The diabetic foot in Germany: Analysis of quality in specialised diabetic footcare centres

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Article points

1. In 2003, the German Working Group on the Diabetic Foot developed certification requirements for diabetic footcare centres.
2. A system was established for accrediting hospitals and outpatient clinics specialised in treating diabetic foot wounds.
3. All centres have to prove the quality of their structure, procedures and evaluation.
4. This evaluation of 130 centres reports that specialised diabetic foot centres have a low major amputation rate compared with standard care in Germany.

Key words
- Diabetic foot centers
- Standards of care
- Epidemiology

Caring for people with diabetic foot ulcers requires both specialist skills and specialist care settings. In Germany, these parameters are required to be assessed according to the guidelines provided by the German Working Group on the Diabetic Foot (2003), which includes such measures as patient outcomes. In this paper, the authors compare the outcomes of diabetic foot complications in inpatients and outpatients in 130 specialist care centres.

In Germany, legislation demands measurement of the quality of management of outpatient and inpatient facilities. In 2003, the German Working Group on the Diabetic Foot developed certification requirements for diabetic foot centres. These certification requirements established proceedures by which specialised centres for the treatment of the diabetic foot syndrome could verify their management quality. In addition, this certification fulfils the demands of the 2006 IDF Global Guideline for Type 2 Diabetes (IDF Clinical Guidelines Task Force, 2006). The goal was to establish comparable diabetic foot centers with clearly defined treatment structures.

Conditions for the certification are quality parameters of the facility's structure, treatment procedures and patient outcomes (*Box 1*; Schaper et al, 2003; IDF Clinical Guidelines Task Force, 2006). Structural quality was based on the qualifications of staff, the facility's spatial conditions and a minimum provision of equipment. Staff members of certified centres must visit each other. Also assessed are the application of available guidelines and documentation systems, the establishment of a multidisciplinary team approach between the facility's staff and other experts involved.

Indicators of outcome quality include:

- rate of amputation (major and minor)

- vascular intervention (surgery, percutaneous transluminal angioplasty)
- death rate
- clinical admission
- foot status 6 months after first documentation of a diabetic foot condition.

Rules for certification were published as part of the annual meeting of the German Working Group on the Diabetic Foot and are also available from the working group's website (http://www.ag-fuss-ddg.de/ [accessed 25.06.2007]). All parameters are checked, presented and benchmarked in an open session of the working group (Müller et al, 2006; Lobmann et al, 2007).

Methods

Interested centres submitted applications for assessment of inpatient or outpatient diabetic foot care. Applications were then checked by a certification committee for correctness and completeness, a process that focuses on the structural equipment, reports of hospitalisations and treatment evaluation.

For the evaluation, each centre documented 30 consecutively seen individuals with diabetic foot lesions. An evaluation of the outcomes was performed 6 months after the initial presentation of each individual.

Details collected as part of the evaluation included:

- patient date of birth
- date of first visit
- classification of the lesion or Charcot
- date of re-evaluation
- occurrence of major and minor amputation
- record of any other procedures
- record of hospitalisation
- classification of the target ulcer after 6 months
- mortality.

Results

Data from 130 certified centres are presented: 84 centres treated outpatients and 46 centres inpatients. A total of 3864 individuals were

Box 1. Requirements for accreditation from the Diabetic Foot Working Group of the German Diabetes Association.

1. Quality of structures

Equipment:
- Surgery (room) chiefly for foot treatment. Dressing trolley, special chair or couch. Adequate illumination.
- Availability of a tuning folk, SW monofilament, reflex hammer, Doppler device, camera and cuffs for measuring closing pressure.
- Sterilised instruments.

Staff:
- All members of the footcare team to be specified by name and qualification.

Co-operation:
- Written agreements of co-operation from involved surgeons, vascular surgeons, diabetologists, podiatrists, inpatient or outpatient facility managers, orthotists and microbiologists.

Emergency service:
- Must be available 24 hours.

2. Quality of procedures

- Treatment according to evidence-based and international guidelines.
- Standardised documentation.
- Adherence to hygiene standards.

3. Quality of results

- Audit (active and passive).
- Public presentation of data at annual convention of the working group.
- Public benchmarking of outcomes.

