Preventing amputation in people with diabetes

Robert Hinchliffe

Professor Vascular Surgery, Bristol NIHR BRC and North Bristol NHS Trust

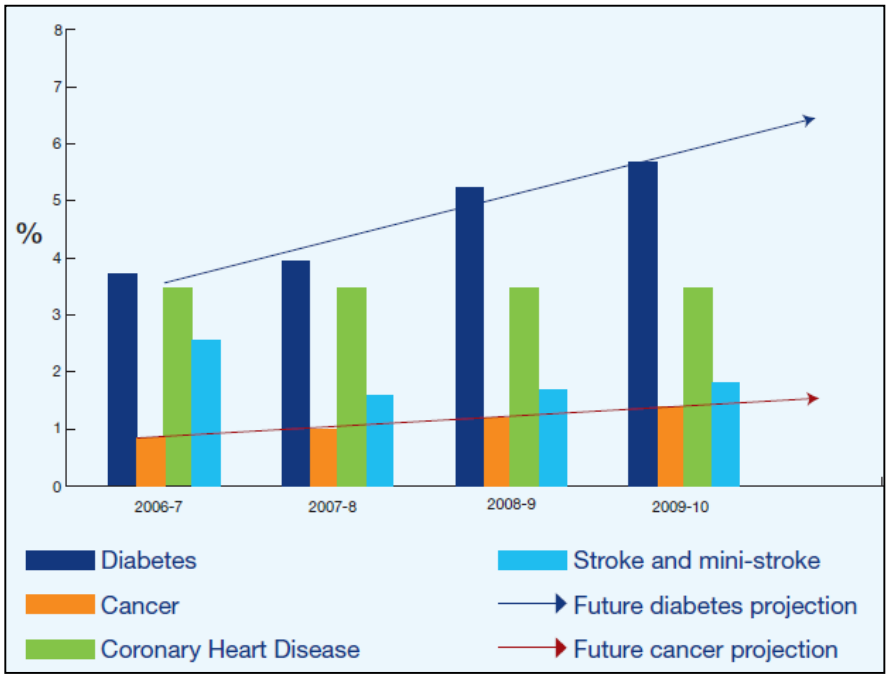
North Bristol NHS Trust

University of BRISTOL

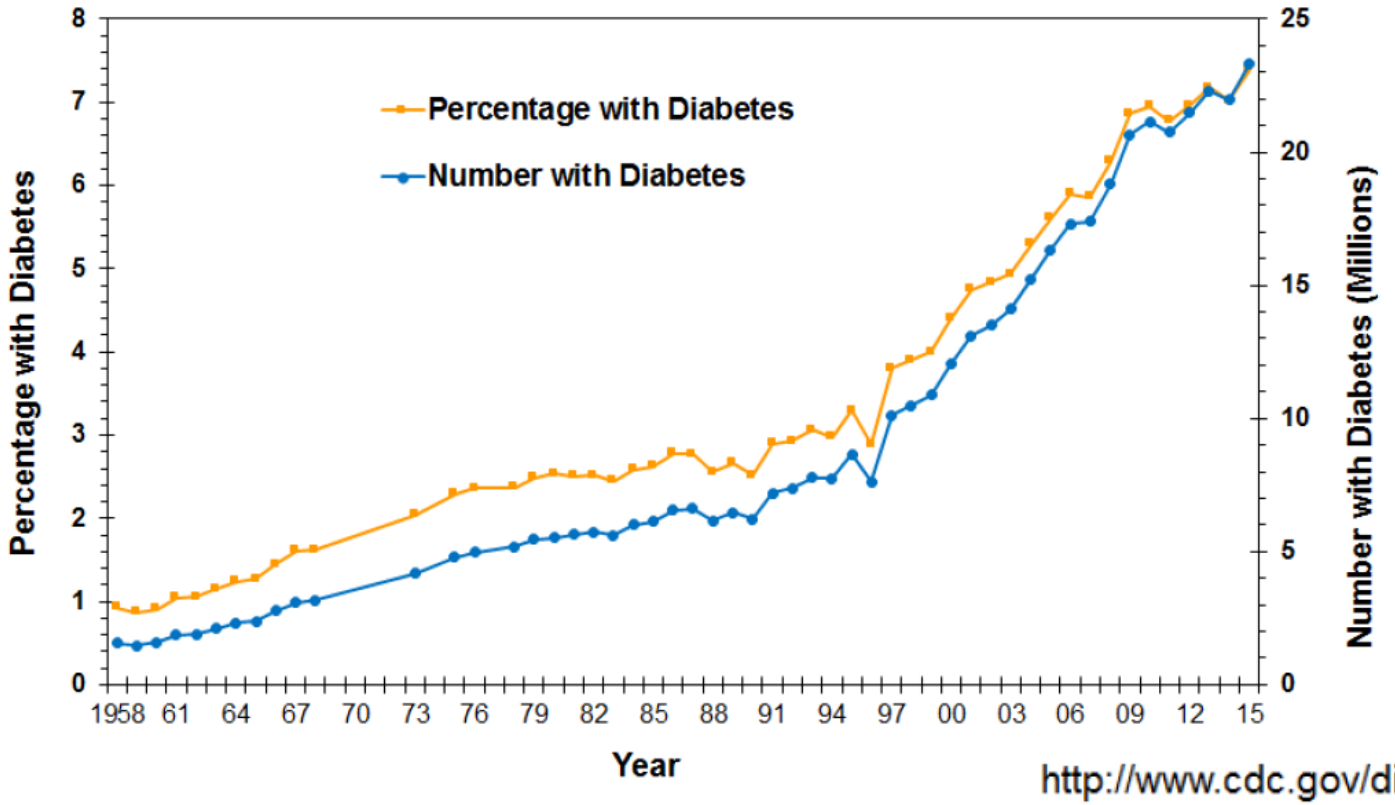
Amputation Prevention in Diabetes

- Epidemiology of diabetes / foot disease
- Natural history
- Local and national strategies / pathways
- Evidence to underpin clinical practice
- Expanding limb salvage options

Epidemiology Diabetes



Epidemiology Diabetes



http://www.cdc.gov/diabetes/data

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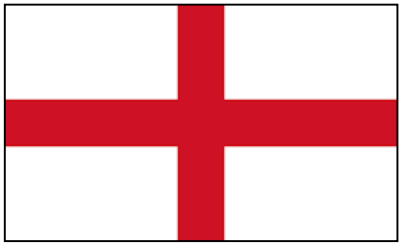
“Record levels of diabetes-related amputations” (Diabetes UK)



2016

8.1 major per 10,000 diabetes

2013

9.1 major per 10,000 diabetes

2008

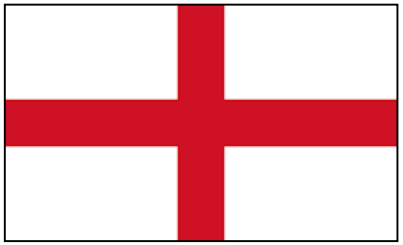
11.1 major per 10,000 diabetes

2004

18.7 major per 10,000 diabetes

Diabetes Care. 2012;35:2588-90

“Record levels of diabetes-related amputations” (Diabetes UK)



2016

21 minor per 10,000 diabetes

2013

19.5 minor per 10,000 diabetes

2008

10.3 minor per 10,000 diabetes

2004

11.7 minor per 10,000 diabetes

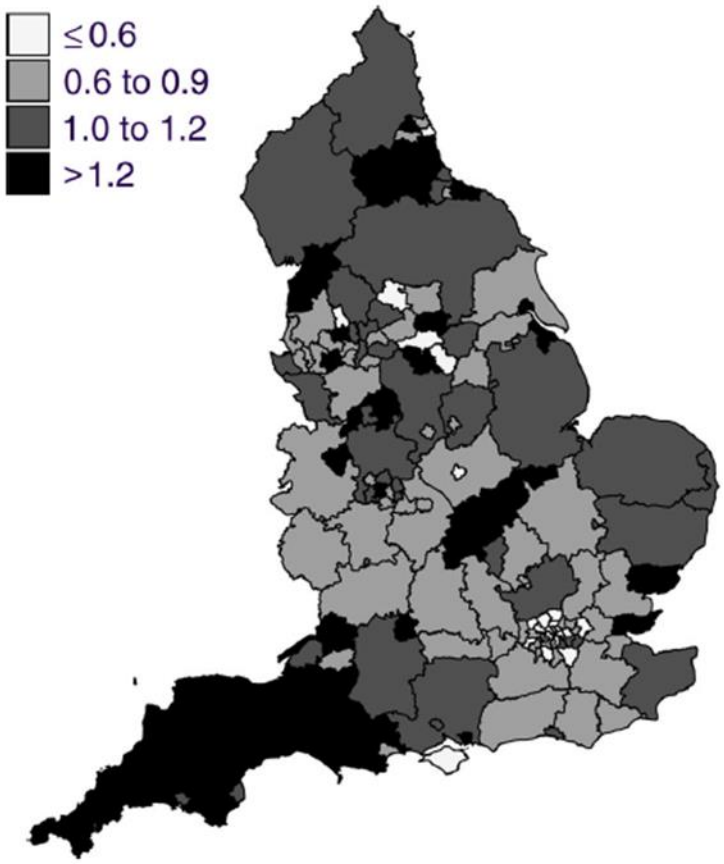
Diabetes Care. 2012;35:2588-90

Scottish Diabetes

- Recording of foot screening
- Patient information nationally
- Risk Stratification Triage System
- CPR for Feet campaign
- On line training programmes to support the implementation of CPR for Feet
- Bespoke SCI-Diabetes Ulcer Management System
- Data collection across Scotland

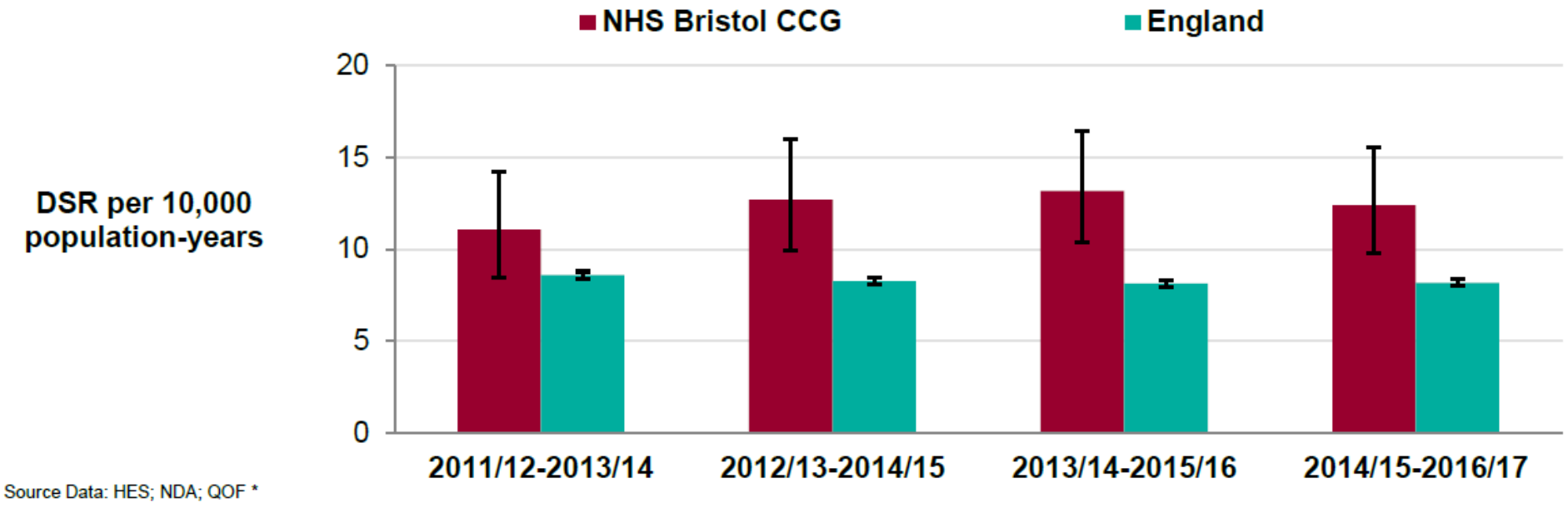
Regional Variation

- 8 fold variation
- Reasons unknown
- Organisation / access care
- Variations in clinical practice
- Commissioning services
- Clinical guidelines



