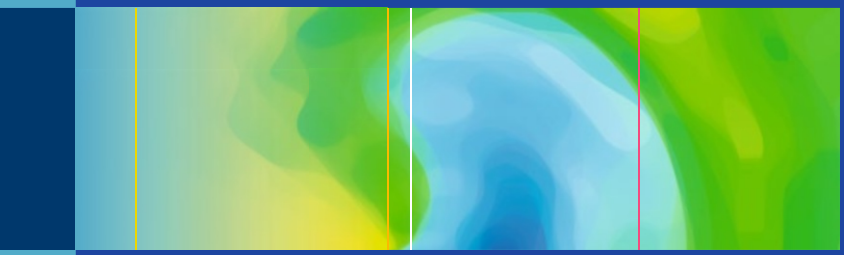
Clifford P. Shearman
Editor



Management of Diabetic Foot Complications

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Editor
Clifford P. Shearman
Vascular Surgery
Southampton General Hospital
Southampton
UK

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Preface

Diabetes is becoming a major challenge for societies the world over, and foot complications are one of the most common complications associated with this disease. Foot ulceration and infection not only impact on the patients' quality of life but also significantly increase their risk of losing their leg, which is a devastating outcome for most people. It is a costly condition to treat.

Foot complications are difficult to prevent and treat when they do occur. However, encouragingly the message about care for patients at risk of developing foot complications is that it needs to be well organised and prompt. Unlike many services it is not a matter of acquiring new technology, increasing personnel or expensive medications. The team is there and all the facilities needed to manage these patients are available. All too often, however, the teams are poorly coordinated. Sometimes being part of a foot care service team feels like playing in a football team, the members of which have never met, the positions haven't been decided and no one knows the rules. It must be even worse for the patient. Where it has been possible to bring together the team across primary and secondary care and identify clear care pathways, the results have been staggering: a dramatic reduction in major amputations, fewer hospital admissions, and reduced costs to the health economy.

This handbook has been written by podiatrists, nurses and doctors, all of whom are working in the field of diabetes foot care. They have described their experiences and how they address clinical challenges. The book is divided into prevention and early management, revascularisation of the ischaemic

limb, prevention of recurrence and how to structure a team. I hope this will provide useful information to anyone responsible for the care of people with diabetes who may be at risk of developing foot complications.

Southampton, Hampshire, UK Clifford P. Shearman

Contents

Contributors

Javier Aragón-Sánchez, MD, PhD Department of Surgery, Diabetic Foot Unit and Endoluminal Therapy, La Paloma Hospital, Las Palmas de Gran Canaria, Spain

Stephen J. Baxter, MB, ChB, FCS Departments of Cardiovascular and Thoracic Surgery, University Hospital Southampton, Southampton, Hampshire, UK

Anthony R. Berendt, BM, BCh, FRCP Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Trust, Oxford, Oxfordshire, UK

Graham C. Bowen, BSc Hons, FCPodMed Department of Podiatry, Solent NHS Trust, St. James Hospital, Portsmouth, Hampshire, UK

Gavin W. Bowyer, MChir, FRCS(Orth) Department of Trauma and Orthopaedics, University Hospital Southampton, Southampton, Hants, UK

Patrick F.S. Chong, MBBS, FRCS The Surrey Vascular Group Network, Frimley Park Hospital NHS Foundation Trust, Frimley, Surrey, UK

Duncan F. Ettles, MBChB (Hons), MD, FRCP, FRCR Department of Radiology, Hull and East Yorkshire Hospitals NHS Trust, Hull, East Yorkshire, UK

Martin Fox, BSc, FFPM RCPS (Glasg) Manchester Leg Circulation Service, Pennine Acute Hospitals Trust, Harpurhey Health Centre, Harpurhey, Manchester, Greater Manchester, UK

Marie Hulse, BSc (Hons) Therapy Department, University Hospital Southampton, Southampton, Hampshire, UK

William J. Jeffcoate, MRCP Department of Diabetes and Endocrinology, Nottingham University Hospitals Trust, City Hospital Campus, Nottingham, UK

Laurie King, BSc (Hons), MSc Diabetic Foot Clinic, Oxford Centre Diabetes Endocrinology and Metabolism (OCDEM), Oxford University Hospitals NHS Trust, Oxford, Oxfordshire, UK

Lisa Jane Lainton, RGN, RM Department of Diabetes and Endocrinology, Stockport Foundation Trust, Stockport, Cheshire, UK

Lynn Ling, MBChB, FRCR Department of Radiology, Hull and East Yorkshire Hopsitals NHS Trust, Hull, East Yorkshire, UK

Rajgopal Mani, MD, PhD/DSc, FACA, FIPEM Medical Physics and Bioengineering, University Hospital Southampton NHS Foundation Trust, Southampton SO16 6YD, UK

Visiting Professor, Shanghai Jiao Tong University School of Medicine, Shanghai, China

Keith G. McCormick, MSc, FFPM RCPS(Glasg) Faculty of Health Sciences, University of Southampton, Highfield Campus, Southampton, Hampshire, UK

Abigail H.M. Morbi, BSc, MBBS, AICSM Department of Vascular Surgery, University of Southampton, Southampton, Hampshire, UK

Paul W. Moxey, MRCS, MD The Surrey Vascular Group Network, Frimley Park Hospital NHS Foundation Trust, Frimley, Surrey, UK

Ian M. Nordon, BM, MSc, MD Departments of Cardiovascular and Thoracic Surgery, University Hospital Southampton, Southampton, Hampshire, UK

Mayank Patel, BM, MRCP, MD Department of Diabetes and Endocrinology, University Hospital Southampton NHS Foundation Trust, Southampton, Hampshire, UK

David A. Russell, MB ChB, MD, PG Dip Clin Ed, FRCS (Gen.surg) Leeds Vascular Institute, Leeds General Infirmary, Leeds, West Yorkshire, UK

Clifford P. Shearman, BSc, MBBS, FRCS, MS Department of Vascular Surgery, University of Southampton, University Hospital of Southampton NHS Foundation Trust, E Level North Wing, Southampton General Hospital, Southampton, Hampshire, UK

Nicola Storer Departments of Cardiovascular and Thoracic Surgery, University Hospital Southampton, Southampton, Hampshire, UK

Raman Uberoi, BMSCPath, MBBchir, MRCP, FRCR Department of Radiology, John Radcliffe Hospital, Oxford, UK

Stella Vig, MB BCh, FRCS, FRCS (Gen Surg) Department of Vascular Surgery, Croydon University Hospital, Croydon, Surrey, UK

Kathryn H. Waite, MBBS, BSc Surgical Department, Croydon University Hospital, Croydon, Surrey, UK

Andrew J. Wigham, BSc (Hons), MBBS, MRCS, FRCR Department of Radiology, John Radcliffe Hospital, Oxford, UK

Chapter 1
Foot Complications in Diabetes: The Problem

Clifford P. Shearman

Background

There are currently in excess of three million people diagnosed with diabetes in England. That amounts to 5.5 % of the adult population and at least a further 2 % remain undiagnosed [1]. The prevalence of the condition is increasing rapidly and it is estimated that 8.5 % of adults will have diabetes by 2020 due to obesity and an aging population.

Foot complications are a common and costly cause for admission to hospital and are strongly associated with the risk of amputation. The cost of foot complications has been estimated at £639–662 million annually or 0.6–0.7 % of the NHS budget [1].

C.P. Shearman, BSc, MBBS, FRCS, MS
Department of Vascular Surgery,
University of Southampton, University Hospital of Southampton NHS Foundation Trust, E Level North Wing,
Southampton General Hospital,
Southampton, Hampshire SO16 6YD, UK
e-mail: cps@soton.ac.uk

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The At-Risk Foot

People with diabetes are prone to foot complications due to neuropathy, arterial disease and infection. Neuropathy is found in up to 28 % of people with diabetes and is more common in those who have had the condition for over 10 years or whose control has been poor. Sensory neuropathy will reduce awareness of injury to the foot, especially due to repetitive trauma such as ill-fitting foot-wear. It also has an effect on proprioception and gait, which alters biomechanical load distribution. Autonomic neuropathy will reduce sweating, resulting in dry and cracked skin, leading to infection. Autonomic regulation of skin blood flow may be lost with shunting through arteriovenous fistulae, producing the pink, warm but ischaemic foot with reduced nutritional blood flow to the tissues. Most importantly, people with diabetes have a four fold increased risk of developing peripheral arterial disease (PAD), and it is estimated that even at the time of diagnosis, 8 % of type 2 diabetics have PAD and one-third of those over the age of 40 years have PAD. The presence of PAD is associated with a 10–16-fold risk of amputation but also a 70–80 % risk of dying from cardiovascular disease (mainly myocardial infraction and stroke) compared to a person with diabetes but no PAD [2].

The immune response of patients with diabetes may be obtunded and neutrophil phagocytosis is impaired due to chronic hyperglycemia. This will not only make the individual more prone to infection in a foot wound, but their systemic response may be reduced and only about one third of patients with a foot infection will have a temperature. The patient may not be aware of infection until advanced and clinicians often underestimate the extent of the infection.

In the person with diabetes, then, it is easy to see how the foot is more vulnerable to damage and injury, often resulting in skin damage and an ulcer. Reduced blood supply due to PAD results in either slow or non-healing of the wound and infection will ensue.

Diabetic Foot Ulcers

Diabetic foot ulcers (DFUs) are extremely common, and the lifetime risk of a patient with diabetes developing a foot ulcer is 15 %. At any one time between 2.2 and 7 % of the diabetic population will have an ulcer, being more common in those over 60 years of age. Based on this it can be estimated that in England at any one time there will be at least 61,400 people with active DFUs [1].

Around two-thirds of DFUs will heal with treatment, but it can be a slow process, often taking more than a year, and over half will get recurrent ulceration within 12 months [3]. DFUs have a significant impact on the quality of life of the patient. Up to 84 % of people reported a major impact of a DFU on their lives including reduced mobility, pain and anxiety and depression [4]. The inability to stand or walk was found to be the most important determinant of their quality of life.

Perhaps most worryingly, the development of a DFU is a major prognostic indicator of mortality risk. Over half of patients who develop a foot ulcer will be dead within 5 years, largely from cardiovascular disease and complications of diabetes [5].

Foot Complications and Amputation

The most worrying complication of a DFU is the progression to limb amputation. This is either due to failure to heal the primary ulcer, recurrent ulceration or chronic infection. Many patients with foot complications who are admitted to hospital require minor amputation (below the ankle, usually digits or trans-metatarsal) as part of the treatment to control infection or remove dead tissue. Although often an essential part of their treatment, the change in foot architecture caused by the amputation will put them at increased risk of further problems.

Between 2007 and 2010 there were 34,104 lower extremity amputations in England, of which 48.9 % were in people with

diabetes. This was a rate of 2.51 for those with diabetes compared to a 0.11 risk for non-diabetics per 1,000 person years (23.3 relative risk) [6]. In this study it was observed that the amputation rate varied eight fold across different health care providers, suggesting a variation in the quality of the service provided. In a similar study between 2003 and 2008, 25,578 major amputations were identified in England of which 39.4 % were in diabetic patients. The adjusted in-hospital mortality rates for major amputation varied between geographical areas from 14.0 to 20.2 % with a median of 16.8 %. Over 50 % of patients had no recorded attempt at revascularisation prior to amputation [7].

Although amputation may be looked on as a final solution for a chronic, often debilitating problem, the evidence does not seem to bear this out and only 37 % will become ambulant to the level they were before [8]. Also, having lost one leg, the risk to the remaining limb increases and around 50 % suffer a contralateral amputation within 5 years.

Diabetic Foot Ulcers: The Economic Impact

Managing patients with DFUs is extremely costly. Marion Kerr on behalf of Diabetes UK has carried out a detailed evaluation of the costs of care of patients with foot complications [1]. Those with less severe ulcers in the community require regular dressing changes and visits to podiatry, orthotics and hospital if the condition worsens. The estimated costs in England of managing this group have been calculated as approximately £325 million. If the condition worsens and the patient requires hospital admission, the annual costs are £213 million and amputation is even more costly, raising the overall hospital and ongoing costs by £125 million. In total the annual total cost of managing people with foot ulceration and amputation in England is between £639–662 million [1].

Preventing one amputation has a major impact not only on the patient but also on the health economy. Based on the published evidence Kerr calculated that one quality adjusted

life year (QALY) cost £25,000, which is below the normal tariff supported by NICE.

The Solution

The road to amputation is a long one and begins with the foot at risk due to neuropathy and ischaemia [9]. The potential to prevent the initial development of complications and the progression of those that are inevitable is apparent but often missed. The screening of people with diabetes will identify those at increased risk and if appropriate, supportive action is taken, such as regular review by a specialist foot care team, ulceration and amputation can be reduced [10]. Foot examination is one of the nine checks recommended by the National Institute for Health and Clinical Excellence (NICE) that should be undertaken annually in people with diabetes. However in England in 2009/10 only 52.0 % of people with type 2 diabetes and 31.9 % of people with type 1 diabetes received all nine care processes [11].

Rapid referral of people who have developed complications is essential. Where services have been organized across primary and secondary care to facilitate this with a multidisciplinary foot care team and network, hospital admissions and amputation rates have been shown to fall, with a considerable cost saving to the local health economy [1]. Despite this, the 2010 NHS Diabetes Inpatient Audit found around 20 % of hospitals treating patients with complications of diabetes had no organized multidisciplinary foot care team.

On a positive note, it appears that not only can considerable improvements in quality of life be achieved by organizing services for diabetics who are at risk or who have developed foot complications, but considerable cost savings can also be made. What is disappointing is that despite this evidence being apparent, over the last decade little progress has been made and considerable variation in amputation rates persist, reflecting varying levels of interest and care available to these patients.

Key Points

- Around 15 % of people with diabetes will suffer a DFU in their lifetime.
- DFUs have a significant impact on quality of life and increase the risk amputation.
- DFUs are a major marker of cardiovascular risk, which can be reduced.
- The cost of managing foot complication of diabetes representing 0.6–0.7 % of all NHS health care spending in England.
- Substantial reductions in hospital admissions and amputations can be made with multidisciplinary foot care teams and networks, which are highly cost-effective.

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Chapter 2
Screening and Treatment of Early Complications in the Diabetic Foot

Graham C. Bowen

Introduction

Foot disease is a potentially devastating complication of diabetes and, as a consequence, a lower limb is lost every 30 s somewhere in the world. In the UK, diabetes-related foot complications are the largest single reason for patients with diabetes to be admitted to hospital [1]. Foot ulceration and infection places a huge burden on healthcare systems, in terms of expenditure and resources to support hospital in-patients and outpatients being managed by primary care and community care services.

Community care for the diabetic foot is delivered primarily by podiatry services whose aim is to prevent foot ulceration in the first instance, manage foot complications and prevent hospital admission and amputation. However, patients commonly present late or the significance of early complications is not fully recognised. It has been suggested that 85 % of limb amputations could be prevented by early intervention.

G.C. Bowen, BSc Hons, FCPodMed
Department of Podiatry, Solent NHS Trust, St James Hospital, Locksway Road, Portsmouth, Hampshire PO4 8LD, UK
e-mail: Graham.Bowen@Solent.nhs.uk

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The United Kingdom Department of Health Quality Improvement, Innovation and Prevention (QIPP) agenda highlights that if strategic goals are not implemented now, the NHS will end up providing crisis intervention to the population, rather than active chronic disease management. Diabetic foot disease clearly characterises this approach. There are few conditions in which prevention and early intervention play such a major role in the prevention of major complications such as amputation. However, all too often the patient's condition is allowed to reach an advanced state before treatment is initiated, by which time the outcome is poor. Late treatment is also the most costly and consumes resources that could have been used for prevention. This chapter illustrates how foot care services can be delivered in alignment with the QIPP agenda and local health demands.

Need for Foot Care Service

Around 10–15 % of the population with diabetes will suffer at foot ulcer at some stage in their lives and approximately 10 % of these ulcers lead to lower limb amputation. Approximately 61,000 people with diabetes in England and Wales are thought to have foot ulcers at any given time, i.e. approximately 2.5 % of the diabetic population [2]. Post amputation 3-year survival rate is poor and up to 50 % of people die within 5 years of having an amputation as a result of diabetes [3].

Apart from the increased risk of amputation, the indirect and often intangible costs of ulceration to the patient are also high. Many individuals with foot ulceration are unable to work and have a poorer quality of life than those without an ulcer [4].

There is evidence that dedicated multidisciplinary diabetes foot clinics are clinically effective and reduce amputation rates [2]. These multi-professional specialist teams include podiatrists, diabetologists and orthotists, and can access a wider range of healthcare professionals who may be called upon for speciality input, depending on the condition of the foot. Those without active diabetic foot disease must also be considered;

strategies should be in place to educate and empower patients and carers on self-management strategies. These models form the basis of national guidelines and continue to be the recommended approach to diabetes foot care [5, 7].

The 2010 prevalence of diabetes in England was 5.4 % of the population; 20–40 % of diabetics will develop neuropathy and a similar number develop peripheral arterial disease (PAD). These conditions are the two strongest predictors of the risk for developing foot ulceration. Identification of patients at increased risk is essential and all patients should be aware of their risk for developing diabetic foot disease and fully understand the consequences of this.

In 2009, investigation of diabetics with foot ulcers on a single vascular ward, identified that 48 % of patients were not known to podiatry prior to admission (personal observation). Late referrals to podiatry contribute to a delay in targeted management of foot ulceration and can be the cause of preventable amputation. Late and delayed referrals can be overcome with a clear diabetic foot pathway as illustrated below.

The aim of a dedicated diabetic foot pathway is to:

- Reduce incidence of foot ulceration by early identification of risk
- Prevent escalation of National Institute for Health and Clinical Excellence (NICE) foot risk classification – for those patients identified as “at low risk”; “at increased risk”; “at high” and “the acute foot”
- Ensure a diabetic foot pathway is utilised effectively for all patients
- Raise awareness amongst healthcare professionals of the extent of diabetic foot problems, possible actions and the consequences of not managing these patients promptly.
- Educate patients who are at risk, informing them about self-care and measures they can take to reduce the risk of foot complications
- Reduce the number of foot-related hospital admissions, non-elective and electives
- Promote healthy lifestyles, mobility, independence and optimise quality of life for all patients

Podiatry Foot Risk Guidance

Podiatry should instil prevention as the basis of all of its work, creating a culture to prevent end stage diabetic foot complications.

Every patient should receive a healthy lifestyle assessment. This assessment will look at lifestyle choices with detrimental effects on health, such as, smoking, obesity and alcohol misuse. Any lifestyle choice that falls outside of the national recommendations will be identified and brief intervention provided (see Chap. 6). Intervention will involve opportunistic advice, discussion, negotiation and encouragement to modify lifestyle. The aim is to motivate individuals to modify lifestyle choice rather than to promote total abstinence. Each Intervention is designed around a customised approach to each public health initiative detailed in this document. Patients requiring specialist intervention will be referred to appropriate organisations. Local health trainers can be utilised when patients who do not need specialist referral would like support in changing their behaviour.

Early identification of people at increased risk and high risk of developing diabetic foot complications is achieved through the use of a Diabetes Foot Assessment (DFA) tool. The DFA tool will indicate the foot risk in accordance with NICE Guidelines and suggests the care pathway the patient should follow. All referrals for diabetic patients into podiatry should be accompanied by a completed DFA. This will enable patients to be directed appropriately to the correct clinic and clinician.

General Management Approach

The approach should be a partnership with shared decision-making between the patient and healthcare professionals. This encourages and supports the patient to take control of their diabetes and modify their lifestyle appropriately.

Patients should have an annual review and this can be done in primary care. However, personnel carrying out this review should be trained to examine the feet and recognise risk factors for ulceration [5]. It is helpful to use a traffic light system (red, amber and green) to rate the risks as these are easily understood by all involved (Appendix 2.1).

Examination of patients' feet should include:

- Testing of foot sensation using a 10-g monofilament or vibration
- Palpation of foot pulses
- Inspection for any foot deformity and footwear

Based on this the foot should be classified as:

- At low current risk
- At increased risk
- High risk
- Acute foot – ulcerated foot/Charcot

At Low Risk

These patients have no evidence of neuropathy, arterial problems or any other risk factor (such as deformity) so are at low risk of foot ulceration. It has been estimated that this group will be 99.6 % ulcer-free after 2 years, i.e., they have a 1 in 500 risk of foot ulceration per year [6]. It is suggested that low risk patients comprise 60–65 % of the adult diabetic population. With such a low risk of foot ulceration, this group do not require routine podiatry, but require annual screening. They should also be given help to modify their cardiovascular risk factors.

Routine screening may be carried out in primary care and does not need to be carried out by podiatrists. A diabetic foot training programme for medical staff, practice nurses and clinical support workers should be provided to ensure that those involved are competent to carry out screening. Patients should be made aware of their risk stratification.

These patients with no significant risk factors should have access to urgent podiatry appointments within 24 h if an ulcer or other foot pathology develops. The local podiatry service should accept referrals for patients categorised as low risk with minor complications such as callus, minor skin abrasions or minor infections and offer a short-term management and empowerment programme for the foot condition, particularly increasing the patient's awareness of good foot-care and prevention of further problems. Patients should be empowered and given the confidence to take charge of their own foot health. Low-risk patients can be discharged from the service following improvement or resolution of their foot complaint and do not need to be monitored by podiatry. This allows podiatry resources to be utilised appropriately.

At Increased Risk

Patients with neuropathy or absent foot pulses detected on screening but who have not had a foot ulcer, are at increased risk of future foot ulceration. This group comprises around 25–30 % of the adult diabetic population and patients have a 3–7 % annual risk of ulceration [6]. National guidelines recommend that this group of patients has regular podiatry care depending on individual need; some may need up to a 3 monthly review. These patients must have immediate (next working day) access to the foot protection team if they develop a new active foot complication, such as ulceration.

It is important to ensure these patients have access to structured education regarding foot health and advice on good diabetes management. Strategies such as enhanced screening, determining foot pressures and customising footwear may provide benefit and prevent ulceration. Often this group is neglected,, resulting in them progressing into the high-risk group.

Podiatry should lead on the enhanced assessment of these patients and arrange a regular review every 3–6 months by the diabetes foot protection team. At each review, the patients feet should be inspected by a podiatrist trained in diabetic foot care and may include foot pressure measurements. Careful vascular assessment and assessment of cardiovascular risk should be undertaken. Most importantly, current foot-wear should be evaluated and advice and help given regarding this, as foot-wear is a major factor in both preventing and causing foot problems. Finally, it is important to re-enforce foot care education and ensure the patient understands what increased risk means.

At High Risk

High risk means that a patient has neuropathy or absent pulses plus foot deformity or skin changes or has suffered a previous foot ulcer. This group of patients comprises 8–12 % of the adult diabetic population and patients have a 40–50 % annual risk of foot ulceration [6]. For this reason they should have close follow-up by podiatrists. Due to the high rate of re-ulceration, it is recommended that these patients have direct access to services with appropriately skilled diabetes-specialist podiatrists. These services should have direct involvement with a multidisciplinary diabetes foot team. Podiatry should lead on the assessment of these patients by arranging frequent reviews by the foot protection team (1–3 monthly). At each review a full examination of the patient's feet should be made and the need for more detailed vascular assessment by a vascular surgeon considered. There should be provision of intensified foot care education and specialist footwear and insoles. Skin and nail care should also be addressed. Many of these patients will have other disabilities or will be immobile and it is essential to ensure they get adequate access to this service.

Ulcerated/Acute Foot Complication

At any one time 1–5 % of diabetes patients will have an active foot ulcer or other foot disease. Considerable resource and time is spent dealing with this group and the re-ulceration rate can be frustrating. These patients should be reviewed frequently in a specialist multidisciplinary diabetic foot clinic with a network of community podiatry foot protection teams that link with primary care and nursing teams to provide continuity of care in between specialist clinic visits.

The model for ulcer care should be led by these multidisciplinary teams (MDT) who are able to provide the appropriate clinical skills, orthotic service, surgical access and radiological support. The expected model is as follows:

- All new foot ulcers to be managed by appropriately skilled and competent practitioners
- Complex diabtetic foot ulcers (DFUs) requiring MDT input should be referred for urgent care
- Prevent emergency hospital admissions for DFUs
- Prevention of avoidable amputations
- Lead physician involvement in delivering care using the NICE guideline 10 recommendations and delivering Inpatients service for diabetes foot (NICE Clinical Guideline 119) [7].

Management of the Diabetic Foot

The structure of the service across primary and secondary care can be confusing for the patient and for those who work in the service. The structure of the teams is illustrated in Fig. 2.1.

Multi-disciplinary team (MDT) management is essential to ensure diagnosis and management of the most complex of the acute foot conditions (NICE Clinical Guideline 10,

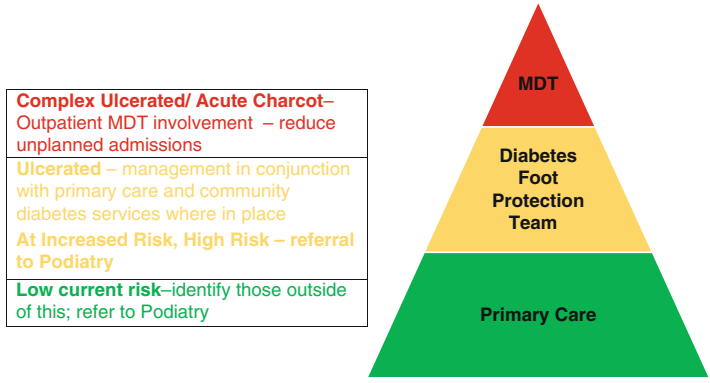

FIGURE 2.1 Diagram illustrating the relationship and function of the teams responsible for providing care to people with diabetes and foot complications

Risk classification – Ulcerated). All patients identified as acute foot or high risk should be given a Red Contact Card. MDT clinics should consist in the main of a diabetes consultant and podiatrist both with specialist expertise in this field to provide expert opinion on the management of complex neuropathic ulceration including medical management, infection control, offloading and imaging. The MDT works well where there is rapid seamless access in to vascular surgery, orthopaedics, orthotics, diabetes specialist nursing, microbiology, radiology, and pharmacy although this list is not exhaustive.

Systems must be in place to allow rapid access to see and access new patients presenting with complex foot disease (including suspected Charcot) and to manage complex acute foot conditions which can be complicated by concomitant PAD, renal failure and other co-morbidities where diagnosis, management and treatment options are unclear or limited due to the complex nature of the condition.

Diabetes Foot Protection Team

Community Podiatry services are ideally placed to form and coordinate the Diabetes Foot Protection Team (DFPT). This team needs to be fully integrated with Primary Care and support the delivery of the Quality Outcome Framework (QoF).

It is clear that podiatry plays a significant role in the management of the diabetic foot and podiatry services should be commissioned with a focus of delivering a dedicated diabetic foot protection team (DFPT). Review of the Allied Health Professional (AHP) toolkit (2012) that was developed for diabetes foot care clearly outlines the pathway and the benefit of Podiatry and other professions in the management of diabetic foot disease. Allied Healthcare Professionals include a number of professions who work both in uni-professional teams and often show their strengths in diabetes care as part of a Multidisciplinary Team (MDT) – should say which professions AHPs include? – isn't this mainly orthotists, podiatrists [8].

The DFPT should use the TRIEPodD-UK Podiatry Competency Framework [9] that clearly describes the skills, training and competency the DFPT require to deliver the correct intervention, assessment and education. All bands of clinical staff can be utilised in this team, which supports primary care and the hospital multidisciplinary team so that there is a comprehensive and seamless pathway in place for any patient with diabetes who presents with a foot concern or problem. This structure and information on how to access the team should be widely publicised so that all patients and members of the health care team are aware of who to contact for varying degrees of foot problems. Many services are not available out of hours and at weekends. This can cause problems, as patients may require help and advice during these times. It is likely that services will be challenged to address this with increasing pressure for health care in the UK to be provided 7 days a week.

The rapid increase in the diabetic population is stretching existing diabetes foot services and an increase in the multidisciplinary workforce may be required to meet demands. There are considerable efficiencies to be achieved in good team working, ensuring there is no duplication of activity. Information technology too may be harnessed to enable information about the patient and their condition to be available to the foot care team across primary and secondary care. Of course the real gain is that well organised foot care services not only benefit patients by reducing amputation rates and improving their quality of life but benefit health care systems due to decreased costs.

Key Points

- Use a risk identification system on clinical records systems (electronic or paper) to identify all patients so that they can have timely access when needed.
- Use a Red, Amber and Green approach for risk identification.
- Ensure all patients are informed of their risk and the impact this has on their foot health.
- Seek enhanced assessment for the increased risk group – the biggest benefit will be gained with these patients.
- Ensure appropriate pathway into podiatry (Diabetes Foot Protection Team) that has a dedicated assessment tool that identifies risk to allow for the quick identification from referral.
- Ensure ongoing education for both patients and health care professionals. This should include audit of outcomes such as amputations, admissions to hospital and new ulcer development.
- Foot care networks drive change and improvements in pathways but must be well structured, managed and resourced.

Appendix 2.1: Foot Care Pathway for People with Diabetes and Foot Complications (Courtesy of Diabetes UK)

PUTTING FEET FIRST

Commissioning/planning a care pathway for foot care services for people with diabetes

BACKGROUND

- The consequences of poor management of the foot in diabetes are considerable: prolonged ulceration and ill-health, gangrene and amputation, depression and death. The annual costs to health care agencies in the UK are estimated to exceed £1billion.
- Good management requires close coordination between different groups of health care professionals. Such coordinated management is not yet widespread.
- Four UK centres have shown that by changing the structure of care, it is possible to reduce the incidence of limb loss by amputation to as little as 20 per cent of its baseline level.
- It is imperative that such re-organisation is implemented in order to improve health outcome and reduce costs.

THE STRUCTURE OF AN EFFECTIVE FOOT CARE PATHWAY

The essential elements of an effective clinical service have been described in Putting Feet First (2009), and Putting Feet First National Minimum Skills Framework (2011), both released jointly by Diabetes UK and NHS Diabetes. These documents define the services to which each person with diabetes should have access – for both prevention and treatment of foot disease. The National Minimum Skills Framework also defines the constitution and responsibilities of the teams necessary to provide these services: the Foot Protection Team (FPT) with a primary responsibility for prevention, and the Multidisciplinary Team (MDT) which should coordinate the management of all new disease. The FPT and MDT must work closely together.

Pathways of care must ensure prompt and effective transition of care across health care boundaries, including traditional boundaries that exist within the community, between community and hospital, and between different specialist groups in hospitals. The publication in April 2011 of new QOF indicators for general practice, together with the NICE Guidelines CG 119, SIGN Guidelines 116 and the NICE Quality Standard 10 completes the picture for the minimum expectations for people with diabetes. The present document demonstrates the way in which these requirements can be brought together in an integrated pathway of care.

COMMISSIONING/ PLANNING

The central roles of the FPT and the MDT have been emphasised in NICE clinical guidelines CG 10 (2004) and CG 119 (2011), SIGN guidelines 116 (2010), as well as in the NICE Quality Standard Statement 10 (2011). The provision of effective ulcer prevention and wound management by such teams should be the basis of the commissioning /planning of foot care services in diabetes.

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TRANSFORMING FOOT CARE SERVICES IN DIABETES

1 PREVENTION OF ACTIVE DISEASE OF THE FOOT IN THOSE AT INCREASED RISK

Referral of those at increased risk to the Foot Protection Team (FPT)* Foot risk status correlates closely with outcome. The need to document risk of each individual with diabetes was incorporated in QOF targets in April 2011. The 2011 NICE Quality Standard 10 and the Diabetic Foot Risk Stratification and Triage (SIGN 116) also states that all people at increased risk will receive regular review by a member of a FPT. People with diabetes should be aware of their risk status and this entitlement. All people at increased risk should be referred promptly to a member of the FPT.

Education of specialist staff and patients It is necessary that those who examine the feet to determine risk status have the necessary training and competence. Training will be a role which can be provided by the FPT. An essential part of the annual review of feet is patient education. The person with diabetes should be aware of the reason for the examination being undertaken, the results of the examination, the services to which they should have access if they require specific preventive measures and action to be taken if they develop a foot problem.

A free online training programme is available at www.diabetesframe.org

* Sometimes referred to as the Foot Care Team

2 TREATMENT OF ACTIVE DISEASE OF THE FOOT

Active disease of the foot includes:

- Ulceration, with or without infection and peripheral arterial disease
- Peripheral arterial disease without ulceration
- Acute Charcot foot
- Painful peripheral neuropathy
- Disease of the foot unrelated to diabetes.

Ulceration All ulcers should be referred to the MDT within 24 hours.

Peripheral arterial disease without ulceration People thought to have symptomatic peripheral arterial disease should be referred either to a vascular surgical unit for assessment, or to the MDT.

Acute Charcot foot People with diabetes and neuropathy who develop unexplained inflammation of the foot should be assumed to have an acute Charcot foot and referred by phone for urgent assessment by the MDT. They should be told not to take weight on the foot until they have been seen.

Painful peripheral neuropathy Guidelines for the management of painful neuropathy have been published (NICE CG 96 and SIGN 116) and this can be supervised in general practice, provided that the GP is confident that the neuropathy is the cause of the pain. Referral to an MDT may be necessary for assessment.

Disease of the foot unrelated to diabetes Symptoms or signs of other diseases should be managed appropriately.

3 MANAGEMENT OF THE PERSON WHOSE FOOT DISEASE HAS BEEN TREATED

Prevention of new foot disease The person who has had an episode of foot disease has a 40 per cent risk of a second episode within 12 months. This group is at highest risk and they should:

- remain under regular review by a member of the FPT or the MDT
- understand the importance of prompt assessment by the MDT of any newly occurring problem.

Reduction of cardiovascular risk The average survival rate at five years is just 50 per cent for people who present with active disease of the foot. Average life expectancy is reduced by 14 years – even in those with predominantly neuropathic disease. As the main cause of increased mortality is cardiovascular, it is essential that all necessary steps are taken to reduce cardiovascular risk.

DIABETES UK
CARE. CONNECT. CAMPAIGN.

