Cost-effectiveness of interventions for chronic wound debridement: an evaluation in search of data

KEY WORDS

- Wound debridement
- Economic evaluation
- Cost-effectiveness
- Cost utility

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Standard practice in the management of chronic hard-to-heal wounds includes debridement; however, to date, no comprehensive economic evaluations of all debridement interventions available in the UK have been reported. **Aims:** This analysis set out to evaluate the cost-effectiveness of larval debridement therapy (LDT) compared with all relevant comparator therapies in UK clinical practice. **Methods:** A decision-tree model was developed to represent the typical treatment of a single patient in clinical practice, comprising a series of monthly treatment cycles over 12 months. **Results:** Initiating treatment with LDT is estimated to be a less costly and more effective debridement strategy than initiating treatment with any of the comparator debridement methods evaluated in the base case. Data limitations and necessary modelling assumptions lead to considerable uncertainty in the modelling results; however, LDT remained cost-effective under all scenarios tested in a range of sensitivity analyses. **Conclusions:** The authors suggest that to understand better the comparative costs and benefits of debridement therapies and to support evidence-based decision-making, further research is needed to improve evidence in this area, particularly relating to quality of life and the resource use associated with therapies to which cost-effectiveness results were sensitive.

The efficient and effective allocation of healthcare resources is vital in the UK and elsewhere in Europe, as the pressure of delivering high-quality healthcare within a finite budget increases. Healthcare decision-making must be grounded in evidence and incorporate information about both the costs and benefits (health outcomes) of healthcare interventions. Economic evaluations provide this synthesis of economic and clinical information, comparing one intervention with a competing alternative in terms of both their costs and consequences. Such analyses may be undertaken prospectively, for example, alongside a randomised controlled trial (RCT), or through decision analytic modelling approaches.

Box 1 below summarises the different types of economic evaluation that can be undertaken in healthcare.

Box 1: Different types of economic evaluation

- **Cost-minimisation analysis (CMA):** outcomes of the two (or more) comparators are assumed equal, thereby resulting in an assessment based solely on comparative cost. Making the assumption of equal outcomes rarely holds in practice.
- **Cost-effectiveness analysis (CEA):** outcomes are one dimensional and measured in naturally occurring units, such as changes in blood pressure or mortality. The incremental cost-effectiveness ratio (ICER) is calculated to determine the additional cost incurred to achieve an additional unit of outcome. If one intervention is both more expensive and more effective than its comparators, lower ICER values represent better value for money and a value judgement will be required to assess whether the cost per extra unit of outcome is worthwhile.
- **Cost-utility analysis (CUA):** an extension of cost-effectiveness analysis in which multi-dimensional health outcomes are reduced to a single index using health utilities and are expressed as quality adjusted life years (QALYs). The use of a standard measure of health benefit enables broader comparisons of cost-effectiveness to be made across different diseases and populations.
- **Cost-benefit analysis (CBA):** costs and outcomes are valued in a common unit – usually money. The financial value of the benefits is compared to the costs, allowing the selection of the intervention with the overall highest financial benefit.

In the UK, CUA is the preferred approach to economic evaluation used by national bodies such as the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) when making decisions about what interventions should be used in the UK.

Chronic wounds

Chronic wounds affect hundreds of thousands of people, particularly older people. These wounds are painful and debilitating, resulting in reductions in quality of life. In 2007, Posnett and Franks estimated that chronic wounds affected 200,000 individuals annually in the UK, at a cost to the NHS of £2.3–£3.1 billion per year (2005/6 prices).

Wound debridement

Standard practice in the management of chronic hard-to-heal wounds includes debridement to remove dead tissue and activate healing by removing slough, exudate and bacteria. A variety of approaches may be used to accomplish this, including larval debridement therapy (LDT), autolytic dressings (hydrogel, honey), mechanical (ultrasound), and surgical treatments (including sharp debridement and hydrosurgical). An economic evaluation comparing LDT to hydrogel was conducted alongside the VenUS II (Dumville, 2009) RCT of LDT in the management and healing of leg ulcers; however, to date, no comprehensive economic evaluations of all debridement interventions available in the UK have been reported.

The aim of this analysis was to evaluate cost-effectiveness of LDT in wound debridement compared to all relevant comparator debridement therapies available in UK clinical practice, in the form of a CUA.

