

Scottish Foot Ulcer Risk Score Predicts Foot Ulcer Healing in a Regional Specialist
Foot Clinic

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Graham Leese (MD)^{1,3}
Christopher Schofield (MB)¹
Brian McMurray (DipPod)²
Gillian Libby. (BSc)³
Judith Golden. (DipPod)²
Ritchie MacAlpine¹.
Scott Cunningham³
Andrew Morris, (MD)^{1,3}
Murray Flett (ChB)⁴
Gareth Griffiths (MD)⁴

Ninewells Hospital, Dundee, DD1 9SY¹
Dundee Community Health Partnership², Westgate Health Centre, Dundee,
University of Dundee, Ninewells Hospital and Medical School³, and Surgery
Ninewells Hospital Dundee⁴

Correspondence to:
Graham Leese
Ward 1 and 2 Ninewells Hospital
Dundee, UK DD1 9SY
Email: graham.leese@tuht.scot.nhs.uk

ABSTRACT

AIMS

Have patients developing ulcers previously been identified as being at high risk of ulceration using the SCI-DC Ulcer Risk score. Does the risk score predicts ulcer healing.

METHODS

All patients attending the diabetes foot clinic with an ulcer had been assessed for foot ulcer risk using the SCI-DC risk calculator, which categorises patients into low, moderate or high-risk of ulceration. Information on foot pulses, neuropathy, foot deformity, previous ulcer, ulcer site, depth, and presence of sepsis was recorded, and related to ulcer outcome. Patients were followed up until outcome was achieved (median 3 months (range1-33months)).

RESULTS

Of patients attending the clinic with a foot ulcer (mean age 67.3 ± 12.7 (SD) years, 68% male), 68% were previously recognised to be at high-risk of foot ulceration, and 98% were high or moderate-risk. Of 221 ulcers, the healing rate was 75% overall, but was lower for high-risk patients compared to other patients (68% vs 93%; $p < 0.0001$). Of the remainder, 3% became chronic ulcers, 12% required minor or major amputation and 10% died with their ulcer. In multivariate analysis, absent pulses, neuropathy, increased age and deep ulcers were associated with poor healing. The combination of neuropathy and ischaemia was particularly associated with poor outcome of an ulcer (61% healing).

CONCLUSION

The Scottish foot ulcer risk score predicts both ulcer development and ulcer healing. The risk score can be a useful initial guide to likely poor healing. The individual criteria contributing to this overall risk are similar to other studies.

INTRODUCTION

Patients with diabetes have an increased risk of lower limb amputation, with an incidence of 50-500 per 100,000 patient years (1-5). The prevalence of diabetes is increasing, and health-care resources for foot problems are often inadequate. It has thus become useful to direct resources towards patients who at the greatest risk of foot ulceration, as ulceration is the usual precursor of amputation. Various individual clinical features have been shown to predict foot ulceration (6-13). Such risk factors have been used collectively to determine a global risk for individual patients (14-17), and some of these have been validated in routine clinical practice (16,17).

We have previously validated the foot screening tool (17) as recommended by the Scottish Intercollegiate Network Guideline (18), which uses the same simple clinical criteria as advocated by the International Working Group on the Diabetic Foot (19). In 3526 patients followed up prospectively for foot ulceration, those categorised initially at being high risk of ulceration, were 83 times more likely to develop a foot ulcer than those at low risk (17). Additionally, patients at low risk had a 99.7% (95% confidence interval: 99.6-99.8%) chance of remaining "ulcer free" after 2.4 years follow-up. This system is now being recommended for use by the Scottish Executive (20), and is supported by software in the Scottish National web-based Diabetes Registry and IT system (21).

We wished to assess the impact of this screening tool on the specialist diabetes foot clinic. In Dundee the specialist diabetes foot clinic is a weekly multi-disciplinary service for any patient with diabetes who has a foot ulcer in Dundee

or Angus – an urban and a rural region of Tayside, Scotland. We wished to assess whether the majority of patients attending the foot clinic had previously been identified at high risk of ulceration, and to see if the foot risk score was predictive of healing.

