

# Benefits of a Multidisciplinary Approach in the Management of Recurrent Diabetic Foot Ulceration in Lithuania

## A prospective study

VYTAUTAS DARGIS, MD  
OLGA PANTELEJEVA, MD  
ALANTA JONUSHAITE, MD

LORETTA VILEIKYTE, MD  
ANDREW J.M. BOULTON, MD, FRCP

**OBJECTIVE** — To assess the ability of a multidisciplinary approach to diabetic foot care to reduce the incidence of recurrent ulceration and amputations compared with standard care in a 2-year prospective study.

**RESEARCH DESIGN AND METHODS** — A total of 145 patients with a past history of neuropathic foot ulcers but no evidence of peripheral vascular disease entered the study. Subjects were screened for their neuropathic and vascular status at baseline, and all received identical foot care education. The intervention group ( $n = 56$ ) was followed by the multidisciplinary team of physicians, nurses, and podiatrists with regular podiatry and reeducation every 3 months and the provision of specialty footwear as required. The standard treatment group was followed in local clinics on a trimonthly basis and received identical screening and education at baseline.

**RESULTS** — There were no significant differences at baseline in age (intervention  $59.2 \pm 13.4$ , standard treatment  $58.5 \pm 11.5$  years), duration of diabetes ( $14.0 \pm 7.1$  vs.  $15.6 \pm 7.8$  years), or neuropathic status (vibration perception threshold [VPT]:  $31.1 \pm 12.1$  vs.  $33.9 \pm 11.3$  V, neuropathy disability score [NDS]:  $8.1 \pm 1.4$  vs.  $7.9 \pm 1.7$ ). All patients had an ankle brachial pressure index (ABPI) of  $>0.9$  and at least one palpable foot pulse. Significantly fewer recurrent ulcers were seen in the intervention group than in the standard treatment group during the 2-year period ( $30.4$  vs.  $58.4\%$ ,  $P < 0.001$ ).

**CONCLUSIONS** — This prospective study has demonstrated the effectiveness of a multidisciplinary approach to diabetic foot care together with the provision of specialty footwear in the long-term management of high-risk patients with a history of neuropathic foot ulcers.

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The association among gangrene, amputation, and diabetes has been recognized for many years. Although traditionally considered to be the result of vascular disease and infection, diabetic foot ulceration is also a consequence of peripheral neuropathy together with pressure that

may be extrinsic or result from an intrinsic abnormality in the foot (1). That specialty centers can achieve a significant reduction in amputations suggests that many ulcers are potentially preventable and are therefore of neuropathic or neuroischemic etiology (2,3). This suspicion was confirmed by

the studies of Pecoraro et al. (4), who studied consecutive American veteran diabetic amputees and demonstrated that neuropathy was a contributory factor in 61% of cases and that 86% of the amputations could have been prevented. However, as shown by Jonson (5), the major obstacle to performing proper estimates and economic evaluations in this area is the lack of effective data. The limited available data have suggested that diabetic persons are at much higher risk for major amputation (6), and patients have a  $>50\%$  chance of losing the contralateral limb within 4 years after the first amputation (7). Nelson et al. (8) confirmed that measures of sensory loss such as impaired vibration perception are significant risk factors for amputation. Education of patients at high risk for amputation has been shown to significantly reduce the future incidence of a major amputation (9). However, virtually no data exist on the neuropathic or vascular status of patients at the time of amputation. One-third of all non-traumatic amputations in Lithuania are the result of diabetes (10). Because neuropathy was a contributing factor in 40% of diabetic amputations, the data suggest that a dramatic reduction of amputations in Lithuania should be achievable (11). Because a past history of ulceration is the strongest risk factor for subsequent recurrent ulcer development, the greatest challenge is to reduce the incidence of recurrent foot problems (12). This article reports the results of a prospective study in Lithuania that compared intensive and conventional management of diabetic patients with a history of neuropathic ulceration.

## RESEARCH DESIGN AND METHODS

A prospective study was designed to evaluate the ability of a multidisciplinary foot clinic to reduce recurrent ulceration and subsequent amputations during a 2-year observation period. Diabetic patients with a history of previous ulceration (Wagner grades I and II) living in the Kaunas region were referred to our rehabilitation

From the Rehabilitation Hospital (V.D., O.P., A.J.), Kaunas, Lithuania; and the Department of Medicine (L.V., A.J.M.B.), The Royal Infirmary, Manchester, U.K.

