (£ sterling) to the NHS		
Debridement method	**Total cost of debridement if 50%* of all leg ulcers were debrided by each method (£ sterling)**	**Comments**
Autolytic	110,548,090	Time consuming and costly, but widely considered as the 'go to' method of debridement
Mechanical	48,255,240	Becoming more popular with the physical debridement pads such as Debrisoft®
Sharp (no pain relief)	42,160,090	Very few nurses have the qualification to debride with a scalpel and are not allowed to cause bleeding of the wound bed. This procedure would need to be carries about by a doctor
Sharp with Lidocaine	23,178,250	Would involve the GP or doctor to debride unless a nurse is appropriately qualified
Sharp with EMLA	24,544,620	The time element for EMLA to provide local anaesthesia would be against this method. Also requires the debridement to be carried out by an appropriately qualified clinician
Larval Therapy	110,548,090	The use of larvae has pockets of advocates. It's regarded as quite a quick method of debridement, but it is very costly and patients generally don't like the thought of maggots despite the development of the self-contained "biobag"
* Conservative estimate from Reedes et al (2013), who claim 50% of venous leg ulcers have a duration >12 weeks, hence are defined as chronic and will need some form of debridement		

The data was input into an Excel spreadsheet that was then formatted to calculate the cost of delivering care associated with debridement procedures. The focus was centred on calculating the cost of each of the various different methods of debriding a leg ulcer. It takes into account current practice to achieve a clean wound bed, a proven and well-documented event that has to be achieved prior to healing (Leaper et al, 2012). In calculating the real cost of a procedure, the additional cost to the NHS of the pharmacy dispensing fees for both devices and pharmaceuticals have been included.

RESULTS

The results summarising the total cost associated with each method of debridement are shown in *Table 2.* From the costs associated with debridement demonstrated in the Excel model, it can be seen that the most common practice of debridement with hydrogels takes a relatively long period of time compared to other methods. This gentle, slow approach may be necessary for some patients, but the extended number of visits makes it a costlier process compared with the other options.

Larval therapy is the most expensive of all the debridement methods analysed and has not been shown in clinical studies to improve the rate of healing in leg ulcers, although it does significantly reduce time for adequate debridement and increased ulcer pain compared to hydrogels (Dumville et al, 2009).

The costs of debridement using localised anaesthesia with Lidocaine, and a eutectic mixture of local anaesthetic (EMLA) cream are relatively similar (£167 versus £177). Because EMLA needs to be applied approximately 1 hour prior to debridement, it is difficult for use in the community environment. Alternatively, multiple sites, local anaesthetic injections using Lidocaine around a leg ulcer, to allow adequate sharp or surgical debridement, need to be given by a qualified practitioner, such as a GP in the community environment. However, it should be recognised that the anaesthetic effect of Lidocaine is short and further considerations may need to take place in terms of pain relief both pre- and post-debridement.

Mechanical debridement using monofilament fibres is growing in popularity in the community sector but is around double the cost of local anaesthesia and sharp debridement.

Published research suggests that around 50% of all venous leg ulcers have been present for more than 12 weeks at presentation and are deemed chronic and all need regular debridement (Reedes et al, 2013). The total cost to the NHS associated with debriding venous leg ulcers in the community environment, using various debriding techniques, is shown in *Table 3*.

DISCUSSION

Demographic and epidemiological data indicate that healthcare demand will increase considerably in the future as a result of the ageing population and a rise in the incidence of chronic diseases, such as diabetes and venous insufficiency. This phenomenon has come to be referred to as the "healthcare time bomb" in the popular press. In the UK, the number of people aged 90 years or older grew from 513,450 in 2012 to 580,000 in 2017 (Office of National Statistics, 2012; Statista, 2017). The ageing population, together with other factors such as lifestyle changes, is driving an upward trend in long-term chronic conditions. In the UK, where the majority of health care is funded from public taxation, economic pressures and changing demographics continue to limit growth in healthcare funding (Harker, 2012). Constraints in budgets, increasing demand for GP services, A&E attendance and hospital admissions, all put pressure on current services (NHS Confederation, 2013).

In addition, evidence predicts a shortfall in the number of qualified healthcare professionals, with the number of full-time district nurses decreasing by 46.4% from May 2010 to July 2017 (Rai-Roche, 2017). In 2011–2012, there were approximately 22,640 nurse training places across the UK, compared with 24,800 in 2010–2015 (Royal College of Nursing [RCN], 2013). Of relevance to the community sector in October 2017, there were 287,100 full-time equivalent nurses and health visitors in NHS England. It has been estimated by the RCN that there are around 5,700 fewer nurses working in community health since October 2010, leaving a shortfall in qualified healthcare providers (The UK's Full Fact Independent Fact Checking Charity, 2017). It seems clear that future demand for wound care services will increase, yet the available resources dedicated to meeting this demand will not rise proportionately. Efficiency and changes to current clinical practice are, therefore, growing in importance, as the UK health system struggles to reconcile the supply of healthcare resources and demand. These concerning figures will pose major logistical challenges to all healthcare providers associated with providing wound care, including resource availability and time to complete initial wound assessments and subsequent treatment including debridement.