PATIENTS AND METHODS

Patients

The study was approved by the Tayside Ethics Committee. All patients had diabetes as defined by the World Health Organisation, and were registered on the web-based Tayside Regional Diabetes Register (21). Health-care professionals undertaking foot examinations, such as Diabetologists, Podiatrists, General Practitioners, Practice Nurses, District Nurses and others, had participated in an education programme delivered by podiatrists or doctors with an expertise in diabetes and foot care. Healthcare professionals had been shown how to use the foot assessment tool and to record the information electronically on the web-based database. The details of the foot risk score are described elsewhere (17). In brief it integrates information on previous history of foot ulceration, assessment of pulses, sensation to 10g monofilament, presence of foot deformity and inability to self-care (Fig 1). The software automatically calculated the patient's individual degree of foot risk, and categorised them into low, moderate and high risk of foot ulceration. Patients underwent foot risk assessment as part of routine clinical care in hospital and General Practice-based Diabetes clinics within Tayside. All electronic information was shared by health-care professionals using the web-based shared electronic record, which is 97% sensitive with a positive predictive value of 97% for the diagnosis of diabetes (21). Foot risk data was collected from the year 2000 onwards.

Information on patients attending the specialist foot clinic with foot ulceration was collected from 01/04/2004 until 31/12/2006. A foot ulcer was defined as a full thickness skin break below the level of the malleoli. The following information was collected on each patient: patient age and sex, ulcer site, the most recent foot risk score. Ulcer size was not measured. Clinical examination was performed by Consultants in Diabetes and Vascular Surgery to record, absence of pulses, absence of sensation to a 10g monofilament, presence of foot deformity, depth of ulcer using the University of Texas ulcer classification system (22), and presence of sepsis. Sepsis was defined clinically as surrounding cellulites or presence of pus. Information on outcome of ulcer, and duration of ulcer from arrival at the specialist foot clinic until final outcome, was recorded. Healing was defined as complete re-epithelialisation of the wound. Non-healing was defined as any patient requiring minor or major amputation, patients with a non-healing ulcer or a patient who died with their ulcer.

A retrospective analysis was performed to determine the predictive nature of the individual clinical criteria and the overall risk score on foot ulcer healing.

Data Analysis

In the data analysis the most recent risk stratification score was used, or the risk score immediately prior to the onset of any ulcer. The unit of analysis was the foot ulcer

Patient demographics and details of ulcer site and outcome were compared for risk factors using chi-squared tests for categorical variables, t-tests for continuous data in dichotomous groups and analysis of variance for continuous data in more than two groups. Duration of ulcer had a skewed distribution and

was presented by median and the inter quartile range and analysed using the Wilcoxon test. Potential predictors of a foot ulcer not healing (male sex, age, ulcer site, ulcer depth, high risk score, absent pulses, neuropathy, foot deformity and sepsis) were each assessed in a univariate regression analysis then all the variables were entered into a multivariate regression model. All analyses were carried out using SAS v8.

RESULTS

Within Dundee and Angus, 7184 patients with diabetes have had a foot risk assessment performed and recorded electronically (51.5% of all patients with diabetes). Of these 62.9% were recorded as being at low risk, 23.9% at moderate risk and 13.1% at high risk of developing foot ulceration.

During the study period there were 221 referrals to the specialist foot clinic for foot ulceration in 198 patients over 33 months. These were all separate episodes, and if there were simultaneous ulcers, the one that took longest to heal was included as the index ulcer. The mean age of patients was 67.3 ± 12.7 years (mean \pm SD). Of these 221 ulcers, 165 (74.7%) healed, 7 (3.2%) became chronic non-healing ulcers, 8 (3.6%) healed after minor amputation, 18 (8.1%) required major amputation and 23 (10.4%) died with their ulcer. Further analysis was performed per referral (n=221). If patients had multiple ulcers at referral, the ulcer that took the longest time to heal was classified as the index ulcer for further analysis. If a patient had a healed ulcer and re-presented with a new ulcer, they were categorised as a new ulcer event.

