Evaluation of the Impact of Chiropodist Care in the Secondary Prevention of Foot Ulcerations in Diabetic Subjects

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OBJECTIVE — To evaluate the influence of regular chiropodist care on the recurrence rate of diabetic foot ulcers within 1 year.

RESEARCH DESIGN AND METHODS — Ninety-one diabetic outpatients with healed foot ulcers (age 65 ± 11 years, 40 women and 51 men, diabetes type 1 (n = 6) or 2 (n = 85), BMI 28.5 ± 4.4, diabetes duration 16 ± 11 years, HbA_{1c} 8.4 ± 1.6%) were randomized to a group that received monthly remunerated routine chiropodist care (n = 47) or a control group (n = 44).

RESULTS — Within a median follow-up of 386 days, ulceration recurred in 18 patients in the chiropodist group and 25 patients in the control group (hazard ratio [HR] 0.60; 95% CI, 0.32, 1.08; P = 0.09). Analysis of ulceration per foot demonstrated a significant reduction (20 vs. 32 ulcerations; Cox relative risk [Cox RR] 0.52; 95% CI, 0.30, 0.93; P = 0.03) in favor of chiropodist care. Per protocol, analysis of patients who actually underwent chiropodist foot care on a regular basis also indicates the beneficial influence of chiropodist care with ulceration in 13 vs. 30 patients (HR, 0.53; 95% CI, 0.30–1.01; P = 0.05) and in 15 vs. 37 feet (Cox RR, 0.46; 95% CI, 0.24–0.90; P = 0.02) for the intervention and control groups, respectively. Minor amputation was required in two patients in the intervention group and one patient in the control group. Four patients in the control group and two patients in the intervention group died during the trial.

CONCLUSIONS — These data suggest that secondary preventive measures by a chiropodist may reduce recurrence of foot ulcers in diabetic patients.

Diabetes Care **26:1691–1695, 2003**

Foot ulceration is a serious problem for diabetic patients that will affect ~15% of them at some time in their life (1–3). Prevention of foot ulcers, which usually precede lower extremity amputations, remains a major challenge in diabetes care (4,5). Various factors such as the presence of neuropathy, peripheral vascular disease, history of a previous foot lesion, and high plantar pressures multiply the risk for foot lesions (2,6–8) and, in combination with trauma, inevitably result in ulceration (9). Apart from avoiding trauma, preventive measures should aim to modify these factors. Callus formation, which is a common finding in the diabetic foot, is associated with high plantar pressures and represents another independent risk factor for the development of foot ulcers (10). There is evidence that callus removal decreases plantar pressure (11). In a randomized controlled trial, podiatric care resulted in lower prevalence of callosities, corns, and ingrown toenails and improved patients' knowledge of foot problems and self-care practices (12) in a primary health care system in Finland. Furthermore, evaluations of the efficacy of educational programs in primary care revealed similar improvements in foot status (13,14).

To date, little is known about the role of chiropodist care of diabetic foot ulcers, in particular, in secondary prevention. In this high-risk population, foot ulceration is estimated to recur in 70% within 5 years (15). Whereas chiropodists play an important role in specialized foot care teams elsewhere (5,16), chiropodist care in Austria is not a part of regular outpatient care or covered by the health care system.

This fact led us to evaluate the effectiveness of chiropodist care for diabetic outpatients. We hypothesized that it could play an important role in the prevention of diabetic foot lesions. Our randomized controlled trial aimed to investigate the influence of chiropodist care in a high-risk population of diabetic patients with a history of ulcers; the clinical end points were ulceration, amputation, and death.

RESEARCH DESIGN AND METHODS

— The study was approved by the local ethics committee of the Karl-Franzens University, Graz, and performed in accordance with the principles expressed in the Declaration of Helsinki. All subjects gave written informed consent prior participation in the study.

Subjects

Adult men and women in routine outpatient care at our diabetic foot clinic were

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Received for publication 23 December 2002 and accepted in revised form 2 March 2003.

Abbreviations: Cox RR, Cox relative risk; HR, hazard ratio.

