

IWGDF guidance on the prevention of foot ulcers in at-risk patients with diabetes

S. A. Bus^{1*}

J. J. van Netten²

L. A. Lavery³

M. Monteiro-Soares⁴

A. Rasmussen⁵

Y. Jubiz⁶

P. E. Price⁷

on behalf of the International
Working Group on the
Diabetic Foot (IWGDF)

¹Department of Rehabilitation Medicine,
Academic Medical Center, University of
Amsterdam, Amsterdam, The
Netherlands

²Diabetic Foot Clinic, Department of
Surgery, Ziekenhuisgroep Twente,
Almelo and Hengelo, the Netherlands

³Department of Plastic Surgery,
University of Texas Southwestern
Medical Center, Dallas, TX, USA

⁴CIDES/CINTESIS – Health Information
and Decision Sciences Department
(U753-FCT), Faculty of Medicine of the
University of Porto, Oporto, Portugal

⁵Steno Diabetes Center A/S, Gentofte,
Denmark

⁶Diabetic Foot Unit, Colombian Diabetes
Association, Bogotá, Colombia

⁷Vice Chancellors' Office, Cardiff
University, Cardiff, Wales, UK

*Correspondence to: S. A. Bus,
Academic Medical Center, Department
of Rehabilitation Medicine, University
of Amsterdam, Amsterdam, The
Netherlands.

E-mail: s.a.bus@amc.uva.nl

Recommendations

1. To identify a person with diabetes at risk for foot ulceration, examine the feet annually to seek evidence for signs or symptoms of peripheral neuropathy and peripheral artery disease. (GRADE strength of recommendation: strong; Quality of evidence: low)
2. In a person with diabetes who has peripheral neuropathy, screen for a history of foot ulceration or lower-extremity amputation, peripheral artery disease, foot deformity, pre-ulcerative signs on the foot, poor foot hygiene and ill-fitting or inadequate footwear. (Strong; Low)
3. Treat any pre-ulcerative sign on the foot of a patient with diabetes. This includes removing callus, protecting blisters and draining when necessary, treating ingrown or thickened toe nails, treating haemorrhage when necessary and prescribing antifungal treatment for fungal infections. (Strong; Low)
4. To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks only, or in thin-soled standard slippers, whether at home or when outside. (Strong; Low)
5. Instruct an at-risk patient with diabetes to daily inspect their feet and the inside of their shoes, daily wash their feet (with careful drying particularly between the toes), avoid using chemical agents or plasters to remove callus or corns, use emollients to lubricate dry skin and cut toe nails straight across. (Weak; Low)
6. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles or toe orthosis. (Strong; Low)
7. To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure-relieving effect during walking (i.e. 30% relief compared with plantar pressure in standard of care therapeutic footwear) and encourage the patient to wear this footwear. (Strong; Moderate)
8. To prevent a first foot ulcer in an at-risk patient with diabetes, provide education aimed at improving foot care knowledge and behaviour, as well as encouraging the patient to adhere to this foot care advice. (Weak; Low)
9. To prevent a recurrent foot ulcer in an at-risk patient with diabetes, provide integrated foot care, which includes professional foot treatment, adequate footwear and education. This should be repeated or re-evaluated once every 1 to 3 months as necessary. (Strong; Low)

10. Instruct a high-risk patient with diabetes to monitor foot skin temperature at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation. (Weak; Moderate)
11. Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the distal toe. (Weak; Low)
12. Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar forefoot ulcer. (Weak; Low)
13. Do not use a nerve decompression procedure in an effort to prevent a foot ulcer in an at-risk patient with diabetes, in preference to accepted standards of good quality care. (Weak; Low)

Introduction

Foot ulcers are a major complication of diabetes mellitus, with high morbidity, mortality and costs [1–3]. Yearly incidence is estimated to be around 2%, but this increases substantially when patients successfully heal from a foot ulcer, with reported recurrence rates between 30% and 40% in the first year [4,5]. Prevention of these ulcers is of paramount importance to reduce the patient and economic burden.

