

COST-EFFECTIVENESS of POLYHEAL in TREATING HARD-to-HEAL VENOUS LEG ULCERS in the UK

^{1,2}Julian F Guest, ¹Erikas Sladkevicius, ³Peter Vowden

¹Catalyst Health Economics Consultants, Northwood, Middlesex UK; ²Postgraduate Medical School, University of Surrey, Guildford, Surrey, UK; ³Vascular Unit, Bradford Royal Infirmary, Bradford, Yorkshire, UK.

INTRODUCTION

- An estimated 3–5% of the population aged >65 years will develop a leg ulcer during their lifetime, with the prevalence increasing to 20 per 1,000 population at the age of 80.3 years [1].
- Modern dressings used in combination with compression bandaging exhibit venous leg ulcer (VLU) healing rates in the region of 50% at 12 weeks. However, more than 20% remain unhealed after one year [2,3].
- Polyheal is a new and innovative approach to wound healing, comprising a suspension of charged polystyrene microspheres which are applied topically.
- This study assessed the cost-effectiveness of Polyheal plus compression bandaging compared to compression bandaging alone in treating hard-to-heal VLUs in the UK.

METHODS

Markov Model

● A 12-month Markov model was constructed depicting the management of hard-to-heal VLUs of >6 months duration in the UK with either Polyheal plus compression bandaging or compression bandaging alone.

● The clinical basis of the model was a multi-centred study in which patients with hard-to-heal VLUs were randomised to receive Polyheal plus compression bandaging or compression bandaging alone. Patients' trial data was used to populate the Markov model.

Model Inputs - Clinical

● During the trial, patients' ulcer sizes were measured weekly up to week 14 after the start of treatment. Time-series forecasting was undertaken to extrapolate ulcer size beyond 14 weeks to 52 weeks using moving averages.

● Patients' ulcer sizes over the 52 weeks were used to construct a Markov model spanning 12 months and comprising six health states (Fig 1).

● Within the model, patients can initially move into one of three health states following the start of therapy (i.e. improved, unchanged or worsened) and remain in a state for one month at a time before moving to another state. Patients who improve can eventually move into the healed state.

● Healed VLUs were adjusted to allow for the probability of recurrence, in accordance with published estimates of VLU recurrence after healing [4]. Within the model, VLUs that recur are managed according to current practice.

Model Inputs - Resource Use

● Within the model, resource use during the first four weeks of treatment was based on the trial. Following the first four weeks of treatment, healthcare resource use was modelled to reflect UK clinical practice, using previously published estimates about treatment patterns for VLUs in the UK [4].

● The model assumes that:

- Patients remain on Polyheal plus compression bandaging or compression bandaging alone for four weeks. Afterwards, all patients receive compression bandaging alone.
- In the first four weeks Polyheal would be applied twice daily.
- Patients would receive 1 nurse domiciliary visit daily for four weeks to change the dressings. Any other dressings would be applied or changed by the patients or their carers.

Model Outputs

● Published utilities for VLUs [5] were assigned to the respective states in the model and unit costs at 2008/09 prices [6–8] were assigned to the estimates of healthcare resource use in the model.

● The model was used to estimate:

- The expected 12-monthly healthcare costs of a patient receiving either treatment.
- The expected effectiveness at 12 months following the start of treatment.
- The expected number of quality-adjusted life years (QALYs) associated with each treatment at 12 months following the start of treatment.
- The cost-effectiveness of Polyheal plus compression bandaging compared to compression bandaging alone at 12 months (i.e. the cost per QALY gained) from the perspective of the UK's National Health Service (NHS).

● The base-case analysis assumed that the cost of Polyheal for 4 weeks' treatment would be £1,400 (i.e. US \$2,120).

Sensitivity Analyses

● Sensitivity analyses were undertaken to identify how the cost per QALY gained with Polyheal plus compression bandaging would change by varying different parameters in the model.

RESULTS

Clinical Outcomes

● The model indicates that Polyheal plus compression bandaging is more effective than compression bandaging alone (Figure 2).

● Use of Polyheal plus compression bandaging is expected to lead to a health gain of 0.825 QALYs (95% CI: 0.823, 0.828) compared to 0.785 QALYs (95% CI: 0.783, 0.787) following use of compression bandaging alone.

