

Optimal emollient treatment and prevention of diabetic foot complications

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Article points

1. Hyperkeratosis and callus formation on the foot is a precursor to the majority of foot ulcers in diabetes.
2. Emollients are a common treatment used to prevent callus formation but there is still a lack of evidence surrounding their optimal use in diabetes foot care.
3. The aims of this project were to develop consensus using a modified Delphi methodology from a multidisciplinary group of experts to provide clarity on the use of emollients in reducing the burden of diabetic foot ulcers.
4. 33 consensus statements were developed and used to produce a questionnaire, which was shared with 232 healthcare professionals involved in diabetes foot care.
5. Responses were analysed and a set of recommendations were developed to provide guidance on the optimal emollient treatment and prevention of diabetes-related foot complications.

Key words

- Callus
- Diabetes
- Emollient
- Foot care
- Ulcer
- Urea

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Foot ulcers in diabetes and their associated consequences (including amputation) present a significant burden to both patients and the NHS. The majority of foot ulcers are preceded by callus formation, effective treatment and prevention of callus will, therefore, reduce the burden of foot ulcers in diabetes. Emollients are a commonly used topical treatment for hyperkeratosis/callus, but there is a lack of evidence regarding optimal use in diabetes foot care.

This project recognises that in diabetes, foot care is managed by a wide range of healthcare professionals (HCPs) who may be working with limited guidance. The aim is to develop consensus from a multidisciplinary group of experts to provide clarity on the optimal use of emollients in reducing the burden of diabetic foot ulcers. Informed by the consensus, this expert group offers a set of recommendations to support the optimal use of urea-based emollients in diabetes foot care.

Methods

A UK steering group met in January 2020 to review the current landscape of emollient use in the treatment and prevention of diabetic foot complications and identify key topics in the diabetes care pathway through discussion (*Table 1*).

The key topics were explored further to generate 30 consensus statements, and after discussion four more were added (Statements 14a, 15a, 16a and 17a) to add granularity regarding the presence of hyperkeratosisⁱ. The statements were collated into a questionnaire using a 4-point Likert scale, ('strongly disagree', 'tend to disagree', 'tend to agree' and 'strongly agree'). This was sent to HCPs (see *Table 1 and 2*) working

in footcare in diabetes in the UK by an independent agency using a third-party database.

Individual scores for each statement were analysed in order to produce an arithmetic agreement score for each. Sub-analysis by role and UK region was carried out to identify any variances in agreement scores (*Table 3*). The threshold of agreement for consensus was predefined at 65% and 'very high' at $\geq 90\%$. Further rounds were considered, but after discussion, the group elected to work with the original responses.

Results

232 UK responses were received and analysed (*Figure 1*).

Discussion

Skin integrity on the foot impacting patients with diabetes

Loss of skin integrity on the foot can lead to severe consequences, (Statement 1, 79% and Statement 2, 93%) and maintaining skin integrity can reduce up to 80% of lower-limb amputations (Statement 3, 93%). The need for referral to specialist care is recognised (Statement 4, 91%), but it is not clear where to refer people when skin integrity is lost (Statement 5, 59%). In the UK, there is substantial variation in the interval between first assessment and arrival at the specialist team (NHS Digital, 2019). Podiatrists agreed with Statement 5 (78%, $n=56$),

ⁱ Defined as thickening of the outer most layer of the epidermis, the stratum corneum, which manifests on the foot typically as scaling, corns or callus and in severe cases may result in fissuring or breakdown of the skin of a patient with diabetes (Hashmi et al, 2015).

