

Widespread non-adherence to guidelines in the operative management of diabetes-related foot disease complications

DEFINITE Collaborators and Vascular and Endovascular Research Network

Correspondence to: Louise Hitchman, Academic Vascular Surgery Unit, Hull Royal Infirmary, Anlaby Road, Hull HU3 2JZ, UK (e-mail: l.hitchman@nhs.net)

The DEFINITE Collaborators and members of the Vascular and Endovascular Research Network executive committee are co-authors of this study and are listed under the heading Collaborators.

Introduction

The incidence of diabetes is increasing^{1–3}. One of the most common complications is diabetes-related foot disease (DFD), which include ulcers and gangrene. If not managed appropriately, DFD can rapidly deteriorate resulting in limb loss and death^{4–6}.

The International Working Group on the Diabetic Foot (IWGDF) and the Global Vascular Guidelines (GVG) provide recommendations on the assessment and management of DFD and chronic limb-threatening ischaemia (CLTI)^{7–12}. It has been hypothesized that adherence to these guidelines varies and could be contributing to poor outcomes¹³.

This study aimed to capture practices of diabetic foot debridement and minor amputation in theatre, to compare practice with the IWGDF and GVG recommendations, and to report the outcomes of patients undergoing debridement or minor amputation for a DFD complication^{7,8}.

Methods

This international, multicentre prospective study was reported with reference to the STROBE guideline¹⁴. The protocol has been published¹⁵.

Eligibility criteria

Patients diagnosed with diabetes mellitus who underwent debridement or minor amputation in the theatre setting for a DFD complication were included in the study.

Outcomes measures

The primary outcome was adherence to the recommendations outlined by the IWGDF and GVG^{7–12}. Adherence was defined by whether practice corresponded with the guidelines, which are noted as IWGDF/GVG-recommended ([Table 1](#)).

Secondary outcomes included incidence of healing, further debridement/minor amputation, major lower limb amputation (MLLA), and death at 90 days after the procedure.

Data collection

Data were collected between 1 December 2021 and 30 September 2022, and included baseline demographics, preoperative, intraoperative, and postoperative practices, and 90-day outcomes.

Data management

Anonymized patient data were entered into a piloted Research Electronic Data Capture (REDCap) database. Data from each centre were checked for completeness and validated¹⁵.

Ethical approval

The study was conducted in compliance with Good Clinical Practice guidelines, the Data Protection Act 2018, and the UK Policy Framework for Health and Social Care Research. Ethical approval was not required in the UK¹⁹. Non-UK centres were required to seek local ethical advice and provide evidence of approval before data collection.

Data analysis

Descriptive statistics were used to report practice and secondary outcomes. Cases refer to the index limb. Univariable regression analysis was used to identify independent predictors of outcomes at 90 days ([supplementary material](#)). Data were analysed using Microsoft® Excel (Microsoft, Redmond, WA, USA) and SPSS® version 28 (IBM, Armonk, NY, USA).

Results

The study included 754 limbs on 753 patients from 30 centres ([supplementary material](#)).

Preoperative assessment

The Wound Ischaemia foot Infection (WIFI) stage was recorded before 130 operations (17.2%) (IWGDF/GVG-recommended). Vascular imaging was performed either before admission or during admission in 60% of cases (27 of 45) with WIFI ischaemia grade 0, 74% (25 of 34) with WIFI ischaemia grade 1, 76% (19 of

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Table 1 Guidelines recommendations that centre practice was compared against

