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Use of the SINBAD classification system and score in comparing outcome of foot ulcer management in three continents

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ABSTRACT

Objective: To compare populations and outcomes of diabetic foot ulcers managed in UK, Germany, Tanzania and Pakistan, and to explore the use of a new score of ulcer type in comparing outcome between different countries

Research Design and Methods: Data from a series of 449 patients managed in UK were used to evaluate the new simplified system of classification, and to derive an aggregate score. The use of the score was then explored using data from series managed in Germany (239), Tanzania (479) and Pakistan (173).

Results: A highly significant difference was found in time to healing between ulcers of increasing score in the UK series (p=0.000, Kruskal Wallis). When data from all centers were examined, a step up in days to healing was noted for those with scores of 3 or more (out of 6). Examination of baseline variables contributing to outcome revealed differences between centers: ischemia, ulcer area and depth contributing to outcome in UK; ischemia, area, depth and infection in Germany; depth, infection and neuropathy in Tanzania and depth alone in Pakistan.

Conclusions: Any system of classification designed for general implementation must encompass all the variables which contribute to outcome in different communities. The adoption of a simple score based on these variables, the SINBAD score, may prove a useful tool to predict ulcer outcome and to enable comparison between different centers.

There is no widely accepted system of classification of diabetic foot ulcers (1-3), The lack of consensus is explained partly by their varying presentation and partly because the specification of a classification depends on its intended use (3). A classification for use in clinical care can be relatively flexible and descriptive, whereas one used for audit must be more structured but simple enough for use in larger populations. This differs from one used for prospective research which should be selective and exclusive (4). While the UT system (5) has been widely adopted, we have argued that the S(AD)SAD system (6) might be better suited to audit because of its greater specificity (3), especially as rather different criteria contribute to outcome in countries which are more (7-11), or less, industrialised (12-15). The inclusion of more criteria makes the system more complicated, however, and harder to apply in routine practice – especially in resource-poor communities where the burden of patient numbers can be enormous (15). The aim, therefore, of the present study was to create a simplified version of the S(AD)SAD classification, in which the original five elements (area, depth, infection, ischemia, neuropathy) are retained, while the structure is simplified by reducing the number of subgroups to two. The modified version, the SINBAD classification, also includes ulcer site because of newer data suggesting this may also be an important determinant of outcome (8,10) (Table 1). The components of the classification can be summed to produce a score of between 0 and 6.

METHODS

The contribution to outcome made by demographic features and baseline ulcer characteristics has been reported in a consecutive cohort of 449 patients referred to a specialist clinic in Nottingham, UK, over four years (8). Each lesion was classified using the S(AD)SAD system (6) at the time of first attendance, and was re-categorized retrospectively for the purposes of the present study using the SINBAD system (Table 1). The data to define *Site* were available from the clinic database. In the SINBAD system, these six elements were graded as follows: *ulcer site* – forefoot (distal to tarso-metatarsal joint), 0, and midfoot/hindfoot, 1; *ischemia* – blood flow relatively intact (at least one pulse palpable on the affected foot), 0, and evidence of ischaemia (neither pulse palpable with signs of reduced tissue perfusion, with or without gangrene), 1; *neuropathy* – was defined as being absent, 0, or present, 1, on the basis of routine examination using either Neurotips® (Owen Mumford) or 10g nylon monofilaments; *bacterial infection* (using clinical signs of infection of either soft tissue or bone proposed by the Infectious Diseases Society of America and the International Working Group on the Diabetic Foot) (16,17); *area* – (the two maximum dimensions at right angles multiplied): $1cm^2$ or less, 0, $>1cm^2$, 1; *depth* – superficial, 0, and deep (reaching to tendon, periosteum, joint capsule or bone), 1 (see Table 1). In addition, the individual grades were summed, making a SINBAD score of 0-6. The contribution made by each of the six elements to outcome (healed versus non-healed) was sought using Chi square and logistic regression. An association was also sought between SINBAD score and median time to healing. These analyses were repeated using data collected prospectively in consecutive series of patients managed in specialist clinics in Dar es Salaam (Tanzania), Karachi (Pakistan) and Soest (Germany). The foot care services in Pakistan are private, whereas those in the other countries are free at the point of delivery and paid for either by central government or personal insurance. The data from the patients managed in Dar es Salaam have previously been used to compare four different systems of classification

(Wagner, UT, S(AD)SAD and PEDIS) (18). The data from Germany have been used to compare with separate populations managed in Tanzania and India (19). Univariate analysis was undertaken seeking differences between baseline variables and outcome (healed versus non-healed, including amputation and death) using Person Chi square or Fisher's Exact tests. Variables with a significance $p<0.05$ entered for multivariate analysis by logistic regression.
It has previously been established with the Caldicott Guardian in Nottingham that ethical approval is not required to analyse anonymised data collected during the course of routine management.

