

Static magnets prevent leg ulcer recurrence: savings for the NHS?

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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 in tackling this (Cullum, 1994). Ulcer chronicity and recurrence are a problem: 60–90% of ulcers are managed in the community, representing 22–50% of the district nurse workload (Lees and Lambert, 1992; Morison and Moffatt, 1994); fewer than 10% of ulcers are managed in hospital clinics (Cullum, 1994).

Standard care for venous leg ulcers involves the use of compression, in the form of bandages or hosiery. However, some patients are reluctant to comply with or cannot tolerate the compression (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; 50–85% of leg ulcer patients attending dermatology outpatient clinics demonstrate sensitivity to one or more allergens that contribute to non-healing and discomfort to the patient, e.g. lanolin, topical antibiotics, cetyl steryl

alcohols, balsam of Peru and parabens (Cullum, 1994).

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

Over two-thirds of leg ulcer sufferers have recurrence and one-third have four or more episodes. Fifty per cent 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 that in general up to 69% of leg ulcers will re-occur within 1 year of healing (Thurlby and 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 because of 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 and 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). However, the need for assessment to exclude compromised arterial supply before the application of compression adds further to the cost (Roe et al, 1993; Stevens et al, 1997). A 2001 study indicated that health promotion (in the context of ulcer prevention) is perceived to be ineffective by community nurses and patients, and leg ulcer after-care services are fragmented (Flanagan et al, 2001). Community nurses expressed a desire to delegate preventive 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 NHS to treat leg ulcers (Thurlby and 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 the price of dressings, nursing time, physician time, hospital stay, home health costs, risks and the

ABSTRACT

The objectives of this survey were to examine the effectiveness of a static magnet device – 4UlcerCare – in preventing recurrence of leg ulcers after healing. Two hundred and eighty-nine randomly selected purchasers of 4UlcerCare were telephoned and asked to complete a short questionnaire. Our focus was on the 211 respondents who had ulcers that had already healed. The average age of subjects was 70.6 years and sex distribution was 55% female to 45% male. Mean duration of leg ulcers before using 4UlcerCare was 4.4 years. Sixty-five per cent of those surveyed had had ulcer recurrence before using 4UlcerCare, with a mean of 2.41 episodes of ulceration. This was close to the expected recurrence rate in the population of 67%. Using 4UlcerCare daily, these respondents' ulcers had healed within an average of 3.57 months. The survey took place an average of 19.94 months after healing. The manufacturers advise wearing 4UlcerCare daily post-healing, and of those respondents that had, none had suffered any recurrence.

Extrapolating these results across the health economy, an estimate has been made of a potential £153.7 million per year saving on leg ulcer care to the NHS.

KEY WORDS

Leg ulcers • 4UlcerCare • Healing • Telephone survey

cost of complications (e.g. infection) and frequency of dressing changes (Kerstein, 2003). These 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 NHS as well as the health systems of other countries.

A role for magnets?

4UlcerCare is a static magnet device that is designed to be applied to the legs of people with leg ulcers to promote healing. In a small scale, double-blind, placebo-controlled study published in the *Journal of Wound Care* in February 2005 (Eccles and Hollinworth, 2005), 4UlcerCare was shown to significantly expedite healing of chronic ulcers (i.e. ulcers that were failing to heal by conventional treatments). Despite the small numbers (26) and other problems encountered in conducting this study, the results were strongly indicative of a significant chronic ulcer healing effect in the 4UlcerCare group that was not seen in the placebo group. All trial patients were receiving standard evidence-based care, the only intervention being 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% ($p < 0.04$).

Before this trial, a survey was conducted of 160 randomly selected users of 4UlcerCare leg wraps (Eccles and Price, 2003). These were selected at random from a data base of 5000 4UlcerCare users.

Customers were contacted randomly from a list of purchasers on Magnopulse's database. No incentives were offered to those surveyed. The only criteria for inclusion were whether the subject answered the telephone and whether they were willing to spend 5 minutes answering questions about their experience with the device.

