

2023

ASSISI (PG)
15/17
GIUGNO 2023
Grand Hotel Assisi

**Congresso
Nazionale
PIEDE DIABETICO
GDS AMD-SID**



La **S**indrome
del **pie**de **diab**etico:
competenze
in azione
con uno sguardo
al futuro

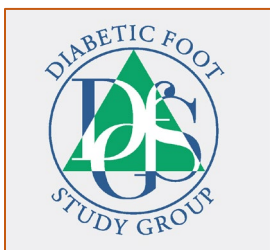
Le novità dall'IWGDF 2023

Roberto Anichini MD

Head of Diabetes Unit Area Pistoiese and Diabetes Foot Unit USL Centro-Toscana, Italy.

European Executive Committee of Diabetic Foot Study Group of EASD .

Vice President of D-FOOT International



10/08/2023

Roberto MD Anichini 2023

ASSISI (PG)
15/17
GIUGNO 2023
Grand Hotel Assisi

**Congresso
Nazionale
PIEDE DIABETICO
GDS AMD-SID**



La **S**indrome
del **piede diabetico**:
competenze
in azione
con uno sguardo
al futuro

Disclosure: Explicit declaration of transparency of funding
sources and relationships with subjects with commercial
interests

Dr Roberto Anichini

No Conflict of interest for this presentation

ANGELINI, ABBOTT, ASTRAZENECA, BOEHRINGER INGELHEIM, BAYER, MOLTENI
JOHNSON&JOHNSON, LILLY, MSD, NOVO NORDISK, SANOFI, TAKEDA,



10/08/2023

Roberto MD Anichini 2023

IWGDF Guidelines on the prevention and management of diabetes-related foot disease

Practical
Guidelines

7 Guidelines

Development and
methodology



IWGDF Practical Guidelines



IWGDF Prevention Guideline



ation Guideline



ideline



PAD Guideline



IWGDF Offloading Guideline



IWGDF Wound Healing Interventions Guideline



IWGDF Charcot



IWGDF Methodology



Please go to

<https://iwgdfguidelines.org/guidelines-2023/>

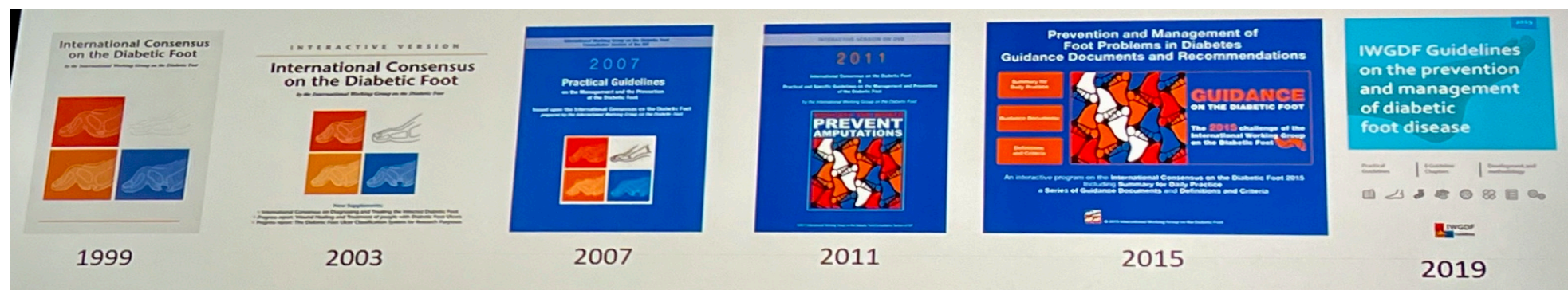
and download the full guidelines

ASSISI (PG)
15/17
 GIUGNO 2023
 Grand Hotel Assisi

Congresso Nazionale PIEDE DIABETICO GDS AMD-SID



La **S**indrome
 del **pie**de **diab**etico:
 competenze
 in azione
 con uno sguardo
 al futuro



ASSISI (PG)
15/17
 GIUGNO 2023
 Grand Hotel Assisi

**Congresso
 Nazionale
 PIEDE DIABETICO
 GDS AMD-SID**



La **S**indrome
 del **pie**de **diab**etico:
 competenze
 in azione
 con uno sguardo
 al futuro

..... Concetto di implementazione linee Guida.....

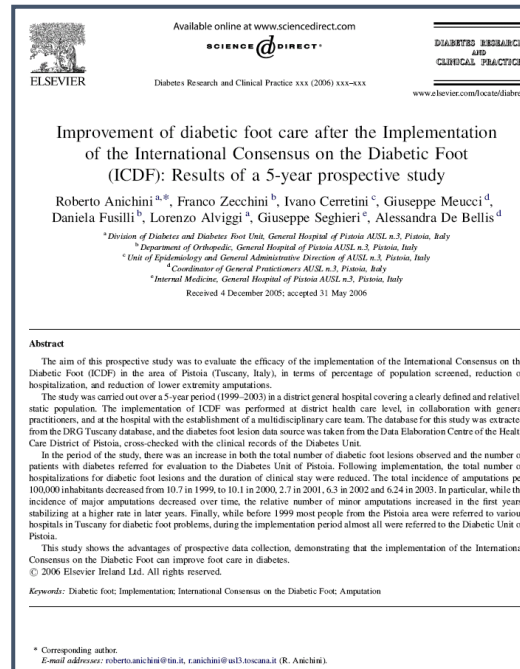
Recepire un documento di consenso tra pari.....

Organizzare...--applicazione/ adattamento al nostro
 vissuto

Migliorare Outcomes



Roberto MD Anichini 2023



Multiprofessional and multidisciplinary approaches (team) in the improvement of the of diabetic foot and implementation International Consensus (National level):

- Mercurio Project 1999
- First interactive course on implementation guidelines.
- (more than 3000 participants on «Diabetic foot meetings»)
- First international consensus translated in no english language



Gruppo di Studio Piede Diabetico
Dr. Luigi Uccioli: coordinatore

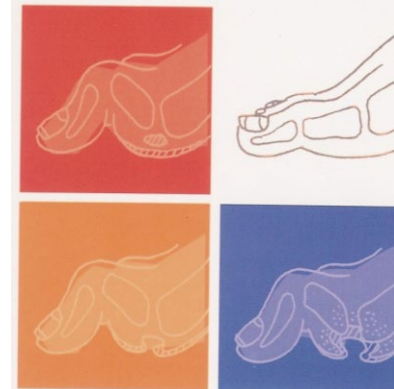
Comitato di coordinamento

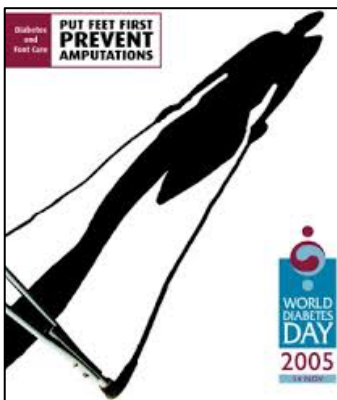
- Dr. Alberto Bruno
- Dr. Carlo Caravaggi
- Dr. Ezio Faglia
- Dr. Cecilia Fondelli
- Prof. Giovanni Ghirlanda

Documento di Consenso internazionale sul Piede Diabetico

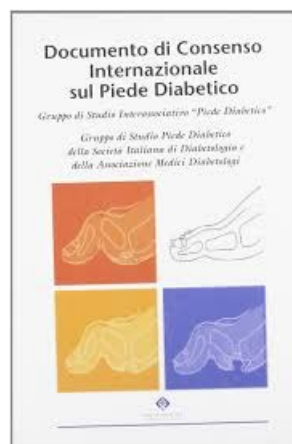
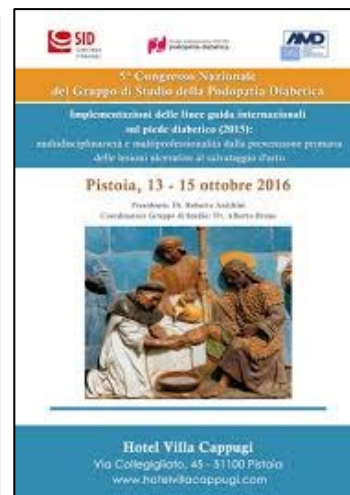
Gruppo di Studio Internazionale Piede Diabetico

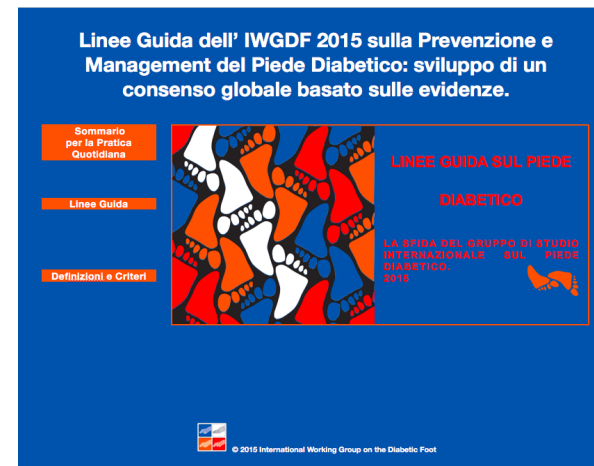
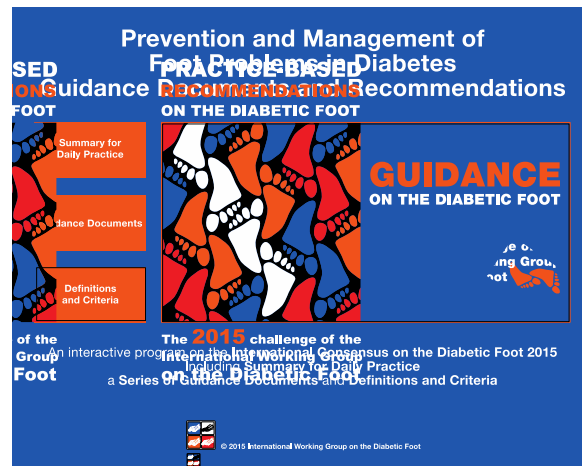
Gruppo di Studio Piede Diabetico
della Società Italiana di Diabetologia





35 years of diabetic foot story in Italy.





Proviamo a riassumere:
dallo studio delle LG..
adattare alla nostra realta'

Approccio multidisciplinare e multiprofessionale

Integrazione tra persone e tra sistemi

Approccio globale al Paziente con Diabete....



Conoscenza dell' IWGDFGL 2023

Abbiamo *ancora* bisogno di linee guida come queste ??

Le Linee guida rispondono alle necessità diffuse in Italia?

ASSISI (PG)
15/17
 GIUGNO 2023
Grand Hotel Assisi

**Congresso
 Nazionale
 PIEDE DIABETICO
 GDS AMD-SID**



La **S**indrome
 del **pie**de **diab**etico:
 competenze
 in azione
 con uno sguardo
 al futuro

Barriers to diabetic foot management in Italy: A multicentre survey in diabetic foot centres of the Diabetic Foot Study Group of the Italian Society of Diabetes (SID) and Association of Medical Diabetologists (AMD)

Marco Meloni ^{a,*}, Silvia Acquati ^b, Carmelo Licciardello ^c, Ornella Ludovico ^d, Mario Sepe ^e, Cristiana Vermigli ^f, Roberto Da Ros ^g

^a Diabetic Foot Unit, Department of Systems Medicine, University of Rome Tor Vergata, Italy

^b Unit of Endocrinology, Pierantoni-Morgagni Hospital, Forlì AUSL Romagna, Italy

^c UFC Malattie disendocrine e dismetaboliche, Centro Catanese di Medicina e Chirurgia, Catania, Italy

^d Unit of Endocrinology, IRCCS Casa Sollievo della Sofferenza, San Giovanni Rotondo, Italy

^e Posturology Centre, Salerno, Italy

^f Unit of Endocrinology, Diabetic Foot Centre, University Hospital Santa Maria della Misericordia, Perugia, Italy

^g Ssd Diabetologia, Monfalcone Gorizia Asugi, Italy

Received 4 October 2020; received in revised form 12 October 2020; accepted 13 October 2020

Handling Editor: G. Targher

Available online ■ ■ ■

Table 1 National average score for each item.

Item	Score
Delayed referral	3.3
Urgent surgery	3.2
Elective hospitalization	3.1
Length of hospitalization	2.7
Management in the community setting	2.7
Elective surgery	2.6
Hospitalization	2.4
Surgical revascularization	2.3
Post-hospitalization management (follow-up management)	2.2
Endovascular revascularization	2.2
Discharge	2.1
Prescription therapeutic footwear	1.9

Linee Guida Italiane dell' IWGDF 2019 sulla Prevenzione e Gestione del Piede Diabetico: sviluppo di un consenso globale basato sulle evidenze

Linee Guida

6 capitoli

Sviluppo e metodologia

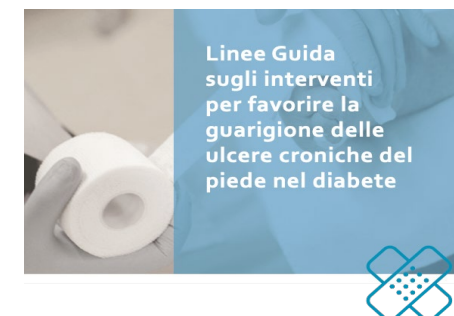
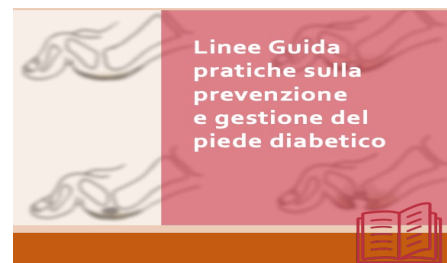


TRADUZIONE ITALIANA A CURA DI:
Gruppo Interassociativo AMD-SID Piede Diabetico



VERSIONE ITALIANA A CURA DEL COORDINAMENTO NAZIONALE GRUPPO PIEDE DIABETICO:

Cristiana Vermigli Coordinatore
Cesare Miranda Coordinatore Eletto
Roberto Da Ros Past Coordinatore
Silvia Acquati
Chiara Goretti
Carmelo Licciardello
Ornella Ludovico
Marco Meloni Mario Sepe





- Linee guida: carattere universale che riuscissero a parlare linguaggio comune a paesi continenti sistemi sanitari, sociali ed economici completamente diversi.
- Dalla logica di lobby (consenso tra esperti) alla obiettività del sistema GRADE.
- Cambio generazionale che ha spostato obiettivi, e prospettive e campi di interessi
- «Grade system» e scarsi dati e contrapposti al fare comune.