Not all patients with diabetes are at risk for ulceration. Key risk factors include presence of peripheral neuropathy, foot deformity, peripheral vascular disease or a history of foot ulceration or amputation of (a part of) the foot or leg [1,6,7]. In general, patients without any of these risk factors do not appear to be at risk for ulceration. For the current guidance, we define the at-risk patient in line with the definition from the International Working Group on the Diabetic Foot (IWGDF) as ‘a patient with diabetes who does not have an active foot ulcer, but who has peripheral neuropathy, with or without the presence of foot deformity or peripheral artery disease, or a history of foot ulcer(s) or amputation of (a part of) the foot or leg’ (Box 1).

In most countries with developed healthcare systems, only patients at risk for ulceration are entitled to reimbursement for preventative foot care. Therefore, only interventions aimed specifically at the prevention of ulcers in at-risk patients are included in this guidance. Within

Box 1. IWGDF definitions

Peripheral neuropathy	The presence of symptoms or signs of peripheral nerve dysfunction in people with diabetes, after exclusion of other causes
Loss of protective sensation	Inability to sense light pressure, for example, as applied with a 10 g Semmes–Weinstein monofilament
Foot deformity	Structural abnormalities of the foot such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, residuals of neuro-osteoarthropathy, amputations or other foot surgery
Peripheral artery disease	Obstructive atherosclerotic vascular disease with clinical symptoms, signs or abnormalities on non-invasive vascular assessment, resulting in disturbed or impaired circulation in one or more extremities
Therapeutic footwear	Some form of customization to the patients foot regarding insole, shoe and/or orthosis

Note: for all IWGDF definitions go to www.iwgdf.org.
Abbreviation: IWGDF, International Working Group on the Diabetic Foot.

this group, those patients with a previous foot ulcer and/or amputation are considered at higher risk for ulceration when compared with those without [1,6]. As such, first foot ulcer and recurrent foot ulcer are considered as separate outcomes of interest.

Various interventions for the prevention of foot ulcers are either used in clinical practice or have been studied in scientific research. These include interventions such as self-management, patient education, therapeutic footwear, or foot surgery, or the combination of two or more of these interventions into integrated foot care.

In this guidance document, recommendations are given for each intervention separately and include a rationale of how we came to each recommendation.¹ This rationale is based on a systematic review of the literature that underlies this guidance [8], together with a consideration of benefits and harm, patients’ values and preferences, and costs related to the intervention.

¹Recommendations in this guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline [68]. For much of the older data found in the systematic review underlying this guidance, we could not calculate or assess for inconsistency, indirectness or imprecision, which are needed to fully assess the quality of evidence. Therefore, we decided to assess the *quality* of evidence on the risk of bias of included studies, effect sizes, and expert opinion, and rate the quality of evidence as ‘high’, ‘moderate’ or ‘low’. We assessed the *strength* of each recommendation as ‘strong’ or ‘weak’, based on the quality of evidence, balance between benefits and harm, patient values and preferences, and costs (resource utilization). The rationale behind each recommendation is described in this guidance.

General recommendations

Should a person with diabetes be screened for foot ulcer risk?

1. To identify a person with diabetes at risk for foot ulceration, examine the feet annually to seek evidence for signs or symptoms of peripheral neuropathy and peripheral artery disease. (GRADE strength of recommendation: strong; Quality of evidence: low)

Rationale

To prevent foot ulceration among patients with diabetes, identification of those at risk for a foot ulcer is essential. Foot examination is an easy method to achieve this goal and should specifically include screening for the loss of protective sensation caused by peripheral neuropathy and for signs or symptoms of peripheral artery disease (PAD), as discussed in the IWGDF guidance on PAD [9]. Even though evidence for a screening interval is lacking, we recommend a yearly screening for a patient who is not at risk for ulceration.

What should an at-risk person with diabetes be screened for?

2. In a person with diabetes who has peripheral neuropathy, screen for a history of foot ulceration or lower-extremity amputation, peripheral artery disease, foot deformity, pre-ulcerative signs on the foot, poor foot hygiene, and ill-fitting or inadequate footwear. (Strong; Low)

Rationale

To identify a patient at risk for foot ulceration, screening is essential. In a patient with signs or symptoms of peripheral neuropathy, foot examination should consist of taking a detailed history of foot ulceration or lower-extremity amputation and screening for the presence of peripheral artery disease and foot deformities [1,7]. Other factors that are associated with foot ulceration that should be screened for include pre-ulcerative signs on the foot such as callus, blisters and haemorrhage, ill-fitting or inadequate footwear and poor foot hygiene, such as improperly cut toenails, unwashed feet, presence of fungal infection and unclean socks [10–12]. Even though evidence from controlled studies does not exist, we advocate screening for these factors.