Two third-party assessors, who were not employees of Magnopulse, completed the questionnaires.

Average ulcer duration among these users was 49 months. The leg wraps were self-applied by patients 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 survey findings were:

- 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.

The current survey was undertaken:

- To determine the effectiveness of 4UlcerCare in prevent-

ing recurrence of leg ulcers after healing

- To estimate any potential cost savings to the significant NHS spending on ulcer management.

Following the Eccles and Hollinworth study, it was decided to investigate the longer-term effects of 4UlcerCare.

Methods

A questionnaire survey was conducted by telephone of 289 randomly selected 4UlcerCare users, using the same method and criteria as the earlier survey discussed above. 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. All participants had a medical diagnosis of leg ulceration. The ulcers were mainly venous (70%) and the remainder were of mixed aetiology. No exclusions were made on the basis of age or sex or on the basis of geographical 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.

4UlcerCare description

The 4UlcerCare wrap contains four strong neodymium magnets, oriented so the magnetic fields are aligned the same way. It is advised that the leg wrap should be worn as much as possible (including overnight). Once the ulcer is healed, it is advised that 4UlcerCare should continue to be worn daily overnight to avoid recurrence. The leg wraps are double lined for comfort, are adjustable (they are held in place by 'hook and loop' fastening tape) and washable. They are available in three standard sizes.

The product is registered as a Class 1 medical device and from March 2006 appears in Part IX of the Drug Tariff.

Guidelines for use

4UlcerCare is fitted comfortably below the knee and above the calf muscle, though not under compression. It is advised that the device is worn continuously 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 multi-layer bandages it is advised that the bandage is pushed down to 2 or 3 fingers width below the 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 (Figure 1).

Results

Of 289 users of 4UlcerCare surveyed, 211 reported having healed ulcers. While a large proportion of the remainder reported that their ulcers were healing, 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.

Of the sample, 95 (45%) were males and 116 (55%) were



Figure 1. 4UlcerCare in place on leg.

females. The mean age was 70.60 ± 0.63 years. There was no significant difference in age between the sexes. The majority of ulcers had been located on the lower leg (41.7%) and ankle (54.5%); the remainder had been on the foot.

Before using 4UlcerCare, the mean duration of ulcers was 52.64 ± 6.58 months (4.4 years). A total of 137 (64.9%) respondents had experienced recurrence of previously healed ulcers, with a mean of 2.41 recurrences. Figure 2 shows the frequency of leg ulcer recurrence in these patients.

Before ulcer healing, 100 (47.4%) respondents had used 4UlcerCare alone (i.e. with no compression), and 111 (52.6%) had used it in combination with prescribed treatments. At the time of the survey, respondents had been using 4UlcerCare for an average 19.94 ± 0.65 months after healing. There was no significant difference in duration of wear of the device after healing between the groups. 4UlcerCare was worn for a mean of 15.85 ± 0.57 hours per day after the ulcer had healed.

Of the 211 patients whose ulcers healed when using 4UlcerCare, none had any further recurrence of their ulcers over the average time of 19.84 months of wearing the product. No patients reported the ulcer getting worse or not improving before healing. Four respondents (excluded from the data analysis) whose long-term chronic ulcers (between 5 and 40 years) healed when using 4UlcerCare did have recurrence, but all four had stopped wearing the 4UlcerCare after their ulcers had healed.

Limitations

It is acknowledged that these results are based on survey evidence, with its dependence on patients who had already purchased the product and also on patients' recall and self-reporting. It is also true that there was no exploration of factors other than compression dressings that may have influenced recurrence. Despite these limitations, the absence of any offered incentives to respondents, the use of third-party assessors, and the very clear endpoints of recurrence or no-recurrence make the results noteworthy.