METHODS

The evaluation reported here was conducted from the perspective of the UK National Health Service (NHS) and Personal and Social Services (PSS) and was informed by relevant peer-reviewed publications, clinical experts in wound care and current clinical practice in the UK. After initial discussions with clinical experts, a structured literature review (to be reported elsewhere), was undertaken to support the development of a model evaluating the cost-utility of LDT against six comparator debridement therapies: mechanical, hydrogel, honey, surgical, sharp, and hydrosurgical.

Identified literature describing economic evaluations, RCTs, observational studies and reviews published between January 2006 and December 2011 were reviewed to provide clinical and economic data for modelling. The review highlighted a dearth of good quality studies published in recent years that evaluated clinical- and/or cost-effectiveness of therapies for the debridement of wounds and promotion of healing, not only for LDT, but for all methods of debridement. Given this problem, where the literature review did not provide sufficient data to define and populate the model fully, health professionals in the field of wound care were consulted to inform plausible assumptions.

Model description

A decision-tree model was developed in Microsoft Excel to replicate the typical treatment of a single patient and is, of necessity, a simplification of the complex treatment of wounds and patient care in real life. Not all forms of debridement are suitable for all wounds and patients; however, this complexity is not represented in the model and comparisons are made only for those wounds for which the considered debridement therapies are appropriate. There is considerable variation in wound care and the treatment pathways seen for debridement in a clinical setting may differ depending on whether care is led by a vascular team or tissue viability nurse. Despite this variation of practice this model aims to represent an 'average' case. Expert clinical opinion informed a number of assumptions incorporated in the model structure (Box 2), which comprised a series of monthly cycles over a one-year horizon. A basic schematic of the model is presented in Figure 1.

A patient entering the model receives the debridement therapy of interest during Month 1 (LDT or one of its comparators). If debridement is not achieved during this period, the patient may receive a different therapy in the next cycle or undergo a clinical intervention, terminating the use of all debridement therapies. Up to six cycles of debridement therapy are modelled in total, after which any undebrided wound leads to clinical intervention.

Within the six-month treatment period, patients are assumed to move from one therapy to another with equal probability, with the exception of surgical-type therapies: surgical, sharp and hydrosurgical

KEY POINTS

- Healthcare spending is under pressure in publically-funded health services.
- Chronic hard-to-heal wounds are a considerable burden on health services and have a high human impact.
- Wound debridement is standard practice to activate healing, but few clinical and economic evaluations are found in the literature.
- Economic evaluation of available wound debridement interventions is important to support healthcare decision-making, but lack of data makes this type of evaluation challenging.
- Estimates from economic modelling reported here suggest that initiating debridement with LDT is a cost-effective strategy.

Box 2: Key modelling assumptions

- The same debridement therapy is not used in consecutive months
- Surgical, sharp and hydrosurgical debridement therapies are not used in consecutive months
- The probability of clinical intervention increases over time for wounds not debrided at the end of a cycle of treatment
- Amputation (lower limb) is the clinical intervention modelled as the 'terminating' event for the treatment of undebrided wounds
- The probability of clinical intervention is higher for autolytic therapies, based on the rates of amputation reported by Ribu et al (2008)
- A fixed cost and effect was applied to the probability of wound infection with each treatment