	Practice recommendation	% of cases concordant
Preoperative practices	'In a person with diabetes and a foot ulcer who is being managed in a setting where appropriate expertise in vascular intervention is available, use Wifl scoring to aid decision-making in the assessment of perfusion and likelihood of benefit from revascularization (Grade recommendation: weak; Certainty of evidence: moderate)' IWGDF ¹⁶	17.7
	'In a person with diabetes and an infected foot ulcer, use the IDSA/IWGDF infection classification to characterize and guide infection management (weak; moderate)' IWGDF ¹⁶	1.0
	'In a person with diabetes and a foot ulcer, use the SINBAD system for communication among health professionals about the characteristics of the ulcer (strength of recommendation: strong; quality of evidence: moderate)' IWGDF ¹⁶	0
	'Use the Wifl classification system as a means to stratify amputation risk and revascularization benefit in a patient with a diabetic foot ulcer and PAD (strong; moderate)' IWGDF ¹⁷	17.7
	'Use an integrated threatened limb classification system (such as Wifl) to stage all CLTI patients who are candidates for limb salvage (strong, low)' GVG ⁸	17.7
	'Treat a person with a diabetic foot infection with an antibiotic agent that has been shown to be effective in a published RCT and is appropriate for the individual patient. Some agents to consider include: penicillins, cephalosporins, carbapenems, metronidazole (in combination with other antibiotic(s)), clindamycin, linezolid, daptomycin, fluoroquinolones, or vancomycin, but not tigecycline (strong; high)' IWGDF/IDSA ⁷	Wifl assessed: 89.9 Wifl not assessed, operation to control infection: 87
	'We suggest not using topical (sponge, cream, and cement) antibiotics in combination with systemic antibiotics for treating either soft tissue infections or OM of the foot in patients with diabetes (conditional; low)' IWGDF/IDSA ⁷	98.2
	'Use any of the following modalities to obtain anatomical information when considering revascularizing a patient's lower extremity: colour duplex ultrasound imaging, CT angiography, magnetic resonance angiography, or intra-arterial digital subtraction angiography. Evaluate the entire lower extremity arterial circulation with detailed visualization of below-the-knee and pedal arteries, in an anteroposterior and lateral plane (strong; low)' IWGDF ¹⁷	Wifl ischaemia grade 0: 46.5 Wifl ischaemia grade 1: 73.7 Wifl ischaemia grade 2: 76.0 Wifl ischaemia grade 3: 69.2
	'Consider revascularization in average-risk patients with advanced limb threat (for example, Wifl stage 4) and moderate ischaemia (for example, Wifl ischaemia grade 1' GVG ⁸	Wifl ischaemia grade 0: 11.6 Wifl ischaemia grade 1: 33.0 Wifl ischaemia grade 2: 64.0 Wifl ischaemia grade 3: 69.2
	'Offer revascularization to all average-risk patients with advanced limb-threatening conditions (for example, Wifl stage 4) and significant perfusion deficits (for example, Wifl ischaemia grades 2 and 3). Consider revascularization for average-risk patients with intermediate limb threat (for example, Wifl stages 2 and 3) and significant perfusion deficits (for example, Wifl ischaemia grades 2 and 3). Consider revascularization in average-risk patients with advanced limb threat (for example, Wifl stage 4) and moderate ischaemia (for example, Wifl ischaemia grade 1' GVG ⁸	Wifl ischaemia grade 0: 11.6 Wifl ischaemia grade 1: 33.0 Wifl ischaemia grade 2: 64.0 Wifl ischaemia grade 3: 69.2
Intraoperative practices	'In a person with diabetes and a possible foot infection for whom the clinical examination is equivocal or uninterpretable, consider ordering an inflammatory serum biomarker, such as CRP, erythrocyte sedimentation rate, and perhaps procalcitonin, as an adjunctive measure for establishing the diagnosis. (weak; low)' IWGDF/IDSA ⁷	CRP: 93.6
	'Collect an appropriate specimen for culture for almost all clinically infected wounds to determine the causative pathogens (strong; low)' IWGDF/IDSA ⁷	57.5
	'For a soft tissue diabetic foot infection, obtain a sample for culture by aseptically collecting a tissue specimen (by curettage or biopsy) from the ulcer (strong; moderate)' IWGDF/IDSA ⁷	65.1
	'During surgery to resect bone for diabetic foot OM, consider obtaining a specimen of bone for culture (and, if possible, histopathology) at the stump of the resected bone to identify if there is residual bone infection (weak; moderate)' IWGDF/IDSA ⁷	MCS: 63.1 Histology: 42.4
Postoperative practices	'We suggest not using topical (sponge, cream, and cement) antibiotics in combination with systemic antibiotics for treating either soft tissue infections or OM of the foot in patients with diabetes (conditional; low)' IWGDF/IDSA ⁷	100
	If an aseptically collected culture specimen obtained during the surgery grows pathogen(s), or if the histology demonstrates OM, administer appropriate antibiotic therapy for up to 6 weeks (strong; moderate)' IWGDF/IDSA ⁷ Presence of an postoperative offloading plan, based on recommendations 1, 2, 3, 4, 7, 8, and 9, in the IWGDF offloading guideline ¹⁸	Soft tissue infection: 40.8 OM with clean sample bone microbiological growth: 29.6 90.3