Table 1. Summary of the results stratified by care setting and incidence of outcomes.

	All centres	Inpatient centres	Outpatient centres
Centres involved	130	46 (35.4 %)	84 (64.6 %)
Patients at presentation	3864	1367	2497
Patients at re-evaluation (after 6 months)	3672 (95.0 %)	1253 (91.7 %)	2487 (99.6 %)
Incidence of death at 6 months	4.6 %	7.0 %	3.3 %
Incidence of Charcot foot	14.3 %	13.1 %	15.0 %
Incidence of major amputations	4.4 %	7.8 %*	2.5 %*
Incidence of minor amputations	17.2 %	25.7 %*	12.6 %*

**P<0.001 for the difference between the frequencies of major or minor amputations in the hospital setting versus in the outpatient clinic.*

Table 2. Change in percentage of study population affected by foot ulcers over 6 months.

	Percentage of patients at presentation versus 6-month re-evaluation		
Ulcer classification	**All centres**	**Inpatient centres**	**Outpatient centres**
Wagner 0	3.6 % versus 54.6 %	2.6 % versus 49.3 %	4.2 % versus 55.8 %
Wagner 1	31.4 % versus 27.0 %	15.1 % versus 26.2 %	40.4 % versus 26.7 %
Wagner 2	31.7 % versus 10.9 %	29.3 % versus 12.8 %	33.0 % versus 9.7 %
Wagner 3	22.5 % versus 3.2 %	31.8 % versus 6.9 %	17.3 % versus 3.6 %
Wagner 4	10.4 % versus 2.3 %	20.6 % versus 4.2 %	4.9 % versus 1.3 %
Wagner 5	0.4 % versus 0.3 %	0.7 % versus 0.6 %	0.2 % versus 0.2 %

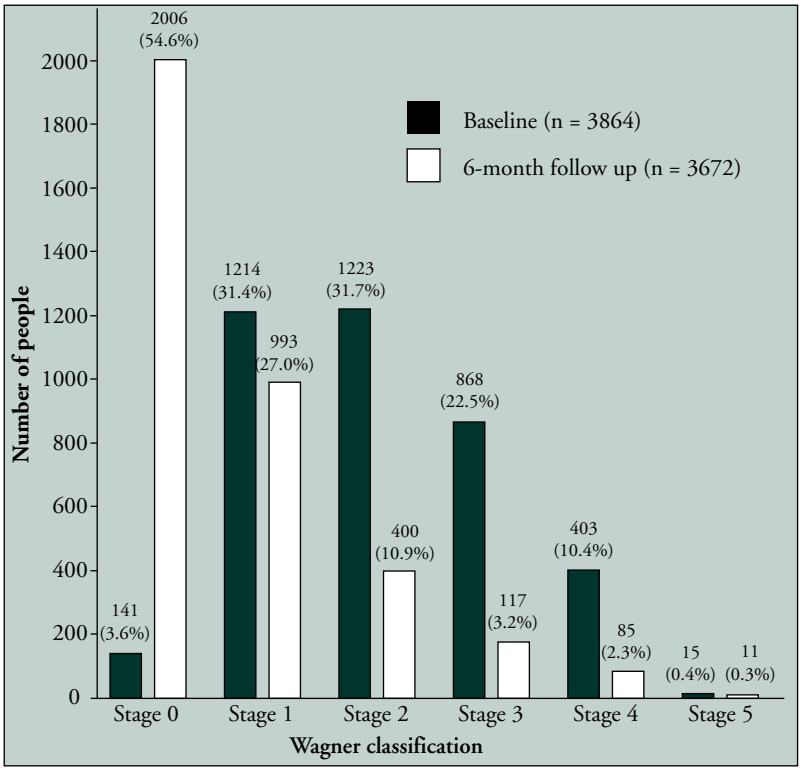

Figure 1. Evaluation of the results of the accreditation procedure of the German Working Group of the Diabetic Foot. This graph shows the Wagner stage evaluation of 3864 people from 130 centres (outpatient: 84; hospitals: 46).

Table 3. Frequency of Charcot foot stratified by Sanders pattern.