Address correspondence and reprint requests to Dr. V. Dargis, Rehabilitation Hospital, Partizanu 17, Kaunas 3042, Lithuania. E-mail: dargisv@takas.lt.

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**Abbreviations:** ABPI, ankle brachial pressure index; NDS, neuropathy disability score; VPT, vibration perception threshold.

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

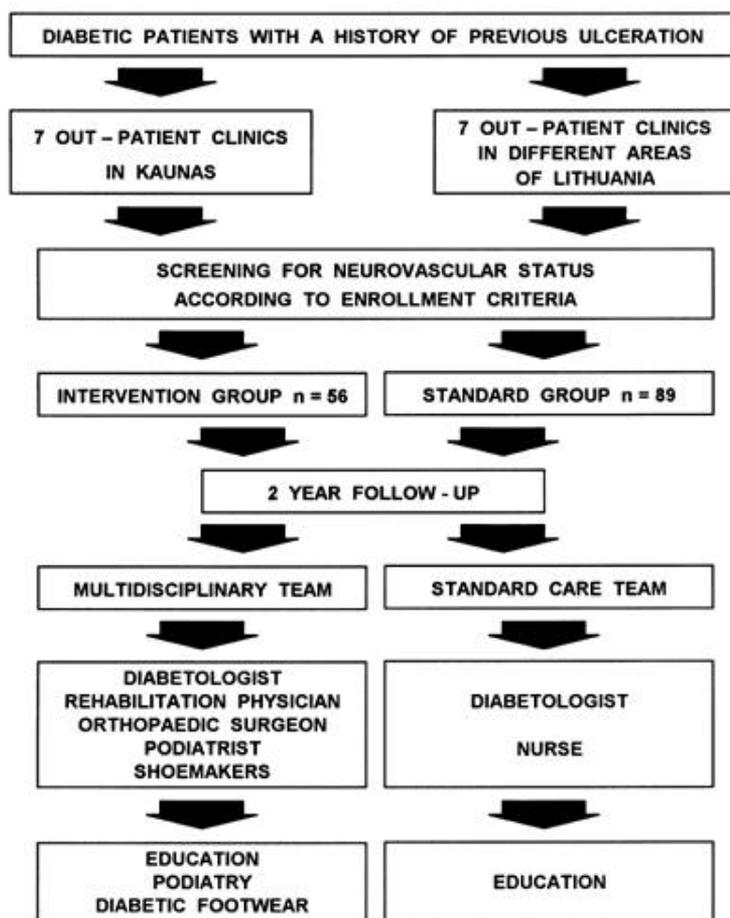


Figure 1—Research design.

hospital at the beginning of 1995 from seven outpatient clinics. Patients attending seven outpatient clinics in other cities in Lithuania were also included in the study. All subjects were screened for neurovascular status in an identical manner. We did not consider randomizing patients to intensive or standard treatment groups to be ethical because previous single-center studies have demonstrated the effectiveness of intensive treatment and education programs (9,13). The patients presenting to the Kaunas clinics formed the intervention group, whereas patients presenting in the other cities formed the standard treatment group (Fig. 1). In addition to the usual clinic data gathered from all new patients, the following data were collected from all diabetic patients. Neurological assessment included neuropathy disability score (NDS) (14) (i.e., vibration, pin-prick, temperature by using a cold tuning fork measured at the great toe, ankle reflex, and vibratory perception threshold [VPT] by using a neurothesiometer from A.R. Horwell Limited, London). The mean

of three VPT readings were taken over the great toe. Variable speeds of increasing voltage were used. The sensory modalities were scored as present (0) or absent (1). The ankle reflexes were scored as normal (0), present with reinforcement (1), or absent (2). Vascular assessment included the number of palpable foot pulses and the ankle brachial pressure index (ABPI) measured with a Doppler ultrasound device (Ultrasound Research Laboratory, University of Technology, Kaunas, Lithuania) and a portable sphygmomanometer. A total of 145 diabetic patients fulfilled following enrollment criteria: previous neuropathic ulceration, NDS  $\geq 6$  and/or VPT  $\geq 25$  V, ABPI  $\geq 0.9$ , and  $\geq 1$  palpable pulse per foot. Patients with a past history of amputations (including partial foot amputations), with Charcot neuroarthropathy, or who could not follow simple instructions or were unable to walk were excluded.