Holman, Diabetologia. 2012;55:1919-25

Public Health England
Diabetic Footcare Profile



Source Data: HES; NDA; QOF *

National Diabetic Foot Audit

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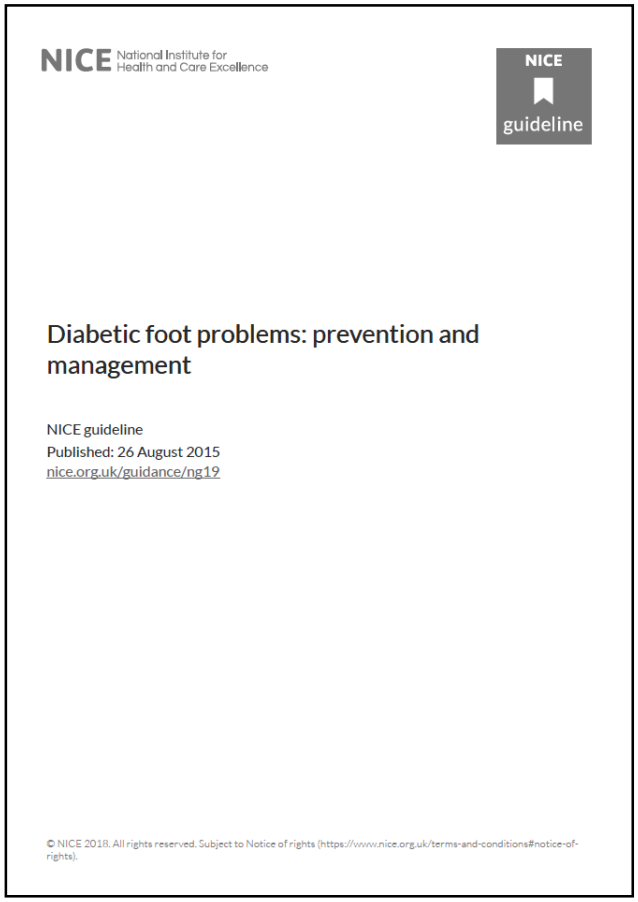
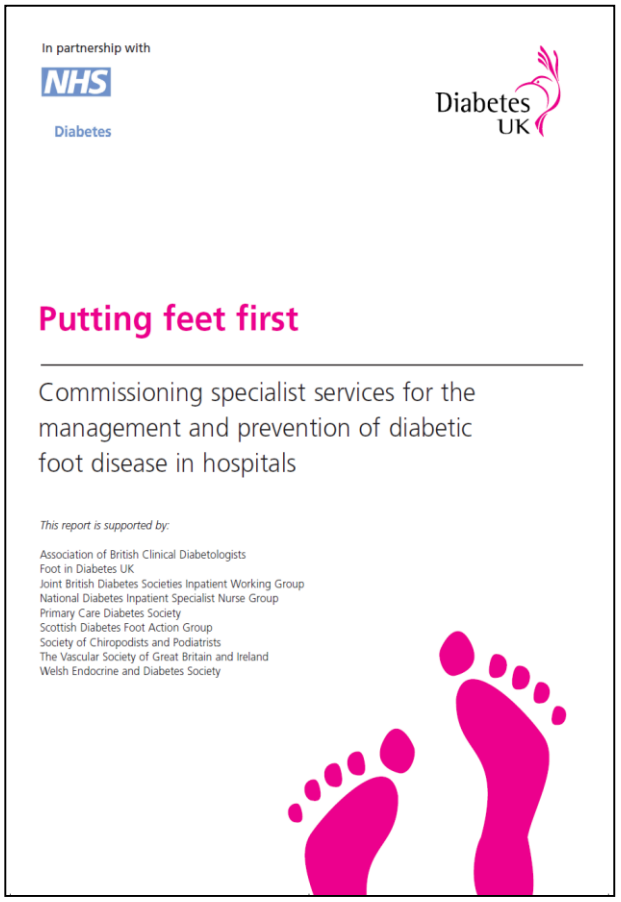
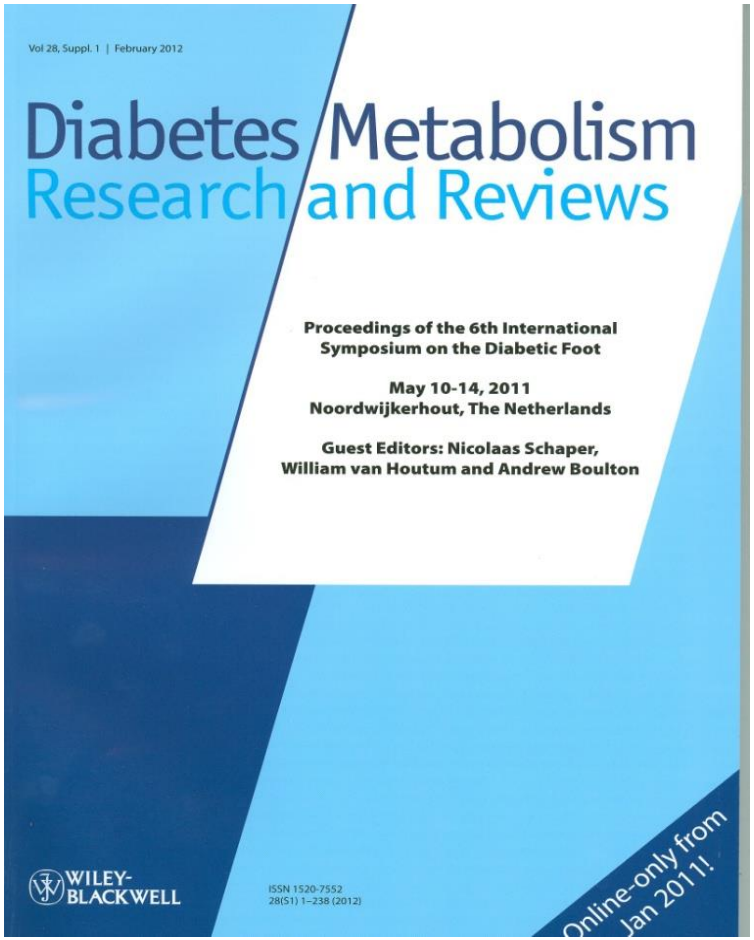
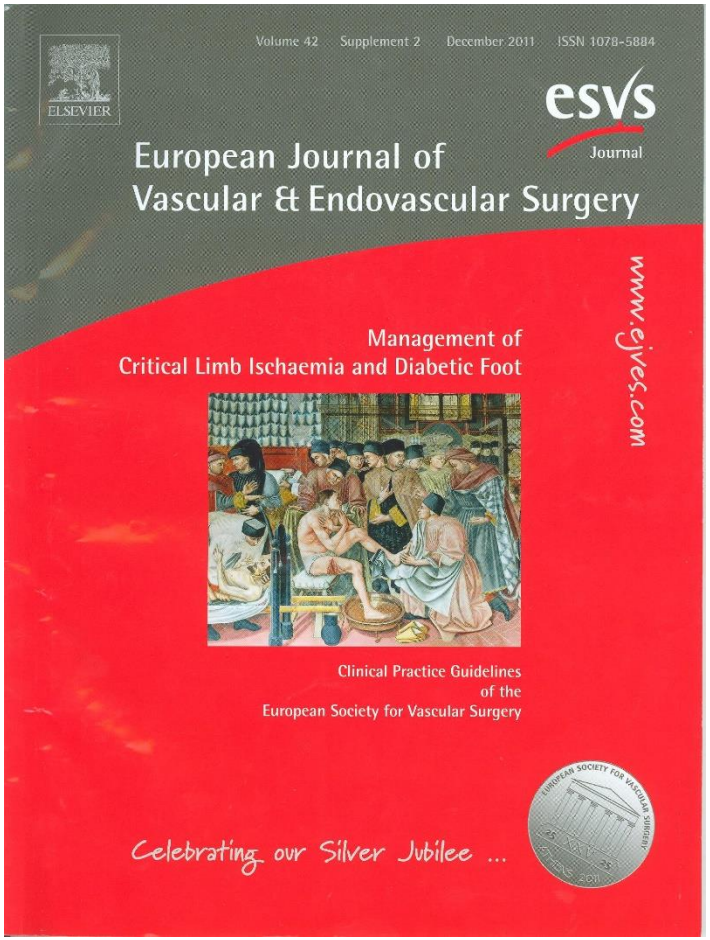
Clinical and commissioning guidance





International guidance





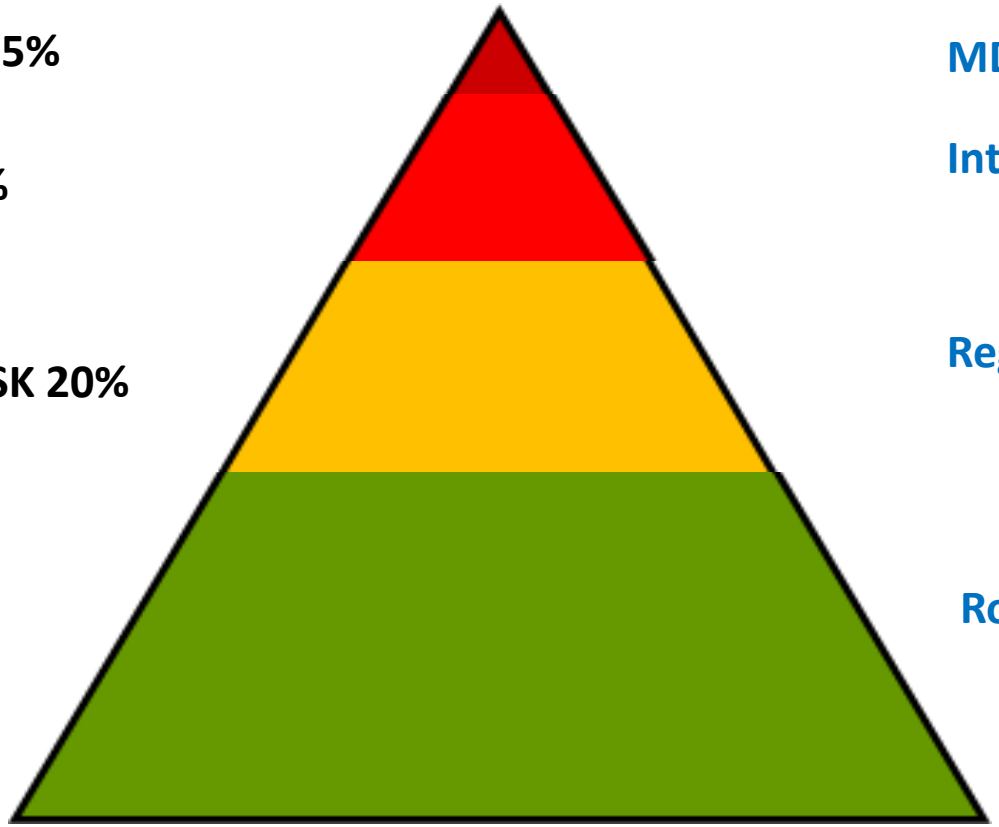
Scale of the problem

ACTIVE ULCER 5%

HIGH RISK 15%

INCREASED RISK 20%

LOW RISK 60%



MDT foot clinic

Intensive foot protection

Regular foot protection

Routine annual screen

Identification of those at risk

- **Low risk (normal pulses, normal sensation)**

Yearly review in primary care (QOF)

- **Increased risk (absent pulses or abnormal sensation)**

Refer to community podiatry (6 monthly review)

- **High risk (absent pulses AND sensation / prev ulcer)**

Refer to community podiatry (3 monthly review)

- **Ulcer**

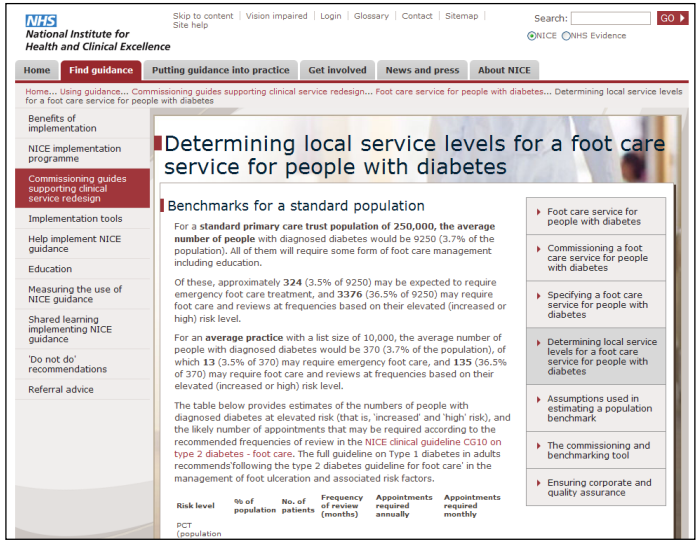
Referral within 24hours to hospital diabetes foot clinic

Diabet Med. 2018;35:1480-1493

Benchmarks for a standard population (NICE 2010)

Average Vascular Unit 800,000

- Diabetes 52,800 (6.6%)
- 1,848 (3.5% of 52,800) emergency foot care **5 EVERY DAY**
- 19,272 (36.5% of 52,800) community podiatry



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Structure & Process of Care

- 82% type 2 diabetes annual foot check
- 85% CCGs providing foot protection pathway
- 80% hospital sites with MDT foot clinic

https://www.nice.org.uk/guidance/NG19/uptake

Structure & Process of Care

- 67% CCGs provide a pathway for foot assessment within 24 hours
- 15% active foot problems referred to a specialist and assessed within 2 days
- 64% foot risk assessment <24 hours admission

https://www.nice.org.uk/guidance/NG19/uptake

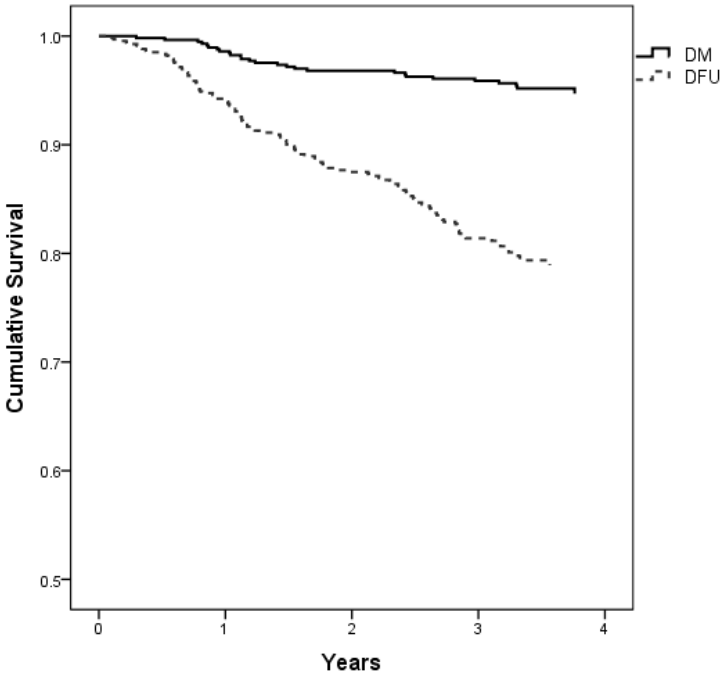
Where is the problem?

"the crucial barrier to diabetic foot care is delay in accessing specialist care"

Diabet Med. 2018;35:1072-1077

Effect of quality of medical care

- Aggressive cardiovascular risk factor management
- Before CV intervention
  5 year mortality 48%
- After CV intervention
  5 year mortality 27%



Brownrigg. J Vasc Surg. 2014;60:982-6
Young. Diabetes Care 2008;31:2143-7

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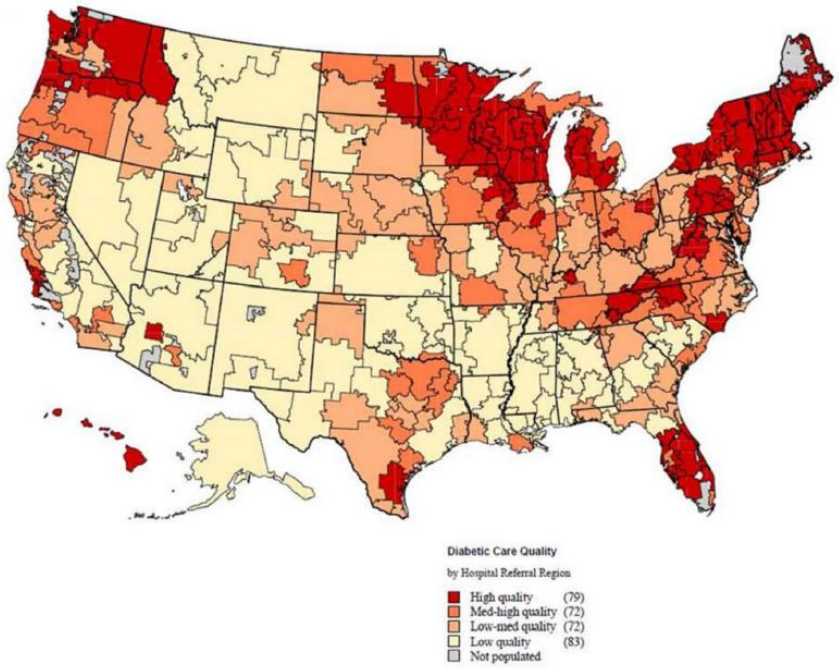
Provision of care in the US

- Regional variations in quality of care in US

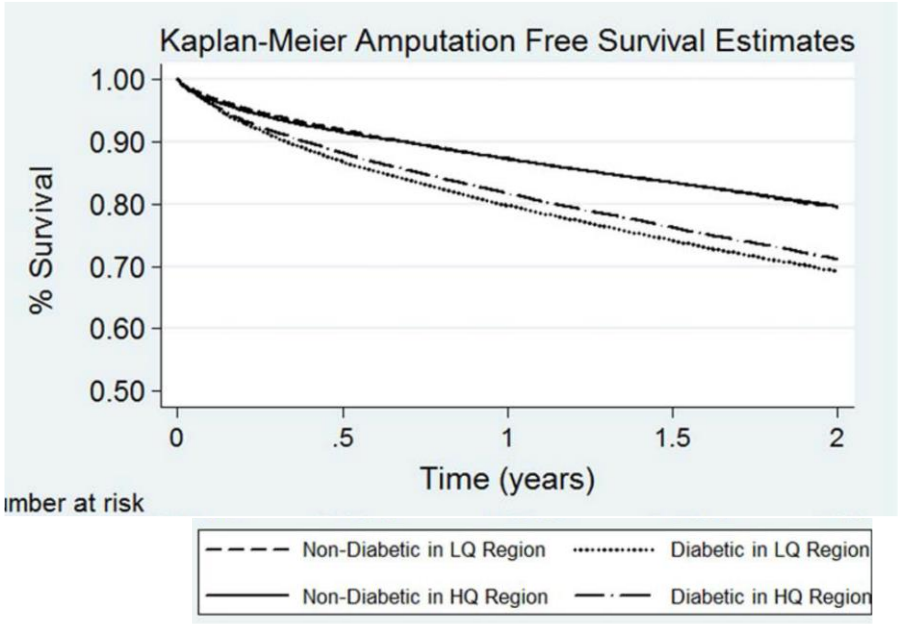
- Revascularisation rates associated with ↓amputation rates ?????