Resource Use and Corresponding Costs

● Use of Polyheal plus compression bandaging instead of compression bandaging alone is expected to lead to a 21% reduction in the requirement for nurse visits (from 43.7 to 34.5 visits) over the first 12 months after the start of treatment (Figure 3), thereby releasing 9 nurse visits per patient for alternative use within the system.

● The 12-monthly healthcare cost of managing patients with Polyheal plus compression bandaging was estimated to be £3,079 (95% CI: £3,055; £3,104), compared to £2,269 (95% CI: £2,256; £2,281) following use of compression bandaging alone (Figure 4).

Cost-Effectiveness Analysis

● Use of Polyheal plus compression bandaging instead of compression bandaging alone is expected to lead to a cost increase of £811 (95% CI: £798; £823) over 12 months and a 5% improvement in health gain of 0.041 QALYs (95% CI: 0.040; 0.041) at 12 months after the start of treatment.

- Hence, the cost per QALY gained with Polyheal was estimated to be £20,000, at an acquisition cost of £350 per week.

● At an acquisition cost of £140 per week, use of Polyheal is expected to generate cost neutrality with the annual cost of managing a patient on compression bandaging alone (£2,269).

● Sensitivity analyses showed that the relative cost-effectiveness of Polyheal plus compression bandaging is very sensitive to the healing rates in both groups, the acquisition cost of Polyheal and the frequency of Polyheal treatment.

● However, the relative cost-effectiveness of Polyheal was less sensitive to changes in other model inputs, such as utility values for health states and number of nurse surgery visits.

Net Resource Implications and Budget Impact

● The current population in the UK is 61.8 million people. Assuming the prevalence of VLUs is 0.2% [9], that would equate to 123,600 people with a VLU per annum. Assuming that 38% of the wounds are long-term non-healing of >6 months duration [10], that would equate to ~47,000 people in the UK with a long-term non-healing VLU of >6 months duration.

● If all 47,000 patients with a hard-to-heal VLU used Polyheal plus compression bandaging (at £140 for a week's treatment) instead of compression bandaging alone, the expected net impact to the NHS would be cost neutral (at £105.2 million) but a 23% reduction in the number of nurse surgery visits (0.5 million) over the first year of treatment from 2.0 to 1.6 million nurse visits.

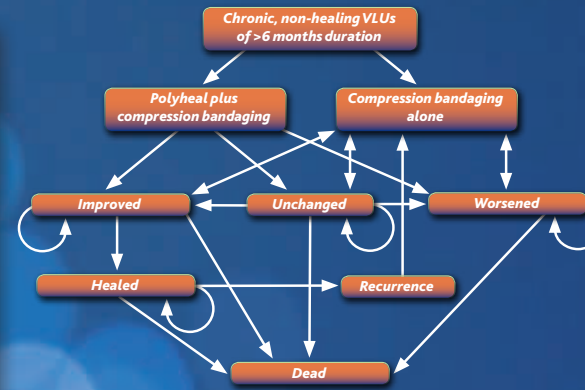


Figure 1: Markov model depicting the management of chronic, non-healing VLUs of >6 months duration with Polyheal plus compression bandaging compared to compression bandaging alone. The arrows depict the possible movement of patients between the different health states.

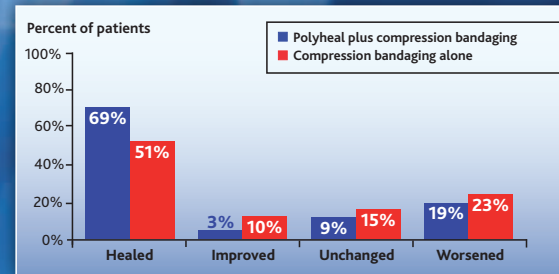


Figure 2: Expected effectiveness at 12 months.

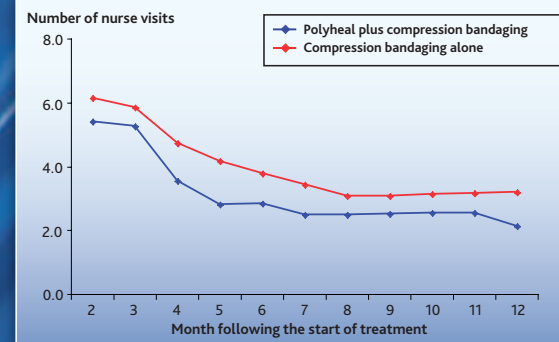


Figure 3: Expected number of nurse visits over 12 months from the start of treatment.