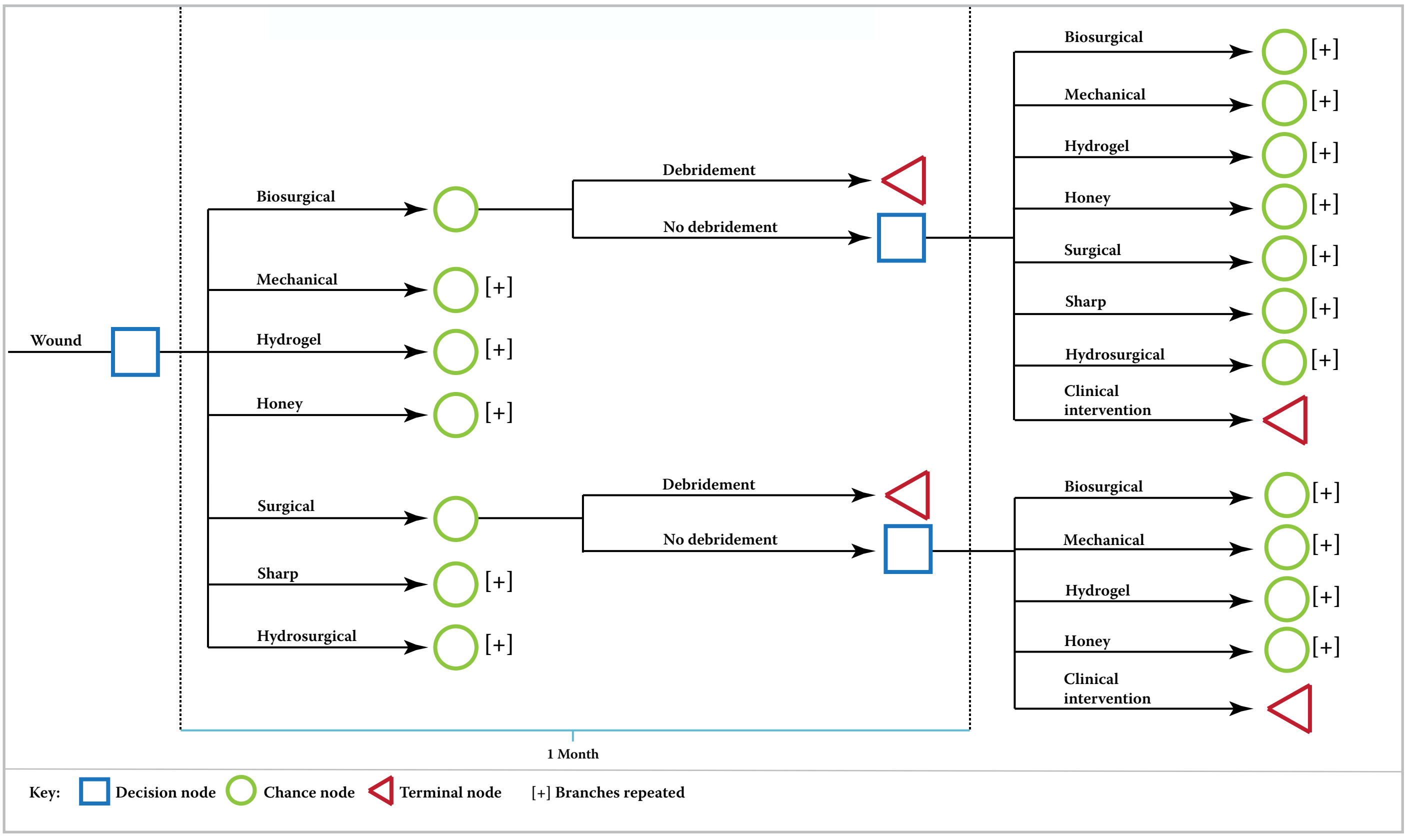

Figure 1: Schematic representation of the cost-effectiveness model.

debridement. Based on expert advice, more than one attempt may be made to achieve debridement with surgical-type therapies within a one-month cycle, although the number of procedures is restricted by the risks associated with general anaesthesia. As with other therapies, if debridement is not achieved with this therapy within one month, a different therapy may be used in the following month; however, surgical-type therapies will not be used successively.

Based on an informed, simplifying assumption, all 'terminating' clinical interventions were modelled as amputation relating to a lower limb or foot wound. In practice, patients might alternatively receive angioplasty, or other major interventions that address the underlying clinical problem responsible for the non-healing wound. This assumption may be considered conservative since other options may deliver greater post-intervention quality of life, while the modest difference in costs between interventions is unlikely to have a significant impact on the analysis.

Clinical effectiveness

Parameter values for the following variables were derived from the published literature where possible and based on informed assumptions where required: probability of debridement; probability of infection; probability of adverse events during treatment; and probability of clinical intervention (Table 1).

Preference was given to information related to bagged larvae where data for both loose and bagged larvae were reported in the literature, as it is the most commonly used form of LDT currently commercially available.