Ann Vasc Surg. 2014;28:1719–1728

Post revascularisation care

- Regional variations in quality of care in US
- Revascularisation rates associated with ↓amputation rates ?????
- Good care structures associated with ↑amputation free survival post bypass



Ann Vasc Surg. 2014;28:1719–1728

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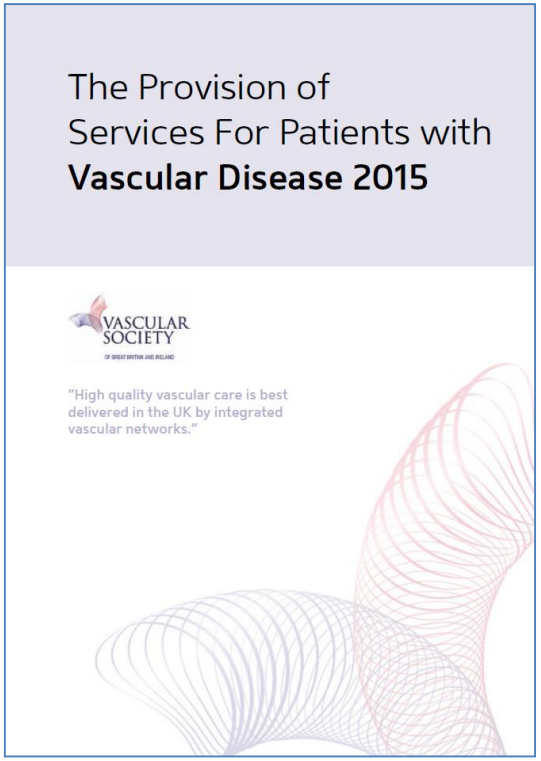
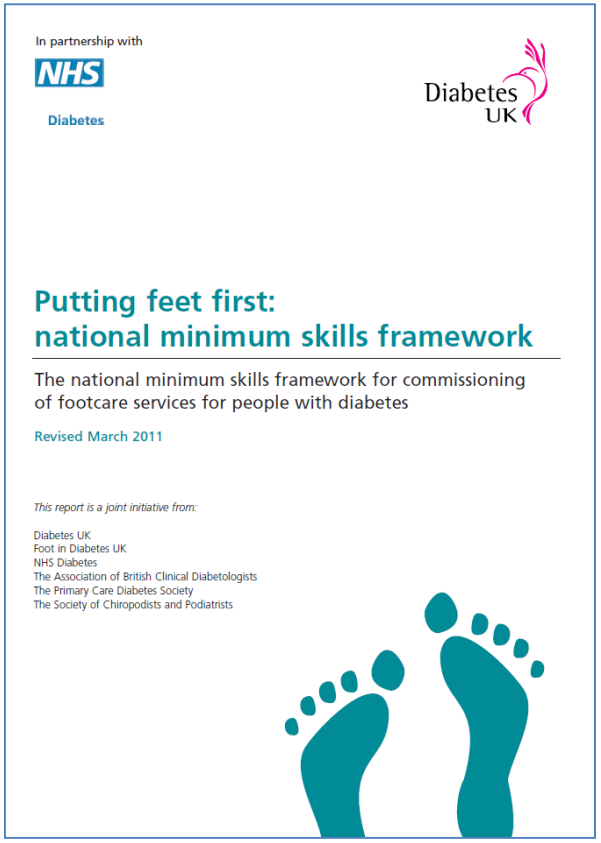
Vascular Surgery role in the diabetic foot

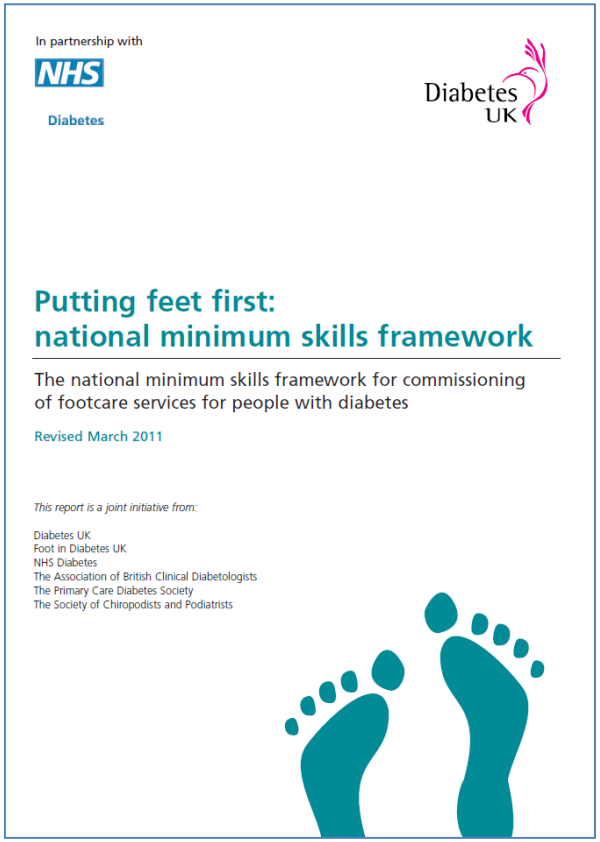
- Revascularisation
- Debridement & amputation
- Part of the MDT
- *“the specialists involved will be determined by local interest / expertise”*



National Minimum Skills Framework



National Minimum Skills Framework



In partnership with

NHS Diabetes

Diabetes UK

Putting feet first: national minimum skills framework

The national minimum skills framework for commissioning of footcare services for people with diabetes

Revised March 2011

This report is a joint initiative from:

Diabetes UK
Foot in Diabetes UK
NHS Diabetes
The Association of British Clinical Diabetologists
The Primary Care Diabetes Society
The Society of Chiropodists and Podiatrists

DDG
Deutsche Diabetes Gesellschaft

Urkunde

Diabetes Zentrum Dr. Tews
Herzbachweg 14E
63571 Gelnhausen

wurde entsprechend der Richtlinien der Deutschen Diabetes Gesellschaft als

Ambulante Behandlungseinrichtung für Patienten mit Typ 1 und Typ 2 Diabetes Zertifiziertes Diabeteszentrum DDG

durch Vorstandsbeschluss anerkannt.

Die Einrichtung ist berechtigt, die Bezeichnung vom 15.12.2015 bis zum 15.12.2018 zu führen.

12.01.2016

Prof. Dr. med. Baptist Gallwitz
Präsident der Deutschen Diabetes-Gesellschaft

Prof. Dr. med. K.-D. Palitzsch
Vorsitzender des Ausschusses Qualitätssicherung, Schulung und Weiterbildung

Size and nature of the problem

"It is likely that the great increase in the number of patients with diabetes over the next decade will have the biggest impact on vascular services. Many of these patients present as an emergency, and are at high risk of amputation. Prompt treatment of the infected diabetic foot and revascularisation, if required, can minimise the risk of subsequent amputation."

POVS 2015

Size of the problem vascular units

- 800,000 population
- 350-400 patients with CLTI every year per *(POVS 2015)*
- 52800 diabetes (6.6% population)
- 3168 DFU patients (6% incidence)
- 1584 with PAD and DFU per year (50% PAD)
- 4 every day

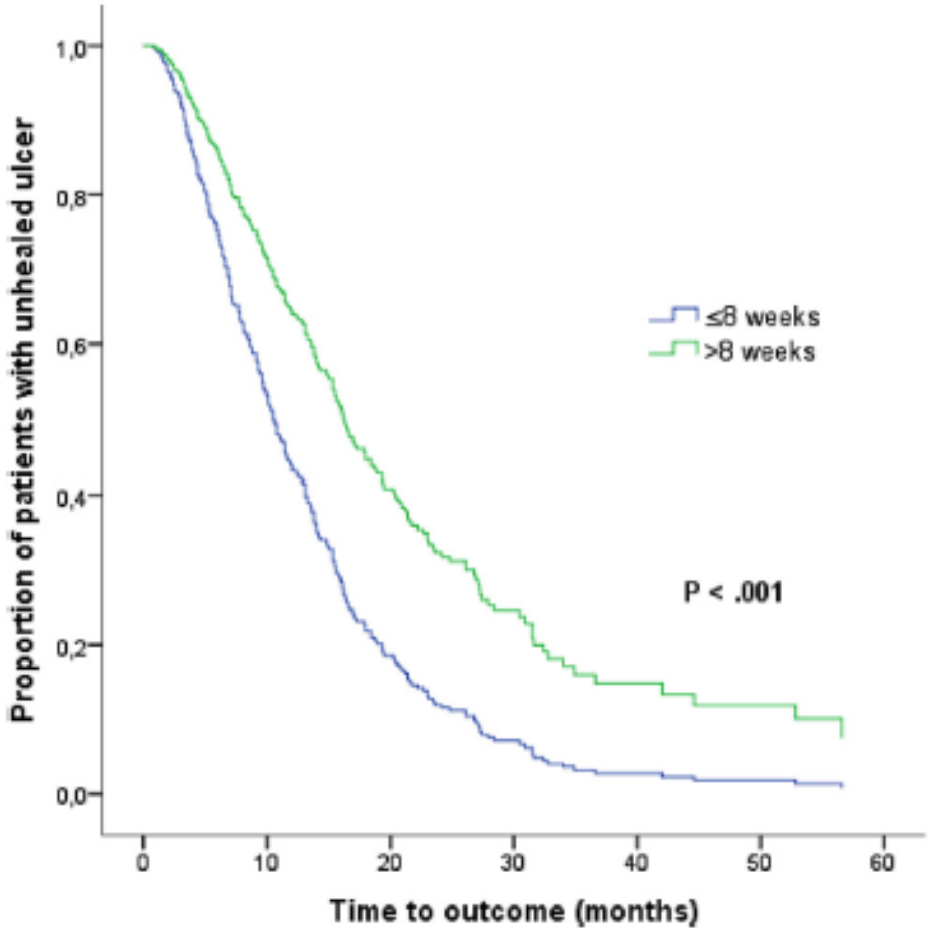
N Engl J Med. 2017;376:2367-2375

Vascular Capacity and Organisation

Endovascular				Bypass		
Year	No. of procs	% bilateral	% elective	No. of procs	% bilateral	% elective
2009	16,345	9.7	76.6	4,337	6.7	65.0
2010	16,500	9.6	76.8	4,581	7.2	65.0
2011	16,988	9.4	77.0	4,396	6.4	66.8
2012	17,214	8.3	75.7	4,248	7.1	66.3
2013	17,179	7.8	74.0	4,314	6.6	64.7