Schema delle linee guida

- ABSTRACT
- LIST OF RECOMMENDATIONS
- INTRODUCTION
- WHAT'S NEW IN THIS 2023 UPDATE
- METHODS
- RESULTS
- RECOMMENDATIONS
- CONSIDERATIONS

2023

IWGDF Guidelines on the prevention and management of diabetes-related foot disease

Practical
Guidelines

7 Guidelines

Development and
methodology



10/08/2023



Roberto MD Anichini 2023

IWGDF Practical Guidelines



IWGDF Prevention Guideline



IWGDF Classification Guideline



IWGDF Infection Guideline



IWGDF PAD Guideline



IWGDF Offloading Guideline



IWGDF Wound Healing Interventions Guideline



IWGDF Charcot



IWGDF Methodology



Nicolaas Schaper
Jaap van Netten
Jan Apelqvist
Sicco Bus
Rob Fitridge
Fran Game
Matilde Monteiro-Soares
Éric Senneville

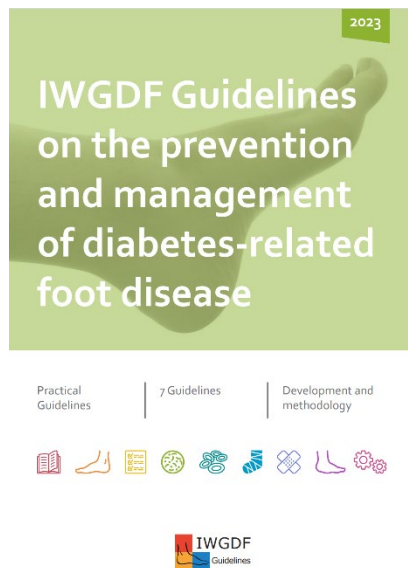


www.iwgdfguidelines.org

Practical guidelines on the prevention and management of diabetes-related foot disease

IWGDF 2023 update





IWGDF Practical Guidelines



In these practical guidelines of the International Working Group on the Diabetic Foot (IWGDF) we describe the **basic principles of prevention and management of diabetes-related foot disease**. This document is a summary of the following evidence-based IWGDF Guidelines (2023 update):

IWGDF Prevention Guideline



IWGDF Classification Guideline



IWGDF Infection Guideline



IWGDF PAD Guideline



IWGDF Offloading Guideline



IWGDF Wound Healing Interventions Guideline



IWGDF Charcot



IWGDF Methodology

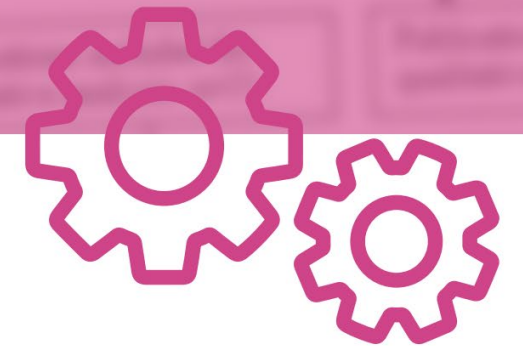


Sicco Bus
Matilde Monteiro-Soares
Fran Game
Jaap van Netten
Jan Apelqvist
Rob Fitridge
Éric Senneville
Nicolaas Schaper

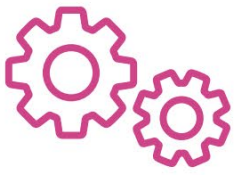
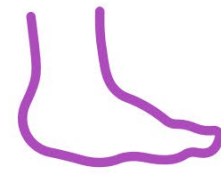
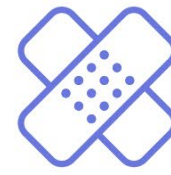


www.iwgdfguidelines.org

Standards for the development and methodology of the 2023 International Working Group on the Diabetic Foot Guidelines



Roberto MD Anichini 2023



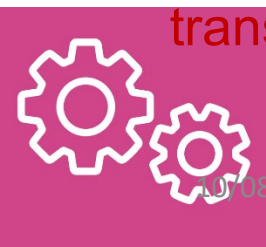
IWGDF Methodology



Diabetes-related foot disease is a source of major patient burden and social costs.

Investing in evidence-based international guidelines on diabetes-related foot disease is important **to reduce this burden and costs**, provided the **guidelines are focused** on outcomes important to **key stakeholders**, evidence-based and properly implemented.

The International Working Group on the Diabetic Foot (IWGDF) has published and updated international guidelines since 1999. The 2023 updates were made using the Grading of Recommendations Assessment Development and Evaluation (GRADE) evidence-to-decision framework. **This concerns formulating relevant clinical questions and important outcomes, conducting systematic reviews** of the literature and meta-analyses where appropriate, completing summary of judgements tables, and writing recommendations that are **specific, unambiguous and actionable, along with their transparent rationale.**

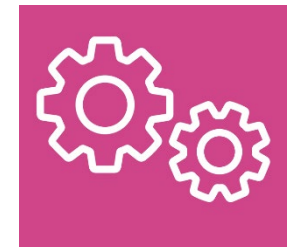


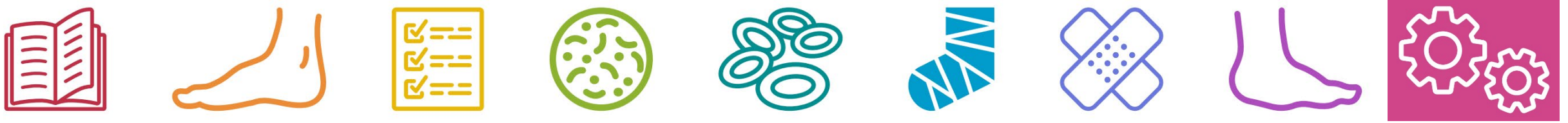
10/08/2023



Conditions for successful management and prevention

- Common knowledge base
- Common language
- Shared sense of urgency and share aims
- Systematic approach
- Multifactorial team approach in diagnosis treatment and prevention





METHODOLOGY USED FOR THE 2023 IWGDF SYSTEMATIC REVIEWS AND GUIDELINES

1. Establishing a diverse expert panel to develop the guideline
2. Defining key clinical questions and important outcomes
3. Performing a systematic review (and meta-analysis)
4. Assessing key summary of judgements items and writing the recommendations and their rationale
5. External review and feedback

Sicco Bus
Isabel Sacco
Matilde Monteiro-Soares
Anita Raspovic
Joanne Paton
Anne Rasmussen
Larry Lavery
Jaap van Netten



www.iwgdfguidelines.org

Guidelines on the prevention of foot ulcers in persons with diabetes

IWGDF 2023 update

Roberto MD Anichini 2023





IWGDF Prevention Guideline



Five Key elements of prevention

1. Identifying the at risk foot (1 recommendation)
2. Regularly inspecting and examining the at risk foot (1R)
3. Educating the patient, family and healthcare providers (5R)
4. Ensuring routine wearing of appropriate footwear (3R)
5. Treating risk factors for ulceration (6R)

1-5 integrated foot care consists of 2 or more of these elements (1R)



IWGDF Prevention Guideline



- LIST OF RECOMMENDATIONS

1. Screen a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of peripheral neuropathy and peripheral artery disease, to determine if the person is at increased risk for foot ulceration, using the IWGDF risk stratification system. (GRADE recommendation: Strong; Certainty of evidence: High)
2. If a person with diabetes has loss of protective sensation or peripheral artery disease, extend the screening using clinical history and further foot examinations to assess for
 1. a history of foot ulceration or lower-extremity amputation;
 2. diagnosis of end-stage renal disease;
 3. presence or progression of foot deformity;
 4. limited foot and ankle joint mobility;
 5. excess callus;
 6. and any pre-ulcerative lesion or ulcer on the foot, to determine their risk for foot ulceration using the IWGDF risk stratification system and to inform treatment. Repeat this screening once every 6-12 months for those classified as IWGDF risk 1, once every 3-6 months for IWGDF risk 2, and once every 1-3 months for IWGDF risk 3. (Strong; High)



IWGDF Prevention Guideline



1. Educate, and after that encourage and remind a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, not walking in socks without shoes, and not walking in thin-soled slippers, whether indoors or outdoors. (Strong; Low)
2. Educate, and after that encourage and remind a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to wash their feet daily (with careful drying, particularly between the toes), use emollients to moisturize dry skin, and cut toenails straight across. (Strong; Low)
3. Educate, and after that encourage and remind a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to examine their feet daily and with the presence or suspicion of having a (pre-)ulcerative lesion, to rapidly contact an appropriately-trained healthcare professional for further advice. (Strong; Low)
4. Provide structured education to a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer. (Strong; Low)



IWGDF Prevention Guideline



Consider coaching a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference between corresponding regions of the left and right foot is above a temperature threshold of 2.2 °C (or 4.0 °F) on two consecutive days, coach the patient to reduce ambulatory activity and consult an adequately trained healthcare professional for further diagnosis and treatment. (Conditional; Moderate)

In a person with diabetes who is at risk of foot ulceration

- a) a. and with no or limited foot deformity, no pre-ulcerative lesions and no plantar ulcer history (IWGDF risk 1-3), educate to wear footwear that accommodates the shape of the feet and that fits properly. (Strong; Low)
- b) and with a foot deformity that significantly increases pressure or a pre-ulcerative lesion (IWGDF risk 2 or 3), consider prescribing extra-depth shoes, custom-made footwear, custom-made insoles, and/or toe orthoses. (Strong; Low)
- c) and with a healed plantar foot ulcer (IWGDF risk 3), prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the person to consistently wear this prescribed footwear, both indoors and outdoors. (Strong; Moderate)



IWGDF Prevention Guideline



9. Provide appropriate treatment for any pre-ulcerative lesion or excess callus on the foot, for ingrown toe nails, and for fungal infections on the foot, to help prevent a foot ulcer in a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3). (Strong; Very low)
10. In a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) and a non-rigid hammertoe with nail changes, excess callus or a pre-ulcerative lesion on the apex or distal part of this toe:
 9. consider digital flexor tendon tenotomy for treating these outcomes and to help prevent a first or recurrent foot ulcer (Conditional; Moderate), or
 10. consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce excess callus on the toe. (Conditional; Low)
11. In a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3), we suggest not to use a nerve decompression procedure to help prevent a foot ulcer. (Conditional; Very low)
12. Consider advising and referring a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) to participate in an 8-12-weeks foot-ankle exercise program, preferably under the supervision of an appropriately trained healthcare professional, and to continue performing foot-ankle exercises afterwards, with the aim of reducing risk factors for ulceration. (Conditional; Low)
13. Consider communicating to a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) that an increase in the level of walking-related weight-bearing daily activity by an extra 1000 steps/day is likely to be safe regarding risk of foot ulceration. Advise this person to wear appropriate footwear when undertaking weight-bearing activities, and to frequently monitor the skin for (pre-)ulcerative lesions. (Conditional; Low)
- 14. Provide integrated foot care for a person with diabetes who is at moderate or high risk of foot ulceration** (IWGDF risk 2 and 3) to help prevent a first or recurrent foot ulcer. This integrated foot care should include at least professional foot care, adequate footwear and structured education about self-care. Repeat this foot care or re-evaluate the need for it once every one to three months for a person at high risk, and once every three to six months for a person at moderate risk, as necessary. (Strong; Low)

WHAT'S NEW IN THIS 2023 UPDATE

- This 2023 guideline updates 2019 guideline on foot **ulcer prevention**
- Used a more thorough **GRADE methodological approach** to the guideline and the systematic review supporting it, by performing meta-analyses, grading effect sizes, grading certainty(quality) of evidence with 'very low' as an option, and developing summary of judgement tables;
- **Added new clinical question** on **psychological intervention** for ulcer prevention;
- Added new important **outcomes**, including health-related quality of life, costs, mortality, self-efficacy,
- well-being and adverse events;
- Split the recommendation on the use of footwear according to the severity of foot deformity present;
- **Reorganized the recommendations for a person with diabetes at risk of foot ulceration** and a non- rigid hammertoe to contain both a surgical and orthotic intervention recommendation; and
- **Updated** the strength of recommendation and the certainty of evidence underlying the recommendation where appropriate based on new available evidence and on using the more thorough GRADE approach.



IWGDF Prevention Guideline



WHAT'S NEW IN THIS 2023 UPDATE

Not so much

Good or bad news??



IWGDF Prevention Guideline



WHAT'S NEW IN THIS 2023 UPDATE

Key Considerations (Future research agenda)

- Robust data are lacking on **whom, how, and when** to screen for ulcer risk.
- High quality data on interventions **to prevent a first foot ulcer** are scarce.
- **Cost and cost-effectiveness** of intervention needs more research.
- **Adherence** to an intervention is crucial in outcomes

Matilde Monteiro-Soares
Emma Hamilton
David Russel
Gulapar Srisawasdi
Ed Boyko
Joseph Mills
William Jeffcoate
Fran Game



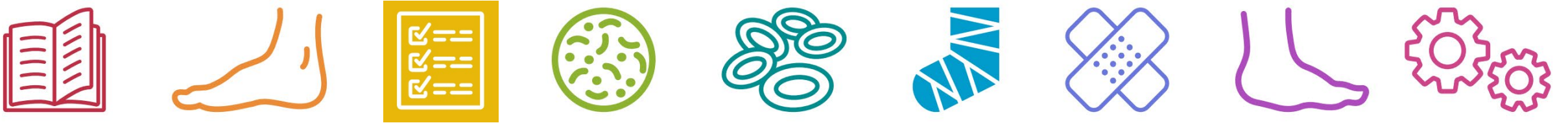
www.iwgdfguidelines.org

Guidelines on the classification of foot ulcers in people with diabetes

IWGDF 2023 update

Roberto MD Anichini 2023

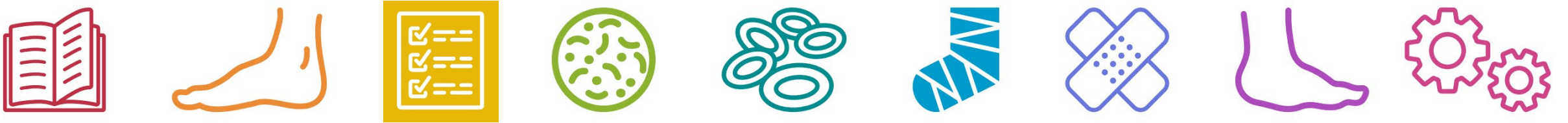




What are classifications ??

(Classification or scoring) systems that attempt to:

- Create more homogeneous groups of patients
- For which similar levels of care should be provided and
- To standardize the modifiable factors that one should focus on to improve clinical outcomes



For what purposes??

- ***NO system fits all.***

Adressed 5 purposes (same as 2019)

- for **communication** among healthcare professionals
- for **predicting the outcome** of an ulcer in a specific individuals.
- for **characterising** a person with an **infected** ulcer.
- for **characterising** a person with **peripheral artery disease**
 - For the **of outcome (s)** of populations



What have we done differently??



2019

Critical review
19 classifications
50 studies

2023

- Systematic review
- 28 classifications
- 149 studies



What have we done differently??

Defined critically important outcomes

- Group elements, external experts, people with diabetes representatives

Grouped them into 4 categories:

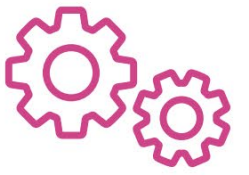
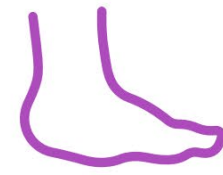
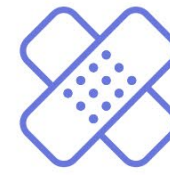
- Clinical outcomes
- Post-baseline clinical outcomes
- Usability
- Use of resources



What have we done differently??

Selected only those conditionally or strongly recommendation (based on summary of judgments for each system.