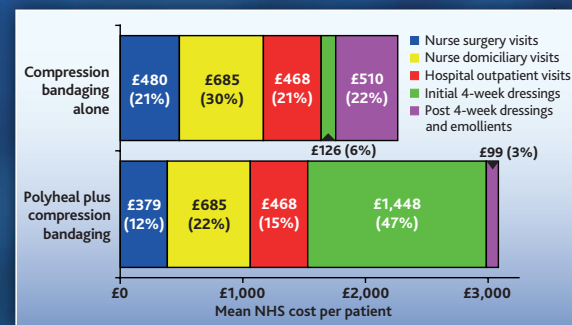


Figure 4: Distribution of expected NHS costs.

DISCUSSION

● The findings from this analysis were based on predicted healing rates and the frequency of Polyheal treatment in the trial. The relative cost-effectiveness to the NHS of using Polyheal plus compression bandaging will be dependent on healing rates and frequency of Polyheal treatment in clinical practice.

● Patients' wound sizes were used as a proxy to determine a patient's transition from one health state to another. However, wound area measurements or percentage changes in ulcer size are only superficial measurements of healing as they fail to take wound depth into account.

● The analysis estimated the cost and consequences of managing chronic, non-healing VLUs over 12 months and does not consider the potential impact of the wounds that remained unhealed beyond that period.

● The model incorporated resource use and utility values for an 'average patient' and does not take into account patients' age, length of wound and suitability of patients for Polyheal and level of clinicians' skills. Neither was the analysis able to consider the impact of other factors that may affect the results, such as co-morbidities, underlying disease severity and pathology of the underlying disease.

● The model excludes costs incurred by patients and indirect costs borne by patients or society.

● Notwithstanding this, Polyheal's acquisition cost is expected to be offset by a reduction in the requirement for nurse visits, thereby releasing NHS resources for alternative use within the system.

CONCLUSION

● Polyheal plus compression bandaging is expected to afford the NHS a cost-effective treatment strategy compared to compression bandaging alone in the management of chronic non-healing VLUs of >6 months duration, but this is dependant on the healing rates observed in the trial being replicated in clinical practice and the frequency of Polyheal treatment.

REFERENCES

1. Mekkes JR, Loots MA, van der Wal AC, et al. Causes, investigation and treatment of leg ulceration. *Br J Dermatol* 2003;148(3):388–401.
2. Franks PJ, Moody M, Moffatt CJ, et al. Randomized trial of cohesive short-stretch versus four layer bandaging in the management of venous ulceration. *Wound Repair Regen* 2004;12(2):157–162.
3. Barwell JR, Davies CE, Deacon J, et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet* 2004;363:1854–1859.
4. Guest JF, Nagy E, Sladkevicius E, et al. Modelling the relative cost-effectiveness of amelogenin in non-healing venous leg ulcers. *J Wound Care* 2009;18(5):2160–224.
5. Clegg JP, Guest JF. Modelling the cost-utility of bio-electric stimulation therapy (Posifect) compared to standard care in the treatment of elderly patients with chronic non-healing wounds in the UK. *Curr Med Res Opin* 2007;23(4):871–883.
6. Drug Tariff 2009. www.drugtariff.com
7. Department of Health NHS Reference Costs 2008/09. www.dh.gov.uk
8. Curtis L. Unit Costs of Health and Social Care 2008. University of Kent, Personal Social Services Research Unit, 2009.
9. Royal College of Nursing. The management of patients with venous leg ulcers. Recommendations for assessment, compression bandaging, cleansing, debridement, dressing, contact sensitivity, training/education and quality assurance. RCN, 1998.
10. Rippon M, Davies P, White R, et al. The economic impact of hard-to-heal leg ulcers. *Wounds UK* 2007;3(2):58–69.

ACKNOWLEDGEMENTS

● This study was sponsored by Polyheal Ltd, Yavne, Israel manufacturers of Polyheal. However, the authors have no other conflicts of interest that are directly relevant to the content of this poster.