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Chapter 3
Emergency Management of the Acute Diabetic Foot

Abigail H.M. Morbi and Clifford P. Shearman

Introduction

The foot of a person with diabetes is at risk for a number of reasons. Neuropathy is common, particularly if diabetes is long-standing and glycaemic control has been poor. Not only does the neuropathy reduce sensation and result in deformity, making the foot susceptible to injury, but the autonomic component may cause arteriovenous shunting and other microcirculatory changes, which result in reduced nutritional skin perfusion, despite a foot that may look pink and feel warm. Initially then, the patient may be unaware of the developing wound. Peripheral arterial disease affecting the main arteries of the lower limb is four times more common in people with diabetes. This may have previously been recognized, causing

A.H.M. Morbi, BSc, MBBS, AICSM
Department of Vascular Surgery, University of Southampton, Southampton, Hampshire, UK

C.P. Shearman, BSc, MBBS, FRCS, MS (✉)
Department of Vascular Surgery, University of Southampton, University Hospital of Southampton NHS Foundation Trust, E Level North Wing, Southampton General Hospital, Southampton, Hampshire SO16 6YD, UK
e-mail: cps@soton.ac.uk

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symptoms such as intermittent claudication but is often asymptomatic, only becoming apparent when a minor wound on the foot fails to heal.

The foot of a person with diabetes then is prone to injury and ischaemia, which reduces the chances of wound healing. Unlike non-diabetic patients they are more susceptible to infection and it is often the infection that results in emergency or urgent presentation [1]. Patients may present with pain, swelling, tissue loss, a hot (infected) or cold (ischaemic) foot and may have generalized symptoms of sepsis including fever, nausea and vomiting. In this chapter, we focus on patients presenting with a red, hot, infected diabetic foot.

Early recognition and management of diabetic foot problems is essential, as delays increase morbidity, mortality and the need for amputation. It should be clear which clinical team and consultant are responsible for the patient and the care pathway can be divided into immediate care, care between 4 and 48 h and ongoing care [2]. There should be an agreed management plan for this condition that can be followed by all members of the health care team (Fig. 3.1).

Immediate Care

Initial Assessment

When assessing any patient in the acute setting with suspected sepsis, it is important to establish that they are cardiovascularly stable. This involves an assessment of airway, breathing and circulation including pulse rate and blood pressure. If the patient has any respiratory or circulatory compromise, appropriate medical support should be urgently requested and the patient moved to an appropriate environment such as a high dependency unit. An urgent measurement of blood glucose should be obtained and the presence of ketones in the urine checked for. In patients with systemic sepsis the foot may not be the main cause and other potential sources of infection, such as the chest or urinary tract, need to be identified. If

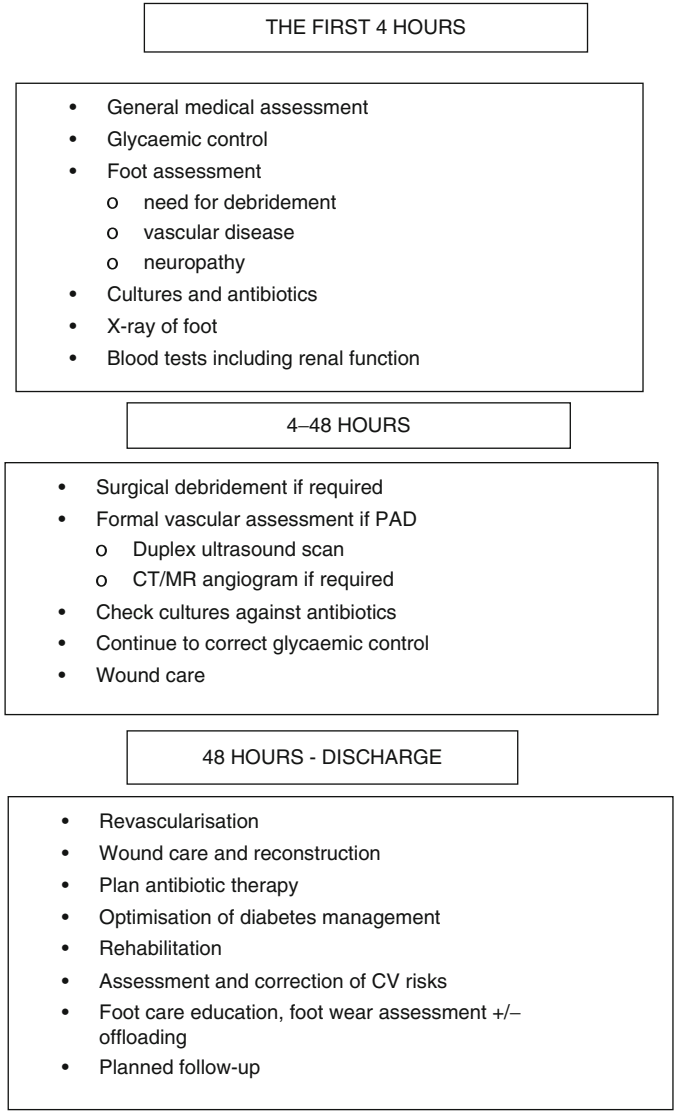

FIGURE 3.1 Treatment pathway outlining key stages and time base in which they should be achieved. *PAD* peripheral arterial disease, *CV* cardiovascular

there is no evidence of compromise, assessment should then involve a thorough history and examination, to establish the severity and spread of infection, the optimal management plan and to ascertain whether or not the foot is viable.

History

It is important to take a detailed medical history, not only concerning the acute presentation, but eliciting the patient's previous diabetic control, other diabetic complications and past medical history. Previous foot problems in particular are important to identify. Obtaining a clear past medical history to include cardiovascular co-morbidities and risk factors is also important. Many patients will not have been aware of a developing foot problem due to neuropathy and an obtunded response to infection until they become extremely unwell.

It is extremely important to distinguish acute limb ischaemia from the infected chronically ischaemic foot. Acute ischaemia is the sudden reduction or cessation of blood supply to a limb to the extent the tissues are immediately threatened. This can be due to emboli associated with an irregular heartbeat (e.g., atrial fibrillation) or the thrombosis of a diseased arterial segment. This is not directly related to diabetes and suspicion of acute limb ischaemia (pain, pulselessness, perishing cold, paresthesia, paralysis and pallor) should prompt immediate referral to a vascular unit.

Key points to consider in history-taking are shown in Table 3.1.

Examination

A systematic and thorough examination is essential. This should include basic observations; pulse, blood pressure, temperature, oxygen saturation and respiratory rate. If there is a systemic response to infection, the patient may be tachycardic, hypotensive, febrile and have a raised respiratory rate.

Table 3.1 Key points when taking a history from a patient with an infected diabetic foot

History of presenting complaint	Past medical history
1. Main symptoms, e.g., hot, red, painful foot	1. Other diabetic complications
2. Duration and speed of onset	2. Cardiovascular co-morbidities (hypertension, stroke, MI, hypercholesterolaemia)
3. Extent – is the whole foot affected/how many toes/both feet?	3. Other co-morbidities
4. Any treatment prior to admission	4. Previous surgery
5. Previous admissions for diabetic foot problems	Drug history – including allergies
6. Type of diabetes (I or II)	Social – smoking, alcohol
7. Is the patient on insulin?	
8. Glycaemic control	

The patient is examined from the end of the bed looking for signs of respiratory distress. Examination of the hands, to include palpating the radial pulse, checking capillary refill time, assessment of skin turgor and peripheral temperature will allow assessment of circulation, and give an indication of whether the patient is peripherally shut-down, septic and dehydrated.

Both feet must be carefully examined and any dressings removed, even on the apparently unaffected foot. When examining the foot, start with observation, looking for erythema, ulceration/tissue loss, any obvious discharge or bleeding and swelling. Callus is an early sign of neuropathy and deformity and tendon shortening may be apparent. Many patients may be too unwell to give a detailed history or may not recall previous foot problems and so comparison should

be made with the non-infected foot. Scars on the limb may indicate previous bypass surgery.

Palpation will ascertain whether there is a change in temperature, pain or tenderness, crepitus and oedema. Crepitus is a particularly important sign to recognize as it implies gas-producing organisms in the soft tissues (gas gangrene) and should prompt immediate surgical involvement. Even in a neuropathic foot, palpation may elicit pain and suggests pressure in the compartments, an indication for urgent surgical decompression. Gentle pressure along the tendons may produce pus in a more distal wound, suggesting proximal tracking of the infection.

Pulses in the leg and foot should be palpated. Pulse palpation can be difficult especially in a swollen foot and ankle brachial pressure indices (ABPI) should also be measured. Although calcification may result in falsely raised ABPIs in some patients, if lowered in the presence of absent pulses, the presence of arterial disease is very likely. Simple tests for sensation such as with a 10-g monofilament should also be performed.

If the foot is red, hot, painful, deformed and swollen but there is no obvious evidence of infection then the diagnosis of Charcot foot must be considered and expert help sought (see Chap. 11).

Investigations

Capillary blood glucose should be tested using the BM strips and venous blood glucose should also be sent, along with HbA1c, to look at recent diabetic control. Venous blood tests should also include full blood count, renal function, C-reactive protein, liver function tests and clotting studies. If intervention is anticipated serum should be grouped and saved. It is likely white blood cell count and C-reactive protein will be raised although in advanced sepsis the white cell count may be low. Establishing the patient's renal function (urea, creatinine and estimated glomerular filtration rate) is important

FIGURE 3.2 Plain x-ray of foot of patient with extensive soft tissue infection tracking into leg. There was palpable crepitus on examination. The patient was desperately unwell and went onto guillotine amputation (see Fig. 3.3)

for the safe prescribing of antibiotics, some of which are nephrotoxic.

It is pertinent to take blood cultures, and to take swabs from the infected area, to investigate the organism causing the infection. When possible deep tissue cultures or aspirates should be taken as surface swabs have limited value. In practice deep tissue cultures are often obtained at subsequent surgical debridement. Cultures should be taken prior to commencing antibiotics, but antibiotics should not be delayed whilst awaiting culture results.

A foot x-ray should be obtained in two views. This may show advanced osteomyelitis with bone destruction and this may need to be removed surgically. Gas in the soft tissues is an important sign to recognize as it implies gas-producing organisms in the tissues and requires urgent surgical input (Fig. 3.2).

Management

Management of the patient with an infected diabetic foot will involve both management of the patient's diabetes and treatment of the acute foot infection.

If the patient is systemically unwell, they are likely to be dehydrated. It is therefore necessary to site a peripheral cannula as he or she will require intravenous fluid resuscitation. It they are not eating, either because they are unwell or because they are starved for possible surgical intervention, they will require a variable rate intravenous insulin infusion (VRIII, previously referred to as an insulin sliding scale), in order to achieve good glycaemic control. Capillary blood glucose monitoring is required, aiming for blood glucose concentrations of 6–10 mmol/L and the VRIII should be carefully adjusted according to the blood glucose level, in line with the local guidelines. 0.45 % sodium chloride with 5 % glucose and 0.15 % potassium chloride should be prescribed as the substrate solution as indicated on the VRIII proforma [3].

In the event that the patient is expected to only miss one meal and does not need to remain nil by mouth, it may be possible to manage them with their regular diabetic treatment, avoiding use of the VRIII [3].

Having established that the patient has an infected foot, broad-spectrum antibiotics should be started according to the local protocol. If the infection is localized to, for example, one toe and the patient has no systemic signs of infection, it may be appropriate to start oral antibiotic therapy with flucloxacillin and metronidazole. If there is any indication that the patient is systemically unwell or that there is severe infection, intravenous antibiotics should be prescribed. Each unit should have its own agreed regimen, based on previous bacterial cultures. Vancomycin, ciprofloxacin and metronidazole will give good broad-spectrum cover in the first instance, whilst awaiting results of cultures and renal function. There are clear guidelines for the safe prescribing of vancomycin. Initial dose is calculated according to the patient's estimated glomerular filtration rate. A trough level should be taken

(venous blood test) before the third dose, which should then be given whilst awaiting the blood results. Trough levels should be between 10 and 15 mg/L. If the level is high, the vancomycin regime will need to be decreased, and if the level is low, the dose will need to be increased or the time intervals between doses will need to be decreased.

The infected foot may be painful and so the prescribing of regular and appropriate analgesia is important. Typically, paracetamol would be the first line treatment, with the WHO-analgesia ladder giving a clear, step-wise approach for increasing analgesia, as required.

At the end of this first phase the patient's glucose levels should be under control, antibiotics commenced and blood tests and radiological imaging obtained. The findings from the history and examination together with the results of investigations should be clearly recorded in the notes together with a treatment plan.

Intermediate Phase (4–48 h)

During this phase it needs to be determined if the patient needs urgent surgical intervention to drain pus or remove dead tissue. This may be essential to prevent further tissue damage and delay inevitably results in a worse outcome. During this period, patients who will require revascularisation should be identified. However, identification of underlying arterial disease should not delay emergency surgery if indicated.

Indications for Surgical Management

Indications for urgent surgical debridement are extensive infected dead tissue, tenderness suggesting infection in the compartments of the foot, clinical or radiological evidence of extensive tracking of infection or an abscess. Rarely, if the patient is extremely unwell and not responding to antibiotics

and supportive therapy, emergency amputation has to be undertaken to remove the source of infection. If the infection is localized to a digit and the patient is systemically well, then antibiotics and observation may be appropriate.

It is rare to see a patient who has been harmed by overzealous intervention but not uncommon to find a patient whose foot has worsened due to delay or underestimation of the extent of the problem. The infected diabetic foot is a surgical emergency and must be treated as such. Clinical assessment is difficult and must be done by a clinician experienced in the field. Usually, careful clinical assessment will identify the extent of the infection, for example redness or tenderness along the peroneus tendons is likely to mean pus has spread into the leg.

If it is determined that surgery is required, this should be carried out as soon as the patient is fit for surgery, in terms of glycaemic control and fluid resuscitation. The patient needs a clear explanation of the planned procedure and should be warned that they will probably need more than one procedure and that it may be more extensive than initially thought. In many patients, regional nerve blocks carried out by an anesthetist using ultrasound control can be very useful. If this is not possible, then general anesthesia is required.

The principles of surgical debridement or surgical toilette are to remove all dead and infected tissue. This means resecting back to bleeding muscle, healthy bone and fat. This can often be far more extensive than expected, but leaving dead tissue will cause continued sepsis and cause more tissue to die back. Massaging along the tendons will often identify proximal tracking, which must be drained. Tissue samples should be sent for microbiological culture.

In patients where sepsis is overwhelming and due to the extent of the infection of the limb, extensive amputation of the leg may have to be considered as a living-saving measure. In this situation a guillotine amputation (simply transecting the limb above the level of infection) is best as it rapidly removes the source of infection in a sick, unstable patient (Fig. 3.3). When the patient's condition has improved, the amputation can be revised to a formal amputation.

FIGURE 3.3 Guillotine amputation of limb above infected area. This was revised to a below knee amputation 4 days later

Foot wounds should be left open and dressed with non-adherent dressings and padding. It will be necessary to apply some pressure to the wound to stem bleeding, but great care must be taken not to damage the surrounding skin. It is a good idea to use orthopaedic wool as a dressing over the pads and apply a crepe bandage over this, in a way that the bandage has no direct contact with the patient's skin.

Wounds must be inspected within 24 h and if there is any concern about the viability of the tissue or residual infection, the patient should be returned to theatre for further wound debridement. Once the wound looks healthy, the patient should be in a relatively safe position and plans to reconstruct the foot can be embarked on.

Diabetic patients have increased morbidity and a peri-operative mortality rate of up to 50 % higher than the non-diabetic population [1]. Reasons for this include multiple co-morbidities, peri-operative infection and poor glycaemic control. Inappropriate use of a VRIII may also result in adverse outcomes [3]. Diabetic patients therefore require certain considerations in the peri-operative period, including avoiding long periods of starvation. They should be managed according to enhanced recovery protocols, encouraging early

normal oral intake, allowing the VRIII to be stopped and the patient's normal diabetic medications to be re-commenced in a timely fashion [4].

Revascularisation

Not all patients with arterial disease need revascularisation and the decision to undertake either angioplasty or surgery can be difficult. In some patients it may be obvious that the foot is threatened due to lack of blood, with little evidence of wound bleeding during debridement. These patients may need emergency revascularisation. In the majority of patients, however, the need for revascularisation becomes apparent over the next few days. No sign of wound bleeding or healing, a low ABPI or transcutaneous oxygen level may prompt the decision to intervene. This decision has to be balanced against the options available for revascularisation in the individual patient and the chances of success. In any patient with evidence of arterial disease, it is worth getting a duplex ultrasound scan early as this gives some idea of the possible options for revascularization if required.

At the end of this phase the patient's foot should be safe, infection treated and attention can be directed to reconstruction and rehabilitation.

Ongoing Care (48 h Onwards)

In the majority of cases, revascularisation, if required, is undertaken once the patient's general condition has been optimized and the procedure carefully planned. Revascularisation procedures have been discussed in detail in Chaps. 8 and 9.

Once the circulation of the foot has been optimized, attention can be directed towards wound healing and reconstruction. A range of adjunctive therapies have been advocated to speed up healing. Topical negative pressure therapy has been widely adopted in this area and while the impression is very

favorable [5, 6], the objective evidence for cost effectiveness is lacking. The use of these treatments varies enormously between centers. Hyperbaric oxygen therapy is extremely costly and not widely available although there is some evidence of reduction in risk of amputation. Growth factors and other local wound therapies are not clearly established and really should only be used in the context of a clinical trial [7].

The range of dressing used is enormous and in practice there is no high quality evidence to suggest benefit of any over simple inert dressings [8]. In our experience one of the greatest inhibitors of wound healing on the foot is oedema, leading to wet discharging wounds, causing surrounding skin damage. Most patients who have suffered foot complications will get lower limb swelling, especially on mobilization. A balance has to be struck between getting the patient up to maintain their mobility and keeping leg swelling to a minimum by elevating the leg as much as practically possible.

Intravenous antibiotics should be stepped down to oral therapy as soon as possible, with oral treatment being continued for at least 7 days (see Chap. 7). When the patient is able to eat normally, their usual diabetic treatment should be recommenced and the VRIII stopped. Diabetic control should be optimized prior to discharge.

Poor glycaemic control and poor foot-care can result in an increased risk of infection. It is therefore essential that patients should be advised with regards to ensuring good diabetic control and foot-care. It should be ensured that they have appropriate foot-wear and that clear arrangements for follow-up in the community have been arranged.

Summary

The emergency presentation of a person with diabetes and a red hot swollen foot is a surgical emergency. The greatest barrier to a successful outcome is delay in assessment and intervention. Foot complications are one of the commonest causes of hospitalisation of people with diabetes and are associated

with a high risk of major amputation if not promptly treated. Any unit likely to see these patients should have clear guidelines in place for their management, including who takes responsibility for delivering the care. The initial assessment must be carried out within the first 4 h of admission to hospital and treatment commenced. This should be possible in most units. If specialist input is required, for example revascularisation, then it may be necessary to transfer the patient to a unit where this service is available.

There is good evidence that where services for emergency care of diabetic foot complications have been well organized, not only do amputation rates fall, but costs to the service are reduced.

Key Points

- Diabetic foot complications often present as an emergency, commonly due to infection.
- Assessment and treatment must be commenced within hours of admission.
- Assessment should be undertaken by an experienced health care professional.
- Guidelines and a care pathway should be available in all units treating these complications.
- Management should include optimization of glycaemic control, as well as focusing on treating the infection.
- Well-organized services save money and reduce amputations.

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Chapter 4
Managing Diabetes in People with Foot Complications

Mayank Patel and Keith G. McCormick

Introduction

Diabetes mellitus is a metabolic disease characterised by uncontrolled hyperglycaemia. The hormone insulin plays an essential role in promoting glucose uptake for use by the body as a metabolic substrate. Type 1 diabetes is characterised by an inability of the pancreatic beta cells to produce insulin, meaning that patients must take insulin to survive. This is available as short-, long-acting, or as a mix of short- and long-acting preparations to be administered subcutaneously. Type 2 diabetes occurs as a consequence of both insulin resistance by the body and beta cell dysfunction. It can be managed through adherence to a healthy diet, with oral hypoglycaemic agents, non-insulin-based injectable treatments, or insulin as needed. The treatments in type 2 diabetes have various modes of

M. Patel, BM, MRCP, MD (✉)
Department of Diabetes and Endocrinology,
University Hospital Southampton NHS Foundation Trust,
Tremona Road, Southampton, Hampshire SO16 6YD, UK
e-mail: Mayank.patel@uhs.nhs.uk

K.G. McCormick, MSc, FFPM RCPS(Glasg)
Faculty of Health Sciences, University of Southampton,
Highfield Campus, Southampton, Hampshire UK

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Table 4.1 Treatments available for diabetes

Oral agent classes (e.g., denotes other agents in same class available)
Biguanides (metformin)
Sulphonylureas (e.g., gliclazide)
Thiazolidinediones (pioglitazone)
Alpha glucosidase inhibitors (acarbose)
Meglitinides (e.g., repaglinide)
Dipeptidyl peptidase-4 (DPP-4) inhibitors (e.g., sitagliptin)
SGLT-2 inhibitors (e.g., canagliflozin)
Injectable treatments
GLP-1 agonists (e.g., liraglutide)
Insulin (short acting; e.g., novorapid, long acting; e.g., lantus, mixed; e.g., humulin M3)

action, which include promoting increased insulin sensitivity by the body, delaying glucose absorption from the gut, increasing insulin secretion, or increasing urinary glucose excretion. Insulin is used in type 2 diabetes when the pancreas fails to respond to other treatments (Table 4.1).

Ultimately, infection and ischaemia are the direct causes of amputation in the diabetic foot. When an individual with diabetes is admitted to hospital, their feet should be inspected routinely regardless of the reason for admission. Foot complications account for considerably more hospital admissions than any other complications of diabetes. In England alone, 120 amputations a week are performed in people with diabetes, many of which could be prevented. Over £119 million is spent each year on these diabetes-related amputations [1].

Individuals with suspected active peripheral arterial disease or foot ulceration, acutely necrotic toes or a warm swollen foot should be referred immediately for specialist assessment. Specialist services available will depend on locality. This should include a specialist podiatry service as

part of a Diabetes Multidisciplinary Team (MDT), supported by a vascular surgery service. Where wounds or pressure sores exist, then involvement of a tissue viability service may also be considered to chart the wound and consider aspects of pressure relief, nutrition and specialist wound care. The presence of infection, with or without ischaemia, requires immediate attention as they both have the ability to rapidly destroy a diabetic foot, particularly in combination. An episode of acute diabetic foot disease is now often referred to as a "foot attack," reflecting its aggressive and potentially devastating nature.

The stress of any acute illness, such as acute diabetic foot disease, can destabilise diabetic control. Part of the body's stress response to acute illness is to prompt a surge in catecholamines, such as adrenaline or cortisol, which result in a rise in blood glucose levels. Hyperglycaemia is known to suppress the immune response to infection, so it is essential that measures are taken early in acute sepsis, regardless of the source, to stabilise diabetic control. The signs and symptoms of infection may be subtle in a patient with diabetes and may present late or be missed by inexperienced clinicians.

Acute Presentation

Whichever ward or department to which a patient with acute active foot disease is admitted, the process of medically stabilising the patient should be consistent. The pathway of resuscitation (airway, breathing, circulation, etc.), as well as local protocols for managing sepsis should always be available and followed. The unwell patient with diabetes and hypotension should have anti-hypertensive medication suspended where relevant, to promote more effective fluid resuscitation. Attention must also be given to aspects of diabetic control. The presence of acute hepatic or renal impairment can reduce drug metabolism, which can result in prolonged drug action. For example, reduced sulphonylurea excretion with moderate renal impairment can be associated with an

Table 4.2 Drugs to review with hepatic or renal impairment in diabetes

Antihypertensive agents
Diuretics
Insulin
Metformin
Non-steroidal anti-inflammatory agents
Sulphonyureas

increased risk of hypoglycaemia, through increased drug action itself, as well as through associated reduced insulin clearance. Other concurrent therapies that a diabetic patient may be taking may risk causing more harm and need to either be withheld or have their doses reviewed (Table 4.2). Often, in the face of acute illness and a presumed state of poor tissue perfusion, with or without a rise in serum lactate, the drug metformin is suspended. This is due to concerns of increasing the risk of lactic acidosis. Also, if it is likely that there will be a need for contrast-based investigations within the next 24–48 h, metformin should be stopped (see Chap. 6).

Acute Hyperglycaemia

Whilst it is highly likely that hyperglycaemia in a patient with acute diabetic foot disease is largely as a consequence of acute sepsis, consideration should always be given to other potentially confounding issues that may need addressing (Table 4.3). In particular, the presence of the emergency states of either diabetic ketoacidosis or hyperglycaemic hyperosmolar state must be excluded, both of which can be a further consequence of acute sepsis in a diabetic patient and require specific treatment protocols to be followed.

It is not uncommon for the acute foot patient to either have their usual insulin regimen or doses adjusted or find themselves commenced on an intravenous insulin infusion

Table 4.3 Causes of acute hyperglycaemia

Acute illness (e.g., sepsis)
Reduced diabetes control through disease progression
Non compliance with usual diabetes treatments
Concurrent or recent steroid treatment
Certain antipsychotic medications
Diabetic ketoacidosis
Hyperglycaemic hyperosmolar state

(previously referred to as a 'sliding scale') to achieve relative normoglycaemia promptly. A variable rate intravenous insulin infusion (VRIII) is used as a means to achieve improved blood glucose control. It is indicated for use in acutely unwell patients, those anticipated to have a long fasting period (two or more meals) or in poorly-controlled diabetes. The convention is to draw up 50 units of actrapid (fast-acting insulin) in 49.5 mL of 0.9 % sodium chloride solution. This is then infused through a syringe pump, alongside a glucose-based fluid (e.g., 0.45 % saline with 5 % glucose and 0.15 % potassium chloride), which is administered using a volumetric infusion pump. The infusion rate of insulin (units/hour) is determined by bedside hourly capillary blood glucose measurement and is likely to be variable. The rate of fluid infused is set to deliver the hourly requirements of the patient. Hypoglycaemia is a common side effect of an insulin infusion. Great care must be taken with regular blood glucose monitoring for patients on an insulin infusion, so as not to cause hypoglycaemia. Local hospital protocols should be followed in all cases of hypoglycaemia in the diabetic patient. Maintaining good blood glucose control during the acute phase of infection and subsequent recovery will do much to promote immune system activity and better wound healing.

Recovering from Acute Diabetic Foot Disease

Patients who are hospitalised for acute diabetic foot disease can find themselves having lengthy hospital stays, with foot disease accounting for a significant percentage of inpatient stays. Hospital Episode Statistics in England recorded 72,459 inpatient spells for 2010–2011 in which diabetes and foot ulcer or amputation codes were recorded; this represented almost 9 % of all admissions with a diabetes code [2]. The increased length of stay is often through clinical necessity, but may also be related to suboptimal diabetic control and errors in diabetes care in hospital.

In our hospital, inpatients with diabetic foot complications receive regular review from the diabetes foot MDT. Aside from the vascular surgical team, this MDT includes a diabetes consultant, specialist nurse, dietician and pharmacist. It is easy to focus on the foot healing process, but in terms of diabetes care, a holistic approach is needed. Much can be done to optimise diabetes care that will greatly impact on recovery from acute foot disease. Managing cardiovascular risk is of huge importance in individuals with diabetic foot disease. Young et al. [3] showed the relative risk of death within 5 years of foot ulceration was 48.5 % lower in a group of patients treated aggressively for cardiovascular risk compared to a group of individuals before the policy was introduced. A large part of supporting care involves taking a non-judgmental and empathetic approach in empowering a patient who may previously have neglected their usual diabetes care, which may in part have contributed to the acute foot presentation.

An admission to hospital may be the first time that a patient with diabetic foot disease is reviewed by a specialist diabetes team. Being able to see the same team repeatedly over the course of an inpatient stay can help to instill confidence and build trust, enforce key educational messages and promote a greater focus on diabetes than prior to admission. An inpatient with foot disease also provides a captive audience for the team to give precise guidance on nutrition, diet

and lifestyle, as well as suggesting weight management measures. Foot disease and obesity do not coexist well together. Plantar pressures in gait can be decreased significantly by weight loss, which can also improve general cardiovascular fitness, lipid profiles and blood pressure.

If it transpires that pre-admission diabetes control had been sub-optimal, through the combination of reflections by the patient, medical records and review of HbA1c, a hospital stay can also be the time when glucose-lowering treatment regimens can be reviewed. Patients are often not made aware of the progressive nature of type 2 diabetes in particular, meaning that that the endocrine function of a failing pancreas is less responsive to usual anti-hyperglycaemic agents over time. It is not uncommon for patients who were admitted on tablets for diabetes to find themselves discharged on insulin. Those new to insulin will need on-going support and education around self-monitoring of blood glucose, the risk of hypoglycaemia, as well as Driver and Vehicle Licensing Agency (DVLA) guidance on safe driving practices when on insulin [4] where applicable.

A post-hospital discharge follow-up appointment with the local diabetic foot clinic/service should be made before discharge, and the patient should be discharged with appropriate pressure-relieving footwear.

Post Hospital Discharge

Post-hospital discharge, for a patient to live well with diabetes and foot disease, it is essential that they are given all the support and knowledge that they need to enable this. Basic foot care education is of vital importance, so patients know how to recognise potential problems before they become acute. Daily foot inspections and regular podiatry appointments are the key to preventing acute episodes. Wearing appropriate accommodative footwear and being familiar with the signs and symptoms of a “foot attack” [5] can ultimately save a patient’s leg. Issues around the need for treatment compliance

should be explored before simply increasing medication doses or starting new agents. To reduce subsequent cardiovascular risk, anti-hypertensive and lipid-lowering therapy should be considered, with agents and doses reviewed periodically as appropriate, based on tolerability and clinical response. Antiplatelet agents should also be considered [6]. Smoking cessation, alcohol reduction and a conversation around which light exercise may be appropriate when the foot is intact, are all important.

A large subgroup of patients who are at increased risk of foot problems, are those with diabetic renal disease. It is well documented that there is a close association between renal failure, foot ulceration, peripheral vascular disease and amputation. Individuals with renal disease and diabetes are highly susceptible to foot ulceration and should be monitored closely. Local guidelines should be considered when antibiotic therapy is required [7].

What must also be considered when managing the diabetic patient with foot disease, whether it is recovering from an acute admission or living with chronic foot problems, is the focus on aiming to maintain a good quality of life. With that in mind, it needs to be recognised that the pursuit of lower blood pressure and lower blood glucose levels may increase the risk of symptomatic hypotension and hypoglycaemia with an associated decrease in quality of life, as well as reduced treatment compliance. Conversely, allowing a patient to live with uncontrolled hyperglycaemia is not without risk either, promoting both a risk of infection and dehydration through osmotic diuresis. Individual targets for both blood pressure and glucose levels need to be agreed upon, with the rationale behind decision-making explained to patients.

Although in most circumstances every effort should be made to save a limb, through gold-standard multidisciplinary treatment, there are occasions when amputation is the treatment of choice, for example, when individuals have a diminished quality of life with multiple foot ulcers, regular episodes of infection undergoing constant hospital visits. It is important for clinicians to recognise this and know when and how to have an informed conversation with the individual.

Disability through life-affecting foot disease can contribute to social isolation, with individuals becoming increasingly house-bound, as they may have lost the ability to drive, for example, or become more carer-dependent. Healthcare professionals should be vigilant for signs of mental illness in this patient group.

Living with diabetes can be daunting, but doing the key things well can help reduce the risk of associated problems later. For further guidance for patients, Diabetes UK, a national diabetes charity, has put together a list of 15 health-checks to which patients with diabetes [8], with or without foot disease, should expect to be entitled. To go into these individually in detail is beyond the scope of this chapter, but the themes are around ensuring that patients are reviewed at least once a year by a healthcare professional who is proficient in providing diabetes care. All healthcare professionals managing patients with diabetes should explain the benefits of having these health-checks, in that potential problems may be developing (asymptomatic proteinuria for example), despite patients feeling well. Appropriate intervention can then be considered earlier rather than later.

Summary

The increasing prevalence of diabetes means that there will be an increased burden of diabetic foot disease. All healthcare professionals who encounter patients with diabetes should be familiar with the basic signs that suggest acute foot problems. Acute diabetic foot disease is a serious issue that requires prompt assessment by an appropriate specialist team. It is important to optimise all aspects of diabetes care to increase the chance of favourable outcomes for this high-risk patient group. An acute diabetic foot problem, particularly infection, can affect diabetic control and the patient's usual diabetic medications may need to be reviewed. A variable rate insulin infusion may be required during the acute admission to hospital.

There is a need for on-going support for this patient group to enable them to feel empowered to manage day-to-day diabetes well. The increased cardiovascular risk they face should also be addressed, through appropriate lifestyle measures and medication-related means. It is essential that all diabetic patients are familiar with the principles of good foot care. They need to know what an 'at risk foot' means or looks like, so that they can seek medical advice promptly, rather than risking amputation through delayed presentation.

Key Points

- Acute diabetic foot disease is common and can be very subtle; vigilance is key.
- Diabetic foot disease is associated with high morbidity and cardiovascular mortality.
- Ensure that prompt patient referral is made to the specialist foot team.
- The diabetes specialist team has a key role in optimising other aspects of diabetes care and providing patient support and education.
- Good glucose control will promote a more prompt recovery from sepsis.
- Post-discharge foot review should be arranged before discharge.
- Regular post-discharge diabetes support is needed for these patients.