Wifl, Wound Ischaemia foot Infection; IWGDF, International Working Group on the Diabetic Foot; IDSA, Infectious Diseases Society of America; SINBAD, Site Ischaemia Neuropathy Bacterial Infection Area Depth; PAD, peripheral arterial disease; CTLL, chronic limb-threatening ischaemia; GVG, Global Vascular Guidelines; OM, osteomyelitis; CRP, C-reactive protein; MCS, microscopy, culture, and sensitivity.

25) with Wifl ischaemia grade 2, and 80% (21 of 26) with Wifl ischaemia grade 3 (GVG-recommended for CLTI).

The preoperative haematological and biochemical results are shown in [supplementary material](#).

Preoperative antibiotic use

Preoperative antibiotics were prescribed in 93.4% of cases (457 of 486) with infection. Antibiotics were prescribed to 77.2% of cases (207 of 268) without infection. In cases of suspected/confirmed osteomyelitis, 451 (91.3%) were prescribed preoperative antibiotics.

Intraoperative practices

Infection was the commonest indication for surgery (64.5%; 486 of 754), followed by dry gangrene (26.0%; 196 of 754), non-healing ulceration (7.0%; 53 of 754), and pain (2.0%; 15 of 754). Digital amputation with or without soft tissue debridement was undertaken in 619 cases (82.1%) and the remainder had soft tissue debridement only.

For soft tissue infection, a sample was sent for microscopy, culture, and sensitivity (MCS) in 47.9% of cases (233 of 486). For suspected/confirmed osteomyelitis, a contaminated bone sample was sent for MCS in 72.5% (358 of 494) and a clean bone sample in 54.9% (271 of 494). Bone for histology was sent in 13.8% of cases (68 of 494). Clean instruments were used to take clean samples of bone in 54.9% of cases (271 of 494) with suspected/confirmed osteomyelitis, and soft tissue in 55.2% (267 of 486) with soft tissue infection.

Revascularization

Nine % (5 of 45) of Wifl ischaemia grade 0, 29% (10 of 34) of Wifl ischaemia grade 1, 64% (16 of 25) of Wifl ischaemia grade 2, and 69% (18 of 26) of Wifl ischaemia grade 3 cases were revascularized.

Postoperative practices

Microorganisms were cultured from 480 samples (63.7%). These were resistant to the antibiotics in 166 cases (22.0%). The antibiotic was adjusted following sensitivities in 139 cases (83.7%). Postoperative offloading was recommended following 465 procedures (61.7%).

At discharge, 107 limbs (14.2%) had undergone further debridement, 48 (6%) a further toe amputation, 27 (4%) a transmetatarsal amputation, 50 (7%) a MLLA, and 15 people (2%) had died.

Ninety-day outcomes

At 90 days, 35.0% of wounds (264 of 754) had healed. Some 113 limbs (15.0%) underwent further debridement, 71 (9.4%) required further digital amputation(s), 26 (3.4%) had a transmetatarsal amputation, 61 (8.1%) underwent MLLA, and 48 patients (6.4%) had died.

The median overall compliance per case was 65.4 (range 0–100%). No individual adherence variables met the criteria to be carried forward into a multivariable analysis.

Discussion

This study reports widespread non-adherence to the IWGDF and GVG guidance in the context of DFD complications managed in the theatre setting. Areas of discordance include objective lower limb assessment, antibiotic prescribing, tissue sampling, and offloading. Clinical outcomes in this study are similar to

those of other large cohort studies^{20,21} conducted in expert centres, despite the variety of practices.

Most recommendations in the IWGDF guidelines and GVG pertinent to this study are conditional based on low-certainty evidence or best practice statements^{7–12}. There is a paucity of high quality RCTs in DFD; the guidelines are based on the best available evidence and, when not available, opinions of a consortium of experts in DFD. Owing to the low certainty in the evidence, the guidelines in their current state of evolution could be interpreted as not being fit for purpose. This can lead to clinicians disagreeing with guideline recommendations and believing that their practice represents consensus recommendations, when it may not. Quality of evidence could explain some of the deviation seen in this study, yet practices, such as pan-prescribing of antibiotics, are more difficult to understand.

