The cost effectiveness of larval therapy in venous ulcers

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The treatment of necrotic ulcers involves considerable nursing time and expense. The current standard treatment involves repeated application of hydrogels. Larval debridement therapy (LDT) has been shown anecdotally to clear ulcers of necrotic slough but has never been compared directly with 'modern' therapies. The aim of this study has been to compare LDT with hydrogel dressings in the treatment of necrotic venous ulcers. 12 patients with sloughy venous ulcers were randomised to receive either LDT or the control therapy – a hydrogel. Effective debridement occurred with a maximum of one larval application in 6/6 patients. 2/6 in the hydrogel group still required dressings at one month. The median cost of treatment of the larval group was £78.64 compared with £136.23 for the control treatment group ($p<0.05$). The study confirms both the clinical efficacy and cost effectiveness of larval therapy in the debridement of sloughy venous ulcers.

Introduction

Recently there has been intense media interest in the use of sterile fly larvae for the treatment of chronic necrotic ulcers[1]. The medical literature from Napoleonic times contains many reports of the successful use of larvae in the removal of sloughy tissue from wounds[3–5]. There has been a distinct paucity of comparative studies on the role of these creatures in wound healing.

Our own anecdotal experience of using larval therapy on necrotic ulcers has given us encouraging results particularly in venous ulcers. The aim of this study has been to compare the efficacy and cost of sterile fly larvae with a conventional pharmaceutical agent for the debridement of necrotic venous leg ulcers.

Methods

All patients referred to the local leg ulcer service were seen by a leg ulcer specialist nurse (AW). Those diagnosed as having a sloughy venous ulcer following routine ulcer assessment, were randomised and entered into one of the two groups. Twelve consecutive patients with venous ulceration, deemed to require debridement were recruited to the study. Patients were excluded if there was evidence of arterial insufficiency or if the patient had undergone previous, failed therapy. Randomisation was by sealed envelope technique to treatment with hydrogel (Group 1) or larval therapy (Group 2).

Group 1. Hydrogel dressing

The control dressing used for debridement of sloughy and necrotic tissue was a standard hydrogel dressing (Intrasite® gel; Smith & Nephew Medical Ltd, Hull) which has been used in many clinical studies on wound healing. The gel was applied as directed by the manufacturer and left in place for a maximum of 72 hours. Once the gel was applied the ulcer was covered with an appropriate secondary dressing (Melolin®, Smith & Nephew Medical Ltd, Hull or Telfa®, Kendall Company (UK) Ltd, Basingstoke).

Group 2. Larval therapy

Sterile larvae of *Lucilia sericata* produced by the Biosurgical Research unit in Bridgend General Hospital (now the Princess of Wales Hospital, Bridgend, Wales) were used in this study. The larvae were stored at room temperature and used the day they were received from the suppliers. The larvae of the size 2–3 mm were introduced into the wound and covered with a specially designed containment dressing. This consisted of a fine nylon mesh laid across an adhesive hydrocolloid border (Granuflex®, ConvaTec Ltd, Uxbridge) to prevent

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Table 1. Table comparing the baseline details of the two groups

	Control group	Larval therapy	*P*
Age	54 (40–75)	58 (48–72)	*ns*
Male:female ratio	3:3	2:4	*ns*
Ulcer size (cm^2)	16 (14–22)	18 (13–25)	*ns*
Proportion of ulcer covered with slough (%)	95 (80–100)	100 (80–100)	*ns*
Ulcer duration (months)	4 (2–6)	5 (2–8)	*ns*

larvae migrating. The dressing was left in place for a maximum of 72 hours then removed and the larvae were replaced if required.

Details of patient age and sex were recorded along with details of ulcer size and duration. All patients were reviewed every 72 hours until debridement had occurred or for a maximum of one month. The outcome measures used for effectiveness were whether or not debridement had occurred within the month and the time to de-slough. The nurse applying the dressings (AW) determined the success of debridement. The amount of slough obscuring the ulcer bed was calculated as a percentage of the total ulcer surface area from mapping of the ulcer onto a clear centimetre grid. When the percentage surface area of slough was less than 5%, the ulcer was said to have been debrided. A measure of exudate, other than the requirement for dressing change, was not used.

The outcome measures for cost were the number of nursing visits required and the costs of nursing time and dressings to achieve debridement or one month of treatment. All dressings were purchased at the standard United Kingdom (UK) costs, which were applied to all calculations (*table 2*). Nursing time was calculated according to the pay scale of an 'F'-grade nurse. The end point of the study was debridement of the ulcer or one month's treatment, whichever was sooner.

All dressings were applied by the same health care worker (AW) who also performed assessments of debridement and completed records of dressing times and costs. Statistical analysis was performed using the non-parametric Mann–Whitney U test. Significance was regarded to have been reached when $p<0.05$.

