



Patient education for the prevention of diabetic foot ulcers

Interim analysis of a randomised controlled trial due to morbidity and mortality of participants

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Introduction

Diabetes mellitus and foot ulcers in combination increase the risk for amputation due to peripheral neuropathy, ischaemia and deep infections. Self-care is fundamental in diabetes management and prevention, and existing guidelines state the need for patient education as a prerequisite to prevent ulceration.^{1–3} Education is recommended, combined with other preventive measures such as regular inspection of the feet by health care professionals, regular podiatry and adjusted shoes and insoles.¹

Previous studies aiming at prevention of ulceration of feet in diabetic patients through education have not been able to show sufficient effect of the interventions.⁴ Description of

Summary

This study was designed to explore whether participant-driven patient education in group sessions, compared to provision of standard information, will contribute to a statistically significant reduction in new ulceration during 24 months in patients with diabetes and high risk of ulceration. This is an interim analysis after six months.

A randomised controlled study was designed in accordance with CONSORT criteria. Inclusion criteria were: age 35–79 years old, diabetes mellitus, sensory neuropathy, and healed foot ulcer below the ankle; 657 patients (both male and female) were consecutively screened.

A total of 131 patients (35 women) were included in the study. Interim analysis of 98 patients after six months was done due to concerns about the patients' ability to fulfil the study per protocol. After a six-month follow up, 42% had developed a new foot ulcer and there was no statistical difference between the two groups. The number of patients was too small to draw any statistical conclusion regarding the effect of the intervention. At six months, five patients had died, and 21 had declined further participation or were lost to follow up. The main reasons for ulcer development were plantar stress ulcer and external trauma.

It was concluded that patients with diabetes and a healed foot ulcer develop foot ulcers in spite of participant-driven group education as this high risk patient group has external risk factors that are beyond this form of education. The educational method should be evaluated in patients with lower risk of ulceration.

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Key words

diabetes mellitus; diabetic foot ulcers; neuropathy; patient education; randomised controlled trial

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pedagogical methods for patient education was insufficiently given in the assessed studies, and it seems that most of the interventions have been based on behaviouristic theory: using information and threats to change patients' behaviour. The designs of the evaluation were too disparate to enable any conclusion regarding effectiveness of the interventions.^{5–14}

Inspired by problem based learning, participant-driven group education identifying patients' perceived problems may help patients to activate and reflect on prior knowledge and past experience; they might thus apply the knowledge to similar situations, related to their chronic

disease.^{15,16} This study was designed to explore whether participant-driven group education had an impact on ulceration during 24 months in a group of patients with diabetes and a previously healed index ulcer (high risk of ulceration, according to the International Consensus on the Diabetic Foot [see Table 1]).¹ The design of the study and interim analysis at six months' follow up are presented.

Method

Design and setting. This is a randomised controlled study in which the effect of participant-driven patient education in group sessions is



compared to standard information on reduction of ulceration in patients with neuropathy and a previous foot ulcer. The study was designed in accordance with CONSORT criteria.¹⁷ It took place at a multidisciplinary foot clinic, to which patients were referred from primary or secondary care from a catchment area of approximately one million inhabitants. The patients were treated by the multidisciplinary team until healing with or without amputation was achieved.¹

After healing of the ulcer, all individuals treated at the centre were provided with adjusted shoes and individually fitted insoles for outdoor and indoor use, and were recommended regular chiropody. They were also advised to contact the foot clinic in the event of any foot symptoms. The patients continued to attend their regular health care service for diabetes treatment and other diseases; for type 2 patients this was given by general practitioners in primary care, and for type 1 patients and complicated type 2 patients health care was provided by hospital specialist clinics.

After the ulcer was healed, consecutively presenting patients fulfilling the criteria for the study were invited to participate; they were risk group 3 according to the risk classification in the International Consensus on the Diabetic Foot (Table 1).¹ The inclusion criteria were previously known diabetes mellitus, signs of sensory neuropathy, age 35–79 years, and healed index ulcer (Wagner grade 1 or more)¹⁸ below the ankle, with or without minor amputation. Exclusion criteria were: present ulcer on the foot/feet below the ankle, co-morbidity or living conditions that inhibited participation and follow up, previous major amputation (transtibial or higher amputation), and reliance on an interpreter.

