

Diabetic foot ulcers: Prevention is in your hands

David Watt discusses a device that is currently available on prescription to prevent a common complication of diabetes—diabetic foot ulcers

by David Watt

Prevention is better than cure, but making sure you have free and easy access to the latest and most efficient approaches to achieve that end can set a challenge.

The burden of diabetes on all NHS resources needs no introduction, but do you ever ask yourself how much you, your colleagues in the NHS—and those with diabetes—would benefit from a realignment of priorities if you had the best toolkit?

Preventing complications

Current high-profile proposals to reduce the incidence of new cases of diabetes are commendable. The outcomes from an increasing application of a multi-disciplinary team approach when problems are presented are encouraging. Surprisingly though, taking steps to ensure that the largest part of the diabetic population—the 3.5 million with no complications—stay that way, seems to slip through the headlines.

Of particular relevance to this is the £1 billion spent last year by NHS England treating diabetic foot ulcers and complications. In round figures, that equates to £2.75 million every day.

Successive campaigns about the number of amputations and how most are avoidable certainly grab the headlines. There is complete agreement that this cannot be allowed to continue: NHS England, Diabetes UK and many more all concur. Action, however, is not always evident.

Foot ulcers lead to amputations

Amputations are the outcome of a frequent complication of the disease. The bigger issue, the precursor of the amputations, are the 100 000+ people diagnosed with a foot ulcer every year. Even more so, the 3.5 million who all have a 25% chance of following suit (National Institute for Health



and Care Excellence (NICE), 2011).

Approximately 300 foot ulcers are diagnosed daily in England alone. Around 50% of those diagnosed with a foot ulcer will not survive 5 years. 80% of amputations are preceded by a foot ulcer and 50% of those who experience amputation will not survive for 2 years.

A recent report entitled *Diabetes 2015—Care in Crisis* stated the following: 'In December 2013, figures from the Yorkshire and Humber Public Health Intelligence Diabetes Footcare Activity Profiles showed that people with diabetes in some areas of England were twice as likely to undergo diabetes-related amputations as the national average.'

A year later in December 2014, Diabetes UK conducted an online survey of 6696 people with diabetes:

- ▶ 32% were not informed about their risk levels at their annual foot check

- ▶ 32% also said they were not given adequate advice about foot care
- ▶ 18% did not have their feet checked for corns, calluses and changes in shape.

According to an analysis of NHS data by Diabetes UK (April 27, 2015), an estimated 414 784 people with diabetes in England are not having an annual foot check (Independent Diabetes Trust, 2015).

Equally alarming is that unlike with other screening programmes, those who do present with risk factors are often not being offered appropriate (sometimes any) treatment options. Consequently, at any one time there are 80 000 people with an active foot ulcer—40 000 of those people will be dead within 5 years.

Light at the end of the tunnel

There is light at the end of the tunnel, though, and you are in control of how quickly your patients can reach it.

‘The NHS therefore has a world first—a product proven to significantly reduce ulceration and available on prescription across the UK’

In 2011 a paper was published in the *British Journal of Diabetes and Vascular Disease* with the results of clinical trials conducted by the NHS. Insoles called Liqua Care had been proven to address the two main causes of a diabetic foot ulcer—excessive peak pressures and reduced circulation. These insoles were shown to be unique in terms of offloading peak pressures and increasing tissue perfusion (Miller et al, 2011).

In 2014 NHS Prescription Services concluded an entirely separate 18 month in-depth evaluation to consider Liqua Care for prophylactic issue in the battle to reduce the incidence of foot ulceration by approving it for general prescription issue. This was the first ever instance of prophylactic insoles gaining approval on the Drug Tariff. Liqua Care is on every UK Drug Tariff.

Crucially, the Prescription Services process included revisiting and checking the status of the original test group nearly 3 years after the tests. This group had all been ‘at risk’ of ulceration and in the opinion of the National Diabetes Foot Coordinator for Scotland, who conducted the clinical trial, would normally be expected to have presented around 75% per capita instances of active ulcers after 3 years. His published observation on the subsequent findings was that they were ‘nothing short of remarkable’—not one single patient had developed an ulcer (Diabetes Times, 2014).

A world first

The NHS therefore has a world first— insoles proven to significantly reduce ulceration and available on prescription across the UK. The typical cost to the NHS of treating a foot ulcer is £5200. These clinically proven insoles cost the NHS just £17.45.

The new NICE (2015) guideline *Prevention and management of diabetes foot ulcers* (NG19) states: ‘For people at moderate or high risk of developing a diabetic foot problem... Assess the biomechanical status of the feet, including the need to provide specialist footwear and

orthoses.’ The only preventative orthosis available on prescription in the UK is Liqua Care.

Due to the thin profile of Liqua Care, patient conformance is excellent as they fit in their normal footwear. Because the insoles get switched from one pair of shoes to another, it also encourages patients to check the inside of the shoes which is particularly important for those with neuropathy.

So now available for your toolkit, there is a twice-over NHS-tested and approved solution with minimal associated cost—to issue every ‘at risk’ patient with the insoles would cost about 0.5 of 1% of the current spend on treatment.

Possible hurdles

A possible hurdle is to the issue of Liqua Care is the local formulary. Because formularies prioritize drugs, it is an unfortunate fact that the listings of appliances may not be as up to date as they might in an ideal world. Ownership of local formularies varies and experience has shown that applications from manufacturers to have a product listed do not get far—the request has to come from the clinicians.

Liqua Care is listed on all computerised prescribing systems. If you find that it is not listed on your local formulary, then the simplest solution is for you to make an approach to the appropriate formulary owner to request it be included. Supporting evidence and qualified endorsement of the insoles’ efficacy is available from Autonomed, the product distributor. Evidence includes UK and international peer-reviewed papers, clinical trial results and journal editorials.

All medical, logical and commercial arguments support the issue of Liqua Care to the 25% of your diabetic patients who, because of presented issues, will fall into the category of ‘at risk’ of developing a foot ulcer.

It would be inconceivable that if patients presented with anomalies in screenings for cancers, retinopathy, blood pressure etc, where proven treatment pathways exist, they would be told to keep a close watch and come back if the condition gets worse. That, however, is a real outcome with diabetic foot issues.

In part this explains the huge incidence of patients presenting foot ulcers, common complications of diabetes, which have much higher mortality rates than cancers of the

Further information

For more information for clinicians, please visit the Liqua Care website: www.liqua-care.co.uk/clinical.asp

prostate, breast, and colon (Diabetes UK, 2015).

Making prevention pay

On hearing of the acceptance by the NHS to issue Liqua Care on prescription, one of the world’s leading experts on diabetic foot disease, David G Armstrong, DPM, MD, PhD, Professor of Surgery and Director of the South Arizona Limb Salvage Alliance (SALSA) wrote: ‘This is absolutely, positively huge. We now can begin working to do what we say we have already been doing: making prevention pay’.

For the very first time there are insoles available across the UK on NHS prescription. They are clinically proven to reduce ulceration and they are inexpensive. Prescribing conforms precisely to NICE/ SIGN Guidelines and for the 25% ‘at risk’, will prevent ulcers and amputations while also saving lives, NHS budgets and resources.

If any barriers exist they are local, straightforward and procedural to negotiate. There has rarely been a better, more deserving, or indeed more literal case of ‘One small step for man...’ with this, the most powerful weapon ever available to reduce the number of diabetic foot ulcers.

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