Table 1. Results by statement.			
No	Topic	Statement	Score
1	Skin integrity on the foot impacting patients with diabetes	Loss of skin integrity on the foot in people with diabetes is life threatening	79%
2		Loss of skin integrity on the foot in people with diabetes is limb threatening	93%
3		Maintaining skin integrity on the foot of people with diabetes can reduce 80% of lower limb amputations	93%
4		All people with diabetes with loss of skin integrity on the foot should have open access to NHS podiatry services within 24 hours	91%
5		It is clear where to refer people with diabetes when skin integrity is lost	59%
6		It is important that all people with diabetes have timely access to a recognised and commissioned diabetes foot pathway	97%
7		It is important that all people with diabetes know and understand how to self-refer to a recognised and commissioned diabetes foot pathway	98%
8	Treating patients with dry skin of the foot	Dry skin is a risk factor for foot ulceration in people with diabetes	96%
9		It is clear how to recognise dry skin on the foot in people with diabetes	83%
10		For people with diabetes, urea-based emollients are more effective than non-urea-based options for dry skin on the feet	85%
11	Treating patients with hyperkeratosis of the foot	Hyperkeratosis is a risk factor to foot ulceration for people with diabetes	93%
12		It is clear how to recognise hyperkeratosis on the foot in people with diabetes	79%
13		Urea-based emollients are more effective for people with diabetes than non-urea-based options for the treatment of hyperkeratosis	88%
14	Selecting appropriate patients for treatment with urea-based emollients	All people with diabetes require daily application of emollient on their feet	81%
14a		All people with diabetes and hyperkeratosis require daily application of emollient for use on the feet	93%
15		All people with diabetes require daily application of urea-based emollient for use on the feet	63%
15a	Selecting appropriate concentration of urea-based emollients	All people with diabetes and hyperkeratosis require daily application of urea-based emollient for use on the feet	84%
16		All people with diabetes and peripheral neuropathy require daily application of urea-based emollient for use on the feet	71%
16a		All people with diabetes and hyperkeratosis and peripheral neuropathy require daily application of urea-based emollient for use on the feet	88%
17		All people with diabetes and peripheral arterial disease require daily application of urea-based emollient for use on the feet	74%
17a		All people with diabetes and hyperkeratosis and peripheral arterial disease require daily application of urea-based emollient for use on the feet	85%
18		Urea-based emollients are available in different concentrations	91%
19		The selection of an appropriate urea-based emollient (based on concentration) requires support from a healthcare professional	87%
20		It is important to select the most appropriate concentration of urea-based emollient according to clinical presentation	90%
21		People with diabetes requiring a urea-based emollient should have this made available via prescription	87%
22		Urea-based emollients should be initiated as early as possible (for daily application) following diagnosis of hyperkeratosis* on a person's foot who has diabetes	92%
23		The recommended concentration of urea-based emollient for treatment of hyperkeratosis* on a person's foot who has diabetes is 10–25%, depending on clinical presentation	91%

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Declaration

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Table 1. Results by statement (continued).

No	Topic	Statement	Score
24	Education surrounding diabetic foot complications	There is a need for clinical guidance for the role of urea-based emollients in preventing certain diabetes foot complications	95%
25		There is a need for more evidence for the role of urea-based emollients in preventing certain diabetes foot complications	91%
26		There is a need for accessible patient education for the role of urea-based emollients in preventing diabetes foot complications	94%
27		Patient behaviour has the greatest impact on outcomes when attempting to prevent diabetes foot complications	94%
28	Budgetary considerations surrounding diabetic foot complications	The financial costs of diabetes foot complications are not acknowledged by the local healthcare economy	81%
29		The financial costs of preventing diabetes foot complications via urea-based emollients is lower than treating the consequences of foot complications	91%
30		For people with diabetes, urea-based emollients are more cost-effective than non-urea-based emollients for use on the feet	84%

Table 2. Respondents' role.

Group	Number of respondents (<i>n</i>)
Podiatrists	56
Dermatologists	53
Diabetologists	57
GP (Diabetes)	50
GP (Podiatry)	13
Not disclosed	3
Total	232

Table 3. Respondents by UK region.