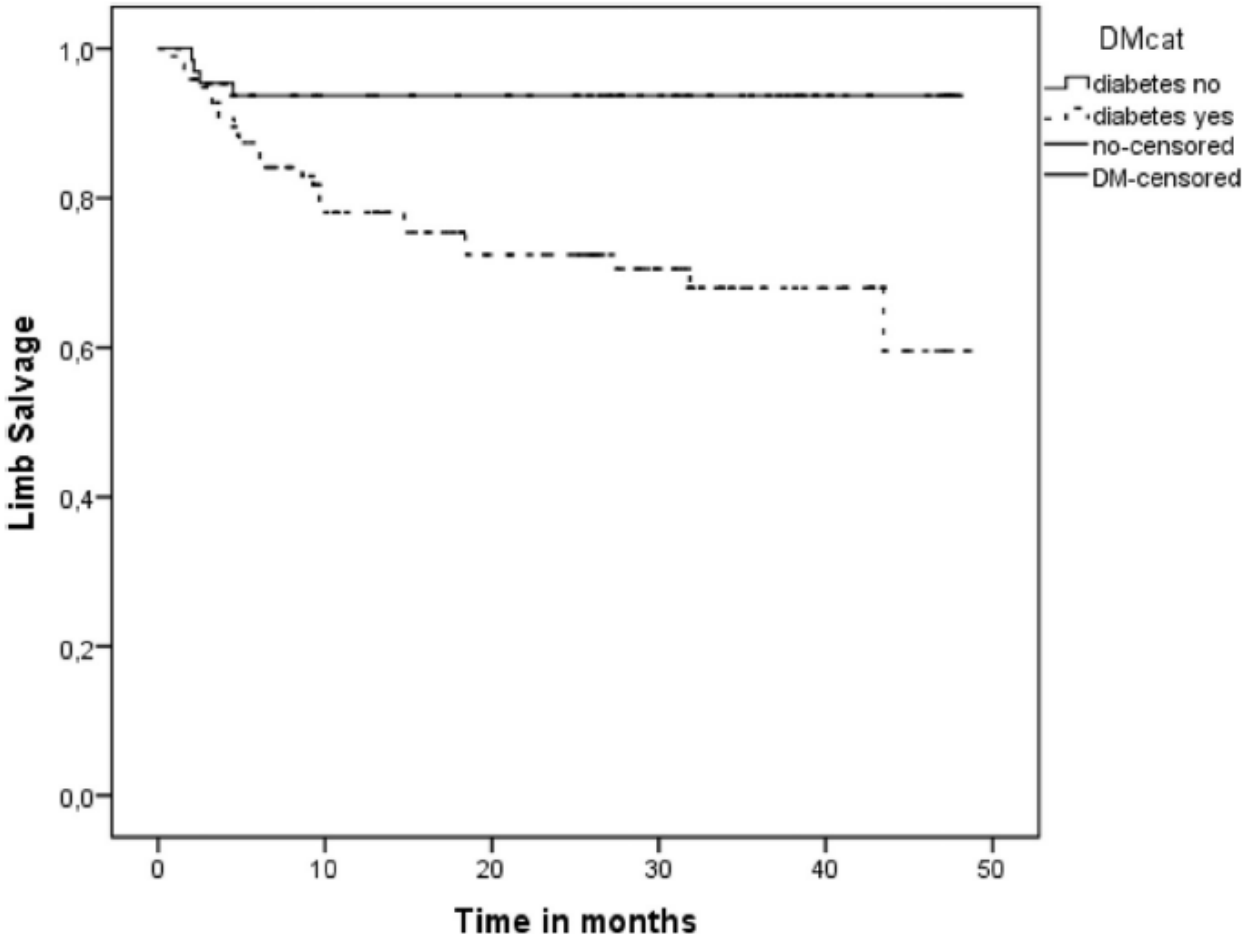
POVS 2015

Early revascularisation – wound healing



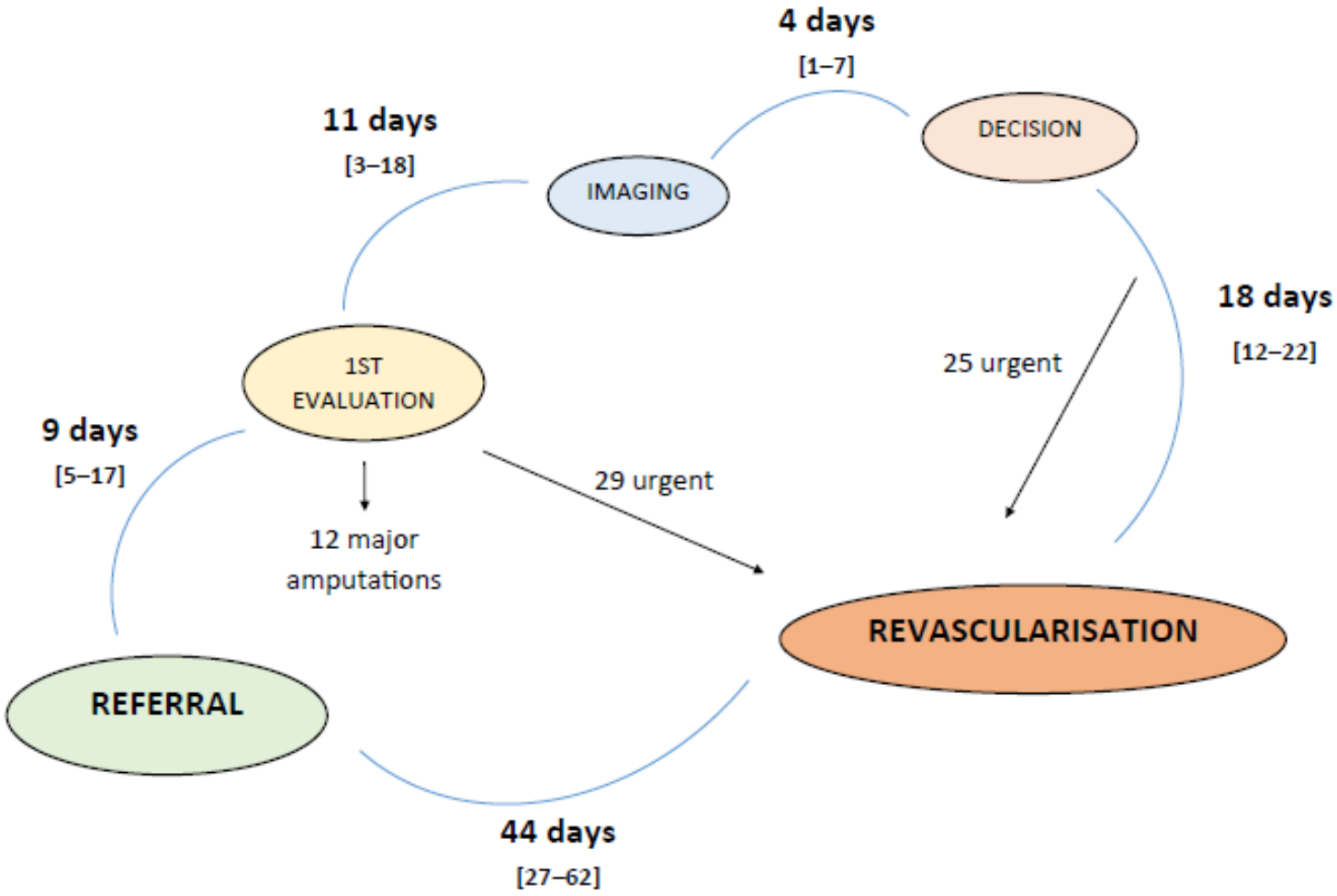
Eur J Vasc Endovasc Surg. 2014;48:440-6

Limb salvage: revascularisation >2 weeks



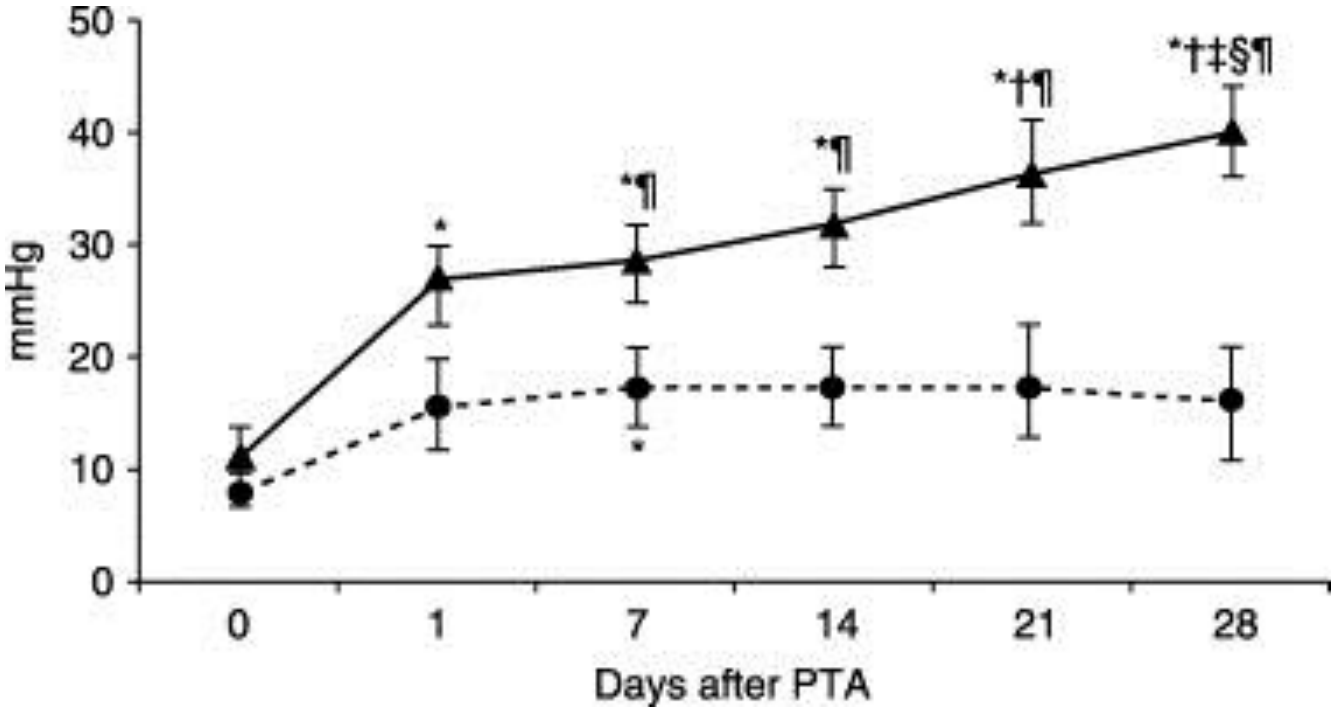
Eur J Vasc Endovasc Surg. 2017;53:206-213

Practical delay common



Eur J Vasc Endovasc Surg. 2017;53:206-213

Perfusion post revascularisation



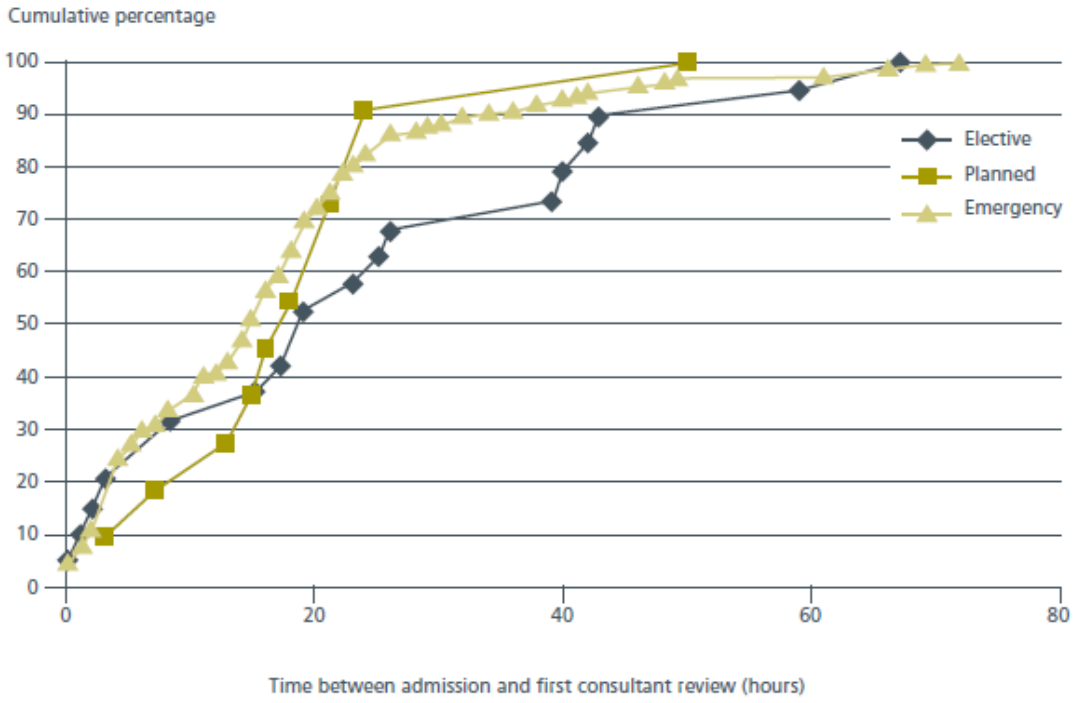
Successful revascularisation group ▲

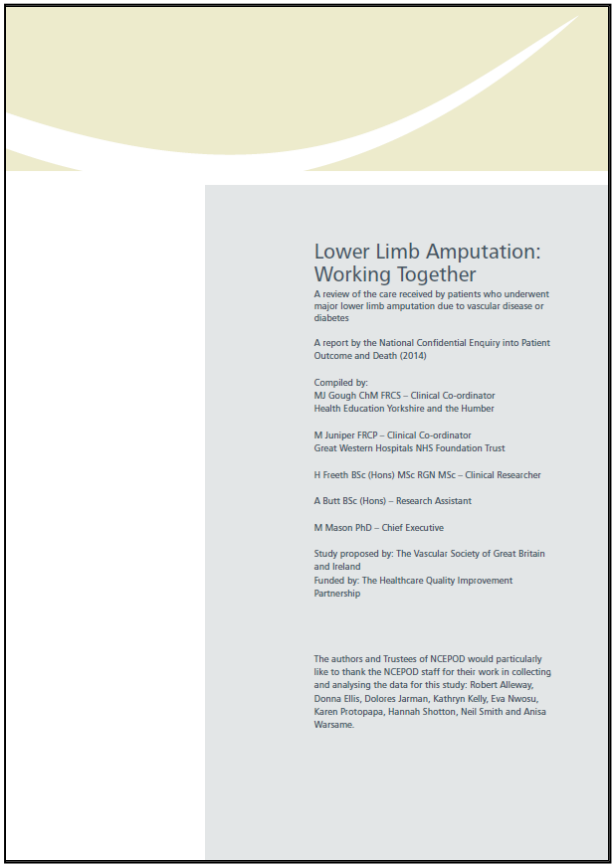
Unsuccessful •

Diabet Med. 2005;22:460-5

Delays to review?

Consultant review within 12-14 hours: 42%





Lower Limb Amputation: Working Together

A review of the care received by patients who underwent major lower limb amputation due to vascular disease or diabetes

A report by the National Confidential Enquiry into Patient Outcome and Death (2014)

Compiled by:
MJ Gough ChM FRCS – Clinical Co-ordinator
Health Education Yorkshire and the Humber

M Juniper FRCP – Clinical Co-ordinator
Great Western Hospitals NHS Foundation Trust

H Freeth BSc (Hons) MSc RGN MSc – Clinical Researcher

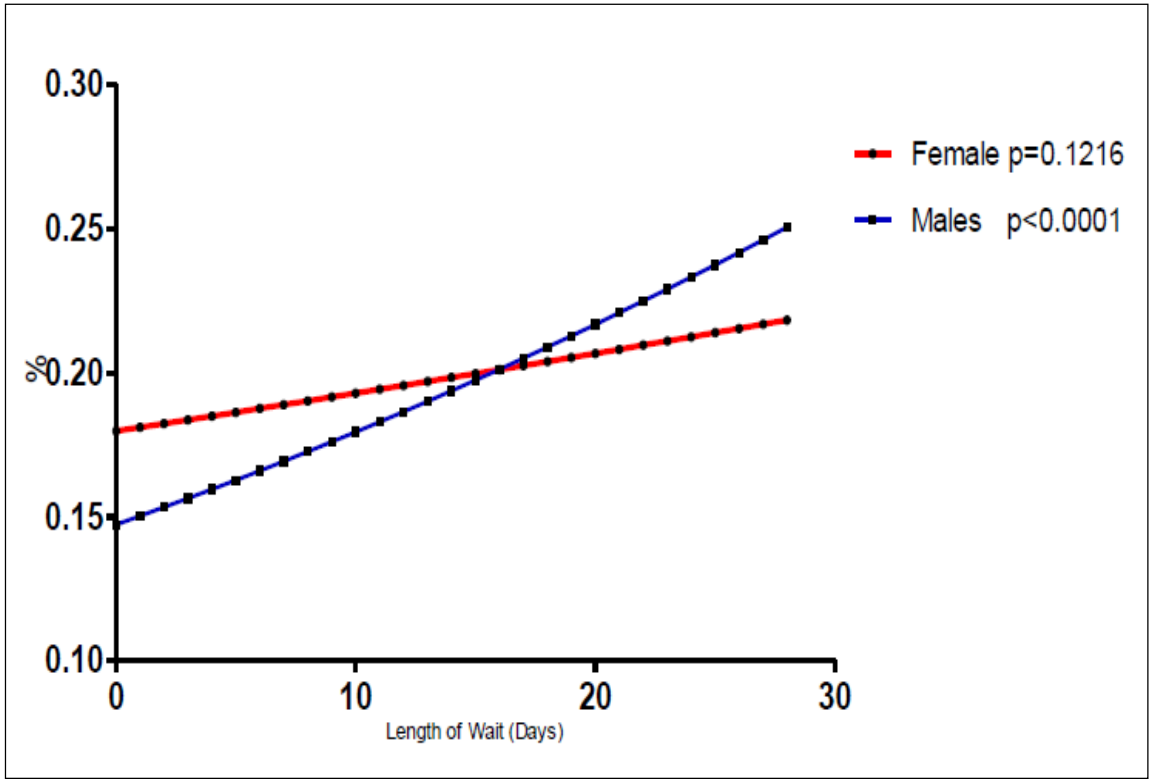
A Butt BSc (Hons) – Research Assistant

M Mason PhD – Chief Executive

Study proposed by: The Vascular Society of Great Britain and Ireland
Funded by: The Healthcare Quality Improvement Partnership

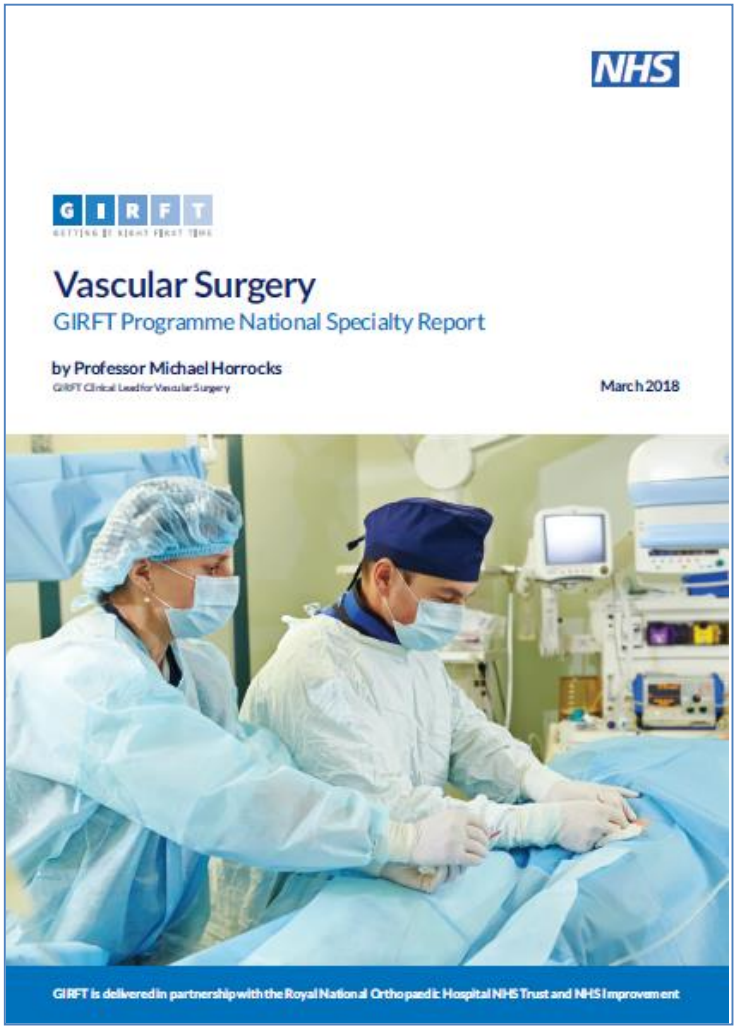
The authors and Trustees of NCEPOD would particularly like to thank the NCEPOD staff for their work in collecting and analysing the data for this study: Robert Alleway, Donna Ellis, Dolores Jarman, Kathryn Kelly, Eva Nwosu, Karen Protopapa, Hannah Shotton, Neil Smith and Anisa Warsame.