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

Table 1—*Baseline characteristics of trial participants*

	Intervention group $n = 47$	Control group $n = 44$
Age (years)	64 ± 10	65 ± 11
Women (*n*)	25	26
Ethnicity: Caucasian (%)	100	100
Type 1 diabetes (*n*)	3	3
Duration of diabetes (years)	18 ± 11	14 ± 10
BMI (kg/m^2)	28.4 ± 4.5	28.6 ± 4.3
HbA_{1c} (%)	8.5 ± 1.6	8.4 ± 1.6
RR systolic/diastolic (mmHg)	147/80	144/80
Insulin therapy (*n*)	38	29
Retinopathy (*n*)	28	25
Nephropathy (*n*)	21	19
Peripheral vascular disease (*n*)	22	20
Therapeutic shoes (*n*)	28	26
Amputation: minor* (*n*)	12	13
Amputation: major† (*n*)	2	3

Data are means ± SD or *n*. *Below ankle; †above ankle.

recruited. After their foot ulcers had healed, they were invited to participate in a trial offering routine chiropodic care for 1 year. Patients had type 1 or 2 diabetes according to the World Health Organization criteria (17). Inclusion required neuropathy assessed by reduced sensitivity to the vibration of a graduated 128-Hz tuning fork (18) or absence of sensation to a 5.07 monofilament (8,19). There were no differences between the groups in either general clinical or foot-related features, such as amputation status, peripheral circulation, or use of therapeutic shoes. The exact baseline characteristics are shown in Table 1.

Study design

The diabetes foot clinic at the University Hospital in Graz is a tertiary referral center for a population of approximately one million people living in the Austrian province Styria. The study was conducted as a single-center, randomized, parallel trial. The subjects fulfilling inclusion criteria were assigned a patient number in ascending order and randomly allocated to the intervention or control group. All sets of sealed codes with randomization numbers containing treatment information were held by a nurse not otherwise involved in the study to ensure allocation concealment. Before randomization, all patients as a matter of course were instructed in the prevention of foot ulcer recurrences. In particular, they were informed about the possible benefit from regular chiropody care, our investigative issue, in their high-risk situation.

Patients assigned to the intervention group were asked to see the chiropodist at least once a month. The treatments were free of charge for these patients. They could select a conveniently located therapist from a list of eligible chiropodists. We, in turn, advised the chiropodists of impending patient visits and advised all patients randomized to the intervention group to start seeing their chosen chiropodist within the next 4 weeks.

For patients allocated to the control group, chiropodist treatment was not specifically recommended. However, the same list of qualified chiropodist was made available to these patients who after informed consent indicated an interest in chiropodist care and were willing to pay for it. In addition, they were asked to report their visits to the study center.

Chiropodist training

Chiropodists in Austria are required to complete a 2-year vocational school following compulsory education at the age of 15 years. Because this chiropodist care is less specialized and not comparable with general podiatric care in other countries, all chiropodists participating in this investigation underwent special training in the diabetic foot syndrome. The training program consisted of 80 sessions, including interactive lectures on etiopathogenesis of the diabetic foot, identification of risk factors, prevention and treatment of diabetic foot lesions, suitable footwear, and educational approaches to patients. Practical work covered the treatment of patients with feet at risk, e.g., cutting or removal of corns and calluses, trimming of nails, treatment of ingrown toenails, application of skin creams, and other hygienic preventive maintenance care. Trainees had the opportunity to apply these skills to patients at our foot clinic under the supervision of the foot clinic staff. The 53 trained chiropodists sufficed to blanket the province.

During the investigation, chiropodists kept a record of patients' visits. Additionally, patients were advised to contact us at our outpatient foot clinic in the event of new or suspected ulceration, intercurrent hospitalization for foot-related complications, or other relevant clinical features. Chiropodists and family doctors of all participating patients, who were informed about trial-related activities, were instructed to refer patients to the study center when there was frank or impending ulceration. Lesions fulfilling the end point ulcer were documented and treated at the study center.

Medical reports were requested when necessary from other health care institutions. None of the patients received additional special training in diabetic foot care. Members of both groups could be referred to the diabetic foot clinic as needed.