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Chapter 5
Predicting Wound Healing in the Diabetic Foot: Measuring Skin Viability

Javier Aragón-Sánchez and Rajgopal Mani

Introduction

Foot ulcers in the diabetic patient frequently lead to further complications and may result in amputation. A foot ulcer may follow different courses before it heals completely, which ideally should occur within 8–12 weeks. Healing may be achieved using different therapeutic strategies, but often complications occur, of which infection is the most common. Treating infected wounds may require the use of antibiotics, hospitalisation for surgical care, revascularisation and, if unsuccessful, amputation. Severe pain is an additional complication, but in diabetic neuropathy, severe ischaemic lesions may be present without pain. The aims of this chapter are to briefly examine the diabetic complications that lead to

J. Aragón-Sánchez, MD, PhD
Department of Surgery, Diabetic Foot Unit and Endoluminal Therapy, La Paloma Hospital, Las Palmas de Gran Canaria, Spain

R. Mani, MD, PhD/DSc, FACA, FIPEM (✉)
Medical Physics and Bioengineering,
University Hospital Southampton NHS Foundation Trust,
Southampton SO16 6YD, UK

Visiting Professor, Shanghai Jiao Tong University School of Medicine, Shanghai, China
e-mail: Rm1@soton.ac.uk

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the development of foot ulcers and subsequent loss of skin viability and discuss objective measurements to prevent and manage diabetic foot ulcers.

Diabetic foot ulcers have a complex pathogenesis associated with complications arising from poorly controlled, long-standing diabetes mellitus. The complications are peripheral neuropathy (PN) and peripheral arterial disease (PAD). Even minor trauma may trigger the development of an ulcer. Infection is not a cause of foot ulcers but ulcers frequently become infected, since host defences are impaired in the diabetic subject. Since these factors can lead to the loss of skin integrity, their presence in pre-ulcerated skin should be detected in order to prevent this complication.

Peripheral Neuropathy

The 10-g Semmes-Weinstein (SW) monofilament is commonly used to detect loss of sensation in foot skin. The SW monofilament is a blunt nylon wire used to touch the skin over the toes, metatarsophalangeal joints, heel, over the arch of the foot and on the dorsum of the foot (Fig. 5.1). With their eyes closed, the patient is asked whether they can feel the touch while the monofilament is pushed against the skin surface until it buckles, as in Fig. 5.1. A score for each foot is given. This semi-quantitative test is reliable, easy to perform, inexpensive and the skill is easily learnt.

The biothesiometer (or neurothesiometer) is a simple hand-held device that gives semi-quantitative assessment of vibration perception threshold (VPT) (Fig. 5.2). A VPT > 25 V is abnormal and has been shown to be strongly predictive of subsequent foot ulceration. A large multicenter study showed a significant increase in risk with each volt increase of VPT over 25 V [1].

The development of a neuropathic ulcer is complex, involving repetitive injuries of which a patient may be unaware on account of loss of sensation. The propensity to injury is also associated with limited joint mobility and

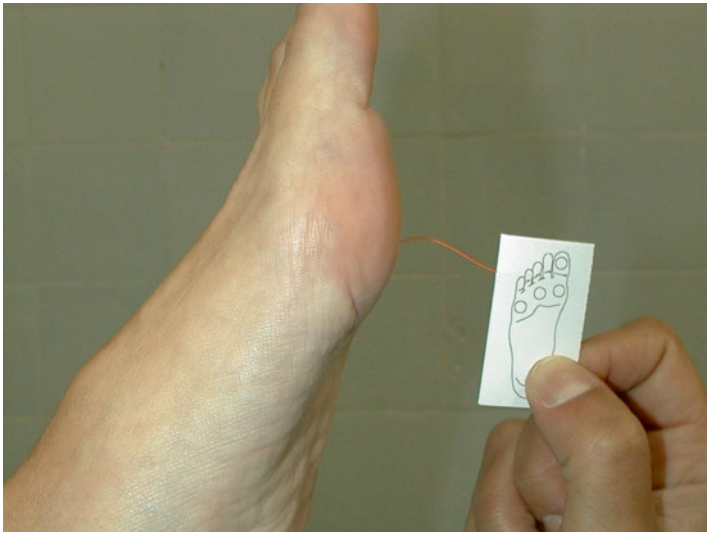

FIGURE 5.1 The Semmes-Weinstein monofilament used to check foot skin sensation. The *open circles* indicate areas tested

structural foot deformities, and hence, high plantar pressures over certain areas that are regarded as *pre-ulcerative areas*. Raised dynamic plantar pressures significantly increase the risk of foot ulceration in patients with PN who have lost protective sensation.

Clinically, findings such as callus, sub-keratosis haemorrhages, blisters, macerated skin, limited hallux dorsiflexion of less than 30°, prominence of metatarsal heads or other types of plantar prominences such as rocker-bottom deformity seen in the Charcot foot, suggest high-pressure areas in the plantar surface of the foot. Patients with a history of foot ulcers or surgery to the metatarsal head may also have high plantar pressures and therefore should be considered as high risk of developing foot ulcers.

Pressure may be measured using platform devices for interface measurement between the foot and the floor as well as in-shoe systems to measure pressure between the

FIGURE 5.2 The measurement of vibration perception threshold on the toe of a diabetic patient

sole of the foot and the shoe. No accepted threshold for the onset of ulceration currently exists since it is difficult to directly compare values obtained using different plantar pressure measurement devices. A threshold of 700 KPa has been suggested for predicting foot ulceration using an EMED® platform [2].

Peripheral Arterial Disease

PAD is important in the aetiology of diabetic foot ulcers. It is essential to detect PAD in the pre-ulcerous diabetic subject in order to prevent skin breakdown. Clinical signs of

PAD include loss of hair on the dorsum of the foot, thin skin and fragile and deformed nails. A history of intermittent claudication suggests the presence of PAD and, although some patients may not experience pain due to neuropathy, walking is usually limited by fatigue.

Rest pain signifies severe PAD. Pallor of the foot on elevation and rubor on dependency suggest the presence of severe ischaemia, but the absence of these signs does not permit its exclusion. The first step in the assessment is palpation of the posterior tibial and dorsalis pedis arteries, which supply the foot. Palpating for pulses is not always easy. Absent pulses usually indicate the presence of PAD, but this does not quantify the perfusion deficit. Objective measurements of the macrocirculation are achieved by measuring the ankle brachial pressure index (ABPI) using Doppler ultrasound, and duplex ultrasound imaging for haemodynamic assessment.

ABPI is measured using a blood pressure cuff and a handheld Doppler probe. It should be measured in the supine patient, with the patient rested (for 5 min). Ankle systolic blood pressure should be measured over the posterior tibial and dorsalis pedis arteries; brachial systolic pressure on the same side should be recorded. If possible the pressure in the peroneal artery should also be recorded as in patients with diabetes this vessel is often preserved and becomes an important blood supply to the foot. The ratio of the highest ankle pressure to the brachial pressure is the ABPI.

ABPI is a simple screening test, and low values are associated with the presence of peripheral vascular disease [3]. An ABPI <0.5 signifies the presence of significant PAD, while values between 0.85 and 1.2 permit the exclusion of significant arterial disease. In the diabetic subject, ABPI may be falsely high due to Mönckeberg sclerosis (calcification of the tunica media), resulting in rigid arteries. It is related to peripheral neuropathy, but does not itself result in ischaemia. The predictive variables related to the presence of calcification in a series of patients admitted with foot disease were duration of diabetes greater than 20 years, retinopathy, albuminuria, and PAD. Patients with calcification of pedal arteries underwent more amputations and re-operations in a series, but differences

FIGURE 5.3 The measurement of toe blood pressure (could be used to derive toe brachial index) using an optical sensor and cuffs (not shown)

in outcomes were related to the association of calcification of pedal arteries with PAD [4].

Since calcification affects digital arteries less commonly, toe pressures are measured either for an absolute value or to derive the toe brachial pressure index (TBI). Toe pressures are measured using an optical probe and a small pressure cuff (in a foot acclimatized in a warm environment [5]) (Fig. 5.3). Toe pressures less than 55 mmHg or a TBI of less than 0.7 strongly suggest the presence of PAD. Pressure measurements are reliable for diagnosis, but colour flow duplex ultrasound is the recommended next step for haemodynamic data to determine clinical management.

Duplex ultrasound imaging yields reliable data on both structure and function of the arteries down to the level of the dorsalis pedis artery. Beyond this the calibre of the vessels is too small to routinely image, and other imaging modalities, such as computerised tomography, are indicated.

Elevating the limb whilst insonating with a Doppler probe (the "Pole Test") is a useful bedside test that can be performed in patients who elevated ankle pressures which seem out of keeping with their symptoms and signs. If the Doppler signal disappears as the limb is elevated an re-appears as it is lowered then the perfusion pressure of that limb is very low [6].

Once an Ulcer Appears

Where an ulcer is present, the aim is to heal the ulcer. However, the most difficult decision is to determine which ulcers will heal without intervention and which will only heal with revascularisation. Most commonly simple observation of the wound is used to assess wound-healing potential. The logic of this is sound, and the percentage change in the area of the foot ulcer after 4 weeks of observation is a robust predictor of healing at 12 weeks. Therefore, patients in whom ulcer size fails to reduce by 50 % over the first 4 weeks of treatment are unlikely to achieve wound healing over a reasonable period [7]. However, this is a slow and potentially dangerous technique, which delays revascularisation in those patients who ultimately need it.

The presence of PAD is an important negative predictor of the outcome of foot ulcers in patients with diabetes [8–10]. However, the effect of PAD in the large vessels on tissue nutritional blood flow and the microcirculation is difficult to quantify and does always indicate that a wound will not heal. Revascularisation procedures are invasive and carry risk to the patient, so they should only be undertaken when there is a clear indication that they are required. The perfusion of the tissues around the ulcer will most likely influence outcome, and a number of techniques to assess the microcirculation have been developed.

Laser Doppler flowmetry, or imaging with optical sensors, can give a direct measure of perfusion by measuring flux. The technique has been successfully applied in the clinical management of burn wounds, where it has a reported accuracy of

92 % to assess burn depth [11]. Laser Doppler imaging is limited by the depth of scanning but has a unique role in research. Clinicians dealing with diabetic skin assessment would benefit by understanding this application.

Skin perfusion pressure (SPP) is measured directly using laser diodes (operating at near infrared wavelengths, which are not affected by skin colour). Sphygmanometer cuffs are used to apply pressure and the laser diodes are placed on the big toe to detect volume changes in blood flow. SPP values greater than 30 mmHg are associated with wound healing.

Measuring transcutaneous oxygen pressure ($TcPO_2$) at 43–45 °C is an indirect assessment of skin viability (Fig. 5.4). $TcPO_2$ is a safe, reliable measurement of tissue blood flow and accurately estimates local skin nutrition. The electrodes are small and can be positioned within 1 cm of a wound edge providing the tissue has been cleaned and dried. The electrodes heat the skin surface (43–45 °C) to obtain maximal vasodilata-

FIGURE 5.4 The measurement of transcutaneous oxygen tension on the dorsum of the foot of a diabetic subject

tion of the skin blood vessels. Care must be taken not to leave the electrode in place for longer than 2 h to avoid skin burns. $TCPO_2$ has been used to predict wound healing on ulcerated diabetic skin, to predict levels of amputation, and in the United States, to select patients for hyperbaric oxygen therapy. The test can be done in most healthcare environments, but oedema and skin thickness affect the measurement. The technique can be difficult to master and there is a learning curve. A $TcPO_2$ of less than 20 mmHg suggest that the wound will not heal, and the probability of amputation increases rapidly as $TcPO_2$ falls below 30 mmHg. An increase of 10 mmHg in $TcPO_2$ reduces the probability of amputation from 30 to 15 %. Reducing oedema, which is an impediment to wound healing, will improve $TcPO_2$, reflecting better skin nutrition.

Skin imaging can be undertaken using intravenous indocyanine green. The molecules of the dye attach to plasma proteins, which will leak into intravascular spaces. The emitted fluorescence may be detected using laser diodes (wavelength in the near infrared range and hence not sensitive to skin colour) [12]. With a short half-life of 3–5 min, repeat scans are more possible. The test can yield a direct estimate of perfusion and is unaffected by tissue metabolism. The test appears to have potential in the management of infected, ischaemic diabetic skin.

Ankle pressures (measuring ABPI), toe pressures (TBI), $TcPO_2$ and SPP are all indirect measurements of skin nutritional blood flow and disappointingly do not closely correlate with each other. Although they have all been shown to be predictive of wound healing to some degree, none has been accepted as a standard and the clinical utility of these tests is yet to be established (Fig. 5.5a–c).

Discussion

Wound treatment must be focused on the underlying cause; neuropathy, ischaemia or neuroischaemia, which is becoming increasingly more evident in Europe [8].

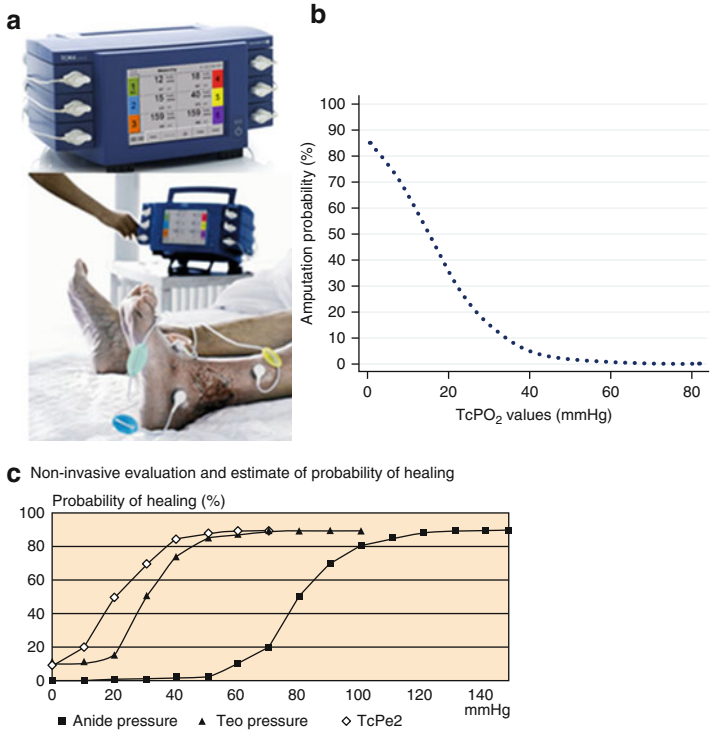

FIGURE 5.5 (**a**, **b**) Transcutaneous oxygen tension ($TcPO_2$). (**c**) The probability of ulcer healing as related to different levels of systolic ankle pressure, toe pressure and $TcPO_2$

In the absence of ischaemia and infection, wounds have a good prognosis, provided off-loading, debridement and good wound-care are undertaken. However, a large proportion of wounds will be neuroischaemic. Wound healing may fail for a number of reasons, but tissue ischaemia is the most powerful predictor of slow or failed wound-healing. While assessments of the macrocirculation are important, they are poor at determining the effects on the microcirculation and nutritional blood flow.

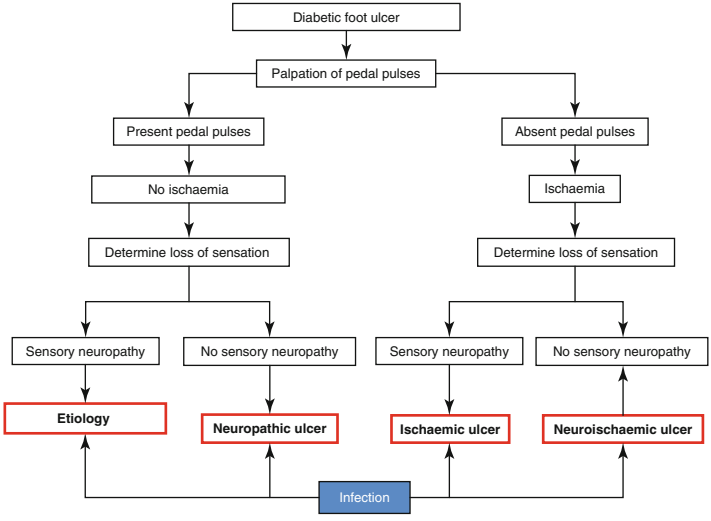

FIGURE 5.6 This flowchart shows the pathways to ulceration in the diabetic foot

From a clinical perspective, a diagnostic approach to the aetiology of diabetic foot ulcers can be achieved following the flowchart shown in Fig. 5.6. In cases where PAD is detected, it should be assumed that ischaemia is involved in the development, progression or worsening of infection, making it essential to evaluate not only the large vessels but also the microcirculation. Although none of the current methodologies are perfect they can help identify patients who need urgent revascularisation.

The increasing prevalence of PAD and diabetes requires that every effort should be made to prevent and maintain skin integrity in the diabetic patient. The diagnosis of neuroischaemia is based on assiduous assessments using both macro- and microvascular measurements. This allows the opportunity to prevent skin breakdown with patient education, good foot-care and early intervention for minor complications.

Key Points

- Prediction of wound healing is difficult.
- Observed wound reduction is predictive but slow and may delay revascularisation in patients who require urgent restoration of blood flow.
- Ischaemia is strongly predictive of poor wound healing.
- Microcirculatory blood flow measurements may aid with identifying the need for revascularisation.
- Novel techniques are needed to assess ischaemia in the tissues, to further optimise diagnosis and investigation and prevent complications of diabetic foot disease.

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Chapter 6
Imaging in the Patient with Foot Complications

Duncan F. Ettles and Lynn Ling

Overview

Imaging and image-guided intervention play key roles in the management of the diabetic patient with foot complications. Plain radiographs, magnetic resonance imaging (MRI), nuclear medicine scintigraphy, computed tomography, ultrasound and digital subtraction angiography with or without endovascular intervention, offer complementary or adjunctive imaging modalities in managing these cases. In this chapter, we consider the imaging of soft tissue and bony infection, neuropathic arthropathy and ischaemia in the diabetic foot. Despite significant advances in imaging techniques, differentiating between osteomyelitis and neuropathic arthropathy can be problematic, but MRI offers important advantages in this respect. Early identification and stratification of peripheral vascular disease contributes to a reduction in overall morbidity and mortality. In the patient with critical limb ischaemia, imaging of the vessels is used to optimise management

D.F. Ettles, MBChB (Hons), MD, FRCP, FRCR
L. Ling, MBChB, FRCR (✉)
Department of Radiology, Hull and East Yorkshire Hospitals NHS Trust, Anlaby Road, Hull, East Yorkshire HU3 2JZ, UK
e-mail: lynn.ling@hey.nhs.uk

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by open or endovascular means and reduce the extent and frequency of amputation.

Plain Radiographs

The investigation of all patients presenting with a new diabetic foot complication should include plain radiographs. This allows rapid assessment of the presence of bony deformity and destruction in neuropathy and overt or established osteomyelitis, as well as identification of soft-tissue gas and radio-opaque foreign bodies. Evidence of vascular calcification is a common feature.

Osteomyelitis is usually the result of contiguous spread of infection from an ulcer or wound. The distribution tends towards the pressure points of the heel or hind-foot, metatarsal heads or forefoot and the interphalangeal joints. The typical radiological features of osteomyelitis include periosteal reaction, cortical erosion, mixed bony lucency and sclerosis (Fig. 6.1). The presence of soft-tissue gas suggests abscess formation, a sinus tract, fascitis or cellulitis (Fig. 6.2). If soft-tissue gas is detected, the joint proximal to it should be carefully evaluated to define the extent of the infection (see Chap. 3). Any bony changes or destruction beneath a soft-tissue ulcer should be considered osteomyelitis until proven otherwise. However, it is well known that plain radiographic abnormalities can lag behind the clinical infection by up to a month and can be limited in their ability to differentiate the bony destruction of osteomyelitis from neuropathic arthropathy. A recent meta-analysis reported a pooled sensitivity of 0.54 and specificity of 0.68 for osteomyelitis [1]. Therefore, osteomyelitis should not be excluded on the basis of plain radiographs alone, except where serial radiographs performed several weeks apart have not demonstrated any bony abnormality. Negative radiographic findings should not delay commencement of empirical antibiotic therapy, pending the results of further imaging or bacteriological investigations. Neuropathic arthropathy occurs as the result of occult recurrent injury due

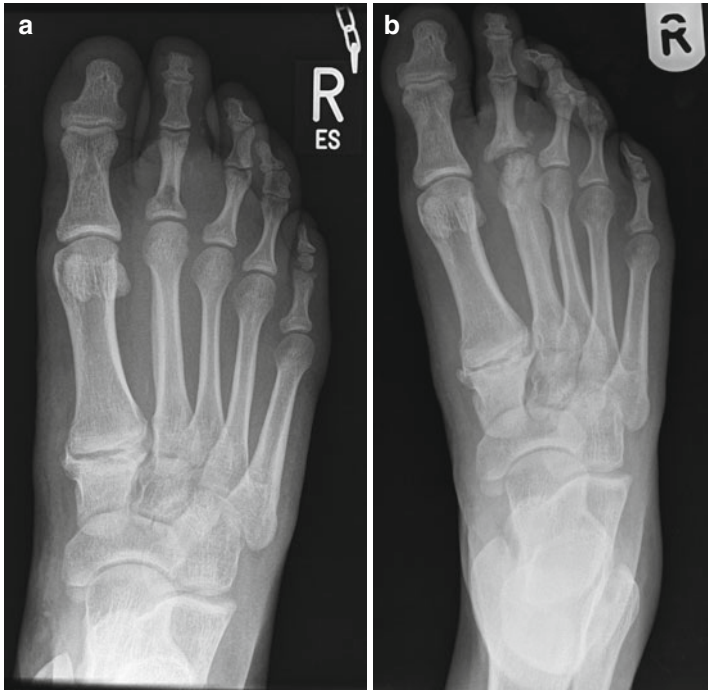

FIGURE 6.1 (**a**) Resorptive change is seen affecting the proximal and middle phalanges of the fifth toe with focal lucency at the base of the proximal phalanx of the second toe. Features are consistent with osteomyelitis. There is also established arthropathy affecting the first tarsometatarsal joint. (**b**) In the same patient after treatment, remodelling and sclerosis of the second metatarsal with cortical erosion of the base of the proximal phalanx is seen consistent with chronic osteomyelitis

to reduced pain and proprioception and impaired healing in diabetic patients. The joint deformity and instability with cartilagenous destruction causes a progressive arthropathy with often typical appearances. The Lisfranc (tarso-metatarsal) joint or midfoot is classically affected with increased load on the cuboid bone and collapse of the foot arch being demonstrated in established cases, clinically presenting with a

FIGURE 6.2 In this patient with cellulitis there is extensive soft-tissue gas along the medial aspect of the foot and ankle. Fracture of the second toe is also demonstrated

'rockerbottom' deformity. On plain radiographs, early changes indicative of the condition are focal demineralisation, fragmentation and flattening of the metatarsal heads. The interphalangeal joints are not commonly involved. Delayed

changes include subchondral cyst formation, erosions and reactive bony hypertrophy.

Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) is the most accurate and next most appropriate imaging tool for assessment of suspected osteomyelitis where plain radiographic findings have been equivocal. In addition to bony abnormalities, MRI provides exquisite detail about the soft tissues and has a reported sensitivity of 90 % and specificity of 82.5 % for the detection of osteomyelitis [2]. MRI provides additional anatomical definition of soft-tissue infection, sinus tracts, abscess formation, joint effusion and necrosis. The characteristic MRI features of osteomyelitis are a diffuse decreased T1-weighted and increased T2-weighted signal intensity of the affected bone, with contrast enhancement (Fig. 6.3). There is often replacement of intramedullary fat around the affected bone and a sinus tract to an ulcer. Secondary findings of an abscess may be identified by its high signal intensity on fat-suppressed imaging with high signal intensity rim-enhancement on post-contrast T1-weighted images.

Features favouring neuropathic arthropathy are the involvement of multiple joints, subchondral cysts and intra-articular loose bodies. In the early or sub-acute stage of neuropathic arthropathy, subchondral bone marrow oedema and bone resorption is the common initial finding. In the late or chronic stage, there is usually established subluxation and dislocation but with minimal bone marrow oedema. In distinction to osteomyelitis, the subcutaneous tissues are usually not involved. However, a mixture of findings can be encountered in patients with pre-existing neuropathic arthropathy who go on to develop infection.

Prior to performing the MRI, it is useful to mark any cutaneous defect so that any sinus tract can be followed and the bone marrow immediately beneath it may be evaluated. MRI is of particular value, not only in determining the need for surgical intervention, but in planning the surgical approach.

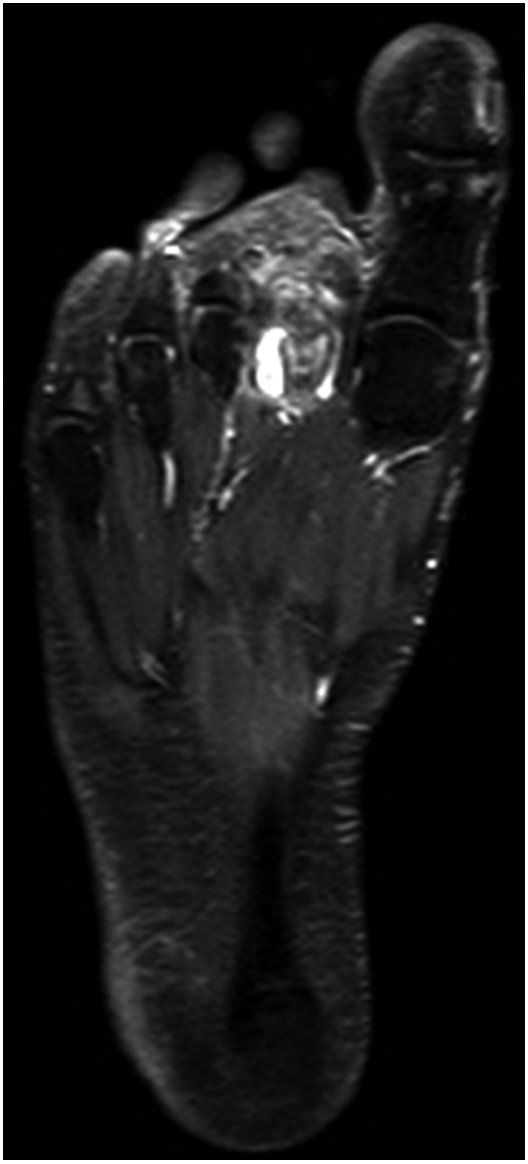

Figure 6.3 MRI (T1-weighted sequence with fat saturation and intravenous contrast) shows bone marrow and soft-tissue oedema centred on the second metatarsal, which enhance with contrast

Magnetic resonance angiography is not routinely performed in patients with diabetic foot complications but is undertaken for the assessment of peripheral vascular disease and in planning revascularisation for critical limb ischaemia. This is described in greater detail below. The potential limitations of MRI relate to its lack of availability in some hospitals and the need for expert interpretation by a specialist in musculoskeletal radiology. Contraindications to MRI include most cochlear implants, older types of cardiac pacemakers, orbital metallic foreign bodies and some surgical implants and prostheses. When MRI is contraindicated alternatives such as nuclear medicine scintigraphy or PET/CT should be considered.

Nuclear Medicine Scintigraphy

The practice of isotope imaging in assessing diabetic foot complications varies considerably and may not be available in some centres. Its principal value lies in the ability to discriminate between infection and other causes of inflammation, but these techniques are limited by a relative lack of resolution and anatomical detail. A number of techniques are utilised, including Technetium (Tc) -labelled bone scans, leukocyte-labelled and anti-granulocyte antibody-labelled scintigraphy and bone marrow scintigraphy. The triple-phase 99mTc-MDP (methylene diphosphonate) bone scan alone is of limited value in assessing diabetic foot complications because although it has high sensitivity in demonstrating areas of high metabolic activity, its specificity is significantly reduced in the presence of any other abnormalities such as fractures, arthropathy, tumour or recent surgery [3]. A four-phase bone scan in which an additional 24-h static image is acquired, is not routinely recommended as it does not increase the specificity of the study for the detection of osteomyelitis.

The triple-phase bone scan is more useful when utilised in conjunction with the Indium-111 or 99mTc-HMPAO (hexamethylpropyleneamineoxime) leukocyte-labelled study to diagnose and differentiate arthropathy from osteomyelitis. If the initial bone scan is negative, osteomyelitis is unlikely. When the

bone scan is positive, the leukocyte-labelled study is performed to confirm or exclude osteomyelitis. However, the leukocyte-labelled study may be positive in the early stages of neuropathic arthropathy, due to reactive joint effusion from peri-articular microfractures. In such cases, if a follow-up scan shows a reduction in leukocyte accumulation, the changes are more likely to be due to arthropathy rather than osteomyelitis. The use of alternative techniques such as bone marrow and anti-granulocyte scintigraphy are likely to be restricted to specialist centres.

Computed Tomography

CT is more sensitive than plain radiography in depicting bony margins and therefore periosteal reaction, cortical erosions and areas of lucencies and sclerosis are more easily identifiable on CT than on plain radiography. CT is also useful for demonstrating dystrophic soft-tissue calcification, soft-tissue gas and foreign bodies. On its own, it has a lower specificity for detecting infection when compared to MRI. However, CT in conjunction with FDG PET (fluoro deoxyglucose positron emission tomography) is useful for differentiating between osteomyelitis, soft-tissue infection and neuropathic arthropathy, with a high sensitivity of 80–95 % and specificity of 90–100 % [4, 5]. The FDG radioisotope tracer accumulates avidly at sites of acute infection whilst the high spatial resolution of CT provides precise localisation of the infection on the fused images, enabling accurate differentiation between non-infective arthropathy, osteomyelitis and soft-tissue infection. It is likely that CT will play an increasing role in imaging of the diabetic foot.

Ultrasound

Two-dimensional ultrasound, like plain radiography, is a readily accessible imaging modality. However its role in managing the diabetic foot is limited. It is most useful for the localisation

of foreign bodies and for guiding aspiration of effusions, abscesses, cysts or sterile collections where clinically indicated. However, duplex ultrasound has a very important role in the assessment of the lower limb vessels in patients with critical limb ischaemia, and this is further described below.

Critical Limb Ischaemia

The severity of peripheral arterial disease (PAD) is often underestimated in the diabetic population because early signs may be masked by concomitant neuropathy. Patients often present with advanced disease or critical limb ischaemia (CLI). Diabetic patients are at much greater risk of developing CLI, leading to amputation. In diabetic patients, the distribution of disease predominantly affects the infra-popliteal circulation, is associated with significant diffuse medial sclerosis and occluded segments of the distal vessels are more common than focal stenoses (Fig. 6.4).

Duplex ultrasound and MR angiography (MRA) are employed for the initial assessment of peripheral vascular disease and for planning revascularisation. Duplex sonography is unique in providing functional assessment of the vessels and is valuable in the follow-up of patients following revascularisation procedures. A three-stage MRA is used to assess the aorto-iliac, femoro-popliteal and infra-popliteal circulation. Imaging of the distal vessels can be problematic in diabetics due to venous "contamination" on the acquired images but various techniques can be used to overcome this problem (Fig. 6.5).

Intra-arterial digital subtraction angiography (DSA) is often considered the gold standard for the evaluation of PVD but is invasive and carries the small risk of contrast-induced nephrotoxicity. This risk needs to be considered in patients with diabetic renal disease but does not preclude the investigation. DSA is increasingly used only when the decision to proceed with endovascular intervention has been determined by non-invasive imaging. All radiology departments have protocols for the administration of contrast media in patients with

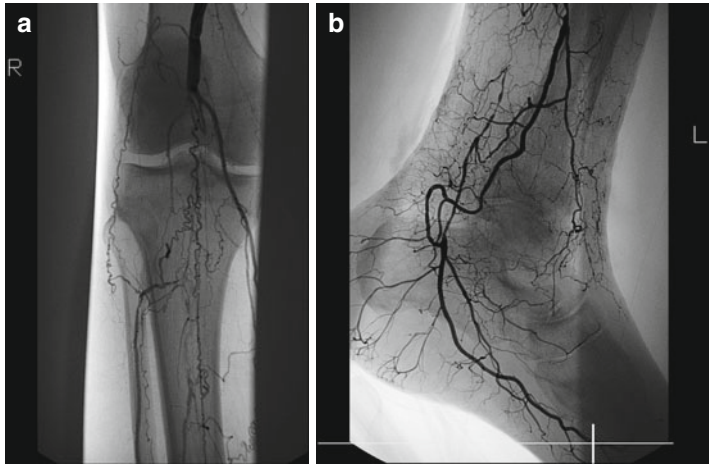

FIGURE 6.4 (**a**) DSA shows occlusion of the popliteal artery and tibio-peroneal trunk with collateralisation to diseased anterior tibial and peroneal arteries. (**b**) The dorsal foot arch is also occluded

impaired renal function, including advice on pre-hydration and use of renal protection drugs. More recent studies have suggested that contrast-enhanced MRA is equivalent or superior to DSA in demonstrating the infra-popliteal vessels [6–8].

Key Points

- Every institution should have a clearly defined referral and multi-disciplinary care pathway in place for managing diabetic foot complications.
- A plain radiograph should be performed at the first presentation of a diabetic foot complication for structural bony assessment.
- Initiation of empirical antibiotic therapy should not be delayed by imaging and microbiology investigations if osteomyelitis is clinically suspected, although subsequent results should guide the choice of therapy.
- MRI is the most useful imaging modality for detecting osteomyelitis and delineating the soft-tissue

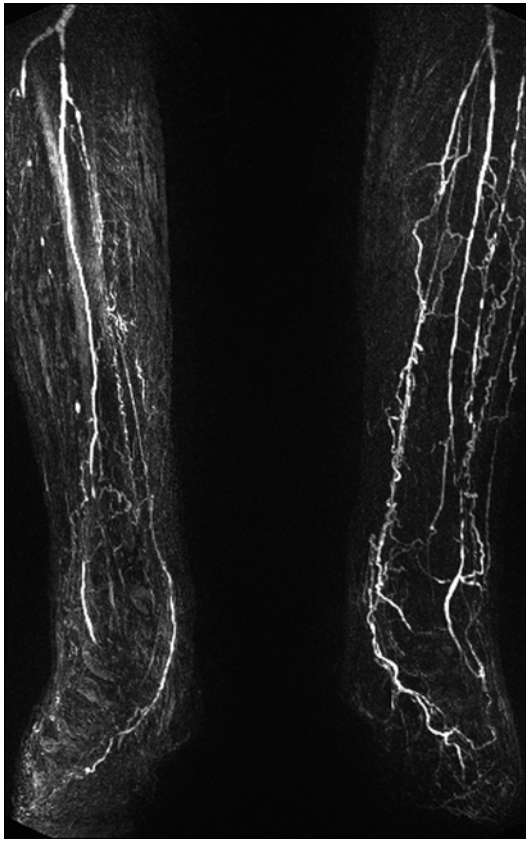

Figure 6.5 Contrast-enhanced MRA showing extensive disease of the crural vessels

extent of infection. If contraindicated, consider performing a PET-CT or a bone scan in conjunction with leukocyte-labelled scintigraphy.