Most venous leg ulcer care is undertaken in the community and the expertise needed for debridement, which should be part of standard wound care, may or will have to be extended. With the tsunami of quality and clinical initiatives being directed at wound care professionals no clarity exists as to whether this goal can be met or who can provide this expertise in addition to their existing roles and responsibilities. Further involvement of GPs trained in surgical debridement of wounds may provide a solution. There are many methods available for wound debridement and a multi-disciplinary approach (for decision making on the extent of debridement needed and the undertaking the planned intervention) needs to be taken, whenever possible. Clearly, wide excision of devitalised tissue requiring regional or general anaesthesia, such as a surgical amputation of a toe or forefoot, is very different from day-to-day removal of superficial necrotic tissue, slough or biofilm which is required at every dressing change. Sharp "complete" debridement, which may need only one session, could be regarded as being a gold standard technique for debridement (Espensen, 2007; Leaper, 1992; Wounds International, 2013) but needs appropriate general or local anaesthesia and sharp instruments, such as scalpels, scissors, curettes and forceps, to remove necrotic and adherent tissue from the wound, either at the patient's home, treatment rooms or in out-patient departments (Brown, 2014). The sterile packs also require instruments which are fit for purpose not flimsy disposable plastic forceps. The

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advantages of such approaches include an excellent selection of the wound material that requires removal and precise assessment of how much to remove through the MDT. It is also the fastest way to achieve a clean wound bed with the potential to optimise the healing process (Gray et al, 2011) with obvious clinical, patient and economic advantages. The major disadvantage of surgical debridement is that the use of sharp instruments causes procedural/operative pain which, by definition, causes pain during routine procedures, such as dressing changes or wound cleansing. This can also be associated with significant wound interventions, such as biopsies or debridement (Brown, 2014). Rapid, adequate control of such pain improves patients' overall experience of the debridement procedure and also improves subsequent compliance to attend future events of this nature and adhere to dressing changes. Patients may deny future consent for the sharp debridement if the first experience was unacceptably painful. In the community, this is more difficult as varied levels of knowledge exist relating to anatomy and how to manage unexpected haemorrhage, as well, as the need for adequate local anaesthesia.

Prior use of hydrogel dressings does help with auto-debridement but also makes desiccated, devitalised tissue easier to remove at sharp debridement sessions but their use alone takes too long. Many other specialised methods are also available to achieve this: hydrotherapy, ultrasound, pressure jets. They are not widely available in the community because of cost, poor evidence of efficacy and can be an infection prevention control issue if biofilm and necrotic material are not contained within the wound debridement area.

USING PAIN CONTROL EFFECTIVELY

The presence of pain during debridement procedures involving surgical instruments can be a barrier both to clinician confidence and overall patient satisfaction with the procedure. The use of pharmaceutical approaches to pain control is associated with the least costs but still have drawbacks. Daily curettage — particularly of biofilm — from the wound bed of venous ulcers at dressing changes, could also potentially be made more feasible with newer emerging forms of delivering multimodal anaesthesia at similar cost levels. The potential for such novel products is to provide a much more rapid and longer lasting effect than the use of injected local anaesthetics or EMLA cream (Cuomo et al, 2015). As an example, there is a growing evidence base, associated with the use of Tri-Solfen® (Medical Ethics Pty Ltd, Melbourne Australia) in a variety of animal husbandry procedures, which provides excellent pain relief and could be considered for human clinical indications (Lomax et al, 2010; Lomax et al, 2013, Espinoza et al, 2013). By achieving early, effective and longer lasting pain relief will lead to optimising wound bed preparation. This could have potentially additional cost-saving benefits by reducing the overall healing time and the associated product and clinical resource usage costs.

Sterile, single-use curettes are inexpensive and involve techniques that are not difficult to master. Alternatively, it has been shown in the cost-modelling of this current study *(Table 2)* that the use of debriding monofilament pads is also relatively inexpensive and usable with little training, although they may not give as rapid a result as with the use of curettage. Interestingly, both these methods appear to be less expensive than the use of larval (biosurgical) therapy and other debridement methods, which have not been considered in the current study as they are not readily available in the community.

It can be seen in *Table 3* that the total yearly costs of debriding leg ulcers to the NHS can be substantial. A conservative estimate has been made that assumes 50% of all venous leg ulcers will require some form of debridement. Within normal clinical practice a mix of the various options will be made and in the community environment, autolytic debridement will be the most common treatment.

CONCLUSION

Better education of debridement techniques, combined with the availability of an easy to use local anaesthetic could lead to increased clinician confidence to use debridement more widely and optimise the preparation of the wound bed. As an example, the development of an easy to apply topical anaesthetic will ensure that the chosen debridement procedure can be carried out more aggressively in the knowledge that the patient will be free from discomfort and pain. Patients themselves would also benefit in seeing debridement as a positive experience, with an impressive contribution to more rapid ulcer healing, and if multiple debridements were necessary compliance to attend clinics would be increased. It is acknowledged that this study utilised a relatively simple model to assess the cost of debridement. Newer more sophisticated databases are being developed to capture both retrospective and prospective information and relate to the true costs of managing and treating wounds (Guest et al, 2015; Phillips et al, 2016). It is hoped that within such models, it will be possible to estimate the costs more accurately of the various steps in wound healing treatment pathways, including those associated with wound debridement.

LIMITATIONS

There are limitations to this cost analysis. It is recognised that the modelling process the authors have used is a first step in assessing the costs associated with various methods of debridement. The data accessed for entry into the model was gained from the peer-reviewed literature and opinion from discussions with key opinion leaders. Real world data prospectively collected by more sophisticated secure anonymised data collection systems or wound registries would be the ideal scenario. While these are emerging and output is appearing in the literature, the coding structures associated with the specific processes of wound debridement are still in development. Secondly, whilst assumptions made relating to the costs of GP events associated with wound debridement are valid, further research is required to reveal the exact frequency of these events. The resource utilisation of practice and district nurses in wound treatment also need higher levels of clarity. WUK

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