All trial-related activities were carried out until the end of the observation period or death of the patient. After an average of 12 months, patients were invited to a follow-up examination at our foot clinic.

Statistical methods

Statistical analysis was performed on the intention to treat population. In addition, we performed a per protocol analysis comparing all patients with at least one chiropodist visit every 5 weeks on average against all other patients. In the patient-oriented analysis, only the first occurrence of an event per patient was analyzed. Time to event analysis was performed by log rank test reporting hazard ratio (HR). HR was computed according to Altman (20). Comparisons of categorical data at the end of the follow-up period were made with Fisher's exact test, and relative risk was reported. Follow-up time between the intervention and control

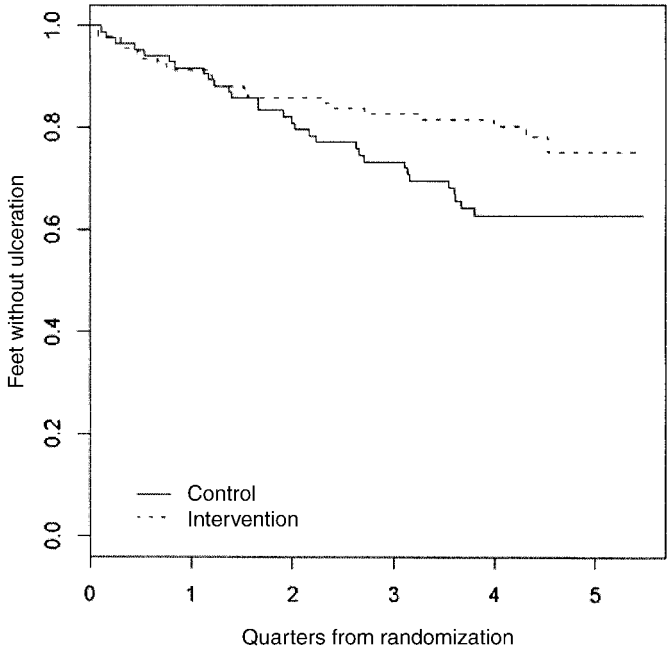

Figure 1—*Time to event plot for ulceration per feet.*

groups was compared with the Wilcoxon test.

In foot-oriented analyses, each lower limb was considered a subject in analysis. The outcome was defined as the first recurrence of ulceration on the foot. Because two legs of a given patient do not represent independent observations, Huber's (21,22) robust variance estimation method, which takes into account the dependency of observations, was used to compute the *P* values and confidence limits. The analyses were performed using the Cox proportional hazard model, and the Cox regression relative risk (e^{β}, Cox RR) was reported. The proportional hazard assumptions were checked as appropriate (23) for all foot-oriented analyses and were not violated. The conventional significance levels of $\alpha = 0.05$ were used throughout. The R (24) package for statistical computing was used for the analysis.

RESULTS — Ninety-three patients with a recently healed ulcer were invited to participate in the trial. Two patients refused to enter the trial for personal reasons. Of 91 patients, 47 with 92 lower limbs were randomized to the intervention group and 44 with 85 lower limbs were randomized to the control group (Table 1).

All 91 patients were followed until the end of the observation period or death. The median follow-up period was 386 days (368–424, 25th-75th percentile). Intertreatment group comparison revealed no difference in follow-up time ($P = 0.64$).

Ulceration: intention to treat

In the chiropodist care group, ulceration recurred in 20 feet, whereas 32 feet in the control group were affected (Fig. 1; Cox RR 0.52; 95% CI, 0.29, 0.93; $P = 0.03$). When analyzed per patient, 18 patients in the chiropodist group suffered from ulcerations compared with 25 patients in the control group (HR 0.60; 95% CI, 0.32, 1.09; $P = 0.09$).

There was no apparent difference in terms of distribution pattern of ulcerations between the two groups. Ulcers were located to 64% at the plantar surface of the forefoot and toes, in 22% at the dorsal toes, in 10% at the rear foot, and in 4% at the dorsum of the foot. Thirteen (62%) of 20 ulcers and 20 (61%) of 32 ulcers were recurrences of ulcers that had healed before the trial in the intervention and control groups, respectively.

