

Static Magnet device, *4UlcerCare*, prevents Leg Ulcer Recurrence: Potential Cost Savings in leg ulcer management

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Abstract

The objectives of this survey were to examine the effectiveness of *4UlcerCare* in preventing recurrence of leg ulcers after healing and also to estimate the potential cost savings to the significant UK National Health System (NHS) spending each year on ulcer management. Subjects surveyed had ulcers for on average 4.4 years before use of *4UlcerCare* but these ulcers healed within an average of 3.57 months after application of *4UlcerCare*. After 19.94 months wearing *4UlcerCare* as advised, 65% of those surveyed that had previously had a mean number of recurrences of 2.41, had no further ulcer recurrence. We have estimated an unprecedented potential 51.2% reduction in spending by the UK NHS, which represents a reduction of at least £153.7 million per year (assuming an annual spend of £300 million per annum).

Keywords: Static magnetic field, leg ulcers, ulcer recurrence, cost saving.

1. Introduction

In a recent double blind placebo controlled study published in the *Journal of Wound Care* in February 2005 (Eccles & Hollinworth, 2005), *4UlcerCare* was demonstrated to significantly expedite chronic ulcer healing (i.e. Ulcers that were failing to heal by usual evidence-based conventional treatments). Despite the small numbers (26) and other problems encountered in conducting this study, the results are strongly in favour of a significant chronic ulcer healing effect in the *4UlcerCare* group but not in the placebo group. All trial patients were having evidence based care, and the only intervention was the *4UlcerCare* leg wrap. At 12 weeks ulcer area in the *4UlcerCare* group was reduced on average by 91.2% whereas in the placebo group there was an average increase in area of 3.8% ($p < 0.04$).

Prior to the above trial, a survey was also conducted of 160 randomly selected users of *4UlcerCare* leg wraps (Eccles & Price, 2003). Average ulcer duration was 49 months i.e. just over 4 years. The leg wraps were self-applied by patients themselves and did not require nurse involvement. The device had been worn for an average of 4 months at the time of the survey. The key findings were as follows:

The key findings were as follows:

- A highly significant reduction ($p < 0.0001$) in ulcer size of 68% was achieved over the treatment period. The average time to heal in those that had complete healing was 3.9 months.
- 72% of those with associated swelling had a significant reduction in swelling after wearing *4UlcerCare* with an average reduction in swelling of 71% ($p < 0.0001$).
- 84.5% had a highly statistically significant reduction in associated leg pain with *4UlcerCare* ($p < 0.0001$).
- The majority, 54.5% reported an improvement in ability to perform daily tasks with 64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

Even using evidence based practice, leg ulcer healing rates are very variable, and ulcers frequently reoccur. No single treatment method stands out as having unsurpassed effectiveness (Cullum, 1994). Ulcer chronicity and recurrence are a problem. Sixty to 90% are managed in the community and this represents 22-50 % of district nurse workload (Lees & Lambert 1992, Morrisson & Moffatt, 1994); fewer than 10% are managed in hospital clinics (Cullum, 1994). Furthermore some patients are reluctant to comply with or cannot tolerate the compression bandages or are unable to leave their homes (Brereton et al, 1997). This is not an insignificant problem when one considers that medium to high compression stockings are recommended for prophylaxis for 5 years after healing of a venous ulcer (Nelson et al, 2004). Contact sensitivity in patients with leg ulcers is also a widespread problem (Cullum, 1994).

There are estimated to be 100,000 ulcer patients in the UK at any one time (Moffatt et al, 1992; Callum et al 1985). Seventy to 90% are venous in origin, 5-20% arterial, 10-15% combined and 5-10% due to other causes such as diabetes, vasculitis, neoplasm, infection, trauma etc. There is an increased prevalence with age so that the average of 1.5 to 1.8 per 1000 population rises to 3 per 1000 at age 61-70 and 20 per 1000 at age 80 and above (Cullum, 1994). Nearly 1% of the population is affected by leg ulcers at some point in their lives.

