

# Assessing the Outcome of the Management of Diabetic Foot Ulcers Using Ulcer-Related and Person-Related Measures

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**OBJECTIVE** — The purpose of this study was to compare different outcome measures in the audit of management of diabetic foot ulcers

**RESEARCH DESIGN AND METHODS** — Data collected prospectively in a consecutive cohort of patients referred to a specialist multidisciplinary foot care clinic between 1 January 2000 and 31 December 2003 were analyzed. A single index ulcer was selected for each patient and classified according to both the Size (Area and Depth), Sepsis, Arteriopathy, and Denervation [S(AD)SAD] and University of Texas (UT) systems. Ulcer-related outcomes (healing, resolution by ipsilateral amputation or by death, and persisting unhealed) were determined at 6 and 12 months and compared with patient-related outcomes (survival, any amputation, and being free from any ulcer) at 12 months.

**RESULTS** — In 449 patients (63.7% male, mean age  $66.7 \pm 13.2$  years), 352 (78.4%) ulcers were superficial [S(AD)SAD/UT grade 1] and 134 of these (38.1% of 352) were neither ischemic nor infected. A total of 183 (40.8% of 449) ulcers were clinically infected, and peripheral arterial disease was present in 216 patients (48.1%). Seventeen patients (3.8%) were lost to follow-up and were excluded from analysis. Of the ulcers, 247 (55.0% of 449) and 295 (65.7%) healed without amputation by 6 and 12 months, respectively. Median (range) time to healing was 78 (7–364) days. Of all index ulcers, 5.8 and 8.0% were resolved by amputation, and 6.2 and 10.9% by death by the same time points; 27.8 and 11.6% persisted unhealed. In contrast, patient-related outcomes revealed that of 449 patients only 202 (45.0%) were alive, without amputation, and ulcer free at 12 months. This group had had 272 (1–358) days without any ulcer. A total of 48 (10.7%) patients had undergone some form of amputation, and 75 (16.7%) had died.

**CONCLUSIONS** — These data illustrate the extent to which ulcer-related outcomes may underestimate the true morbidity and mortality associated with diabetic foot disease. It is suggested that when attempts are made to compare the effectiveness of management in different centers, greater emphasis should be placed on patient-related outcome measures.

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The morbidity and mortality associated with diabetic foot lesions remain extremely high (1), and management needs to be optimized to ensure the best outcome. Although it is accepted that the institution of rapid access to expert multidisciplinary service is an essential component of care (2,3), there are remarkably few data to justify partic-

ular approaches to the treatment of different types of foot ulcers. Evidence of the efficacy of specific interventions depends on the completion of robust clinical trials, whereas evidence of the overall effectiveness of a management strategy requires some form of systematic audit, using methods that allow comparison between different units. If such a comparative au-

dit is controlled for case mix, it would provide an invaluable benchmark against which other units may compare their performance. For this to be done, it is necessary to establish clinically meaningful outcome measures.

Outcome measures are of two broad types: those that relate primarily to the ulcer and those that relate more to the patient. Ulcer-related outcome measures are commonly used in clinical trials and are appropriate for studies designed to assess either the efficacy or the effectiveness of interventions directed to improving wound healing (4). Such ulcer-related outcome measures include healing, a change in ulcer area, and resolution of the ulcer by amputation. However, ulcer-related measures are not necessarily appropriate markers of the overall quality of clinical care and may not be the best measures of the effectiveness of practice in different specialist units. Thus, an index ulcer may heal, whereas the patient remains incapacitated by the presence of another (persistent or newly occurring) ulcer, by the effects of the treatment (e.g., amputation) of the original problem, or by comorbidity. It is for these reasons that patient-centered measures must also be considered, and these include survival, all amputations, ulcer-free status, duration of ulcer-free survival, well-being, and disability (5,6). Implicit in the choice of any outcome measure of the effectiveness of care, however, is the need for the process to be simple enough to be undertaken on a routine basis in all presenting patients and at one or more fixed intervals after presentation. We have therefore sought to determine the outcome of management in a consecutive series of patients presenting to a single specialist unit over a 4-year period and to compare the use of both ulcer-related and person-related measures.