RESULTS

Data from the 449 consecutive cases managed in Nottingham were used to analyse outcomes according to the simplified baseline categories, and to explore the significance of the aggregate SINBAD score. The median time to healing in the 323 cases which healed without amputation was determined for ulcers with different SINBAD scores, and a highly significant difference between groups was found: Chi square 37.324, p=0.000 (Kruskal Wallis). Data from the other three centers were then classified according to the new system.
Table 2 summarises baseline demographic details and outcomes of the ulcers managed at the four centers. Outcomes were determined at a fixed date in each center; the median time to outcome varied from 30 to 91 days, with maximum durations of follow-up ranging from 973 to 1344. The prevalence of ulcers of different SINBAD score in the four centers is shown in Table 3 and the median time to healing (of those ulcers that healed without amputation) in Table 4.

Univariate analysis revealed significant differences between the baseline categories associated with outcome (healing versus non-healing) in the four centres (Table 5). Ulcer depth was the only variable associated with healing in the series from Karachi, although trends to differences were observed for site (p=0.069, Fisher's Exact) and for ischemia (p=0.090, Fisher's Exact). The results of multivariate analysis are shown in Table 6.

DISCUSSION

This study reveals that different baseline ulcer characteristics are associated with outcome in the different countries. It also shows that these characteristics can be expressed in an aggregate SINBAD score, with a score of 3 or more being associated with a step-up in time to healing and in eventual failure to heal. The SINBAD score may therefore represent a system for defining ulcer type which could be applied worldwide. A strength of the study is that it employs data collected prospectively in consecutive series of patients. A limitation lies in the outcome data being based variable duration of follow-up and this weakens to some extent the descriptive analysis of eventual outcome: healing, non-healing, amputation and death. The results confirm the marked differences in the nature of foot lesions managed in different countries, as well as in patient age, as previously reported (19). Those in less-industrialised countries are approximately 15 years younger and as there is also a lower prevalence of peripheral arterial disease, foot ulcers in developing countries tend to be caused by trauma from inappropriate, or non-existent, footwear and are frequently complicated by infection. When access to free health care is not available (as in Pakistan), or delayed because of initial reliance on traditional healers (as in Tanzania), patients may present late and with infection which is more severe. It has been estimated that the management of a single ulcer costs on average between 0.3 and 5.5 times the average total monthly expenditure for a household in Pakistan (Mansoor Ali et al., unpublished data). It is probably for such

reasons that in the series from these two countries relatively uncomplicated lesions (those with SINBAD scores of 0-2, see Table 3) were under-represented, while the number lost to follow-up was high.

The differences in patient population and ulcer type emphasise the need for using appropriate systems of classification if any attempt is to be made to compare ulcer outcomes between centers. Such systems must encompass all the variables which may be associated with outcome and our findings reveal that these vary considerably, with only depth being common to all centers on univariate analysis (Table 5). By using an aggregate scoring system, however, it is possible to obtain a measure of ulcer type which is independent of the specific factors of which it is comprised and enables such comparisons to be made. Inspection of Table 4 reveals a clear step up in time to healing between SINBAD scores of 2 and 3 in each of the four centers, suggesting that those with ulcers of Grade 3 or greater are at particular risk.

Interesting differences were also observed between outcomes in the studied populations in UK and Germany. The main difference between the two lies in the strong association which exists in Germany between infection and outcome, whereas the association was only weak in UK and lost on multivariate analysis. The incidence of amputation (major and minor combined) was also much higher in the German cohort (19.2% versus 8.0%), although it is important to note that the two series were not concurrent, dating from 1998-1999 and 2000-2003, respectively, and the incidence of amputation for all new ulcers in Soest has since fallen by 60% (unpublished data). In 1998-9, however, it is possible that it was more usual in Germany to manage osteomyelitis by early elective excision of bone, whereas most centers in UK reserve amputation for those with either overwhelming infection or who fail to respond to initial antibiotic treatment (19,20). In this respect, the findings in Germany resembled those in North America, where a similarly close association has been shown between outcome (incidence of amputation) and infection at baseline (5), and where early surgery is more usual practice. Conversely, some 11.6% of the population managed in UK had persisting disease at the time of assessment in the present series, compared with 0% in Germany. Moreover, the time to healing was longer in UK than in any of the other three centers for ulcers of all grades and while this could reflect less effective care, it could also result indirectly from lower incidence of amputation and an attempt to achieve healing without surgery in a greater proportion of the population. Detection of differences such as these highlight the value of comparative audit and pinpoint the need for formal assessment of the advantages and disadvantages of different strategies of care.