Rates of clinical intervention

In the base case scenario, clinical intervention (amputation) rates were assumed to be low during the first six months of treatment. After the first month of debridement therapy, 0.5% of modelled patients who had undergone unsuccessful LDT, mechanical, surgical, sharp, or hydrosurgical debridement, received clinical intervention and ceased debridement therapy. Over the following months, the modelled proportion of patients with undebrided wounds receiving clinical intervention rose: 0.5%, 1%, 2% and 2.5%. The equivalent rates for autolytic therapies were 1%, 1%, 2%, 4% and 5%. At the end of Month 6, any wounds still not debrided resulted in a clinical intervention.

Healthcare resource use and cost data

Table 2 details the cost inputs implemented in the base case. Where available healthcare resource use and costs were derived from published sources, PSSRU Unit Costs (2011) and National Reference Costs (2011). Where necessary published costs were inflated to 2010/2011 costs using appropriate OECD PPP indices (OECD, 2010/11). Where published resource use and related cost data were not available, estimates were elicited from clinical experts based on their experiences of current practice.

The cost of LDT, published by Dumville et al (2009), was updated and calculated from the weighted average cost per treatment from the manufacturer's (Biomonde Ltd) sales data (Data on file), to determine a cost per application of LDT (£234). This cost is higher than the costs of LDT used by Dumville et al (2009) and, thus, any bias introduced by its implementation will be in favour of the comparator therapies.

Quality Adjusted Life Years

To calculate quality adjusted life years (QALYs), utility values* were required to weight the life years associated with the various treated and untreated health states within the model. These were derived from published literature where possible and assumptions made based on other treatment outcomes where necessary. Parameter values derived were baseline utility, utility associated with therapies, decrement of infection (per event), utility after clinical intervention (amputation), and decrement of utility related to other adverse events (Table 2).

*a measure that represents preference based valuation of quality of life in a particular health state.

Table 1: Clinical effectiveness data input parameter values in the base case analysis

Debridement Therapy	Biosurgical LDT		Mechanical Ultrasound		Autolytic				Surgical		Sharp		Hydrosurgical	
					Hydrogel		Honey							
Parameter	Value	Data source	Value	Data source	Value	Data source	Value	Data source	Value	Data source	Value	Data source	Value	Data source
Number of treatments conducted	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.91	Granick et al (2006)	2	Assumption based on Granick et al (2006)	1.2	1.18 from Granick et al (2006) and 1.4 from Mosti et al (2005)
Probability of debridement	76.70%	Bagged larvae; Dumville et al (2009)	60.00%	Assumption based on other data and expert opinion	63.20%	Dumville et al (2009)	60.00%	Assumption based on other data and expert opinion	95.00%	Expert opinion	95.00%	Expert opinion	95.00%	Granick et al (2006)
Probability of infection per month of treatment	17.50%	Bagged larvae; Dumville et al (2009)	25.00%	Assumption based on other data and expert opinion	26.00%	Dumville et al (2009)	44.40%	Gethin & Cowman (2009)	21.00%	Assumption based on other data	25.00%	Assumption based on other data	25.00%	Assumption based on other data
Probability of treatment related adverse events during treatment	9.60%	Bagged larvae; Dumville et al (2009)	5.35%	Assumption based on other data and expert opinion	7.70%	Dumville et al (2009)	7.70%	Assumption based on other data and expert opinion	5.35%	Caputo et al (2008)	5.35%	Caputo et al (2008)	5.35%	Caputo et al (2008)

RESULTS

As an indicator of value for money, incremental cost effectiveness ratios (ICERs) were calculated based on the difference in costs incurred and benefits provided by LDT compared to the named comparator. In the UK, the commonly accepted norm for a new intervention to be adopted is £20,000 per QALY gained. This is much the same as in other European jurisdictions and we have used this as our benchmark for acceptable cost-effectiveness.

The results for the base case CUA of LDT versus each of the comparator debridement methods are shown in Table 3.

Figure 2 shows that all plots of incremental costs and QALYs estimated for LDT, compared with all alternatives, fall in the lower right quadrant of the cost-effectiveness plane. Thus, LDT appears to be the dominant therapy — ie it is expected to be more effective and less costly than all alternatives considered.

Sensitivity analysis

The limited availability of data and variation in clinical wound care and debridement practice lead to a high degree of uncertainty surrounding the data inputs and assumptions made during the development of the model. The potential consequences of this uncertainty were explored through sensitivity analysis, as follows.