Of the 221 referred ulcers, 97 were superficial (43.9%), 40 were deep (18.1%), and 84 were down to bone

(38.0%). In addition 117 ulcers (52.9%) were infected whilst 104 (47.1%) were not. Superficial ulcers were more likely to heal than deep ulcers or ulcers to bone (88%, 68% and 63% respectively; chi-squared $p < 0.001$). Non-infected ulcers were more likely to heal than infected ulcers (81% vs 69%; $p = 0.02$). Of all ulcers, 151 were in males (68.3%) and 70 in females (31.7%). There was no difference in mean age of males (67.2 \pm 11.8 years) and females (67.5 \pm 14.6 years).

Of the 221 ulcers, the most recent previous foot risk score was “low risk” in 5 (2.3%), “moderate risk” in 52 (23.5%), and high risk in 164 (74.2%). Overall 154 (69.7%) had absent foot pulses, 181 (81.9%) had absence of sensation to 10g monofilaments, 33 (14.9%) had a foot deformity, and 88 (39.8%) had a previous foot ulcer. Of the 221 ulcers, 108 (48.9%) were sited on a toe, 41 (18.6%) at a metatarsal head, 3 (1.4%) on the dorsum of the foot, 54 (24.4%) on the heel and 15 (6.8%) elsewhere. The numbers in each risk category in the general population were 943 for high risk (13.1% of 7184), 1720 for moderate risk (23.9% of 7184) and 4521 (62.9%) for low risk. For patients in the community the rate of attending the specialist foot clinic with a foot ulcer was 171 per 1000 for high risk patients (164/943), 30.2 per 1000 for moderate risk (52/1720) and 1.1 per 1000 for low risk (5/4521). The rate of referral to the specialist foot clinic with a foot ulcer for high risk patients was 157 times higher than that of low risk, and 5.8 times higher than moderate risk. Moderate risk patients were 27 times more likely to be referred than low risk.

Data on the impact of foot ulcer risk score on healing of foot ulcers is shown in Table 1. Patients at high risk of ulceration were less likely to heal than low or moderate risk patients (68% vs

93%; $p < 0.0001$), although there was no difference in the site of ulceration for such patients (table 1). Patients at high risk of ulceration were slightly older, and took longer for their ulcers to heal (table 1). The impact of absent foot pulses and presence of neuropathy on healing is shown in table 2. The rate of healing for patients with absent pulses was similar to those with neuropathy (89.7% vs 91.7%), but in patients who had both clinical criteria, the healing rate was significantly lower (61.2%; $p < 0.0001$). Patients with absent pulses were more likely to develop ulcers on their toes, whilst metatarsal head ulcers were more common in those with neuropathy (table 2). Healing rates, ulcer sites and time to healing were similar between those with, and those without previous foot ulceration (table 2). Although twice as many males than females presented with foot ulceration, the rates of healing were similar between the sexes (Table 1). Males were more likely to have toe ulcers whilst females were more likely to develop heel ulcers. For the 33 patients with a foot deformity, 26 healed (78.8%), whilst in the 188 patients without a foot deformity, 139 healed (73.9%: no significant difference).

For patients categorised as “high risk” of ulceration, absent foot pulses, neuropathy, increasing age, deep ulcer, or sepsis were all significant risk factors for a non-healing ulcer on univariate analysis (Table 3). On multivariate analysis absent pulses, neuropathy, increasing age and ulcer depth remained significant.

DISCUSSION

Although the foot risk tool was developed (18) and validated (17) to predict the likelihood of foot ulceration in routine clinical practice, it appears that it is also a predictor of healing for

patients who subsequently develop a foot ulcer. The healing rate was 68% in high risk patients and 93% in low and moderate risk patients. The site of foot ulceration was no different between the different foot risk groups. Of the five criteria comprising the risk score, only neuropathy and absent pulses were significant predictors of poor healing, showing that these were the main useful criteria within a “high risk” score that predicted poor healing. Although neuropathy or absent foot pulses on their own were associated with healing rates of 93% and 88% respectively, the combination of neuropathy and absent pulses was a good predictor of poor healing (61%). Our data shows how a combination of neuropathy and ischaemia predicts much poorer outcome than either criteria alone.