- Evidence of critical limb ischaemia warrants urgent specialist vascular assessment for revascularisation, to prevent minor and major amputation. Duplex ultrasound, MRA and DSA are complementary imaging modalities for planning revascularisation.

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Chapter 7
Treatment of Infection in the Diabetic Foot: The Use of Antibiotics

Anthony R. Berendt

Introduction

Infection in the diabetic foot is a feared complication, and rightly so since it may result in the need for amputation; infection is associated with amputation either as a final insult to the foot on top of other pre-existing problems, or as an overwhelming and destructive acute event necessitating amputation in its own right. The management of diabetic foot infection requires a multi-disciplinary approach. Antibiotics, a focus of this chapter, are usually necessary, but rarely sufficient, to control infection and its consequences. This chapter highlights the fact that consideration of the role of antibiotics must be part of a more general understanding of all other essential steps in the management of infection in the diabetic foot.

A.R. Berendt, BM, BCh, FRCP
Bone Infection Unit, Nuffield Orthopaedic Centre,
Oxford University Hospitals NHS Trust,
Windmill Road, Oxford, Oxfordshire, UK
e-mail: tony.berendt@ouh.nhs.uk

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The Ten Essential Steps in Managing Infection in the Diabetic Foot

1. Decide if infection is present, or unlikely (Diagnosis)
2. Assess the threat that infection poses to the patient, the limb, and the foot (Classification)
3. Decide what help is needed and where treatment is best offered (Referral and Admission)
4. Debride and probe the wound
5. Take cultures as needed
6. X-ray the foot and consider other imaging
7. Consider if osteomyelitis (bone infection) is present
8. Choose a wound care regime
9. Choose an antibiotic
10. Ensure there is well-understood plan for immediate treatment and aftercare

Step-by-Step Management of Infection in the Diabetic Foot

1. **Decide if infection is present or unlikely.** Infection is the clinical manifestation of a biological struggle between a pathogen invading host tissue and the host inflammatory response mobilising to destroy the pathogen. Clinical examination should focus on the presence and extent of the inflammatory response around any ulcer or wound and elsewhere in the foot. Infection in the diabetic foot is defined clinically, as the presence of two or more of the cardinal signs of inflammation (local heat, swelling, erythema, or wound purulence). More subtle changes may also convince experts of the presence of infection, such as a change in character of the exudate, odour associated with drainage, or alterations in the granulation tissue present. Diabetic foot infection is not generally defined by microbiological cultures because all wounds are colonised by bacteria. The diversity of species present, even when known pathogens are among them, make superficial

cultures poor predictors of the real cause of infection in the deeper tissues. Systemic features such as fever, rigors or vomiting are commonly absent even with significant infection, so their absence does not rule out infection. However, when present, they are important markers of severity.

2. **Assess the threat that infection poses to the patient, the limb, and the foot (Classification).** In rare cases, diabetic foot infection can be life-threatening due to bacteraemia or sepsis syndrome. More commonly it can be limb-threatening through gangrene or necrotising fasciitis or it may threaten parts of the foot, resulting in the need for minor amputation if there is significant infection, necrosis or abscess formation,. Making an assessment of severity is important in dictating the next steps in management. The Infectious Diseases Society of America (IDSA) has produced a simple and validated classification system for diabetic foot infection, which considers infections as mild, moderate, or severe.

   (a) **Severe infections** are any in which there is significant systemic compromise including fever; where there is evidence of accompanying critical limb ischaemia; or where there is evidence of necrotising fasciitis or gas gangrene (these are usually accompanied by systemic features). Severe infections are life threatening, and require emergency referral for inpatient hospital treatment.

   (b) **Moderate infections** are those without severe features where there is extensive spread of infection within the skin or deep tissues. A relatively broad category, moderate infections may have cellulitis extending greater than 2 cm from the wound edge, and/or infection or necrosis involving subcutaneous structures including tendon, bone and joint. There may be abscess formation in subcutaneous tissues or the deep spaces of the foot. Moderate infections are potentially limb threatening and require urgent referral for assessment and possible inpatient treatment.

(c) **Mild infections** are not associated with systemic features or deep tissue involvement. They are confined to skin structures, with erythema extending for less than 2 cm from the wound edge. Mild infections can be treated on an outpatient basis provided there are no reasons to admit after following the other steps outlined here.

3. **Decide what help is needed and where treatment is best offered (Referral and Admission).** Severe and moderate infections need urgent referral to a specialist setting, such as a multi-disciplinary diabetic foot team, or an acute medical service with access to specialist input. Many mild infections can be managed in the community, provided the patient will be able to self-care (or be supported at home) and be able to comply with antibiotic treatment and with the wound care measures required, including ulcer off-loading and the reduced mobility that is often associated with this. There is often a need for a multi-disciplinary assessment of an infected diabetic foot that may, depending on severity, require some or all of:

   (a) Diabetes team and acute medical input for improved metabolic control and management of sepsis
   (b) Podiatric input for wound debridement, dressing and offloading measures
   (c) Vascular surgery for revascularisation
   (d) Orthopaedic surgery (foot and ankle specialist) for foot-sparing surgery
   (e) Infection specialists for antibiotic advice
   (f) Radiology

4. **Debride and probe the wound.** Diabetic foot infection is usually in the context of a foot ulcer and as a result, there is commonly a mixture of infected viable and dead tissue, pus, slough, eschar and callosity. To establish a better healing environment and allow antibiotics to function optimally, debulking of the infection, by removing devitalised tissues, is an important early step. This can be undertaken by a podiatrist, tissue viability nurse, or

surgeon, provided they have been appropriately trained in sharp debridement and understand the anatomy of the foot. In densely neuropathic feet, debridement can sometimes be undertaken without anaesthetic, but caution must always be exercised especially when more extensive debridement is planned. When there is doubt about the extent of infected and dead tissue after an initial superficial debridement, a more formal surgical procedure will be necessary. Probing of the wound, using a blunt sterile metal probe, is a valuable technique that:

(a) Allows better evaluation of wound depth and the wound edges
(b) May allow detection of foreign bodies in the wound
(c) May allow detection of the involvement of tendons or joint
(d) May allow the direct palpation of bone (the "probe to bone" test), which has moderate predictive value for osteomyelitis

The probe should be grasped between thumb and index finger with a pinch grip and applied to the wound with sufficient force so that the probe will penetrate slough but will slide back through the thumb and finger if intact soft tissue or bone is encountered. In the latter case, a distinctive "rock-like" sensation is felt. Versions of the test using forceps, wooden sticks, or bacteriological swabs have not been validated.

Following probing and debriding of the wound, the clinician will have formed an opinion of the extent of the wound and the infection, and have moved the wound into a better condition for healing once infection is treated.

5. **Take cultures as needed**. Cultures are not always required. In mild infections where there has been no previous treatment, the primary pathogens are reliably the gram positive cocci, namely Staphyloccus aureus and beta-haemolytic Streptococci. However in moderate infections, or where there have been previous rounds of antibiotic treatment, the identity of the pathogens is less predictable.

In general, the more severe the infection, the greater the range of pathogens isolated from deep tissues, including anaerobes and gram negative organisms. Similarly, the greater the level of prior treatment and prior contact with healthcare systems, the greater the likelihood of colonisation with multi-resistant organisms such as MRSA. When cultures are obtained, they should be taken after debridement, preferably by curettage or as a small tissue sample. For the microbiological diagnosis of osteomyelitis, bone biopsy can be valuable, provided samples can be taken in circumstances where contamination of the sample is unlikely. In chronic stable situations, such as bone biopsy for osteomyelitis, it may be practical to stop antibiotics to obtain cultures. In acute situations, particularly in severe infection, there should not be undue delay in antibiotic treatment merely to obtain cultures; blood cultures and some form of wound culture after a preliminary debridement of the wound are usually possible, but if wound debridement is not readily available, antibiotic treatment should commence without delay.

6. **X-ray the foot and consider other imaging.** X-rays have value for imaging the bones of the foot but will also give some information about soft tissues, vascular calcification, radio-opaque foreign bodies (such as fragments of insulin needles trodden on unawares by a neuropathic patient) and gas in the soft tissues. They thus have a value as part of the acute assessment. These are mainly non-diagnostic for osteomyelitis when Charcot neuro-osteoarthropathy is present, since many of the changes of infection (sclerosis, lucency, and bone destruction) are also seen in diabetic Charcot foot. Progressive changes, especially under an unhealed ulcer, are more suspicious, but require serial X rays and the passage of time. Other imaging modalities have specific roles. Ultrasound may help localise foreign bodies, fluid collections, show inflammation (e.g., around tendon sheaths) and identify if a sinus extends to bone. MRI is the favoured, most robust, means to investigate for osteomyelitis, though its value falls in chronic infection

and after multiple surgeries, where there may be more sclerotic bone (that does not show signal changes of inflammation) and where some signal changes persist for non-infective reasons, such as mechanical stress.

7. **Consider if osteomyelitis (bone infection) is present.** The presence of osteomyelitis will at the least require a longer planned duration of antibiotics and may also require surgery depending on the state of the overlying soft tissue and the extent and location of involvement of the bone. It is not always necessary to remove infected bone in diabetic foot osteomyelitis (up to two-thirds of infections involving the smaller bones of the foot may be managed with prolonged antibiotics alone) but a decision regarding surgery is best made in a multi-disciplinary context. This allows considered decisions to be made that factor in overall prognosis, treatment goals, implications of antibiotic treatment (and the options based on known pathogens), and the likelihood of major changes in foot biomechanics if surgery does proceed. As stated above, the positive diagnosis of osteomyelitis commonly depends on MRI for imaging, and bone biopsy for culture (and ideally histology).

8. **Choose a wound care regime.** It is of little value to undertake all of the above steps with care and then to leave the wound poorly dressed or protected. As most diabetic foot infection arises in the context of a foot ulcer, it is of paramount importance not only to treat the infection but to optimise healing time for the ulcer. This is partly to prevent persistent ulceration leading to a recurrence of infection (with greater risks over time of involvement of bone, joint or other deep structures) but also because persistent ulceration increases the risk of amputation. Wound care regimes should be evidence based (avoid expensive and unproven wound healing technologies) and should not only manage the wound drainage and promote healing, but should include an ulcer offloading strategy. Offloading with contact casting or by other means is likely to be

important. For these reasons, involvement of podiatry and possibly tissue viability and wound care expertise remains important.

9. **Choose an antibiotic.** Antibiotic selection should be based on the severity of the infection. There is a range of antibiotics in common use in diabetic foot infection; some have a specific licence for the treatment of complicated skin and skin structure infection, some have a specific licence for diabetic foot infection, and others are widely used, but on an un-licenced basis (their use extrapolated from related conditions, but never formally evaluated in diabetic foot infection). Evaluation of the evidence for antibiotic use by international guidelines committees suggests, to date, that there is no one superior antibiotic that should always be used [1]. Rather, at each level of severity, there are a number of choices (Table 7.1). The principles underlying antibiotic selection are therefore:

   (a) Choose antibiotics that are narrow in spectrum for mild infection, and that are initially more broad spectrum for moderate and severe infection
   (b) Rationalise antibiotic use as soon as cultures are available (where taken)
   (c) Give oral therapy for mild infection unless there are unusual host circumstances (e.g., allergies, unable to tolerate oral medication)
   (d) Give initial intravenous therapy for severe and moderate infections in in-patients, stepping down to oral therapies as soon as clinical progress, and culture results, permit
   (e) Use antibiotics rationally and consistently, ideally using the IDSA, or International Consensus on the Diabetic Foot, guidance, to create local guidelines that can take into account local factors (resistance patterns, cost, availability, hospital formulary).
   (f) Treat mild infections with a week of treatment; moderate and severe with 2–3 weeks; osteomyelitis with 6 weeks if infected bone remains after debridement, 12 weeks if there is remaining dead and infected bone, and with a soft tissue regimen if the whole of the infected bone has been removed (e.g., toe amputation).

Table 7.1 Antibiotics and their properties commonly used in the treatment of diabetic foot infections

Infection severity	Probable pathogen(s)	Antibiotic agent	Comments
Mild (usually treated with oral agent[s])	*Staphylococcus aureus* (MSSA); *Streptococcus* spp.	Dicloxacillin	Requires QID dosing; narrow-spectrum; inexpensive
		Clindamycin[b]	Usually active against community-associated MRSA, but check macrolide sensitivity and consider ordering a "D-test" before using for MRSA. Inhibits protein synthesis of some bacterial toxins
		Cephalexin[b]	Requires QID dosing; inexpensive
		Levofloxacin[b]	Once-daily dosing; suboptimal against *S. aureus*
		Amoxicillin-clavulanate[b]	Relatively broad-spectrum oral agent that includes anaerobic coverage
	Methicillin-resistant *S. aureus* (MRSA)	Doxycycline	Active against many MRSA & some gram-negatives; uncertain against streptococcus species

(continued)

TABLE 7.1 (continued)

Infection severity	Probable pathogen(s)	Antibiotic agent	Comments
		Trimethoprim/ sulfamethoxazole	Active against many MRSA & some gram-negatives; uncertain activity against streptococci
Moderate (may be treated with oral or initial parenteral agent[s]) or severe (usually treated with parenteral agent[s])	MSSA; *Streptococcus* spp.; Enterobacteriaceae; obligate anaerobes	Levofloxacin[b]	Once-daily dosing; suboptimal against *S. aureus*
		Cefoxitin[b]	Second-generation cephalosporin with anaerobic coverage
		Ceftriaxone	Once-daily dosing, third-generation cephalosporin
		Ampicillin-sulbactam[b]	Adequate if low suspicion of *P. aeruginosa*

	Moxifloxacin[b]	Once-daily oral dosing. Relatively broad-spectrum, including most obligate anaerobic organisms
	Ertapenem[b]	Once-daily dosing. Relatively broad-spectrum including anaerobes, but not active against *P. aeruginosa*
	Tigecycline[b]	Active against MRSA. Spectrum may be excessively broad. High rates of nausea and vomiting and increased mortality warning. Nonequivalent to ertapenem + vancomycin in one randomized clinical trial
	Levofloxacinb or ciprofloxacin[b] with clindamycin[b]	Limited evidence supporting clindamycin for severe S. aureus infections; PO & IV formulations for both drugs
	Imipenem-cilastatin[b]	Very broad-spectrum (but not against MRSA); use only when this is required. Consider when ESBL-producing pathogens suspected
MRSA	Linezolid[b]	Expensive; increased risk of toxicities when used >2 weeks

(continued)

Table 7.1 (continued)

Infection severity	Probable pathogen(s)	Antibiotic agent	Comments
		Daptomycin[b]	Once-daily dosing. Requires serial monitoring of CPK
		Vancomycin[b]	Vancomycin MICs for MRSA are gradually increasing
	Pseudomonas aeruginosa	***Piperacillin-tazobactamb***	TID/QID dosing. Useful for broad-spectrum coverage. *P. aeruginosa* is an uncommon pathogen in diabetic foot infections except in special circumstances
	MRSA, Enterobacteriacae, *Pseudomonas*, and obligate anaerobes	Vancomycin[c] plus one of the following: ceftazidime, cefepime, *piperacillin-tazobactamb*, aztreonam[b], or a carbapenem[b]	Very broad-spectrum coverage; usually only used for empiric therapy of severe infection. Consider addition of obligate anaerobe coverage if ceftazidime, cefepime, or aztreonam selected

Reprinted from Lipsky et al. [2], Table 8, by permission of Oxford University Press and Infectious Diseases Society of America

Agents in boldface type are those that have been most commonly used as comparators in clinical trials. The only agents currently specifically FDA-approved for diabetic foot infections are shown in italics

Narrow-spectrum agents (e.g., vancomycin, linezolid, daptomycin) should be combined with other agents (e.g., a fluoroquinolone) if a polymicrobial infection (especially moderate or severe) is suspected
Use an agent active against MRSA for patients who have a severe infection, evidence of infection or colonization with this organism elsewhere, or epidemiological risk factors for MRSA infection
Select definitive regimens after considering the results of culture and susceptibility tests from wound specimens, as well as the clinical response to the empiric regimen
Similar agents of the same drug class can probably be substituted for suggested agents
Some of these regimens do not have FDA approval for complicated skin and skin structure infections
Abbreviations: *CPK* creatine phosphokinase, *ESBL* extended-spectrum β-lactamase, *FDA* US Food and Drug Administration, *IV* intravenous, *MIC* minimum inhibitory concentration, *MRSA* methicillin-resistant Staphylococcus aureus, *MSSA* methicillin-sensitive Staphylococcus aureus, *PO* oral, *QID* four times a day, *TID* three times a day
[a]Agents approved for treating skin and skin structure infections on the basis of studies that excluded patients with diabetic foot infections (e.g., ceftaroline, telavancin) are not included
[b]Agents shown to be effective in clinical trials including patients with diabetic foot infections
[c]Daptomycin or linezolid may be substituted for vancomycin

(g) It is unclear if prolonged intravenous therapy is necessary even in bone infection; highly bioavailable oral antibiotics can be considered if expert advice indicates they are likely to be effective against the identified pathogens.
(h) When an antibiotic regimen appears to be failing unexpectedly, re-evaluate the foot and the patient, particularly for evidence of further necrosis or deep infection requiring further drainage or debridement, and for evidence of un-addressed ischaemia. Do not merely broaden antibiotic treatment without careful thought and consultation, or without taking further cultures prior to the antibiotic change.

10. **Ensure there is well-understood plan for immediate treatment and aftercare.** When the patient leaves hospital or the clinic, it should be with an infection that is responding to treatment, and most likely with a healing foot wound. The completion of treatment is firstly the full control of the infection, and secondly the successful healing of the ulcer or wound. The following will therefore be required:

(a) A full antibiotic plan, with backup options defined in the event of emerging intolerance or allergy
(b) A wound care plan
(c) Ulcer offloading strategy (total contact cast, aircast, scotchcast, felt)
(d) Appropriate control of diabetes and other comorbidities
(e) Home support
(f) Follow up in the home and at the hospital or clinic
(g) Communication between primary and secondary care teams and with the patient and carers
(h) Patient education in the steps needed to complete treatment of the infection, to heal the ulcer, and to prevent recurrence.

Summary

Managing diabetic foot infection requires a multi-disciplinary team approach, to bring together expertise in wound evaluation and care. It should include the management of critical confounders of infection such as necrosis and ischaemia, antibiotic selection and use, medical (including diabetic) management optimisation, and careful discharge planning, to include social care where indicated and patient education.

Key Points

- Diabetic foot infections should be managed within an appropriately skilled multidisciplinary team
- The diagnosis of infection is largely based on clinical signs and the severity of infection should be clearly determined using a recognised classification system.
- Wound care is essential, including debridement of dead and infected tissue and appropriate wound dressings.
- Choice of antibiotic should be based on the severity of the infection, cultures if available and local guidelines.
- The duration of antibiotic therapy should be planned based on the clinical picture and severity. However, it should be reviewed based on the risks of continuing antibiotic versus the likelihood of healing.
- Antibiotics treat infection; they do not heal wounds.

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Chapter 8
Endovascular Revascularisation: When and How

Andrew J. Wigham and Raman Uberoi

Introduction

Critical limb ischaemia (CLI) is the most severe form of peripheral arterial disease (PAD) and is defined as a state of inadequate perfusion of the leg, manifested by rest pain or tissue loss, which in severe cases may necessitate amputation. Approximately 30 % of patients with CLI will require amputations and 20 % will die within 6 months of diagnosis [1]. In addition, CLI has a major impact on ambulation, the patient's quality of life, and places a large financial burden on the healthcare system.

The incidence of diabetes and its complications is increasing at an alarming rate. Diabetic patients are more likely to develop PAD, and those who progress to CLI have higher rates of amputation than non-diabetic patients. The lifetime risk of foot ulceration in a diabetic patient lies between 15 and 25 %. Diabetic patients with PAD will also have a higher

A.J. Wigham, BSc (Hons), MBBS, MRCS, FRCR
R. Uberoi, BMSCPath, MBBchir, MRCP, FRCR
Department of Radiology, John Radcliffe Hospital,
Headley Way, Oxford OX39DU, UK
e-mail: a.wigham@doctors.org.uk

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risk of cardiovascular events, which need to be managed appropriately.

Diabetic foot disease is multi-factorial and involves a complex interplay between ischaemia, neuropathy and abnormal foot anatomy. Sensory neuropathy leads to progressive loss of protective sensation and autonomic neuropathy can result in dry skin, which is highly susceptible to cracking and fissuring. Response to infection and wound healing can be impaired, particularly in those with poor glycaemic control. Therefore, diabetic patients with foot ulceration must be managed by a specialised multi-disciplinary team. Studies have shown that the costs of implementing specialist diabetic foot teams can be offset by subsequent reductions in foot complications and amputation rates (see Chap. 16).

Diabetic Vascular Disease

Diabetes leads to multiple metabolic abnormalities, which promote atherogenesis, such as dyslipidaemia, hypertension, hyperglycaemia and insulin resistance. These contribute to endothelial cell dysfunction, resulting in vasoconstriction, inflammation and ultimately atherogenesis. In addition, abnormal platelet function is thought to lead to a heightened thrombotic potential.

Diabetic macrovascular disease is associated with florid calcification of the intimal plaque and media. The disease tends to be diffuse with poor collateral circulation particularly between the infra-geniculate vessels. Perfusion defects are consequently more severe in diabetic patients.

Non-diabetic PAD, predominantly affects the aorto-iliac, femoral and popliteal arteries. The pattern in diabetic vasculopathy is different with increased prevalence of disease in the below knee vessels. The below knee vessels, referred to as ‘the run off vessels’, include the anterior tibial, posterior tibial and peroneal arteries. A study by Graziani et al. [2] analysed the angiographic findings in 417 diabetic patients with CLI; they demonstrated that the vascular involvement is

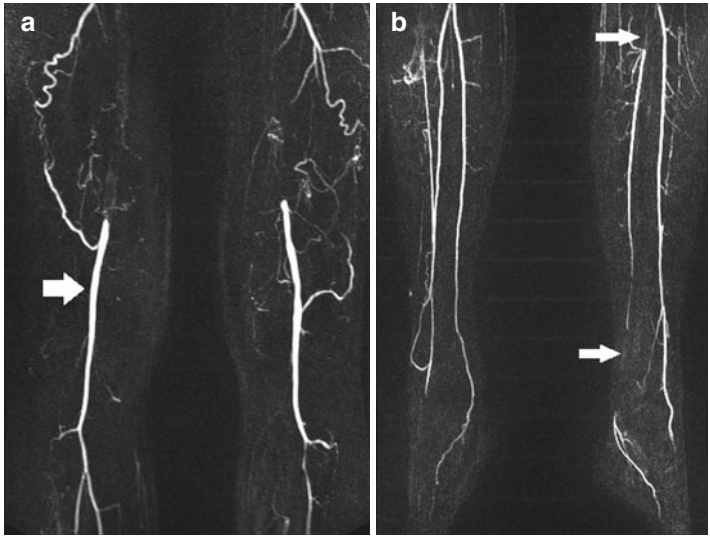

FIGURE 8.1 Reconstructed MRA images demonstrating the typical combination of SFA and infra-geniculate disease found in diabetic PAD. (**a**) Bilateral SFA occlusions with collateral reconstitution of the popliteal artery (*arrow*). (**b**) Bilateral proximal occlusions of the anterior tibial artery and multi-level occlusive disease of the left posterior tibial artery (*arrow*)

extremely diffuse, and particularly severe in the tibial arteries with a high prevalence of long occlusions. The most common pattern of disease found in diabetic patients is a combination of stenotic/occlusive disease of the superficial femoral artery (SFA) and multifocal infra-geniculate occlusions (Fig. 8.1).

Treatment Options

Multiple factors need to be considered before considering revascularisation. These include clinical findings, degree of tissue loss, degree of ischaemia, the age of the patient, life expectancy, co-morbidities and the level and extent of arterial disease.

It must be ensured that all patients are on best medical therapy – this includes optimising glycaemic control and treatment of hypertension and dyslipidaemia. Optimal wound care, treatment of infection and good foot care are also vital, both pre- and post-procedure.

There are two options for revascularisation of the diabetic limb; endovascular treatment or surgical bypass. The Transatlantic Inter Society Consensus (TASC) classification system of PAD, first published in 2000 [1] and revised in 2007 [3], is based on the morphological characteristics of the arterial lesions, and was designed to guide the treatment of symptomatic patients (Table 8.1). In brief, TASC II recommendations for femoro-popliteal disease are endovascular therapy as first-line treatment for type A and B lesions and surgery for "good risk" type C lesions and type D lesions. The TASC recommendations for infra-popliteal arterial disease are endovascular treatment of type A and B lesions, and bypass for type C and D lesions. TASC II did conclude that there is growing evidence to support endovascular therapy for infra-popliteal disease.

Endovascular revascularisation was first performed in 1964 by Charles Dotter. Since then there has been continued development of endovascular techniques and equipment particularly for infra-popliteal disease and the indications for endovascular intervention continue to expand.

There is limited level 1 evidence comparing endovascular treatment with open bypass. The BASIL trial was published in 2005 [4] and demonstrated that at 1 year that there was no difference in amputation or overall survival between patients with severe limb ischaemia treated initially with bypass surgery or endovascular therapy. At 2 years there was a survival advantage in the bypass group and a trend towards improved amputation-free survival. BASIL comprised a heterogeneous group of patients with both above- and below-knee disease, and no sub-group analysis of diabetic patients was performed. BASIL showed vein grafts had better long-term patency than prosthetic grafts. This data has been used to suggest angioplasty for short-term revascularisation, and bypass surgery if the patient has reasonable life expectancy and suitable anatomy.

Table 8.1 TASC classifications for infrapopliteal and femoropopliteal arterial disease

TASC infrapopliteal classifications	
Type A	Single stenosis shorter than 1 cm in the tibial or peroneal vessels
Type B	Multiple focal stenosis of the tibial or peroneal vessel, each less than 1 cm in length.
	One or two focal stenosis, each less than 1 cm long at the tibial trifurcation
	Short tibial or peroneal stenosis in conjunction with femoropopliteal PTA
Type C	Stenoses 1–4 cm in length
	Occlusions 1–2 cm in length of the tibial or peroneal vessels
Type D	Tibial or peroneal occlusions longer than 2 cm
	Diffusely diseased tibial or peroneal vessels.
TASC femoropopliteal classification	
Type A	Single stenosis <10 cm in length or single occlusion <5 cm in length
Type B	Multiple lesions each <5 cm
	Single stenosis or occlusion <15 cm not involving the infrageniculate popliteal artery
	Heavily calcified occlusion <5 cm in length
Type C	Multiple stenosis or occlusion totaling >15 cm with or without heavy calcification.
	Recurrent stenoses or occlusions that need treatment after two endovascular interventions
Type D	Chronic total occlusion of the common or superficial femoral artery (>20 cm, involving the popliteal artery)
	Chronic total occlusion of the popliteal artery and proximal trifurcation vessels.

A recent study that performed propensity score analysis of 1,023 patients with CLI, of whom 262 underwent percutaneous transluminal angioplasty (PTA) and 761 surgical bypass, reported similar 5 year results for leg salvage (75.3 % vs. 76 %), survival (47.5 % vs. 47.3 %) and amputation-free survival (37.7 % vs. 37.3 %) [5].

Endovascular treatment is less invasive and has lower post-procedural morbidity. A study that used the National Surgical Quality Improvement Program database showed the composite mortality and morbidity rate of infra-inguinal bypass was as high as 19.5 % [6].

The improved durability of newer endovascular therapies, improvements in technical methodology, comparable outcomes from endovascular therapies and low procedural morbidity has led to many groups proposing an endovascular first approach for TASC C and D lesions.

There has been controversy regarding whether a failed endovascular procedure may jeopardise open surgery options. As long as an undamaged, unstented landing zone is preserved, a failed PTA does not seem to preclude future bypass [3]. Surgical options may be affected by stents at potential bypass anastomotic sites, and close collaboration between endovascular practitioners and vascular surgeons is required. Robust surveillance strategies must be in place following PTA to ensure additional treatment can be performed if required.

Endovascular Treatment

Pre-procedure

There are a number of important pre-procedural considerations. The patient needs to be able to lie flat and still for the procedure (possibly for a number of hours) and if they are unable to do this then anaesthetic support for sedation and possibly general anaesthetic may be required. Pre-procedural imaging and previous endovascular interventions must be

carefully reviewed. Recent blood tests should be available, particularly renal function. Aspirin should be continued pre-procedure and has been shown to reduce the incidence of peri-procedural thromboembolic events. If the patient is on warfarin this should be stopped, aiming for an INR <1.5 before intervention is performed.

Treatment Site

The principle of any vascular intervention is to first ensure that inflow is restored (i.e., the most proximal level of disease is treated), before considering more distal intervention. Whilst much emphasis is placed on the below-the-knee (BTK) disease in patients with diabetes it is important to remember this principle and ensure that proximal iliac or femoral disease is adequately treated. It is also important to relate the severity of the clinical presentation to the planned endovascular treatment. For example, patients with intermittent claudication and combined SFA and BTK disease may derive sufficient benefit from treatment of the SFA disease alone, whereas patients with tissue loss usually require multi-level intervention.

A relatively recent concept is that of angiosome treatment, which has particular relevance to treating diabetic ulceration. The foot is divided into distinct vascular territories or angiosomes, one each from the anterior tibial (AT) and peroneal arteries (PA) and three from the posterior tibial (PT) artery. The AT supplies the dorsal side of the foot and toes, the PA supplies the lateral ankle and lateral heel, and the PT perfuses the plantar surface of the foot and the medial heel. There are small collateral vessels in the foot known as choke vessels, which are often compromised in diabetic patients. Studies have suggested that restoration of direct perfusion of the affected part of the foot, based on the angiosome concept, results in improved ulcer healing. Angiosome-targeted perfusion may not be possible due to severe disease of the target vessel. Some operators propose that, if possible, multiple vessels should be re-canalised. This technique improves total

foot perfusion, and provides some insurance against subsequent blockage. We would initially try to treat the target angiosome vessel supplying the area of the foot with the ulcer or wound, but if this was not possible then we would attempt to restore flow in other vessels.

Arterial Access

We use ultrasound guidance for all arterial punctures, as this reduces access site complications. The access route depends on the planned site of intervention. Antegrade access indicates the sheath is pointing in the direction of arterial flow, and retrograde access against the arterial flow. Antegrade common femoral artery access is usually employed for infra-inguinal disease, because the straight-line approach allows more "pushability" when trying to cross lesions and is preferable when performing a very distal intervention. Antegrade access may not be possible in obese patients or those with heavily scarred groins.

Retrograde common femoral artery access and an 'up and over' approach enable simultaneous assessment and treatment of iliac disease, and is appropriate for treating common femoral artery (CFA) or proximal SFA disease. A contralateral approach requires longer guide-wires, catheters and balloons, and monorail systems may prove useful. A contralateral approach may not be successful in patients with very tortuous or angulated iliac arteries.

Retrograde popliteal or below knee vessel access is becoming increasingly common for the treatment of more complex cases. Dedicated micro-puncture systems and pedal access sheaths are available for such cases.

Crossing Lesions

The first stage of endovascular recanalisation is crossing the lesion. This can be achieved either intra-luminally or in the sub-intimal plane. There has been much debate over which

type is preferential, but in practice, the type of lesion usually dictates the crossing technique. Stenoses are usually crossed intra-luminally and longer occlusions typically require a sub-intimal approach

To create a sub-intimal channel, a guide catheter is pointed towards the arterial wall at the proximal aspect of the occlusion and a hydrophilic guide-wire is passed into the space between the intima and media. The looped guide-wire is used to dissect a sub-intimal tract and then passed back into the true lumen at the distal end of the occlusion. Angioplasty then displaces the atheromatous and calcified intimal and medial layers to the contralateral side of the lumen, thus creating a neo-lumen. Care should be taken not to extend the created sub-intimal tract too distally, so as to preserve collaterals as well as possible distal targets for bypass. Re-entry into the true lumen may not be possible, particularly in extensively calcified vessels (reported up to 10–15 % of cases). Specialised re-entry devices are available such as the Outback® (Cordis) and Offroad® (Boston Scientific, Natick, MA, USA) devices. The Outback device is a 6F compatible catheter with a sharp, hollow 22G needle that can be directed towards and used to puncture back into the true lumen.

Occlusive disease in the tibial vessels often requires a combination of sub-intimal and intra-luminal approaches. Sub-intimal approach is best for cases with predominantly atheromatous disease, limited calcium and a good distal target vessel. Intra-luminal crossing is better in diffuse disease, cylindrical calcification and in small target vessels (sub-intimal angioplasty can exacerbate vascular insufficiency by damaging small collaterals). The intra-luminal approach may require the use of chronic total occlusion wires (CTO), which have weighted tips, providing the necessary force to break through occlusions.

Retrograde recanalisation is an effective and increasingly utilised technique when an antegrade approach has proved unsuccessful. As previously described, access is obtained either in the tibial vessels or popliteal artery and the occlusion is crossed from below.

The advent of lower profile balloons and narrow calibre wires and catheters has allowed effective treatment of complex distal tibial and pedal disease. There are numerous complex techniques that have been described for the treatment of below the knee disease including trans-collateral retrograde re-canalisation and pedal loop retrograde recanalisation. The pedal loop technique is of particular value when a proximal occlusion stump is unavailable or when distal disease makes retrograde puncture impossible. The dorsalis pedis and the lateral plantar arteries (distal PT branches) communicate through the deep perforating artery. A low-profile guide-wire can be navigated through these collaterals, resulting in a loop connecting the anterior and posterior tibial arteries. From this position, retrograde tibial recanalisation and angioplasty can be performed.