At-risk patients require more frequent foot screening than patients who are not at risk. The aim of more frequent screening is early identification of factors that can increase the chances of developing a foot ulcer, followed by providing appropriate preventative foot care. For example, early diagnosis and treatment of pre-ulcerative signs on the foot may prevent foot ulcers, as well as more severe complications such as infection and hospitalization. Even though evidence for the effectiveness of a screening interval in at-risk patients does not exist, we recommend the following screening frequency (Table 1):

Is the treatment of a pre-ulcerative sign on the foot effective in preventing a foot ulcer in an at-risk patient with diabetes?

3. Treat any pre-ulcerative sign on the foot of a patient with diabetes. This includes removing callus, protecting blisters and draining when necessary, treating ingrown or thickened toe nails, treating haemorrhage when necessary and prescribing antifungal treatment for fungal infections. (Strong; Low)

Rationale

Pre-ulcerative signs on the foot, such as callus, blisters or haemorrhage, appear to be a strong predictor of future ulceration [10,12]. These signs require immediate treatment by a foot care professional. The effectiveness of treating these pre-ulcerative signs on the prevention of a foot ulcer has not been directly investigated. Indirect evidence of benefit is that removal of callus reduces plantar pressure, an important risk factor for ulceration [13,14]. The benefits of treatment of pre-ulcerative signs by a trained foot care professional outweigh the potential harm of such treatment and come at relatively low costs.

Table 1. The IWGDF Risk Classification System 2015 and preventative screening frequency

Category	Characteristics	Frequency
0	No peripheral neuropathy	Once a year
1	Peripheral neuropathy	Once every 6 months
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity	Once every 3–6 months
3	Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation	Once every 1–3 months

Abbreviation: IWGDF, International Working Group on the Diabetic Foot.

What should an at-risk patient with diabetes avoid when walking at home or outside?

4. To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks only, or in thin-soled standard slippers, whether at home or when outside. (Strong; Low)

Rationale

No studies have been performed on the effect of walking barefoot, in socks or in thin-soled standard slippers, on risk of foot ulceration. However, there are many large prospective studies that show that at-risk patients with diabetes have elevated levels of mechanical plantar pressure during barefoot walking, which are a significant independent risk factor for foot ulceration and should therefore be reduced [15]. In addition, walking barefoot, in socks or in thin-soled standard slippers has other harmful effects in at-risk patients with diabetes such as lack of protection against thermal or external trauma.

What self-management interventions should a patient perform on a regular basis?

5. Instruct an at-risk patient with diabetes to daily inspect their feet and the inside of their shoes, daily wash their feet (with careful drying particularly between the toes), avoid using chemical agents or plasters to remove callus or corns, use emollients to lubricate dry skin and cut toe nails straight across. (Weak; Low)

Rationale

Although no evidence is available for any of these self-management interventions in relation to the prevention of a foot ulcer, they enable early detection of pre-ulcerative signs on the foot and contribute to basic foot hygiene. This is likely to help prevent a foot ulcer.

Is footwear effective in preventing a first or recurrent non-plantar foot ulcer in an at-risk patient with diabetes?

6. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar foot ulcer. When a foot deformity or a pre-ulcerative sign is

present, consider prescribing therapeutic shoes, custom-made insoles or toe orthosis. (Strong; Low)

Rationale

One randomized controlled trial (RCT) with high risk of bias showed a positive effect of therapeutic footwear on the prevention of foot ulcers in at-risk patients, most of whom had no ulcer history [16]. Another RCT with high risk of bias showed a clear trend but no significant effect of shear-reducing insoles on preventing foot ulcers [17]. A third RCT with low risk of bias showed that digital silicon orthoses can significantly reduce first toe ulcer incidence in at-risk patients with pre-ulcerative lesions [18]. No controlled studies exist on the specific role of footwear to prevent a *non-plantar* foot ulcer. However, ill-fitting footwear has been identified as an important cause of non-plantar foot ulceration [11], suggesting that properly fitting footwear may reduce ulcer incidence. In properly fitting footwear, the shoe should not be either too tight or too loose. The inside of the shoe should be 1–2 cm longer than the foot. The internal width should equal the width of the foot at the metatarsal phalangeal joints (or the widest part of the foot), and the height should allow enough room for all the toes. Evaluate the fit with the patient in the standing position, preferably at the end of the day. Those patients with a foot deformity or a pre-ulcerative sign may need further adaptations to their footwear, which may include therapeutic footwear, custom-made insoles or a toe orthosis.

