Diabetes foot screening: what is needed to do this in a real world primary care setting?

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Article points

1. People with foot ulcers were significantly older than those without, and had higher HbA_{1c}, raised creatinine and greater social disadvantage.
2. Absence of monofilament was more common in people with a foot ulcer, as was absence of foot pulses.
3. More accurate determination of foot deformity and pedal circulation in the UK GP setting may improve the predictive value of a future risk model for use in primary care.

Key words

- Diabetes
- Foot ulcer
- Health Care Delivery
- Modelling
- Risk

Authors

Author details can be found on page 64.

Foot ulceration is the most common complication in diabetes with a lifetime risk of 25% (Boulton et al, 2008). The condition portends significant excess morbidity and mortality in individuals with diabetes already facing reduced life expectancy and unfavourable prognosis. The authors' aim was to determine how data collected in the course of diabetes reviews of patients in UK primary care can inform a risk model to predict *de novo* foot ulcer presentation. The authors found that people with foot ulcers were significantly older than those without, and had higher HbA_{1c}, higher serum creatinine and greater social disadvantage. Absence of monofilament sensation was more common in people with a foot ulcer, as was absence of foot pulses. However, more accurate determination of foot deformity and pedal circulation in the UK GP setting may improve the predictive value of a future risk model for use in primary care.

Foot ulceration is a major complication of type 1 and type 2 diabetes. The lifetime risk of foot ulceration in people with diabetes is 25% (Boulton et al, 2008). The authors aimed to determine how data routinely collected can inform a risk model to predict *de novo* foot ulcer presentation in the primary care setting. Data were available on 15,926 individuals without foot ulcers and 1,127 individuals with new foot ulcers over 12-year follow-up in UK primary care. The authors examined known risk factors and added putative risk factors in the logistic model.

People with foot ulcers were 4.2 years older than those without and had higher HbA_{1c}, creatinine and Townsend score indicative of higher social disadvantage. Absence of monofilament sensation was more common in people with foot ulcers, likewise was absence of foot pulses.

There was no difference between people with or without foot ulcers in smoking status, gender, history of stroke or foot deformity, although foot deformity was reportedly extremely rare (0.4% in people with foot ulcers, 0.6% in people without foot ulcers). Combining risk factors in a single logistic regression model gave modest predictive power with an area under the receiver operating characteristic (ROC) curve of 0.65. The prevalence of ulceration in the bottom decile of risk was 1.8% and in the top decile 13.4% (compared to a overall prevalence of 6.5%). Thus the presence of all six risk factors gave a relative risk of 7.4 for development of a foot ulcer over 12 years.

The authors have made some progress towards defining a variable set that can be used to create a foot ulcer prediction model. However, more accurate determination of foot deformity/pedal circulation in primary care should improve the predictive value of such a future risk model, as will identification of additional risk variables, such as ability to bend down to reach the foot.

What is already known about this subject?

Foot ulceration presages significant excess morbidity and mortality in individuals with diabetes

already facing reduced life expectancy, as well as unfavourable prognosis.

What is the key question?

The authors' aim was to determine how data collected during the course of diabetes reviews of patients in UK primary care can inform a risk model to predict *de novo* foot ulcer presentation.

What are the new findings?

People with foot ulcers were significantly older than those without and had higher HbA_{1c}, raised creatinine and greater social disadvantage. Absence of monofilament was more common in people with a foot ulcer, as was absence of foot pulses. More accurate determination of foot deformity and pedal circulation in primary care foot screening may improve the predictive value of a future risk model for use in primary care.

Background

As mentioned previously, foot ulceration is the most common complication in diabetes with a lifetime risk of 25% (Boulton et al, 2008). The condition portends significant excess morbidity and mortality in people with diabetes already facing reduced life expectancy (Boulton et al, 2005; 2008; Ghanassia et al, 2008). Established aetiological risk factors for foot ulceration in diabetes are sub-optimally controlled diabetes, peripheral neuropathy, peripheral vascular disease, foot deformity and previous foot ulceration.