- DIAFORA
- IDSA/IWGDF
- SINBAD
- University of Texas Wound Classification System
- (Meggitt) Wagner
- WIFI

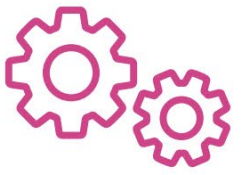
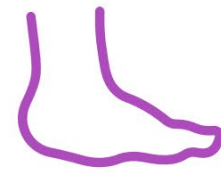
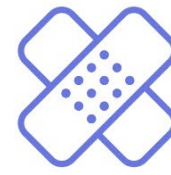


What have we done differently?? *Clinical use*

Table 1: Summary of judgments for the classifications considered as suitable for clinical use

Classification/ judgment	DIAFORA	IDSA/IWGDF	SINBAD	UTWCS	Wagner	WIFI
Problem priority	Yes	Yes	Yes	Yes	Yes	Yes
Test accuracy	Accurate	Accurate	Accurate	Accurate	Accurate	Accurate
Desirable effects	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Undesirable effects	Trivial	Small	Trivial	Trivial	Trivial	Trivial
Certainty of evidence of test accuracy	Low	Low	Low	Low	Low	Low
Certainty of evidence of test's effects	Very low	Very low	Very low	Very low	Low	Very low
Certainty of evidence of management's effect	Very low	Very low	Very low	Very low	Low	Very low
Certainty of the evidence of link between test result/management	Low	Low	Low	Low	Low	Low
Certainty of effects	Very low	Very low	Very low	Very low	Low	Very low
How much people value the main outcome	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability
Balance of effects	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention
Resources required	Negligible costs and savings	Moderate costs	Moderate savings	Moderate costs	Negligible costs and savings	Moderate savings
Certainty of evidence of required resources	Low	Low	Low	Low	Very low	Very low
Cost effectiveness	Does not favor either	Does not favor either	Probably favors the intervention	Does not favor either	Does not favor either	Probably favors the intervention
Equity	Probably no impact	Probably reduced	Probably increased	Probably reduced	Probably increased	Probably reduced
Acceptability (to stakeholders)	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes
Feasibility	Probably yes	Probably yes	Yes	Probably yes	Yes	Probably no

Note: For each colour a stronger shade implies a stronger assessment, Green filling represents a positive judgment (this is, supporting the use of the system), Blue filling represents a neutral judgment (this is, a balance between supporting or not the use of the system), and Red filling represents a negative judgment (this is, not favouring the use of the system). IDSA/IWGDF: Infectious Diseases Society of America/ International Working Group on the Diabetic Foot; UTWCS: University of Texas Wound Classification System.



What recommendations have changed??

Same as 2019

In a person with diabetes and a foot ulcer, use the SINBAD system for communication about the characteristics of an ulcer between healthcare professionals, and clearly stating the presence or absence of each of the composing variables.
(Strength of recommendation: Strong; Certainty of evidence: Low)

NEW

- In a person with diabetes and a foot ulcer, when resources exist in addition to an appropriate level of expertise and it is considered feasible, consider using **the Wifl** system for communication about the characteristics of an ulcer between healthcare professionals, but with characterisation of each of the composing variables.
(Conditional; Low)

IWGDF Classification Guideline



Table 2: SINBAD system

Category	Definition	Score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area Ulcer	Ulcer < 1 cm ²	0
	Ulcer ≥ 1 cm ²	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total possible score		0 – 6



Table 3: WIfI system

Wound

Grade	DFU	Gangrene
0	No ulcer Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	No gangrene
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	No gangrene
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement Clinical description: major tissue loss salvageable with multiple (≥ 3) digital amputations or standard TMA $\pm$ skin coverage.	Gangrenous changes limited to digits
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer $\pm$ calcaneal involvement Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or non-traditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis $\pm$ calcaneal involvement

Ischaemia

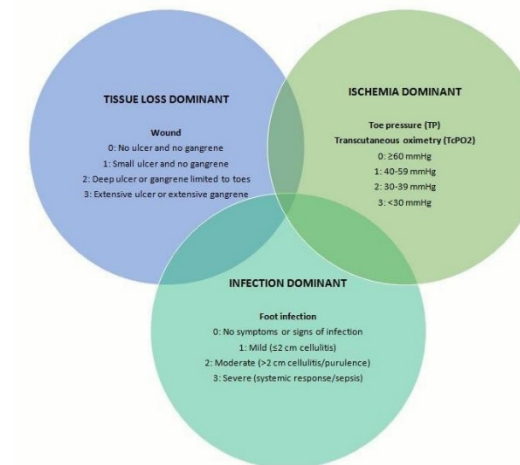
Grade	ABI	Ankle systolic pressure (mmHg)	TP, TcPO ₂ (mmHg)
0	≥ 0.80	> 100	≥ 60
1	$0.6 - 0.79$	$70 - 100$	$40 - 59$
2	$0.4 - 0.59$	$50 - 70$	$30 - 39$
3	≤ 0.39	< 50	< 30

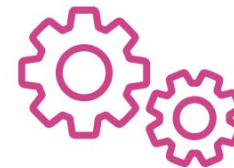
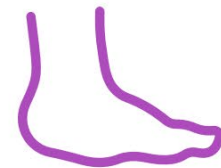
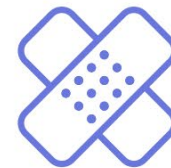
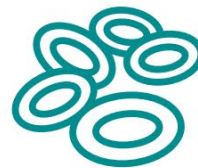


Foot Infection

Grade	Clinical manifestations
0	No symptoms or signs of infection Infection present, as defined by the presence of at least 2 of the following items: - Local swelling or induration - Erythema > 0.5 to ≤ 2 cm around the ulcer - Local tenderness or pain - Local warmth - Purulent discharge (thick, opaque to white, or sanguineous secretion)
1	Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (e.g., trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis)
2	Local infection (as described above) with erythema > 2 cm, or involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as described below)
3	Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: - Temperature $> 38^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$ - Heart rate > 90 beats/min - Respiratory rate > 20 breaths/min or PaCO₂ < 32 mm Hg - White blood cell count $> 12,000$ or < 4000 cu/mm or 10% immature (band) forms

ABI: Ankle-Brachial Index; PaCO₂: Partial Pressure of Carbon Dioxide; SIRS: Systemic Inflammatory Response Syndrome; TcPO₂: Transcutaneous Partial Oxygen Pressure; TMA: Transmetatarsal Amputation; TP: Toe Pressure





What recommendations have changed??

IWGDF Classification Guideline



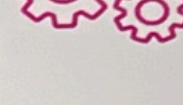
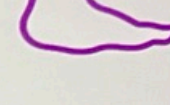
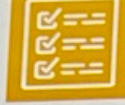
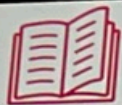
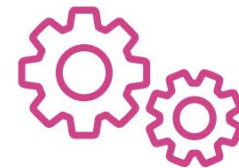
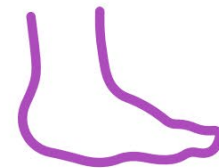
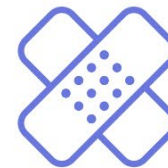
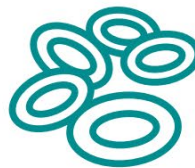
To classify
an infection
(version
(Strong;L

Table 4: IDSA/IWGDF system

Clinical manifestations	Infection severity	PEDIS grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of ≥ 2 manifestations of inflammation (purulence, or erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤ 2 cm around the ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness	Mild	2
Infection (as above) in a patient who is systemically well and metabolically stable but which has ≥ 1 of the following characteristics: cellulitis extending >2 cm, lymphangitic streaking, spread beneath the superficial fascia, deep-tissue abscess, gangrene, and involvement of muscle, tendon, joint or bone	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (e.g. fever, chills, tachycardia, hypotension, confusion, vomiting, leucocytosis, acidosis, severe hyperglycaemia, or azotaemia)	Severe	4

/!!!

with diabetes
ulcer, when
dition to an
expertise and it
le, consider
System
low)



What have we done differently?

- Used a thorough GRADE methodology approach

Systematic
review

Summary
of findings
for each
system

Certainty
evidence
for each
system

Summary
judgments
for each
system

Identify
recommended
systems

Select best
system(s)
for each
purpose



www.iwgdfguidelines.org



Éric Senneville
Zaina Albalawi
Suzanne van Asten
Zulfiqarali Abbas
Geneve Allison
Javier Aragón-Sanchez
John Embil
Larry Lavery
Majdi Alhasan
Orhan Oz
Ilker Uçkay
Vilma Urbançic-Rovan
Zhang-Rong Xu
Edgar Peters



www.iwgdfguidelines.org

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes

IWGDF/IDSA 2023



Roberto MD Anichini 2023



Overall:confirmation of the 2019 guidelines

2019	2023
Do not use molecular microbiology techniques (instead of conventional culture) for the first-line identification of pathogens from samples in a patient with a diabetic foot infection. (Strong; low)	Use conventional, rather than molecular, microbiology techniques for the first-line identification of pathogens from soft tissue or bone samples in a patient with a diabetes-related foot infection. (Strong; Moderate)
In a person with diabetes and suspected osteomyelitis of the foot, in whom making a definitive diagnosis or determining the causative pathogen is necessary for selecting treatment, collect a sample of bone (percutaneously or surgically) to culture clinically relevant bone microorganisms and for histopathology (if possible). (Strong; low)	In a person with diabetes for whom there is suspicion of osteomyelitis of the foot (before or after treatment), consider obtaining bone (rather than soft tissue) samples for culture, either intraoperatively or percutaneously. (Conditional; Moderate)
Do not routinely use topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy (with or without instillation). (Weak; low)	We suggest not using the following treatments to address diabetes-related foot infections: (a) adjunctive granulocyte colony-stimulating factor treatment or (b) topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy (with or without instillation). (Conditional; Low)
We suggest not using any currently available topical antimicrobial agent for treating a mild diabetic foot infection. (Weak; moderate)	



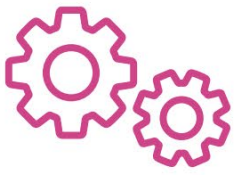
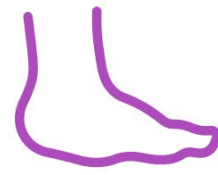
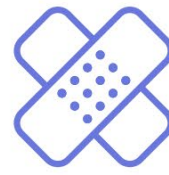
Overall:confirmation of the 2019 guidelines

2023

Use Conventional, Not PCR (Strong;Moderate)

Use bone biopsy for DFO (Conditional;Moderate)

No Adjunctive treatments (Conditional;Moderate)



What's new

2023

3 weeks of antibiotic therapy after minor amputation for osteo
(Strong; Moderate)

Medical approach forefoot osteo without:

- need for immediate surgery
- peripheral artery disease
- exposed bone. (Conditional; Low)

Minimum follow-up duration of 6 months for osteo (Best Practice Statement)



08/08/2023



IWGDF
Guidelines

www.iwgdfguidelines.org



New recommendations

- Consider a duration of up to 3 weeks of antibiotic therapy after minor amputation for diabetes-related osteomyelitis of the foot and positive bone margin culture and 6 weeks for diabetes-related osteomyelitis without bone resection or amputation (conditional, low).
- Consider performing surgical resection of infected bone combined with systemic antibiotics in a person with diabetes-related osteomyelitis of the foot. (Conditional; Low)
- Consider antibiotic treatment without surgery in case of (i) forefoot osteomyelitis without an immediate need for incision and drainage to control infection, and (ii) without peripheral artery disease, and (iii) without exposed bone. (Conditional; Low)
- Use the outcome at a minimum follow-up duration of 6 months after the end of the antibiotics therapy to diagnose remission of diabetes-related osteomyelitis of the foot (Best Practice Statement)

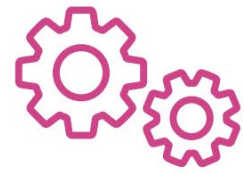
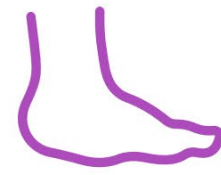
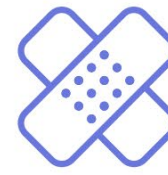


Table 1: The classification system for defining the presence and severity of an infection of the foot in a person with diabetes^a

Clinical classification of infection, definitions	IWGDF/IDSA classification
No systemic or local symptoms or signs of infection	1 / Uninfected
Infected: At least two of these items are present: - Local swelling or induration - Erythema > 0.5 but < 2 cm^b around the wound - Local tenderness or pain - Local increased warmth - Purulent discharge And, no other cause of an inflammatory response of the skin (e.g., trauma, gout, acute Charcot neuro-arthropathy, fracture, thrombosis, or venous stasis)	2 / Mild
Infection with no systemic manifestations and involving: - erythema extending ≥ 2 cm from the wound margin, and/or - tissue deeper than skin and subcutaneous tissues (e.g., tendon, muscle, joint, and bone)	3 / Moderate
Infection involving bone (osteomyelitis)	Add "(O)"
Any foot infection with associated systemic manifestations (of the systemic inflammatory response syndrome [SIRS]), as manifested by ≥ 2 of the following: - temperature, > 38°C or < 36°C - heart rate, > 90 beats/min - respiratory rate, >20 breaths/min, or PaCO₂ < 4.3 kPa (32 mmHg) - white blood cell count >12,000/mm³, or < 4G/L, or > 10% immature (band) forms	4 / Severe
Infection involving bone (osteomyelitis)	Add "(O)"

Note: The presence of clinically significant foot ischaemia makes both diagnosis and treatment of infection considerably more difficult.

^a infection refers to any part of the foot, not just of a wound or an ulcer.

^b in any direction, from the rim of the wound.

^c if osteomyelitis is demonstrated in the absence of ≥ 2 signs/symptoms of local or systemic inflammation, classify the foot as either grade 3(O) (if <2 SIRS criteria) or grade 4(O) if ≥ 2 SIRS criteria) (see text).