The Kaunas diabetic foot clinic was established at the Rehabilitation Hospital in 1994. The clinic is staffed by a multidisciplinary

team consisting of a diabetologist, a rehabilitation physician, a podiatrist, orthopedic surgeons, and shoemakers. The intervention group received podiatry, education, and specialty footwear at the Kaunas center for 2 years. The standard treatment subjects were all screened at the baseline visit by visiting staff from Kaunas who also provided identical standard foot care education and advice at this first visit. The intervention group received podiatry at least every 3 months and more often if required. Provision of routine preventive podiatric foot care included callus removal, cutting and grinding the toe nails, and individual silicone orthoses to redistribute pressure. Once a recurrent ulcer developed, debridement was performed that included removal of the callus around the ulcer, and dressings were changed regularly. The intervention and standard treatment groups received the same essential foot care education at enrollment, and all patients were seen at 3-month intervals. Basic foot care education included explanation of the study, presentation of video materials, a session with the diabetologist, and the provision of illustrated educational materials. Subjects in the intervention group received podiatry and reeducation every 3 months in response to individual foot problems, whereas subjects in the standard treatment group received education provided by the local endocrinologist or nurse and follow-up review examinations from local physicians every 3 months. All patients from the intervention group were provided with extra-depth shoes and plastazote, multiform, or silicone insoles made by our hospital shoemakers. For some patients with plantar ulcer recurrences, we produced removable casts such as the Scotch cast boot (15). At each visit to any of the clinics, a detailed history was taken for all patients regarding any recurrent foot problems in the preceding 3 months, and feet were carefully examined for any evidence of recurrent foot problems. No prophylactic foot surgery was performed in either group.

Statistical analysis of the results was conducted with statistical packages (STATISTICA version 4.3, StatSoft, Tulsa, OK; EPI-INFO version 7, World Health Organization, Geneva). A  $\chi^2$  test was used to compare the ulcer recurrences among intervention and standard groups. Data are means  $\pm$  SD and 95% CIs. Analysis of variance was used to assess differences in the means between the intervention and standard treatment groups.

Table 1—Patient characteristics at enrollment

Variable	Intervention group	Standard treatment group
Sex (F/M)	29/27	47/42
Age (years)	59.2 ± 13.4	58.5 ± 11.5
Diabetes duration (years)	14.0 ± 7.1	15.6 ± 7.8
Type of diabetes (type 2/type 1)	47/9	67/22
Insulin/oral agents	40/16	71/18
NDS	8.1 ± 1.4	7.9 ± 1.7
VPT (V)	31.1 ± 12.1	33.9 ± 11.2
ABPI	1.14 ± 0.14	1.10 ± 0.17
Previous ulcers (n)	2.3 ± 0.9	2.1 ± 1.0
Foot deformities (%)	87.5	85.4

Data are means ± SD, %, or n. P values were NS for all variables.

**RESULTS** — Of the 21 patients who did not complete the study, 8 were in the intervention group, and 13 were in the standard treatment group. The reasons for patients not completing the study included deaths (13 patients), health-related problems (4 patients), and patients who did not follow simple instructions (4 patients). The causes of death were myocardial infarction (three intervention, five standard treatment), stroke (one intervention, two standard treatment), and two sudden deaths in the standard treatment group (unknown cause). There were no significant differences in age (intervention 59.2 ± 13.4 vs. standard treatment 58.5 ± 11.5 years), duration of diabetes (14.0 ± 7.1 vs. 15.6 ± 7.8 years), number of previous ulcers (2.3 ± 0.9 vs. 2.1 ± 1.0), or foot deformities (87.5 vs. 85.4%) between the two groups. The ratio of sexes was similarly not significant, and 78.6% of all patients had type 2 diabetes. Neuropathic status did not differ between intervention and standard treatment groups (VPT 31.1 ± 12.1 vs. 33.9 ± 11.3 V, respectively; NDS 8.1 ± 1.4 vs. 7.9 ± 1.7, respectively). All patients had an ABPI of >0.9 (Table 1). New ulcers and ulcers appearing at a previous ulcer site are included in the term *recurrent ulcers*. All recurrent ulcers occurred under the plantar aspect of the foot, and there were no differences between the two cohorts in those ulcers appearing at previous ulcer sites and new sites. Patients with recurrent ulcers were counted only once during the follow-up period (first ulcer recurrence only). Hospitalization was needed for two patients from the intervention group and for eight patients from the standard treatment group with ulcers. The intervention group had significantly fewer recurrent ulcers during the 2-year period than the