It was a surprise to find that having a previous foot ulcer or having a foot deformity were not predictors of poor healing. The majority of these patients had neuropathy but not vascular disease. This combination of features seems to put patients at risk of recurrent ulceration (22,23), but with ulcers that tend to heal well when managed appropriately. Although age is not part of the risk score, it was a predictor of poor ulcer healing, and non-healing has previously been associated with age (23).

It was noticeable that 68% of referrals were male, when 53% of the diabetes population are male in Tayside. It has been shown that women are more active in self-care and prevention for acute diabetes-related foot problems, whilst men are more likely to seek help from others and take a passive approach (24). This may mean that women develop fewer foot ulcers, and when they do, may be more likely to successfully self-manage simple ulcers. In our study there was a non-significant trend

towards women having a higher prevalence of neuropathy, suggesting that women may have more “advanced” diabetic foot disease when they present with foot ulceration. This may also explain why there was no sex difference in the healing rates of foot ulcers, if women have more advanced disease, but are better at caring for their own feet (24). Alternatively, foot ulcers in males may just respond well when cared for by others.

The majority of patients referred to the specialist foot clinic with a foot ulcer had previously been identified as being at high risk of foot ulceration. Patients identified as being at high risk were 157 times more likely to attend the specialist foot clinic with an ulcer than low risk patients. The corresponding value for moderate risk was 27 times increased risk. These relative risks are greater than those observed in our prospective community based follow-up of all ulcers, where the risks were 83 and 6-fold increased respectively (17). This may be because in the Community study many of the foot ulcers in the low risk patients healed relatively rapidly and were not referred to the specialist foot clinic, and therefore would not be included in the current analysis, which may exaggerate the relative difference in outcome between low and high risk patients. Of patients attending the foot clinic with a foot ulcer 68% had already been identified as being at “high risk” and 98% at “high” or “moderate risk”. High risk patients represent 12% of the diabetes population, and high/moderate risk patients represent 36% of them. This is reassuring that the foot risk tool is effective at identifying patients likely to ulcerate. In addition, high risk groups of patients could be specifically targeted with preventative measures, such as education or more regular podiatry, to try and avoid future foot ulcers.

Ulcer healing rates were marginally better in this study at 75% compared to other reported series with a healing rate of 65-67% (23,25-27), even though there was a high rate of arteriopathy (70%) and the average patient age was 67years. This may be because we followed up our patients until there was final outcome, rather than having a defined duration of follow-up. However, in our study the amputation rate of 12% and death rate of 10% were similar to the rates reported in the literature of 8-17% amputation and 4-17% deaths (23,25-27). These remain alarmingly high. We also know that patients with diabetes who undergo amputation are subsequently more likely to die and suffer further amputations, than non-diabetic amputees (28). Overall, the patients seen in our specialist foot clinic are similar to those seen in other foot clinics. Predictors of an ulcer *not* healing were similar to previous studies. The main predictors of non-healing appear to be ischaemia (our data 23, 29-31), age (our data, 23), ulcer depth (our data, 29,30,32) and ulcer size (29,33,34). Sepsis has been associated with amputation, especially in the presence of ischaemia (26), and in our study was a borderline predictor of a non-healing ulcer. This may reflect a fairly aggressive use of antibiotics. Previously neuropathy has not been a predictor of poor healing (23,29), however it is a predictor of re-ulceration (17,22,23). In the current study neuropathy did predict poor healing, but we demonstrate that appears to be mainly when in the presence of ischaemia, rather than in patients with isolated neuropathy. Previously it has been shown that toe ulcers heal better than foot ulcers (30), but our data showed similar healing rates.

There are other standardised clinical assessment tools which both monitor ulcer progression and predict healing (22,23). These are ideal in the setting of the specialist foot clinic. However, in the community setting, where many patients are cared for by non-specialists, the current foot risk tool could be a useful initial guide to clinicians about foot ulcer healing, without the need to understand and remember new and more complex grading schemes. It could be recommended that patients with “high risk” feet who develop ulcers, should be prioritised towards specialist foot clinics at an early stage because of the lower chance of healing. This may be particularly helpful in areas with restricted availability of health-care resources. Once in the specialist foot clinic the more sophisticated schemes to monitor progression and predict healing of the ulcer would be the most appropriate to use.