Table 2: Characteristics suggesting a more serious diabetes-related foot infection and potential indications for hospitalisation.^{4, 17-19}

A. Findings suggesting a more serious diabetes-related foot infection	
<i>Wound specific</i>	
Wound	Penetrates to subcutaneous tissues (e.g., fascia, tendon, muscle, joint, or bone)
Cellulitis	Extensive (>2 cm), distant from ulceration, or rapidly progressive (including lymphangitis)
Local signs / symptoms	Severe inflammation or induration, crepitus, bullae, discoloration, necrosis or gangrene, ecchymoses or petechiae, and new anesthesia or localised pain
<i>General</i>	
Presentation	Acute onset/worsening or rapidly progressive
Systemic	Fever, chills, hypotension, confusion, and volume depletion
Laboratory tests	Leukocytosis highly elevated C-reactive protein, or erythrocyte sedimentation rate, severe or worsening hyperglycemia, acidosis, new/worsening azotaemia and electrolyte abnormalities tests
Complicating features	Presence of a foreign body (accidentally or surgically implanted), puncture wound, deep abscess, arterial or venous insufficiency, lymphedema, immunosuppressive illness or treatment, acute kidney injury
Failing treatment	Progression while on apparently appropriate antibiotic and supportive therapy

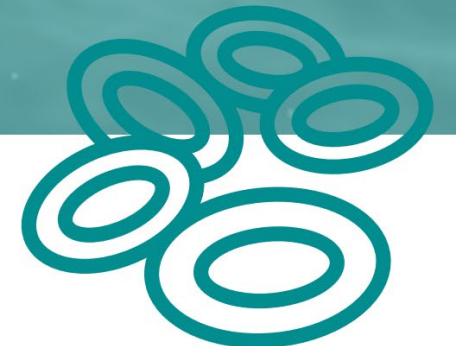
B. Factors that should lead to considering hospitalisation	
Severe infection (see findings suggesting a more serious diabetes-related foot infection above)	
Metabolic or haemodynamic instability	
Intravenous therapy needed (and not available/appropriate as an outpatient)	
Diagnostic tests needed that are not available as an outpatient	
Severe foot ischaemia is present	
Surgical procedures (more than minor) required	
Failure of outpatient management	
Need for more complex dressing changes than patient/caregivers can provide	
Need for careful, continuous observation	

Robert Fitridge
Vivienne Chuter
Joseph Mills
Robert Hinchliffe
Nobuyoshi Azuma
Christian-alexander Behrendt
Edward Boyko
Michael Conte
Misty Humphries
Lee Kirksey
Katharine McGinigle
Sigrid Nikol
Joakim Nordanstig
Vincent Rowe
David Russell
Jos van den Berg
Maarit Venermo
Nicolaas Schaper



www.iwgdfguidelines.org

The intersocietal IWGDF, ESVS, SVS guidelines on the diagnosis, prognosis and management of peripheral artery disease in patients with diabetes mellitus



Intersocietal PAD guideline (2023 update)

[Home](#) > [Guidelines 2023](#) > [Intersocietal PAD guideline \(2023 update\)](#)

The Intersocietal 2023 PAD Guidelines are a unique collaboration between the International Working Group on the Diabetic Foot (IWGDF), the European Society for Vascular Surgery (ESVS), and the American Society for Vascular Surgery (SVS).

The Intersocietal 2023 PAD Guidelines are currently in the final stages. The IWGDF has formally approved them, ESVS and SVS are in the final stage towards formal approval. Once the guidelines have been formally approved by all societies, they will be published here.

[Download the Intersocietal PAD Guideline here when available](#)

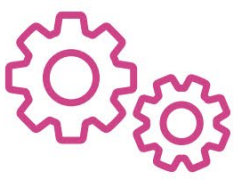
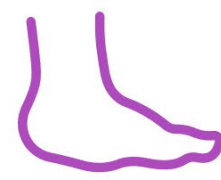
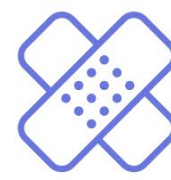
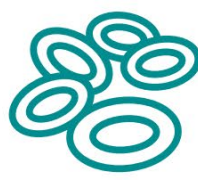


PAD



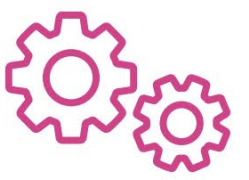
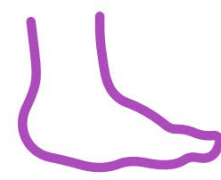
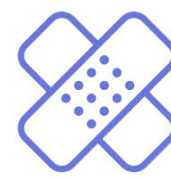
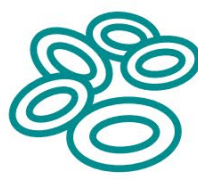
PAD guideline

- Aim is to have consistent suite of recommendations for PAD assessment and management in diabetes-related foot disease internationally
- Developed in collaboration with the 2 major international vascular societies (ESVS and SVS) – 6 working group members from each of 3 societies
- Working group expertise- vascular surgery, interventional radiology, angiology, podiatry, endocrinology
- External experts and patient representative involvement
- *Approved by IWGDF Editorial Board, ESVS and SVS*



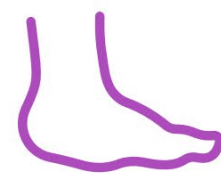
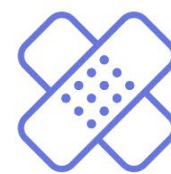
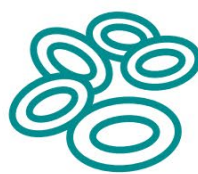
Peripheral arterial disease (PAD) guideline based on 3 systematic reviews:

1. Effectiveness of bedside investigations to diagnose PAD in people with diabetes mellitus (with or without a foot ulcer or gangrene)
2. Performance of non-invasive bedside vascular testing for the prediction of wound healing or amputation among people with foot ulcers in diabetes
3. Effectiveness of revascularisation of the ulcerated foot in patients with diabetes and PAD



Recommendations

- Diagnosis: 5 recommendations (1 is a Best Practice Statement)
- Prognosis: 5 recommendations
- Treatment: 15 recommendations (14 are Best Practice Statements)
 - Includes recommendations on the principles of management of diabetes, lipids and antithrombotics



What's New? – New recommendations

- In a person with diabetes **without** a foot ulcer in whom a non-emergent invasive foot procedure is being considered, PAD should be excluded by performing assessment of pedal Doppler waveforms in combination with ankle-brachial index (ABI) and toe-brachial index (TBI). (Best Practice Statement)
- In a person with diabetes and **a foot ulcer or gangrene** we suggest the presence of PAD and other causes of poor healing should always be assessed. Diabetes-related microangiopathy should not be considered the primary cause of foot ulceration, gangrene or poor wound healing without excluding other causes. (Conditional, low)

How to Perform Vascular Assessment in a Person with Diabetes and a Foot Ulcer?

1

Palpation of foot pulses

Presence of foot pulses does not reliably exclude PAD

- Pedal Doppler arterial waveforms
- Ankle systolic pressure and ankle brachial index
- Toe systolic pressure and toe brachial index

- Triphasic Doppler waveforms
- Ankle brachial index 0.9-1.3
- Toe brachial index ≥ 0.75

PAD is less likely

2

Severe ischemia:

- Ankle systolic pressure $< 50\text{mmHg}$ or
- Ankle brachial index < 0.5 or
- Toe pressure $< 30\text{mmHg}$

Abnormal values but not severe ischemia:
Is there infection or ulcer deeper than skin?

Yes

No

Irrespective of the results of bedside tests, when the ulcer is not healing within 4-6 weeks:

3

CONSULTATION WITH VASCULAR SPECIALIST



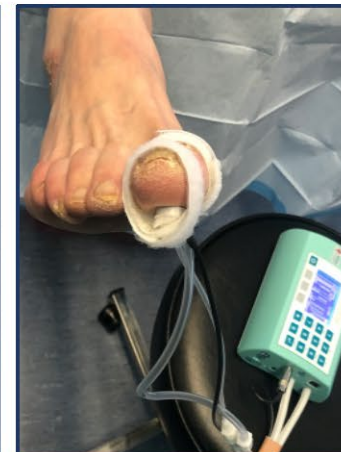
Posterior tibial artery



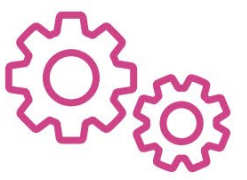
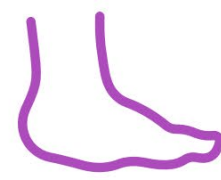
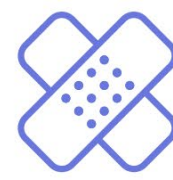
Dorsalis pedis artery



Ankle systolic pressure

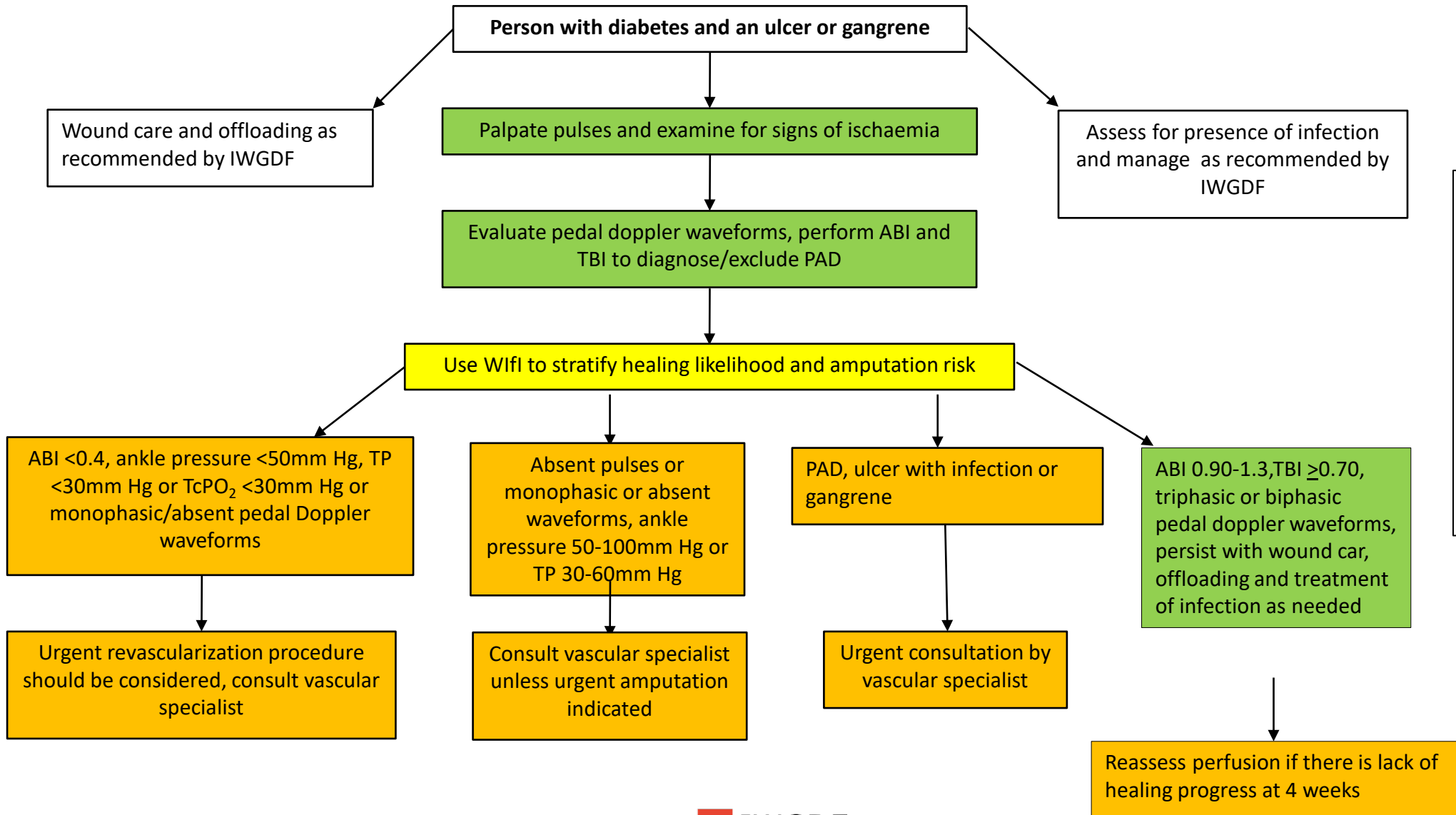


Toe systolic pressure

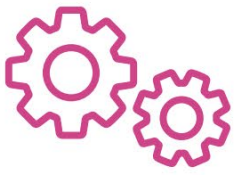
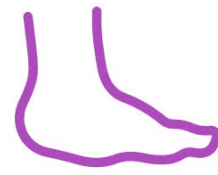
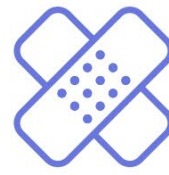


New Recommendations

- In a person with diabetes, PAD and a foot ulcer or gangrene who **has an adequate single segment saphenous vein** and in whom infrainguinal revascularisation is indicated and who are suitable for either approach, **consider bypass in preference to endovascular therapy (Conditional, moderate)**
- A person with diabetes, PAD and a foot ulcer or gangrene, should be treated in **centres with expertise** in, or rapid access to, endovascular and **surgical bypass** revascularisation.
- Make treatment decisions based on patient risk and preference, limb threat severity, anatomic distribution of PAD, and the availability of autogenous vein



Colour code:
yellow=conditional recommendation,
green=strong recommendation,
orange= best practice recommendation



Person with diabetes, PAD and an ulcer, gangrene in whom revascularization is indicated

Image arterial system from aorta to pedal arch using;
Arterial colour duplex ultrasound
CT Angiography
MR Angiography or
DS Angiography

Patient deemed unfit for bypass or
arterial lesion considered suitable
for straightforward endovascular
procedure

DS angiography $\pm$ intervention

Ideally target artery supplying
angiosome associated with ulcer or
gangrene

Assess great saphenous vein for suitability for bypass if open
bypass or endovascular intervention likely indicated

Patient suitable for bypass or
endovascular procedure

Image great saphenous vein(s)

Suitable single segment GSV

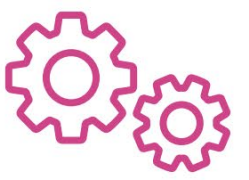
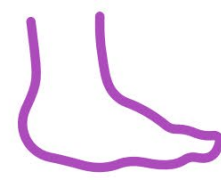
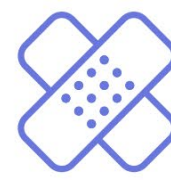
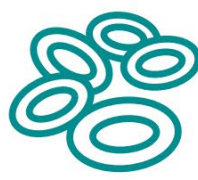
Consider bypass

Single segment GSV suitable
for bypass not available

Endovascular procedure or
bypass

Colour code:
yellow=conditional
recommendation,
orange= best practice
recommendation

10/08/2023



Members of the intersocietal IWGDF, ESVS and SVS guidelines on PAD in people with diabetes mellitus and a foot ulcer

- IWGDF: Rob Fitridge (co-Chair), Viv Chuter (secretary), Nicolaas Schaper, Nobuyoshi Azuma, Edward Boyko, Sigrid Nikol
- ESVS: Rob Hinchliffe (co-Chair), Christian-Alexander Behrendt, Joakim Nordanstig, David Russell, Jos van den Berg, Maarit Vanermo
- SVS: Joe Mills (co-Chair), Michael Conte, Misty Humphries, Lee Kirksey, Katharine McGinigle, Vincent Rowe