Ulceration: per protocol

The actual frequency of chiropodist visits by patients in either group was determined by analyzing data collection sheets that were filled out at patient interviews during the follow-up examination. Four patients who were allocated to the control group had regular chiropodist care at least every 5 weeks on average. Fifteen patients randomized to the intervention group had no or infrequent chiropodist care within the trial period. As a result, 36 patients with 71 lower limbs actually had frequent foot care by a chiropodist, whereas 55 patients with 106 lower limbs did not.

Per protocol, analyses support the beneficial influence of chiropodist care. Whereas 13 patients with regular chiropodist care developed a new foot lesion, 30 patients with no or infrequent visits presented with a new ulcer (HR, 0.53; 95% CI, 0.30–1.01; $P = 0.05$). In a feet oriented per protocol analysis, ulceration occurred in 15 lower limbs with regular chiropodist care, whereas 37 lower limbs in the per protocol control group had a new lesion (Cox RR, 0.46; 95% CI, 0.24–0.9; $P = 0.02$). A summary of all results concerning ulceration is presented in Table 2.

Table 2—*Results for recurrence of ulceration*

Analysis	Intervention *n* (%)	Control *n* (%)	Cox RR/HR	95% CI	*P* value
Feet, intention to treat	92 (22%)	85 (38%)	0.52	0.30–0.93	0.03
Feet, per protocol	71 (21%)	106 (35%)	0.46	0.24–0.90	0.02
Patient, intention to treat	47 (38%)	44 (56%)	0.60	0.32–1.08	0.09
Patient, per protocol	36 (36%)	55 (55%)	0.53	0.30–1.01	0.05

n, subjects at risk; %, ulceration/subjects (patients or lower limbs) at risk.

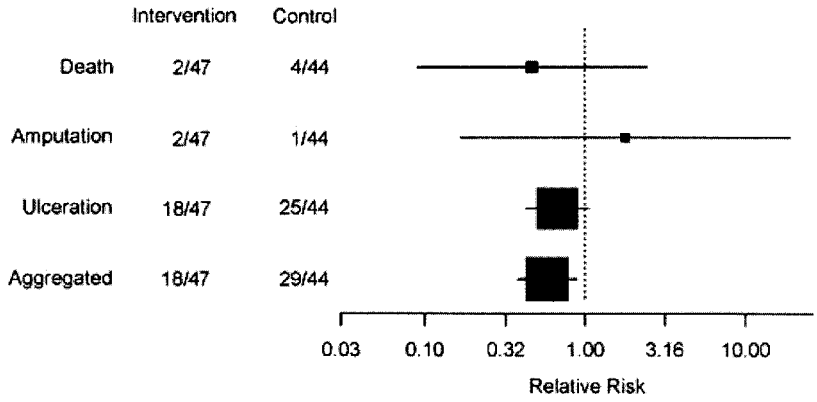

Figure 2—*Intention to treat analysis at the end of follow-up for aggregated end points ulceration, amputation, and death.*

Amputation and death

Two patients in the intervention group required two minor amputations, whereas one minor amputation was required in the control group. All amputations were unavoidable subsequent to ulceration. There were no major (above ankle) amputations. During the study, four patients in the control group and two patients in the intervention group died; all were due to cardiovascular events.

Aggregate end point

At the end of follow-up, the aggregated end points for ulceration, amputation, and death showed a significant overall reduction in the intention to treat analysis (Fig. 2), 18 vs. 29 events (HR, 0.54; 95% CI, 0.30–0.96; $P = 0.03$), and in the per protocol analysis, 13 vs. 34 events (0.49; 0.28–0.91; $P = 0.02$) for the intervention and control groups, respectively.