The incidence of foot ulcers is around 2.2% per annum in the UK with an average 7,000 people with diabetes undergoing leg, foot or toe amputation each year (Heald et al, 2018). The financial burden is very significant in terms of healthcare costs and long-term consequences. The annual NHS expenditure on diabetes foot-related care is estimated to be at least £639mn–£662mn (Diabetes UK, 2014). Consequently, better precision in understanding the risk calculus in relation to development of diabetic foot ulcers and the likelihood of death in such individuals will result in reduced health services costs with potential cost savings over the longer term.

The NICE guideline NG19, which was published in August 2015 (NICE, 2015) on the management of diabetes foot problems indicated there is still no good evidence to support any particular schedule for monitoring and foot examination in relation to prediction of risk of diabetes foot ulceration. This study aimed to provide an evidence base to address this gap.

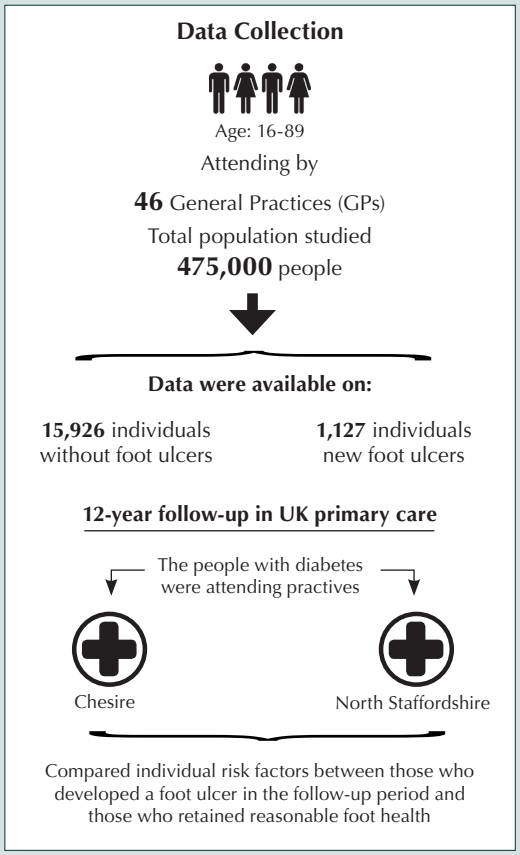

Figure 1. Flow chart methods of diabetes foot screening.

The recently published PODUS study (Crawford et al, 2015) has shown that risk assessment procedures for individuals recommended by NICE can be simplified. This was discussed by Monteiro-Soares et al (2017), who concluded that although all the existing classifications are valid to be applied in a high-risk clinical context and have a very high capacity to categorise as low risk those individuals with diabetes who will not develop a foot ulcer, further research is needed in the primary care setting in this area.

A validated risk assessment tool that can be applied in primary care has the potential to lead to improvements in patient care and in the cost effectiveness of screening for diabetes foot complications. There is already in place in Scotland a standardised online foot screening tool called SCI-Diabetes, which collects all known risk factors and automatically calculates risk. The training is available at *www.diabetesframe.org website.*

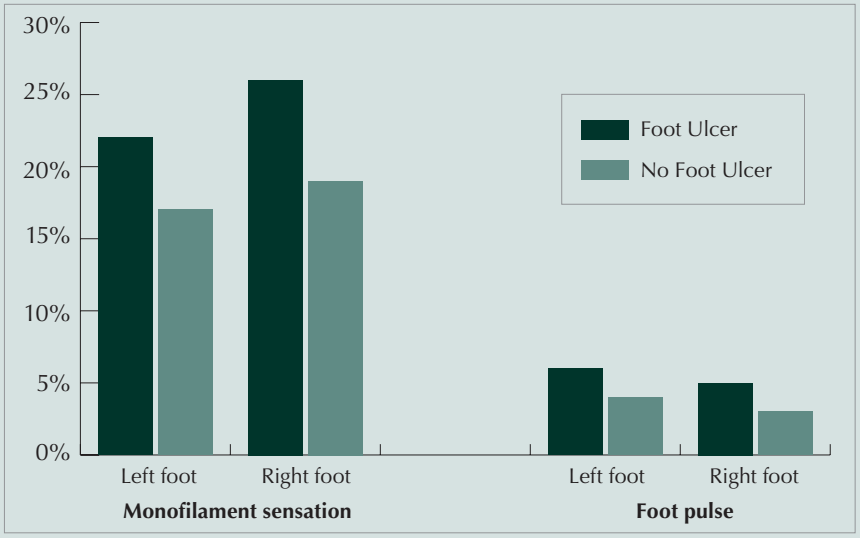

Figure 1. Presence of monofilament sensation and foot pulse in individuals with or without foot ulcers.