We know little about the adherence of patients to wearing properly fitting footwear before an ulcer has developed. Patients may value the role of properly fitting footwear to prevent ulcers, but some still consider their footwear to be the cause of their problems. Furthermore, anecdotally, many patients prefer not to wear bulky custom-made shoes when they have not yet experienced a foot ulcer.

Is therapeutic footwear effective in preventing a recurrent plantar foot ulcer in at-risk patients with diabetes?

7. To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking (i.e. 30% relief compared with plantar pressure in standard of care therapeutic footwear) and encourage the patient to wear this footwear. (Strong; Moderate)

Rationale

Two RCTs with very low risk of bias have demonstrated that therapeutic footwear that has proven to effectively offload to the foot can significantly reduce the risk of a recurrent plantar foot ulcer, provided that the patient wears the footwear [5,19]. Effect sizes were large (46.1–63.6% relative risk reduction compared with standard of care therapeutic footwear), but effect may vary across patients. These data confirm earlier findings in three RCTs of mixed methodological quality on the efficacy of therapeutic footwear: relative risk reductions compared with control condition: 52.5–70.2% [16–18]. Another RCT, with low risk of bias, assessed the effect of therapeutic insoles and did not show a significant effect on ulcer recurrence compared with standard footwear; the relative risk reduction was only 12% [20]. However, this study did not use insoles with proven efficacy in offloading plantar pressure.

The benefits of continuously wearing footwear with a proven offloading effect outweigh the potential harm; available trials have infrequently reported any harm related to footwear. Clinicians should encourage patients to wear prescribed footwear whenever possible. The costs of prescribing therapeutic footwear with demonstrated offloading effect may be quite high as it requires the measurement of barefoot or in-shoe plantar pressure for which equipment to date is relatively expensive. However, these costs should always be regarded in association with the benefit of ulcer prevention. Cost-effectiveness has not been studied to date, but in our opinion, footwear designed or evaluated using plantar pressure measurement is likely to be cost-effective when it can reduce ulcer risk by 50% (a risk reduction demonstrated in most of the aforementioned trials on this topic).

This recommendation is predicated on the availability of both therapeutic footwear and technology for pressure measurement. Not in all regions and clinical settings, however, plantar foot pressure can be measured. For these cases, we recommend to prescribe therapeutic footwear using available state-of-the-art scientific knowledge on footwear designs that effectively offload the foot.

Is patient education effective in preventing a first foot ulcer in an at-risk patient?

8. To prevent a first foot ulcer in an at-risk patient with diabetes, provide education aimed at improving foot care knowledge and behaviour, as well as encouraging the patient to adhere to this foot care advice. (Weak; Low)

Rationale

While the efficacy of patient education to prevent a first foot ulcer has not been studied in a controlled trial design, two large non-controlled studies showed convincingly that those patients who are adherent to the advice given in the education programme are at much lower risk of developing a first foot ulcer than those who are not adherent [21,22]. Even though controlled studies on efficacy to prevent a first foot ulcer have not been performed to date, we believe that patients who are at risk for ulceration should receive some form of education. Such education should consist of information on foot complications and their consequences, on preventative behaviour, such as wearing adequate footwear and self-management of foot health, and on seeking professional help in a timely manner when patients identify a foot problem.

Is integrated foot care effective in preventing recurrent foot ulcers in at-risk patients with diabetes?

9. To prevent a recurrent foot ulcer in an at-risk patient with diabetes, provide integrated foot care, which includes professional foot treatment, adequate footwear and education. This should be repeated or re-evaluated once every 1 to 3 months as necessary. (Strong; Low)

Rationale

We define an integrated foot care programme as an intervention that minimally includes professional foot care, patient education and adequate footwear, which are repeated or re-evaluated on a regular basis. One RCT, one non-randomized controlled trial and three non-controlled studies all reported significantly lower percentages of recurrent ulcers in patients who received integrated foot care compared with those who did not [23,24], or in those patients who were adherent to a programme compared with those who were not [25–27]. None of the studies reported any complications or other harm related to the programme.

