THE DIABETIC FOOT IN GERMANY 2005 -2011
ANALYSIS OF QUALITY IN SPECIALISED DIABETIC FOOT CARE CENTERS

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for the quality management representatives of the working group diabetic foot of the
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Abstract

In 2003, the German Working Group on the Diabetic Foot developed a certification procedure and requirements for diabetic foot care centers. The goal was to establish comparable diabetic foot care centers with clearly defined standards of care. The Working Group on the Diabetic Foot and the German Diabetes Society established a system for accrediting hospitals and outpatient clinics specialised in treating diabetic foot wounds. All centers have to prove the quality of structure (staff, premise and facilities), quality of procedures and the quality of evaluation. Actual we present the 7 years results of these Centers. Compared with data of the standard care system of the German health care system these specialized centers show reduced rates of major amputations.

Diabetic Foot centers, standards of care, epidemiology
Introduction

In 2003, the German Working Group on the Diabetic Foot developed a certification procedure and requirements for diabetic foot centers. The goal was to establish comparable diabetic foot centers with clearly defined treatment structures.

The certification requirements were orientated according to the standards of international diabetic foot care guidelines. The procedures were reworked several times and correspond to the 2005 International Diabetes Federation (IDF) Global Guideline for Type 2 Diabetes. Conditions for the certification are quality parameters of the facility's structure, treatment procedures and the patient outcome (Schaper et al 2003; IDF Clinical Guidelines Task Force 2006). Structural quality based on the qualifications of staff, facility spatial conditions as well as a minimum of equipment (table 1). The application of available guidelines and documentation systems as well as the establishment of a team approach between the facility's staff and other experts involved (vascular surgeon, orthopedic surgeon, radiologist, podiatrist, orthopedic shoemaker, etc.) belong to the requirements of procedure's quality.

Staff members of certified centers must visit each other. Outcome quality encloses: rate of amputation (major and minor), vascular intervention (surgery, percutaneous transluminal angioplasty), death rate, clinical admission and foot status six months after the first documentation of a patient. All parameters are checked, presented and benchmarked in an open session of the working group (Mueller 2006; Lobmann 2007).

In Germany, the legislature demands measures of quality management of outpatient and inpatient facilities. This certification established a quality management for specialized centers for the treatment of the diabetic foot syndrome. In addition, this certification fulfills the demands of the 2005 IDF Global Guideline (Bauer 2003; Morbach 2004; IDF Clinical Guidelines Task Force 2006).

Methods
Rules for certification were published on the annual Meeting of the German Working Group on the Diabetic Foot and on the working group’s homepage (www.ag-fuss.ddg.de). Interested centers can submit applications for inpatient and/or outpatient diabetic foot care. All applications are checked by a certification committee for correctness and completeness. This is focused on the structural equipment, the reports of hospitations and the treatment evaluation.

For the evaluation each center had to document 30 consecutively seen patients with diabetic foot lesions. An evaluation of the outcome had to be performed six months after the initial presentation of the patient.

Topics of the evaluation were patients ID, date of birth, date of first visit, classification of the lesion (Wagner/Armstrong), Charcot (Sanders/Levin); date of re-evaluation, amputation (major / minor), other procedures, hospitalization, classification of the target ulcer after six months and death.

Data from 18532 patients over a time of seven years are presented. 269 enters were certificated in 2012; 193 centers treated outpatients and 76 centers inpatients.

Results

There was a total of 18532 patients; using the Wagner ulcer classification system, the stages were represented as follows: stage 0: 674, stage 1: 6932, stage 2: 5750, stage 3: 3653, stage 4: 1466 and stage 5: 57 patients (figure1).

At the six-month follow-up assessment 18160 Patient underwent the follow-up corresponding to a recovery rate of 98%. At the follow up a substantial improvement could be seen; 55% of all patients had a complete healing of the documented lesions. Data for all patients and years are given in table 2.

There was a distinctive difference between the distribution of cases of the patients treated in outpatient centers and the inpatients. The outpatient foot centers saw a majority of Wagner stage 1 (87%) and stage 2 (71%) patients. Stage 1 patients (n=902) were rarely admitted to inpatient care. (54%)
A special type of the Diabetic Foot Syndrome, the osteoarthropathy or Charcot foot, was found in 9.2% (n=1712) of the cases under study. These patients can be further categorized using the Sanders patterns classification, based on the anatomical location of the arthropathy: pattern I: 543, pattern II: 491, pattern III: 465, pattern IV: 163 and pattern V: 50.

Most important our data indicated a low level of major (above-ankle) amputations with 3.1% (n=574). Substantially more patients underwent a minor (below-ankle) amputation; 17.5% (n=3254).

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

The rate of hospitalization proved to be an important parameter with 6054 patients requiring admission. Of these 6054 patients with a diabetic foot lesion 3122 patients were initially treated in outpatient centres (a referral rate of 24.9%) and 2932 patients of the inpatient had to be re-hospitalized because of any medical reason.

A total of 733 patients died during the evaluation phase of six month (4,0%).

In general, a significant improvement or even a complete wound healing could be seen in patients treated in the foot clinics, as long as the lesion was still in Wagner stage 1-4 at the initial presentation. For Wagner stage 5 patients as expected, there was no substantial improvement and in most cases, surgical intervention – usually a major amputation – was necessary.

In 10729 cases a clinical significant Infection was present (58%); an infection was diagnosed with 75.8% of the inpatients and 53.3% of the outpatients, respectively.

In 7818 patients (42%) a peripheral arterial occlusive disease was diagnosed (Doppler, Duplex or DSA resp. aMRI); 2154 of them underwent a revascularization (12% of all patients with DFS and 28% of patients with AOD).

All over the time, we found comparable and reproduceable results for every yearly calculation since 2005 (s. Table 3).
Discussion

These data underline our findings in the first analysis of 2007 (Lobmann 2007) and represent the quality of the treatment outcome of diabetic foot lesions in specialized centers in Germany.

The data reflect a lower rate of the relationship between major and minor amputations in the certified centers compared to the up to now available epidemiological data in Germany (Trautner 2001; Heller 2004).

The main risk of a non-traumatic major amputation in hospitalized patients with diabetes mellitus in Germany varies in the literature from 10 to 20 percent.

Our data show clearly that specialized structures and specifications of quality allow to reduce major amputation rates.

This analysis presents reproducible data (18532 ulcerations and 6-months follow up) of defined and obligatory procedures/standards for diagnosis and treatment of the diabetic foot on amputation rate, level of amputations and mortality.

Mortality of this group of patients was still high (4.0%) during the observation time.

The worse outcome of Wagner 4 and 5 lesions leads to demand an early diagnosis and treatment begin to prevent higher levels of the diabetic foot lesion with elevated rates of complications.

Infection and arterial occlusive disease are the most important co–factors in diabetic foot lesions and have a main impact on the need of amputation.

The data and the procedure of accreditation of the working group are of interest for the health care system and insurances. Some Health care insurances accept the accreditation of the German Diabetes Society as necessary condition for the reimbursement.

The German Working Group has established comprehensive quality assurance measures for diabetic foot care centers and implemented country-wide. In addition, data from a very large patient cohort could be gained from this system of certified diabetic foot centers.
Literature