Participants. Patients aged 35–79

Category	Risk profile	Check up frequency
0	No sensory neuropathy	Once a year
1	Sensory neuropathy	Once every 6 months
2	Sensory neuropathy and signs of peripheral vascular disease and/or foot deformities	Once every 3 months
3	Previous ulcer	Once every 1–3 months

Table 1. Risk categorisation system according to the International Consensus on the Diabetic Foot¹

years (n=657; 482 men/175 women) were, at the time of healing, consecutively screened for participation in the study 2008–2010. Due to co-morbidity, major amputation, geographical reasons or reliance on an interpreter, 407 were excluded from further screening. In all, 250 patients were eligible for participation and these were contacted by letter or by telephone, or while visiting the foot clinic. A total of 119 patients declined to participate. Reasons for patients meeting the inclusion/exclusion criteria but declining participation were lack of time, did not believe in the intervention, lived too far away, perceived co-morbidity, or no given reason.

A total of 131 patients accepted the invitation and were randomised to either intervention or standard information. Patients receiving the intervention sometimes had to wait several weeks before a group of a minimum of three men or women could be formed. During this period, 10 patients were lost for participation, three developed a new foot ulcer while waiting for a group session to take place, and one patient died.

Intervention. All participants were provided with adjusted shoes and individually fitted insoles for outdoor and indoor use, and were recommended regular chiropody. All patients attending the diabetes foot clinic received standard information

provided by a registered nurse (diabetes specialist nurse) working at the foot clinic. This consisted of oral and written instructions on self-care based on the International Consensus on the Diabetic Foot.¹ This was repeated to the patients in the control group immediately after randomisation.

In the intervention group, the patients in addition actively participated in discussions that started from the question 'Where do foot ulcers come from?', asking questions of each other and of a diabetes specialist nurse, thus building up the self-confidence that may enable them to manage different situations. In all, 14 group sessions were provided: 10 for men and four for women, with two to five participants in each group. Each patient participated once in the group sessions. The sessions were led by a diabetes specialist nurse (MAG), were held in the clinic's conference room, lasted about 60 minutes each and were taped. In accordance with the findings of Hjelm *et al.*,¹⁹ we chose to organise separate groups for men and women due to observations that men and women have different attitudes towards health perception, choice of shoes and self-care of the feet.

Hypothesis. Participant-driven patient education in group sessions will contribute to a statistically significant reduction in new ulceration during six months, compared to standard information.



Primary outcome. This was the number of new foot ulcers during a six-month observation period after the introduction of preventive participant-driven patient education in group sessions.

Sample size. Previous studies have shown a high ulceration rate for these patients.^{20,21} Based on these studies, it was estimated that to find a reduction in 24 months' incidence of new foot ulcers in the full study from 35% to 15% (two-sided, 80%, $p < 0.05$), 72 completed patients were required in each group. This is an interim analysis of the study designed to detect differences between groups after two years.

Randomisation was carried out by SPSS version 14.0, and an individual not involved in the study prepared numbered envelopes marked with either intervention or standard information. No stratification was done. After signed informed consent, envelopes were selected consecutively.

Statistical analysis. Descriptive statistics in SPSS version 18 were used, giving Pearson's χ^2 for comparison of groups and linear logistic regression analysis for the analysis of factors recorded at study start related to ulceration: peripheral vascular disease, previous minor amputation, smoking, type 1 or 2 diabetes. Ulcer location, cause of ulcer, visits to a chiropodist, smoking and use of prescribed shoes were recorded at the six-month follow-up visit.

In addition, a Kaplan-Meier analysis was performed.