## RESEARCH DESIGN AND METHODS

### Clinical management

The specialist multidisciplinary clinic for the management of diabetic foot lesions is administered at the City Hospital, Not-

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**Abbreviations:** S(AD)SAD, Size (Area and Depth), Sepsis, Arteriopathy, and Denervation; UT, University of Texas.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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**Table 1—Spectrum of ulcer types presenting to a single specialist unit between 1 January 2000 and 13 December 2003, classified according to the S(AD)SAD system (8)**

Variable	Grade 0	Grade 1	Grade 2	Grade 3
Size (area)	—	272	108	69
Size (depth)	—	352	57	40
Sepsis	246	90	73	40
Arteriopathy	163	94	182	10
Denervation	90	117	236	6

Grade 0 (skin intact) lesions were excluded. Area grade 0, skin intact; 1, <1 cm<sup>2</sup>; 2, 1–3 cm<sup>2</sup>; 3, >3 cm<sup>2</sup>. Depth grade 0, skin intact; 1, skin and subcutaneous tissue only; 2, muscle; tendon or joint capsule; 3, periosteum and bone. Sepsis grade 0, clean; uninfected; 1, superficial slough and debris; 2, soft tissue infection; 3, osteomyelitis. Arteriopathy grade 0, both pulses palpable; 1, one pedal pulse missing or both reduced; 2, both pulses missing; 3, gangrene. Denervation grade 0, no evidence of neuropathy; 1, some loss of protective sensation; 2, marked loss of protective sensation; 3, Charcot foot.

tingham, U.K., by two specialist diabetologists working in close collaboration with vascular and orthopaedic surgeons, two specialist podiatrists, an orthotist, plaster theater nurses, and a diabetes nurse specialist. The clinic serves a mainly urban/suburban population of ~300,000, predominantly Caucasian, people in the northern half of Nottingham. Patients are seen frequently, usually at intervals of 1–4 weeks and generally until healing occurs. Clinic sessions are held twice each week, but patients are also seen at any time according to clinical need. Management follows agreed international recommendations (7) and is outpatient based, with patients being admitted to the hospital only for attempted revascularization, amputation, treatment of limb-threatening infection, or management of intercurrent illness.

### Ulcer database

Comprehensive records have been kept of clinical practice since the clinic was established in 1982, and the current form of the database was adopted on 1 January 2000 and is freely available (8). Data entries are made only at the time of outpatient clinic attendance, and the database thus excludes those who are managed entirely as in-patients or who are either lost to follow-up or transferred to the care of others after a period of in-patient treatment. Basic demographic information is recorded for every patient, and a log is kept of every foot lesion. All lesions are classified at the time of first assessment in the outpatient clinic, using the Size (Area and Depth), Sepsis, Arteriopathy, and Denervation [S(AD)SAD] classification, which grades cross-sectional area, depth, infection, ischemia, and neuropathy (9). The clinical methods used were those that could be easily applied to a large consec-

utive cohort during the course of routine clinical practice, as previously described (9). It is possible to use the same data to classify each lesion also using the University of Texas (UT) system (10). Date of lesion onset is also recorded, but because it is often impossible to define this date with precision, it is recorded simply by month of onset. The date of healing was estimated as closely as possible from the evidence provided by the patient. If the patient is unable to provide this information, the date of healing was taken as the date of the clinic visit when it was first noted. If a patient dies, the date of death is entered automatically into the hospital information system. For those who die or are otherwise lost to follow-up, an attempt was made to determine ulcer outcome by a manual search of their hospital records.

### Population

All patients presenting to the clinic with a new foot ulcer between 1 January 2000 and 31 December 2003 were included. A foot ulcer was defined as a full-thickness break in the skin occurring on or below the malleoli of either foot. Lesions in which the epithelium appeared to be intact (such as infection without an obvious portal of entry, acute Charcot foot without ulceration, or a blister or unrelated disease of the skin) were excluded. An index ulcer was selected as the first registered for that person in that time window but not necessarily the first ulcer that that person had ever had. If there was more than one ulcer at first presentation, the index ulcer was taken as the largest or most clinically significant. In 17 patients, baseline information concerning the first ulcer was incomplete and in these cases the patient's next occurring ulcer was selected as the index lesion.