Angioplasty or Stent?

The two principal endovascular therapeutic options are balloon angioplasty or stent. Angioplasty alone may be sufficient; however, extensive disease, long occlusions and calcification are predictors of a sub-optimal result. A poor angioplasty result with slow flow, extensive intimal dissection, or elastic recoil is unlikely to remain patent. Further prolonged inflation angioplasty may be successful but if not, then stenting should be considered (Fig. 8.2).

Old-generation balloon expandable metal stents are rarely used in the femoro-popliteal segment and have been replaced by self-expanding Nitinol (nickel-titanium alloy) stents. These have elastic and thermal memory properties and better conformability due to their superior resistance to torsion, flexion, extension and compression. Self-expanding stents are usually oversized 1 mm to vessel diameter.

The use of stents has been shown to improve the immediate and haemodynamic and clinical results of iliac angioplasty. However, for short non-occlusive iliac disease, stand-alone angioplasty is still reasonable, with primary stent placement reserved for more complex or occlusive disease.

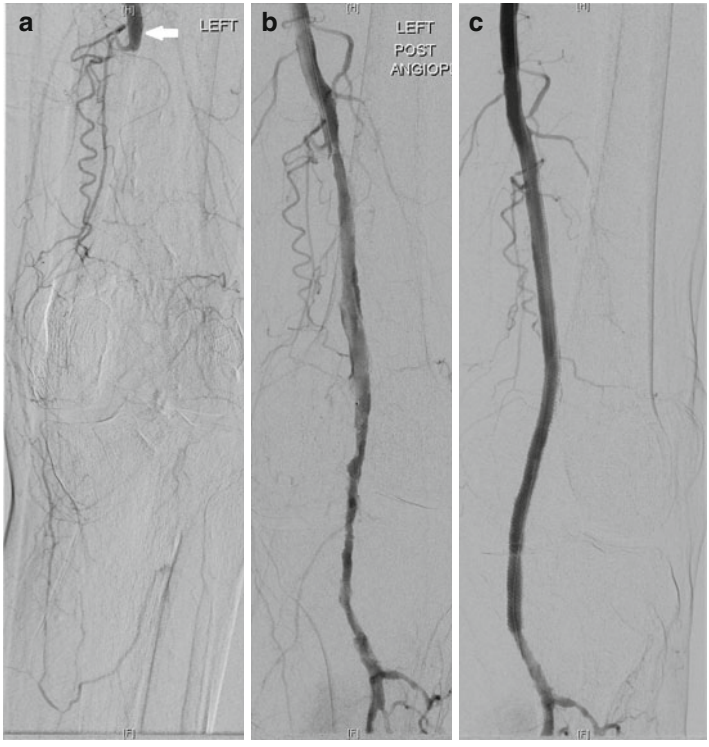

FIGURE 8.2 Diabetic patient with CLI. (**a**) DSA image demonstrating long SFA/popliteal occlusion (*arrow*) and multifocal infrageniculate disease. (**b**) The occlusion was crossed subintimally and angioplastied. Post-angioplasty image demonstrates a suboptimal result with residual stenoses and flow-limiting dissection. (**c**) Completion image following SFA stent placement

The STAG trial comparing primary stenting for iliac occlusive disease demonstrated a reduction in major procedural complications, predominantly distal embolisation, in the stent group. Some data suggest that covered stents have better outcomes than bare metal stents (BMS). The COBEST trial comparing covered stents with bare metal stents for iliac disease demonstrated a benefit in terms of freedom from

restenosis in the covered stent group; at 18 months 95.4 % in the covered stent group were free of binary restenosis compared with 82.2 % in the BMS group.

Numerous trials have been performed comparing stent and angioplasty in the femoro-popliteal segment. In summary, these suggest that PTA is the best option for short focal lesions but in longer lesions, self-expanding stents have better long-term patency. The RESILIENT trial, which compared angioplasty to bare metal stent in SFA disease, demonstrated a significantly better 12-month primary patency and freedom from re-intervention rate in the stent group, 87.3 % versus 45.2 %. This freedom from re-intervention benefit in the stent group was maintained to 3 years [7]. Predictors of the need for stenting include TASC D lesions and vessel wall calcification. Primary stenting may be indicated in recurrent stenosis.

Stents can also be performed in the BTK vessels. There is no level 1 data to support primary bare metal stenting over angioplasty and stenting is reserved for suboptimal results following angioplasty, such as residual stenosis or flow-limiting dissection. If there are proximal stenoses affecting the anterior tibial artery and tibio-peroneal trunk, kissing balloons can be employed.

It should be noted that the majority of studies comparing endovascular treatments concentrate on technical end-points and clinical outcome data is much more limited. A Cochrane review performed in 2009 identified eight randomised trials comparing SFA angioplasty with stenting and only one of these assessed effect on quality of life.

Drug-Eluting Technologies

The leading cause of endovascular failure is recurrent stenosis due to neointimal hyperplasia. This is analogous to scar formation at the angioplasty site or in the stent and is due to inflammatory mediator release from damaged endothelial cells, leading to smooth muscle cell proliferation (Fig. 8.3).

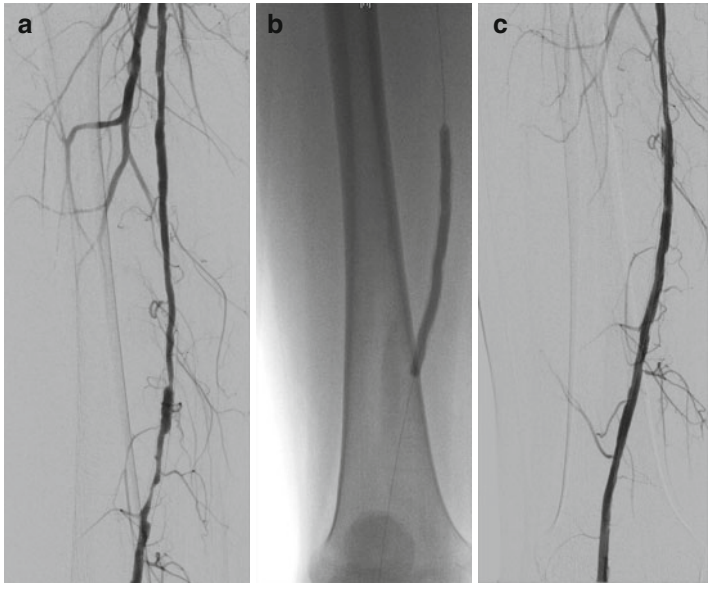

FIGURE 8.3 Diabetic patient who had previously undergone SFA angioplasty and stent presented with recurrent short-distance claudication. (**a**) DSA image demonstrating SFA in-stent re-stenosis due to neointimal hyperplasia. (**b**) Angioplasty of the stenotic segment with drug-eluting balloon. (**c**) Completion angiography demonstrating resolution of stenosis

Drug-eluting balloons (DEB) and drug-eluting stents (DES) have been shown to significantly reduce neointimal hyperplasia and restenosis rates. The two most commonly used agents, which are bonded to the balloon or stent, are Paclitaxel and Sirolimus. Paclitaxel is a plant alkaloid and inhibits mitogen-activated protein kinase, thus halting the cell cycle in the M phase. Sirolimus is a macrolide antibiotic and immunosuppressive agent and is a potent inhibitor of smooth muscle migration and proliferation.

The Zilver PTX® trial compared Paclitaxel drug-eluting stent with bare metal stent and angioplasty. Results demonstrated superior primary patency and reduced restenosis rate in the Paclitaxel-coated stent group compared with the bare

metal stent group. These results were maintained at 4-year follow-up (primary patency 75 % vs. 57.9 %) [8]. A number of trials, including LEVANT I, THUNDER and FemPac, have shown improved durability for DEB angioplasty compared to plain angioplasty with a comparable safety profile. The LEVANT 1 trial showed that at 6 months, late lumen loss was 58 % lower for the DEB group. The FemPac trial demonstrated improved freedom from target vessel revascularisation (19 % vs. 47 %) and freedom from angiographic restenosis (9 % vs. 33 %) in the DEB arm at 6 months.

Drug-eluting technologies are also used in the treatment of BTK vessels, and the evidence regarding their efficacy continues to grow. A trial by Schmidt et al. demonstrated reduced early restenosis rates using drug-coated balloons [9]. The DEBATE-BTK study, looking specifically at treatment of BTK disease in diabetic patients, demonstrated reduced restenosis rates and target vessel occlusion rates in the drug-eluting balloon group. Drug-eluting stents can also be employed in infra-geniculate disease. A recent meta-analysis demonstrated increased patency and freedom from target vessel revascularisation in drug-eluting stents compared to bare metal stents [10].

Drug-eluting technologies are significantly more expensive, but a number of studies have shown that the initial higher index costs are offset in time, due to reduced rates of re-intervention. As drug-eluting technologies improve and costs decrease, it seems likely that they will play an increasing role, particularly in diabetic patients, who are known to have a higher incidence of restenosis. However, the clinical benefit to patients in terms of wound healing and prevention of amputation has yet to be established.

A number of other, less commonly used technologies are available for the treatment of peripheral vascular disease. These include atherectomy devices, laser and cryoablation. Atherectomy devices rather than pushing plaque into the vessel wall, aim to remove plaque burden from the vessel. A variety of atherectomy devices are available that employ different atherectomy technologies, each with different advantages dependent on the composition of the plaque.

Theoretically, atherectomy can achieve stent like results without the need to leave a stent or foreign object behind. It is hypothesised that combining atherectomy with drug-eluting balloons will allow greater penetration of the anti-proliferative agent and further reduce restenosis rates. Cryoplasty proposes to induce controlled apoptosis of the vessel wall thus reducing smooth muscle proliferation and reducing apoptosis. Laser-assisted angioplasty was first described in the 1980s, but despite initial enthusiasm is not widely used.

Complications

Complications following endovascular intervention include access-site haemorrhage, major medical complications and distal thromboembolism or vessel occlusion. Accurate assessment of true complication rates is hampered by varying definitions of what constitutes a major or minor complication. Moreover, the on-going improvement in angioplasty techniques means conclusions about current outcomes cannot always be obtained from older literature.

The rate of major medical complication (stroke, myocardial infarction and renal failure) is low and has been reported between 1.8 % [11] and 2.4 % [12]. Access vessel complications include pseudoaneurysm, arteriovenous fistula formation and access-vessel dissection or occlusion. A study by Dick et al. reported an access-site complication rate of 4.9 % [11].

Access-site pseudoaneurysms can often be treated with either ultrasound-guided compression or thrombin injection. On-going access-site haemorrhage usually requires surgical repair. A 2002 study by Axisa et al. showed that emergency surgical intervention was required in 2.3 % of cases, with the commonest aetiologies being haemorrhagic complications and acute limb ischaemia [12]. Retroperitoneal bleeding may be amenable to endovascular treatment with stent placement.

Distal vessel occlusion can occur as a result of flow limiting dissection or a thromboembolic event. Flow-limiting dissection can usually be treated with prolonged balloon inflation or

stent placement. Occlusion due to thromboembolism can be treated with either aspiration thrombectomy or thrombolysis. Some cases may require surgical embolectomy.

Post-procedure Care

Immediate post-operative care comprises access site care to ensure haemostasis; this can be achieved with manual compression (usually 10 min in duration) followed by a period of bed rest and observation. Various closure devices are available which reduce time to achieve haemostasis and allow earlier ambulation. Closure devices are usually reserved for larger sheath sizes, with manual compression used for 4F systems. Closure devices are particularly useful in non-compliant patients who will be unable to lie still and flat.

Stents should undergo regular duplex surveillance to identify in-stent restenosis and enable re-intervention before occlusion occurs.

Drug Therapy

Patients require good glycaemic control during the procedure and this may necessitate a sliding scale insulin infusion. Metformin is an oral hypoglycemic agent and is predominantly eliminated by renal excretion. Contrast-induced nephropathy can theoretically result in metformin accumulation and may precipitate lactic acidosis, a rare but recognized side effect. The Royal College of Radiology (UK) guidelines for contrast administration state that in patients with serum creatinine in the normal range and eGFR >60 mL/min there is no need to stop Metformin post-procedure. If there is evidence of renal impairment, then the decision to stop metformin for 48 h should be made in conjunction with the referring clinician. The American College of Radiology guidelines are similar. In patients with normal renal function and no known comorbidities, there is no need to discontinue metformin nor is there a need to check creatinine following the procedure. In patients with multiple comorbidities who have normal

renal function, metformin should be discontinued at the time of the examination, withheld for 48 h and then renal function reassessed before re-starting metformin. In patients taking metformin who are known to have renal dysfunction, metformin should be suspended at the time of contrast injection and renal function closely monitored until safe administration of metformin can be assured.

During the procedure, intra-arterial heparin (3–5,000 units) is administered to prevent thrombus formation. There is good evidence that patients undergoing angioplasty benefit from aspirin therapy, with clopidogrel being a useful alternative in patients who cannot tolerate aspirin. There is indirect evidence from coronary revascularisation data to support the use of dual therapy with antiplatelet agents to reduce occlusion rates following angioplasty or stent placement. However, this will increase bleeding complications. In our practice we commonly use dual antiplatelet therapy for a period of 3–6 months, followed by lifelong single-agent treatment after SFA stent placement.

Combination warfarin and anti-platelet therapy is not indicated. The WAVE study, comparing warfarin plus anti-platelet therapy with anti-platelet therapy alone, demonstrated no benefit in terms of preventing major atherothrombotic events but was associated with an increase in life-threatening bleeding (4 % vs. 1.2 %) and haemorrhagic stroke (1.3 % vs. 0 %). There is no evidence at present supporting the use of the newer anti-coagulant medications such as Rivaroxaban and Dabigatran.

Key Points

- Patients with diabetic foot disease must be managed by a multidisciplinary team. Medical therapy involves glycaemic control and treatment of hypertension and dyslipidaemia.
- Diabetic foot ulceration is multifactorial due to a combination of vascular disease, neuropathy and predisposition to infection.

- Patients with diabetes have a higher risk of peripheral arterial disease and critical limb ischaemia. The arterial disease tends to be more aggressive, with extensive involvement of the below-knee vessels.
- All diabetic patients with foot ulceration should be suspected of having underlying arterial disease until proven otherwise. Appropriate assessment and investigation allows early detection and treatment.
- Endovascular treatments have proven efficacy with lower procedural morbidity than open repair. The evolution of endovascular technologies and techniques means complex patterns of arterial disease are now treated successfully. Drug-eluting technologies may further enhance durability of endovascular treatments.
- Medical treatment in patients with critical limb ischaemia, including wound care and surveillance is vitally important for functional limb preservation.

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Chapter 9
Surgical Revascularisation of the Diabetic Foot

Paul W. Moxey and Patrick F.S. Chong

Background

Peripheral arterial disease (PAD) affects 50 % of patients presenting with a diabetic foot ulcer. If PAD is left untreated, non-healing wounds will occur and in many cases will deteriorate, threatening both the patient's limb and their life. PAD gives rise to stenoses or occlusions of the lower limb arteries by the accumulation of atherosclerotic plaques within the vessel lumen, preventing optimal perfusion of the affected limb. Procedures to either bypass or re-open the diseased arterial segment are termed revascularisation and can take the form of either endovascular radiological guided intervention (angioplasty or stenting) or open surgical bypass. To date, only one randomised trial compares the outcomes of open versus endovascular treatment for critical limb ischaemia. The BASIL study concluded that if a patient had more than a 2-year life expectancy and extensive tissue loss they

P.W. Moxey, MRCS, MD (✉)
P.F.S. Chong, MBBS, FRCS
The Surrey Vascular Group Network,
Frimley Park Hospital NHS Foundation Trust,
Portsmouth Road,
Frimley, Surrey GU16 7UJ, UK
e-mail: paul.moxey@nhs.net

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should be offered surgical revascularisation in the first instance [1]. However, BASIL was not performed exclusively in patients with diabetes and the last patient was randomised 10 years ago in 2004. In that time, exciting endovascular techniques have evolved with drug-eluting balloons and drug-eluting stents promising to overcome the problem of early re-stenosis in the tibial vessels, following intervention in diabetic patients, although there is still no clear consensus [2].

Introduction

Goals of Revascularisation

The main goal of revascularisation in the diabetic foot patient is to help the patient achieve successful limb salvage with restored limb function and quality of life.

Revascularisation in the diabetic foot with ischaemia and tissue loss should be carried out as soon as possible, as delays may lead to further tissue loss and major amputation.

Indications for Revascularisation

The main indication for revascularisation in the diabetic foot patient is critical limb ischaemia causing rest pain and tissue loss with either non-healing wounds or gangrene. It is important to appreciate that the presence of peripheral neuropathy may cause some patients to present late to the multidisciplinary diabetic team, because of a lack of pain perception despite advanced tissue loss in the foot. In some patients with severe foot sepsis and extensive tissue loss, it may be expedient to debride and drain the foot even before any attempt at investigation or treatment for any underlying arterial disease. Delays may lead to irreversible foot tissue loss and consequent major amputation. Analysis of UK Hospital Episode Statistics data revealed that more than half of patients who underwent major lower limb amputation between 2003 and 2008 had no attempt at revascularisation prior to losing their limb [3].

Diagnosis of Pad

The diagnosis of peripheral arterial disease (PAD) can be confirmed clinically by bedside examination of the patient's lower limb arterial pulses. The use of non-invasive modalities in the vascular lab such as ankle and toe pressures and transcutaneous oxygen tension on the foot will help identify those who need re-vascularisation. Imaging with duplex ultrasound or MR or CT angiography will help plan the procedure and digital subtraction angiography may be required in some cases to identify the distal vessels.

Principles of Revascularisation

In our practice, the patient's clinical findings and results of their arterial investigations and vascular imaging are discussed in a multidisciplinary meeting, prior to making the final decision regarding the optimal approach to revascularisation of the limb. The patient's fitness and co-morbidities are reviewed as a whole so as to assess the surgical risks involved and their suitability for either endoluminal intervention or open surgical bypass. This section will discuss the pre-treatment patient work-up and optimisation, operative planning and consent, the techniques of surgical bypass or endovascular therapy and finally post-operative follow-up and surveillance.

Pre-treatment Work-Up

The majority of diabetic patients with PAD will also have ischaemic heart disease, renal impairment and respiratory disease and these must be taken into consideration before proceeding with treatment. A patient presenting with foot sepsis is also likely to have grossly elevated blood sugar levels and will require optimisation of glycaemic control. Acute severe sepsis in the diabetic foot is a surgical emergency requiring early diagnosis and urgent debridement of devitalised

tissue and drainage of pus. This is paramount to foot preservation and successful limb salvage with subsequent revascularisation. The patient should be started on broad-spectrum intravenous antibiotics and deep tissue cultures including bony biopsies sent to microbiology to allow specific targeting of antimicrobial therapy. An anaesthetic review is required for optimisation of the patient's co-morbidities in order to stratify their risk from intervention for revascularisation, so that a fully informed consent process can take place prior to treatment. It should be considered that symptomatic palliation, with or without primary amputation is a valid and acceptable treatment option. This may be in the patient's best interests if the risks of intervention are unacceptably high in frail, unfit patients or if there is extensive, irreversible tissue loss extending into the proximal foot and calf.

Poor pre-operative glycaemic control is associated with higher mortality and morbidity in diabetic patients. All patients undergoing revascularisation should have their HbA1c levels checked as an indication of long-term glycaemic control, over the preceding 2–3 months. Multidisciplinary team input is needed to gauge the severity of PAD and foot disease, urgency of intervention and whether it is worthwhile delaying surgery to improve glycaemic control. In the acute setting, rapid stabilisation of the patient's blood sugar levels using infusions of insulin may be required but must be monitored and adjusted appropriately with the patient transferring to a more formal insulin regime as early as possible. Any renal impairment should be identified and optimised prior to intervention. Patients who are undergoing renal replacement therapy are a high-risk group and are three times more likely to die following surgical bypass compared to those without renal impairment. Early input from the renal medicine team is therefore advised. Patients with renal replacement therapy requirements should only undergo surgical revascularisation if there are on-site renal replacement facilities available such as haemodialysis. Likewise, patients with symptomatic cardiac disease will require urgent cardiology review and an ECG and

cardiac echocardiogram prior to definitive treatment. It is possible to perform revascularisation with a regional anaesthetic if patients have severe respiratory disease.

The vascular anaesthetist must review the patient before treatment can proceed. Ideally this assessment should occur before the day of planned intervention to allow anaesthetic recommendations to be implemented in the pre-operative period. In particular new beta-blockade should not be started immediately before surgery but if required, should be commenced at least 6 weeks prior to surgery. Many diabetic patients with extensive tissue loss cannot wait 6 weeks and this reinforces the need to involve anaesthetic colleagues early in the process for guidance and advice.

Surgical Bypass

Open surgical bypass to the distal tibial vessels or the pedal vessels remains the gold standard for revascularisation in diabetic limb salvage. The principle aim of open surgical revascularisation is the restoration of "straight-line" blood flow to the foot via a native anatomical tibial artery crossing the ankle joint, not via collaterals. If "straight-line" blood flow can be achieved, the patient stands the best chance of wound healing with an 85 % limb salvage rate at 1 year [4]. Longer-term follow-up data for surgical bypass show that durability for target vessel patency and limb salvage rates are superior to endovascular techniques. However surgical bypass procedures are often time-consuming with longer in-patient stays and in-hospital morbidity and mortality is higher than endovascular intervention [5].

Therefore unfit patients who are not suitable candidates for surgical bypass should be considered for an endovascular approach. Most open surgical bypass procedures are done under a regional anaesthetic, which also allows for foot debridement following revascularisation, at the same sitting. Patients may stay in hospital for 5–10 days post-operatively

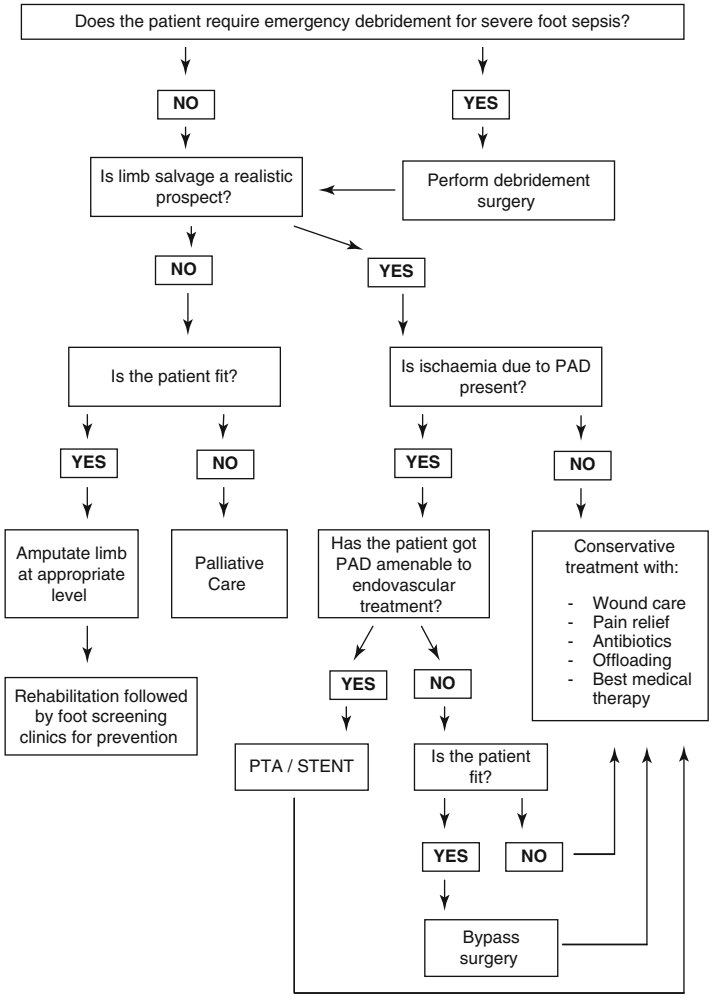

FIGURE 9.1 Pathway for revascularisation of the diabetic foot

and require extensive physiotherapy and occupational therapy input in order to regain lower limb function.

Figure 9.1 is a flow chart outlining the decision-making steps that should be considered when managing a diabetic patient with a foot ulcer.

Choice of Bypass Conduit

There are three choices when considering a conduit for bypass surgery. By far the superior choice is the patient's own vein. Second are synthetic man-made grafts composed of either ring-supported "Dacron" or ePTFE. Both will usually be reinforced on the outside with spiral plastic supports to prevent kinking. A recent development are ePTFE grafts "rifled" on the inside to produce spiral flow of blood within the conduit, to reduce neointimal hyperplasia at the anastomosis and increase longevity. Although early results for these grafts are encouraging, no long-term data exists at present. The final option is cadaveric vein, which has been cryopreserved after harvest from a post-mortem donor. Cadaveric vein use in the UK has been limited, largely due to cost and the limited outcome data available.

A pre-operative duplex scan for vein mapping is essential as it allows assessment of the venous conduit quality (>3 mm is considered acceptable) and aids accurate intra-operative conduit harvesting, avoiding complications with skin flap necrosis. Vein is the preferred gold-standard conduit for bypass procedures as they have more durable patency rates and are less likely to suffer infection compared to prosthetic Dacron or ePTFE conduits. As well as the great saphenous vein and short saphenous vein, the basilic and cephalic arm veins can be harvested to good use.

The Inflow Vessel

The proximal inflow vessel must be as disease-free as possible and is usually the infra-inguinal common femoral artery, but it can be derived from the supra-inguinal external iliac or the infra-inguinal profunda femoris or superficial femoral artery. In diabetic patients it is often possible to perform shorter bypasses, using the popliteal artery behind the knee as an inflow vessel. This removes the need for a longer venous conduit required to perform femoral distal bypass, with equally good long-term results achieved for the shorter

bypasses. In some patients, angioplasty and stenting of the iliac arterial segment may be required beforehand, to allow the use of the common femoral artery as the inflow vessel.

The Outflow Target Vessel

The distal outflow target vessel for graft anastomosis is typically the most disease-free tibial artery identified on angiography. Ideally it should cross the ankle into the plantar pedal arch to provide a realistic chance of ulcer healing. The distal outflow target vessel can be the popliteal artery above or below the knee or the best-quality infra-geniculate tibial artery crossing the ankle joint, which may or may not be in continuity with the plantar pedal arch in the foot. The nomenclature of lower limb bypass surgery reflects this.

Popliteal target – femoro-popliteal bypass
Tibial vessel target – femoro-distal bypass
Plantar pedal arch target – femoro-ultra distal bypass

Technical Considerations During Bypass Surgery

The small size of distal target arteries makes the anastomosis in femoral-distal bypass more technically challenging, with a greater chance of early failure. Wherever possible the most proximal landing zone in the target vessel should be used. Magnifying surgical eyewear e.g. Loupes, should be worn by the operating surgeon performing the distal anastomosis. This enables accurate, small, evenly-spaced suture bites to be taken and the identification of debris or small intimal flaps.

Prior to venous conduit harvesting, it is helpful to mark the course of the vein pre-operatively using ultrasound, to facilitate accurate skin incisions during vein harvest and to confirm the vein size (>3 mm in diameter ideally) and the quality of the vein (i.e. that it is free from thrombophlebitis). The great saphenous vein (GSV) is most commonly used and arises in the foot and passes anterior to the medial malleolus

at the ankle, ascending the leg medially and superficial to the muscles within its own facial envelope, before diving deep in the groin to join the common femoral vein at the saphenofemoral junction. The GSV is 'harvested' or disconnected from the venous system and used to carry higher pressure oxygenated arterial blood distally. Over time, the thin-walled GSV becomes 'arterialised' to the point that at revision surgery it can be difficult to tell a vein graft from a native artery.

Vein grafts are more infection-resistant and durable compared to prosthetic grafts. An infected graft often results in limb loss as revision surgery is often difficult and risky. Vein grafts do not develop the impervious bio-layer of bacteria that an artificial graft does, making antibiotic treatment feasible in the first instance. Occasionally the contralateral great saphenous vein or the basilic and cephalic veins in the arm are harvested as conduits in preference to prosthetic grafts. If an individual segment of vein is not of sufficient length to complete the bypass, two or three segments of vein can be harvested and 'spliced' together, to produce one long conduit.

Veins taper up in size from 2 to 3 mm at the ankle to around 8–10 mm at the sapheno-femoral junction in the groin, as more tributaries drain into them. They contain one-way valves that prevent blood returning to the foot under the effects of gravity, when a patient is upright and stationary. These two points must be borne in mind when deciding on how to anastomose the vein graft onto the arteries. If the vein is reversed in direction to counter the effects of the valves, a size mismatch occurs with a large diameter artery proximally but a small-diameter vein and vice-versa at the distal end. This can usually be corrected for in the popliteal segment, but more distally it can be technically challenging to join a 10-mm diameter vein graft to a 2-mm tibial artery. In these cases it may be preferable to leave the vein in-situ, passing a valvulotome instrument down the vein that cuts and destroys the valve leaflets, allowing reverse flow of blood within the vein. There are no differences in long term outcomes between reversed or in-situ vein techniques for bypass. An in-situ bypass may help to avoid a size mismatch

between smaller target vessels and the venous conduit but may take slightly longer to harvest and prepare with a valvulotome. There is also a small risk of injury to the venous conduit as the valvulotome is passed. The authors recommend using an expandable valvulotome, which can prepare vessels as small as 1.5 mm in diameter.

The decision to perform either a reversed vein bypass or an in-situ vein bypass comes down to surgeon experience and choice. We favour the in-situ technique for distal bypass onto tibial vessels and reverse vein grafting in the more proximal popliteal or tibio-peroneal trunk. At the end of any revascularisation procedure it is important to quality-control the operation by ensuring the aim of increasing perfusion to the foot has been achieved. This consists of a visual examination of the foot to confirm it has "pinked-up" with capillary refill combined with a handheld Doppler check for flow in the vessel distal to the graft. If the graft is not running, it must be explored as a small intimal flap or thrombus blocking the graft can be easily rectified. Occasionally, an on-table angiogram may be necessary to establish if or why a graft is not running and it is standard practice in our unit to have the patient on an x-ray compatible operating table.

If wound debridement or minor amputation is needed, the surgical wounds should be completely dressed and the foot re-prepared and draped before this takes place, to protect against surgical site infection.

Other non-bypass surgical procedures for groin level PAD, such as femoral endarterectomy and "patch-plasty" may be performed as a hybrid procedure, in combination with either retrograde angioplasty and stenting of the ipsilateral iliac inflow artery or antegrade downstream angioplasty and stenting of the femoral and popliteal run off vessels.

Post-operative Surveillance and Follow Up

Regular surveillance of a surgical bypass graft is essential for the early detection of haemodynamically significant graft-threatening stenosis, with a peak systolic velocity ratio (PSVR)

of more than 2.5. These usually occur at the proximal and distal anastomoses as a result of neointimal hyperplasia, but can occur within the graft itself. The narrowing reduces flow velocity within the graft and ultimately will lead to thrombosis and graft occlusion. Identification of haemodynamically significant lesions at an early stage allows them to undergo angioplasty, thus preserving the graft, a process called assisted primary patency. There is debate as to the frequency with which these surveillance scans should be performed, but we would suggest every 6 months for the first 2 years and annually thereafter. In addition to regular graft surveillance it is essential that patients be advised to stop smoking and that they be prescribed a statin and anti-platelet medication provided there are no contraindications. Risk factor modification and best medical therapy play a vital role in preventing the patient re-presenting with further critical ischaemia.

Novel Concepts in Revascularisation

Recently, there has been increased advocacy for revascularisation of the target vessel feeding the relevant angiosome with tissue loss. Data from studies supporting this angiosome concept of revascularisation in the diabetic foot, suggests there may be faster ulcer healing if blood flow in the relevant infra-geniculate tibial artery is improved. Those who argue against the angiosome concept point to the greater importance of ensuring that the target vessel is in continuity with an intact deep plantar arch, to support the durability of any surgical bypass or endovascular procedure for infra-geniculate arterial disease [6, 7].

Autologous stem cell therapy is an exciting area of promise for the treatment of ischaemia in the diabetic patient, who has tissue loss and no treatment options left for revascularisation, either via endovascular therapy or surgical bypass. Following stem cell therapy, improvement is seen in $TCpO_2$ measurements and in patient-reported pain scores. A lack of convincing limb salvage data to date means stem cell therapy remains a research tool, with conventional methods of

revascularisation remaining the main-stay of treatment for diabetic patients with tissue loss and PAD.

Finally, it is important for clinicians to classify their patients according to the severity of arterial disease clinically (e.g., Rutherford classification) and anatomically (e.g., TASC classification) together with classification of the degree of severity of tissue loss (e.g., PEDIS or University of Texas classification). This allows meaningful comparison of outcomes for future studies comparing different modalities of treatment for PAD in the diabetic foot patient.

Key Points

- Early and accurate assessment of arterial limb perfusion using clinical examination, toe and ankle pressures, $TcPO_2$ and non-invasive imaging modalities is vital for successful diabetic limb salvage.
- A diagnostic digital subtraction angiogram (DSA) is essential for planning distal arterial bypass surgery.
- Emergency surgery for the debridement of severe foot-threatening sepsis and tissue loss should be prioritised before limb revascularisation.
- Extensive infra-geniculate tibial PAD is best treated with surgical bypass in fit patients with endovascular therapy reserved for higher-risk patients.
- Post-treatment surveillance should include optimisation of best medical therapy, regardless of the form of revascularisation used. Haemodynamic assessment of vein bypass grafts with duplex scanning is vital to detect and treat graft-threatening problems early.

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Chapter 10
Amputation Above the Ankle: Achieving the Best Outcome for the Patient

Nicola Storer, Marie Hulse, Ian M. Nordon, and Stephen J. Baxter

Introduction

The aim of amputation is to provide the patient with the best functional outcome to meet their daily requirements within the confines of their other co-morbidities. A major amputation should not be a viewed as a quick solution to attain wound healing.