Hydrosurgical therapy

Although surgical-type debridement is typically achieved with approximately two attempts, hydrosurgical therapy was reported in two published studies to require an average of only 1.18 or 1.4 attempts to achieve debridement (Granick, 2006; Caputo, 2008). A fairly conservative estimate of the number of hydrosurgical procedures conducted (1.2) was taken in the base case. Varying the number of hydrosurgical procedures (n=1.18, 1.4, 1.9) had little impact on the incremental results and none on the overall cost-effectiveness conclusions.

Clinical (terminating) interventions

The rates of clinical intervention (amputation) over time could not be identified in the literature and are subject to uncertainty as a result. Based on the higher rates of amputation reported for autolytic therapies (Ribu et al, 2008), the base case assumes higher rates of clinical intervention over time for hydrogel and honey compared to other initial therapies. To test the consequences of uncertainty around these assumptions, two scenario analyses were conducted. Firstly, a more gradual increase of clinical intervention was applied over time, escalating to the assumption of clinical intervention for all undebrided wounds at the end of six months; and secondly, the same rates were assumed across all therapies (including autolytic).

Table 2: Cost and health related utility data input parameter values in the base case analysis

Costs			Health utilities		
Parameter	**Value**	**Data source(s)**	**Parameter**	**Value**	**Data source**
Cost of therapy (per month or procedure)			Health utility associated with therapy		
LDT	£571.31	Soares et al (2009), Hall et al (2010)	LDT	0.562	Soares et al (2009), Dumville et al (2009)
Mechanical – Ultrasound	£190.95	Watson et al (2011)	Mechanical - Ultrasound	0.515	Watson et al (2011)
Autolytic – Hydrogel	£246.67	Dumville et al (2009)	Autolytic – Hydrogel	0.559	Dumville et al (2009)
Autolytic – Honey	£250	Expert opinion	Autolytic – Honey	0.55	Assumption (expert opinion)
Surgical	£2,320	NHS Reference costs 2010/11	Surgical	0.55	Assumption (expert opinion/other therapy values)
Sharp	£1,370	NHS Reference costs 2010/11	Sharp	0.55	Assumption (expert opinion/other therapy values)
Hydrosurgical	£2,620	Granick et al (2006) (converted to GBP)	Hydrosurgical	0.55	Assumption (expert opinion/other therapy values)
Infection	£621	NHS Reference costs 2010/11*	Baseline utility value of uninfected wound	0.6	Iglesias et al (2004)
Clinical intervention	£6,508	NHS reference costs 2010/11: weighted cost of amputation with/out major cc (40%) and foot procedures (60%) according to Ribu et al (2008)	Decrement of infection (per event)	0.007	Nelson et al (2006)
Adverse events	£36	GP visit PSSRU Unit Costs 2011**	After clinical intervention	0.54	Nelson et al (2006); relating to amputation

*Department of Health. NHS Reference costs 2010/11. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131140 Accessed October 2012
**Curtis L. Unit Costs of Health and Social Care. Kent: Personal Social Services Research Unit, 2011. www.pssru.ac.uk/pdf/uc/uc2011/uc2011.pdf Accessed October 2012

Table 3: Base case incremental results of LDT compared to alternative debridement therapies

Debridement comparison made with LDT	Incremental cost	Incremental QALYs	ICER
vs. surgical	-£3,373	0.0015	Dominant
vs. sharp	-£1,638	0.0020	Dominant
vs. hydrosurgical	-£2,268	0.0008	Dominant
vs. mechanical (ultrasound)	-£45	0.0055	Dominant
vs. hydrogel	-£26	0.0009	Dominant
vs. honey	-£176	0.0008	Dominant