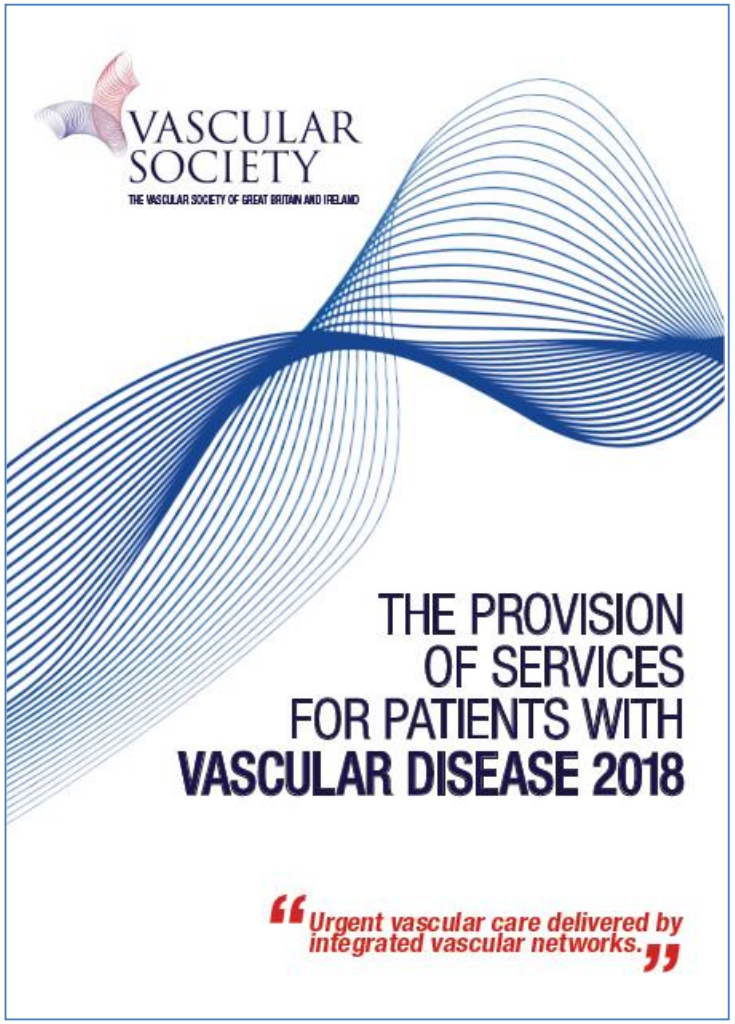
Major amputation



England in-hospital amputation mortality following major amputation

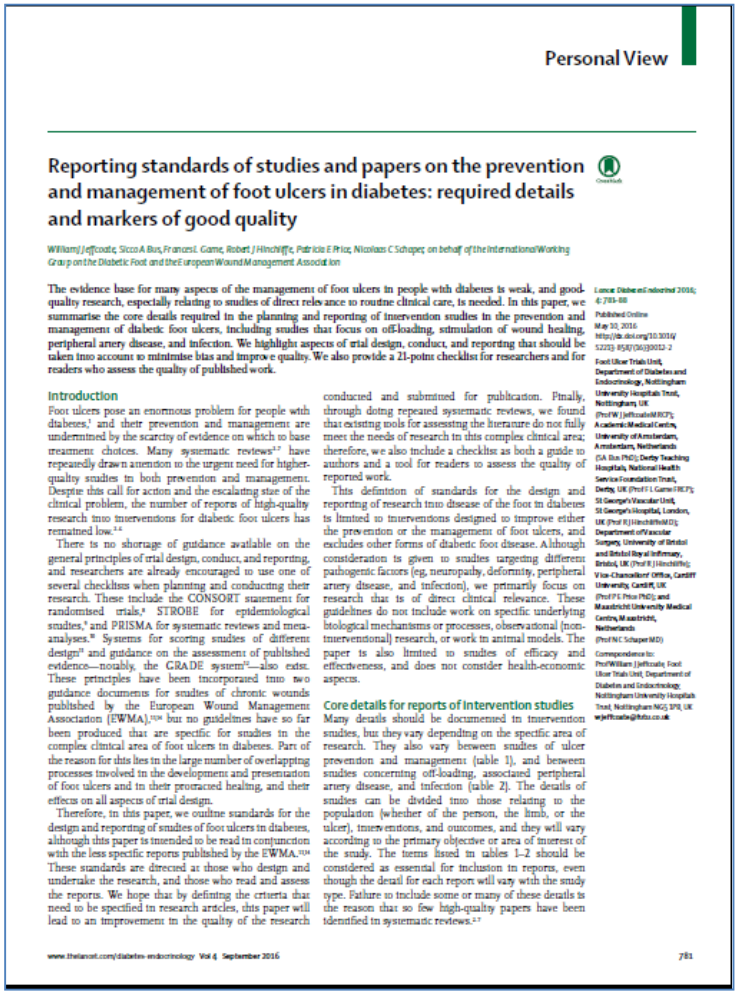
Eur J Vasc Endovasc Surg. 2012;44:485-90


NHS
GIRFT
Vascular Surgery
GIRFT Programme National Specialty Report
by Professor Michael Horrocks
GIRFT Clinical Lead for Vascular Surgery
March 2018
GIRFT is delivered in partnership with the Royal National Orthopaedic Hospital NHS Trust and NHS Improvement


VASCULAR SOCIETY
THE VASCULAR SOCIETY OF GREAT BRITAIN AND IRELAND
THE PROVISION OF SERVICES FOR PATIENTS WITH VASCULAR DISEASE 2018
"Urgent vascular care delivered by integrated vascular networks."

Evidence for vascular interventions

- Low quality studies
- Small / no blinding
- Report diabetes separately
- No reporting standards
- No core outcome set



Personal View

Reporting standards of studies and papers on the prevention and management of foot ulcers in diabetes: required details and markers of good quality

William J Jeffcoate, Sicco A Bus, Francesl. Game, Robert J Hinchliffe, Patricia E Price, Nicolaas C Schaper, on behalf of the International Working Group on the Diabetic Foot and the European Wound Management Association

The evidence base for many aspects of the management of foot ulcers in people with diabetes is weak, and good-quality research, especially relating to studies of direct relevance to routine clinical care, is needed. In this paper, we summarise the core details required in the planning and reporting of intervention studies in the prevention and management of diabetic foot ulcers, including studies that focus on off-loading, stimulation of wound healing, peripheral artery disease, and infection. We highlight aspects of trial design, conduct, and reporting that should be taken into account to minimise bias and improve quality. We also provide a 21-point checklist for researchers and for readers who assess the quality of published work.

Lancet Diabetes Endocrinol 2016; 4: 781–88

Published Online May 30, 2016 http://dx.doi.org/10.1016/S2213-8587(16)30012-2

Foot Ulcer Trials Unit, Department of Diabetes and Endocrinology, Nottingham University Hospitals Trust, Nottingham, UK (Prof W J Jeffcoate MCRT); Academic Medical Centre, University of Amsterdam, Amsterdam, Netherlands (SA Bus PhD); Derby Teaching Hospitals, National Health Service Foundation Trust, Derby, UK (Prof F L Game FRCP); St George's Vascular Unit, St George's Hospital, London, UK (Prof R J Hinchliffe MD); Department of Vascular Surgery, University of Bristol and Bristol Royal Infirmary, Bristol, UK (Prof R J Hinchliffe); Vice-Chancellors' Office, Cardiff University, Cardiff, UK (Prof P E Price PhD); and Maastricht University Medical Centre, Maastricht, Netherlands (Prof N C Schaper MD)

Correspondence to: Prof William J Jeffcoate, Foot Ulcer Trials Unit, Department of Diabetes and Endocrinology, Nottingham University Hospitals Trust, Nottingham NG5 1PB, UK wjeffcoate@hotmail.co.uk

Introduction

Foot ulcers pose an enormous problem for people with diabetes,[1] and their prevention and management are undermined by the scarcity of evidence on which to base treatment choices. Many systematic reviews[2–7] have repeatedly drawn attention to the urgent need for higher-quality studies in both prevention and management. Despite this call for action and the escalating size of the clinical problem, the number of reports of high-quality research into interventions for diabetic foot ulcers has remained low.[2,6]

There is no shortage of guidance available on the general principles of trial design, conduct, and reporting, and researchers are already encouraged to use one of several checklists when planning and conducting their research. These include the CONSORT statements for randomised trials,[8] STROBE for epidemiological studies,[9] and PRISMA for systematic reviews and meta-analyses.[10] Systems for scoring studies of different design[11] and guidance on the assessment of published evidence—notably, the GRADE system[12]—also exist. These principles have been incorporated into two guidance documents for studies of chronic wounds published by the European Wound Management Association (EWMA),[13,14] but no guidelines have so far been produced that are specific for studies in the complex clinical area of foot ulcers in diabetes. Part of the reason for this lies in the large number of overlapping processes involved in the development and presentation of foot ulcers and in their protracted healing, and their effects on all aspects of trial design.

Therefore, in this paper, we outline standards for the design and reporting of studies of foot ulcers in diabetes, although this paper is intended to be read in conjunction with the less specific reports published by the EWMA.[13,14] These standards are directed at those who design and undertake the research, and those who read and assess the reports. We hope that by defining the criteria that need to be specified in research articles, this paper will lead to an improvement in the quality of the research conducted and submitted for publication. Finally, through doing repeated systematic reviews, we found that existing tools for assessing the literature do not fully meet the needs of research in this complex clinical area; therefore, we also include a checklist as both a guide to authors and a tool for readers to assess the quality of reported work.

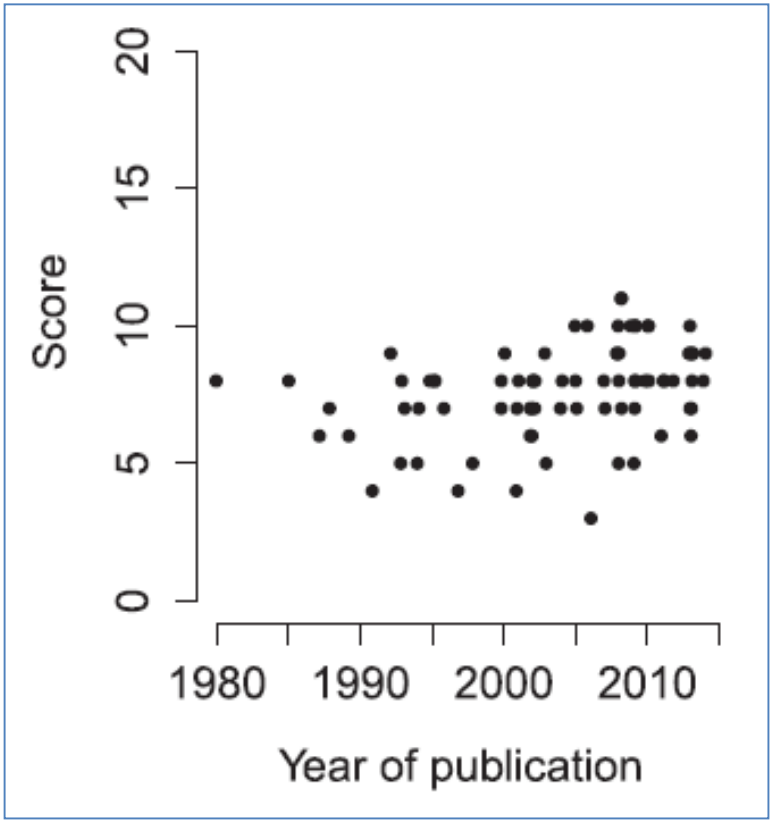
This definition of standards for the design and reporting of research into disease of the foot in diabetes is limited to interventions designed to improve either the prevention or the management of foot ulcers, and excludes other forms of diabetic foot disease. Although consideration is given to studies targeting different pathogenic factors (eg, neuropathy, deformity, peripheral artery disease, and infection), we primarily focus on research that is of direct clinical relevance. These guidelines do not include work on specific underlying biological mechanisms or processes, observational (non-interventional) research, or work in animal models. The paper is also limited to studies of efficacy and effectiveness, and does not consider health-economic aspects.

Core details for reports of intervention studies

Many details should be documented in intervention studies, but they vary depending on the specific area of research. They also vary between studies of ulcer prevention and management (table 1), and between studies concerning off-loading, associated peripheral artery disease, and infection (table 2). The details of studies can be divided into those relating to the population (whether of the person, the limb, or the ulcer), interventions, and outcomes, and they will vary according to the primary objective or area of interest of the study. The items listed in tables 1–2 should be considered as essential for inclusion in reports, even though the detail for each report will vary with the study type. Failure to include some or many of these details is the reason that so few high-quality papers have been identified in systematic reviews.[2–7]

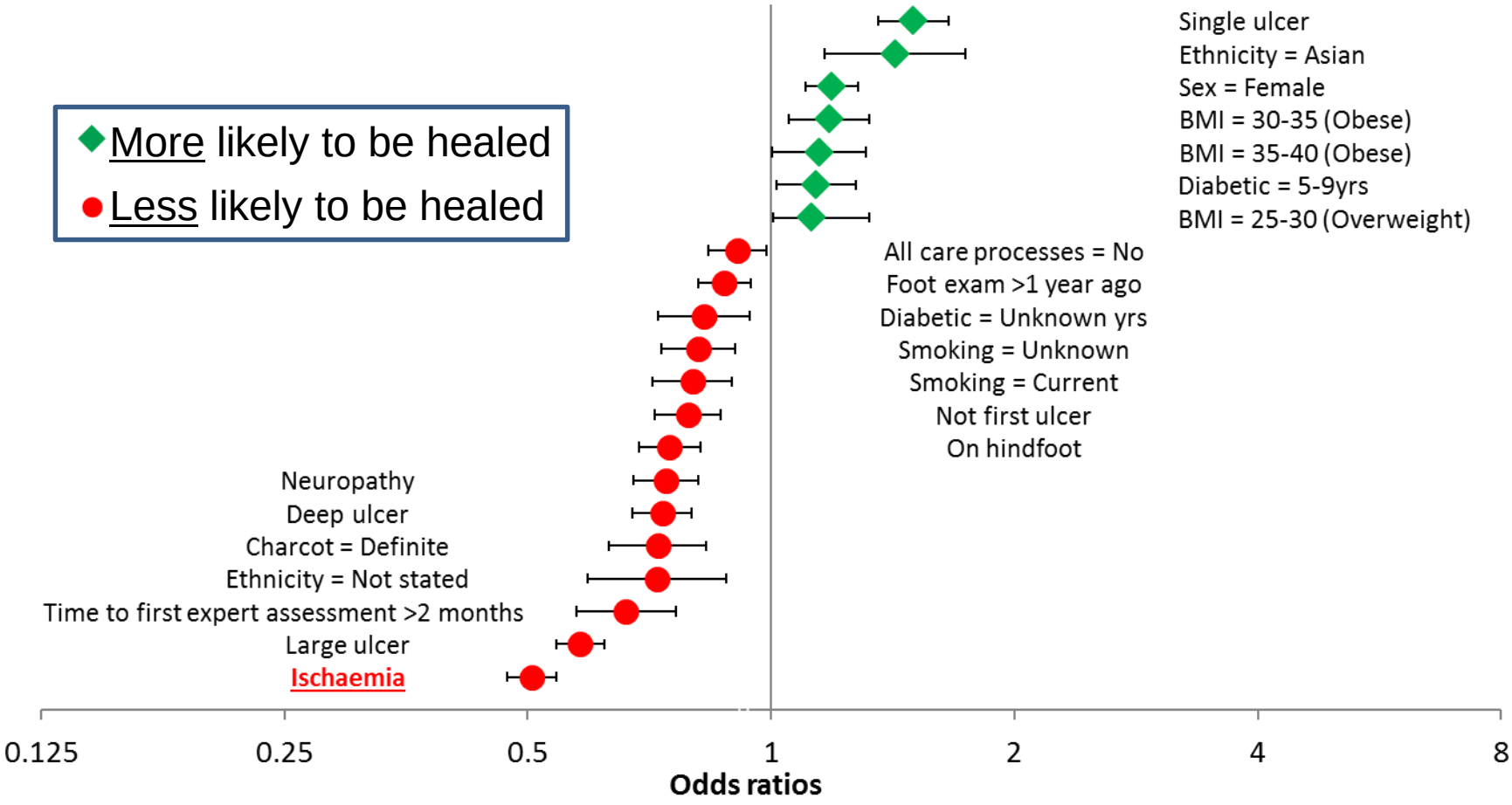
Quality of studies to inform clinical practice in diabetic foot and PAD

- Total score: 21
- Design
- Conduct
- Outcome
- Median score 8/21



Eur J Vasc Endovasc Surg. 2018;56:401-408

Factors associated with being alive and ulcer-free at 24 weeks (NDFA)



Who will benefit from revascularisation?

- Historical definition of CLI unhelpful
- PAD common (50%)
- Ulceration multi-factorial
- Crural disease

What proportion of patients with PAD and ulceration are revascularised?