Group	Number of respondents (<i>n</i>)
England (North)	31
England (East or Midlands)	48
England (South or South West exc. London)	29
England (London)	39
Scotland	22
Wales	9
Northern Ireland	2
Other UK territory	2
Not disclosed	50
Total	232

but none of the other groups achieved consensus agreement, with the lowest levels being amongst dermatologists (47%, *n*=53), suggesting that for those in general and non-podiatry roles, referral routes may be unclear.

People with diabetes should have timely access to a recognised and commissioned diabetes foot pathway (Statement 6, 97%) and they should know how to self-refer to this service (Statement 7, 98%). It is important that referral routes are clear and

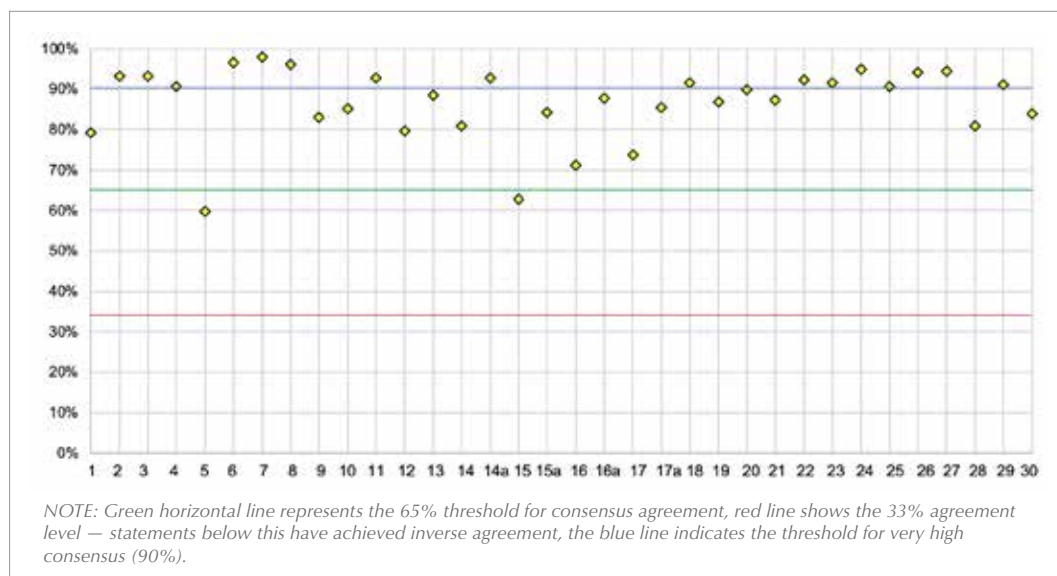


Figure 1. Consensus Scores by Statement.

accessible, as evidence suggests that early referral is associated with better patient outcomes at 12 weeks and lower ulcer severity (NHS Digital, 2019). A specific foot protection service should be in place in the community alongside robust protocols and clear local pathways for continued and integrated care across all settings (NICE, 2019).

Treating patients with dry skin of the foot

There is clear recognition by almost all responders that dry skin is a key risk factor of foot ulceration in people with diabetes (Statement 8, 96%).

It is clear how to recognise dry skin in practice (Statement 9, 83%) and tools to grade classifications of dry skin are available; however, patients may require education to recognise signs of dry skin (American Diabetes Association, 2004; NICE, 2019). Patient education should be comprehensive and ongoing and should cover foot health. Reduction in future risks for people with diabetes may be further improved by the inclusion of prompts for the presence of dry skin in primary care templates.

Once dry skin is detected on the foot, treatment with a urea-based emollient is more effective than non-urea-based options (Statement 10, 85%). Urea is a naturally occurring substance within the skin, which holds water within the epidermis, reduces epidermal thickness and possesses antimicrobial properties (Cork and Danby, 2009; Grether-Beck et al, 2012; Bristow, 2013).