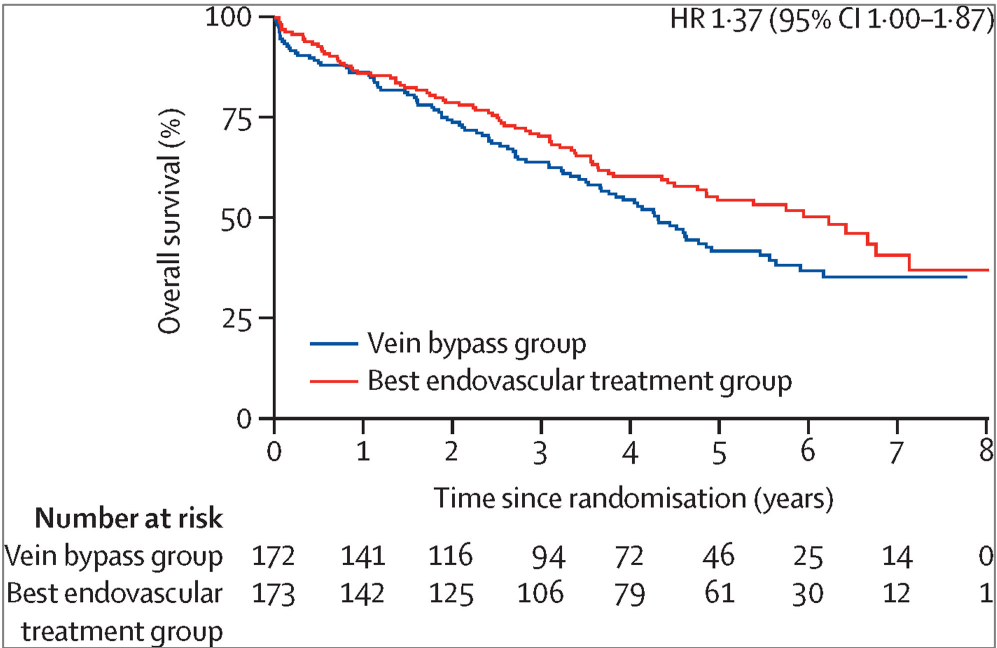
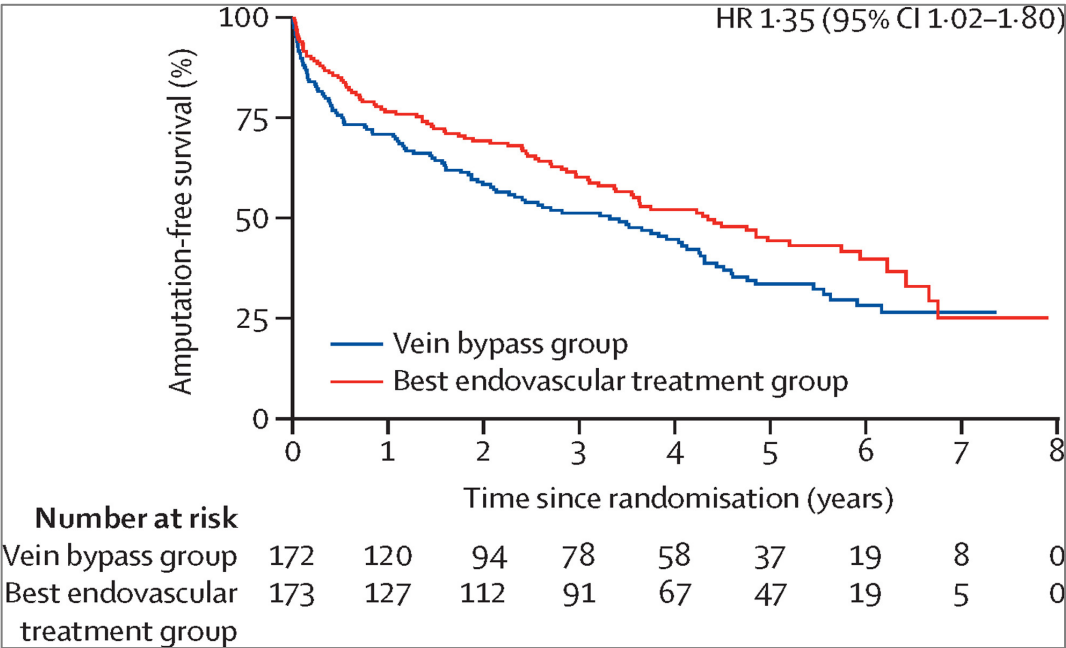
Significato da approfondire (1)

Global Vascular Guidelines on the management of Chronich limb-threatening ischemia.:
M.Conte et Al. Journal of Vascular Surgery June 2019.

1. Term: The term of CLTI da preferire a Critical limb Ischemia.
2.The optimal revascularization strategy is also influenced by the availability of autogenous vein for open bypass surgery. Recommendations for EBR are based on best available data, pending level 1 evidence from ongoing trials. Vein bypass may be preferred for average-risk patients with advanced limb threat and high complexity disease, while those with less complex anatomy, intermediate severity limb threat, or high patient risk may be favored for endovascular intervention.

A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial Prof Andrew W Bradbury, MD, Catherine A Moakes, MSc, Matthew Popplewell, MD, Lewis Meecham, FRCS, Gareth R Bate, PGDip, Lisa Kelly, PGDip, Prof Ian Chetter, MD, Athanasios Diamantopoulos, PhD, Arul Ganeshan, FRCR, Jack Hall, MSc, Simon Hobbs, MD, Prof Kim Houlind, MD, Hugh Jarrett, MSc, Suzanne Lockyer, MSc, Jonas Malmstedt, MD, Jai V Patel, FRCR, Smitaa Patel, MSc, S Tawqeer Rashid, PhD, Athanasios Saratzis, MD, Gemma Slinn, MPhil, Prof D Julian A Scott, MD, Hany Zayed, MD, Prof Jonathan J Deeks, PhD

The Lancet Volume 401 Issue 10390 Pages 1798-1809 (May 2023) DOI: 10.1016/S0140-6736(23)00462-2





Significato da approfondire (2)

- 1. In the BASIL-2 trial, a best endovascular treatment first revascularisation strategy was associated with a better amputation-free survival, which was largely driven by fewer deaths in the best endovascular treatment group.**
2. These data suggest that more patients with chronic limb-threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion should be considered for a best endovascular treatment first revascularisation strategy.

RESEARCH SUMMARY

Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

Farber A et al. DOI: 10.1056/NEJMoa2207899

CLINICAL PROBLEM

Patients with chronic limb-threatening ischemia (CLTI) require timely revascularization to improve perfusion and reduce the risk of amputation. Whether an initial strategy of surgical revascularization or endovascular therapy results in superior outcomes is unclear.

CLINICAL TRIAL

Design: An international, prospective, open-label, randomized trial assessed whether endovascular revascularization was superior to surgical revascularization in patients with CLTI caused by infrainguinal peripheral artery disease.

Intervention: 1830 adults with CLTI who were enrolled in two parallel cohorts — the first including 1434 patients with a great saphenous vein adequate for conduit and the second including 396 patients requiring an alternative bypass conduit — were randomly assigned to receive surgical or endovascular treatment within 30 days. The patients were considered to be suitable candidates for either procedure. The primary outcome was a composite of a major adverse limb event (above-ankle amputation or major limb reintervention, including a new bypass graft or graft revision, thrombectomy, or thrombolysis) or death from any cause.

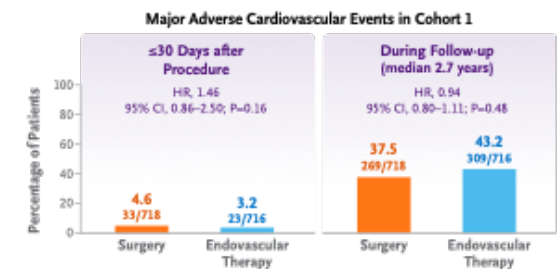
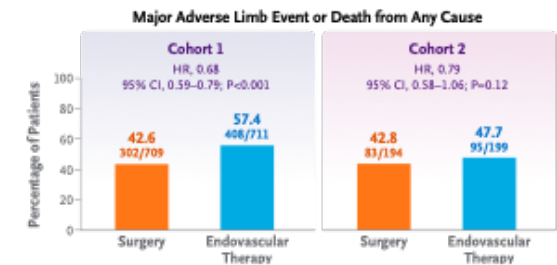
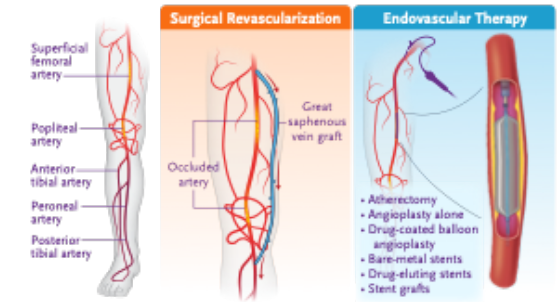
RESULTS

Efficacy: In cohort 1, during a median follow-up of 2.7 years, a primary-outcome event occurred less frequently in the surgery group than in the endovascular-therapy group. In cohort 2, during a median follow-up of 1.6 years, the incidence of a primary-outcome event was similar with the two procedures.

Safety: In both cohorts, there was no material between-group difference in serious adverse events within 30 days after the procedure or in major adverse cardiovascular events.

LIMITATIONS AND REMAINING QUESTIONS

- Study results may have been influenced by selection or operator bias as a consequence of the pragmatic trial design and implementation.
- Patient suitability for procedures was determined locally and varied according to study site and individual investigator.
- Enrollment targets were not met for patients overall and for women.



CONCLUSIONS

Among patients with CLTI who had a great saphenous vein adequate for surgical revascularization, clinical outcomes with an initial treatment of surgery were superior to those with endovascular therapy; however, in patients who required an alternative bypass conduit, outcomes were similar with the two procedures.

ASSISI (PG)

15/17

GIUGNO 2023

Grand Hotel Assisi

Congresso Nazionale
PIEDE DIABETICO
GDS AMD-SID

La **S**indrome del **pie**de **di**abético: competenze in azione con uno sguardo al futuro

EDITORIALS



Surgical Revascularization — Best for Limb Ischemia?

Jonathan Golledge, M.Chir., F.R.A.C.S.

THE NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Surgery or Endovascular Therapy for Chronic Limb Ischemia

TO THE EDITOR: In the BEST-CLI trial, in which Farber et al. (Dec. 22 issue)¹ compare surgery and endovascular therapy for chronic limb-threatening ischemia, the definition of the composite primary outcome — a major adverse limb event or death from any cause — is problematic. The number of deaths was substantial, and the vast majority occurred more than 30 days after the trial intervention. Presumably, these deaths were related to the patients' existing conditions, which were abundant, and not to the randomized intervention. Thus, the primary outcome definition exaggerates the frequency of intervention failures and underestimates the relative difference in effectiveness of the trial interventions. An alternative composite outcome definition — a major adverse limb event or postoperative death — would be more appropriate. A summary that is based on the authors' outcome definition might be that approximately half the patients had an intervention failure, with surgery somewhat less likely to fail than endovascular therapy. However, a more optimistic summary based on the alternative definition might be that for most patients, the intervention was a success, with surgery less likely to fail than endovascular therapy. Furthermore, investigators of endovascular therapy would be provided with a more appropriate comparison of the relative effectiveness of the two interventions.

John D. Roberts, M.D.
Yale University School of Medicine
New Haven, CT
john.d.roberts@yale.edu

No potential conflict of interest relevant to this letter was reported.

1. Farber A, Menard MJ, Conte MS, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. *N Engl J Med* 2023;387:2095-16.

DOI: 10.1056/NEJMe2309713

TO THE EDITOR: In the BEST-CLI trial, the surgical group and the endovascular group had a similar percentage of participants receiving statin treatment. A study by Arya et al. showed that high-intensity statin therapy lowered the relative risk of death by 15% and the risk of amputation by 22% as compared with low-to-moderate-inten-

sity statin therapy in patients with peripheral artery disease.² Although no information is provided about the dose of statin in the BEST-CLI trial, high-intensity statin treatment could have had an effect on the primary outcome. In addition, 60 to 70% of the patients in each group had diabetes mellitus. Since the Food and Drug Administration approved the sodium-glucose cotransporter (SGLT2) inhibitor canagliflozin in 2013, many patients' existing conditions, which were abundant, and not to the randomized intervention. Thus, the primary outcome definition exaggerates the frequency of intervention failures and underestimates the relative difference in effectiveness of the trial interventions. An alternative composite outcome definition — a major adverse limb event or postoperative death — would be more appropriate. A summary that is based on the authors' outcome definition might be that approximately half the patients had an intervention failure, with surgery somewhat less likely to fail than endovascular therapy. However, a more optimistic summary based on the alternative definition might be that for most patients, the intervention was a success, with surgery less likely to fail than endovascular therapy. Furthermore, investigators of endovascular therapy would be provided with a more appropriate comparison of the relative effectiveness of the two interventions.

Yujing Kida, M.D., Ph.D.
Takashimadara Chuo General Hospital
Tokyo, Japan
yujing.kida@gmail.com

No potential conflict of interest relevant to this letter was reported.

1. Arya S, Khakhria A, Binney ZO, et al. Association of statin dose with amputation and survival in patients with peripheral artery disease. *Circulation* 2018;137:3475-85.

2. Neal B, Perkovic V, Mahaffey KW, et al. Canagliflozin and cardiovascular and renal events in type 2 diabetes. *N Engl J Med* 2017;376:644-57.

3. Udell JA, Yuan Z, Rush T, Scragano NM, Galis R, Ranawat N. Cardiovascular outcomes and risks after initiation of a sodium glucose cotransporter 2 inhibitor: results from the EAGLE population-based cohort study [evidence for cardiovascular outcomes with sodium glucose cotransporter 2 inhibitors in the real world]. *Circulation* 2018;137:3475-85.

DOI: 10.1056/NEJMe2309713

TO THE EDITOR: The BEST-CLI investigators provide urgently needed evidence on the best treatment for patients with peripheral artery disease with critical limb ischemia. In 2005, the BASIL trial¹ showed that endovascular therapy with balloon angioplasty was inferior to bypass surgery with respect to amputation-free survival. Later evidence suggested better vessel patency with endovascular therapy with stent implantation than with balloon angioplasty alone.² Therefore, a large-scale, randomized trial that compared bypass surgery with endovascular therapy plus stent implantation was urgently needed.

Unfortunately, in the endovascular-therapy

N ENGL J MED 386:13 NEJM.ORG MARCH 16, 2023

The New England Journal of Medicine

Downloaded from nejm.org at AZIENDA USL TOSCANA CENTRO on June 14, 2023. For personal use only. No other uses without permission. Copyright © 2023 Massachusetts Medical Society. All rights reserved.

THE NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

group of the BEST-CLI trial, more than 50% of the patients were treated with balloon angioplasty alone. Some observers may argue that this method does not represent the best endovascular therapy. A recent patient-level pooled analysis of randomized trials comparing bypass surgery with endovascular therapy plus stent implantation in patients with peripheral artery disease involving the femoropopliteal segment showed similar major adverse limb events and amputation-free survival in the two groups after a median follow-up of 2 years.³ We are looking forward to the subanalyses of the BEST-CLI data with respect to bypass surgery as compared with endovascular therapy with stent implantation.

Serdar Farhan, M.D.
Birgit Vogel, M.D.
Prakash Krishnan, M.D.
Kahn School of Medicine at Mount Sinai
New York, NY
prakash.krishnan@mountsinai.org

No potential conflict of interest relevant to this letter was reported.

1. Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet* 2005;366:1020-34.

2. Schillinger M, Sabeti S, Lowee C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med* 2006;354:1879-88.

3. Farhan S, Faermann PB, Borkman E, et al. Revascularization strategies for patients with femoropopliteal peripheral artery disease. *J Am Coll Cardiol* 2023;81:158-70.

DOI: 10.1056/NEJMe2309713

TO THE EDITOR: Farber et al. report a lower rate of technical success in the endovascular-therapy group (85%) than in surgical group (98%) in cohort 1 in the BEST-CLI trial. This divergence in success explains almost the entire difference in the primary outcome between the two groups, because technical failure inevitably leads to repeat revascularization attempts. This difference in success rates accounts for the immediate separation of the Kaplan-Meier curves for the primary outcome of major adverse limb events or death from any cause, because the definition of major adverse limb events includes repeat revascularization.