Over two thirds of leg ulcer sufferers have recurrence and a third have 4 or more episodes. Fifty percent of ulcers are open for 9-12 months, 20% are open for 2 years and 8% are open for more than 5 years (Cullum, 1994). It is estimated in general up to 69% of leg ulcers will re-occur within 1 year of healing (Thurlby & Griffiths, 2002). Major reviews of health care in the UK have concluded that there is widespread variation in practice, and evidence of unnecessary suffering and costs due to inadequate management of venous leg ulcers in the community (NHS Centre for Reviews and Dissemination, 1997: Audit commission, 1999). Despite the introduction of community leg ulcer clinics, there is no strong evidence that they are better than home visits (Thurlby & Griffiths, 2002), and concern has been expressed over the uncontrolled study that formed the basis for their introduction (Fletcher, 1995). It has been suggested that efforts to improve the management of chronic ulcers of the leg should focus on primary health care (Callam et al, 1985). The need for assessment to exclude compromised arterial supply prior to the application of compression due to the risk of

gangrene adds further to the cost (Roe et al, 1993; Stevens et al, 1997). Health promotion (in the context of ulcer prevention) is perceived to be ineffective by community nurses and patients and leg ulcer aftercare services are fragmented. Community nurses expressed a desire to delegate preventative aspects of leg ulcer care to home carers rather than to participate in health promotion strategies to support healing behaviours (Flanagan et al, 2001).

It has been estimated that £400 million is spent each year by the UK NHS to treat leg ulcers (Thurlby & Griffiths, 2002) although some estimates are even higher than this at £600 million per year (Laing, 1992; Simon et al, 2004). The total costs are generated by price of dressing, nursing time, physician time, hospital stay, home health costs, risks and the cost of complications (e.g. infection) and frequency of dressing changes (Kerstein, 2003). These estimates amount to between £1100 and £5000 being spent on each patient per year. For comparison, in the USA the annual cost of wound care has been estimated to be \$3 billion annually (National Institutes of Health release, Oct 2000). Clearly, chronic ulceration is a problem and a major financial burden on the UK NHS as well as other non-UK healthcare resources.

Given the increasing evidence, cited above, for the effectiveness of *4UlcerCare* in expediting resolution of even chronic ulcers it was decided to perform this survey to determine:

- 1) The effectiveness of *4UlcerCare* in preventing recurrence of leg ulcers after healing.
- 2) To estimate any potential cost savings to the significant NHS spending in the UK on ulcer management

2. Methods

A questionnaire survey was conducted by telephone of 289 randomly selected *4UlcerCare* users. Verbal consent was obtained and also consents for the data to be used as part of a scientific analysis to assess the efficacy of the products. No exclusions were made on the basis of age or sex or on the basis of location. No incentives were offered to those taking part in the survey. It is important to note that the *4UlcerCare* leg wraps were self-applied by patients themselves and did not require nurse involvement. The questionnaire used in the study is shown in Fig 1.

4UlcerCare Description

The *4UlcerCare* wrap contains four powerful neodymium magnets (2000gauss). Each magnet has patented and unique directional plates that allow the negative (south-facing) enhanced magnetic field to be absorbed deeper into the tissues; it is thought that this gives more effective and longer lasting effect. It is advised that the leg wrap should be worn as much as possible (including overnight). Once healed *4UlcerCare* should be worn overnight to avoid recurrence. The wraps are fitted below the knee and above the calf muscle and are held in place by “hook and loop” fastening tape. The leg wraps are double lined for comfort, and are adjustable and washable (available in 3 standard sizes). The product is registered as a Class 1 Medical Device.

Guidelines for use: *4UlcerCare* is fitted comfortably below the knee (not under compression) and above the calf muscle. It is advised that the device is worn for 24 hrs a day during active ulceration. It is not unusual to have some increase in leakage at around 6 weeks but usually for only a few days. After healing, *4UlcerCare* should be

worn overnight to prevent recurrence. If *4UlcerCare* is used in conjunction with 3 or 4 layer bandages it is advised that the bandage is pushed down to 2 or 3 fingers below knee (it is generally accepted that as long as a bandage extends to above the calf that compression effectiveness is unlikely to be compromised) and to wear *4UlcerCare* above the bandage just below the knee but against the skin. This was the case in the double-blind trial.