Professional foot care, by a professional trained in diabetic foot problems, can consist of callus removal, drainage of large blisters, protection of small blisters, treatment of ingrown or thickened nails, treatment of haemorrhage or antifungal treatment for fungal infections, as necessary. Patient education should be repeated regularly, as two RCTs [28,29] demonstrated no effect on ulcer prevention of a single session of patient education. Education should be aimed at improving foot care knowledge and behaviour, as well as offering the patient

support in adhering to this advice. For suggestions on adequate footwear see Recommendations 6 and 7. There is no information available on costs and cost-effectiveness of integrated foot care. A recent publication from the US suggested that there was an increase in hospital admissions for a diabetic foot ulcer after Medicare cancelled financial coverage in one US state for preventative treatment given by podiatrists [30].

Is self-management of foot health effective in preventing a first or recurrent foot ulcer in at-risk patients with diabetes?

10. Instruct a high-risk patient with diabetes to monitor foot skin temperatures at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation. (Weak; Moderate)

Rationale

Self-management of foot health is considered by many to be an important component of foot care in at-risk patients with diabetes. Self-management can include many interventions, but we found no evidence to support any specific intervention, with the exception of home monitoring of foot skin temperature. Three RCTs, either with low or very low risk of bias, showed that monitoring of plantar foot skin temperature on a daily basis with an easy-to-use infrared thermometer, combined with subsequent preventative actions when elevated temperatures were noted, is effective over standard treatment to prevent foot ulcers in high-risk patients (IWGDF risk classification 2 or 3; [31–33]). As all three RCTs were from the same research group, generalizability of these findings is uncertain.

Professionals may value home monitoring as an easy-to-use and relatively inexpensive method, with potentially high clinical value, empowering patients in the care of their own feet. However, adherence was an important factor in the conducted RCTs, and patients, in particular those who have not had a foot ulcer, may find the requirement for daily assessment a burden. False-positive and false-negative outcomes of temperature measurements may unnecessarily concern or stress patients and affect their confidence in this approach [34]. To our knowledge, home monitoring of foot temperature is currently not implemented in foot care of high-risk patients with diabetes, which may be related to patient values or preferences, lack of easy access to calibrated equipment, lack of information on cost-effectiveness and implementation feasibility.

Are surgical interventions effective in preventing a foot ulcer in at-risk patients?

11. Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the distal toe. (Weak; Low)

Rationale

Seven retrospective case series of percutaneous digital flexor tendon tenotomy performed to heal distal toe ulcers noted recurrence rates ranging between 0% and 20% in a total 231 treated patients, over a mean follow-up between 11 and 36 months [35–41]. Four of these studies also reported on the effects of flexor tendon tenotomy of a toe where no ulcer was present at the time of the procedure. In a cumulative total of 58 patients with impending ulcers (i.e. abundant callus on tip of the toe or thickened nails), no ulcer occurrence was found in a mean 11–31 months follow-up [37,38,40,41]. While controlled studies on this topic are lacking, we consider this a promising procedure in a patient who has a distal toe ulcer, or a pre-ulcerative sign on the distal toe, that fails to respond to conservative treatment and requires normalization of foot structure to prevent ulceration.

The possible benefits of digital flexor tenotomy likely outweigh the harm, as few complications have been reported. Patients who have pre-ulcerative lesions for which they have frequent conservative treatment that does not improve outcome may value and prefer treatment by flexor tenotomy. The procedure is easily performed in an outpatient setting, with no need for subsequent immobilization, and is not likely to negatively affect foot function. Costs and cost-effectiveness of this procedure have not been evaluated. Possible adverse effects of the surgery, although minimal, should be discussed with the patient.

12. Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar forefoot ulcer. (Weak; Low)

Rationale

Primarily aimed at healing recalcitrant forefoot plantar ulcers, one RCT (with low risk of bias) and several non-controlled studies have shown a positive effect of Achilles tendon lengthening in preventing ulcer recurrence in the

short and long term, with generally large effect sizes [42–48]. One small RCT (with low risk of bias) [49], two retrospective cohort studies (with varying risk of bias) [50,51] and several non-controlled studies [52–56] found efficacy of single or pan metatarsal head resections to prevent ulcer recurrence, with generally large effect sizes found. One retrospective cohort study with high risk of bias and two small non-controlled studies showed low ulcer recurrence rates after metatarsal-phalangeal or interphalangeal joint arthroplasty [57–59]. One retrospective cohort study on osteotomy showed a non-significant 60% reduction in ulcer recurrence compared with conservative treatment, while one non-controlled study showed no ulcer recurrence after osteotomy [60,61]. While effect sizes are often large, very few studies show the efficacy of these interventions in well-designed controlled studies.

Possible complications and side effects of these surgical offloading techniques include post-operative infection, new deformities, gait problems and transfer ulcers [42,62]. Therefore, it is not clear if the benefits outweigh the harm. In any case, these techniques should be primarily used in patients to heal a foot ulcer that is recalcitrant to conservative treatment and that is expected to have high risk of recurrence if the foot structure is not changed. Patient values and preferences for these approaches are unknown, although we expect patients to value an intervention as high when it can prevent ulcers, but as low when it causes complications such as significant gait or balance problems. The costs of surgical interventions can be much higher than for conservative treatment, but cost-effectiveness is unknown. Clinicians should carefully discuss possible adverse effects of the surgery with the patient.

13. Do not use a nerve decompression procedure in an effort to prevent a foot ulcer in an at-risk patient with diabetes, in preference to accepted standards of good quality care. (Weak; Low)

Rationale

We found two retrospective cohort studies with high risk of bias and three non-controlled studies that investigated nerve decompression in the prevention of foot ulcers in at-risk patients with diabetes [63–67]. Although with positive results (one retrospective cohort study reported a significantly lower ulcer incidence in the operated leg compared with the contralateral non-operated leg of the same patient), the risk of bias of these studies was high, information on post-operative complications was scarce and (most importantly) nerve decompression was not compared with accepted

standards of good quality preventative care. Most studies were also from the same research group, further limiting the generalizability of these results. With various non-surgical interventions available that can be considered standard of good quality care to prevent a foot ulcer in an at-risk patient, nerve decompression should not be used, until more evidence for its efficacy compared with conservative treatment is obtained from appropriately designed controlled studies.

Key controversies

1. Peripheral neuropathy is the most important risk factor for the development of foot ulcers in patients with diabetes, but research on the prevention or treatment of neuropathy is relatively scarce. A stronger research focus in this area is needed.
2. Robust data are lacking on whom, how and when to screen for the risk of foot ulceration. High-quality data on the benefit of interventions to prevent a first foot ulcer are scarce. As the event rate (foot ulceration) is relatively low in a population without a previous ulcer, large groups of patients need to be targeted, and it is unclear if the benefits will outweigh harm and costs. Studies are urgently needed to better define the categories of patients that will benefit from preventative interventions and what specific types of interventions should be included.
3. Costs and cost-effectiveness have not been investigated for any of the interventions described in this guidance, and more attention to cost aspects is warranted.
4. The vast majority of studies underlying this guidance are single intervention studies, yet preventative foot care for at-risk patients with diabetes nearly always consists of an integrated care approach. While studies on integrated foot care show some evidence of effectiveness in preventing a recurrent ulcer, unfortunately, the exact content of this integrated strategy is frequently poorly described, hampering generalizability to other settings.
5. Adherence to an intervention has been shown to be crucial in preventing foot ulcers [5,22,25,26,33]. It is consistently reported that patients who do not adhere present with higher rates of ulceration. A stronger focus is urgently needed on development, evaluation and implementation of methods that improve adherence to preventative diabetic foot treatment.
6. While there is some evidence to support surgical interventions for the prevention of a recurrent ulcer in selected patients, these interventions are not without risk. The exact role of these surgical procedures compared with conservative approaches in the prevention of ulceration is still unclear and requires appropriately designed controlled studies.

Conflicts of interest

LL is on the speaker's bureau for Osiris, Integra, PamLabs and Smit & Nephew, a consultant for KCI, PamLabs and

Innovacyn, a stock owner in Prizm Medical and received research grants from Osiris, MacroCure, ThermoTrek, Integra, GlaxoSmithKline, KCI, Cardinal and Dipexium. SB, JvN, AR, MMS, YJ and PP have no conflicts of interest.

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