Concomitant illness and treatment

Two patients in the intervention group and one patient in the control group underwent percutaneous transluminal angioplasty of lower limb arteries. Three patients in the control group and one patient in the intervention group were hospitalized for treatment of phlegmona in consequence of an ulcer. In addition, in the chiropody group six patients were hospitalized: three subjects for ischemic stroke, one for treatment of hypertensive crisis, one for elective ophthalmologic, and another one for orthopedic surgery not related to the diabetic foot syndrome (knee replacement). Hospitalization for treatment of ischemic stroke, hyperglycaemia, myocardial infarction, and burns was required for four patients allocated to the control group. During the observation period, there was no difference in the level of therapeutic footwear use.

CONCLUSIONS — For the first time, a randomized controlled trial has demonstrated that chiropodist care, following a structured chiropodist education program for the diabetic foot, can reduce the recurrence rate of ulcerations in a high-risk group of diabetic patients with a history of foot lesions. The beneficial effect in the intention to treat analysis was not only consolidated but also reinforced by a per protocol analysis of patients undergoing regular chiropodist care.

The effectiveness of general podiatric care in prevention of foot ulcers has been studied extensively and implemented in different health care systems. In contrast, little evidence is available on the effectiveness of chiropodist care as a single, modifying intervention. In diabetic patients with low risk for development of foot lesions, a combination of education and podiatric care showed significant improvement of foot care knowledge and patient behavior after 1 year (12) without demonstrating differences in ulceration or amputation rate in a long-term follow-up (25). In the U.K., a population-based screening program with consecutive stratification and inclusion in a foot protection program for high-risk patients, including chiropodist care, produced a significant reduction in major amputations and nonsignificantly lowered rates for minor amputations and ulcerations (16). Likewise, a retrospective analysis of ~250,000 patients with diabetes or vascular disease in the U.S. demonstrated a reduction of the lower-extremity amputation rate in patients who had had podiatric care (26). A randomized controlled trial demonstrated that patient instruction by podiatrists reduced the amputation and ulceration rate at 1-year follow-up in patients with recurrent foot problems (27). In contrast, after the 2-year follow-up, Carrington et al. (28) found no differences in reamputation frequency in patients with prior unilateral amputation who underwent a foot care program with instruction and podiatric care. Overall, preventive measures are likely to be particularly effective in patients at high risk for foot lesions. Various multidisciplinary programs that provided complete foot care resulted in prevention of ulceration and amputation (5,29–33). However, in primary prevention, really conclusive evidence for a positive effect of chiropodic foot care in terms of ulceration and amputation has not yet been delivered. Thus, it is important to emphasize that the results of our trial may only be applied to a high-risk population with a history of foot ulceration (34).

Although our results are more than suggestive of a positive effect on the incidence of ulcer recurrence, some matters must be viewed with caution. Patients randomized to the control group had to pay for their chiropodist visit, whereas it was free for the intervention group. Remuneration could represent a potential confounding variable. The per protocol analyses, however, reinforced the fact that regular chiropodist care, whether or not remunerated, was associated with the observed beneficial effect in this investigation.

Furthermore, regular chiropodist visits promote patients' awareness of complications through educational approaches, which were implemented in our intervention. These factors may have contributed to the beneficial outcome of this investigation. In addition, the small number of patients limits our single center study. Only a large multicenter, multinational trial could exclude local sources of variation.

Our high overall recurrence rate of foot-related problems indicates that this high-risk patient group urgently needs professional foot care. Many countries offer integrated care models for the diabetic foot. Germany recently passed a law on structured professional foot care (35). Our study indicates that the introduction of an effective chiropodist service in countries like Austria is justified.

In conclusion, our investigation dem-

onstrated that regular chiropodist care was effective in preventing about every second ulceration. Accordingly, the chiropodist should play an important role in the multidisciplinary diabetic treatment team, and professional foot care should be provided to all high-risk diabetic patients.

Acknowledgments— This trial was supported by the Styrian Government (Project Number FA8B-22.0-207/97-3ad).

The excellent technical assistance of all participating chiropodists is acknowledged. We thank Hermann Talowski for assistance in organizing chiropodist training sessions, Gerhard Neubauer for statistical advice, and Eugenia Lamont and Clara Horvath for reviewing the manuscript.

The results were presented in part at the Annual Meeting of the Austrian Diabetes Association in November 2002.

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