2.1 Statistical Methods

For the comparison of the two group means for the duration of use when *4UlcerCare* was used alone and when it was not used alone a two-sided t-test was used (parametric test was chosen as sample size is large). For the comparison of the recurrence rate observed in the study (0%) with that expected in the population (66.67%) a two-sided normal approximation to the binomial test for testing an observed proportion with an expected one was used. For both hypothesis tests the significance level was taken to be 5% ($p < 0.05$).

3. Results

Of 289 users of *4UlcerCare* surveyed 211 were recorded as having healed ulcers. A large proportion of the remainder reported that their ulcers were healing. However, since the focus of the survey was an investigation of the rate of recurrence those with ulcers that had not completely healed were excluded from our analyses. The following results are based on the 211 subjects with healed ulcers.

Mean age was $70.60 \pm \text{SE: } 0.63$ years; Males: 95 (45.0%) Females: 116 (55.0%). There was no significant difference in age between the sexes (Males: Mean: $69.76 \pm \text{SE: } 1.06$ Females: Mean: $71.25 \pm \text{SE: } 0.75$). The majority of ulcers were located on the lower leg (41.7%) and ankle (54.5%); the remainders were on the foot. Mean duration of ulcer prior to the use of *4UlcerCare* was 52.64 (4.4 years) $\pm \text{SE: } 6.58$ months. Ulcers had recurred in 137 (64.9%) with a mean frequency of $2.41 \pm \text{SE: } 0.13$ (recurrences). Fig 1 shows the frequency of leg ulcer recurrence in the 137 patients that had recurrences.

Prior to ulcer healing 100 (47.4%) *4UlcerCare* alone and 111 (52.6%) had used *4UlcerCare* in combination with other prescribed treatments. Mean duration of wearing *4UlcerCare* after ulcer healing was $19.94 \pm \text{SE: } 0.65$ months. There was no difference in duration in either the *4UlcerCare* only group and the group that used it in combination with other prescribed treatments in duration of wear of the device after ulcer healing [*4UlcerCare* used alone: mean: $20.06 \pm \text{SE: } 10.01$ months; duration of use when *4UlcerCare* not used alone: Mean: $19.84 \pm \text{SE: } 9.02$ months: Difference in means: 0.22; 95% CI: -2.38 to 2.82; $P = 0.868$ (NS)]. *4UlcerCare* was worn for a mean of $15.85 \pm \text{SE: } 0.57$ hours per day after the ulcer had healed.