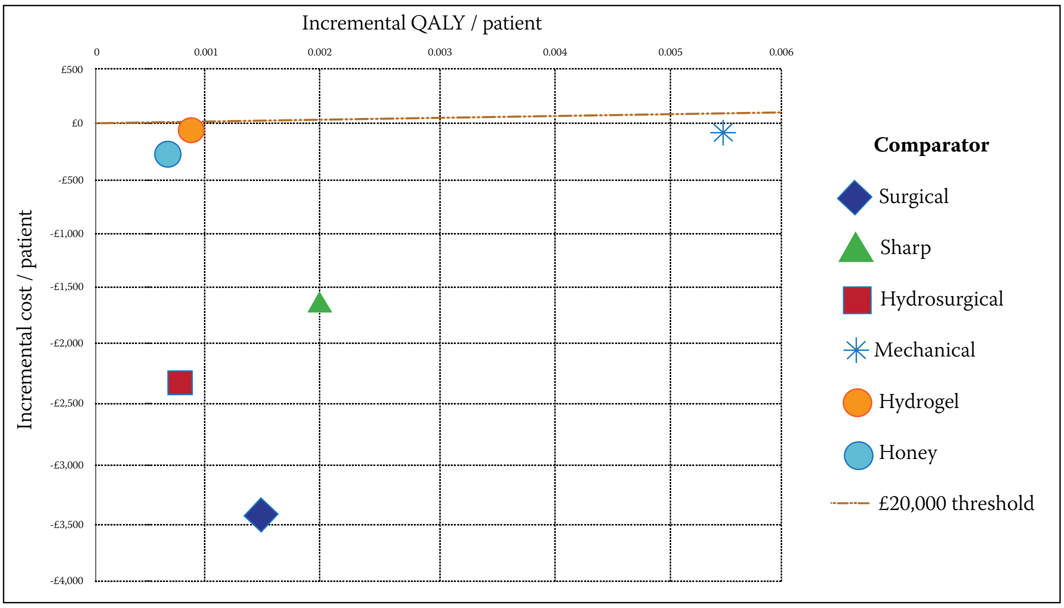

Figure 2: Graphical representation of base case results of LDT compared to alternative debridement therapies on the cost-effectiveness plane.

Increasing the rate of clinical intervention over time for undebrided wounds across all therapies (month 1 to 5: 1%, 2%, 10%, 25% and 50% for honey/hydrogel; 0.5%, 1%, 5%, 10%, and 25% for all other therapies) made little difference to the incremental results and no difference to the cost-effectiveness conclusions of the base case. When the same rates were assumed across all therapies (month 1 to 5: 0.5%, 1%, 5%, 10% and 25% for all other therapies), LDT was no longer dominant compared to hydrogel.

Although estimated to provide higher QALYs in these scenarios, LDT was predicted to be more expensive compared to hydrogel. Nevertheless, with an ICER of £14,802 per QALY gained, LDT would still be considered to be cost-effective at a threshold of £20,000 per QALY.

Infection and adverse event rates

Scenarios were tested in which the infection rate associated with surgical-type therapies was applied per month of treatment, rather than per procedure as in the base case; however, these rates were not found to be drivers of results. Due to the relatively low incidence of adverse events associated with debridement therapies, and their low cost and utility consequences, adverse events where not found to be a driver of results.

Other sensitivity analysis

A range of further sensitivity analyses were conducted as presented in Table 4. Figure 3 presents the results of the sensitivity analysis in the form of tornado plots for mechanical, hydrogel and honey — the debridement methods closest to LDT in the base case results — and also for surgical debridement. The cost of LDT and the probability of its success in achieving debridement were found to be the key cost drivers, while the utilities associated with LDT and its comparator were key drivers of accumulated benefits.

DISCUSSION

This is the first attempt we are aware of to estimate the cost-effectiveness of multiple options for debridement against a common comparator — LDT. Under the majority of scenarios modelled, LDT was estimated to be a cost-effective therapy for wound debridement. The base case results suggest that initiating treatment with LDT may be a dominant intervention compared to hydrogel, honey, mechanical, surgical, sharp, and hydrosurgical debridement methods. That is, adopting the use of LDT may result in both cost savings and greater benefits for a patient over one year.