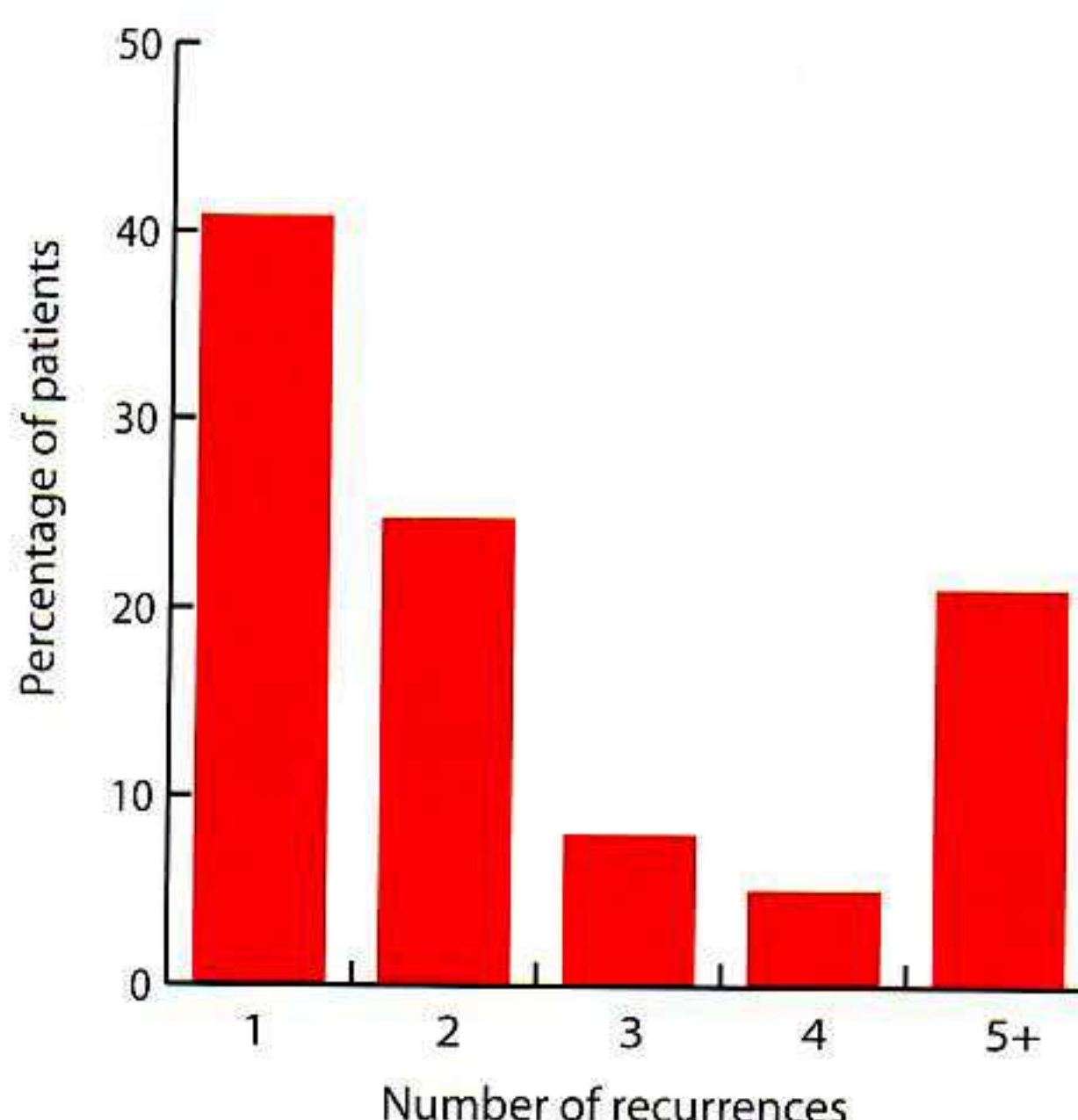


Figure 2. Frequency of leg ulcer recurrence (before using 4UlcerCare) in 137 of 211 patients surveyed.