- Eurodiale Study
- 14 experienced European centres
- >1,000 new DFU
- Clinical guidance / MDT

DIABETICMedicine

DOI: 10.1111/j.1464-5491.2008.02445.x

Original Article: Complications

Delivery of care to diabetic patients with foot ulcers in daily practice: results of the Eurodiale Study, a prospective cohort study

L. Prompers, M. Huijberts, J. Apelqvist*, E. Jude†, A. Piaggesi‡, K. Bakker§, M. Edmonds¶, P. Holstein**, A. Jirkovska††, D. Mauricio‡‡, G. R. Tennvall§§, H. Reike¶¶, M. Spraul***, L. Ucciolì†††, V. Urbancic‡‡‡, K. Van Acker§§§, J. Van Baal¶¶¶, F. Van Merode**** and N. Schaper

Division of Endocrinology, Department of Internal Medicine, University Hospital Maastricht, Maastricht, the Netherlands, *Department of Endocrinology, University of Malmö, Malmö, Sweden, †Diabetes Centre, Tameside General Hospital, Ashton under Lyne, UK, ‡U.O. Semplice Piede Diabetico, Dipartimento di Endocrinologia e Metabolismo, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy, §Chair IDF Consultative Section and International Working Group on the Diabetic Foot, Heemstede, the Netherlands, ¶Diabetic Department, Kings College Hospital, London, UK, **Copenhagen Wound Healing Centre, Bispebjerg Hospital, Copenhagen, Denmark, ††Diabetes Centre, Institute for Clinical and Experimental Medicine, Prague, Czech Republic, ‡‡Department of Endocrinology & Nutrition, Hospital de Sant Pau, Autonomous University of Barcelona, Spain, §§Swedish Institute for Health Economics (IHE), Lund, Sweden, ¶¶Innere Abteilung, Mariannen Hospital, Werl and ***Mathias-Spital, Diabetic Department, Rheine, Germany, †††Policlinico Tor Vergata, Department of Internal Medicine, Rome, Italy, ‡‡‡Department of Endocrinology, University Medical Centre, Ljubljana, Slovenia, §§§St Joseph Clinic, Department of Endocrinology, Borken, Belgium, ¶¶¶Department of Surgery, Twenteborg Ziekenhuis, Almelo and ****Department of Health Organization, Policy and Economics, Maastricht University, Maastricht, the Netherlands

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Abstract

Aims To determine current management and to identify patient-related factors and barriers that influence management strategies in diabetic foot disease.

Methods The Eurodiale Study is a prospective cohort study of 1232 consecutive individuals presenting with a new diabetic foot ulcer in 14 centres across Europe. We determined the use of management strategies: referral, use of offloading, vascular imaging and revascularization.

Results Twenty-seven percent of the patients had been treated for > 3 months before referral to a foot clinic. This varied considerably between countries (6–55%). At study entry, 77% of the patients had no or inadequate offloading. During follow-up, casting was used in 35% (0–68%) of the plantar fore- or midfoot ulcers. Predictors of use of casting were male gender, large ulcer size and being employed. Vascular imaging was performed in 56% (14–86%) of patients with severe limb ischaemia; revascularization was performed in 43%. Predictors of use of vascular imaging were the presence of infection and ischaemic rest pain.

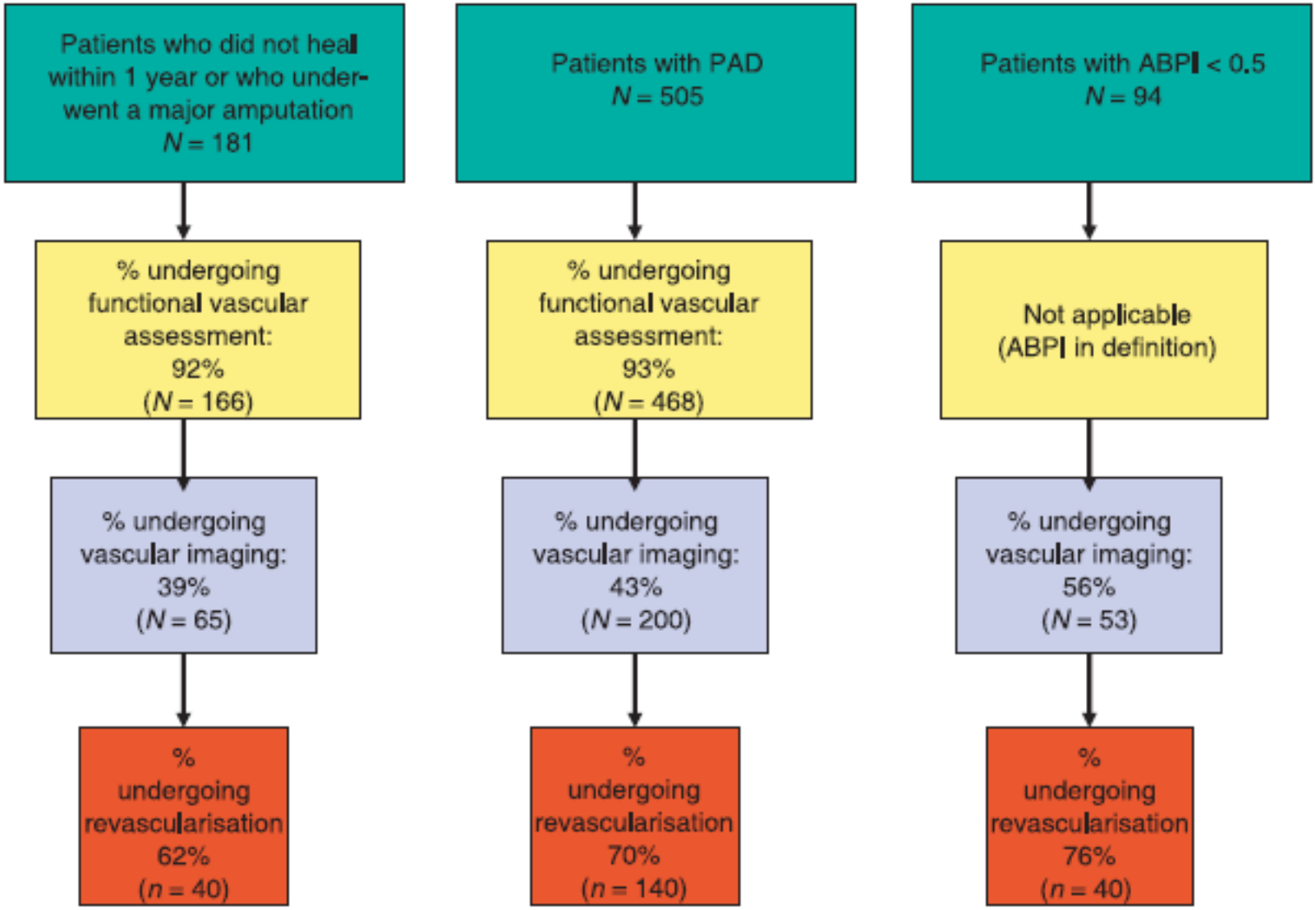
Conclusion Treatment of many patients is not in line with current guidelines and there are large differences between countries and centres. Our data suggest that current guidelines are too general and that healthcare organizational barriers and personal beliefs result in underuse of recommended therapies. Action should be undertaken to overcome these barriers and to guarantee the delivery of optimal care for the many individuals with diabetic foot disease.

Diabet. Med. 25, 700–707 (2008)

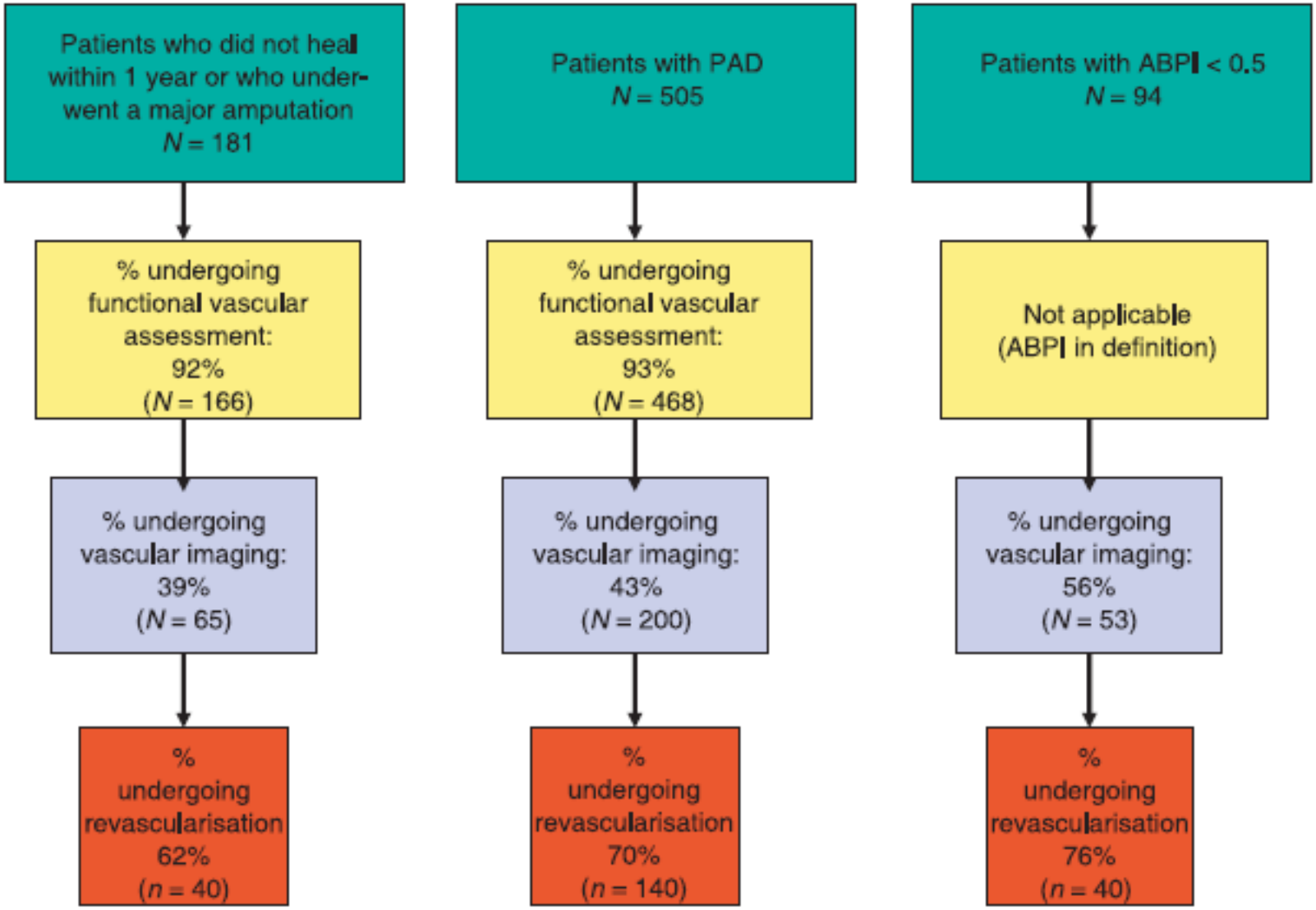
Keywords diabetic foot, PAD, infection, deliver of care

Abbreviations ABPI, ankle brachial pressure index; CRF, case record form; MRA, magnetic resonance angiography; PAD, peripheral artery disease; TCC, total contact casting

Correspondence to: Leonne Prompers, MD., Department of Internal Medicine, University Hospital Maastricht, P. Debeyelaan 25, PO Box 5800, 6202 AZ Maastricht, the Netherlands. E-mail: leonne.prompers@intmed.unimaas.nl



Diabet Med. 2008;25:700-7



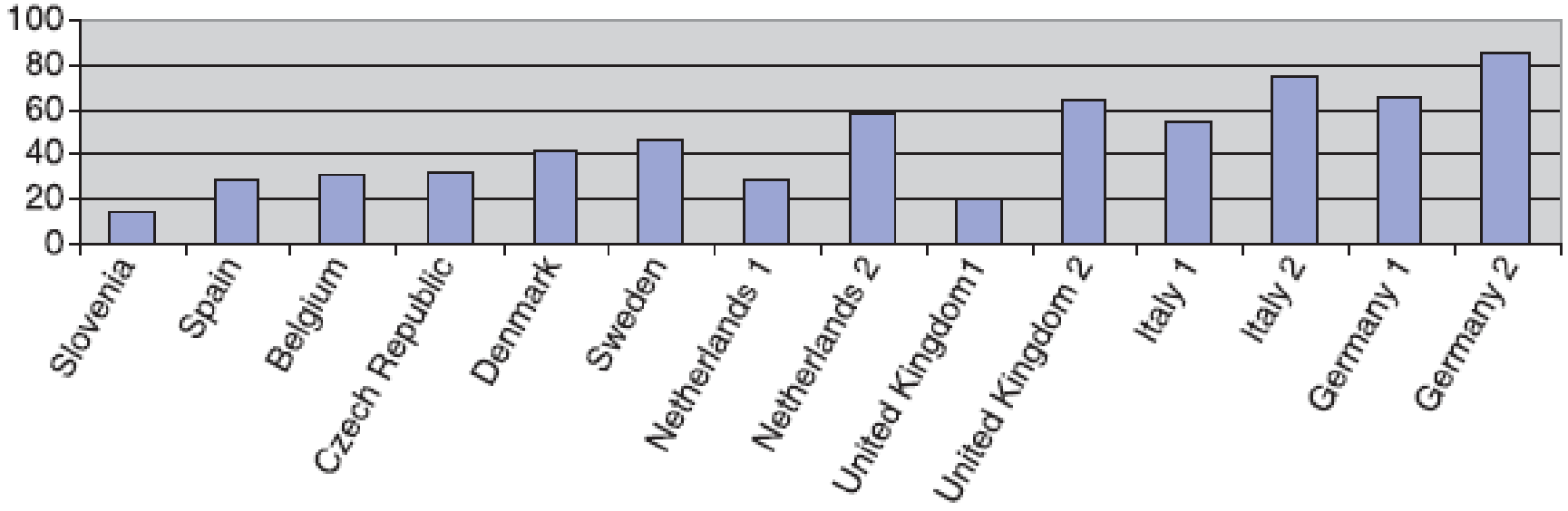
22%

28%

43%

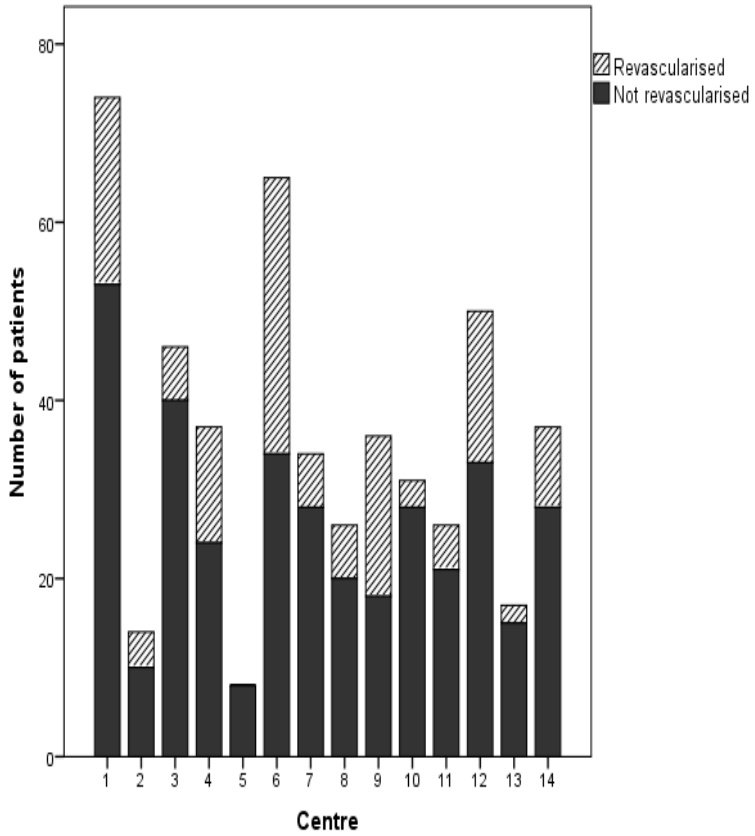
Diabet Med. 2008;25:700-7

Vascular imaging



Diabet Med. 2008;25:700-7

Variation in revascularisation rates



Diabet Med. 2008;25:700-7

North Bristol NHS Trust

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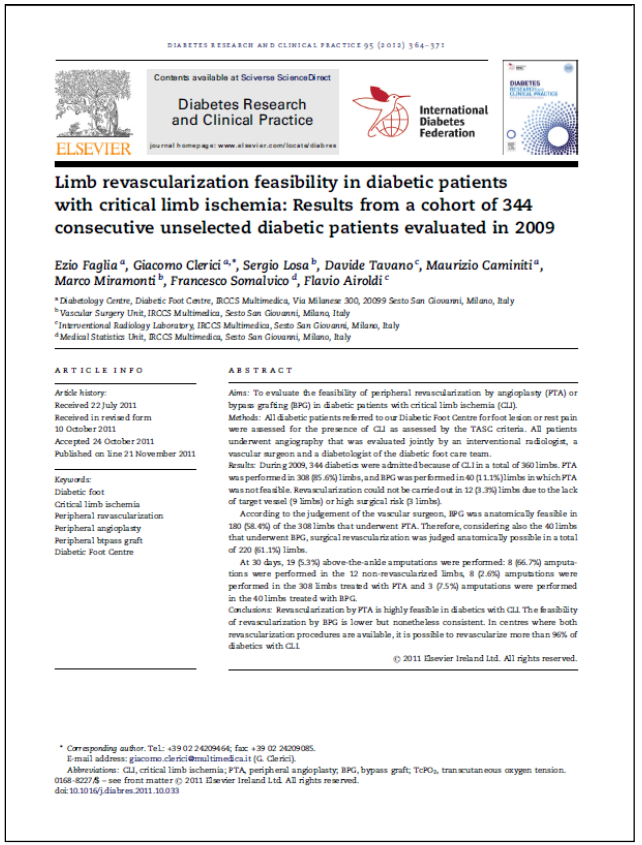
Variation