Treating patients with hyperkeratosis of the foot

Diagnosis of hyperkeratosis is clear, and it is recognised as a risk factor for ulceration (Statement 12, 79%; Statement 11, 93%). Hyperkeratosis is associated with 26% the foot problems seen by UK podiatrists and treating this is the most common activity performed by the profession in a typical working day (Farndon, 2015). In diabetes, calluses are associated with significant pain (in severe neuropathy, the calluses are not painful) and reduction in quality of life (Farndon, 2015). The presence of callus is associated with an 11-fold risk of ulcer formation (Hamatani et al, 2016).

It is important that HCPs recognise hyperkeratosis and take appropriate action through initiation of treatment (where appropriate) and clear referral to local NHS diabetes foot services within 24 hours. Where emollient treatment is initiated, the use of urea-based emollients is considered to be a more effective treatment for hyperkeratosis than non-urea-based options by respondents.

Selecting appropriate patients for treatment with urea-based emollients

Dry skin contains up to 50% less urea than is physiologically found in healthy skin. Urea-based emollients at the proper concentration are able to compensate for the lack of urea and rehydrate the skin (Augustin et al, 2019).

In order to maintain foot skin integrity and potentially reduce the incidence of foot ulcers (and the consequences of foot ulcers), all people with diabetes should use an emollient on the feet every day (Statement 14, 81%), and where there are signs of hyperkeratosis, peripheral neuropathy or peripheral arterial disease, daily application of a urea-based emollient should be used as early as possible (Statements 14a–17a; agreement range 71–93%). Strong consensus was achieved for the use of urea-based emollients in diabetes patients with hyperkeratosis (Statement 14a, 93%). Daily frequency of application of a urea-based emollient should be based on risk — people at higher risk of ulceration may require application more than once per day.

Selecting appropriate concentration of urea-based emollients

Urea-based emollients are available in different concentrations (Statement 18, 91%) and risk factors of patients should be considered, this requires professional advice to initiate the appropriate use of urea-based emollients (Statement 19, 87%). For topical application, the urea concentration and type of vehicle used should be based on the individual condition of the skin, patient age, and the underlying dermatosis (Augustin et al, 2019). The severity of dry skin and hyperkeratosis at presentation is an important factor when selecting a urea-based emollient (Statement 20, 90%). Evidence suggests that in the treatment of hyperkeratosis, concentrations of urea-based emollients above 20% will provide keratolytic effects by unfolding cohesion proteins between corneocytes (Augustin et al, 2019).

There are cost implications if the patient is expected to purchase over the counter treatments. In order to avoid the impact of ulceration and ultimately, amputation, people with diabetes who require a urea-based emollient should have this made available via prescription at the earliest appropriate time (Statement 21, 87%) and with a urea concentration of 10–25% (above 25%, the emollient action becomes more keratolytic than hydrating; Bristow, 2016).

At each diabetes review/foot care screening, the early use of urea-based emollients should be considered by the clinic and patients referred to a commissioned diabetes foot pathway as needed.

Education surrounding diabetic foot complications

Respondents agreed strongly with all four of the consensus statements in this section (Statements 24–27; agreement range 91–95%). There is a clear need for the inclusion of the role of urea-based emollients in preventing foot ulcers (and other complications associated with diabetes) in people with diabetes by effectively treating dry skin and hyperkeratosis (Statement 24, 95%).

Whilst callus is recognised as a risk factor for foot ulceration in people with diabetes (NICE, 2019), further recommendations regarding the appropriate use of urea-based emollients, and integrating their use into local NHS care pathways, is required. In addition, patient information sources (e.g. Diabetes UK, www.nhs.uk) should be updated to include the role of urea-based emollients in helping to maintain good foot health and reduce the likelihood of an ulcer.

This is particularly important given the strong consensus that patient engagement has the greatest impact on outcomes in preventing diabetes foot complications (Statement 27, 94%) and NHS diabetes services in particular should consider how this information may be delivered to the local diabetes population. The NHS spends almost £1bn on healthcare related to foot ulceration and amputation in diabetes each year (Kerr et al, 2019). Therefore, delivering comprehensive education focused on prevention of foot ulcers may improve both outcomes for people with diabetes and reduce the significant costs of managing ulcers to the NHS. One of the ways that this could be achieved is through inclusion of foot care in diabetes patient education initiatives in the same vein as Dose Adjustment for Normal Eating (DAFNE).