Sanders pattern	Frequency (%)
I	182 (4.7 %)
II	155 (4.0 %)
III	141 (3.6 %)
IV	59 (1.5 %)
V	16 (0.4 %)

evaluated. *Table 1* shows a summary of the results stratified by care setting and incidence of outcomes.

Figure 1 shows the number of occurrences of diabetic foot ulcers according to their Wagner classification at baseline and after 6 months. At the 6-month follow-up assessment, a substantial improvement could be seen: more than half (54.6%) of all participants experienced complete healing of the documented lesions and only 17 % were classified as Wagner stage 2 or above. The changes in the ulcer severity over six months for each care setting are shown in *Table 2*.

There was a distinct difference between the distribution of cases treated in outpatient centres and those admitted as inpatients. The outpatient foot centres saw a majority of Wagner stage 1 and 2 cases (75.1 %), whereas those with stage 4 ulcers were treated primarily as inpatients. Individuals with Wagner stage 1 ulcers were rarely admitted to inpatient care.

Osteoarthropathy, or Charcot foot, was recorded in 553 (14.3 %) of the cases examined. These individuals can be categorised further using the Sanders patterns classification, based on the anatomical location of the arthropathy (see *Table 3*).

The results of the evaluation indicate a low level of major (above-ankle) amputations – only 170 (4.4 %) were recorded over the study period. Substantially more people underwent a minor (below-ankle) amputation (666; 17.2 %).

This evaluation included only facultative information on the type of minor amputation and vascular reconstructive measures; an in-depth statistical analysis of the minor amputations was therefore not possible.

The rate of hospitalisation proved to be an important parameter, with 1378 people requiring admission. Of these 1378, 661 were initially treated in outpatient centres (a referral rate of 26.6 %) and 717 were later re-hospitalised.

In general, a significant improvement, or even complete wound healing, could be seen in people treated in the outpatient foot clinics as long as the lesion was still in Wagner stage 1–4 at the initial presentation. As expected for Wagner stage 5

Page points

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2. The data reflect a lower rate of major and minor amputations in specialist centres compared with the available epidemiological data for Germany as a whole.
3. The next evaluation, scheduled for the next year or so, should provide elucidating data on the development of quality in the participating centres.

ulcerations, there was no substantial improvement and, in most cases, surgical intervention – usually a major amputation – was necessary.

Of the cases examined, an infection was diagnosed in 33.7% of inpatients and 34.3% of outpatients.

The rates of arterial revascularisation were comparable between the inpatient and outpatient groups: 14.6% and 14.1%, respectively. However, Armstrong stage D occured significantly more often in the inpatient group (45.4%) compared with the outpatient group (25.3%).

In total, 179 (4.6%) people died during the observation time and the mortality was significantly higher for inpatients (7% versus 3.3%; $P<0.001$).

Discussion

These data represent the first analyses of the treatment outcomes of diabetic foot lesions in specialised centers in Germany.

The relatively high rates of Charcot foot reflect the selective nature by which people are referred to diabetes specialists.

The poor outcomes associated with lesions classified as Wagner 4 and 5 lesions demand early diagnosis and treatment to prevent progression of the diabetic foot lesion and elevated rates of complications.

Owing to the incidence of arterial occlusive disease, the rate of revascularisation procedures seems to be relatively low. The forthcoming evaluation sheet from the working group will give a closer inspection with separate evaluation items.

The data reflect a lower rate of major and minor amputations in specialist centres compared with the available epidemiological data for Germany as a whole (Trautner et al, 2001; Heller et al, 2004).

This analysis presents the first German data collected using defined standards that include amputation rate and mortality in the treatment of the diabetic foot in specialist centres.

Both the data from this analysis and the proceedures of the German Diabetes Association by which accreditation is granted should be of interest to people working in other healthcare systems. In Germany, some insurance companies require treatment centres to be accredited by the German Diabetes Association in order for medical costs accrewed by the treatment of diabetes-related foot conditions be reimbursed.

The next evaluation, scheduled for the next year or so, should provide elucidating data on the development of quality in the participating centres.

The German Working Group on the Diabetic Foot has established comprehensive quality assurance measures for diabetic footcare centres and implemented them nationally. In addition, useful data from a very large treatment cohort has been gained. ■

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