We also note that this trial had an unacceptably high number of patients who were lost to follow-up and a large number of protocol deviations. Across the four trial cohorts, a total of 363 patients were lost to follow-up, withdrew consent, or were excluded due to data issues, which represents 10.8% of the overall analysis cohort.

Matthew T. Finn, M.D.
Pradeep Nair, M.D.
Craig Walker, M.D.

N ENGL J MED 386:13 NEJM.ORG MARCH 16, 2023

The New England Journal of Medicine

Downloaded from nejm.org at AZIENDA USL TOSCANA CENTRO on June 14, 2023. For personal use only. No other uses without permission. Copyright © 2023 Massachusetts Medical Society. All rights reserved.

Cardiovascular Institute of the South
Gray, LA

Dr. Nair reports receiving consulting fees from Bard, Philips, CardioFlow, and Sormedico. Dr. Walker reports receiving consulting fees from Abbott, Boston Scientific, Bard, Lake Regional Medical, Medtronic, and Philips, receiving lecture fees from Abbott, Bard, BioCryst, Inceptiv, Bristol Myers Squibb/Sanofi, Therapeutics Therapeutics, Janssen Pharmaceuticals, and Asahi Intec, having an equity interest in CardioFlow, Euphrates Vascular, Venkoo, Hemolac, MicroMedical, and Pylone Solutions, and receiving peripheral vascular training from Abbott, Bard, Boston Scientific, and Philips. No other potential conflict of interest relevant to this letter was reported.

DOI: 10.1056/NEJMe2309713

TO THE EDITOR: In cohort 1 of the trial by Farber et al. (which included 1454 patients with a single-segment saphenous vein), surgery was associated with a lower risk of major adverse limb events and death than endovascular therapy (42.6% vs. 57.4%), whereas in cohort 2 (which included 396 patients requiring alternative conduits) outcomes were similar (42.8% vs. 47.7%). However, even in this well-designed trial, the results need to be interpreted with caution. Technical success rates with endovascular treatment were remarkably low (80 to 85%), which indicates that advanced techniques were not routinely applied.¹⁻³ Furthermore, more than one quarter of femoropopliteal lesions were treated with balloon angioplasty alone, which is known to be inferior to contemporary drug-coated balloon and stent technologies.⁴ After endovascular failures, which were the main trigger of increased subsequent event rates, only 66 patients (61%) underwent surgery, which indicates a widely applied "endovascular only" strategy. Despite similar baseline characteristics in the two cohorts, markedly different event rates were noted in the endovascular group (57.4% in cohort 1 and 47.7% in cohort 2), which suggests unexpectedly high variability in treatment efficacy, whereas the almost identical event rates in the surgical groups (42.6% in cohort 1 and 42.8% in cohort 2) are unlikely to suggest the superiority of the single-segment saphenous-vein bypass.

Grigoris Korosoglou, M.D.
GRH Hospital Weinheim
Weinheim, Germany
gkorosoglou@hotmail.com

Jihad Mustapha, M.D.
Advanced Cardiac and Vascular Centers
Grand Rapids, MI

Thomas Zeller, M.D.
University Hospital Freiburg—Bad Krozingen
Bad Krozingen, Germany
No potential conflict of interest relevant to this letter was reported.

N ENGL J MED 386:13 NEJM.ORG MARCH 16, 2023

The New England Journal of Medicine

Downloaded from nejm.org at AZIENDA USL TOSCANA CENTRO on June 14, 2023. For personal use only. No other uses without permission. Copyright © 2023 Massachusetts Medical Society. All rights reserved.

1. Schmidt A, Banaschuk V, Perkowski M, et al. Retrograde tibio-peroneal access for complex infrapopliteal occlusions: short- and long-term outcomes of 554 endovascular interventions. *JACC Cardiovasc Interv* 2019;12:1714-26.

2. Korosoglou G, Schmidt A, Stavroulakis K, et al. Retrograde access for the recanalization of lower limb occlusive lesions: a German experience report in 1530 consecutive patients. *JACC Cardiovasc Interv* 2022;15:146-51.

3. Kojima A, Al-Aissi V, Orsopoulos G, Roche-Sigle G, Tan KT, Raju DK. Drug-eluting balloon angioplasty versus stenting of balloon angioplasty for peripheral arterial disease of the lower limbs. *Cochrane Database Syst Rev* 2016;6:CD013193.

4. Kimura NI, Xing SH, Ashraf RN, et al. Pooled analysis of peripheral arterial disease associated with improved overall survival and limb salvage in patients with chronic limb-threatening ischemia. *J Vasc Med Biol* 2017;29(5):342-348.

DOI: 10.1056/NEJMe2309713

THE AUTHORS REPLY: In response to Roberts et al. although a composite of major adverse limb events or death from any cause was chosen as a primary outcome in the BEST-CLI trial, a composite of major adverse limb events or postoperative death was a key secondary outcome. In the two cohorts, patients in the surgery group were less likely to have had a major adverse limb event or postoperative death than were those in the endovascular group (hazard ratio, 0.53 in cohort 1 and 0.62 in cohort 2).

In response to Kida, we reported details regarding baseline medical therapy in the article, and guideline-directed medical therapy 30 days after the index procedure was increased. For example, in cohort 1, 75% of the patients received statins and 85% received at least one antiplatelet agent. Comprehensive analyses of medical therapies that we used in the trial are ongoing.

In response to Farhan et al.: when we analyzed the as-treated population (including cross-overs to endovascular therapy) and per-limb data, 19% of the patients in cohort 1 and 15% of those in cohort 2 were treated with balloon angioplasty alone. Similarly, drug-eluting stents or drug-coated balloons were used in 50% of the patients in cohort 1 and in 52% of those in cohort 2, rates that are similar to recent data from the Vascular Quality Initiative.⁵

In response to Finn et al.: in our trial, we reported intention-to-treat outcomes, which is unusual as compared with other reports of endovascular therapy and regulatory trials that excluded patients in whom lesions were not successfully crossed with a wire. The technical failure rate of 15% that was reported for the endovascular group of cohort 1 is within the range described in published reports involving patients

with diffuse severe occlusive disease.^{1,2} Furthermore, a significant difference in the primary outcome in favor of surgery remained after sensitivity analyses that excluded technical failure or major adverse limb events that occurred within 30 days. For these reasons as well as the sustained difference in event rates over the entire follow-up period, it is a misrepresentation to suggest that the treatment effect was inordinately driven by early events. In addition, the loss to follow-up and withdrawal rates in our trial are not surprising, given the challenges inherent in patient populations with chronic limb-threatening ischemia.⁴

In response to Korosoglou et al.: we point out that nonrandomized comparisons across the two parallel cohorts are inherently confounded. The superiority of a single segment of saphenous vein over a prosthetic bypass graft is well established in the surgical literature and was not a hypothesis of our trial. However, one may assume that surgical options that were available to patients in cohort 1 as compared with those in cohort 2 were inherently different and may have influenced approaches taken after failure of endovascular interventions. Additional analyses of the trial data may provide more information and insights.

Alk Farber, M.D.
Boston University School of Medicine
Boston, MA
alkfarber@bu.edu

Kenneth Rosenfield, M.D.
Massachusetts General Hospital
Boston, MA

Matthew T. Menard, M.D.
Brigham and Women's Hospital
Boston, MA

Since publication of their article, the authors report no further potential conflict of interest.

1. Mokhpara A, Saadodin Z, Bretger DJ, et al. Nationwide trends in drug-coated balloon and drug-eluting stent utilization in the femoropopliteal artery. *J Vasc Med Biol* 2020;32:156A.

2. Shiozawa T, Takagi H, Gregg A, et al. Predictability of the Global Limb Anatomic Staging System (GLASS) for technical and limb-related outcomes: a systematic review and meta-analysis. *Eur J Vasc Endovasc Surg* 2022;64:32-40.

3. Farber A, Menard MJ, Conte MS, et al. Validation of the correlation between angiogram-based target arterial path, mid-term limb-based patency, and the global limb anatomical staging system. *Heart Vessels* 2022;37:496-504.

4. Cisek RC, Torgerson K, Zhang C, Wikman R. Overview of the critical 2023 TASC Classification System Devices Advisory Panel on Limb-related 014 drug-coated percutaneous transluminal angioplasty catheter for below-the-knee lesions in critical limb ischemia. *Cardiovasc Interv Med* 2023;13(5):43.

DOI: 10.1056/NEJMe2309713

Copyright © 2023 Massachusetts Medical Society

N ENGL J MED 386:13 NEJM.ORG MARCH 16, 2023

The New England Journal of Medicine

e37(1)



IWGDF third edition «Epical battle» ‘Angioplasty first’ strategy

SPECIAL ARTICLE

Treatment of peripheral arterial disease in diabetes: A consensus of the Italian Societies of Diabetes (SID, AMD), Radiology (SIRM) and Vascular Endovascular Surgery (SICVE)

A. Aiello ^a, R. Anichini ^b, E. Brocco ^c, C. Caravaggi ^d, A. Chiavetta ^e, R. Cioni ^f, R. Da Ros ^g, M.E. De Feo ^h, R. Ferraresi ⁱ, F. Florio ^j, M. Gargiulo ^k, G. Galzerano ^l, R. Gandini ^m, L. Giurato ⁿ, L. Graziani ^o, L. Mancini ^p, M. Manzi ^q, P. Modugno ^r, C. Setacci ^l, L. Uccioli ^{n,*}

^aP.O. Campobasso — ASReM, Campobasso, Italy

^bServizi di Diabetologia, USL 3, Pistoia, Italy

^cPoliclinico Abano Terme, Presidio Ospedaliero ULSS 16, Veneto, Italy

^dIstituto Clinico “Città Studi”, Milan, Italy

^eA.O. Cannizzaro, Catania, Italy

^fDipartimento Radiologia Diagnostica, interventistica e medicina nucleare, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy

^gCentro Diabetologico Monfalcone (GO) — Ass2, Gorizia, Italy

^hU.O.S. Diabetologia A.O.R.N. “A. Cardarelli”, Naples, Italy

ⁱEmodinamica Interventistica Cardiovascolare, Istituto Clinico Città Studi, Milan, Italy

^jIRCCS “Casa Sollievo della Sofferenza”, San Giovanni Rotondo, Italy

^kChirurgia Vascolare, Azienda Policlinica S. Orsola-Malpighi, Bologna, Italy

^lDepartment of Surgery Vascular and Endovascular Surgery Unit, University of Siena, Siena, Italy

^mDipartimento Diagnostica per immagini, Imaging molecolare, radioterapia e radiologia interventistica, Policlinico Universitario Tor Vergata, Rome, Italy

ⁿDiabetic Foot Unit, Dept of Internal Medicine, Policlinico Universitario Tor Vergata, Rome, Italy

^oUnità Operativa di Cardiologia Invasiva, Istituto Clinico “Città di Brescia”, Brescia, Italy

^pIstituto Dermatologico Immacolata IRCCS, Rome, Italy

^qRadiologia Interventistica, Policlinico Abano Terme, Presidio Ospedaliero ULSS 16, Veneto, Italy

^rDipartimento Malattie Cardiovascolari Fondazione Giovanni Paolo II, Università Cattolica Sacro Cuore, Campobasso, Italy

Received 5 June 2013; received in revised form 31 October 2013; accepted 1 December 2013

Available online 25 December 2013

KEYWORDS

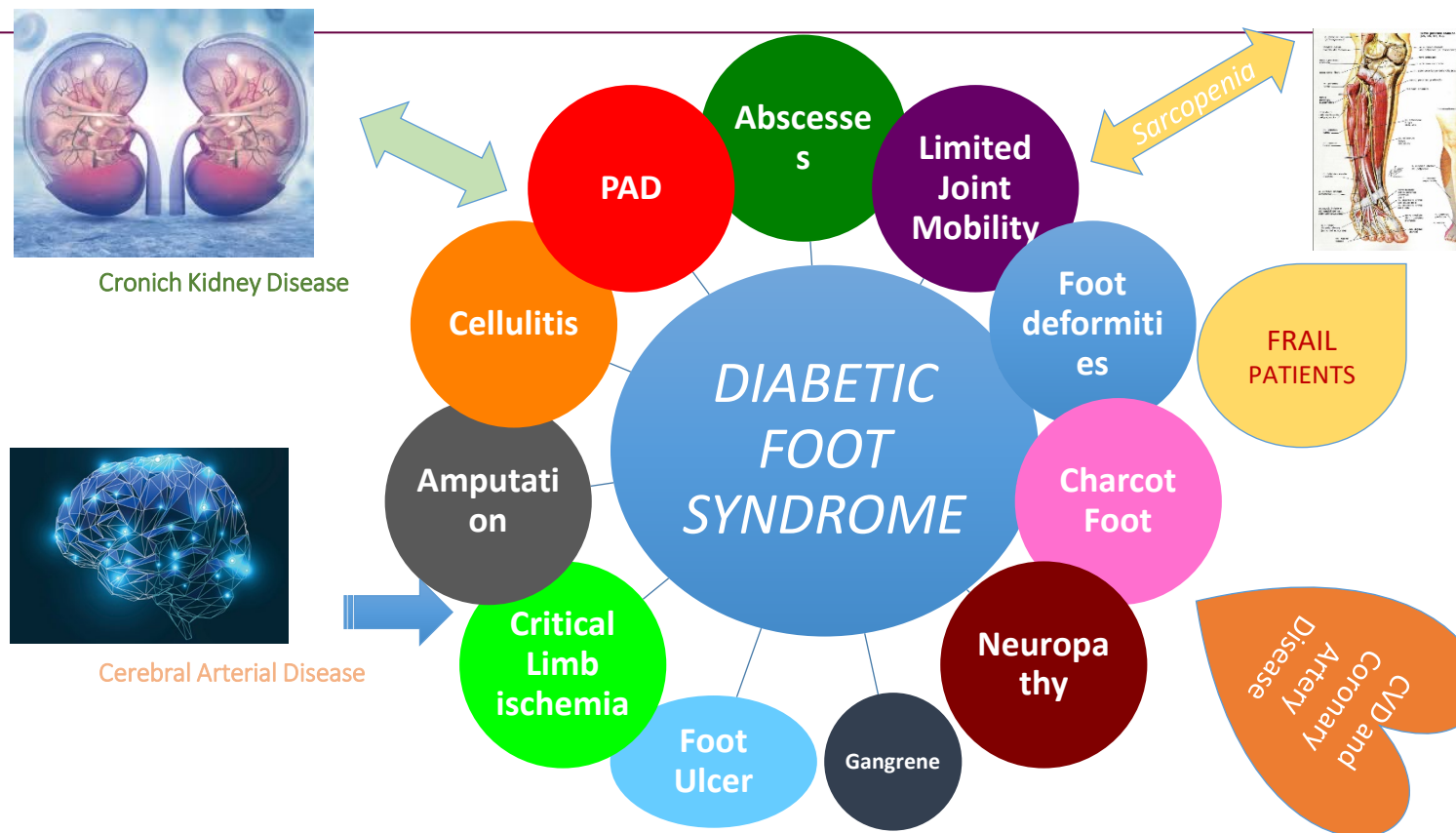
Diabetic foot;
Peripheral arterial
disease;
Angioplasty;
Limb salvage

Abstract Diabetic foot (DF) is a chronic and highly disabling complication of diabetes. The prevalence of peripheral arterial disease (PAD) is high in diabetic patients and, associated or not with peripheral neuropathy (PN), can be found in 50% of cases of DF. It is worth pointing out that the number of major amputations in diabetic patients is still very high. Many PAD diabetic patients are not revascularised due to lack of technical expertise or, even worse, negative beliefs because of poor experience. This despite the progress obtained in the techniques of distal revascularisation that nowadays allow to reopen distal arteries of the leg and foot. Italy has one of the lowest prevalence rates of major amputations in Europe, and has a long tradition in the field of limb salvage by means of an aggressive approach in debridement, antibiotic therapy and distal revascularisation. Therefore, we believe it is appropriate to produce a consensus document concerning the treatment of PAD and limb salvage in diabetic patients, based on the Italian experience in this field, to share with the scientific community.