- Consecutive series
- 344 diabetes + CLI
- 97% revascularised
  (86% PTA, 11% bypass)



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International Diabetes Federation

Limb revascularization feasibility in diabetic patients with critical limb ischemia: Results from a cohort of 344 consecutive unselected diabetic patients evaluated in 2009

Ezio Faglia [a], Giacomo Clerici [a,], Sergio Losa [b], Davide Tavano [c], Maurizio Caminiti [a], Marco Miramonti [b], Francesco Somalvico [d], Flavio Airoldi [c]*

[a] Diabetology Centre, Diabetic Foot Centre, IRCCS Multimedica, Via Milanese 300, 20099 Sesto San Giovanni, Milano, Italy
[b] Vascular Surgery Unit, IRCCS Multimedica, Sesto San Giovanni, Milano, Italy
[c] Interventional Radiology Laboratory, IRCCS Multimedica, Sesto San Giovanni, Milano, Italy
[d] Medical Statistics Unit, IRCCS Multimedica, Sesto San Giovanni, Milano, Italy

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Diabetic Foot Centre

ABSTRACT

Aims: To evaluate the feasibility of peripheral revascularization by angioplasty (PTA) or bypass grafting (BPG) in diabetic patients with critical limb ischemia (CLI).
Methods: All diabetic patients referred to our Diabetic Foot Centre for foot lesion or rest pain were assessed for the presence of CLI as assessed by the TASC criteria. All patients underwent angiography that was evaluated jointly by an interventional radiologist, a vascular surgeon and a diabetologist of the diabetic foot care team.
Results: During 2009, 344 diabetics were admitted because of CLI in a total of 360 limbs. PTA was performed in 308 (85.6%) limbs, and BPG was performed in 40 (11.1%) limbs in which PTA was not feasible. Revascularization could not be carried out in 12 (3.3%) limbs due to the lack of target vessel (9 limbs) or high surgical risk (3 limbs).
According to the judgement of the vascular surgeon, BPG was anatomically feasible in 180 (58.4%) of the 308 limbs that underwent PTA. Therefore, considering also the 40 limbs that underwent BPG, surgical revascularization was judged anatomically possible in a total of 220 (61.1%) limbs.
At 30 days, 19 (5.3%) above-the-ankle amputations were performed: 8 (66.7%) amputations were performed in the 12 non-revascularized limbs, 8 (2.6%) amputations were performed in the 308 limbs treated with PTA and 3 (7.5%) amputations were performed in the 40 limbs treated with BPG.
Conclusions: Revascularization by PTA is highly feasible in diabetics with CLI. The feasibility of revascularization by BPG is lower but nonetheless consistent. In centres where both revascularization procedures are available, it is possible to revascularize more than 90% of diabetics with CLI.

* *Corresponding author.* Tel.: +39 02 2409464; fax: +39 02 2409085.
E-mail address: giacomo.clerici@multimedica.it (G. Clerici).

Abbreviations: CLI, critical limb ischemia; PTA, peripheral angioplasty; BPG, bypass graft; $TcPO_2$, transcutaneous oxygen tension.

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Prediction of revascularisation outcomes

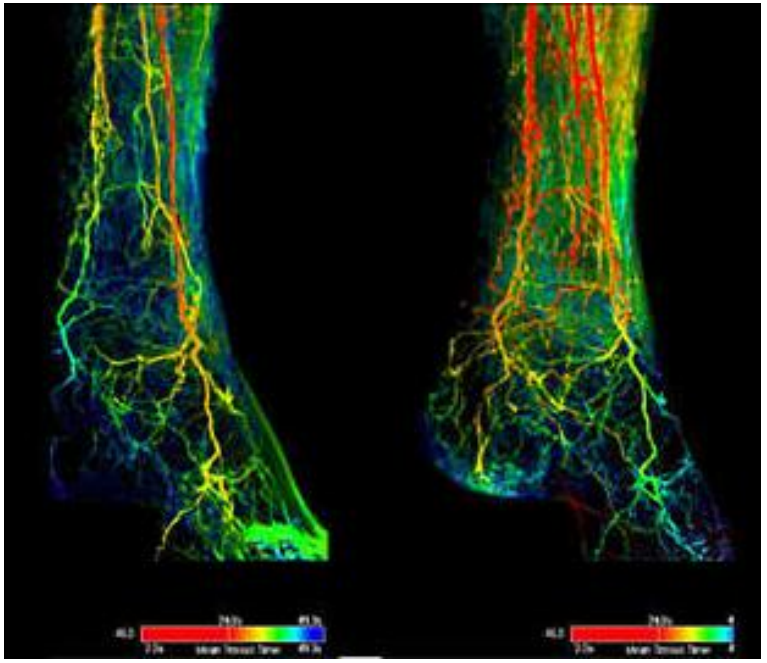
Variable[a]	*30 days*	*6 months*	*12 months*	*24 months*
BASIL				
Survival		0.700 (0.60-0.80)	0.651 (0.56-0.74)	0.664 (0.59-0.74)
Survival (DM only)		0.769 (0.63-0.91)	0.717 (0.60-0.83)	0.668 (0.55-0.79)
FINNVASC				0.533 (0.45-0.62)
Survival	0.581 (0.44-0.73)		0.506 (0.41-0.60)	
AFS	0.576 (0.34-0.81)		0.543 (0.46-0.63)	
AFS (bypass only)			0.548 (0.39-0.71)	
AFS (DM only)	0.732 (0.58-0.88)			
Modified PREVENT	0.578 (0.44-0.72)		0.582 (0.48-0.68)	0.627 (0.54-0.71)
Survival	0.537 (0.27-0.80)		0.582 (0.50-0.67)	
AFS			0.595 (0.44-0.75)	
AFS (bypass only)				
AFS (DM only)			0.581 (0.45-0.71)	

AFS, Amputation-free survival; *CI*, confidence interval; *DM*, diabetes mellitus.
[a]Data are presented as area under the ROC curve (95% CI).

Moxey P. J Vasc Surg 2013;57:1-7

Tools to aid clinical decision making

- Wound
- Ischaemia
- Foot infection
- Patient



J Vasc Surg. 2014;59:220-34

Society for Vascular Surgery (WIfI) - Wound

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
1	Small, shallow	No gangrene
2	Deeper ulcer	Gangrene limited to digits
3	Extensive deep ulcer (midfoot)	Extensive gangrene (midfoot)

Society for Vascular Surgery (WIfI) - Ischaemia

Grade	ABI	Ankle systolic pressure	Toe pressure, TcPO2
0	≥0.80	>100mmHg	≥60mmHg
1	0.6-0.79	70-100mmHg	40-59mmHg
2	0.4-0.59	50-70mmHg	30-39mmHg
3	≤0.39	<50mmHg	<30mmHg

Society for Vascular Surgery (WIfI) – foot Infection

- 0 – no symptoms / signs of infection
- 1 – local swelling, erythema (<2cm), tender/pain, purulent discharge
- 2 – erythema>2cm + deeper structures
- 3 – as above + SIRS

Risk of amputation at 1 year

	Ischemia – 0				Ischemia – 1					Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H		L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H		L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H		M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H		H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3		fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4

J Vasc Surg. 2014;59:220-34

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Estimated likelihood of benefit from revascularisation

(assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

Very low = VL = clinical stage 1

Low = L = clinical stage 2

Moderate = M = clinical stage 3

High = H = clinical stage 4

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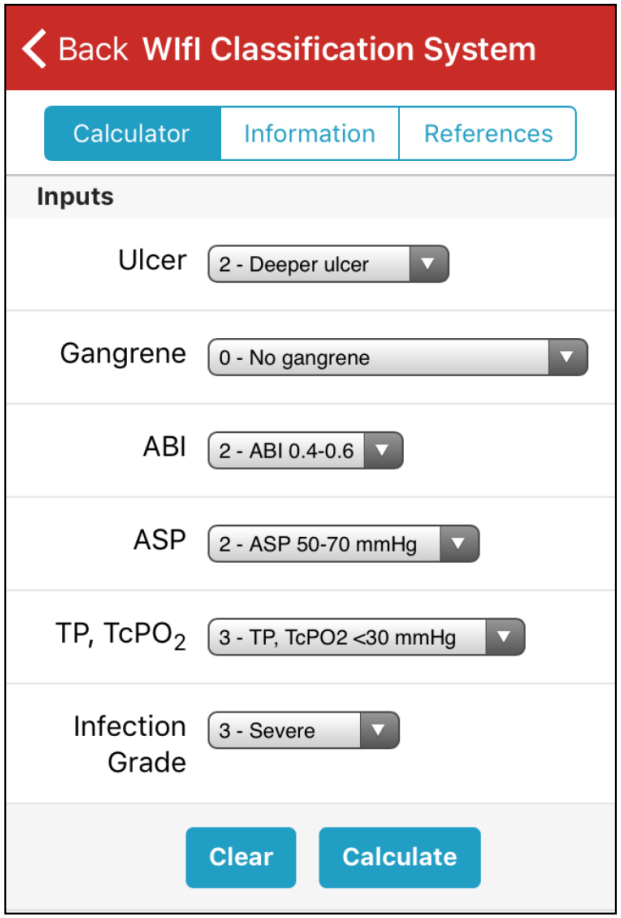
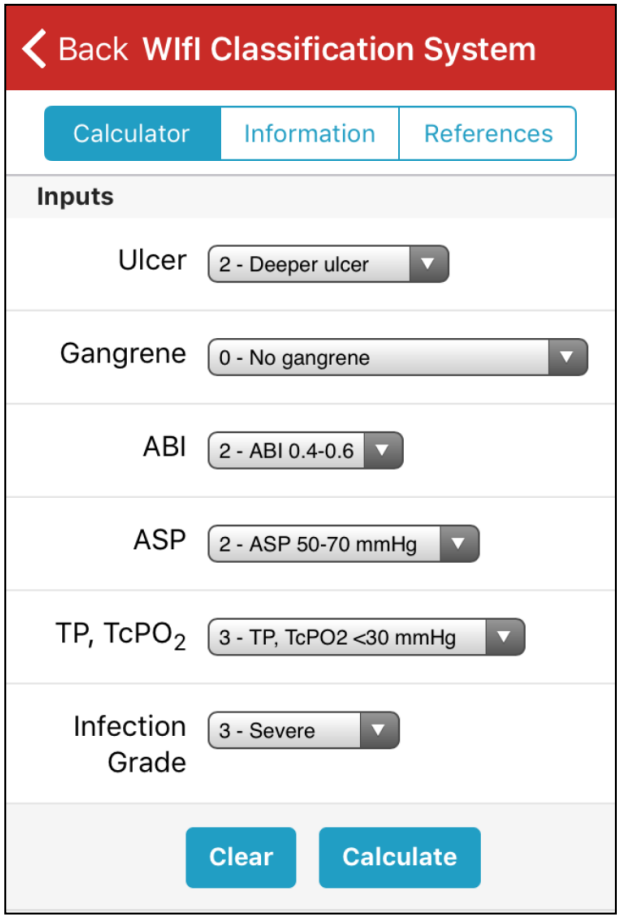

Back WIfI Classification System
Calculator
Information
References
Inputs
Ulcer
2 - Deeper ulcer
Gangrene
0 - No gangrene
ABI
2 - ABI 0.4-0.6
ASP
2 - ASP 50-70 mmHg
TP, TcPO2
3 - TP, TcPO2 <30 mmHg
Infection Grade
3 - Severe
Clear
Calculate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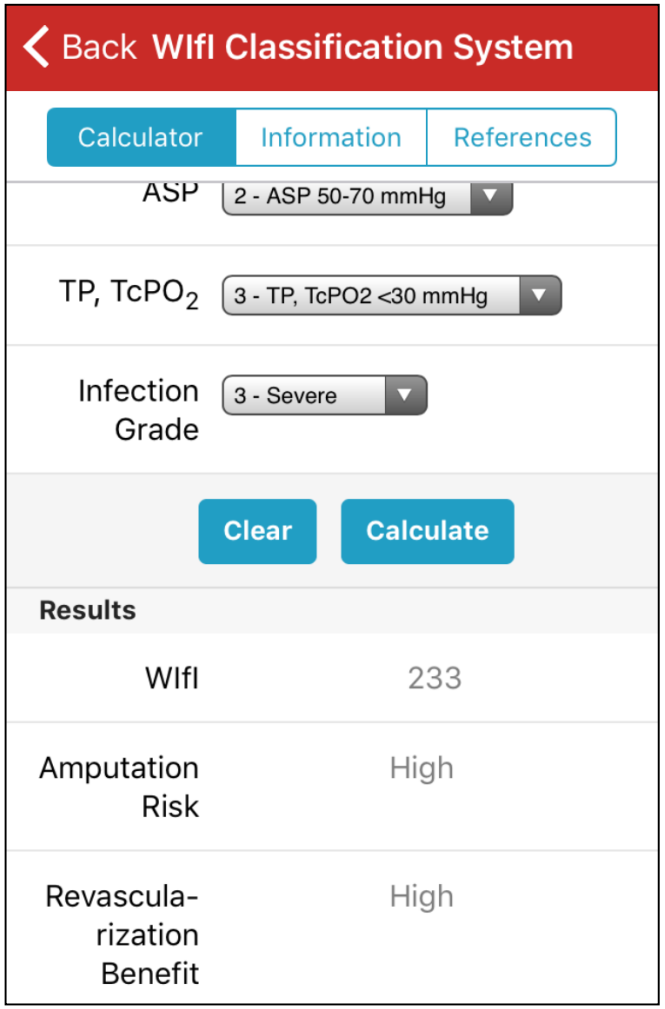
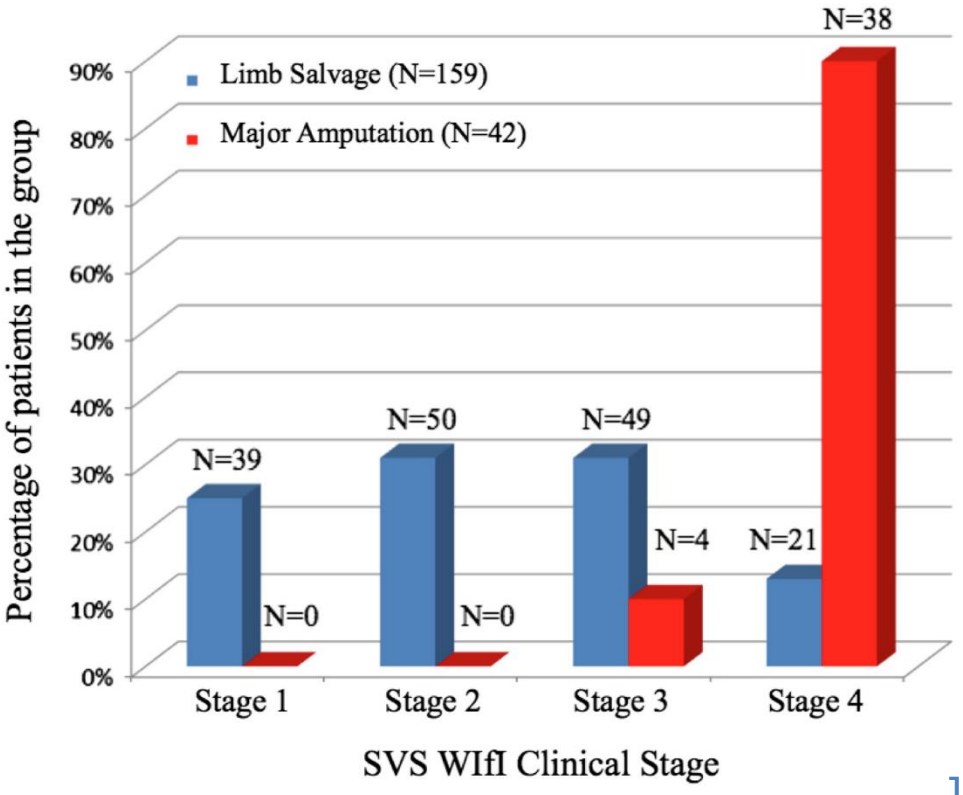