The authors' aim was to determine how data collected in the course of diabetes reviews of people in UK primary care can inform what additional data need to be collected, in order to enable a model for foot ulcer risk prediction to be applicable in the primary care setting. Prior foot ulceration was not included as people with a history of this are already closely monitored and are at greatly elevated risk of further ulceration (Anderson et al, 2018).

Methods

Pseudo-anonymised electronic health records were examined in a retrospective cohort of all men and women aged 16–89 years, attending 46 general practices (GPs) in Central/Eastern Cheshire and Derbyshire, UK. The total population of the geographical area studied is 475,000 people. The area is a mixed urban and rural environment with a wide range of socioeconomic situation from significantly disadvantaged urban areas to highly affluent suburbs and rural areas (*Figure 1*). The prevalence of significant social disadvantage (based on multiple measures) was 23% (Townsend Score) (Townsend, 1988).

Data were available on 15,926 individuals without foot ulcers and 1,127 individuals with new foot ulcers over 12-year follow-up. The choice of follow-up period was such as to maximise the duration of follow-up of the individuals to enable a significant number of foot ulcer cases to be identified in relation to the modelling to be conducted.

The authors examined known risk factors and added putative risk factors in the logistic model: age, HbA_{1c}, creatinine, Townsend score, smoking status, gender, absence of monofilament response, absence of foot pulse and presence of foot deformity.

Individuals were eligible for inclusion if they had a diagnosis of diabetes prior to cohort entry at January 1, 2004 to allow long-term follow-up. They had no prior history of foot ulceration. Data search was performed through the centralised data facility afforded by Egton Medical Information Systems (EMIS®), a commercial organisation that provides health information for all but one GP practice in Cheshire. Search terms for included all relevant Read codes (NHS Digital, 2018) for diabetes and foot ulceration together with relevant Read codes for the variables included in the analysis. 'Missingness' in terms of any data point was defined as the variable not being available in the period between January 1, 2004 and December 31, 2005. For the final model, only individuals with all variables available were included. The data are exported from the EMIS database in a CSV format. Data cleaning was performed in using Stata 13 (Statacorp). The predictors used in developing the multivariable prediction model were those routinely recorded in the primary care setting.

Co-author Heald conducted the search with the assistance of an experienced collaborator in search methodology using Read codes from EMIS. Permission for this study was sought through the local information governance committees.

Statistical analysis

Exploratory data analysis was performed using Stata 13. Analysis included comparison of risk factors between people with or without foot ulcers and for prediction of risk, stepwise selection of predictors without pre-categorising the continuous predictors. Patient-related data are quoted as arithmetic means with standard deviation. Those individuals with a history of foot ulceration were excluded from logistic risk modelling. Goodness of fit was tested using the Hosmer-Lemeshow test (HL test).

Results

Foot ulcers occurred in 1,127 of the 17,053 individuals (7%), after a median time of 5.0 years (IQR 2.6, 8.1 years). Those who developed foot ulcers were significantly older at baseline (mean age 77.9±(sd) 14.1 versus 73.8±16.9 years) than those

without, and had higher HbA_{1c}% (mean 7.9±1.9 versus 7.5±1.7)/HbA_{1C} mmol/mol (63±21/59±19) (*P*<0.0001), creatinine (µmol/L) (100±46 versus 93.0±39) (*P*=0.0001) and social disadvantage a measured by Townsend Score (a higher score relates to greater social disadvantage) (-0.72±2.84 versus

-1.14±2.70) (*P*=0.02). Absence of monofilament sensation was significantly more common in people with a foot ulcer (left foot 21.5%; right foot 26.2% versus people without a foot ulcer (left foot 16.5%; right foot 18.8%) (*P*<0.0001) as was absence of one or more foot pulses (*P*=0.017) (*Figure 2*).