The translation of international guidelines to regional healthcare systems can be challenging as international guidelines often do not take into account different healthcare perspectives, in terms of availability of resources, costs, patient expectations, personalization for patients with complex co-morbidity, and may contradict national guidelines^{22,23}. This means that some practices, such as the use oral antibiotics instead of intravenous antibiotics to alleviate hospital bed capacity pressures, are justifiable and do not represent a lower quality of care. This could explain some of the variation seen in the present study.

Complexity of guidelines documents is another barrier to implementation. The IWGDF guidance and GVG documents are both comprehensive and nuanced regarding which patients a recommendation may be applicable to. Greater supervision from consultant surgeons in theatre, inclusion of IWGDF guidelines in vascular resident training, along with wider dissemination of guidelines to increase awareness, possibly linked to payment by compliance with key recommendations, may increase guidance adherence.

Interestingly, this study did not find that guideline adherence was associated with 90-day outcomes. This is likely because of the study design, short follow-up, and narrow spread of compliance. It is possible, if centres were to improve concordance with the guideline recommendations, improved adherence would be associated with improved outcomes.

Conclusion

This study has demonstrated widespread suboptimal practices in the surgical management of DFD complications. Diabetic foot multidisciplinary teams should strive towards improved guideline adherence and support research to strengthen the quality of evidence underpinning international guidelines.

Collaborators

B. Renwick, M. Gannon, S. Kerr, R. Melvin, A. Ingram (Aberdeen Royal Infirmary, Aberdeen, UK); D. Bosanquet, I. Fabre, S. Yew, J. Moreau, M. Dewi, D. Lowry, A. Clothier, T. Hutchings (Aneurin Bevan University Health Board, Cardiff, UK); J. Boyle, C. Wijewardena, M. Chowdhury, G. La Torre, H. Grewal, A. Ansari, D. Lawson (Cambridge University Hospitals, Cambridge, UK); S. Nandhra, L. Ugwumba, T. El-Sayed, A. Altahir, H. Elkashef, S. Jones, J. Arkle, R. Khalil, J. Ramsay, C. Nesbitt (Freeman Hospital, Newcastle, UK); S. Paravastu, V. V. Jayaprakash (Gloucester Royal Hospital, Gloucester, UK); R. L. G.