Results

Despite no formal case matching protocol, the two groups were comparable in terms of age, sex, ulcer size and duration (*table 1*).

Effectiveness

Table 3 shows the results in the two treatment groups. Debridement occurred more rapidly in the LDT where patients only required one application of larvae. In the hydrogel group only 2 patients were de-sloughed within the month. One patient required 42 visits ultimately, another 30 (*figure 1*). One patient who had persistent necrotic slough after 13 visits was changed to LDT after the end of the study period and the slough was rapidly resolved.

Cost

The nursing time required per ulcer treated (*figures 1 & 2*) was significantly greater in the standard group compared with the LDT group [median number of visits required = 19 *vs.* 3; $p<0.05$, median time = 375 hours *vs.* 75 hours; $p<0.05$]. The cost of nursing time (*figure 3*) was therefore significantly greater in the standard group compared with the LDT group [median cost £53.85 *vs.* £10.77; $p>0.05$]. The cost of dressing materials – excluding larvae – (*figure 4*) was greater in the standard group [median cost £89.55 *vs.* £9.87; $p<0.05$].

Costs based on a maximum treatment time of one month showed a total cost for the larvae group of £492 (including larvae) against £1054 in the hydrogel group. Overall, taking into account the £58.00 purchase cost of larvae, the median cost of treatment of the larval group was £78.64 compared with £136.23 for the control treatment group ($p<0.05$). There were no additional costs for storage of larvae and all larval populations appeared healthy at the time of application.

Discussion

Although our leg ulcer specialist is attached to the vascular unit, the service is mainly community based. Two patients of group 1 and two of group 2 were treated

Table 2. Table of costs used in the study

Nursing time	£8.60
Hydrogel (intrasite gel)	£1.38 per 8 gm sachet
Sterile dressing pack	£0.70
Absorbent cotton gauze	£0.60 per metre
Crepe bandaging	£1.27
Granuflex	£2.18
Nylon mesh	£0.90
Larvae	£58.00

Table 3. Table comparing number of visits, time and costs required to achieve resolution of slough in venous ulcers between patients treated with larval therapy and standard therapy with hydrogel. Number of visits applies to actual number, time and costs and is limited to a maximum of 30 days therapy

	Number of visits	Nursing time (mins)	Nursing costs (£)	Dressing costs (£)	Larval cost (£)	All costs (£)
Larvae	3	175	25.13	8.98	58.00	92.11
	3	55	7.88	10.75	58.00	76.63
	3	80	11.49	22.87	58.00	92.36
	3	80	11.49	10.75	58.00	80.25
	4	70	10.05	8.98	58.00	77.03
	2	60	8.61	6.88	58.00	73.49
Hydrogel	10	200	28.70	106.80		135.50
	15	300	43.05	69.90		112.95
	23	575	115.46	155.48		270.94
	42	840	120.54	198.76		319.30
	13	195	28.01	35.88		63.89
	30	450	64.65	72.30		136.95

Figure 1. Plot of number of visits required to achieve debridement of venous ulcers in group 1 patients (hydrogel) and group 2 (larval therapy). Dressings required changing on average every three days. The two cases in whom ≥30 visits were required applies to the total treatment time including that beyond one month

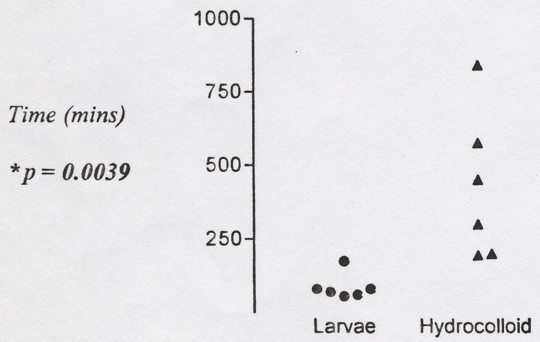


Figure 2. Plot of nursing time (in hours) to attempt debridement of venous ulcers in group 1 patients (hydrogel) and group 2 (larval therapy) in one month or until debridement

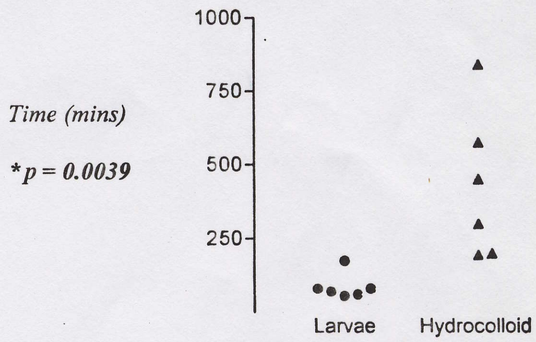


Figure 3. Plot of cost of nursing time to attempt debridement of venous ulcers in group 1 patients (hydrogel) and group 2 (larval therapy) in one month or until debridement