Back WIfI Classification System
Calculator
Information
References
ASP
2 - ASP 50-70 mmHg
TP, TcPO2
3 - TP, TcPO2 <30 mmHg
Infection Grade
3 - Severe
Clear
Calculate
Results
WIfI
233
Amputation Risk
High
Revascula-rization Benefit
High

Validation of the WIFi Score



J Vasc Surg. 2015;61:939-44

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Increasing limb salvage pool

- Endovascular technology
- Bypass surgery
- Advanced reconstruction
- Cell based therapies
- Wound care (dressings)

Technical feasibility of angioplasty in patients with diabetes and CLTI

- Anterior tibial artery success:

2005 - 92% stenosis >4cm and 24% occlusions >2cm

- Posterior tibial:

85% stenoses and 11% occlusions

- Peroneal:

84% stenosis and 26% occlusions

Faglia. EJVES 2005;29:620-7

Technical feasibility of angioplasty in patients with diabetes and CLTI

- Anterior tibial artery success:

2005 - 92% stenosis >4cm and 24% occlusions >2cm

2012 - 87% stenoses >2cm and 90% occlusions >2cm

- Posterior tibial:

85% stenoses and 11% occlusions

95% stenoses and 100% occlusions

- Peroneal:

84% stenosis and 26% occlusions

75% stenoses and 99% occlusions

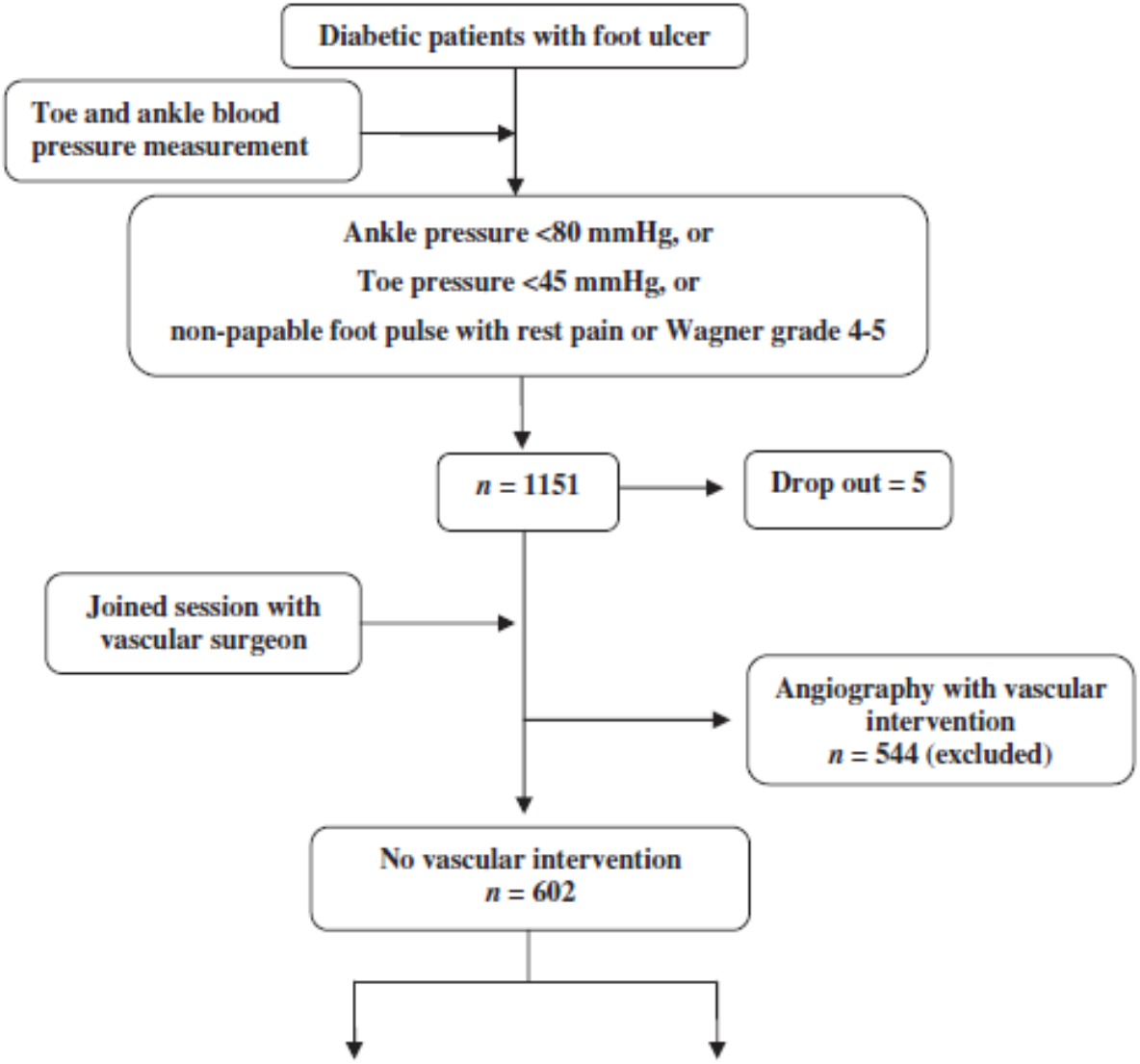
Faglia. EJVES 2005;29:620-7
Faglia. Diabetes Res Clin Pract. 2012;95:364-71

Which revascularisation technique?

Toe pressure, mmHg	Open (n=24)	Endovascular (n=57)	P-value
Pre-intervention, mean (+/-SD)	28.3 (+/-26.8)	38.2 (+/-28.3)	0.15
Post-intervention	62.7 (+/-27.7)	71.7 (+/-35.0)	0.27
Change	34.3 (+/-24.0)	35.6 (+/-24.1)	0.60
P value	<0.0001	<0.0001	

J Vasc Surg. 2012;56:380-6

Natural history ‘severe PAD’ not revascularised?



Elgzyri T, Eur J Vasc Endovasc Surg. 2013;46:110-7

Outcomes	No angiography n=319 (53%)	Angiography without intervention n=283 (47%)	Total n=602 (100%)
Ongoing ulcer	2 (-)	2 (-)	4 (-)
Primary healing	119 (37)	108 (38)	227 (38)
Healed after minor amputation	34 (11)	38 (13)	72 (12)
Healed after major amputation	40 (13)	61 (22)	101 (17)
Deceased unhealed with/without amputation	123 (38)	74 (26)	197 (33)
Drop-out	1 (-)	0 (-)	1 (-)

Elgzyri T, Eur J Vasc Endovasc Surg. 2013;46:110-7

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Elgzyri T, Eur J Vasc Endovasc Surg. 2013;46:110-7

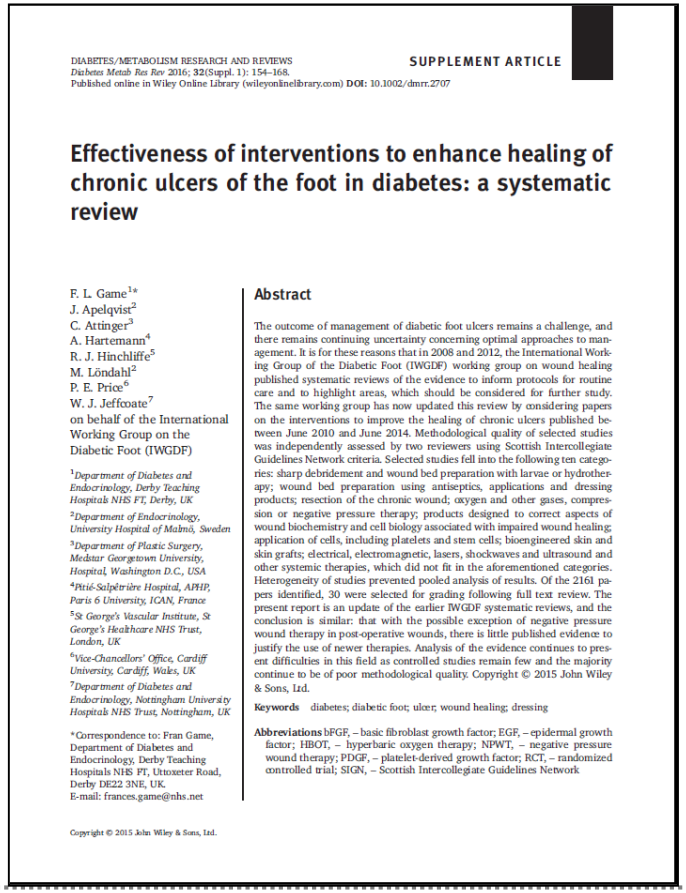
Factors associated with ulcer healing in those non-revascularised?

	Odds ratio	P-value
Pain	0.59 (0.38-0.91)	0.016
Ankle pressure >50mmHg	2.44 (1.27-4.66)	0.007
Serum creatinine >130µmol/L	0.55 (0.34-0.88)	0.012
Ischaemic heart disease	0.52 (0.34-0.81)	0.004
Cerebrovascular disease	0.41 (0.27-0.64)	<0.001
Wagner grade ≥3	0.51 (0.33-0.77)	0.002

Elgzyri T, Eur J Vasc Endovasc Surg. 2013;46:110-7

Wound care products

- Poor quality
- Few blinded RCTs
- Simple non-adherent dressings
- No reporting standards
- No core outcome set



DIABETES/METABOLISM RESEARCH AND REVIEWS
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Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/dmrr.2707

SUPPLEMENT ARTICLE

Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: a systematic review

F. L. Game[1]*
J. Apelqvist[2]
C. Attinger[3]
A. Hartemann[4]
R. J. Hinchliffe[5]
M. Löndahl[2]
P. E. Price[6]
W. J. Jeffcoate[7]
on behalf of the International Working Group on the Diabetic Foot (IWGDF)

[1]*Department of Diabetes and Endocrinology, Derby Teaching Hospitals NHS FT, Derby, UK*
[2]*Department of Endocrinology, University Hospital of Malmö, Sweden*
[3]*Department of Plastic Surgery, Medstar Georgetown University, Hospital, Washington D.C., USA*
[4]*Pitié-Salpêtrière Hospital, APHP, Paris 6 University, ICAN, France*
[5]*St George's Vascular Institute, St George's Healthcare NHS Trust, London, UK*
[6]*Vice-Chancellors' Office, Cardiff University, Cardiff, Wales, UK*
[7]*Department of Diabetes and Endocrinology, Nottingham University Hospitals NHS Trust, Nottingham, UK*

*Correspondence to: Fran Game, Department of Diabetes and Endocrinology, Derby Teaching Hospitals NHS FT, Uttoxeter Road, Derby DE22 3NE, UK.
E-mail: frances.game@nhs.net

Abstract

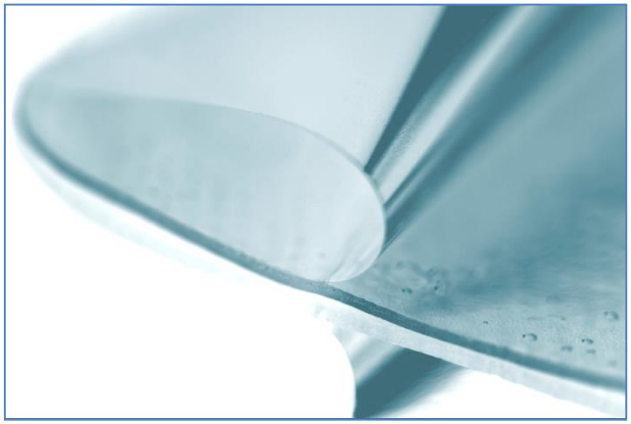
The outcome of management of diabetic foot ulcers remains a challenge, and there remains continuing uncertainty concerning optimal approaches to management. It is for these reasons that in 2008 and 2012, the International Working Group of the Diabetic Foot (IWGDF) working group on wound healing published systematic reviews of the evidence to inform protocols for routine care and to highlight areas, which should be considered for further study. The same working group has now updated this review by considering papers on the interventions to improve the healing of chronic ulcers published between June 2010 and June 2014. Methodological quality of selected studies was independently assessed by two reviewers using Scottish Intercollegiate Guidelines Network criteria. Selected studies fell into the following ten categories: sharp debridement and wound bed preparation with larvae or hydrotherapy; wound bed preparation using antiseptics, applications and dressing products; resection of the chronic wound; oxygen and other gases, compression or negative pressure therapy; products designed to correct aspects of wound biochemistry and cell biology associated with impaired wound healing; application of cells, including platelets and stem cells; bioengineered skin and skin grafts; electrical, electromagnetic, lasers, shockwaves and ultrasound and other systemic therapies, which did not fit in the aforementioned categories. Heterogeneity of studies prevented pooled analysis of results. Of the 2161 papers identified, 30 were selected for grading following full text review. The present report is an update of the earlier IWGDF systematic reviews, and the conclusion is similar: that with the possible exception of negative pressure wound therapy in post-operative wounds, there is little published evidence to justify the use of newer therapies. Analysis of the evidence continues to present difficulties in this field as controlled studies remain few and the majority continue to be of poor methodological quality. Copyright © 2015 John Wiley & Sons, Ltd.

Keywords diabetes; diabetic foot; ulcer; wound healing; dressing

Abbreviations bFGF, – basic fibroblast growth factor; EGF, – epidermal growth factor; HBOT, – hyperbaric oxygen therapy; NPWT, – negative pressure wound therapy; PDGF, – platelet-derived growth factor; RCT, – randomized controlled trial; SIGN, – Scottish Intercollegiate Guidelines Network

LeucoPatch Trial

ProNOx1 Study (Nitric oxide)



Explorer study
(Sucrose octasulphate)

Lancet Diabetes Endocrinol. 2018;6:186-196
Lancet Diabetes Endocrinol. 2018;6:870-878
Wound Repair Regen. 2018;26:228-237

MIDFUT Trial

MIDFUT
Comparing treatments for diabetic foot ulcers

Group 1: Treatment as usual (TAU)

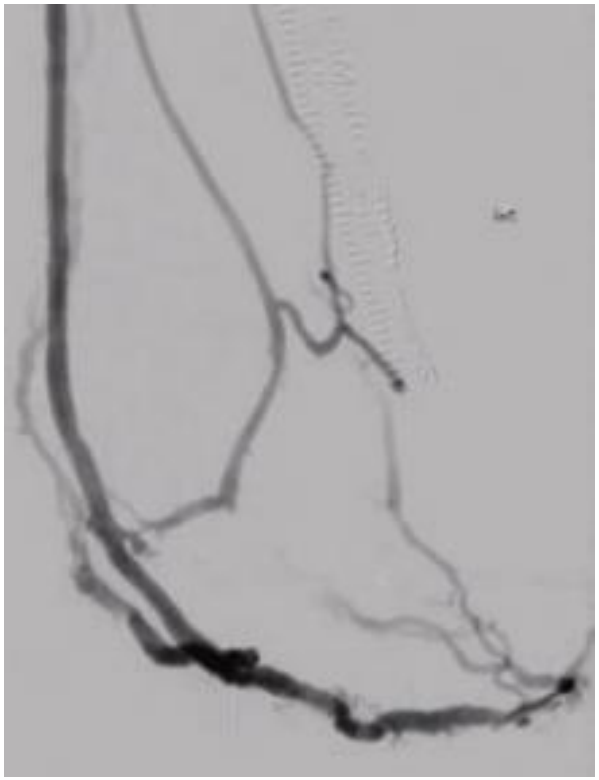
Group 2: TAU + hydrosurgical debridement (HD)

Group 3: TAU + HD + Negative pressure (NPWT)

Group 4: TAU + HD + decellularised dermal allograft (DCD)

Group 5: TAU + HD + DCD + NPWT

Alternatives



Conclusions

- Adapt to meet demand – urgent/emergency
- Opportunity for pathway improvements
- Encourage better evidence
- Renaissance in wound dressings
- Benefit new/alternative revascularization strategies uncertain