FAQs

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Expert Panel Report: The role of topical oxygen therapy in the management of diabetic foot ulcers?

What is the Expert Panel Report: The role of topical oxygen therapy in the management of diabetic foot ulcers?

The Expert Panel Report: The role of topical oxygen therapy in the management of diabetic foot ulcers (DFU) covers the role, current evidence and practicalities of topical oxygen therapy (TOT) in diabetic foot care in the UK[1]. The Expert Panel Report also recommends a new treatment algorithm for the use of TOT.

Who developed the Expert Panel Report?

The Expert Panel Report Working Group includes:

- Paul Chadwick (Chair), Visiting Professor, Birmingham City University
- Mike Edmonds, Professor of Diabetic Foot Medicine, King's College London, and Consultant Physician, King's College Hospital
- Adam Fox, Highly Specialist Podiatrist, Cardiff and Vale UHB – Podiatry
- Richard Leigh, Consultant Podiatrist, Royal Free London NHS Foundation Trust, and Visiting Professor, PSMU
- Duncan Stang, Diabetes Foot Co-ordinator, Scotland
- Stella Vig, Consultant Vascular and General Surgeon, Croydon University Hospital
- Luxmi Dhoonmoon, Nurse Consultant Tissue Viability, Central and North West London NHS Foundation Trust (Reviewer)

Treatment algorithm for the use of topical oxygen therapy (TOT)

The Expert Panel Report Working Group developed and updated an algorithm developed by Stang et al (2018)[2] for the initiation of a haemoglobin spray in DFU care in Scotland, to be relevant for topical oxygen therapy options.

The treatment algorithm summarises:

- TOT is an adjunct to standard care and should be considered after four weeks of standard care if non-healing is apparent
- There are patient comorbidities, complications or wound characteristics that would suggest early use of TOT (prior to four weeks of standard care) could be beneficial to healing and lead to quicker wound healing including:
    - Peripheral arterial disease (PAD) where:
    - Revascularisation is inappropriate

- Revascularisation intervention is unsuccessful
- Ulcer pain
- Evidence of non-healing at amputation site
- Evidence of non-healing at post-revascularisation amputation site
- Wounds after slough debridement[3]

- It would not be suitable to consider early use of TOT in the presence of wound or patient deterioration (e.g. size, pain, worsening infection)

Diabetic Foot Ulcers (DFUs)

What are DFUs?

- DFUs are just one complication of diabetes mellitus, which can lead to non-healing wounds and amputations if left unmanaged. Unlike other chronic wounds, DFUs are often complicated by other wide-ranging diabetic and metabolic changes, such as neuropathy and vascular disease[4], which can make them particularly difficult to manage and heal
- Individuals who develop a DFU are also at greater risk of premature death, myocardial infarction and fatal stroke than those without a history of diabetic foot ulceration[5]

What is the burden of DFUs in the UK?

- Each year, an estimated 2–2.5% of people with diabetes develop a DFU[6]
- It has been estimated that there were 169,000 DFUs across the UK, equating to 5% of adults with diabetes[7]
- DFU is the largest single reason for hospital admissions among people with diabetes[8]
- 85% of amputations are preceded by a DFU[9], which can deteriorate quickly if not managed efficiently. Therefore, NICE (2015)[10] recommend that patients should be referred promptly to a specialist multidisciplinary foot team within one working day to reduce the risk of amputation and cost of treatment. However, almost half of providers did not report having a pathway in place for the assessment of urgent referrals within 24 hours (46 percent)[11]

What are the estimated healthcare system costs associated with DFUs in the UK?

The NHS cost of DFUs is estimated at £1 billion per year[10,12], but this does not include the additional social costs to the patient, such as reduced mobility and sickness absence, which are estimated at £13.9 billion per year. The indirect, intangible costs to the person with DFU are also high, with many experiencing a poorer quality of life than those without them[13].

What is a measure prediction of DFU healing?

An accepted measure or prediction of DFU healing is a percentage wound area reduction of 10–15% per week or 40% after four weeks of treatment[14,15].

What are the contributing factors to ulceration aetiology?

- In most patients with a DFU, peripheral neuropathy, ischaemia or both, are contributory factors to the ulceration aetiology
- Ischaemia is a restriction in blood supply to tissues and can be local to the wound or systemic, as in peripheral arterial disease (PAD). Patients with both peripheral neuropathy and PAD (neuroischaemia) have been shown to have higher re-ulceration and amputation rates than those with peripheral neuropathy alone[16]
- Estimates show PAD is a complicating factor in the management of nearly 65% of all DFUs[17]

Oxygen therapy

What is the role of oxygen in wound healing?

- Oxygen is a well-known requirement in wound healing. It is critically important for cell metabolism and pathways for wound healing, such as the angiogenesis and revascularisation, cell metabolism and energy production, synthesis of connective tissue and infection resistance
- Sustained oxygen delivery, either intrinsically from the blood supply or extrinsically via topical oxygen, is vital for the healing of non-healing wounds, especially for wounds associated with PAD and DFUs[16]

Granulox®

What is Granulox®?