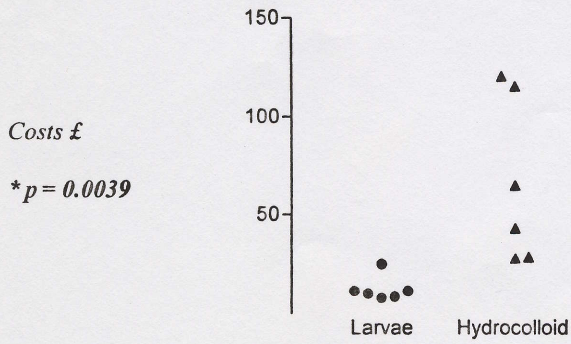
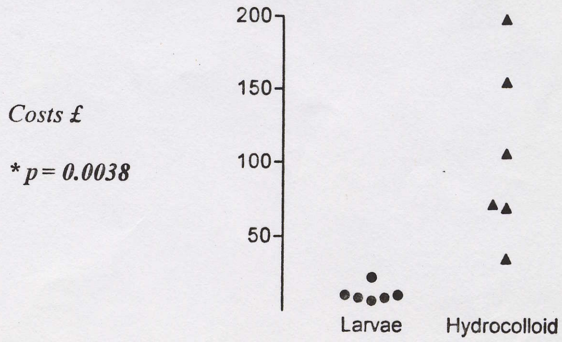


Figure 4. Plot of cost of dressings used to attempt debridement of venous ulcers in group 1 patients (hydrogel) and group 2 (larval therapy) in one month or until debridement



in the community, the remaining 8 patients were treated in hospital. The 'leg ulcer nurse' had successfully used larval therapy in the community in the past. The costs described in this study do not take account of travel expenses incurred but similarly do not take account of the cost of in-patient stay. For inpatients then, the total costs of standard therapy are likely to be many fold increased compared with larval therapy, for which patients are likely to be discharged much sooner. It is interesting to speculate on the implication of usage and costs, if larval therapy were a prescribable item.

Although the endpoint of therapy is debridement of the ulcer base, another outcome measure is the amount of discharge from the ulcer. The number of visits required to achieve successful debridement is dependent on the amount of discharge and hence the frequency with which dressings needed to be changed. This is a highly subjective test of debridement and has not been thoroughly validated. Indeed, it could be argued that the wounds in both groups discharged equally but the dressings in one group were better at absorbing it than the other. We attempted to minimise the differences made by the secondary dressings by standardising their application by the same health care worker. There is clearly a significantly greater variability in this in the standard therapy group compared with LDT group in whom the number of changes of dressings was consistently 3 (+/ − 1).

This small study clearly demonstrates significant improvement in the time required to debride varicose ulcers using LDT and that this therapy is cost effective. There are deficiencies in this study, however. Assessments of debridement and exudate were not blinded. This, and the subjective nature of the measures used, makes our results vulnerable to an element of bias, although the large differences between the two study groups are unlikely to be explained by this alone.

The study does not use healing rates as the main outcome measure. Undoubtedly, for the patient, this is the most important outcome. However, we believe that debridement facilitates wound healing. Furthermore some other products (enzymes) are primarily used for debridement and therefore removal of slough as an outcome measure is valid. Indeed, healing rates have subsequently been measured in this group and found to be comparable. Future studies would do well to include formal assessment of healing rates within the study protocol.

Although formal assessment of quality of life was not used in this study, the general acceptance by patients of the use of larval therapy was very good. No patient declined randomisation and those receiving larval

the end of therapy. The technique for applying larvae is easily taught. Since the time of this study, both hospital based nurses and district nurses have mastered the techniques required. This has made LDT a much more widely available and used technique in our practice.

The findings of this study suggest that larval debridement is more cost-effective than standard hydrogel for the debridement of sloughy venous ulcers. A larger study is required to confirm these results and to convincingly demonstrate whether LDT should become established as a standard debridement agent in venous ulcers.

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References

1 Palmer J. Grubby cure down at the insquirmary. *Daily Mirror* 1996 (Feb 23).
2 Thomas S, Jones M, Shutler S, Jones S. Using larvae in modern wound management. *Journal of Wound Care* 1996; **5**(2): 60–69.
3 Boon H, Freeman L, Unsworth J. Wound care. Larvae help debridement – case reports. *Nursing Times* 1996; **92**(46): 76–80.
4 Weil GC. A biological, bacteriological and clinical study of larval or maggot therapy in the treatment of acute and chronic pyogenic infections. *American Journal of Surgery* 1993; **9**: 36–48.
5 Chemin E. Surgical maggots. *Southern Medical Journal* 1986; **79**: 11–43.