Flumignan, C. D. Q. Flumignan, L. C. U. Nakano, P. Schippers, F. A. Pereira Jr, N. C. Pegas (Hospital Sao Paulo, Sao Paulo, Brazil); L. Hitchman, J. Walshaw, B. Ravindhran, R. Lathan, G. Smith (Hull Royal Infirmary, Hull, UK); J. Shalhoub, M. Ahmad, J. Shea, T. Howard (Imperial College Healthcare NHS Trust, London, UK); K. Elsanhoury, G. Eskandar, K. Mekhaeil, K. Scott, M. Enc, F. Mannan (James Cook University Hospital, Middlesbrough, UK); S. Chowdhury, A. E. Abdelmageed (King Saud Medical Centre, Riyadh, Saudi Arabia); D. Russell, A. Jones (Leeds Teaching Hospitals NHS Trust, Leeds, UK); N. Dattani, T. El-nakhal, E. Katsogridakis, A. Duncan, L. Musto (Leicester Vascular Institute, Leicester, UK); D. Proctor, S. Parsapour, S. Lewis, A. Hassan (London Northwest University Healthcare NHS Trust, London, UK); A. Abdelal, N. Elzefzaf, N. Yasser, G. A. Antoniou (Manchester University Foundation Trust, Manchester, UK); A. Singh, L. Alhoussan, V. Venkateswaran, F. Feil, S. Dindyal (Mid and South Essex NHS Trust, Basildon, UK); O. Lyons, R. Benson, E. Lim, M. Sze (Christchurch Hospital, Christchurch, New Zealand); M. Khashram, O. Hart, Z. Vincent, N. Xue, M. Pottier, S. Gormley, C. Tong (Waikato Hospital, Hamilton, New Zealand); D. Pang, A. Patil, L. Ngam, C. Macleod (Ninewells Hospital, Dundee, UK); I. Aziz, P. Stather, A. Abuduruk (Norfolk and Norwich University Hospital NHS Foundation Trust, Kings Lynn, UK); J. Manson, D. Howard, S. Hussain, H. Glatzel, N. James, M. Rafil, N. Marlow (Oxford University Hospitals NHS Trust, Oxford, UK); A. Meldrum, K. Hussey, C. Jones, E. Shepherd (Queen Elizabeth University Hospital, Glasgow, UK); R. Fitridge, K. Hon, K. Kour, S. Ng (Royal Adelaide Hospital, Adelaide, Australia); T. Hardy, S. Muse, D. Ching, S. Donoghue (Royal Devon and Exeter Hospital, Exeter, UK); D. Thompson, R. Forsythe, S. Chan, K. Powezka, D. Wu, C. Kuronen-Stewart, A. Winarski (Royal Infirmary Edinburgh, Edinburgh, UK); P. Lapolla, B. Cirillo (Policlinico Umberto I Sapienza University of Rome, Rome, Italy); N. Al-Saadi, M. Dowdeswell, S. McDonald, K. Al-Hashimi, S. Jones, K. Merriman (Shrewsbury and Telford Hospital NHS Trust, Shrewsbury, UK); A. Hassouneh, U. Sadia, A. Jaipersad (University Hospitals of North Midlands, Stoke-on-Trent, UK); K. G. Moulakakis, C. Papageorgopoulou, S. Kakkos, A. Tsimpoukis, S. Papadoulas, N. Kouri, K. Nikolakopoulos (University Hospital of Patras, Pio, Greece); M. D'Orta, S. Lepidi, B. Grando (University Hospital of Trieste, Trieste, Italy); A. Nickinson, G. Gamtkitsulashvili, I. Enemosah, N. Storer, K. Gabab, M. Dingwell, Y. Premadasan (University Hospitals of Southampton NHS Foundation Trust, Southampton, UK); C. Karkos, M. Mitka, A. Soteriou, N. Asaloumidis, K. Papazoglou (Hippocratio Hospital, Thessaloniki, Greece); N. Condie, H. Abdullahi, F. Shafeek, T. Lyons (Worcestershire Acute Hospitals NHS Trust, Worcester, UK); G. Ambler, R. A. Benson, P. Birmpili, R. H. J. Blair, D. C. Bosanquet, N. Dattani, B. L. Gwilym, L. Hitchman, K. Hurndall, M. Machin, S. Nandhra, S. Onida, A. Saratzis, J. Shalhoub, A. A. Singh, N. Al-Saadi, L. Shelmerdine (Vascular and Endovascular Research Network Executive Committee).

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Supplementary material

Supplementary material is available at BJS online.

Data availability

Access to the DEFINITE data is available upon written request to the corresponding author.

Author contributions

Louise Hitchman (Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Writing—original draft, Writing—review & editing), Ruth Benson (Conceptualization, Funding acquisition, Methodology, Investigation, Writing—review & editing), Graeme Ambler (Conceptualization, Methodology, Writing—review & editing), Panagiota Birmpili (Conceptualization, Methodology, Investigation, Project Administration, Writing—review & editing), Robert H. J. Blair (Conceptualization, Writing—review & editing), Dave Bosanquet (Conceptualization, Methodology, Investigation, Writing—review & editing), Nikesh Dattani (Conceptualization, Writing—review & editing), Brenig Gwilym (Conceptualization, Methodology, Investigation, Validation, Formal analysis, Writing—review & editing), Katherine Hurndall (Methodology, Writing—review & editing), Matthew Machin (Methodology, Writing—review & editing), Sandip Nandhra (Conceptualization, Funding acquisition, Investigation, Methodology, Validation, Writing—review & editing), Sarah Onida (Methodology, Writing—review & editing), Athanasios Saratzis (Methodology, Writing—review & editing), Joseph Shalhoub (Conceptualization, Investigation, Methodology, Writing—review & editing), Aminder A. Singh (Funding acquisition, Investigation, Methodology, Writing—review & editing), Nina Al-Saadi (Writing—review & editing), Lauren Shelmerdine (Writing—review & editing), and DEFINITE collaborators (Investigation, Validation, Writing—review & editing)

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