This study highlights the difficulties in achieving foot ulcer healing in patients with diabetes. Increasing age, and distal peripheral vascular disease are particularly difficult clinical problems. We have also demonstrated that the Scottish foot ulcer risk score predicts healing of foot ulcers, as it provides an integrated assessment of arteriopathy and neuropathy. The majority of patients referred to the specialist foot clinic with an ulcer have already been identified as being at high risk, providing an opportunity for targeted educational with such patients.

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Table 1. Patient criteria, and outcomes of foot ulcer in patients presenting to the specialist foot clinic for male/female patients and according to SCI-DC clinical risk score (17) of foot ulceration. NS= non significant

	Male N=151	Female N=70	p-value	Low and moderate risk N=57	High risk N=164	p-value	All patients N=221
Male, N (%)	-	-	-	44 (77.2)	107 (65.2)	NS	151 (68.3)
Age, mean years (sd)	67.2 (11.79)	67.5 (14.56)	NS	62.7 (13.76)	68.9 (11.96)	0.001	67.3 (12.70)
No foot pulses, N(%)	106 (70.2)	48 (68.6)	NS	-	-	-	154 (69.7)
Sensation to 10g monofilament, N (%)	119 (78.8)	62 (88.6)	NS	-	-	-	181 (81.9)
Foot deformity, N (%)	21 (13.9)	12 (17.1)	NS	-	-	-	33 (14.9)
Duration of ulcer, median months (IQR)	3 (2-6)	2 (2-4)	NS	2 (2-4)	3 (2-6)	0.04	3 (2-5)
Ulcer site, N (%)							
Toe	83 (55.0)	25 (35.7)		31 (54.4)	77 (47.0)		108 (48.9)
Metatarsal head	28 (18.5)	13 (18.6)		9 (15.8)	32 (19.5)		41 (18.6)
Dorsum	2 (1.3)	1 (1.4)		1 (1.8)	2 (1.3)		3 (1.4)
Heel	29 (19.2)	25 (35.7)		13 (22.8)	41 (25.0)		54 (24.4)
Other	9 (6.0)	6 (8.6)	0.05	3 (5.3)	12 (7.3)	NS	15 (6.8)
Ulcer depth, N(%)							
Superficial	60 (39.7)	37 (52.9)		31 (54.4)	66 (40.2)		97 (43.9)
Deep	25 (16.6)	15 (21.4)		10 (17.5)	30 (18.3)		40 (18.1)
Bone	66 (43.7)	18 (25.7)	0.04	16 (28.1)	68 (41.5)	NS	84 (38.0)
Sepsis, N (%)	86 (56.9)	31 (44.3)	0.07	28 (49.1)	89 (54.3)	NS	117 (52.9)
Outcome, N (%)							
Healed	115 (76.2)	50 (71.4)		53 (93.0)	112 (68.3)		165 (74.7)
Chronic ulcer	2 (1.3)	5 (7.1)		0 (0)	7 (4.3)		7 (3.2)
Minor amputation	7 (4.6)	1 (1.4)		1 (1.9)	7 (4.3)		8 (3.6)
Major amputation	12 (7.9)	6 (8.6)		1 (1.9)	17 (10.4)		18 (8.1)
Died	15 (9.9)	8 (11.4)	NS	2 (3.8)	21 (12.8)	0.0001	23 (10.4)

Table2. Patient criteria, and outcomes of foot ulcer in patients presenting to the specialist foot clinic. Data analysed according to absent pulses and neuropathy, as well as history of previous foot ulcer. NS= non significant