### Outcomes

Ulcer outcomes were defined at 6 and 12 months after initial registration and categorized as healing (defined as complete epithelialization without discharge), persisting unhealed, and resolution by either ipsilateral amputation (minor or major) or death. Patient outcomes were survival, being ulcer-free at 6 and 12 months, number of ulcer-free days, and all amputations (minor and major). A nonhealing wound after minor amputation (amputation limited to the foot) was entered as a new ulcer. A nonhealing wound occurring after a major (transtibial or transfemoral) amputation was not registered because it did not affect the foot. For the purposes of calculating time to onset of any new or recurrent ulcer, the date of onset of the new episode was taken as the 15th day of the month in which it occurred, with negative values recorded as 0 days. Within the limits imposed by the imprecision of defining the dates of ulcer healing and ulcer recurrence, the total number of ulcer-free days before the end of the 12-month period or to death was calculated for each patient as previously described (5).

**RESULTS** — During the 4-year period of recruitment, 449 patients (286 men, 63.7%) presented with a new foot ulcer. Mean ( $\pm$ SD) age was  $66.7 \pm 13.2$  years. Of the patients, 53 (11.8%) had type 1 diabetes, 339 (75.5%) had type 2 diabetes, and for 57 (12.7%) the diabetes type was not recorded. Duration of diabetes before presentation of the index ulcer was  $15.6 \pm 11.2$  years. A total of 17 patients (3.8%) were lost to follow-up, and outcome was unknown.

### Ulcer types

The spectrum of ulcer types, classified according to the S(AD)SAD classification, is given in Table 1. The majority of ulcers had a cross-sectional area <1 cm<sup>2</sup> and were confined to more superficial soft tissues; 286 ulcers (63.7%) were associated with some degree of peripheral arterial disease in the affected limb, whereas 359 (80.0%) had some impairment of peripheral sensation. The spectrum of lesions, as classified by the UT system (9), is presented in Table 2. The median (interquartile range) duration of index ulcers before referral to the specialist service was 29 (11–61) days.

**Table 2—Spectrum of ulcer types presenting to a single specialist unit between 1 January 2000 and 31 December 2003, classified according to the UT system (9)**

Stage (infection/ischemia)	Grade (depth)		
	1: Superficial ulcer	2: Ulcer to tendon or capsule	3: Ulcer to bone or joint
1: Clean ulcer	134	8	1
2: Nonischemic infected ulcer	70	15	5
3: Ischemic noninfected ulcer	93	8	2
4: Ischemic infected ulcer	55	26	32

Grade 0 (skin intact) lesions were excluded.

### Ulcer-related outcomes

Ulcer-related outcomes at 6 and 12 months are summarized in Table 3. A total of 295 (65.7%) index ulcers healed at some stage in the course of follow-up, but only 266 (59.2%) remained healed at the end of the 12 months. The median (range) time from presentation to healing in the 295 ulcers that healed was 78 (7–364) days and 79 (7–364) in the subset that remained healed at 12 months.

### Person-related outcomes

Person-related outcomes at 12 months are summarized in Table 4. Only 223 patients (49.7%) were alive and ulcer-free at 12 months, and 21 of these had had an amputation (either major or minor). Of the total 48 (10.7%) who had had an amputation (24 major, 5.3%), 41 were alive at 12 months, but 18 had a persisting ulcer, and in a further 2 the ulcer status was unknown. Of the 202 patients who were alive without amputation and were ulcer-free, the median (range) number of ulcer-free days in the 12 months of follow-up was 272 (1–358). Of the 21 who were alive and ulcer-free after an amputation, the number of ulcer-free days was 197 (42–360). Of the 19 who died ulcer-free, the number of ulcer-free days before death was 125 (9–324).

**Table 3—Ulcer-related outcomes at 6 and 12 months in 449 ulcers consecutively managed in a single specialist unit between 1 January 2000 and 12 December 2003**

	6 months	12 months
Outcome		
Healed	234 (52.1)	266 (59.2)
Healed prior to death	13 (2.9)	29 (6.5)
Persisting unhealed	125 (27.8)	52 (11.6)
Resolved by ipsilateral amputation	26 (5.8)	36 (8.0)
Resolved by patient death	28 (6.2)	49 (10.9)
Outcome unknown	23 (5.1)	17 (3.8)
Total	449	449

Data are n (%).