Amputation should be undertaken with the view that this often last in a series of procedures is providing the patient with an opportunity of durable comfort and quality of life. Therefore, the patient should be thoroughly assessed and the procedure carefully performed with their specific daily func-

N. Storer • S.J. Baxter, MB, ChB, FCS (✉)
Departments of Cardiovascular and Thoracic Surgery, University Hospital Southampton, Trenoma Road, Southampton, Hampshire SO16 6YD, UK
e-mail: Stephen.baxter@uhs.nhs.uk

M. Hulse, BSc (Hons)
Therapy Department, University Hospital Southampton, Southampton, Hampshire, UK

I.M. Nordon, BM, MSc, MD
Departments of Cardiovascular and Thoracic Surgery, University Hospital Southampton, Southampton, Hampshire, UK

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tional requirements in mind. Every patient will have different challenges to face and it is not possible to provide a rigid protocol to cover all eventualities. However, we have discussed specific points within the care pathway that we believe are important or those that are commonly overlooked. This chapter is divided into logical sections, although the sequence of these stages may vary according to the presentation and clinical situation of each patient.

Factors Affecting the Decision to Offer Amputation

Major amputation may be indicated when

- The patient's own limb is no longer viable.
- A prosthetic limb will offer a better quality of life than their own limb.
- There is uncontrolled infection.
- There is uncontrolled pain from ischaemia and revascularisation is not possible.
- The patient requests the procedure in preference to high-risk revascularisation.

To allow the patient to gain benefit their life expectancy should be longer than 2–3 months, otherwise their remaining days will be spent recovering from major surgery. This can be difficult to assess, but many patients at the end stage of their life will suffer accelerated deterioration of their legs and they and their carers need careful counselling about what the realistic expectations of amputation are. The in-hospital mortality rate for amputation is high (16.8 %) and up to one third of patients will be dead within 12 months of amputation suggesting we have room to improve in this area [1, 2].

Individual patient factors, social circumstances and the clinical situation must be carefully assessed by the multidisciplinary team, to determine what needs to be changed or improved to optimise the patient's quality of life for the future. These may require time-consuming alterations to the home environment so must be commenced as soon as possible to avoid delay in the patient leaving hospital.

A fitter patient may need more careful assessment as to the appropriate level of amputation. In these patients the optimum level for best functional rehabilitation may not necessarily be the most distal amputation site possible and they can benefit from multiple or higher risk procedures to salvage future mobility compared to a frailer, more immobile person, in who wound healing may be the first priority.

Assessment of Co-morbidity and Functional Status

Many individual factors may indicate poor outcome after amputation. Sometimes these can be optimised prior to intervention but if not they can help give a realistic prediction of the outcome to the patient and their carers.

Good cardio-respiratory function is important not only to get through the peri-operative period but to manage the increased work of walking with a prosthetic. This workload is increased by obesity, which will increase the demands on upper body strength as well as impair exercise tolerance. Obese patients may also have problems with fitting of prostheses and earlier onset of osteoarthritis.

It is important to assess the residual limb, which will have to take increased load and perform more work. If it is affected by major joint arthritis, joint contractures, poor muscle strength or reduced sensation, this will make it harder for the patient to ambulate. Dependent oedema is common in immobile patients who have generalised cardiovascular disease. If the patient has oedema in the good leg, it is likely they will also develop it in the stump and this makes limb fitting very challenging and often results in an inability to use the prosthesis.

Assessment of Cognitive Ability and Motivation

Decreased visual acuity, presence of peripheral neuropathy and a poor sense of balance have a major impact on the patient's ability to use a prosthesis safely. A patient with cognitive impairment including short-term memory loss will be

at risk of falls following an amputation as they are often not aware, or forget, that their leg is no longer there. They may be better off with their own limb, even if it does not provide an optimal level of function. Patients need to have insight, be motivated and engage with therapy to gain the most from rehabilitation and reach their predicted target of mobilisation. One of the commonest problems, understandably, is reactive depression. While the team must be aware of this and provide support, if it is marked, expert input is required at this critical time of the patient's recovery.

Assessment Functional Requirements

This must include inspecting the home environment, including access, the need to use steps or stairs, wheelchair access through doorways and turning spaces, toilets, kitchens, bedrooms and bathrooms. The importance of determining the social needs and expectations of patients is vitally important and their main targets may not be obvious unless these are explored with the patient. The impact on the patient's family and carers must be established and support planned for the expected changes.

Many patients will have been working up to the time of amputation and plans with the employer need to be explored to help the patient to return to work.

Indication for Amputation: Ischaemia Versus Sepsis

The main underlying condition bringing about the need for amputation can have a marked influence on the timing and conduct of the operation. In patients with acute infection, the degree of infected tissue will determine how aggressive the debridement needs to be to control the infection. The most extreme example of this is a guillotine amputation. Chronic infection can result in a gradual loss of functional architecture of the foot. There will be a higher post-operative wound

infection rate and consideration may be given to continuing antibiotic therapy for a period of time following an amputation. Due to inflammation these patients have increased blood loss during surgery and the use a tourniquet is advisable.

The decision as to whether to attempt revascularisation before amputation to ensure wound healing or gain a more distal amputation is particularly difficult. There are often considerable advantages to pre-amputation revascularisation and this should be considered, but ultimately it will depend on what interventions are possible and the fitness of the patient to undergo these. In patients with severe ischaemia due to disease above the inguinal ligament, it can be difficult to get even an amputation to heal and consideration should be given to improving the inflow, particularly if there is an endovascular option. In patients with severe disease of the common femoral artery involving the profunda artery, profundaplasty may allow a below knee amputation to heal.

Deciding on the Level of Amputation

Generally, below-knee amputation will give a better result in terms of function than a more proximal amputation, but may carry a higher risk of failure to heal. However there are a number of factors that should be considered, as in some patients, even the best below-knee amputation is of little benefit and may in fact be a disadvantage to the patient.

Expected Level of Function

If the patient is likely to mobilise on a prosthesis, the residual (and contra-lateral) limb must be able to support that degree of function. If the patient's contra-lateral leg has severe ulceration or arthritis this may not be possible.

The remaining joints in the amputated limb (knee and hip) must be mobile, pain-free and powerful enough to support

the prosthesis. A fixed flexion deformity of the knee joint will make wearing of a prosthesis impossible and may lead to ulceration of the stump due to pressure on the bed.

Limb volume needs to be reasonably stable and if there is a history of significant dependant oedema, it is likely that volume of the residual limb will also fluctuate when the patient tries to mobilise or wear the prosthesis. This leaves the patient with either an uncomfortably tight or a loose prosthesis that they can't wear.

If the patient is going to remain chair-bound due to other co-morbidities, then lap length (length of remaining femur) is most important and greater degrees of hip stiffness can be accommodated. In these patients, knee disarticulation may a better functional outcome than trans-femoral amputation.

Healing Potential

There are a number of assessments that can be carried out pre-operatively to determine the propensity for an amputation to heal. However, clinical examination, especially palpation of the peripheral pulses, is still probably the most commonly used assessment. The presence of a pulse directly proximal to the level of proposed amputation is a very strong indicator of successful primary healing [3]. The pattern of arterial disease on imaging can be important not only in planning the level of amputation but in determining whether this can be improved by revascularisation if appropriate. The position of previous operation scars, the extent of damaged or infected tissue and the quality of the skin may all influence the amputation level. Leg shape can make a significant difference not only to the performance of the operation but to healing and function later.

There are a number of objective tests that can be done such as isotope skin perfusion studies, transcutaneous oxygen tension $TcPO_2$ and laser Doppler studies (see Chap. 5). However none of these tests has been widely adopted and there is no absolute level at which healing will not occur [4].

Of course this underlines that the successful healing of an amputation depends on a number of factors, ranging from blood supply through to surgical expertise.

General Factors

Many patients with chronic diabetic foot disease will be malnourished. If very marked, with low serum albumin and oedema, wound healing will be problematic and unless there is time to correct their nutritional state before amputation, this may prompt a more proximal amputation in a frail patient or a temporising procedure to control the sepsis in a fitter patient. If the patient is very unwell but amputation needs to be undertaken (e.g., for uncontrolled infection) then proximal amputations (through knee and above knees are quicker and more likely to heal). Guillotine amputations in the leg are useful in that they allow rapid control of infection with the ability to convert to a formal below-knee amputation when the patient is fitter.

Pre-operative Assessment and Education

Patients and their families need realistic expectations of what they will be able to achieve following a major amputation. All patients facing an amputation should be referred to the Disablement Services Centre to have a formal pre-prosthetic assessment and to meet the team who will be looking after them. Many patients get reassurance from meeting people who have already had amputations and who can give them a realistic insight into how they will find the process. Most importantly at this stage, information must be clear and accurate, but also uniform across the whole team. There is nothing more likely to make a patient lose confidence then conflicting information. Ideally, there should be an information pack that all members of the team have agreed to use.

Phantom limb sensation will always be present. Early postoperative phantom pain is very common, but usually settles

as the wound heals and the inflammation subsides. It may remain in 10–15 % but appears less common in end bearing stumps such as knee disarticulation. Although the pre-operative use of an epidural anaesthetic can be useful for pain control, it is no longer used to decrease the incidence of phantom limb pain.

Wherever possible, early assessment of the patient's environment to which they will return, both home and work, should be undertaken to avoid delays following rehabilitation, which can be demoralising.

Unless the patient is very unwell due to infection in the leg or non-viable tissue, correctable medical conditions should be addressed, e.g., respiratory function optimised with bronchodilators and physiotherapy and anaemia corrected.

Amputation Procedures: Surgical Tips

The most important factor is the experience of the team undertaking the operation. Amputations should not be left to junior surgeons to undertake without supervision. As this is a high-risk operation it should not be undertaken out of hours by emergency teams, whose experience may be variable [5].

There are also some general practical points, which can be applied to all amputations:

- Always perform the procedure in adequately perfused tissue and be over-cautious in the frail patient.
- Leave no devitalised material, e.g., bone wax, bone chips, excessive amounts of suture material, fascia or tendon (keeping to tissue planes during surgery helps prevent this).
- Myodesis (fixing muscle to the bone) is an important part of optimising long-term function (see below).
- If required, the skin flaps can be adjusted to make use of healthy tissue without compromising long-term function.
- Nerve catheters (for local anaesthetic infiltration) and suction drains are low-risk devices and should be used.

- Avoid adhesive post-operative dressings as their removal increases discomfort in an already anxious patient.
- In patients with chronic infection, continue therapeutic antibiotics for about 5 days post-operatively.
- Be aware of post-operative pressure points within the residual limb (end of the trans-tibial limb or under the femoral condyles after a knee disarticulation).

Tissue Cover

Ideally the stump should have good quality, sensate mobile skin over healthy tissue. We orientate scars away from areas of contact or bone ends, but sometimes compromise with less healthy skin to maintain mobility and compensate for poor quality skin by varying sockets and liners. We only do this in discussion with the rehabilitation team.

Trans-tibial

Up to 15° of fixed flexion deformity of the knee can be accommodated with good patient compliance. However with poor compliance, dementia or poorly controlled chronic pain, a flexion contracture is more likely to end up with wound breakdown (pressure related) or a non-functional limb.

Skew flaps, long posterior flaps or rarely, equal flaps are used. Each procedure has its advantages and disadvantages. The skew flap is held to be less bulbous and allows easier limb fitting. However, there is no evidence favouring one technique over another and it should be determined by individual patient factors and the surgeon's experience with the technique [6].

Avoid a bulbous stump by either doing a fish-mouth (skew) incision or scalloping the corners of the Burgess flap to reduce the bulk laterally. Leave a good length of tibia below the joint and aim to transect the tibia 12–15 cm below the tibial tuberosity.

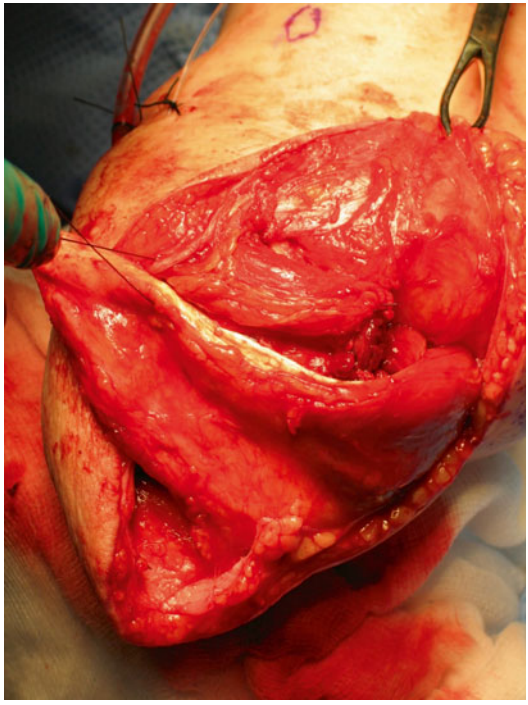

FIGURE 10.1 Gastronemius muscle being placed below the tibialis anterior muscle flap (with its vascular pedicle)

Put a significant bevel on the anterior edge of the tibia, as this point pushes against the socket of the prosthesis (a Gigli saw is good for this but pneumatic power saws can also be used). Use the periosteal elevator to clear all tissue off the proximal fibula circumferentially, to allow it to be cut 5 cm shorter than the tibia.

Once the bones have been divided, strip the muscle off the distal tibia (flush with the bone) to improve access to the neurovascular bundle (also useful during a knee disarticulation).

Avoid skin adherence by using a tibialis anterior muscle or a gastrocnemius-soleus myodesis, or by placing the scar over the anterior tibia with a skew flap (Fig. 10.1).

Knee Disarticulation

Knee disarticulation is usually the preferred option, when compared to a transfemoral amputation, as it provides a better level of functioning, a better quality of life and possibly less phantom limb pain. Blood loss from this procedure is minimal and no tourniquet is required. The surgical technique, which avoids bone transection, is less of a physiological challenge and so is ideal for frail patients.

When designing the skin flaps, ensure that there is no skin loss around the circumference of the femoral condyles or there will be too much tension in the skin closure, with an increased risk of breakdown (Fig. 10.2).

Try and avoid a scar under the femoral condyles (weight bearing surface). Leave the patella in its usual anatomical position (though the underlying fat-pad can be removed to allow the patella ligament to be attached to the anterior cruciate ligament). It need not be removed as long as it does not impinge on the weight-bearing surface. Despite good wound healing from a Gritti-Stokes procedure, we think these are best avoided as the patella often becomes unstable, making the limb non-functional.

Synovial fluid leakage is a common problem and a suction drain should always be used. The drain should not be removed before a minimum of 5 days or after that when drainage is consistently less than 50 ml in 24 h. Wound complications are common in up to 25 % of patients, but can usually be dealt with simply.

Trans-femoral

This amputation will give a higher chance of healing but compromised mobility due to the extra energy needed to walk with an above knee prosthesis. The prosthesis extends up to the ischial tuberosity (the patient sits on it, like a bicycle saddle). It is thus uncomfortable to sit in a chair, as it has been designed for walking, and the patient may also need to remove the prosthesis to go to the lavatory.

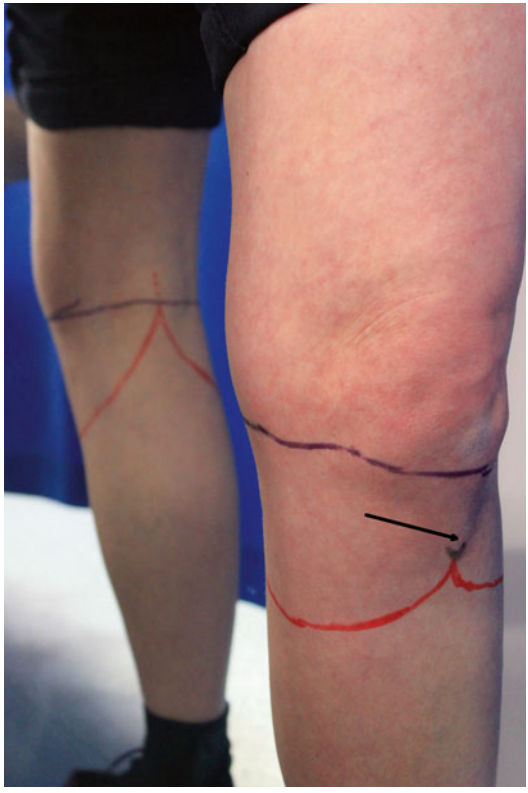

FIGURE 10.2 Design of medio-lateral flaps for knee disarticulation. *Red line* skin incision, *black line* joint of knee, *arrow* tibial tuberosity

Placing a sandbag under the ipsilateral buttock during surgery helps a balanced myodesis, by allowing access to the operative site with the hip in its neutral position. Posteriorly, the muscle implantation into the linea aspera of the femur should be stripped in the cranio-caudal direction and a haemostat clip works well for this (e.g. Dunhill).

When planning the flaps it is best to leave the stump as long as possible, although it is important to ensure that at least 12-cm clearance from the knee joint is achieved to allow for placement of the mechanical joint mechanism. The skin

flaps should be loose (but not enough to develop skin folds) to allow for some retraction.

Myodesis of the patella tendon and adductor longus and biceps femoris muscles with the hip in a neutral position (parallel to the bed) is important. It creates a stronger residual limb, a good shape for fitting, keeps a mobile tissue covering over the bone and reduces the chances of lateral deviation of the femur. Without a myodesis of the adductor muscles, the residual limb will tend to abduct during ambulation, thus increasing the required effort for walking. The myodesis is achieved by drilling two holes in the end of the femur and fixing the adductors and hamstrings with a non-absorbable suture. Quadriceps femoris (patella tendon) is secured over the top of the stump to the posterior muscle group.

Shorter stumps will tend to develop fixed flexion (and abduction) contractures of the hip due to uncompensated action of the ilio-psoas muscle. The risk of this complication can be reduced by disconnecting the insertion of the tendon of this muscle from the lesser trochanter (especially if the patient has poor compliance, dementia or poorly controlled chronic pain). However, always try to leave the femoral head and trochanters in place to enhance sitting stability.

Post Operative Management

Wound Management

We usually close the skin with absorbable subcuticular sutures as this makes the stump management easier for the rehabilitation team. Dressings should be removed at 48 h to check for skin viability and any residual infection. This is a good opportunity to remove the suction drain.

Stump compression is useful, but in the presence of poor perfusion should not be applied for long periods without visualising the stump. We tend to use compression bandaging or Blue-line Tubigrip®, depending on the shape of the residual limb, and review the wound at 48–72 h.

Minimising oedema is the key to good wound healing. We limit it by optimising nutrition, treating cardiac and renal dysfunction, elevating the residual limb, exercise and massage. Stump boards for wheel chairs will help keep the limb elevated.

Early palpation of the stump may identify fluid collections and if associated with signs of infection, these must be drained. If identified early this usually avoids complete wound breakdown. If a wound does break down, then surgical debridement followed by topical negative pressure therapy may well be able to salvage a functional limb.

Rehabilitation

This should start on the first post-operative day with residual limb handling, mobilising and strengthening exercises, bed mobility, sitting balance, transfers and lavatory skills. An important element of this is on-going provision of reassurance and education to both the patient and their family and carers.

Prospective prosthetic users are usually fitted with compression socks around day 7 and these are worn for increasing durations depending on the tolerance of the patient.

Progression is made to early walking aids around days 7–10, depending on the wound and the progression with rehabilitation. Access visits to the patient's home are planned to take place as soon as possible while, in the interim, the patients focus on the functional tasks of bathroom and lavatory skills, increasing exercise tolerance in their wheelchairs and increasing independence.

Prior to discharge the patients are taught strategies to cope with falls and they will also have a home visit.

Care of the Contra-lateral Limb

After an initial assessment of this limb, we protect it using pressure care techniques, including an appropriate mattress on the bed and chair, offloading the heel when the contralateral leg is elevated and regular skin emollients. It is essential

to ensure that the patient has appropriate protective footwear during periods of physiotherapy and mobilisation in their wheelchair.

Acute Pain Management

We routinely place nerve catheters intra-operatively. A standard epidural catheter is placed under the epineurium of the main nerve bundle at the time of surgery and brought out through the skin. A continuous infusion of 0.125 % bupivacaine is administered for the first 4–5 days. Although there is no high-quality evidence of benefit, we find them very helpful and they may reduce major analgesic use [7]. As they have a very low complication rate, even a marginal benefit to the patient makes them worthwhile. It is common to see neuropathic features of pain early in the post-operative period. These will decrease as the stump heals, but only time will then tell how prominent the neuropathic component will be become. End-bearing limbs (knee disarticulations) seem to be associated with a lower incidence of phantom pain in the long term.

Key Points

- Amputation may be the patient's best chance to gain a good quality of life.
- Patients and families need careful counselling about the realistic outcomes.
- Assessment of level of amputation is complex but largely based on the experience of the surgical and rehabilitation team.
- Amputation should be undertaken by experienced surgical teams on planned (elective) operating lists.
- Good surgical technique is essential and myodesis should be performed whenever possible.
- Rehabilitation needs careful planning and co-ordination with discharge plans.

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Chapter 11
Neuro-osteoarthropathy: The Charcot Foot – Pathology, Diagnosis, and Treatment

William J. Jeffcoate

Description

The Charcot foot is a syndrome, and has no definition. It is, however, a condition in which subacute or chronic inflammation of the soft tissues and of the skeleton of the foot is associated with increased bone breakdown and joint dislocation – with a consequent increased risk of fracture and deformity. The deformed foot may develop secondary ulceration at points of increased pressure and friction, and the resultant ulcers may become infected. Infection of the ulcer may lead in turn to infection of the bone (osteomyelitis) – leading to further skeletal damage.

W.J. Jeffcoate, MRCP
Department of Diabetes and Endocrinology,
Nottingham University Hospitals Trust, City Hospital Campus,
Hucknall Road, Nottingham NG5 1PB, UK
e-mail: william.jeffcoate@gmail.com

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History

Jean-Martin Charcot was an eminent physician active in Paris in the second half of the nineteenth century. In 1868 he described the occurrence of painless inflammatory arthritis of the spine and larger joints of the lower limb in people with tertiary syphilis, and the condition was later named "Charcot's disease" by Sir James Paget. The first cases involving the foot were described by an English surgeon, Herbert William Page, in 1881, and by Charcot himself in 1883. It was first reported as a complication of diabetes by Jordan in 1936.

Names

The Charcot foot is known by a variety of medical terms, variously including the words/roots "neuropathic," "osteo" (affecting bones), "arthro" (affecting joints), and "-pathy." Strictly, it should include the term "sarco-" to indicate that the soft tissues are also affected. It is, however, simplest to refer to the condition simply as the "Charcot foot." When it first presents it is often described as being "acute," even though the history may be of several weeks or months at the time of presentation. The term "chronic" is used with imprecision. It is more precise to use the terms "active" and "inactive" instead of "acute" and "chronic."

Causes

Neuropathy

It is thought that the presence of some form of neuropathy is essential for the Charcot foot to develop. It is, however, not clear which particular modalities of denervation are most important. It is possible that none is obligatory but that each contributes to a varying extent in different individuals. This

would explain why very similar disease of the foot may occur in people with distal symmetrical neuropathy (as in diabetes, leprosy, or alcohol abuse), with disease of the spinal cord (tabes dorsalis from tertiary syphilis; syringomyelia) or with traumatic denervation.

Sensory Neuropathy

Loss of pain sensation – whether loss of sensation of deep pain (as in tabes dorsalis) or more superficial pain (as is usual in distal symmetrical neuropathies) – is significant because the patient is unaware of the severity of the disease, and may continue to walk on the affected foot and cause further damage.

Motor Neuropathy

Loss of innervation of the long flexors and extensors to the foot, as well as the intrinsic small muscles, causes abnormalities of the spread of forces through the foot during normal gait, leading to points of increased pressure. This is made worse by the glycation and shortening of connective tissue that occur in diabetes.

Vasomotor Neuropathy

Abnormal regulation of flow through small blood vessels may potentiate the inflammation, which is a central feature of the acute Charcot process.

Loss of Neuropeptide Release

It is possible, but not proved, that failure of nerve terminals to release neuropeptides (including calcitonin-gene related peptide, CGRP) may also play a part since these peptides may modulate the inflammatory process.

Inflammation

It is currently thought that the key change that triggers the onset of the Charcot process is the onset of inflammation in the foot. Inflammation is marked by the increased expression of pro-inflammatory cytokines, principally TNF-α and IL-1ß, by leucocytes. Pro-inflammatory cytokines then trigger increased expression of the nuclear transcription factor, NFkappaB, which has a number of effects, including stimulation of the maturation of osteoclasts – which results in local bone breakdown [1].

The onset of inflammation may be caused by one of a number of events, including minor trauma, an episode of infection and the occurrence a preceding ulcer. Such inflammation would normally be short-lived, but the inflammation in the Charcot foot is not self-limiting, and persists. The persistence of the inflammation results in continuing activation of the NFkappaB pathway, which in turn causes continuing bone breakdown and makes the foot increasingly vulnerable to trauma.

Predisposition to Inflammation in Diabetes

A number of aspects of diabetes may predispose to the onset of inflammation through pre-existing potentiation of the RANKL-NKkappaB signalling pathway. These include the influence of glucose, reactive oxygen species and lipids.

Factors Encouraging Persistence of Inflammation

It is likely that the dominant factor is loss of protective sensation as a result of sensory neuropathy. Because painlessness renders the person unaware of the extent of the damage, it will predispose to continuing trauma through inappropriate weight-bearing.

Other Factors Linked to the Onset of Charcot Disease

People with renal failure are at increased risk of developing a Charcot foot. Amongst those with renal failure, the subgroup at particularly high risk includes those that undergo renal transplantation and especially combined kidney-pancreas transplantation.

Epidemiology

There are no reliable data on either the incidence or prevalence of Charcot foot disease in diabetes. It is usually said that the lifetime risk is of the order of 3 per thousand (i.e., approximately 1 % of all people with diabetes related neuropathy), but it is likely that it is very much higher than this. A town or city in England with a total population of 500,000 will have about 25,000 people with known diabetes and the experience of a specialist foot care centre serving such a population is that they will see some 15–20 new cases of Charcot disease each year. The *annual* risk is therefore just less than one per thousand of all people with diabetes and the lifetime risk may be 10–20 times higher.

Diagnosis

It is essential that the condition is suspected in any person who has diabetes complicated by neuropathy and who presents with unexplained inflammation in the foot (Fig. 11.1). At the moment it is rarely considered – simply because the condition is thought by most clinicians to be rare. The result is the diagnosis is frequently delayed by weeks or months and the condition of the foot may deteriorate considerably during this time. Delayed diagnosis may lead to limb loss.

FIGURE 11.1 Inflammation of the foot and lower leg in the acute phase of Charcot foot (*left*). Residual deformity apparent in the same leg after the swelling has regressed (*right*)

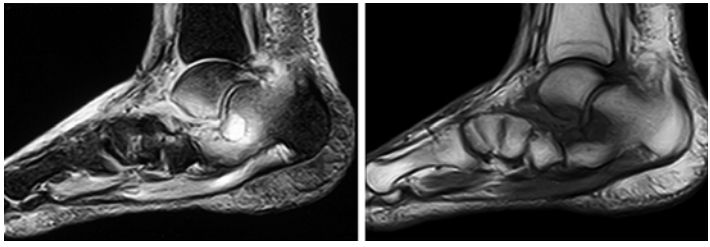

FIGURE 11.2 The MRI appearance of Charcot foot in the acute phase, with inflammation of the bone marrow and soft tissue being apparent as enhancement on the left (T2-weighted) image, and as suppression on the right

Once the condition is suspected, the person should be referred promptly to an expert in the field and should have a plain x-ray (taken weight-bearing to exaggerate any radiological signs of loss of integrity of the skeleton of the foot). If the x-ray is normal and the disease is still suspected, the person should have an MRI of the foot as soon as possible and should remain non-weight bearing until it is done (Fig. 11.2).

The MRI will highlight inflammation of both soft tissue and bone, even in the absence of overt fracture or dislocation. A CT scan may also highlight small fractures that are not apparent on a plain x-ray. It is possible that newer imaging techniques will prove to have added diagnostic value.

Treatment

There is no specific treatment that has been proved to be of benefit. Anti-inflammatory agents could theoretically limit the inflammatory process, but they have never been formally assessed in this condition. Non-steroidal anti-inflammatory agents would also be contraindicated in people with renal disease. In the absence of any specific therapy, there is only one therapeutic option available, and that is immobilisation of the foot (called "off-loading"). Immobilisation (which should ideally be achieved with a non-removable, below knee fibreglass cast) has two aims: (1) to interrupt the cycle of persistent inflammation by splinting the foot, and (2) to protect the foot from traumatic injury at a time when the bones and joints are susceptible.

When an inflamed foot is immobilised in a fibreglass cast, the inflammation settles within days. Indeed, the inflammation and soft tissue swelling settle so quickly that the cast will usually need to be replaced within a week because it will no longer fit the foot sufficiently snugly. In cases of doubt, this rapid resolution of inflammation with immobilisation provides strong suggestive evidence supporting the diagnosis. In established disease, casts need to be changed each 1–3 weeks until the disease enters remission. This frequent change of cast also enables the foot to be frequently checked – to ensure that its condition of the foot has not deteriorated from, for example, ulceration caused by rubbing.

Casting should be continued until the Charcot process is thought to have entered remission. Remission may be judged simply by regression of the clinical signs of residual inflammation (including comparison of skin temperature on the two sides) but there are no other objective measures. Repeat

MRI may give an indication of resolution of bone marrow oedema but it is expensive. Overall, casting is continued for a period of months. For reasons that are not clear, the reported duration of casting may vary from less than 6 months (reported in the USA and Denmark) to 12 months or more (reported in the UK).

Surgery

Active Phase

Surgery involving exostosis and arthrodesis of one or more bones and joints may be adopted in the active phase by some specialist units, especially when there is acute, gross deformity, such as dislocation of the ankle joint. Such surgery may be associated with the use of external fixation using a frame in order to protect the foot. However, the majority of surgeons are reluctant to operate in the active phase.

Inactive Phase

When the inflammatory phase has entered remission, surgery may be considered in an attempt to correct residual deformity and to make foot more functional.

Major Amputation

Sometimes the deformity and complications of the condition are such that the best option for long term function and well-being is to undertake major amputation. In developing nations and in impoverished populations, early amputation may sometimes be the only option for the care of people with more severe disease.

Complications

Ulceration and Infection

The Charcot foot occurs in people with neuropathy and people with neuropathy are the group who are most susceptible to ulceration of the foot. Ulceration is more likely if there is deformity and this is obviously a common consequence of the Charcot process. Ulceration may also be more likely if the foot is enclosed within a fibreglass cast.

When ulceration is complicated by infection, there is a very high risk of osteomyelitis developing in the underlying bone. Such osteomyelitis can be very difficult to eradicate and may be a factor leading to loss of the limb.

Psychosocial

It is becoming increasingly apparent that people who have a Charcot foot are very likely to become depressed, and to suffer a major reduction in quality of life. Part of this relates to the inevitable restriction in usual daily activities resulting from both the disease and its treatment, and is obviously worsened by the long course of the disease, the need for frequent specialist surveillance and the lack of clear markers to indicate progress.

Aspects of Long-Term Management

Prevention of Late Ulceration

People who have residual deformity are at high risk of ulceration and ideally require long term surveillance by an expert podiatrist or physician, combined with long-term provision of

effective orthoses, i.e. fitted footwear [2]. People who have had one Charcot foot should be alerted to the possibility of contralateral disease and should be urged to seek expert advice if suggestive inflammation occurs on the other side.

Cardiovascular Risk

People with neuropathy and foot disease (whether Charcot foot or neuropathic ulcer) have been reported to have a life expectancy which is reduced by an average of 14 years. The most likely cause for this is cardiovascular disease and hence long term specialist surveillance is needed to reduce cardiovascular risk as much as possible.

Key Points

- Charcot foot is uncommon but all health care professionals should be aware of it. The diagnosis should be seriously considered in any person with diabetes-related neuropathy who presents with inflammation of the foot.
- Charcot foot is an inflammatory condition involving the bones, joints and soft tissues and is closely linked to diabetic neuropathy.
- Weight bearing must be avoided if the diagnosis is suspected.
- Treatment is focused on off-loading and avoidance of weight bearing. The role of surgery is unclear and should be undertaken only by experts.
- Long-term follow-up is essential in view of the risk of foot ulceration, further episodes and increased associated cardiovascular risk.

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Chapter 12
The Role of the Orthopaedic Surgeon in Diabetic Foot Complications

Gavin W. Bowyer

Introduction

This chapter discusses the role of the orthopaedic surgeon in dealing with the diabetic patient with foot complications. Orthopaedic surgeons have a role in the multi-disciplinary management of diabetics and a particular part to play when there is deformity, fracture, bony prominence and infection. Orthopaedic surgeons also have a part to play in recognising the diabetic foot at risk. This chapter does not cover the issues around providing orthopaedic surgery for patients with known and controlled diabetes, but rather focuses on the situation where foot and ankle complications have occurred.

Neuropathy is common in people with diabetes, particularly if the condition is long-standing and control is poor. Neuropathy leads to dry, cracked and relatively stiff skin, foot deformity and reduces sensation and proprioception. These factors predispose the foot to ulceration and infection and up to 25 % of people with diabetes will suffer a foot ulcer at some stage in their life. Charcot neuro-arthropathy is relatively

G.W. Bowyer, MChir, FRCS(Orth)
Department of Trauma and Orthopaedics,
University Hospital Southampton, Tremona Road,
Southampton, Hants SO16 6YD, UK
e-mail: gwbowyer@aol.com

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uncommon, but diabetic neuropathy is the commonest predisposing factor for this condition. Orthopaedic surgeons must be able to recognise the foot at risk and be aware of how to treat these conditions, as well as help prevent recurrence.

Recognizing the Diabetic and the Foot at Risk

Some patients presenting in an orthopaedic clinic may have undiagnosed diabetes or may be aware of their diabetes, but the connection to the presenting foot problem may not have been made. The orthopaedic surgeon can thus have a role in recognising the condition and appreciating that the foot is at risk. There are key features in the history, examination and on foot x-ray, which should point to diabetes and a vulnerable foot.

