Haemoglobin spray in sloughy wounds - A real world, 200-patient, retrospective cohort controlled, evaluation of clinical effectiveness – interim results at 12 weeks

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Introduction

A large number of wounds develop healing complications resulting in wound slough, a viscous mix of fibrin and devitalised tissue that is notoriously time-consuming and difficult to manage, and contribute to loss of quality of life through malodour and increased exudate and risk of strike-through. Sloughy wounds are associated with poor vascularisation and diminished oxygen supply or heighted oxygen demand. Correspondingly, improvement of oxygen availability is increasingly recognised as a key element for achieving slough elimination and improved healing. Facilitated diffusion using haemoglobin is a promising approach to increase oxygen availability in the wound bed to improve healing in sloughy wounds, but has so far not been evaluated in a real-world care context with a representative control cohort.

Method

A controlled evaluation with two cohorts was undertaken in a primary care clinic where a haemoglobin spray (Granulox®, infirst Healthcare) was used in a cohort of 100 patients presenting with sloughy wounds (at least 10% slough coverage), with patients recruited in May through July 2015 and compared with a cohort of 100 patients selected from the same period the year prior using the same protocol, retrospectively, from the same clinic (Control). Haemoglobin spray was provided free of charges by infirst Healthcare. No changes to care practices or dressings were made unless medically required, i.e. due to changes in exudate levels or wound size. The initial 4 weeks promising results for the haemoglobin spray cohort was previously presented (Hunt 2015) with further data now available. Results were evaluated on standard wound evaluation metrics including wound surface area reduction, resource utilisation, and adverse events, as well as ease of use, and patient acceptability. Wound healing at 12 weeks was set as primary (interim) outcome as part of an ongoing 6-month evaluation study.

Results

At the 12-week primary endpoint mean wound size reduction was -96%, vs -57% in the Control ($p<0.01$), and 83/100 (83%) wounds had healed vs 47/96 (49%) in the Control ($p<0.01$). A significant difference vs Control was also observed before 12 weeks. At 4 weeks 98/100 (98%) of wounds in the haemoglobin spray group had demonstrated positive wound size reduction vs 61/99 (62%) in the control ($p<0.01$). At 8 weeks the mean size reduction was nearly 3 times greater in the haemoglobin group; at -93% vs -32% ($p<0.01$) and 1.7 times more wounds closed at 75/100 (75%) vs 43/98 (44%) ($p<0.01$). Secondary outcome evaluation showed mean pain scores significantly lower from week 2 onwards ($p<0.01$), despite being higher at baseline in the haemoglobin group. Also slough and exudate levels saw significantly faster improvements vs Control within as little as one week, with slough reduced by a mean of -67% vs -8% in Control ($p<0.01$), and the number of patients with high exudate reduced from 75 to 7 vs 57 to 47 in the Control ($p<0.01$). At 4 weeks, 95/100 (95%) of patients in the haemoglobin spray group were slough free vs 40/99 (40%) in the Control ($p<0.01$). At the 8-week review 99/100 patients were slough free vs 61/98 in the Control ($p<0.01$). Resource use analysis over the 12-follow-up, showed -47% fewer dressing changes, and total cost of care savings of -53% (-£707 cost /pt, excluding the cost of haemoglobin spray and not considering additional self-care benefits realised) vs Control; driven by lower dressing costs (-59%, -£73/pt), lower nursing costs (-47%, -£485/pt), and fewer unplanned surgical interventions (1 vs 14, -£142/pt). All costs based on NHS tariff prices if available. Five patients died in the Control group, unrelated to their wounds. There were no deaths in the haemoglobin spray group. Two patients required treatment with antibiotics in the Control, one patient in the haemoglobin group. The primary endpoint results were also robust in light of covariance (ANCOVA) to account for variations in baseline values, with the effect of haemoglobin spray on wound size reduction at 12 weeks $p<0.01$ also when controlling for baseline wound size ($p=0.26$), prior wound persistence ($p=0.02$), and patient age ($p=0.03$). No adjustments for multiple analysis was made for reported p-values.

Discussion

The haemoglobin spray treatment group had substantially improved healing outcomes in sloughy wounds vs the retrospective control cohort, with 40% percentage points greater average healing speed and significantly more wounds healed by week 12. These healing benefits also translated into improved quality of life through reduced pain and exudate and substantial total cost of care savings of more than 50%. Longer-term savings are likely to be substantially higher and future research should aim to assess the effectiveness of haemoglobin spray when used in sloughy wounds over the longer-term, over six months – an evaluation already in progress and for which this evaluation reports the half-way outcome.

Conclusion

Adoption of haemoglobin spray in the treatment of sloughy wounds is expected to realise substantial healing benefits to patients.

References

Hunt S (2015). Topical oxygen-haemoglobin use on sloughy wounds: positive patient outcomes and the promotion of self-care. Wounds UK, 11 (4).