There was no difference between people with or without foot ulcers in smoking status, gender, history of stroke or foot deformity, although foot deformity was extremely rare (0.4% in people with foot ulcers, 0.6% in people without foot ulcers).

The best prediction was obtained by stepwise selection of predictors in a logistic regression model without pre-categorising the continuous predictors. In this case, the statistically significant predictors were: HbA_{1c}, age, monofilament sensation absent, creatinine and history of stroke. This model, gave modest predictive power, with an area under the ROC curve of 0.65 (95% CI 0.62–0.67). The absolute risk of ulceration in the bottom decile of risk was 1.8% and in the top decile 13.4%. Thus, the presence of all six risk factors gave a relative risk of 7.4 for development of a foot ulcer over 12 years. The final model where p = probability of a foot ulcer developing was: Log(p/(1-p))-6.398+{0.217×HbA_{1c}} + {0.023×Age}+{0.380×[Monofilament sensation absent]}+{0.003×creatinine} {-0.505×[history of stroke]}.

Discussion

Some progress has been made in defining the data that need to be collected to develop a viable model for foot ulcer prediction. More accurate determination of foot deformity and pedal circulation in the UK GP setting may improve the positive predictive value of the model. Previous studies suggest that these risk factors may have strong predictive value. It is clear that vascular dysfunction must be severe, in order to predispose to ulcer formation. However, diminished sensation appears to be implicit in ulcer formation. An insensate foot means that trauma, even minor is not sensed (Boulton et al, 2008; Ghanassia et al; 2008).

We have demonstrated that age over 55 years, serum creatinine over 150µmol/L, HbA_{1C} over 9.5% (80 mmol/mol), social disadvantage, absent monofilament sensation and absent foot pulse are relevant to evaluation of the risk of foot ulceration. Other factors, including smoking status, gender and foot deformity were not associated with the development of a foot ulcer. This compares with the Seattle study findings (Boyko et al, 2006), which identified a similar group of risk factors, including impaired vision, tinea pedis and onychomycosis in US veterans. However, their model also included previous foot ulcer and prior amputation both of which are associated with a very significantly elevated risk of future ulceration. In the PODUS meta-analysis of 16 cohort studies (Crawford et al, 2015) from more than 16,000 people, female sex was protective when the data in the PODUS dataset were analysed but this effect was not maintained in the validation analysis using the external cohort dataset.

Readily available clinical information has substantial predictive power for the development of diabetic foot ulcer (Crawford et al, 2015; Monteiro-Soares et al, 2017; Anderson et al, 2018) and may help in accurately targeting persons at high risk of this outcome for preventive interventions. As stated above, Boyko et al in 2006 found HbA_{1C}, impaired vision, prior foot ulcer, prior amputation monofilament insensitivity, tinea pedis and onychomycosis to be predictive factors for future foot ulceration. In a systematic review of individual patient data, (Crawford et al, 2015) (PODUS study) it was determined that the 10g monofilament test most consistently identifies those people with diabetes who are at risk of foot ulceration, regardless of if they are at low, moderate or high risk of ulceration. An inability to feel a 10-g monofilament was at least as predictive as the groups of tests currently recommended in national and international clinical guidelines.

The lack of significant contribution from vascular supply to the likelihood of foot ulceration is relevant to healing processes but perfusion has to be severely reduced, to compromise the integrity of the soft tissues and predispose to ulceration. Furthermore, determination of absence of foot pulses may be less accurate than determination of loss of sensation using a monofilament. The difference in laterality

of the foot in relation to the risk prediction model is intriguing in our results and may simply relate to the low frequency of pulse absence in people with foot ulcers. It may also be the case that in the primary care setting there is sometimes inaccurate evaluation of foot pulses, which could potentially be improved through use of arterial doppler studies. Irrespective of this, the modelling indicates that some clear risk factors that predict future foot ulceration can be identified.

Additional risk variables will need to be identified to improve prediction to clinically useful levels to predict foot ulcers. The authors suggest that inability to see or reach the foot be added as a risk factor, as should accurate recording of foot deformity. Type of footwear, including new shoes, is another potential risk factor that will be included in a future model.

In relation to foot deformity, which was under reported, the authors propose that training of practice nurses with regard to the accurate recording of minor, but still clinically significant, foot deformity is conducted by the local podiatry team.