Discussion

In a double-blind controlled study of 4UlcerCare, Eccles and Hollinworth (2005) have provided evidence that this device can expedite the healing of chronic leg ulcers when used in conjunction with standard compression treatment, with an average reduction of ulcer area of 91.2% after 12 weeks of treatment. This is compared with an average increase in ulcer area of 3.8% in the placebo group ($p < 0.001$) who were maintained on the best conventional ulcer management alone. The current survey provides further strong circumstantial evidence that 4UlcerCare was able to promote healing of chronic ulcers after an average time of only 3.57 ± 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 the manufacturer's instructions (to wear at least 8 hours overnight) after the ulcer was healed. It

Box 1. Cost calculations

Basic assumptions:

100 000 people in the UK with leg ulceration

Average cost of conventional treatment is £3050 per year (Cullum, 1994)

a) The cost per year for conventional treatment (including nurse time) is £305 million

b) If those 100 000 people were provided with 4UlcerCare, the cost would be £2 million (the wholesale cost of 4UlcerCare to the NHS is £20)

♦ Add the cost of conventional treatment during the average 3.57 months it takes an ulcer to heal using 4UlcerCare ($100\,000 \times £907$)

♦ Add the cost of conventional treatment to healing for the 25% of people whose ulcers do not heal using 4UlcerCare ($25\,000 \times £2143$)

Total cost = £2 000 000 + £90 700 000 + £53 570 000 = £146 270 000

This equates to a potential saving to the NHS of £158 730 000

KEY POINTS

- ♦ Leg ulceration affects at least 100000 people at any one time in the UK.
- ♦ The cost to the NHS is up to £600 million per year.
- ♦ A telephone survey of people who had used the magnetic device 4UlcerCare indicated rapid healing and no recurrence when the product was worn in accordance with the manufacturer's advice.
- ♦ If the results are confirmed, the use of 4UlcerCare could save the NHS over £150 million per year.

came as a surprise to find that none of the 211 subjects who had continued to use 4UlcerCare after their ulcers had healed experienced any further recurrence of their leg ulcers. This compares with 65% of those surveyed having had ulcer recurrence before using 4UlcerCare.

When comparing the recurrence rate observed in the study with that expected in the population (67%) the p-value is highly significant (i.e. $p < 0.0001$). The 95% confidence interval (CI) for the observed recurrence rate is -0.06-0.06, while the 95% CI for the difference in the two rates is 0.61-0.74. This 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. In this regard, it is telling that the four respondents in this survey 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 and Hollinworth, 2005).

The Eccles and Hollinworth study has been criticized on the basis of its relatively small sample size. This survey, however, lends support to the study's findings in relation to the healing effect of 4UlcerCare on chronic leg ulcers.

It has been estimated that as much as £600 million per year is spent by the 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. The findings from the this survey of people with healed ulcers, 47.4% of whom had used 4UlcerCare alone without any other treatment, could mean a dramatic potential cost saving to the NHS (Box 1). The savings would be apparent on the basis of quicker ulcer healing, non-recurrence of ulcers and a reduction in nurse time that is normally required – most subjects in this survey self-applied the device.

These figures may even be underestimates, as they assume that normal multilayer compression would still be applied until ulcers had healed. However, the ulcers seem to have healed and not recurred irrespective of the presence or absence of these dressings, reflecting the findings of the earlier study (Eccles and Hollinworth, 2005). 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.

The results suggest that there is nothing to be lost by using the 4UlcerCare device as an adjunct to existing standard compression treatment. Further research into the effectiveness of this device may well lead to a change in the way that we manage chronic leg ulcers in the future.

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 post-healing, none had suffered any recurrence despite 65% of them having previously experienced recurrence.

While larger clinical trials are needed, the use of 4UlcerCare appears to have potential to generate a significant reduction in spending by the NHS on ulcer management. **BJCN**

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