standard treatment group (30.4 vs. 58.4%, respectively; odds ratio [95% CI] 0.31 [0.14–0.67],  $\chi^2$  10.86,  $P < 0.001$ ) and fewer amputations (7% [3 minor and 1 major] versus 13.7% [8 minor and 4 major], respectively). The recurrent ulceration rate was thus almost halved (Fig. 2).

**CONCLUSIONS** — Litzelman et al. (13) have confirmed the value of a multidisciplinary approach to education and self-care for diabetic patients in general practice. A significantly lower incidence of serious foot lesions was observed in their intervention group. However, the greatest risk of ulceration is among those patients with a previous history of ulceration (12,16). In this study, we confirmed the value of a mul-

tidisciplinary approach for such a high-risk group and observed a 2-year incidence rate of 30% in the intervention group compared with 58% in the standard treatment group. In addition to the significant difference in the ulcer rate observed during the study, even the recurrence rate in the standard treatment group is comparable to that previously reported from established foot centers (17). In contrast with previous reports, however, all patients in our study were aware that they were participating in a follow-up study, which may explain the comparable rates. Because no major differences have been found in risk factors for diabetic foot ulceration throughout Europe (18), widespread adoption of such educational and preventative strategies should result in a reduction of recurrent ulceration. Such an outcome would indeed be welcome because recurrent ulcers are so common, and >80% of amputations are preceded by ulcers (4).

Other factors are important in the pathogenesis of foot ulcers. Frykberg et al. (19) recently emphasized the relative contributions of neuropathy and foot pressure abnormalities when studying racial differences. In our study, all subjects were Caucasian, and all were neuropathic, but it was not possible to assess foot pressures. Despite the intervention, ~15% of these high-risk patients ulcerated each year, thus emphasizing the need to study other important contributory factors to foot ulceration such as psychosocial aspects (20).

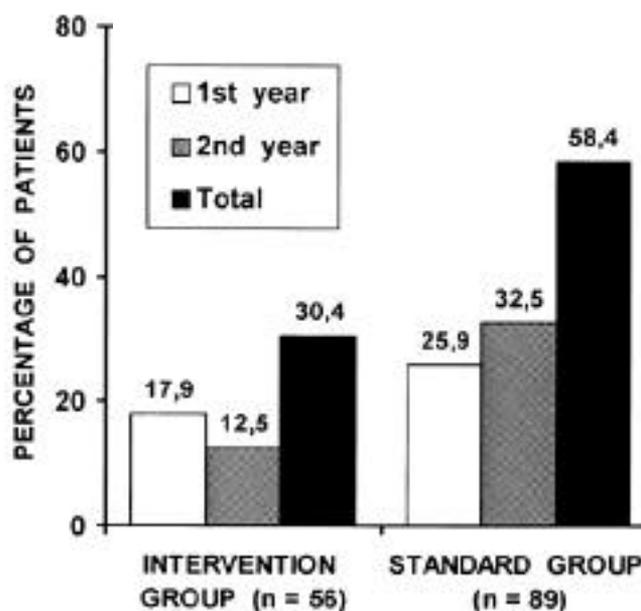


Figure 2—Recurrent foot ulcer rates: 2-year follow-up.

In conclusion, this prospective study has demonstrated the effectiveness of a multidisciplinary foot clinic and the provision of specialty footwear in the long-term management of patients with a history of foot ulceration. Reduction of recurrent ulceration by 50% is an important step in achieving the goal of the St. Vincent Declaration, which is to reduce the rate of diabetic amputations.

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