All debridement methods appear to be similar in terms of overall quality of life impact for patients, partially attributable to the assumed practice of changes in treatment for undebrided wounds; however, there appears to be a meaningful estimated difference in costs between treatments. LDT is estimated to be cost saving compared to surgical-type therapies in the base case analysis and also the majority of sensitivity analyses performed. The costs accumulated over one year were more closely

Table 4: Results of univariate sensitivity analyses

Variable changed	**LDT vs. surgical**	**LDT vs. sharp**	**LDT vs. hydrosurgical**	**LDT vs. mechanical**	**LDT vs. hydrogel**	**LDT vs. honey**
Rates						
Probability of debridement with LDT (69% to 84%)^	Dominant	Dominant	Dominant	£29,307/ QALY	£358,373/ QALY	£43,564/ QALY
				Dominant	Dominant	Dominant
Probability of infection° (+/- 10% of mean)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
Probability of AEs° (+/- 10% of mean)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
Costs						
LDT cost per bag (£195 to £295)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
			C-E		Dominated	
Clinical intervention* (£3,174 to £12,418.50)	Dominant	Dominant	Dominant	Dominant	£20,182/ QALY	Dominant
					Dominant	
Infection** (£1,268)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
All costs (+/- 10% of mean)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
Utilities						
Baseline utility (+/- 5% of mean)	Dominant	Dominant	C-E	Dominant	Dominant	Dominant
			Dominant			
During LDT therapy (+/- 10% of mean)	Dominant	Dominant	Dominant	Dominant	Dominant	Dominant
	C-E	C-E	C-E		£7,214/QALY	C-E
During comparator therapy [only]^^	C-E	C-E	C-E	Dominant	£16,061/ QALY	C-E
	Dominant	Dominant	Dominant		Dominant	Dominant

*across all therapies, ^ up/down 10% of base case value, *all toe amputation versus all leg amputation,**NHS reference costs with CC (base case used cost without CC) ^^bounds of 95% CI tested if available, else ± 10% of base case value capped at baseline. 10% lead to greater extremes than those CIs available.
C-E: cost-effective at threshold of £20,000/QALY