NUMBER OF RECURRENCES OF LEG ULCERS IN STUDY POPULATION

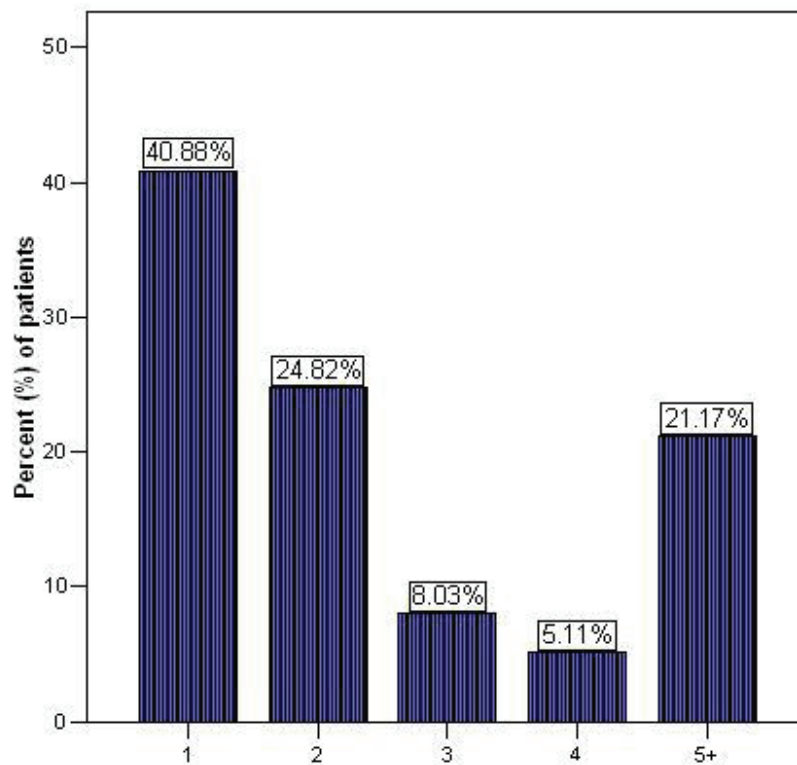


Fig 1. Frequency of Ulcer Recurrence

Frequency of leg ulcer recurrence in 137 patients of our sample of 211 patients surveyed.

None of the 211 patients had any further recurrence of their ulcers over the average time of 19.84 months of wearing 4UlcerCare. There were 4 subjects (excluded from the data analysis) whose chronic ulcers (5,9,10 and 40 years and all of whom had had recurrent ulcers; one, twice, thrice and numerous) healed (in 2,4,5 and 9 months) but returned. All 4 subjects had ceased to wear the 4UlcerCare after their ulcers had healed). Furthermore, prior to ulcer healing, no patients reported the ulcer getting worse or not improving.

Fig 2 shows the cost calculations and potential savings to the NHS based on the above results demonstrating that 4UlcerCare seemed to prevent ulcer recurrence when worn as per the Manufacturers advice for at least 8 hours (usually at night) per day.

FIG 2. COST CALCULATIONS

(a) The cost per year for the **conventional treatment (includes Nurse time)**:

$100,000 \text{ sufferers} \times \text{£}3,050^* / \text{year} = \text{£}305,000,000 / \text{year}$

where $\text{£}3,050^* = \text{average cost of conventional treatment} (\text{£}1100 - \text{£}5000)$

* Average of $\text{£}1100$ and $\text{£}5000$ (Cullum, 1994). Note the correspondence of the total figure with the estimated UK NHS annual spend of between $\text{£}300$ - $\text{£}600$ million.

$$(b) 100,000 \times £20^{**} + 100,000 \times £907^{***} + 25\% \times 100,000 \times £2143 = £146.3 \text{ million}$$

£2 million (cost of 4UlcerCare) + £90.7 million (cost of conventional treatment for 3.57 months) + £53.57 million (cost of conventional treatment for ulcers not healed with 4UlcerCare)

** £20 = wholesale cost of 4UlcerCare to the UK NHS

*** £907 = cost of conventional treatment (average £3,050/ yr) for 3.57 months (average time that the ulcers were healed) assuming that all of these patients are on conventional treatment as well.

£2143 = cost of conventional treatment for a further 12 – 3.57 months for ulcers failing to heal after 3.57 months of 4UlcerCare

**Thus, UK NHS potential cost savings on a £300 million annual spend:
(a)-(b) = £153.7 million**

This represents a 51.2% cost saving

4. Discussion

Eccles and Hollinworth (2005) in their double- blinded controlled study of 4UlcerCare have provided evidence that this device can expedite the healing of chronic leg ulcers with average reduction of ulcer area of 91.2% after 12 weeks of treatment (compared with an average increase in ulcer area of 3.8% in the placebo group ($p < 0.001$) that were maintained on the best evidence-based ulcer management). The current survey provides further strong circumstantial evidence that 4UlcerCare was able to promote healing of chronic ulcers (mean duration 4.4 years) after an average time of only $3.57 \pm \text{SE: } 0.20$ months. Of 289 4UlcerCare users that were surveyed 211 had healed ulcers and a large proportion of the remainder had healing ulcers.