**CONCLUSIONS**— These data reflect the outcome in a consecutive series of patients attending a single specialist center over a 4-year period. It is difficult to quantify the effect of referral practice on this population, and it is likely that more trivial lesions were managed entirely in primary care and also that occasional others will have been managed solely with in-patient care or by other medical teams. Two recent surveys undertaken in the community served by the hospital revealed that 53 and 60%, respectively, of all active ulcers were managed in our clinic (J. Burnside, W. Wells, F. L. G., W. J. J., unpublished data). Nevertheless, it is believed that the clinic cares for the great majority of significant lesions in those who live in the local catchment area. The results emphasize the poor prognosis of lesions managed in such a service, with only 59.2% of all ulcers healing at some stage without amputation within 12 months and another 8.0% being resolved by amputation (major or minor).

These findings bear comparison with two other large cohort studies. Apelqvist (11) reviewed the eventual outcomes in 1,073 ulcers managed between 1983 and 1996 and reported a rate of healing without amputation of 66.5%, which was very

similar. The rate of death of 16.7% was also similar, but the number undergoing amputation (major or minor) of 16.7% was higher in the Swedish study. Another cohort study was undertaken simultaneously in two centers, Manchester, U.K., and San Antonio, Texas, in 1998–1999 (12), in which 194 patients were followed until healing or for a minimum of 6 months. Of the ulcers, 15% resulted in an amputation, but 65% healed without amputation, and the median healing time was only 5 weeks. Only 16% of ulcers persisted unhealed at the end of the observation period, and 4% of the patients died.

It is of interest that the final reported rate of primary healing (without amputation) of ulcers was very similar in the three cohorts, at 65.0, 65.7, and 66.5%, even though the incidence of amputation, when calculated as ulcer-related outcome, was much lower in the present study. Healing was achieved earlier in the Manchester/San Antonio study, and although this may reflect more effective treatment, it should be noted that the patients managed in this study were younger, with a mean age of 56.6 (compared with 66.7 in the present study) years. Only 27.3% of the patients in the Manchester/San Antonio study had any evidence of peripheral arterial disease, compared with 61.5% in the present cohort. These differences emphasize the need to define the baseline population of both ulcers and patients with care in comparative studies.

These comparisons between the three studies rely, however, on the use of ulcer-related outcomes, and the results of the present work indicate the extent to which such ulcer-related outcomes may underestimate the morbidity and mortality associated with the condition. Thus, we have found that whereas almost 60% of index ulcers healed at some stage, only 45.0% of patients were alive and ulcer-free (with or without amputation) after 12 months of follow-up. Similarly, the use of ulcer-related outcomes gives an underestimate of the overall mortality: only 36 (8.0%) of index ulcers were resolved by death by 12 months, whereas a total of 75 patients (16.7%) died within the same time period, the remaining patients having died after their index lesion healed. The incidence of amputation (major and minor combined) when expressed as an ulcer-related outcome was 36 (8.0%), whereas a total of 48 patients (10.7%) actually underwent surgery, with 12 having

**Table 4—Person-related outcomes at 12 months in 449 people consecutively presenting to a single specialist unit between 1 January 2000 and 12 December 2003**

Outcome	Frequency	%
Alive, without amputation and ulcer free	202	45.0
Alive, without amputation and with persisting ulcer(s)	111	24.7
Alive, after amputation (major or minor), and ulcer free	21	4.7
Alive, after amputation with unhealed amputation site*	7	1.3
Alive, after amputation with another ulcer elsewhere	11	2.4
Alive, ulcer status unknown	23	5.1
Alive, after amputation ulcer status unknown	2	0.7
Died, without amputation and ulcer free	19	4.2
Died, without amputation and with persisting ulcer(s)	49	10.9
Died, after amputation	7	1.6
Total	449	

\*Applies only to minor amputations, because unhealed major amputation sites are not registered as “foot ulcers.”

an amputation for a lesion other than the index ulcer. Ultimately, however, the principal aim for the patient is early healing, ideally without surgery, and enjoying as many ulcer-free days as possible (5). We have therefore explored the use of days of ulcer-free survival as a measure of the effectiveness of management in future work, and the median number of ulcer-free days enjoyed by the 202 patients with ulcers that healed without amputation in this cohort was 272 in the 12 months after referral.

These observations confirm the need for care in planning studies to compare the effectiveness of management in differ-

ent centers. Such studies are urgently needed if there is to be a general move toward improving the standards of expert management of patients who present with this disabling condition.

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