Undiagnosed diabetes must be borne in mind when patients present with "odd" neurology affecting their feet, or when there is ulceration or infection. A spontaneous, non-traumatic foot-drop will often arise from a diabetic mononeuropathy affecting the common peroneal nerve.

Neuropathy, rather than vasculopathy, is the underlying process causing most diabetic foot complications, and the patient may complain of burning, dysaesthesia, and paraesthesia. It is not uncommon, however, for the patient to report that their feet feel numb, even though there is often a painful sensation present, and people with diabetes often struggle to describe how their feet actually feel.

Findings on clinical examination may alert the orthopaedic surgeon to the possibilities of underlying diabetes. The autonomic component to the neuropathy causes the typical dry, scaly, cracked skin of the diabetic foot. Loss of protective sensation is predictive of the foot at-risk. Regular, routine screening is an essential component of diabetic management [1] and the Semmes-Weinstein monofilament is cheap and effective. In an orthopaedic clinic, where monofilament testing is not routinely performed, testing joint position sense at the great toe metatarsophalangeal (MTP) joint may be

revealing. The patient with neuropathy is often unable to detect the direction of passive movement at the first MTP joint, if asked to look away or close their eyes whilst the surgeon moves the toe up and down.

The finding of calcification of the dorsalis pedis or posterior tibial artery in the foot and ankle on plain x-ray is virtually pathognomonic for diabetes. Further radiological signs of importance are osteolysis, which erodes the phalanges and distal metatarsals, stress fractures, and disruption at the midfoot/forefoot junction (Lisfranc disruption) in the absence of significant trauma. Not all of these radiological signs will be present in each case (Fig. 12.1).

Clinical Management

The Infected Diabetic Foot

Osteomyelitis is common in diabetics with an established ulcer, but the diagnosis and management present challenges and must be tackled in a multi-disciplinary way to optimise the chance of clearing the infection. This will involve input from vascular and orthopaedic teams, as well as a microbiologist, diabetologist and a nursing/tissue care team. Some form of surgery is usually required, be it surgical sampling and debridement of the wound, or more extensive resection, amputation or stabilization.

It is unusual to have a diabetic foot infection without an obvious portal of bacterial entry, most commonly a neuropathic ulcer. It is important to distinguish superficial colonisation from true infection, so superficial swabs are of little value; tissue samples are needed, from the soft tissues and from bone if this is accessible through the wound or ulcer [2].

For acute sepsis or spreading infection, empirical antibiotic therapy might be used, aimed at Gram-positive cocci. It is better, however, to have tissue culture and antibiotics targeted at the appropriate organism, which is often antibiotic-resistant, especially in chronic or previously treated cases.

FIGURE 12.1 (**a**) Charcot changes in the tarso-metatarsal joints with subluxation of the lateral four rays, going laterally, so that the space between the first and second metatarsals is increased (*arrowed*). This foot is unstable, although the forefoot and hindfoot are virtually unaffected. (**b**) Collapse at the midfoot in the same patient is obvious, and the bony prominences in the midfoot are indicated with *arrows*. There is fragmentation dorsally and dorsal subluxation of the base of the first metatarsal. (**c**) The foot has been stabilised with screws across the second and third tarsometarsal joints and a locking plate to reduce and hold the first tarsometatarsal joint

Locally agreed protocols are important in guiding the acute care teams who may be initially admitting these cases, and should be agreed by the multi-disciplinary team.

If the foot is mechanically unstable as well as infected, the orthopaedic surgeon may have a particular part to play in providing stability through the limited use of internal or external fixation. The techniques of fixation will include standard plates and screws, as well as potentially some novel stabilization with long bolts and screws specifically designed for use in the diabetic foot. These provide intramedullary support from the metatarsals in the forefoot through into the midfoot and on into the talus. This offers cantilever beam support for the foot. Techniques are being developed to place a fixation plate on the plantar aspect of the foot skeleton, the tension side of the collapsing foot, working as a tie-beam support. The normal concerns about not putting metalwork into an infected area might be set aside in these cases, as stability is itself important in providing an environment in which the infection can be treated effectively. If the foot heals and infection is controlled, then the metalwork could potentially be removed later if there are fears that it is itself colonised with bacteria.

Suspected Charcot Disease

Diabetes is the most common cause of Charcot foot in the developed world, but it is still a relatively rare complication, affecting approximately 1 % of diabetics. The patient has usually had known diabetes for more than a decade, and is in their fifth or sixth decade of life. The presentation is often with a hot, warm and swollen joint or foot, without much pain. The mismatch between minimal pain but severe disruption and fragmentation on x-ray is typical.

There is sometimes a debate as to whether or not the foot is infected or whether there is inflammation from a Charcot foot – the former is unusual unless there has been a breach of the skin, and in the latter the redness goes when the foot is elevated for 10 min.

The most characteristic x-ray pattern is one of fragmentation or fracture around the ankle and forefoot, with subluxation or dislocation in the mid-foot, particularly at the mid-foot/fore-foot junction (the Lisfranc joints).

Special investigations such as MRI or bone scanning are difficult to interpret, as they do not give a reliable distinction between Charcot and infection; they are sensitive, but lack specificity. These investigations may, however, be useful in assessing the extent of either of those processes.

In essence, clinical examination is the key to diagnosis: if there is no breach in the skin, presumptive diagnosis is Charcot. If the skin locally is, or has been, ulcerated, assume infection and obtain tissue samples. Both processes can, of course, co-exist.

Established Charcot Disease

Charcot proceeds through the three phases described by Eichenholtz: fragmentation, coalescence, and then consolidation. The evidence (which is not of high quality) supports bracing and protective weight-bearing early in the disease. This support, with serial casts or a special boot, must be maintained throughout the inflammatory and fragmentation phase, which may last more than a year.

It is important to watch for subluxation or dislocation of the joints in the mid-foot or mid-foot/fore-foot junction. The consequent development of deformity and bony prominence in the plantar aspect of the mid-foot must be guarded against, and it is in this area that orthopaedic surgery might be helpful [3].

The operative principles are as follows:

- Stabilise, and reduce where possible, the dislocations:
  - Combined osteotomies, bone resection and arthrodesis may be required to correct the deformity.
  - The technique of fixation is “bespoke” to deal with the given pattern of foot instability and collapse, and might involve plates and/or screws.

- Excise bony prominences.
- Fix fractures:
  - Ankle or foot fractures might need fixation, if this is going to give stability to the foot, maintain alignment and avoid collapse and bony prominence.
  - The calcaneal tubercle fracture in Charcot should be managed non-operatively in an equinus cast.

Foot Ulceration

Factors leading to foot ulceration include peripheral neuropathy, vascular insufficiency, poor glucose control, forefoot pressure overload and smoking.

It is axiomatic that prevention is better than cure, particularly in the case of diabetic foot ulcers. Much attention has been paid to the role of patient and physician education, podiatric care and custom insoles, but the overwhelmingly important intervention is regular foot screening.

The role of the orthopaedic surgeon might be in off-loading the forefoot or removing or realigning bony prominences. The Achilles tendon is often contracted and tight in the diabetic, throwing excessive load onto the forefoot; this can be relieved by a tenotomy or step-cut lengthening. Healing of a plantar neuropathic ulcer is improved in those who have an Achilles tendon lengthening in combination with total contact casting. Although there is evidence that the forefoot pressure increases again with time, ulcer recurrence rates in those who have a tendon release plus casting are less than half that which occurs in patients treated with total contact casting alone [4]. The procedure is simple and quick and can be performed under local anaesthetic and the presence of an infected foot ulcer.

Ankle Fractures

Diabetics are considered at higher risk of wound complications [5] and have impaired bone healing after fractures, particularly when there is peripheral neuropathy or absent pedal

pulses (there are, however, few high-quality studies to support this observation). Unstable fractures should still be treated with standard operative stabilisation techniques, with an emphasis on careful soft tissue handling [6]. Implants and fixation should be robust enough to withstand the occasional non-compliance with restriction of weight-bearing, and consideration should be given to using reconstruction plates or locking plates (not simple 1/3 tubular plates) as a neutralisation plate. It is usual to advise a prolonged period of restricted weight-bearing with protection in a cast or support boot (although, again, the evidence for this approach is lacking).

Key Points

- Be aware that the diabetic might present with "odd" neurology affecting the foot, and this can be indicative of a foot at risk of major complications.
- Be aware that the finding of calcification in the arteries of the foot is indicative of diabetes, until proven otherwise.
- Charcot disease of the foot is diagnosed mainly on clinical rather than radiological grounds. The typical presentation is in long-established diabetics in middle age, and represents a major risk to the foot. Supportive bracing will need to be prolonged, and if the unstable foot becomes deformed and develops bony prominences, orthopaedic surgery might be helpful, especially in the coalescence and consolidation phases of the disease.
- It is important to obtain tissue samples when dealing with foot infection and certainly when there is suspected osteomyelitis. Osteomyelitis is unusual unless there has been ulceration (or surgery).
- Orthopaedic foot surgery can help to stabilize the collapsing diabetic foot and prevent or remove bony prominences that would leave the foot vulnerable to ulceration.

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Chapter 13
Cardiovascular Risks in People with Diabetes Foot Complications

Martin Fox and Lisa Jane Lainton

Overview: Defining the Main Issues

The overwhelming challenge facing people with diabetic foot disease and the clinicians who treat them is the current imbalance of perception around what the risks to life and limb actually are. The emphasis of prevention and treatment over the last 30 years since the development of multidisciplinary foot teams has been about limb protection and amputation prevention. The most common fear of patients and clinicians treating diabetic foot disease is that of amputation. The grave reality, however, is that whilst 15 % of people with diabetic foot ulcers may have lost a leg at 10 years, up to 70 % will have died and over half of these deaths are cardiac- or cerebrovascular-related [1]. We see, treat and remember the

M. Fox, BSc, FFPM RCPS (Glasg) (✉)
Manchester Leg Circulation Service,
Pennine Acute Hospitals Trust, Harpurhey Health Centre,
1 Church Lane, Harpurhey, Manchester,
Greater Manchester M9 4BE, UK
e-mail: Martin.fox@nhs.net

L.J. Lainton, RGN, RM
Department of Diabetes and Endocrinology,
Stockport Foundation Trust, Stockport, Cheshire, UK

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patients who have lost a leg, but we can so easily forget those who have died of a potentially modifiable cause.

This reality of diabetic foot disease-associated cardiovascular mortality outweighing amputations in people with diabetes appears to be almost universally neglected, ignored or left for someone else to deal with by many clinicians and consequently also by the very patients who present to us. This is despite the substantial and growing clinical evidence base that highlights death rates associated with diabetic foot ulcers are worse than those of the common cancers [2].

When looking at the bulk of clinical literature on diabetic-related foot disease, the overwhelming trend is for foot ulcer or amputation-focused clinical research, audit and outcome targets. This seems disproportionate to the need for more mortality-focused research, audit and outcome targets, linked to cardiovascular (CV) risk management. Why do we as clinicians working with diabetic foot complications who exert so much effort on ulcer care focus so little on managing the specific modifiable CV risks, so strongly associated with loss of both life and limb in diabetes patients?

There are some questions that we can ask ourselves, our diabetes teams and associated health care colleagues, which if answered honestly, may help us start to tackle CV risk management and the associated high mortality rates – the 'elephant in the room' of diabetes foot disease – more successfully.

1. Who is responsible for CV risk management in people with foot disease?
2. Are we resting our foot ulcer patients to death?
3. How can we best communicate with patients about CV and mortality risks?

Who Is Responsible for CV Risk Management in People with Foot Disease?

National clinical guidance and incentives are in abundance to help inform clinicians on how to best manage diabetes foot complications – from initial detection via foot screening, to

podiatry access, wound care and specialist care from within the diabetes multidisciplinary team. In the United Kingdom, the Scottish Intercollegiate Guidelines Network (SIGN) and National Institute for Health and Clinical Excellence (NICE) have widely advocated CV risk management and the Quality Outcomes Framework used in primary care (QOF) has incentivised it for peripheral arterial disease, but not for the diabetic foot! However, in the 10 years since NICE first published guidance on diabetes-related foot disease [3], there has been little clarification about who is actually responsible for associated CV factor management. Is it the foot screening service, the podiatry service, the multidisciplinary foot team, the diabetes specialist nurse or the GP? The podiatrist may assume the GP is dealing with it, the GP may assume the diabetes team is leading on it, the diabetologist and vascular surgeon may assume the diabetes or practice nurse is picking it up and they in turn might hope that the diabetes specialist podiatrist is tackling it as part of foot ulcer management. In reality, often nobody is doing it systematically, comprehensively, routinely and in line with best clinical guidance. GPs and primary care services are seen as largely responsible for CV risk management in the population generally, but are they and their practice nurses familiar with diabetes-related foot disease and the context of associated morbidity and mortality risks? NICE have made it explicit in their guidance that the multidisciplinary foot team has a key role to play [3], but these teams are usually embroiled in the urgent and important business of foot ulcer and Charcot neuroarthropathy management. The non-urgent, but equally important business of CV risk management, is often overlooked.

Diabetic reviews, incentivised by QOF and widely implemented throughout the UK over the last decade, include checking for signs of diabetes foot disease. However, the focus again is predominantly on foot ulcer and identification of amputation risk [3] and disappointingly there are no direct links to the broad range of CV targets that sit elsewhere within QOF.

CV management in its real sense involves a variety of specific activities and interventions, from information giving, negotiating changes in health behaviours and beliefs,

medication review, prescribing, referrals to support services, continuity and follow-up. Put together well, these interventions are perhaps best demonstrated in cardiac rehabilitation service models, the likes of which have been widely set up and made available for people with cardiac disease [4].

Such programs integrate exercise into the overall treatment plan that includes lipid management, blood pressure control, smoking cessation, nutrition education and weight reduction, diabetes mellitus treatment, and psychosocial intervention. With the use of this multifaceted approach, cardiac rehabilitation and secondary prevention programs have been associated with up to a 56 % improvement in survival among patients after myocardial infarction and a 28 % reduction in risk of recurrent myocardial infarction [5].

For people with diabetes and a high risk of CV-related morbidity and mortality, however, there are no such structured and multifaceted services available currently. Cardiovascular risk management for people with diabetes foot complications all too often remains a low priority or disorganised series of activities the importance of which are too rarely communicated to the patient who is of course the person most motivated to do something.

CV Exercise: Are We Actually Resting Our Diabetic Foot Patients to Death?

CV exercise as part of a structured and supervised cardiac rehabilitation programme has been shown to be highly effective in reducing cardiac-related and total mortality [5]. In people with diabetes generally, exercise has been shown to have broad benefits in relation to CV reduction, morbidity and mortality [6] and in people with diabetes and peripheral neuropathy, exercise has helped with reducing pain and improving neuropathic symptoms [7]. Similarly in people with peripheral arterial disease, it is broadly recommended for all people with intermittent claudication, to help improve pain free walking distances [8].

However, in one particular sub-group of the diabetes population, exercise has been directly or indirectly withdrawn or advised against, mainly by the very clinicians who lead on their care. This sub-group, of course, are people with foot ulcers or Charcot neuroarthropathy, and it is the multidisciplinary foot teams and foot protection teams who actively or passively advise a reduction in exercise, often bringing this key CV intervention to a halt for months years, or for life. The reason behind this highly questionable practice is probably the fear that exercise will result in 'overloading' the ulcerated, Charcot or healed foot, leading to deteriorating foot disease or re-ulceration. This concern is well meaning, but not particularly linked to any good clinical evidence. Thus, the broad CV benefits of exercise are often withheld for these people. This advocacy of prolonged 'rest' to protect the high-risk foot can in turn lead to months or years of inactivity and no regular CV exercise. Even after amputation due to diabetic foot disease, CV exercise as part of the treatment and rehabilitation package is rarely actively promoted or provided to survivors, in the way it is for survivors of heart attacks.

The concept of 'rest your bad foot' is stamped indelibly into patient information leaflets, the verbal advice given and therefore into the memories, existing fears and subsequent health related behaviour of these patients. Do we inadvertently 'rest' them to death?

If we question what we are doing by looking at the clinical evidence for guidance, it becomes clear that very little has been done to date in researching, auditing or justifying our current 'embargo on exercise' for patients with diabetic foot disease. Indeed the existing clinical evidence contradicts our current stance and brings into question the whole concept of 'rest'. Exercise has not been shown to increase the incidence of diabetic foot ulcers in people with existing peripheral neuropathy [9] and has not been shown to increase re ulceration in people who have healed from foot ulcers [10].

Bearing in mind the known benefits of exercise generally and the high CV-related mortality rates for people with peripheral neuropathy, peripheral arterial disease, foot ulcers,

Charcot foot and amputation, isn't it time we fundamentally changed our non-evidence based paradigm around exercise and diabetic foot disease?

How Do We Best Communicate with Patients About CV Risks Factor Management?

The American Heart Association has recently promoted the seven modifiable components of ideal CV health [11]. These are:

- Not smoking
- Regular exercise
- Healthy diet
- Body mass index
- Cholesterol
- Blood pressure
- Blood glucose

Subsequently, a study has been done to assess the knowledge of these components in a cross-section of patients. It found that 37 % of respondents did not know that diabetes itself is a CV risk and 63 % could not identify the seven components [12]. If you ask a cross-section of your current diabetes patients attending the foot clinic to name the common modifiable CV risks, their current known CV risk profile and their personal targets for each risk, will you be engaged in a useful patient/clinician conversation, or will you receive a blank look?

As an extension of this issue of influencing patient knowledge, it is clear that the relative risks associated with diabetes-related foot disease are rarely communicated to patients in a way they can understand, reflect on and take personal action to effectively reduce. Inaccurate perceptions of CV risks by clinicians and the challenges of communicating them in an understandable and patient-centred way has been suggested as a key barrier to patients taking on cardio-protective changes generally [12]. A clear example of how we fail

FIGURE 13.1 The patient with obvious cardiovascular risks

patients is in the structured written information we provide them once they have diabetes foot complications. Most current diabetes foot leaflets shy away from providing CV risk management information, preferring instead to focus on well-meaning but non–evidence-based advice, such as 'avoid walking barefoot', 'dry between your toes' or 'change your socks daily' [13]. Until we start to communicate the realities of CV risks to our diabetes foot disease patients in useful and meaningful ways, can we really help them lead longer, healthier lives?

One of the main challenges for the clinician faced with a patient who has obvious and multiple CV risks (Fig. 13.1) is how to start the discussion. It is perhaps much easier to give

some standard advice such as 'you must reduce your walking and rest, to help heal that foot ulcer' than to ask an open question such as, 'would you like to know what the long-term risks are for people who have diabetes and a foot ulcer?'

How to Tackle These Issues: Putting CV Risk Management at the Forefront of Diabetes Foot Care

The paradigm shift needed for CV risk management involves all providers of diabetes foot care services from foot screening, podiatry, wound care and multidisciplinary foot teams. The whole emphasis on saving more limbs needs to be rebalanced with the need to save more lives. Discussing CV risks along with limb risk, signposting patients towards medicine review (e.g., antiplatelet agents or intensified blood pressure control) or lifestyle change support (e.g., smoking cessation or weight management) and reviewing these issues on a regular basis is the responsibility of all clinicians working with diabetes foot disease.

Diabetes multidisciplinary teams and associated clinical services are made up of an eclectic mix of very highly skilled clinicians, often vying for individual clinical ideals. We must, however, unite on this theme to prioritise and deliver a single CV risk management approach and one set of simple consensus agreed CV targets. We must agree and clarify within our teams who is leading on and who shares responsibility for CV risk identification, management, review and discussion.

Amongst the plethora of limb-focussed diabetes foot literature, green shoots of CV-related emphasis are now emerging. For example, where multidisciplinary diabetes foot teams have systematically introduced aggressive CV risk factor management in people with foot ulcers, outcomes around 5-year mortality rates have been seen to dramatically improve, from 48 to 26.8 % [14]. Success in CV risk factor reduction in people with diabetes has also been demonstrated where

nurse-led clinics have been set up to focus on the key modifiable risks [15].

Although there is a lack of direct clinical evidence to show the benefits of CV exercise in people with diabetic foot complications, the current norm of actively withdrawing or advising against this intervention surely must be one of our key priorities for change. Is it beyond our means to design, provide and actively promote prescribed, 'low impact', chair-based CV exercise for all our patients with foot disease, in particular those with foot ulcers, Charcot neuroarthropathy, or those who have already had an amputation. Could this not be done in partnership with existing cardiac rehabilitation services, to start to offer people with diabetes foot complications the same safe, supervised, effective exercise intervention, that their 'cardiac cousins' already have access to?

As a start point for clinicians wanting to tackle all these themes, simply discussing CV risks with patients can start to improve their perceptions, understanding and intent to initiate health changes [12]. An example of a CV risk discussion leaflet developed and used by a nurse and podiatry-led peripheral arterial disease service is shown in Fig. 13.2 [16]. This was based on gaining local clinician consensus and endorsement on CV targets sourced from a range of best national guidance (Fig. 13.3). Similar structured patient information, with simple numeric targets, linked to signposting towards available local support services could be developed by clinicians working with diabetes foot disease patients, to help achieve a balanced perspective on CV risks and the potential benefits of managing them better.

Such a standardised multidisciplinary foot team approach to CV risk identification, discussion and targets can help to develop a common language and common goals, which can only help to reinforce key messages. Utilising the 'seven components for ideal CV health' as a common reference point and priority for continued professional development with all clinicians involved with diabetes-related foot disease, may help simplify the information, messages, language and targets we discuss with our patients.

Name:

If you make specific health related changes, you can reduce your personal risks of heart attacks, strokes or worsening leg problems.The more changes you make, the more your risks can be reduced. We will support you to make any of these changes if you are interested.

Risk Factors for Circulation Damage	You (tick)	Interested in reducing risk (Y/N)
Smoking Any amount of tobacco / nicotine		
Raised blood lipids (cholesterol) Total is greater than 4 or LDL is greater than 2		
Raised blood pressure Resting blood pressure is greater than 140/90		
Raised blood glucose (with diabetes) HbA1c is greater than 7.0 or 53 (new measure)		
Lack of cardiovascular (heart) exercise Less than 2.5 hours per week of light exercise		
Excessive weight Body mass index is greater than 30		

Based on our assessment and your decisions today, we will refer you to the following people / teams for further treatment or support

- —— Your GP (for review of medicines, blood pressure, cholesterol)
- —— Quit Smoking Team (for support / information to help you quit)
- —— PARS (for support with increasing leg / cardiovascular exercise)
- —— Weight Management Team (for support with reducing weight)
- —— A Vascular Surgeon (to consider surgery or other treatment)

We will review this plan with you in ____ months time

The North Manchester Leg Circulation Service Tel. 0161 861 2439

FIGURE 13.2 Example of a cardiovascular risk discussion leaflet used by a nurse and podiatry-led peripheral arterial disease service (Reprinted with permission from Pennine Acute Hospital NHS Trust)

All patients with a **confirmed diagnosis** of PAD should have an individually agreed management plan, which is to be reviewed periodically with their GP, the Leg Circulation Service or the Hospital Vascular Team.

The management plan will include targeting cardiovascular risk factors, limb problems and negotiating treatment options (lifestyle, medicines, surgery) by GPs, Nurses and Allied Health Professionals involved in management of the lower limb

PAD / CV risk management	Target	Source
•Antiplalelletherapy	Initiate for all with established PAD	NICE 2010, SIGN 2006
•Lipid lowering therapy	Initiate for all with established PAD	NICE 2010, SIGN 2006
•Hypertension	BP < 140/90 mmHg	NICE 2006
•Smoking	Aim for quit	SIGN 2006
•Obesity	BMI < 30	NICE 2006
•Light cardiovascular exercise	30 / 45 mins, 3 to 5 times per week	DOH 2004
•Giycaemic control (if has diabetes)	HbA1c < 7.0 % or < 53 mmol/mol	NICE 2008, IFCC 2007

This pathway is based on PAD consensus from SIGN, TASC II , NICE, Target PAD and local expert opinion

Contact numbers for general advice regarding PAD or main hospital numbers for Vascular Registrar advice if urgent

General advice (Mon- Fri, 8.30am - 4.30pm)	Urgent advice - on-call Vascular / Surgical Registrar
Leg Circulation Service 0161 861 ****	Pennine Acute Hospitals Trust 0161 624****
(For patients with North Manchester GPs)	Manchester Royal Infirmary 0161 276****

Figure 13.3 Consensus endorsed CV targets, sourced from a range of best national guidance (Reprinted with permission from Pennine Acute Hospital NHS Trust)

Summary

Ultimately, taking the initiative at every opportunity to open the discussion on modifiable CV risk with our diabetes foot disease patients and to then touch base frequently on this theme in the context of their foot disease is a decision for individual clinicians to make. Only by starting the conversation will we ever really start to challenge existing lack of knowledge or inaccurate health-related beliefs and impact on the shocking mortality outcomes we see currently. Considering the effort that patients and clinical teams expend to achieve wound healing in the foot, it seems a great pity that many patients then suffer an avoidable cardiovascular death. It is no longer good enough to reassure ourselves that at least the patient died with both legs still on.

Key Points

- Start by increasing awareness and understanding of the seven modifiable components of ideal CV health.
- Negotiate shared team responsibility for CV risks assessment, management and review and identify a CV 'lead'.
- Look at how to best communicate the key messages, within teams and with patients.
- Learn how local cardiac rehabilitation teams do it and utilise their expertise.
- Consider facilitating and actively offering 'low impact' cardiac rehabilitation type exercise to all people with diabetes foot complications.

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Chapter 14
Foot Care and the Prevention of Recurrent Ulcers

Laurie King

Introduction

Diabetic foot ulceration is a common complication of diabetes that affects approximately 1 in 20 patients but is largely preventable. The risk factors for ulceration include having had a previous foot ulcer, peripheral neuropathy (insensitivity), dry or cracked skin, deformity (claw toes, prominent metatarsal heads/high metatarsal arch), abnormal biomechanics, high plantar foot pressures, callus formation and peripheral arterial disease.

As well as poor-fitting footwear, lack of awareness of the risks increase the chance of foot damage. The United Kingdom National Institute of Health and Clinical Excellence (NICE) advises that extra vigilance should be used in patients who have poor vision, live alone, who smoke, who are over 70 years of age, and who have had long duration of diabetes, or are socially deprived [1].

This suggests that with regular foot care (which assumes that access to such care is readily available), a reduction of

L. King, BSc (Hons), MSc (✉)
Diabetic Foot Clinic, Oxford Centre Diabetes Endocrinology and Metabolism (OCDEM), Oxford University Hospitals NHS Trust, Old rd, Headington, Oxford, Oxfordshire OX3 7LJ, UK
e-mail: laurie.king@nhs.net

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foot pressures, patient education/empowerment and good control of diabetes, the prevention of recurrent foot ulceration should be an achievable aim.

The majority of diabetic foot ulcers should be preventable and it is well known that the precursor to amputation is commonly ulceration. It may be thought that with increasing knowledge and awareness of risk factors and preventative measures, that amputation rates should be decreasing. This, however, this does not seem to be the case. In the United Kingdom, the NHS Atlas of Variation Diabetes [2] indicated a six-fold variation in major amputation rates in different areas in England, with the total number of amputations likely to increase to 7,000 by 2015 [2]. So what is preventing a reduction in amputations and ulceration?

The Issues

Who Provides the Foot Care?

Since 2004, a clear pathway of care has been laid out by the National Institute of Clinical Excellence (NICE) in its foot care pathway clinical guidance CG10 [3]. However, the pathway is complicated and it is beyond the resources of most Multidisciplinary Diabetes Teams (MDT) to refer every diabetic foot ulcer to it. No clear definition of who should make up the team is given and not all geographical areas have an MDT. If it does exist, the team is most likely to reside in a hospital, and it is doubtful that this care is provided 24 hours a day.

A similar situation arises in the definition of the community-based Foot Care Protection Team (FPT) and which healthcare professionals it should consist of. Again, it is doubtful that this care is provided 24 hours a day. Problems with communication between primary and secondary care are likely to be compounded by these teams working independently with no common medical record system.

Financial constraints have resulted in the under-funding of many community podiatry departments, leaving the FPT without

the obvious key player, the podiatrist. Also, many hospitals do not have full-time podiatry input and some MDTs do not have dedicated full-time podiatrists. The reality is that patients with diabetic foot ulcers are seen by general practitioners, district nurses, practice nurses and community podiatrists, with varying levels of expertise, who often have no specific training in recognising diabetic foot complications. This can result in delayed referral, resulting in poor outcomes "Time is tissue."

What Foot Care Should Be Provided?

Little high-quality evidence is available in terms of robust randomised controlled trials, limiting the detail available in the NICE diabetic foot guidelines.

Should all callus be debrided, and if so by who and how often? What off-loading is practical for most patients after their ulcers have healed? Empirically, podiatrists in the UK have used felt padding to offload the foot for over 40 years to good effect, but little research has been undertaken hence evidence is lacking in this area and the practice is falling into disuse by some FPTs. Should diabetic patients receive specialist footwear and orthoses? Research again in this area is poor.

What Standard of Care?

The other major issue to tackle is the competency of health care professionals. If patients are to be assessed for risk status, callus is to be debrided, offloading devices such as casts, orthoses, and specialist footwear are to be made and education given what is the standard of competency and how is it determined in those delivering the service?

Preventative Education

Despite widespread adoption, there is little hard evidence that education is effective in preventing diabetic foot ulceration, or regarding who should give it and how should it

be delivered. Information is delivered in a variety of forms (leaflets, videos, word of mouth) with little standardisation across all health-care professionals in the pathway. Structured education often has little foot care information embedded in it, is aimed mostly at newly diagnosed patients and is expensive both in terms of resources and patient time.

Solution to the Problems of Preventing Foot Ulceration

Realistic Integrated Pathways

Pathways of care should be simple to follow (Fig. 14.1). The problem is that in most parts of the UK, patients with diabetic

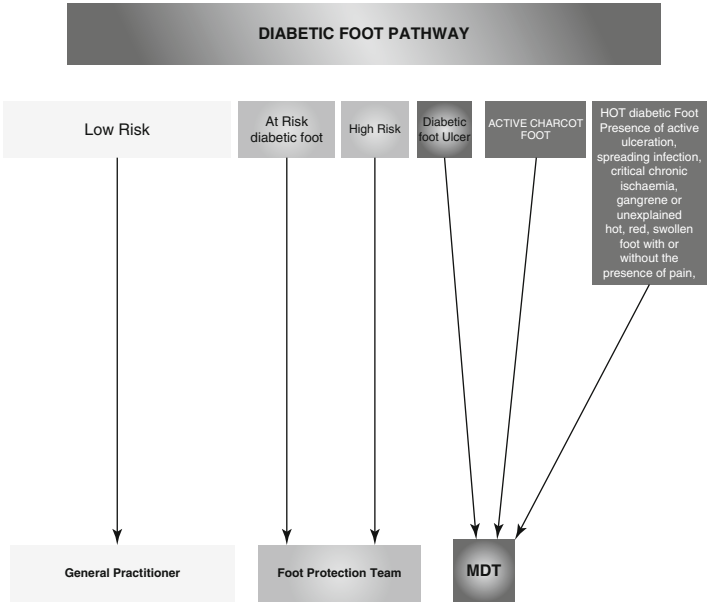

Figure 14.1 Clear diabetic foot pathway as per NICE CG 10

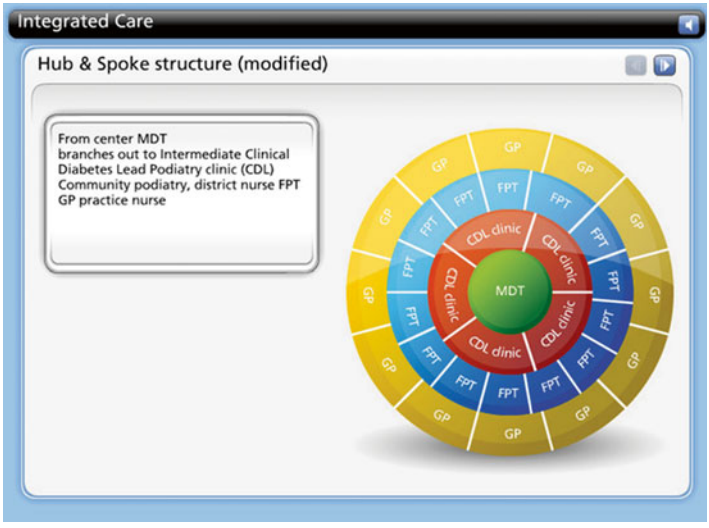

FIGURE 14.2 Hub and spoke structure of care

foot ulcers are seen by everyone in the care pathway. It would be more realistic if podiatrists rotated into the MDT at least one day a week and then provided care in an intermediate diabetic foot clinic in the community, with strong communication links to the MDT. Seamless care could then be provided along a hub and spoke model as indicated in Fig. 14.2, with foot care starting in primary care with the GP, branching out to the FPT, then Intermediate clinical diabetes-led podiatry clinics (CDL), and then on to MDT clinics in secondary care.

With scare resources, the MDT, using images from primary care, can use telemedicine to monitor and record the progress of patients. Based on these images, treatment plans can be formulated.

The intermediate clinic could be used to act as gatekeeper for patients with new ulceration and active diabetic foot disease, with seamless access to the hospital-based MDT if required (Fig. 14.3).