This survey aimed to determine the self reported frequency of recurrence of leg ulcers in those who continued to use 4UlcerCare as per manufacturer's instructions (to wear at least 8 hours overnight) after the ulcer was healed. It came as a surprise to find that none of the 211 subjects who had used 4UlcerCare (as per the above manufacturer's instructions) after their ulcers had healed for an average duration of 20 months had had any further recurrence of their leg ulcers. The compares with 65% of those surveyed having had ulcer recurrence with a mean number of recurrences of 2.41 prior to using 4UlcerCare. When comparing the recurrence rate observed in the study with that expected in the population (66.67%) the p-value is highly significant (i.e. $p < 0.0001$). The 95% confidence interval (CI) for the observed recurrence rate is: -0.06 to 0.06 while the 95% CI for the difference in the two rates is: 0.61 to 0.74. The above means that we can be very sure that the recurrence rates after using 4UlcerCare are very small. Repeating the study 100 times, we would be 95% certain that the recurrence rate fell within the range -0.06 to 0.06. Supportive of the effectiveness of the device in preventing recurrence was the fact that 4 subjects in this survey (excluded from the data analysis) who did not continue to wear 4UlcerCare after their ulcers had healed did indeed have a recurrence of their ulcers. The mechanisms by which 4UlcerCare may expedite ulcer healing and prevent recurrence are discussed elsewhere (Eccles & Hollinworth, 2005).

The double-blind study referred to above (Eccles & Hollinworth, 2005) has been criticized on the basis of their study of a relatively small group. Impressive and suggestive as the results were (see above) it is now difficult to deny in the face of these survey results that their findings must represent a real healing effect of *4UlcerCare* on chronic leg ulcers.

It has been estimated that as much as £600 million per year is spent by the UK NHS on ulcer management. A large proportion of these costs are taken up by District Nurse time in the management of ulcers that are both chronic and failing to heal or ulcers that are recurrent. Taking an average of £1100 and £5000 yields an average spending per ulcer patient of £3,050 per patient per year and total expenditure of £305,000,000 /year. However, the findings from the current survey, 47.4% of whom had used *4UlcerCare* alone without any other treatment, would mean a dramatic reduction in cost saving to the NHS. The savings would be apparent on the basis of quicker ulcer healing, non-recurrence of ulcers (zero of 211 in this study) and a reduction in Nurse time that is normally required to help manage ulcers that are failing to heal or are recurrent. Most subjects in this survey self-applied the device, which is simply fastened by a self-securing “hook and loop” mechanism around the leg below the knee and above the calf. This means that in most cases nurses would not be required to apply or re-apply the *4UlcerCare* device as it is so easy to self-apply. We have estimated conservatively a potential 51.2% reduction in spending by the NHS, which represents at least a reduction of £153.7 million per year (Fig 2). These figures may even be underestimates as we have assumed that normal 3 and 4 layer dressings would still be applied until ulcers had healed. The reality is that ulcers seem to have healed and not recurred irrespective of presence or absence of these dressings. This agrees with the findings of Eccles and Hollinworth (2005) where the average change in ulcer size in the placebo group, all of whom were still having compression dressings applied (as per best evidence-based care), was actually + 3.8%, a slight increase in ulcer size after 12 weeks. A simpler and cheaper covering may well suffice if *4UlcerCare* is being used. This would of course lead to even less nurse time input and a further reduction in the cost of dressings and perhaps negate the need for other long-term preventative advice and support to be given to patients. Furthermore, because *4UlcerCare* seems to expedite leg ulcer healing without compression this would negate the need for arterial blood supply analysis when compression bandages are being considered and also given the lack of compliance of some ulcer patients with compression bandages there is likely to be an increased compliance with a therapy that does not require compression. In summary there appear to be numerous potential advantages to the use of *4UlcerCare* over the current methods of leg ulcer treatment:

- 1) An inexpensive and simple treatment modality that can be self-applied
- 2) More consistent healing of leg ulcers
- 3) More rapid healing of leg ulcers
- 4) Less need for nursing input due to ease of application of the device as well as more rapid healing and
- 5) A dramatic reduction in leg ulcer recurrence
- 6) A reduction in the need for preventative health promotion strategies
- 7) Elimination of the need to check for arterial blood supply compromise prior to treatment

- 8) Due to all of the above- a potential £153.7 million (51.2% reduction) in cost saving to the current rate of UK NHS spending on leg ulcer management.