There were limitations to the dataset that was collected. However, this does reflect the way that data that is routinely collected in UK primary care at diabetes reviews. There are caveats with regards to the drawing of conclusions from data routinely collected data (Bohensky et al, 2010; Hemkens et al, 2016). The point of the paper was to describe how the most could be made of the data collected and improve its quality.

In conclusion, the purpose of the study was to determine what variable may go into a systematic study to look at the determinants of foot ulceration in GP practices. Derivation of a clinically applicable predictive algorithm would come out of the data generated by such a study.

The findings of this study will inform what additional data should be collected in primary care to enable model development for prediction of future foot ulceration. More accurate determination of foot deformity and pedal circulation in the primary care setting should improve the positive and negative predictive value of any future model, as will identification of additional risk variables. The development of a validated and standardised system (as already present in Scotland), which collects all known risk factors and automatically calculates risk, is something that would be very valuable to rollout for all people involved in foot screening in England. Training has been extended on the *www.diabetesframe.org* website to be suitable in England. ■

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Online CPD activity

Visit www.diabetesonthenet.com/cpd to record your answers and gain a certificate of participation

Participants should read the preceding article before answering the multiple choice questions below. There is ONE correct answer to each question. After submitting your answers online, you will be immediately notified of your score. A pass mark of 70% is required to obtain a certificate of successful participation; however, it is possible to take the test a maximum of three times. A short explanation of the correct answer is provided. Before accessing your certificate, you will be given the opportunity to evaluate the activity and reflect on the module, stating how you will use what you have learnt in practice. The new CPD centre keeps a record of your CPD activities and provides the option to add items to an action plan, which will help you to collate evidence for your annual appraisal.

1. What is the approximate lifetime percentage risk of foot ulceration in people with diabetes? Select ONE option only.

   A. 25
   B. 33
   C. 50
   D. 66
   E. 75

2. According to Heald et al (2019), which one of the following risk factors is more likely to be prevalent in those people with foot ulcers than without? Select ONE option only.

   A. Higher social deprivation
   B. History of foot deformity
   C. History of stroke
   D. Male gender
   E. Smoking

3. What is the most common complication of diabetes? Select ONE option only.

   A. Foot ulceration
   B. Myocardial infarction
   C. Nephropathy
   D. Retinopathy
   E. Stroke

4. According to Heald et al (2019), which one of the following risk factors was not clearly associated with the presence of foot ulcers? Select ONE option only.

   A. Absence of foot pulses
   B. Higher creatinine
   C. Higher HbA_{1c}
   D. Obesity
   E. Older age

5. According to *www.digital.nhs.uk* data, approximately how many people with diabetes undergo leg, foot or toe amputations each year? Select ONE option only.

   A. 7,000
   B. 35,000
   C. 100,000
   D. 350,000
   E. 700,000

6. What is the approximate annual NHS expenditure (£ million) on diabetes foot-related care? Select ONE option only.

   A. 6.5
   B. 13
   C. 65
   D. 130
   E. 650

7. According to 2015 NICE guidance (NG19), which is the single most appropriate evidence-based recommendation about the frequency of monitoring in relation to the prediction of risk of diabetes foot ulceration? Select ONE option only.

   A. When needed
   B. Three monthly
   C. Six monthly
   D. Twelve monthly
   E. No good evidence

8. According to Heald et al's 2019 study, people with a history of which one of the following risk factors were excluded from the risk modelling algorithm? Select ONE option only.

   A. Hypertension
   B. Peripheral neuropathy
   C. Previous foot ulceration
   D. Smoking
   E. Vascular dementia

9. According to Heald et al's 12-year review of 17,053 individuals, which one of the following was the LEAST common finding? Select ONE option only.

   A. Absence of one or more foot pulses
   B. Absence of microfilament sensation
   C. History of myocardial infarction
   D. History of stroke
   E. Foot deformity

10. According to Crawford et al (PODUS study, 2015), which one of the following most consistently identifies those people with diabetes who are at risk of foot ulceration? Select ONE option only.

    A. Absence of one or more foot pulses
    B. HbA_{1c} >80 mmol/mol
    C. Impaired vision
    D. Monofilament insensitivity
    E. Presence of tinea pedis