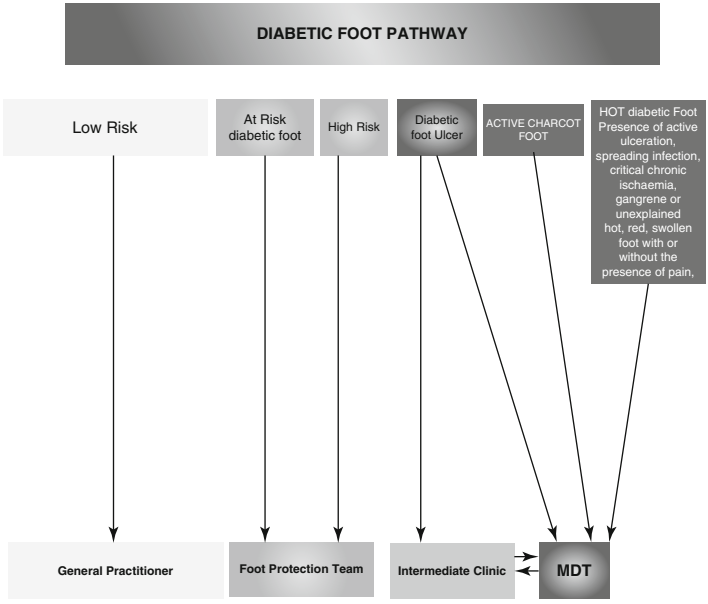

FIGURE 14.3 Practical integrated care pathway

Standardised Care

As part of the Quality Outcomes Framework (QOF), diabetic patients should have their feet examined for palpable pulses, evidence of peripheral arterial disease, skin changes, foot deformity, and the presence of an ulcerated foot at present or in the previous 15 months. Their feet should be tested with 10-g monofilaments or tuning forks (128 Hz) to assess for peripheral neuropathy [4].

Patients should then be placed into the appropriate risk classification:

- Low risk – normal sensation, palpable pulses
- Increased risk – neuropathy or absent pulses
- High risk – neuropathy or absent pulses plus deformity, or skin changes or previous ulcer (within the previous 15 months)
- Ulcerated foot/Active foot disease

It is important to ascertain who has carried out this assessment and to what standard. The assessment needs to documented in the patient's records so that it is immediately apparent to any health-care professional treating the patient.

One solution to help standardise diabetic foot assessment and screening would be an e-learning programme, similar to the one used by the Foot Risk Awareness and Management Education (FRAME) project set up by the Scottish Government and Edinburgh University [5]. This could provide some clinical governance and ensure that the same standard of assessment is used by all health-care professionals.

The Society of Chiropodists and Podiatrists, together with the Scottish foot action group, have produced a range of competencies for the delivery of diabetic foot care across the diabetic foot risk spectrum. These competencies could be used by all who provide care for diabetic foot patients [6]. This would give patients the assurance that they will be treated by a clinician with competencies specific to the management of the diabetic foot, relative to their level of need, and reassure employers that their staff have the necessary skills required to safely treat patients in their care.

Preventative Diabetic Foot Care

Some diabetic foot ulceration is the result of an accidental injury that cannot be avoided, but in many cases, burning an insensitive foot on hot water bottles, on hot surfaces such as sand, or pavements in hot countries whilst on holiday, or walking barefoot and sustaining injury can be avoided by increasing awareness of these risks with education. The importance of checking for foreign objects in shoes, avoiding badly fitting shoes that rub and cause blisters and ulceration are preventative actions that can be re-enforced to the patient. Here education may prove helpful if the patient understands the advice and is empowered to help themselves.

FIGURE 14.4 The use of felt to offload dorsal deformity

The development of ulceration at high pressure areas from deformity resulting in callus formation can be averted by regular podiatry, offloading the foot from the ground and from the shoe.

The provision of specialist footwear must be a multidisciplinary decision, to include the patient, podiatrist and orthotist and should be timely, with patient follow-up and review after any footwear or orthoses are issued and any problems rectified. Ill-fitting specialist footwear results in a waste of resources and a loss of confidence by patients in the whole process.

Many cases of dorsal re-ulceration can be avoided with the use of felt to act as an interface between the foot and the upper part of the shoe (Fig. 14.4). Although there is no level 1 evidence for this approach, a consensus exists from the likes of the International Working Group for the Diabetic Foot (IWGDF) [7, 8], and others [9] in the form of expert opinion based on best practice guidelines [7–9].

Engagement and Empowerment of Patients

In order to engage patients and empower them in their own care, they should be told which risk group they are in and should be given appropriate tailored information according to the components that make up that risk group. For example, for those with reduced sensation advice on how to protect

their feet and from what. In a patient with poor arterial supply advice should be given on how to modify lifestyle, e.g., give up smoking, and what to look for in terms of warning signs of complications developing.

Patients should be informed about foot deformity, offloading pressure, special footwear and orthotics. Regular podiatry care may be necessary with skin changes such as excessive callus formation to keep this pared down. Choosing and checking new footwear and what to avoid if going travelling are all simple but important pieces of advice.

It is vitally important to ensure patients know what to do in a foot emergency, "Foot Attack," to include who to contact and how. The patient should be aware of the triggers for seeking help, such as the signs of infection, ulceration, and sudden changes in foot shape (Charcot foot) [10].

The Scottish Foot Action Group have produced foot information leaflets in English, Urdu, Cantonese, Bengali, Polish and Arabic tailored to the "Low risk," Moderate risk," "High risk," "Ulcerated" and "Charcot foot," as well as" footwear advice" and "what extra care to take on holiday" [11]. Diabetes UK, in their "Putting Feet First" campaign, endorses these leaflets [11] and provides general advice in their "Ten Steps Toward Healthy Feet" [10, 12].

Key Points

- People with diabetes should be more involved in their own care and be given information appropriate to their risk stratification, to include how to recognise a foot emergency (a Foot Attack) and where to seek help.
- Commissioners of health services need to resource and deliver an integrated diabetic foot care pathway.
- Standards of care should be monitored nationally, and the impact this has on amputation rates should

be measured via audit and feedback into the audit cycle process.
- Healthcare professionals should have the competency to assess for the risks of diabetic foot disease and to treat its complications.
- There should be an evidenced-based national diabetes foot care implementation plan. Where evidence is lacking, best practice should be identified and research undertaken to provide suitable evidence.

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Chapter 15
Foot Deformity and Pressure Management in the Diabetic Foot

David A. Russell

Introduction

The foot is a versatile organ whose functions include the ability to absorb shock on heel-strike, being malleable to adapt to uneven surfaces, whilst at the same time acting as a rigid lever for propulsion during toe-off. This normal function is reliant on the complex interplay between the joints of the hind-foot and mid-foot, in particular movements at the sub-talar and mid-tarsal joints. The combination of dorsiflexion/plantarflexion, abduction/adduction and inversion/eversion leads to the triplanar movements of pronation (dorsiflexion, abduction and eversion) and supination (plantarflexion, adduction and inversion).

During the gait cycle the foot is initially supinated on heel strike, with initial contact on the lateral plantar aspect of the heel. In this position the foot is malleable and therefore able to absorb the initial strike but also to accommodate variation in terrain. As the body moves over the foot during the stance phase of the gait cycle, the foot moves from supination

D.A. Russell, MB ChB, MD, PG Dip Clin Ed, FRCS (Gen.surg)
Leeds Vascular Institute, Leeds General Infirmary,
Great George Street, Leeds, West Yorkshire
LS1 3EX, UK
e-mail: davidrussell1@nhs.net

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to pronation as pressure-loading on the foot transfers from the lateral heel across the foot to the first metatarsal. The move to pronation is accompanied by a change in the biomechanics of the foot to the rigid lever, which continues as the load is transferred from the first metatarsal to the hallux for toe-off.

Foot Deformity in the Diabetic Foot

Neuropathy

Although sensory neuropathy is the most commonly described element in neuropathic ulcers, the motor component of diabetic peripheral polyneuropathy plays a key role in the development of foot ulcers. Motor neuropathy causes wasting of the intrinsic muscles of the foot (lumbricals and interossei), leading to deformities such as claw or hammer toes. Unopposed action of the long extensor tendons leads to plantar retrograde forces on the metatarsal heads, leading to prominence of the metatarsal heads, pulling these proximal to the plantar fat pads. This leads to the classical neuropathic foot appearance with high pressure areas dorsally over the proximal interphalangeal (PIP) joints and on the plantar aspect over the metatarsal heads.

Tissue Glycosylation

Glycosylation of tendons and joint capsules leads to reduction in joint mobility and tendon contracture. Tightening of the Achilles tendon is often associated with the development of plantar forefoot ulcers. Achilles contracture raises the posterior portion of the calcaneum, leading to a negative calcaneal inclination angle and increased plantar forefoot pressures. This phenomenon is also associated with increased lateral plantar ulcers following trans-metatarsal amputation.

Charcot Neuropathic Osteoarthropathy

Charcot neuropathic osteoarthropathy classically affects the tarso-metatarsal joints but may occur anywhere in the foot. Still poorly understood, the disease starts with an acute phase characterised by hyperaemia, swelling and joint destruction, secondary to increases in osteoclast activity. This is followed by a period of stabilisation with absorption of bone fragments, fusion and coalescence of the joints. Finally, there is a period of remodelling. If untreated during the acute phase, there is collapse of the normal bony architecture, classically leading to rocker-bottom deformity of the mid-foot.

Minor Amputations

All minor amputations disturb the normal biomechanics of the foot and the consequences should be considered in any decisions regarding surgical debridement of the diabetic foot.

The toes tend to buttress the neighbouring digits and minor toe amputation may lead to valgus drifting of the medial toes. Amputation of the second toe will lead to hallux valgus deformity, with increased risk of subsequent ulceration of the first metatarsophalangeal (MTP) joint. Leaving a residual stump of toe where possible will allow the adjacent toes to remain supported and minimise this.

The hallux plays a major part in the propulsive phase of the gait cycle. Hallux amputation causes transfer of weight to the second toe and metatarsal with risk of transfer ulceration over these sites. Further, the hallux supports rotation of the first metatarsal head and thus hallux amputation also minimises the ability of the first metatarsal to bear weight. This increases pressure under the second and third metatarsal heads, but also along their shafts, with risk of fractures. Maintaining the attachment of the Windlass mechanism by preserving the proximal 1 cm of the proximal phalanx of the hallux minimises this risk.

Partial ray amputations can lead to increased pressure under adjacent metatarsal heads. The axis of rotation means

that the first and fifth metatarsals act as isolated rays, whilst the central three rays act as a functional unit. Thus, amputation of the first or fifth ray has higher risk of transfer ulceration in the adjacent ray than amputation of a single central ray. Amputation of two central rays (with or without an outer ray) leads to significant biomechanical disturbance, high risk of transfer ulceration and should lead to consideration of primary trans-metatarsal amputation. Furthermore, the insertion of the tibialis anterior tendon into the base of the first metatarsal, and the peroneus brevis tendon into the fifth metatarsal, should be preserved where possible. If this bone must be excised, the tendon should be preserved for future tendon transfer, to prevent development of pronation and supination deformities, respectively.

Trans-metatarsal amputation leads to unopposed action of the Achilles tendon, due to division of the long extensors. Suturing together the flexor and extensor tendons over the bone end does not prevent this. This leads to an equinovarus deformity and subsequent risk of ulceration under the end of the remnant fifth metatarsal. The risk is increased as the amputation site moves proximally in the forefoot. Percutaneous Achilles tendon lengthening at the time of trans-metatarsal amputation has reduced this risk from 50 % to less than 10 % in some series and is now performed routinely by the author.

Pressure Management in the Diabetic Foot

All of the aforementioned conditions can lead to focal areas of maximum peak pressure in excess of 1,000 kPa on weight bearing. It is this repetitive pressure insult, combined with shear forces, which leads to eventual tissue breakdown and foot ulceration, the precursor to major amputation in diabetic patients. In addition, sensory neuropathy removes the protection of pain resulting from a high-pressure stimulus.

One of the key components in management of patients with either high-risk diabetic feet or those with established ulceration is peak pressure off-loading. Although

predominantly performed with footwear, surgical methods or adjuncts can also be applied. "Off-loading" is a misnomer, as all methods aim to redistribute pressure rather than truly remove all pressure from the foot.

Off-Loading Footwear

Standard footwear, particularly fashion footwear, has poorly cushioned insoles, which offer little in the way of pressure redistribution from high-pressure areas. It is well established that pressure relief with therapeutic off-loading footwear is an integral part of the management of diabetic foot ulcers. There is less evidence to confirm the benefit of off-loading footwear as a prophylactic measure, but this is also widely practiced.

There is a wide range of off-loading footwear available, fitting largely into three categories: simple offloading shoes, with or without total contact insoles; more complex off-loading shoes such as forefoot off-loaders and cast shoes; devices which extend above the ankle and have a calf load-bearing component such as walkers (e.g., Aircast boot) and total contact casts (TCCs). The degree of off-loading varies widely between categories, with simple devices achieving as little as 16 % pressure reduction whilst TCCs can reduce peak pressure in the forefoot by as much as 87 % (Fig. 15.1) [1]. It can be seen from Fig. 15.1 that the workhorse devices used in the majority of diabetic limb-salvage clinics in the UK lie towards the least effective end of the spectrum, whilst forefoot off-loading shoes and those with a calf component are much more effective.

Efficiency of footwear in off-loading correlates directly with ulcer healing rates and the duration to ulcer healing. A recent metaanalysis confirmed TCC healing rates of 79.3–95 % (with the exception of one study with healing rates of 68 %) at ≥12 weeks [2]. By contrast a bi-valved TCC will heal less than 30 % of ulcers in a similar time period. Forefoot off-loading shoes and half shoes have moderate efficacy and will

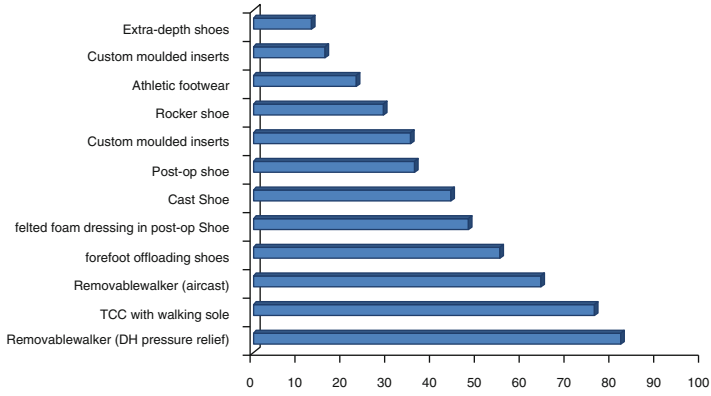

FIGURE 15.1 Pressure reduction by commonly used off-loading footwear (Modified from Cavanagh and Bus [1])

heal around 60 % of neuropathic forefoot ulcers, although time to healing is prolonged when compared to the TCC. Standard therapeutic shoes (used most commonly in many clinics) have poor efficacy, healing less than 25 % of ulcers with a mean time to healing of greater than 60 days [2].

This data suggests that the off-loading strategies employed in the majority of patients, certainly within the authors unit, are less effective than available alternatives. Both the National Institute for Health and Care Excellence (NICE) and the International Working Group on the Diabetic Foot (IWGDF) recommend use of TCC for neuropathic foot ulcers [3, 4]. However, this is contraindicated in patients with infection and significant ischaemia and therefore 76 % of patients enrolled into the Eurodiale study would be ineligible for this treatment modality [5]. Application of TCC requires skilled technicians to minimise the risk of ulceration from ill-fitting casts, and can take up to 60 min fitting time, which would overwhelm many diabetic limb-salvage clinics. These reasons may explain why TCC is only use routinely for neuropathic ulceration in 2 % of US centres [6].

A second anomaly is the difference in performance between the TCC and bi-valved TCC. A previous study has

shown that patients wear their off-loading device for only 29 % of steps per day, despite believing that they are being highly compliant [7]. They tend to wear the device out of the house, but wear normal footwear or slippers in the house. Conversion of a removable walker to a non-removable device (the instant TCC, iTCC), usually by use of a cohesive bandage, can greatly reduce the application time whilst achieving similar healing rates to the TCC.

The issue remains that persuading patients to agree to non-removable devices, particularly if this affects the ability to work or drive, can be difficult. Our unit has occasionally had to resort to treatment contracts, or threats to discharge from care, for non-compliant patients with deteriorating ulcers despite best removable off-loading, who refuse TCCs. Off-loading is a balance between acceptability of the footwear, to maximise compliance, versus the effectiveness of that footwear in ulcer healing. Because of this, we continue to use a policy of simple off-loading footwear or forefoot off-loaders as a primary modality, with scotch cast boots used as second-line, reserving walkers or TCC for the most complex or resistant cases. Future work should be directed towards novel technologies to allow more effective off-loading in footwear acceptable to patients, and to monitor compliance.

Surgical Off-Loading

The most important surgical consideration is the impact of minor amputations on future risk of ulceration. In a follow-up study of patients subjected to hallux or first ray amputation, 60 % had one further amputation, 21 % two further amputations and 7 % three further amputations [8], leading to some suggesting that those requiring a first ray amputation should have a primary trans-metatarsal amputation. The role of percutaneous Achilles tendon lengthening as an adjunct to trans-metatarsal amputation has already been discussed.

A number of surgical strategies to off-load specific diabetic foot abnormalities have been described. These can be useful

in specific circumstances but infection rates in patients with neuropathy undergoing curative corrective procedures for ulceration is approximately 20 %.

Digital Ulcers

Flexible claw-toe deformities of the hallux or lesser toes with associated apical ulcers can be treated by flexor tenotomy, with healing rates in excess of 95 % reported in the literature. Similarly, dorsal interphalangeal (IP) joint ulcers in a flexible clawed toe can be treated with extensor tenotomy, again with excellent healing rates [9].

Arthroplasty of the hallux or lesser toes can be performed to correct deformities. More commonly, the hallux ulceration is related to reduction in movement of the first MTP joint, in which case a Keller-type arthroplasty is more appropriate, but can be associated with high peri-operative infection rates in this setting.

Plantar Forefoot Ulcers

For non-tunnelling ulcers, metatarsal head osteotomy may be considered but more commonly ulcers are undermined, and either a single dorsal metatarsal head excision or pan-metatarsal head excision may be considered, particularly if the toes are normal. If a pan-metatarsal head excision is considered, it is important to maintain the normal metatarsal head parabola. Improved healing rates, reduced ulcer recidivism and reduced infective episodes during healing have been reported with this procedure versus best off-loading.

Achilles tendon lengthening does not improve ulcer healing versus TCC for plantar forefoot ulcers, but there is evidence to suggest this does reduce recurrence rates.

Injection of silicone under the metatarsal heads has been shown to increase tissue thickness and reduce plantar forefoot peak pressures in patients with plantar callus, with a trend towards reduced callus formation compared to treatment with saline injection [10].

Charcot Foot

Surgical intervention for Charcot is primarily reserved for correction of abnormalities after the stabilisation phase. Exostectomy may be performed to reduce plantar pressures in those with a rocker-bottom deformity. Similarly mid-foot and hind-foot corrective procedures can be helpful and should be discussed with an interested foot and ankle surgeon.

Key Points

- Foot deformity is a common sequel of diabetes and its complications.
- Off-loading is a key component in the management of patients with diabetic foot disease. Patient education is a mandatory to maximise compliance.
- Off-loading devices are more effective, both in ulcer healing, and time to ulcer healing, if irremovable and extending above the ankle.
- Surgical off-loading should be considered in patients failing to respond to off-loading footwear, provided conditions for ulcer healing have otherwise been optimised.
- It is vital that these patients are managed within a multi-disciplinary team with skilled orthotists, and that any associated ischaemia or infection are identified and treated promptly.

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Chapter 16
The Role of the Multidisciplinary Team in the Management of Diabetic Foot Complications

Stella Vig and Kathryn H. Waite

Introduction

Diabetic foot complications are a global problem with increasing incidence of diabetes secondary to an ageing and more obese population. The most common diabetes-specific reason for hospital admission in the UK is the diabetic foot ulcer. This complication amounted to over one million bed days in England in the year 2009/2010 and significant resources are spent caring for these patients [1]. In fact, it is thought that one in every £150 spent by the NHS is towards the care of diabetic feet [2]. Each year, patients with diabetes undergo more than 6,000 major amputations in the UK. The number of amputations is increasing, and if current rates continue, is expected to

S. Vig, MB BCh, FRCS, FRCS (Gen Surg) (✉)
Department of Vascular Surgery, Croydon University Hospital, London Road, Croydon, Surrey CR77YE, UK
e-mail: stella.vigs@croydonhealth.nhs.uk

K.H. Waite, MBBS, BSc
Surgical Department, Croydon University Hospital, Croydon, Surrey UK

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exceed 7,000 per year by 2015/2016 [3]. Major amputations are associated with a 50 % two-year mortality rate in patients with diabetes [4]. Although data has been resourced from the UK, there is a similar impact to the healthcare systems globally.

The gravity of this mortality statistic is strikingly evident, especially when compared to that of many of the most common malignancies. We know that we can reduce the rates of major amputation, and therefore both the associated morbidity and mortality, by forming and supporting structured and integrated diabetic foot care pathways, led by multidisciplinary teams (MDTs). The term "foot attack" is used to describe an injury to a foot, or feet, of someone with diabetes, that may rapidly require an amputation and may not be immediately recognised by the patient, carers or clinicians [2]. There is a complex interplay between the pathophysiological processes in diabetes that culminate in foot attacks and their complications [5]. Ischaemia (both macro- and microvascular), peripheral neuropathy, immunosuppression and structural joint changes collude to form a foot more likely to be subject to trauma, more likely to become infected and less likely to heal promptly. Figure 16.1 demonstrates a typical foot attack, and the natural history may lead to life-threatening results [6]. Swift recognition and management of the foot attack saves lives and limbs. This is a central aim of the MDT in diabetic foot care.

The management of a foot attack requires the knowledge and skills of a diverse range of specialities and disciplines to provide optimal care and long-term reduction of risk of recurrence. The effectiveness of the MDT in the care of the diabetic foot cannot be underestimated [5]. Serial studies have demonstrated the improved outcomes, decreased complications and the cost-effectiveness of the MDT [2, 6, 7].

How Should This Work?

The definition of the MDT is often understood as incorporating only the clinicians within secondary care with very specialist expertise. In fact, the team is much larger and diverse,

Figure 16.1 A typical foot attack

encompassing professionals from both primary and specialist care and also the patient throughout the course of their disease.

There are four key components to ensuring that the risk of developing foot complications in patients with diabetes is minimised. These are:

1. Patient education
2. The foot protection team
3. The multidisciplinary team
4. A foot care pathway

Patient Education

Patients and carers are key to recognising or alerting clinicians. Sometimes, it can be that the foot "is just not right." This recognition is a challenge in some patients with diabetes who have sight problems, which prevent direct vision of their feet and therefore prevent them from identifying the subtle change within the foot. Similarly, neuropathy may mask the pain that would ordinarily trigger initial recognition of a new ulcer and autonomic neuropathy will ensure that a foot will remain warm to touch even with a compromised blood supply. The engagement of patients and carers in daily checks of their feet allows an early trigger when the foot is different from normal. It is then vital that patients and carers understand where they can find help and how quickly this should occur. Diabetes UK has recently produced a free booklet named "Recognising the Foot Attack," which documents the signs to look out for and provides space to record the phone numbers of key contacts. Patient leaflets are available in many languages and are a way of encouraging conversations within a family or group.

All patients with diabetes should have a foot check as part of the annual diabetes surveillance.

This allows each patient to be triaged as normal, low risk, at risk or high risk of developing future diabetic foot complications [8]. It is important that this risk is explained clearly to patients and that they are then referred appropriately to the foot protection team.

The Foot Protection Team

The foot protection team (FPT) includes general practitioners, practice nurses, podiatrists, district nurses and diabetes specialist services. These are the core components of the triage system, which ensures patients are educated, risk-stratified and monitored to decrease the risk of progression to an acute foot attack. These are often located within com-

munity services but need to have rapid access and good communication with secondary care colleagues. Many members of the team may also have contracts to work within secondary care. This service should be seamless with that of the MDT in specialist care, allowing rapid and shared care pathways to occur both into and out of the services.

The absolute prevention of complications may not be possible, but their burden will be reduced by appropriate advice and early referral should they develop. All diabetic patients should be triaged and allocated a risk category (to be reviewed at least annually) [8]. Those assessed as being at risk or as low risk should be reviewed by the FPT as per agreed protocols. Each visit provides an opportunity to educate and re-educate the patient and their carers. This responsibility of the FPT for education extends to the education of fellow healthcare professionals, to adequately assess and stratify diabetic feet.

The FPT is essential to the management of selected cases in the community, i.e. patients who are high-risk or have active disease, who would otherwise require MDT management. Patients discharged back to nursing homes, care homes or with poor mobility or difficulty with transport may not be able to manage the regular secondary-care appointments required to monitor healing. The implementation of a shared-care protocol after discharge, with clear individual care planning, will reduce the risk of non-compliance and hospital re-admission. A successfully treated foot attack still places that individual as a high-risk patient and highlights the ongoing need for long-term management plans.

These patients may need specialist footwear and off-loading devices as well as fundamental advice with regard to emollients and simple lifestyle advice, to include not walking in bare feet! Each patient needs to be counselled in the context of their lifestyle: the sole breadwinner for a family may need to work on a building site wearing the offending steel toe–capped boots, rather than wearing an off-loading cast, to ensure that they can work every day. The role of the FPT as an educator and patient advocate is crucial in ensuring

patient compliance, which will reduce the risk of re-occurrence of diabetic foot complications.

Not every individual with diabetic foot disease can be looked after within secondary care and so a large support network in the community is essential is helping to manage these patients at home, and avoid un-necessary admissions.

The Multidisciplinary Team

Each hospital trust should have a named foot care MDT. It is difficult to delineate exactly whether this team needs to be "actual," where all members meet regularly, or "virtual," with an ability to put the right clinicians into the right environment at the right time for the individual patient. The team should include diabetologists, accident and emergency (A&E) consultants, vascular surgeons, orthopaedic and/or plastic surgeons, diagnostic and interventional radiologists, podiatrists/podiatric surgeons, microbiologist, tissue viability nurses (or nurses with knowledge and experience of wound dressing), diabetes specialist nurses, orthotists, physiotherapists, plaster technicians and rehabilitation specialists. The MDT should have access to the advice and skills of other professionals, including medical photography. Within the MDT, there should be a named clinical lead, who most frequently is a diabetologist by trade, but this will vary on the individual team and their availability.

In 2011, the National Diabetes Inpatient Audit (NaDIA) found that 75 hospital sites (40.5 %) did not have a multidisciplinary team comprising a diabetologist with expertise in lower limb complications, a surgeon with expertise in managing diabetic foot problems, a diabetes specialist nurse, a specialist podiatrist and a tissue viability nurse. There had been no improvement from the previous year [9].

Referral criteria and referral pathways should be documented clearly and made accessible for the FPT, primary care practitioners and other non-specialists throughout the catchment area. A dedicated telephone and/or fax referral service

should be available [10]. Referrals can be reviewed and directed onwards to the appropriate MDT discipline to be seen in the appropriate time period.

The sign-posting of the services of the multi-disciplinary team is of great significance, and the Diabetes UK patient information leaflets provide a space for this information to be documented. A&E staff must be aware of the needs of patients with diabetic foot complications and of the need for rapid intervention. The inclusion of the A&E consultant is crucial to ensuring patients are not referred appropriately to secondary care and then turned away by inexperienced front-line staff.

Commissioners should demand agreed service standards for the MDT, with an outcome framework implemented to reduce amputation rates and diabetic foot complications. This will reduce overall healthcare spending, as complex diabetic foot complications are increasingly high-cost. Early intervention in diabetic foot complications reduces the number of secondary care admissions and therefore bed occupancy, thereby reducing cost.

The Foot Care Pathway

This is essential in providing a framework for care that can be shared by all professionals, patients and carers. The framework needs to take into consideration that the diabetic foot or the foot attack may have many aetiologies as well as treatment pathways. The most important concept is that the patient is treated within the right skill-set and right time-frame for their needs.

Patients with a foot attack or active foot disease need to be assessed rapidly. The guidelines suggest a review within one working day of presentation. This is often interpreted as a referral within one working day. It is more practical that the degree of urgency of referral is discussed with a specialist within the FPT or MDT within 24–48 h. This will allow triaging of the foot ulcer in context of other risk factors and co-morbidities. This

service needs to be accessible 7 days a week. This may be difficult to deliver within existing foot care services without the involvement of A&E staff (in the MDT), who are already commissioned as a 24-h, 7-day service.

The causative factors in the development of a foot attack or ulceration may be pressure or trauma; however, this can be compounded by infection, ischaemia, neuropathy or any combination of these. The competencies of the specialists will enable safe care plans to be implemented. A full assessment of the feet on presentation to an MDT clinician should include the assessments as outlined in Table 16.1.

The patient may simply require offloading, as their footwear may have compromised the skin. The combination of education, new footwear, and the off-loading of pressure from the ulcerated site will allow the foot to heal. Even with significant neuropathy this approach will allow healing without intervention. This will require skills from podiatry, orthotics and may require biomechanical assessment to understand why the ulcer has occurred.

The presence of a foot deformity, callus or a previous fracture may increase forces exerted at particular pressure points (most commonly on the plantar aspect). The intervention of skilled podiatrists or plaster technicians will allow off-loading in custom or non-custom footwear. Onward referral to ortho-

Table 16.1 Essential assessments during the foot attack

1. Inspection for structural foot deformity
2. A comprehensive neurological assessment of the foot
3. A comprehensive vascular assessment including Doppler waveform analysis, ankle brachial, toe brachial pressure index calculation and/or radiological imaging of the lower limb vasculature
4. Foot x-ray or MRI of the foot
5. Examination of footwear
6. Assessment of sepsis

paedic or podiatric surgeon for structural correction will allow healing, reduce long-term risks and reduce complications.

Ulceration in a limb with compromised arterial inflow is a surgical emergency. It should be recognised and managed as such. It is essential that the vascular status of any limb suffering a foot attack is interrogated to assess the inflow to the foot. This may be classified as macrovascular or microvascular disease. Any suggestion of vascular compromise must prompt urgent specialist vascular assessment. Critical limb ischaemia in a patient with diabetes is indicated if the toe pressures are <50 mmHg or ABPI <0.7. A non-healing ulcer or an ulcer associated with rest pain would indicate a need for radiological or surgical revascularisation. This decision will be made in conjunction with the patient, carers and MDT, as this decision needs to restore quality of life whilst also being associated with a favourable risk: benefit ratio. An immobile patient requiring hoisting with limited quality of life may gain some benefit from a prolonged revascularisation attempt but may benefit more from an amputation. These decisions are complex and are best made within a well-governed MDT.

It is important to remember that symptomatic varicose veins or the significant swelling after deep venous thrombosis will also increase the risk of ulceration, often secondary to poorly-fitting footwear. These patients may need venous intervention or management with compression hosiery. These need to be fitted correctly, as mal-fitting compression hosiery can lead to further foot deformities.

The patient presenting with a Charcot joint is hard to diagnose without a high degree of suspicion. It is often confused with an infected foot or a deep vein thrombosis. It is absolutely essential that these patients are rapidly assessed with the MDT to allow stabilisation of the deteriorating mid- or forefoot. This may take several months and needs on-going education and advice from the specialist team.

The addition of infection to a diabetic foot or neuroischaemic foot compounds the problem. Urgent debridement and drainage of pus reduces the risk of gangrene and gas

gangrene within the plantar space and thereby reduces the risk of amputation. The surgical toilette needs to happen with 24–48 h, as any delay results in increasing tissue loss, reducing the likelihood of salvaging a viable foot.

A foot x-ray or MRI will allow differentiation of soft tissue infection or osteomyelitis. Broad-spectrum antibiotics within locally agreed antibiotic guidelines should be commenced promptly. Pus, tissue or bone samples will direct further antibiotic therapy with culture and sensitivities. These patients often need further debridement, which may be undertaken by a competent clinician from a variety of disciplines: podiatric, vascular, orthopaedic or general surgery. These patients need regular review of their wounds and microbiology results. The presence of osteomyelitis may be an indication for a minor or major amputation if associated with significant tissue loss. The level at which this amputation is planned should be determined via an MDT discussion (including physiotherapy and rehabilitation teams). This should be at a level that is best suited to the individual's long-term mobility, whilst balancing the need to debride non-viable tissues with a margin.

Osteomyelitis may also be treated with antibiotics and this regime will be planned with the advice of microbiology specialists. These may be given intravenously and this can be facilitated in the community with shared-care protocols via a PICC (peripherally inserted central catheter) line. This affords a degree of independence for a patient who could otherwise require admission for the duration of treatment (6–8 weeks in total). Significant debridement needs to be undertaken by a clinician with the competencies, knowledge of associated anatomical structures and understanding of post-operative lower limb function. It is essential that the coverage of the debrided area is considered and this may occur through primary or secondary closure. This may necessitate a discussion with plastic surgery services. The wider availability of skin and tissue substitutes has allowed early coverage of diabetic foot amputation sites and wounds and therefore earlier return to normality.

Table 16.2 ALS foot

Remember: ALS for the Foot
Aetiology: Understand the underlying aetiology of the Foot Attack and prevent further disease progression
Life Threat: Ensure survival of the individual and long term protection
Salvage of the limb: Ensure limb salvage with functionality
Foot: Prevent contralateral foot disease

Although care and management are focused around the presenting problem (i.e. the acute foot problem), the MDT acts in a holistic fashion, treating the whole individual, rather than just the affected extremity. The mnemonic "ALS Foot" prompts clinicians to consider each of the domains outlined in Table 16.2.

Patients need to be assessed holistically and educated that the "Foot Attack" should be considered as the equivalent of a Myocardial Infarction. Aggressive risk management should be implemented, not only to treat this event, but to modify risk factors to prevent further episodes. Patients discharged from MDT care should be made known to the FPT and should be given the correct advice with leaflets to prevent re-admission. It is essential that on-going audit of all outcomes is undertaken and adverse results regularly discussed within the team.

Key Points

- Evidence suggests that the integrated, structured diabetic foot care pathway requires a dedicated FPT and MDT to deliver a clinically and financially effective service.
- Seamless work between the FPT and MDT, between primary and secondary care, is essential to the success of the foot care pathway.

- MDTs facilitate the provision of prompt assessment and intervention by the required disciplines when patients present with foot attacks.
- The thorough assessment during a foot attack includes that of the foot itself (structural, neurological, vascular, radiological and footwear) and that of the individual (remembering ALS foot).
- Major amputations, and their associated morbidity and mortality, can be avoided by early recognition and treatment of diabetic foot problems, with the help of the FPT and the foot care MDT.

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