5. Conclusion

4UlcerCare users with healed ulcers (211 of 289 randomly surveyed) had ulcers for an average of 4.4 years before use of *4UlcerCare* but these ulcers healed within an average of 3.57 months after application of *4UlcerCare*. After 19.94 months wearing *4UlcerCare* as advised, the 65% of those surveyed that had previously had a mean number of recurrences of 2.41, had no further ulcer recurrence. These differences in recurrence rates are highly statistically significant. The use of *4UlcerCare* to expedite ulcer healing and prevent ulcer recurrence would lead to a very significant reduction in spending by any government or Healthcare system on ulcer management.

References

Audit Commission. *First assessment: A review of District Nursing Services in England and Wales*. 1999. Audit Commission Publications, London

Brereton L, Morrell J, Collins K, Walter S, Peters J & Brooker C. *Patients' tolerance of leg ulcer treatments*. Br J Community Health Nurs 1997; 2: 427-435.

Callum MJ, Ruckley CV, Harper DR, Dale JJ. *Chronic ulceration of the leg: extent of the problem and provision of care*. BMJ 1985; 290: 1855-6

Cullum N. *Leg Ulcers: A review of research in nursing management in the community*. Bandolier, 1994, www.jr2.ox.ac.uk/bandolier/band10/b10-2.html

Eccles NK, Hollinworth H. *A pilot study to determine whether a static magnetic device can promote chronic leg ulcer healing*. Journal of Wound Care 2005, 14(2): 64-67

Eccles NK, Price DR. *Survey to determine the effectiveness of Magnopulse 4UlcerCare On Leg ulcer healing and Leg pain*, 2003. www.magnopulse.com

Flanagan M, Rotchell L, Fletcher J, Schofield J. *Community nurses', home carers' and patients' perceptions of factors affecting venous leg ulcer recurrence and management of services*. J Nurs Manag 2001; 9 (3): 153-159

Fletcher A. *A review of classic research: community clinics for leg ulcers. Critique III*. J Wound Care 1995; 4: 471-472

Kerstein MD. *Economics of quality ulcer care*. Dermatology Nursing, 15 (1); 59-61

Laing W. *Chronic venous diseases of the leg*. London: Office of Health Economics, 1992.

Lees TA, Lambert D. *Prevalence of lower limb ulceration in an urban health district*. Br J Surg, 1992, 79 (10): 1032-4

McGuckin M, Brooks J, Cherry G. *Venous leg ulcers: the role of the GP and District Nurse*. Nursing Standard 2000; 14(40): 46-48

Moffatt CJ, Franks PJ, Oldroyd M et al. *Community services for leg ulcers and impact on healing*. BMJ, 1992, 305: 1389-92

Morrell CJ, Walters SJ, Dixon S, Collins KA, Brereton LML, Peters J, Brooker CGD. *Cost effectiveness of community leg ulcer clinics: randomized controlled trial*. BMJ 1998; 316: 1487-1491

Morrisson M & Moffatt CJ. *A colour guide to the assessment and management of leg ulcers*. 2nd edition. Mosby, London

Nelson EA, Bell-Syer S and Cullum NA. *Compression for preventing recurrence of venous ulcers (Cochrane Review)*. The Cochrane Library (Issue 1). Chichester, UK: John Wiley & Sons, Ltd.

NHS Centre for Reviews and Dissemination. *Compression Therapy for venous leg ulceration*. Effective Health Care 3(4): 1-12

Roe BH et al. *Assessment, prevention and monitoring of chronic leg ulcers in the community: report of a survey*. J Clinical Nursing 1993; 2: 299-306

Rotchell L. *Introduction and auditing of a nurse leg ulcer service*. Professional Nurse 1999; 14(8) 545-550

Schofield JK et al. *Management of leg ulcers: healing rates following implementation of locally agreed guidelines for Community Nurses*. Br J Dermatol Suppl 1997; 50: 49

Simon DA, Dix FP & McCollum CN. *Management of venous leg ulcers*. BMJ, 2004; 328 (7452), 1358-1362

Stevens J et al. *A community/hospital leg ulcer service*. J Wound Care 1997, 6 (2): 62-8

Thurlby K, Griffiths P. *Community leg ulcer clinics vs home visits: which is more effective?* British Journal Community Nursing, 2002, 7 (5): 260-264