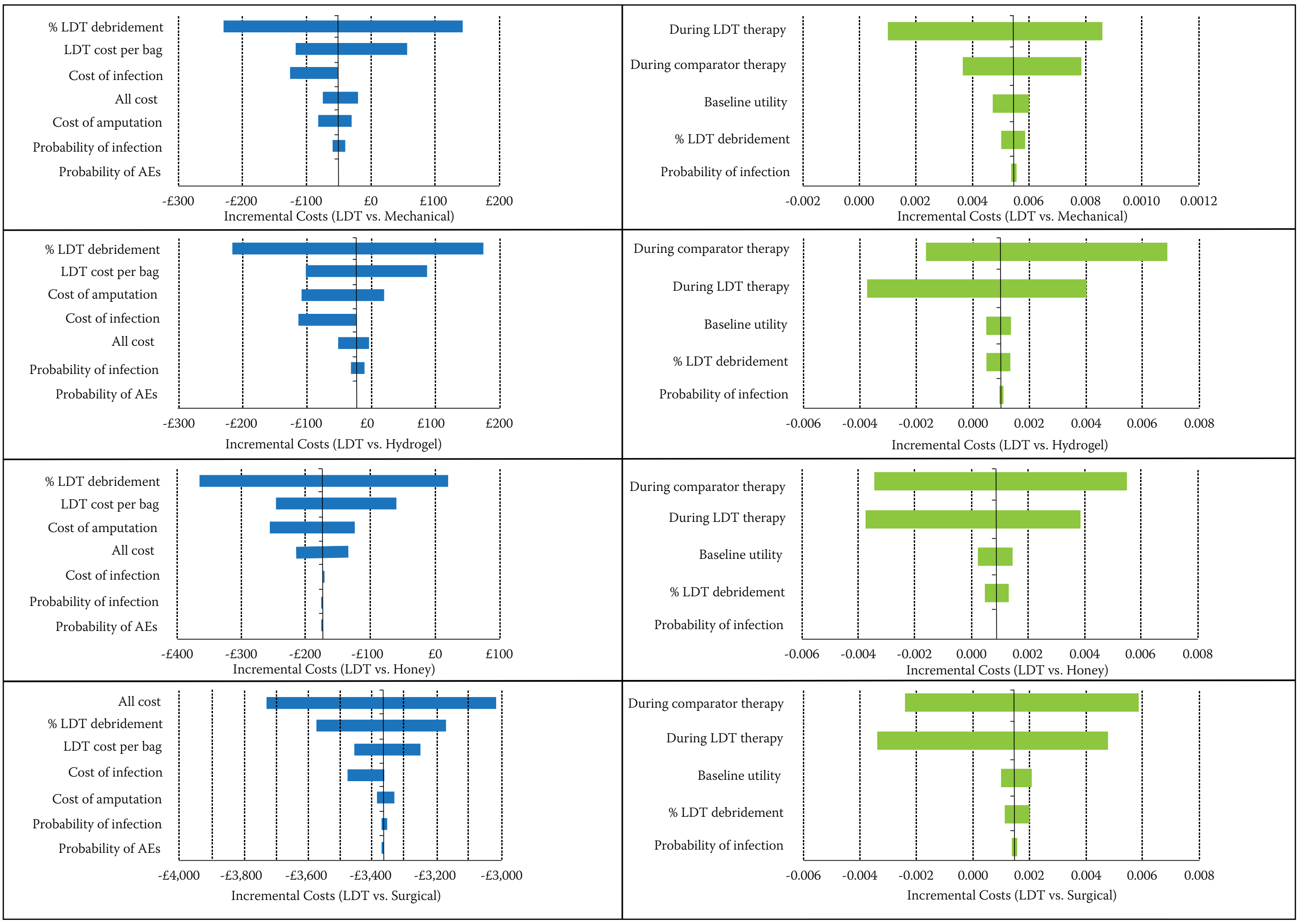

Figure 3: Tornado plots — sensitivity analyses for LDT vs. mechanical, hydrogel, honey and surgical debridement therapies. AE = adverse event.

comparable when initiating treatment with LDT and the other non-surgical therapies; however, LDT was estimated to be cost saving in the base case and in many cases tested in sensitivity analyses.

To address the uncertainty around our results, we undertook a sensitivity analysis, which highlights the parameter inputs that are most influential for overall costs and outcomes. It is particularly important to have strong evidence for the chosen values of these influential parameters. The sensitivity analysis conducted showed that the cost of LDT and the probability of its success in achieving debridement were the key cost drivers, while the utility values associated with the debridement interventions were key drivers of accumulated benefits, emphasising the importance of robust quality of life evidence in this area. The cost of treatment was a significant driver for surgical therapies due to their higher cost compared to the other debridement therapies considered.

In undertaking this research we faced a number of challenges relating to the variation in wound presentation and care in clinical practice and the lack of comparative data based on good quality RCTs of the available interventions. Despite the heterogeneity of patients, complexity of debridement approaches and variation in wound care pathways observed in clinical practice, the model developed for this analysis was necessarily simple. In reality, treatment may be tailored to the type of wound presented and its progression; in such cases, changes in debridement therapy may happen over different time intervals and some debridement methods more frequently follow others. For example, one debridement method may be used for a short time to rid the wound of most sloughy tissue (surgical) or soften hard eschar (autolytic), followed by another debridement therapy, such as LDT, for a longer period of time. Our simple model gives an overall picture of the comparative cost-effectiveness of therapies in circumstances where any of the available debridement methods would be clinically appropriate.

An additional issue is that published data available in this area is limited, which alters both the level of complexity that can be accommodated in modelling and the reliability of any results modelling can provide. The consequent reliance on expert opinion to inform data inputs and modelling assumptions is a major limitation of the modelling described here.

Further limitations as a result of data paucity include possible issues concerning consistency of studies from which parameter values were derived, choice of modelled endpoint and type of wound modelled. The primary endpoint modelled was wound debridement; however, modelling the treatment of wounds until healing, including any recurrences, would be superior. No distinction could be made between wound types, despite known differences between diabetic foot or venous leg ulcers.

The described data limitations and structural assumptions lead to great uncertainty in the modelling results; however, it was difficult to quantify the impact of this uncertainty through probabilistic sensitivity analysis due to the paucity of data to support the specification of sampling distributions and reasonable ranges for parameter values. Full probabilistic sensitivity analysis is strongly recommended should sufficient data become available in the future.

CONCLUSIONS

Despite its limitations the model provides useful information regarding the cost-effectiveness of LDT and important insights for both healthcare professionals and budget holders regarding the influential factors associated with treatment that determine the cost-effectiveness of debridement therapy.

The modelling process has enabled the identification and specification of gaps in available evidence relating to wound debridement. Our findings suggest that undertaking further research to improve this evidence base, particularly in the areas of quality of life and resource use associated with therapies, is of great importance if the costs and effects of wound debridement are to be better understood and to support evidence-based decision making.

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Declaration of interests

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