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TABLE 1. The SINBAD system for classifying and scoring foot ulcers

Category	Definition	SINBAD Score	Equivalent S(AD)SAD categories
Site	Forefoot	0	-
	Midfoot and hindfoot	1	
Ischemia	Pedal blood flow intact: at least one pulse palpable	0	0-1
	Clinical evidence of reduced pedal blood flow	1	2-3
Neuropathy	Protective sensation intact	0	0-1
	Protective sensation lost	1	2-3
Bacterial infection	None	0	0-1
	Present	1	2-3
Area	Ulcer $<1cm^2$	0	0-1
	Ulcer $\geq 1cm^2$	1	2-3
Depth	Ulcer confined to skin and subcutaneous tissue	0	0-1
	Ulcer reaching muscle, tendon or deeper	1	2-3
	TOTAL POSSIBLE SCORE	**6**	

TABLE 2. Baseline demographic details and outcomes in the four centers

	Nottingham	Soest	Dar es Salaam	Karachi
N	449	239	479	173
% Type 2 (if known)	86	89.5	98.0	98.8
Mean age (SD)	66.7 (13.2)	69.4 (10.6)	54.5 (11.3)	53.2 (12.2)
% male	63.7	59.0	66.8	66.5
Eventual healing (%)	65.7*	72.0	48.0	59.0
Persisting unhealed	11.6	0	14.4	0
Resolved by amputation (%)	8.0	19.2	12.1	8.1
Unhealed at time of death (%)	10.9	8.8	3.8	0.6
Outcome unknown (%)	3.8	0	21.7	32.4
Median (range) time to outcome (days)	91 (6-1344)	70 (1-967)	30 (0-973)	60 (1-1088)

TABLE 3. Prevalence (%) of ulcers of different SINBAD score in the four centers

SINBAD score	Nottingham, (N=449)	Soest, (N=239)	Dar es Salaam (N=479)	Karachi (N=173)
0	2.9	2.9	1.0	0
1	18.9	13.0	8.6	0
2	36.7	26.4	23.4	2.3
3	18.2	16.3	17.7	31.8
4	15.1	18.8	33.0	49.7
5	6.3	19.7	15.9	15.6
6	1.8	2.9	0.4	0.6

TABLE 4. Median (range) time to healing (days) per SINBAD score for ulcers which healed in each center

SINBAD score	Nottingham, (N=449)	Soest, (N=239)	Dar es Salaam, (N=479)	Karachi (N=173)
0	77 (7-243)	19 (2-37)	36 (25-40)	-
1	77 (7-1029)	39 (7-91)	24 (5-47)	-
2	70 (7-1344)	56 (9-145)	29 (4-519)	28 (12-44)
3	126 (14-1330)	78 (19-375)	42 (7-404)	57 (7-384)
4	140 (21-693)	131 (22-497)	61 (8-574)	92 (7-1088)
5	113 (42-427)	273 (110-461)	68 7-226)	101 (18-387)
6	577 (384-770)	269(103-421)	-	-

TABLE 5. Significant associations (Chi square) between baseline variables and outcome (healing versus persisting non-healing plus unhealed at death plus amputation) in the four centers

SINBAD baseline variable	Nottingham	Soest	Dar es Salaam	Karachi
Site			4.131 (p=0.027)	
Ischemia	22.302 (p=0.000)	28.615 (p=0.000)		
Neuropathy			12.508 (p=0.000)	
Bacterial infection	5.082 (p=0.019)	44.354 (p=0.000)	41.633 (p=0.000)	
Area	24.535 (p=0.000)	54.539 (p=0.000)		
Depth	27.154 (p=0.000)	64.137 (p=0.000)	30.753 (p=0.000)	11.496 (p=0.000)

TABLE 6. Significant independent associations (logistic regression) between baseline variables and outcome (healing versus persisting non-healing plus unhealed at death plus amputation) in the four centers

SINBAD baseline	Nottingham 95%CI (p)	Soest 95%CI (p)	Dar es Salaam 95%CI (p)	Karachi*
Site			0.340-0.894 (p=0.016)	
Ischemia	2.046-7.484 (p=0.000)	2.695-14.228 (p=0.000)		
Neuropathy			1.466-9.345 (p=0.006)	
Bacterial infection		1.963-20.325 (p=0.002)	1.596-7.781 (p=0.002)	
Area	1.436-4.461 (p=0.001)			
Depth	1.322-5.009 (p=0.005)	3.950-49.970 (p=0.000)		

* The Karachi data were not assessed since only one variable achieved significance on univariate analysis