Granulox® is an oxygenating haemoglobin spray for the treatment of chronic wounds, including DFUs, venous leg ulcers, arterial leg ulcers, and mixed leg ulcers for the secondary healing of surgical wounds and pressure sores[18]. It can also be used on healing of sloughy and infected wounds. It can be used as an adjunct to standard of care wound treatment[19].

How does Granulox® work?

Granulox® is a portable and easy-to-use spray. When Granulox® is sprayed on a wound, highly purified haemoglobin is released. This binds with oxygen from the environment and diffuses through the wound exudate, and the haemoglobin supplies the base of the wound topically with oxygen. The oxygen supply to the base of the wound supports wound healing and patient outcomes.
Granulox® can be applied when the wound dressing is changed, and at least every three days for optimal results.

What benefits has Granulox® shown?

Studies report that using Granulox® results in shorter healing time, reduced pain scores and total cost savings for healthcare providers compared to standard of care[20].

Additional benefits include:

- Twice as many chronic wounds healed at 8–16 weeks compared to standard of care[3,18,19]
- Time to heal diabetic foot ulcers 50% shorter than with standard of care[19]
- Treatment costs in diabetic foot ulcers at least 40% lower than with standard of care[20]
- More than 70% of patients reported lower average pain scores at four weeks than with standard of care in chronic wounds[3]
- 99% less slough in chronic wounds after four weeks compared to 33% with standard of care

References: 1. Chadwick P, Edmonds M, Fox A, Leigh R et al (2019) Expert Panel Report: The role of topical oxygen therapy in the management of diabetic foot ulcers. The Diabetic Foot Journal. 2. Stang D, Young M, Wilson D et al (2018) The role of topical oxygen therapy in the management of diabetic foot ulcer wounds in Scotland: round table recommendations. The Diabetic Foot Journal 21(1): 56–61. 3. Hunt S, Elg F (2017) The clinical effectiveness of haemoglobin spray as adjunctive therapy in the treatment of chronic wounds. J Wound Care 26(9):558–568. 4. Wounds International (2013) International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers. London: Wounds International. Available from: www.woundsinternational.com. 5. Brownrigg JR, Davey J, Holt PJ et al (2012) The association of ulceration of the foot with cardiovascular and all-cause mortality in patients with diabetes: a meta-analysis. Diabetologia 55(11): 2906–12. 6. Diabetes UK (2017) Improving footcare for people with diabetes and saving money: an economic study in England. London: Diabetes UK. Available at: https://bit.ly/2lR6jXU (accessed 04.07.18). 7. Guest JF, Ayoub N, McIlwraith T et al (2015) Health economic burden that wounds impose on the National Health Service in the UK. BMJ Open. 8. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J (2005) The global burden of diabetic foot disease. Lancet 366(9498): 1719–24. 9. Edmonds M (2013) Modern treatment of infection and ischaemia to reduce major amputation in the diabetic foot. Curr Pharm Des 19: 5008–15. 10. National Institute for Health and Clinical Excellence (2015) Diabetic foot problems: prevention and management [NG19]. London: NICE. Available at: www.nice.org.uk/ng19 (accessed 28.02.19). 11. National Diabetes Foot Care Audit – Fourth Annual Report, England and Wales, 01 April 2015 to 31 March 2018. 12. Kerr M (2017) Diabetic Foot Care in England: an economic study. London: Insight Health Economics for Diabetes UK. 13. Vileikyte L (2001) Diabetic foot ulcers: a quality of life issue. Diabetes Metab Res Rev 17: 246–9. 14. Frykberg RG, Banks J (2016) Management of diabetic foot ulcers: a review. Federal Practitioner 33(2): 16–23. 15. Hingorani A, LaMuraglia GM, Henke P et al (2016) The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg 63:3S–21S. 16. Lewis J, Lipp A (2013) Pressure-relieving interventions for treating diabetic foot ulcers. Cochrane Database Syst Rev 2013; 1:CD002302. 17. Bus SA, van Deursen RW, Armstrong DG, et al (2016) Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review. Diabetes Metab Res Rev 32(suppl 1): 99–118. 18. Elg F, Hunt S (2018) Hemoglobin spray as adjunct therapy in complex wounds: Meta-analysis versus standard care alone in pooled data by wound type across three retrospective cohort controlled evaluations. SAGE Open Medicine: Jun 6:2050312118784313. 19. Hunt S. Elg F (2016) Clinical effectiveness of hemoglobin spray (Granulox®) as adjunctive therapy in the treatment of chronic diabetic foot ulcers. Diabetic Foot & Ankle 7:33101. 20. Brüggerjürgen B, Hunt S. Eberlein T (2017) Wound management in diabetic foot ulcer (DFU) – Incremental cost-analysis of treating diabetic neuropathic foot lesions with adjunct hemoglobin contact spray in Germany. Gesundh ökon Qual manag 22:1–8. 21. Hunt S, Elg F, Percival S (2018) Assessment of clinical effectiveness of haemoglobin spray as adjunctive therapy in the treatment of sloughy wounds. Journal Wound Care 27(4): 210-219.

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