	No foot pulses (no neuropathy) N=33	Neuropathy N=67	No pulse and neuropathy N=121	p-value	No previous foot ulcer N=133	Previous foot ulcer N=88	p-value
Male, N (%)	26 (78.8)	39 (65.0)	80 (66.1)	NS	91 (68.4)	60 (68.2)	NS
Age, mean year (sd)	73.5 (7.52)	58.05 (14.36)	71.06 (9.71)	<0.0001	66.61 (12.80)	68.54 (12.39)	NS
Ulcer duration, median months (IQR)	2 (1-4)	2 (2-4)	3 (2-7)	0.02	3 (2-5)	3 (2-6)	NS
Ulcer site, N (%)							
Toe	22 (66.7)	25 (41.7)	58 (47.9)		68 (51.1)	40 (45.5)	
Metatarsal head	2 (6.1)	19 (31.7)	16 (13.2)		21 (15.8)	20 (22.7)	
Dorsum	0 (0)	2 (3.3)	1 (0.8)		2 (1.5)	1 (1.1)	
Heel	8 (24.2)	10 (16.7)	36 (29.8)		34 (25.6)	20 (22.7)	
Other	1 (3.0)	4 (6.7)	10 (8.3)	0.01	8 (6.0)	7 (8.8)	NS
Ulcer depth N(%)							
Superficial	14 (42.4)	32 (55.3)	47 (38.8)		66 (49.6)	31 (35.6)	
Deep	6 (18.2)	10 (16.7)	23 (19.0)		22 (16.5)	18 (20.7)	
Bone	13 (39.4)	18 (30.0)	51 (42.2)	NS	45 (33.8)	38 (43.7)	NS
Sepsis, N (%)	17 (51.5)	29 (48.3)	68 (56.2)	NS	69 (51.9)	47 (54.0)	NS
Outcome, N (%)							
Healed	29 (87.9)	62 (92.5)	74 (61.2)		103 (77.4)	62 (70.4)	
Chronic ulcer	0 (0)	0 (0)	7 (5.8)		4 (3.0)	3 (3.4)	
Minor amputation	0 (0)	1 (1.5)	7 (5.8)		4 (3.0)	4 (4.5)	
Major amputation	2 (6.1)	2 (3.0)	14 (11.6)		9 (6.8)	9 (10.2)	
Died	2 (6.1)	2 (3.0)	19 (15.7)	<0.0001	13 (9.8)	10 (11.4)	NS

NS= non significant

Table 3. Univariate and multivariate regression analysis of variables potentially predictive of foot ulcer not healing (Odds ratios and 95% confidence intervals). “High Risk” not included in multivariate analysis as it is comprised of other component criteria

	Univariate analysis			Multivariate analysis		
	OR	(95% CI)	p	OR	(95% CI)	p
<i>Male sex</i>	0.78	(0.413 – 1.484)	NS	0.67	(0.313 – 1.446)	NS
Age (+1 year)	1.05	(1.023 – 1.085)	0.0006	1.04	(1.002 – 1.078)	0.04
Ulcer site						
Meta head vs toe	0.88	(0.375 – 2.098)	NS	1.59	(0.562 – 4.515)	NS
Dorsum vs toe	1.58	(0.137 – 18.106)	NS	8.53	(0.234 – 310.77)	NS
Heel vs toe	1.45	(0.702 – 2.990)	NS	1.56	(0.668 – 3.646)	NS
Other vs toe	0.79	(0.207 – 3.011)	NS	1.14	(0.241 – 5.445)	NS
Ulcer depth						
Deep vs superficial	3.41	(1.392 – 8.356)	0.007	2.93	(1.081 – 7.935)	0.03
Bone vs superficial	4.14	(1.958 – 8.766)	0.0002	4.87	(1.846 – 12.842)	0.001
<i>High risk</i>	6.16	(2.114 – 17.902)	0.0009			
<i>Absent pulses</i>	6.14	(2.325 – 16.213)	0.0002	4.78	(1.570 – 14.531)	0.006
<i>Neuropathy</i>	3.63	(1.229 – 10.698)	0.02	4.98	(1.556 – 15.953)	0.006
<i>Previous ulcer</i>	1.46	(0.793 – 2.702)	NS	1.11	(0.546 – 2.235)	NS
<i>Foot deformity</i>	0.76	(0.312 – 1.871)	NS	0.68	(0.237 – 1.974)	NS
<i>Sepsis</i>	1.87	(0.998 – 3.491)	0.051	1.14	(0.503 – 2.600)	NS

NS=not significant

Figure 1: Foot risk stratification Scheme