© 2013 Elsevier B.V.



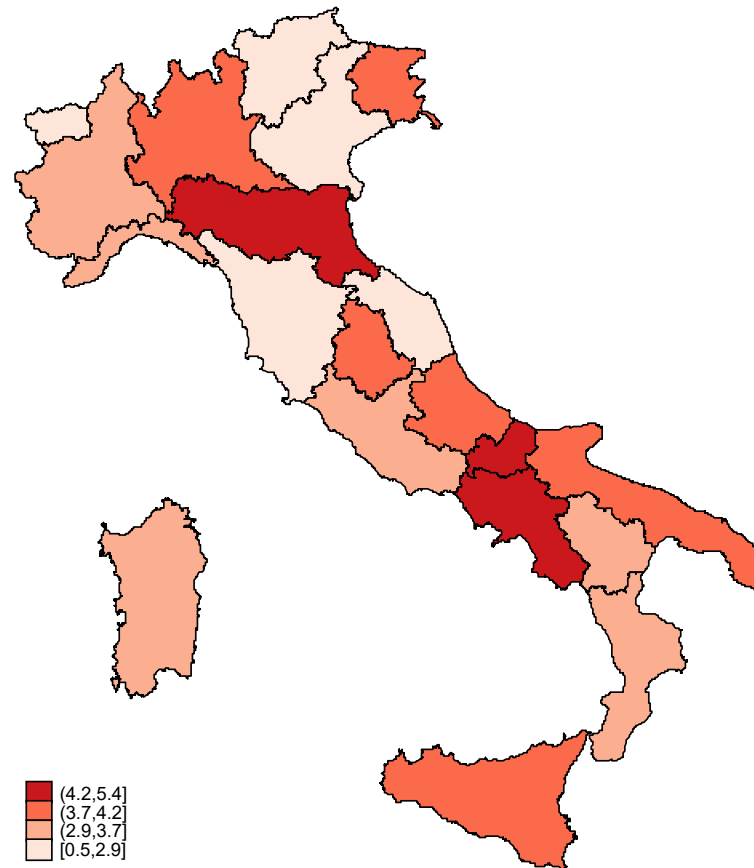
The Diabetic Foot Syndrome... Today *Patient Centered (Holistic Approach)*



So.....the very nature of ulcers change: from neuropathic to neuroischemic

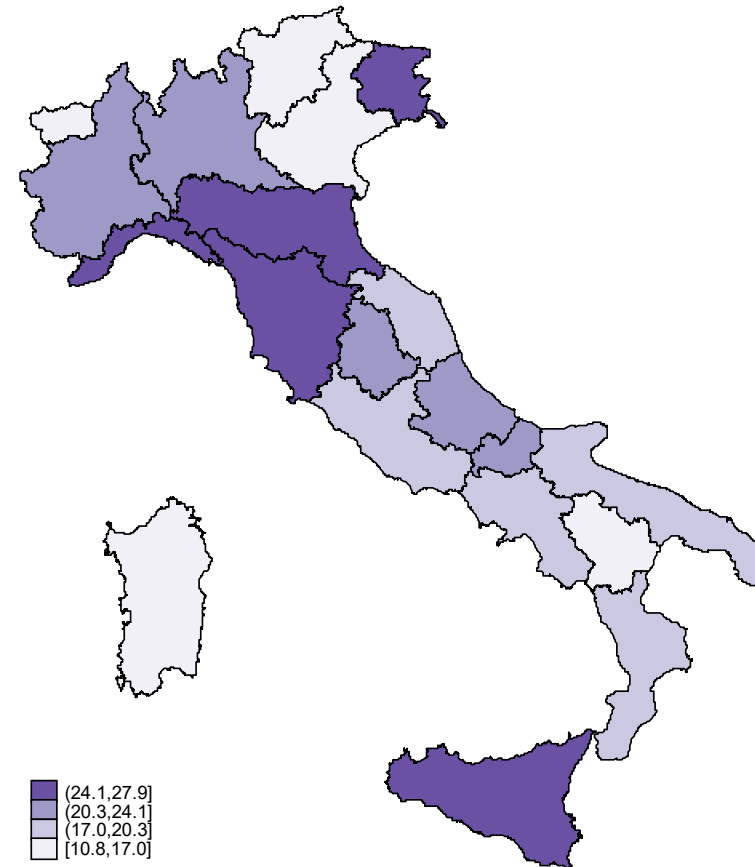
Amputations and Revascularization Rates in DM

Major Amputations



per 100.000 inhabitants

Revascularizations



per 100.000 inhabitants



Significato da approfondire (2)

1. Dati italiani di AGENAS Programma Esiti negli anni.
2. Outcomes (amputazioni), rivascolarizzazioni.....
Numero e tipo di rivascolarizzazioni
3. Popolazioni, organizzazione. Sistema sanitario
expertise, evidenze scientifiche pubblicate.....



Significato da approfondire (2)

ARTERIOPATIA periferica nel paziente diabetico è un'entità unica ??

BAD (BIG ARTERY DISEASE) NON RAPPRESENTA PIU' LA PRINCIPALE CAUSA DELLE MANIFESTAZIONI CLINICHE DELLA PAD

SAD (SMALL ARTERY DISEASE) E MAC (MEDIAL ARTERIAL CALCIFICATION) SONO 2 FACCE DELLA STESSA MEDAGLIA: UNA MALATTIA OSTRUTTIVA EPIDEMICA ALIMENTATA DA ETA', DIABETE E DIALISI CHE PORTA ALLA CLTI (Chronic Limb-Threatening-Ischemia)

I pazienti con CLTI con un quadro importante di SAD-MAC , presentano a 2aa:

- **solo il 30% di tasso di guarigione**
- **rischio più elevato di amputazione maggiore**
- **fallimento e reinterventi vascolari e del piede**

R. Ferraresi. BAD and SAD-MAC: a new scenario for CLTI. Mar 2021. American College of Cardiology.

Roberto MD Anichini 2023



Significato da approfondire (note R. Ferraresi)

1. La rivascularizzazione è elemento fondamentale della cura. **Lungi da noi il rifiuto di una scelta chirurgica**, tuttavia, come scritto nel documento di consenso italiano e come ribadito nelle Global Vascular Guidelines (GVGs), **la scelta tra un approccio open o uno endo deve essere fatta seguendo un preciso e condiviso algoritmo di scelta**. Tale algoritmo, al di là delle differenti coniugazioni, prevede degli step precisi e chiari, per esplicitarli seguirò il **PLAN concept delle GVGs**:
2. **Paziente**. La **valutazione globale** (olistica piace oggi dire) del paziente è il primo ineludibile punto. Sempre e solo una visione **internistica** del paziente può dirci quali sono gli spazi di intervento. Davanti ad una epidemia di vecchi con multiple comorbidità ed aspettative di vita spesso ridotte è essenziale che l'internista/diabetologo coordini una visione globale e dia a ciascun attore della cura il necessario spazio tecnico di intervento. Ogni protagonismo tecnico (e lo dico io, uno degli autori dell'arte acrobatica endovascolare), va ricondotto all'essenzialità della cura ed al reale bisogno clinico del paziente. In questi giorni al LINC più volte, davanti a giovani colleghi che mi chiedevano consigli tecnici ho risposto che la medicina è servizio, non acrobazia.
3. **Piede**. Come chiaramente afferma la classificazione Wlfl, **le condizioni del piede sono diverse ed hanno diversi fabbisogni di perfusion**. Ogni rivascularizzazione deve essere guidata da questo concetto. Non si rivascularizza per il piacere di dimostrare skill nei vasi BTK, ma per offrire al paziente una via di guarigione. Ancora una volta servizio e non acrobazia.
4. **Anatomical pattern of disease**. Inaccettabile qualunque indicazione endo o open che non consideri il quadro ostruttivo dei vasi. Qualora il quadro ostruttivo sia tale da indicare come migliore un approccio open, se le condizioni del paziente lo permettono, se le condizioni del piede lo richiedono, se è presente una vena safena di calibro adeguato, allora e solo allora il bypass trova la sua corretta indicazione.



concludere

- Sarà compito di questo congresso, dei colleghi che si occupano linee guida di individuare il nostro upgrade a tali affermazioni.
- Cercando di valorizzare di più le nostre pubblicazioni scientifiche.

Sicco Bus
David Armstrong
Ryan Crews
Cahterine Gooday
Gustav Jarl
Klaus Kirketerp-Moller
Vijay Viswanathan
Peter Lazzarini



www.iwgdfguidelines.org

Guidelines on offloading foot ulcers in persons with diabetes

IWGDF 2023 update

Roberto MD Anichini 2023





LIST OF RECOMMENDATIONS

1. 1a. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, **use a non-removable knee-high offloading device as the first choice** of offloading treatment to promote healing of the ulcer. (GRADE recommendation: Strong; Certainty of evidence: Moderate)
2. 1b. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for which a non-removable knee-high offloading device is to be used, **choose either a total contact cast or non-removable knee-high walker** based upon local resources and the person's individual factors and acceptability. (Conditional; Moderate)
2. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for whom a non-removable knee-high offloading device **is contraindicated** or not tolerated, consider using either a removable knee-high or ankle-high offloading device as the **second choice of offloading treatment to promote healing** of the ulcer, and encourage the person to use the device during all weight-bearing activities. (Conditional; Low)
3. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, do not use, and educate the person not to use conventional footwear or standard therapeutic footwear over an offloading device, to promote healing of the ulcer. (Strong; Low)
4. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for which offloading devices are not available, **consider using felted foam in combination with appropriately fitting footwear as the third choice of offloading treatment to promote healing of the ulcer.** (Conditional; Very Low)

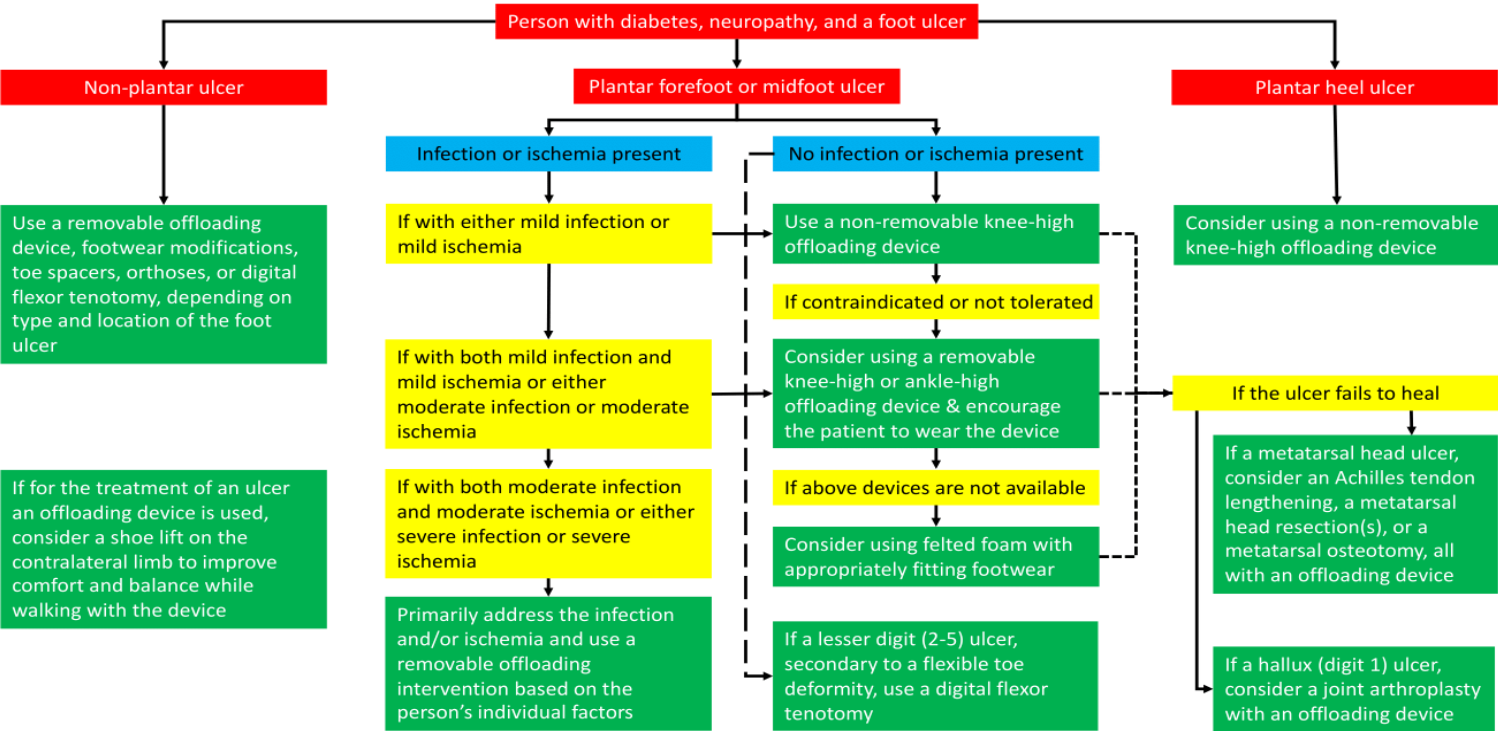


1. 5a. In a person with diabetes and a neuropathic plantar metatarsal head ulcer for which non-surgical offloading treatment fails, consider using **Achilles tendon lengthening** in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Moderate)
2. 5b. In a person with diabetes and a neuropathic plantar metatarsal head ulcer for which non-surgical offloading treatment fails, consider **using metatarsal head resection in combination with an offloading device** to promote and sustain healing of the ulcer. (Conditional; Low)
3. 5c. In a person with diabetes and a neuropathic hallux ulcer for which non-surgical offloading treatment fails, consider **using joint arthroplasty in combination with an offloading device** to promote and sustain healing of the ulcer. (Conditional; Low)
4. 5d. In a person with diabetes and a neuropathic plantar ulcer on metatarsal heads 2-5 for which non-surgical offloading treatment fails, **consider using a metatarsal osteotomy** in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Very low)
6. In a person with diabetes and a neuropathic plantar or apex ulcer on digits 2-5, secondary to a flexible toe deformity, **use a digital flexor tenotomy** to promote and sustain healing of the ulcer. (Strong; Moderate)
7. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischaemia, consider **using a non-removable knee-high offloading device to promote healing of the ulcer**. (Conditional; Low)



8. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischaemia, or with either moderate infection or moderate ischaemia, **consider using a removable offloading device to promote healing of the ulcer. (Conditional; Low)**
9. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischaemia, or with either severe infection or severe ischaemia, primarily address the infection and/or ischaemia, **and use a removable offloading intervention** over no offloading based on the person's individual factors, to promote healing of the ulcer. (Strong; Very low)
10. In a person with diabetes and a neuropathic plantar rearfoot ulcer, consider using a non-removable knee-high offloading device over a removable offloading device to promote healing of the ulcer. (Conditional; Very low)
11. In a person with diabetes and a non-plantar foot ulcer, use **a removable offloading device, footwear modifications, toe spacers, orthoses, or digital flexor tenotomy**, depending on the type and location of the foot ulcer, to promote healing of the ulcer. (Strong; Very low)
12. In a person with diabetes and a foot ulcer for which **a knee-high or ankle-high offloading device is used**, consider also using a shoe lift on the contralateral limb to improve the person's comfort and balance while walking in the device. (Conditional; Very low)

Figure 1: Flow diagram on the recommended offloading treatment for a person with diabetes and a foot ulcer



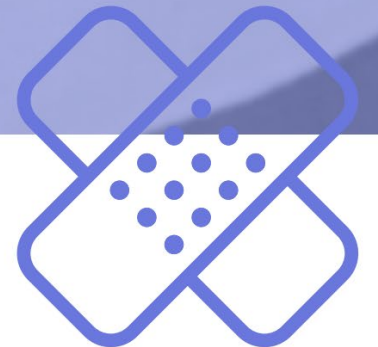
Pam Chen
Nalini Campillo Vilorio
Ketan Dhatariya
William Jeffcoate
Ralf Lobmann
Caroline McIntosh
Alberto Piagessi
John Steinberg
Prash Vas
Vijay Viswanathan
Stephanie Wu
Fran Game



www.iwgdfguidelines.org

Guidelines on interventions to enhance healing of foot ulcers in people with diabetes

IWGDF 2023 update





Recategorisation of some interventions:

- Debridement
- Dressing and Topical applications
- Oxygen and other gases
- Physical alteration of wound bed
- Skin substitutes
- Autologus products, growth factors, and other cellular Therapy
- Pharmacological
- Negative Pressure wound therapy
- Educational psychological and Behavioural



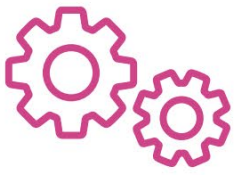
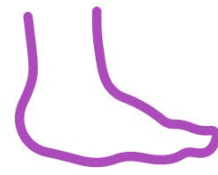
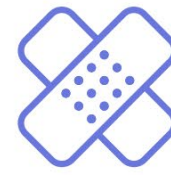
10/08/2023



IWGDF Wound Healing Guideline



- Principles of wound management, including debridement, wound bed preparation and newer technologies involving alternation of wound physiology to facilitate healing, are of utmost importance when attempting to heal a chronic diabetes-related foot ulcer.
- These include the use of sucrose octasulfate dressings, the use of negative pressure wound therapies for post-operative wounds, the use of placental derived products, the use of the autologous leucocyte/platelet/fibrin patch, the use of topical oxygen therapy, and the use of hyperbaric oxygen, **although in all cases it was stressed that these should be used where best standard of care was not able to heal the wound alone and where resources were available for the interventions.**



1. **Do not** use autolytic, biosurgical, hydrosurgical, chemical or laser debridement over standard of care. (GRADE Strength of recommendation: Strong; Certainty of evidence: Low)
2. **Do not routinely** use enzymatic debridement as opposed to standard of care (i.e. sharp debridement) to improve wound healing outcomes in people with diabetes and a foot ulcer. (Strong; Low)
 - 2.a In specific situations where the availability of sharp debridement **may be limited by access to resources** and/ or availability of skilled personnel, consider using enzymatic debridement. (Conditional; Low)
3. **Do not** use any form of ultrasonic debridement over standard of care (i.e. sharp debridement). (Strong; Low)
4. **Do not** use surgical debridement in those for whom sharp debridement can be performed outside a sterile environment. (Strong; Low)
5. **We recommend the frequency of sharp debridement should be determined by the clinician based on clinical need. (Strong; Low)**
6. **Do not** use topical antiseptic or antimicrobial dressings for wound healing of diabetes-related foot ulcers. (Strong; Moderate)
7. **Do not** use honey (or bee related products) for the purpose of wound healing in diabetes-related foot ulcers. (Strong; Low)
8. **Do not** use collagen or alginate dressings for the purpose of wound healing of diabetes-related foot ulcers. (Strong; Low)
9. **Consider the use of the sucrose-octasulfate impregnated dressing** as an adjunctive treatment, in addition to the best standard of care, in non-infected, neuro-ischaemic diabetes-related foot ulcers which have had insufficient change in ulcer area with best standard of care including appropriate offloading for at least 2 weeks. (Conditional; Moderate)
10. **Do not** use topical phenytoin for the purpose of wound healing in diabetes-related foot ulcers. (Strong; Low)
11. **Do not** use any dressing based or topical applications impregnated with herbal remedies for the sole purpose of wound healing in diabetes-related foot ulcers. (Strong; Low)
12. **Consider the use of hyperbaric** oxygen as an adjunct therapy in neuro-ischemic or ischemic diabetes-related foot ulcers where standard of care alone has failed and where resources already exist to support this intervention. (Conditional; Low)
13. **Consider the use of topical oxygen** as an adjunct therapy to standard of care for wound healing in people with diabetes-related foot ulcers where standard of care alone has failed and resources exist to support this intervention. (Conditional; Low)



14. Do not use other gases (e.g. cold atmospheric plasma, ozone, nitric oxide, CO₂) in comparison to standard of care for wound healing in people with diabetes-related foot ulcers. (Strong; Low)
15. Do not use any interventions reported in the field of physical therapies for wound healing in the management of diabetes-related foot ulcers. (Strong; Low)
16. We suggest not using cellular skin substitute products as a routine adjunct therapy to standard of care for wound healing in patients with diabetes-related foot ulcers. (Conditional; Low)
17. We suggest not using acellular skin substitute products as a routine adjunct therapy to standard of care for wound healing in patients with diabetes-related foot ulcers. (Conditional; Low)
18. Do not use autologous skin graft skin substitute products as an adjunct therapy for wound healing in patients with diabetes-related foot ulcers. (Strong; Low)

standard of care. (Conditional; Low)

20. Consider the use of autologous leucocyte, platelet and fibrin patch for diabetes-related foot ulcers as an adjunctive therapy to standard of care, where best standard of care alone has been ineffective, and where the resources and expertise exist for the regular venepuncture required. (Conditional; Moderate)
21. We suggest not using other cell therapy as an adjunct therapy to standard of care for wound healing in people with diabetes-related foot ulcers. (Conditional; Low)
22. We suggest not using growth factor therapy as an adjunct therapy to standard of care for wound healing in people with diabetes-related foot ulcers. (Conditional; Low)
23. Consider the use of placental derived products as an adjunct therapy to standard of care for wound healing in people with diabetes-related foot ulcers where standard of care alone has failed. (Conditional; Low)
24. Do not use pharmacological agents promoting perfusion and angiogenesis to improve wound healing outcomes over standard of care. (Strong; Low)
25. Do not use pharmacological agents that supplement vitamins and trace elements to improve wound healing outcomes over standard of care. (Strong; Low)
26. Do not use pharmacological agents that stimulate red cell production or protein supplementation to improve wound healing outcomes over standard of care. (Strong; Low)
27. Do not use other pharmacological agents to improve wound healing outcomes over standard of care. (Strong; Low)
28. Consider the use of Negative Pressure Wound Therapy as an adjunct therapy to standard of care for the healing of postsurgical diabetes-related foot wounds. (Conditional; Low)
- 28a. Do not use Negative Pressure Wound Therapy as an adjunct therapy to standard of care for the healing of non-surgically related diabetes foot ulcers. (Strong; Low)
29. We do not recommend any specific educational and lifestyle support programmes over standard of care to improve healing of diabetes-related foot ulcers. (Strong; Low)

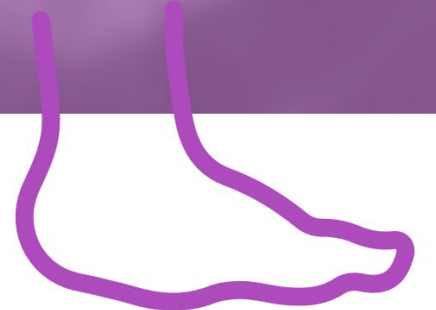
Dane Wukich
Nicolaas Schaper
Catherine Gooday
Arun bal
Robert Bem
Avneesh Chhabra
Mary Hastings
Crystal Holmes
Nina Petrova
Maria Gala Santini Araujo
Éric Senneville
Katherine Raspovic



www.iwgdfguidelines.org

Guidelines on the Diagnosis and Treatment of Active Charcot Neuro- osteoarthropathy in persons with diabetes mellitus

Roberto MD Anichini 2023





List of Recommendation

- DIAGNOSIS

1. Always consider active Charcot neuro-osteoarthropathy in a person with diabetes mellitus, neuropathy and intact skin when there are clinical findings of an increase in temperature, oedema, and/or redness of the foot, compared to the contralateral foot. Best Practice Statement.
2. Consider using infrared thermometry to measure skin temperature of the feet in a person with diabetes mellitus and suspected Charcot neuro-osteoarthropathy with intact skin, using a standardised approach to the measurement of temperatures to allow for more accurate comparison over time. (GRADE recommendation: Conditional; Certainty of the evidence: Low)
3. When using infrared thermometry to measure skin temperature of the feet in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy with intact skin, consider calculating temperature difference between both legs, using the highest temperature on the affected foot or ankle in comparison with the same anatomic point on the contralateral extremity. (Conditional; Low)
4. In a person with diabetes mellitus with bilateral active Charcot neuro-osteoarthropathy (CNO) and intact skin or with unilateral CNO and intact skin in the absence of the contralateral limb, ascending temperature gradients (toe-knee) may be useful for comparison over time. Best Practice Statement.
5. Initiate knee high immobilization/offloading promptly while further diagnostic studies are performed to confirm or rule out active Charcot neuro-osteoarthropathy (CNO) when active CNO is suspected in a person with diabetes mellitus and intact skin. (Strong; Low)



List of Recommendation

1. **Perform plain X-ray** of the foot and ankle in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy. Ideally, bilateral plain X-rays should be performed, if possible, for comparison purposes. Best Practice Statement.
2. Perform X-rays that include the anteroposterior (AP), medial oblique, and lateral projections in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy. The ankle and foot views should include the AP, mortise, and lateral projections. Ideally, standing (also known as “weight-bearing”) radiographs should be performed. If a patient is not able to bear weight on their feet, non-weight-bearing radiographs are an alternative, but may not demonstrate malalignments that are more apparent in the standing position. Best Practice Statement.
3. **Perform Magnetic Resonance** Imaging in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy with normal appearance of the plain X-rays to diagnose or exclude the disease and its activity. (Strong, Moderate)
4. If Magnetic Resonance Imaging is unavailable or is contraindicated in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy, consider a nuclear imaging scan (scintigraphy), CT (computed tomography) scan, or SPECT-CT (Single Photon Emission Computed Tomography) to support the diagnosis of active Charcot neuro-osteoarthropathy (Conditional; Low). 10. We suggest not using C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), white blood count, alkaline phosphatase, or other blood tests in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy with intact skin to diagnose or exclude the disease. (Conditional; Low)
5. 10. **We suggest not using C-reactive protein (CRP), erythrocyte** sedimentation rate (ESR), white blood count, alkaline phosphatase, or other blood tests in a person with diabetes mellitus and suspected active Charcot neuro-osteoarthropathy with intact skin to diagnose or exclude the disease. (Conditional; Low)



List of Recommendation

- IDENTIFICATION OF REMISSION

11. Consider measurement of skin temperature of the affected and unaffected limb with serial examinations to monitor disease activity in a person with diabetes mellitus and active Charcot neuro-osteoarthropathy with intact skin. (Conditional, Low)
12. We suggest not using soft tissue oedema alone to determine when active Charcot neuro-osteoarthropathy is in remission. (Conditional; Low)
13. We suggest that the findings of temperature measurement, clinical oedema, and imaging should all be considered when concluding that active Charcot neuro-osteoarthropathy is in remission. (Conditional; Low)
14. We suggest that frequency of appointments for assessing disease activity in active Charcot neuro-osteoarthropathy should depend on specific factors such as fluctuation in oedema volume, co-morbidities, the risks associated with treatment and recovery, access to assistance with home treatment needs, and a person's progress and recovery. (Conditional; Low)



List of Recommendation

- TREATMENT

15. Use a non-removable knee-high device to immobilise and offload the foot to promote remission of the disease, and prevention or progression of deformity in a person with active Charcot neuro-osteoarthropathy and intact skin. (Strong; Low)
16. Consider using a total contact cast in the treatment of active Charcot neuro-osteoarthropathy with intact skin in a person with diabetes mellitus. A knee-high walker rendered non-removable can be considered as a second choice in order to immobilise and offload the foot. (Conditional; Low)
17. A removable knee-high device worn at all times can be considered as the third treatment choice in a person with diabetes mellitus, active Charcot neuro-osteoarthropathy and intact skin of the foot for whom a non-removable knee-high offloading device is contraindicated or not tolerated. (Conditional; Low)
18. We suggest not to use a below the ankle offloading device (e.g. surgical shoe, postoperative sandal, custom moulded shoe, or slipper cast) in the treatment of active Charcot neuro-osteoarthropathy and intact skin, given the inadequate immobilisation of the diseased bone and joints, and limited off-loading capacity. (Conditional; Low)
19. Treatment with a knee-high offloading device should be considered as soon as possible once the diagnosis of active Charcot neuro-osteoarthropathy is considered. (Strong; Low)
20. In a person with active Charcot neuro-osteoarthropathy who is being treated with a knee-high device, we suggest using assistive devices to reduce weight-bearing on the affected limb. (Conditional; Low)



Evaluation system (mancanza nelle linee guida 2023)

- analyze results
- encourage clinicians to focus on the geographic variation issue; systematic benchmarking
- spread the Population Medicine perspective;
- engage clinicians in a stable community of practice in order to identify gaps in integration and practical models of Integrated Care



Conoscenza dell' IWGDFGL 2023

Abbiamo *ancora* bisogno di linee guida come queste ??

Le Linee guida rispondono alle necessità diffuse in Italia?



Awareness= Consapevolezza da diffondere

- Patologia grande impatto sociale, sanitario, economico.
- Sindrome Piede diabetico necessita ad ogni livello incremento di:

Behaviours: comportamenti

Knowledge: conoscenza

Skills: abilità

- ATTRAVERSO anche *Applicazioni* delle linee guida (IWGDF)



CONCLUSIONI

- Linee guida adattate alla cultura, conoscenza, elaborazione di ogni paese, sistemi sanitari.
- Necessità di linee guida capaci di parlare alla società agli **stakeholders**
- **Dalla teoria alla prassi All' organizzazione**
- **Da leggere studiare e integrare con la nostra esperienza.**

2023

ASSISI (PG)
15/17
GIUGNO 2023
Grand Hotel Assisi

**Congresso
Nazionale**
PIEDE DIABETICO
GDS AMD-SID



La **S**indrome
del **piede diabetico**:
competenze
in azione
con uno sguardo
al futuro

GRAZIE PER L'ATTENZIONE



9/08/2023