KEY POINTS

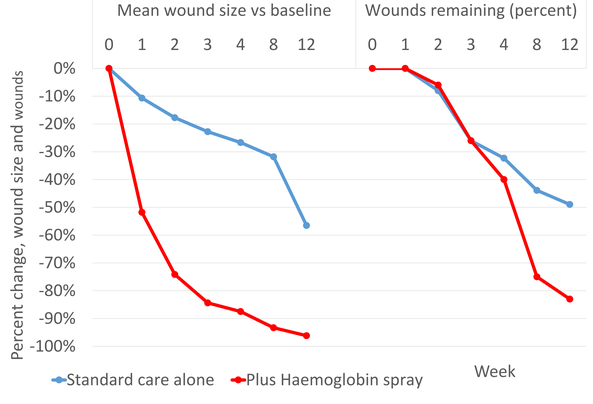
- Sloughy wounds are associated with poor vascularisation and diminished oxygen availability
- Granulox® haemoglobin spray enables increased oxygen availability in the wound bed - aiding healing by aiding oxygen diffusion
- By adopting Granulox® as part of standard care for sloughy wounds, mean healing times and total cost of care were reduced by half, with observed mean savings of £707 per patient within 12 weeks vs a retrospective control cohort.

Acknowledgements and Conflicts of interest

infirst Healthcare provided the haemoglobin spray free for the evaluation, but did not influence on the design, data collection or analysis. Sharon Hunt and Fredrik Elg provide advisory and speaking services to pharmaceutical and other healthcare organisations, including but not limited to, infirst Healthcare Ltd.

More than double the average wound size reduction and number of wounds healed by week 12

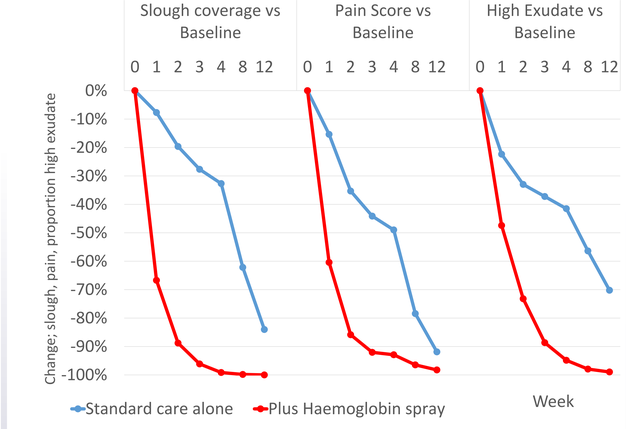
Change in wound size vs baseline, and wounds healed by week 12*



*Size change robust to variations in baseline age, wound size and persistency ($p<0.01$)

Rapid and effective slough elimination, at substantially greater rate than standard care alone already from Week 1

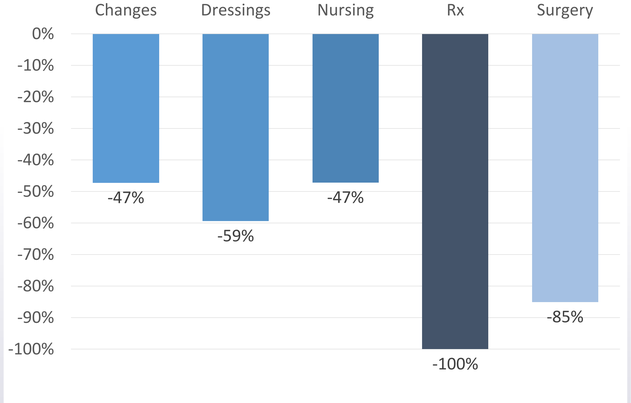
Improvements of key wound healing indicators at week 1*



*Improvements in epithelial and granulation tissue in proportion to slough reduction

Substantial reductions in resource demands across all major cost of care drivers within 12 weeks

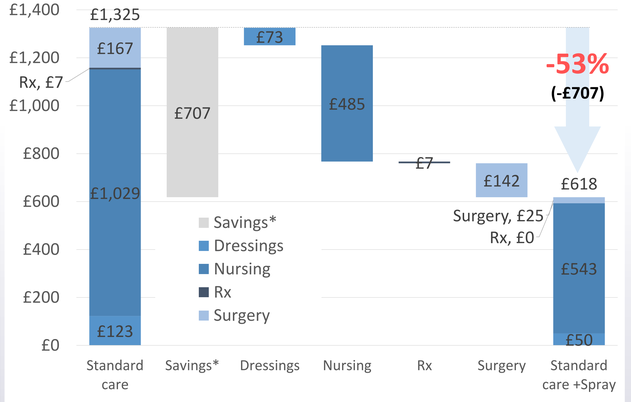
Total resources over 12 weeks, vs standard care, by cost type*



*Costs based on NHS Tariff, where available, else lowest local formulary cost

Total cost of care reduced by over half within 12 weeks of introduction of haemoglobin spray as adjunct therapy

Mean costs and savings per patient over 12 weeks*



*Haemoglobin spray provided free by the manufacturer.

Presented at Wounds UK, Harrogate Nov 14-16, 2016