Budgetary considerations surrounding diabetic foot complications

The average Clinical Commissioning Group (CCG) spends around £5.8m a year on diabetes foot problems; more than the combined cost of the four most common cancers. Reducing the prevalence of severe ulcers by one third would reduce the cost of ulcer care by around £1m a year per CCG (The College of Podiatry, 2020).

It is clear that the financial costs to the health system are under-prioritised (Statement 28, 81%).

Reducing diabetic foot complications may involve additional prescribing costs of preventative treatment, but there is strong agreement that this will be lower than the costs associated with treatment of the consequences of diabetic foot complications (Statement 29, 91%).

Conclusion

Diabetes-related foot ulcers have a significant impact on patient outcomes and NHS resource. Foot ulcers are associated with increased rates of amputation and mortality in people with diabetes. Dry skin and hyperkeratosis are identified risk factors for foot ulcers and treating these conditions effectively may reduce occurrence of ulcers and the NHS costs associated with them.

There were high levels of agreement that people with diabetes in the presence of hyperkeratosis, peripheral neuropathy or peripheral arterial disease should be treated with daily application of a urea-based emollient, and that this treatment should be made available by prescription at the earliest appropriate time to prevent progression to ulceration.

The high levels of consensus provide a strong platform for the recommendations made by the steering group and support the need for improved management of diabetes foot concerns (particularly hyperkeratosis) at the earliest point in order to reduce the incidence and consequences of diabetes foot ulcers. These recommendations are offered in order to provide guidance on the optimal emollient treatment and prevention of diabetes-related foot complications.

Limitations

There was a strong response from England (197/232) compared with other parts of the UK. The overall results were, therefore, heavily influenced by practice in England.

This consensus was focussed specifically on clinical opinion with a view to defining and recognising the issues attached to emollient use in diabetic foot care. Patient experience may help to further the understanding of the personal burden of foot ulcers.

Summary

The results of the consensus have provided a

Recommendations.

1. All HCPs (regardless of setting) who manage patients with diabetes should know where to refer when skin integrity is lost.
2. People with diabetes and dry skin (especially hyperkeratosis) should have daily application of a urea-based emollient, initiated as early as possible.
3. People with diabetes and either peripheral neuropathy or peripheral arterial disease should have daily application of a urea-based emollient, initiated as early as possible.
4. The concentration of urea-based emollient for treatment of hyperkeratosis on a person's foot who has diabetes is 10–25%, depending on clinical presentation.
5. Urea-based emollients should be made available via prescription for people with diabetes.
6. There is a need for more research on the effectiveness of urea-based emollients in patients with diabetes and foot complications.
7. There is a need for clinical guidance for the role of urea-based emollients in preventing certain diabetes foot complications.
8. There is a need for accessible and understandable patient education for the role of urea-based emollients in preventing diabetes foot complications.
9. The financial costs of diabetes foot complications must be acknowledged by the local healthcare economy.
10. It should be acknowledged that the acquisition cost of urea-based emollients is often lower than treating the consequences of diabetes foot complications.

strong indication of the attitudes of clinicians to the use of urea-based emollients in the management and prevention of foot ulcers in diabetes and other complications. The steering group were able to form a strong set of recommendations to provide clarity around the role of urea-based emollients in foot ulcers in diabetes and ultimately improve outcomes for people with diabetes in both the short and long term, as well as reducing the burden of managing the complications of foot ulcers in diabetes to the NHS.

It is hoped that this consensus review may act as a springboard to raise the burden of diabetic foot care and complications in diabetes with those involved at every stage of service provision to ensure that this issue is recognised in practice and treated optimally. ■

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