Follow up. After six months, the feet of all participating patients, regardless of intervention, were evaluated. The evaluation was performed by the same nurse who provided the intervention. The visits were made either at the foot clinic or in the patient's home, depending on the patient's

	Intervention (n=61)	Control group (n=70)	Total (n=131)
Age (years)	37–78 (median 64)	35–79 (median 64)	35–79 (median 64)
Male/female (n)	46/15	50/20	96/35
Living alone/with partner (n)	19/42	19/51	38/93
Current smoker (n)	8	15	23
Type 1/2 diabetes (n)	22/39	21/49	43/88
HbA _{1c} (mmol/mol)	65 (± 19)	70 (± 18)	67 (± 19)
Coronary insufficiency (n)	8	12	20
Coronary heart disease (n)	11	13	24
Hypertension (n)	39	31	70
Nephropathy (n)	14	15	29
Retinopathy (n)	54	62	116
Peripheral vascular disease (n)	13	16	29
Minor amputation (n)	16	16	32
Self-reported duration of previous ulcer (weeks)	2–520 (median 26)	2–520 (median 26)	2–520 (median 26)

Table 2. Baseline characteristics of included patients (n=131)

preference. At the follow-up visits, all patients were encouraged to continue with adequate self-care behaviour. The feet were visually inspected, touched and photographed from the dorsal, plantar and heel perspectives. Any ulcer was assessed according to Wagner,¹⁸ in addition to its location on the foot and its cause, the ulcer was recorded according to the patient's account. The photographs were later assessed by a diabetes specialist physician (JA) with long experience in the assessment of foot ulcers in patients with diabetes. Patients who were not using prescribed shoes or who did not attend chiropody were told where to obtain these services. All patients with a new ulcer were referred to the multidisciplinary foot

clinic – this was done as soon as the ulcer was identified, regardless of whether it was before or at the six-month evaluation.

Definitions. *Diabetes mellitus:* defined arbitrarily as type 1 diabetes if diagnosed before 30 years of age and as type 2 diabetes if age at diagnosis was 30 years or more.²² HbA_{1c} was measured using IFCC values.²³

Retinopathy: defined after fundus photography by an ophthalmologist.²⁴

Coronary heart disease: angina pectoris or myocardial infarction.^{23,25}

Ulcer: based on Wagner's grading system, an ulcer is considered present if it is Wagner grade 1 or more, while grade 0 is considered as no ulcer.¹⁸

Neuropathy: signs of sensory polyneuropathy were tested using a



		Intervention (n=40)	Control (n=58)	Total (n=98)
New ulceration:	No ulcer (n)	21 (52%)	36 (62%)	57 (58%)
	New ulcer (n)	19 (48%)	22 (38%)	41 (42%)
Cause of ulceration:	Stress ulcer (n)	7 (37%)	6 (27%)	13 (32%)
	Trauma (n)	9 (47%)	4 (18%)	13 (32%)
	Other (n)	3 (16%)	12 (54%)	15 (37%)
Location of ulcer:	Big toe & other toes (n)	11 (58%)	8 (36%)	19 (46%)
	Plantar (n)	4 (21%)	6 (27%)	10 (24%)
	Other, including heels (n)	4 (21%)	8 (36%)	12 (29%)

Table 3. Outcome after 6 months (n=98 patients)

biothesiometer (Bio-Medical Instruments, Newbury, OH, USA) and defined as present at biothesiometer values of 30V or more on any foot.²⁶

Ischaemia: considered present at ankle pressure <80mmHg or toe pressure <45mmHg.²⁷

Duration of previous ulcer: defined as the estimated number of weeks from ulcer development until healed as defined by Wagner grade 0.¹⁸

Cause of ulcer: defined according to the medical history from the patient or his/her relatives and was confirmed by inspection of feet and footwear.¹

Location of ulcer: grouped into big toe, other toes, plantar ulcer, multiple ulcers, heel ulcer, and other location. Three or more lesions on the same foot were considered as multiple ulcer.²⁸

Amputation: defined as minor amputation if one or more toes, or some part of the foot at or below the ankle, were amputated, and major amputation was defined as amputation above the ankle.²⁹

Ethics. Patients who agreed to participate in the study received the written patient information one week before the baseline visit, and written informed consent was signed before randomisation. The study was carried out in accordance with the principles of the Declaration of Helsinki³⁰ and was approved by the

Regional Ethical Board of Southern Sweden 179/2008.

Results

Out of 657 healed patients, 250 individuals (38%) met the inclusion/exclusion criteria. Out of these 250 eligible patients, 131 (52%) agreed to participate. Of the included patients, 27% were female, 33% had type 1 diabetes, 89% had retinopathy, 29% lived alone, 22% had peripheral vascular disease and 18% were current smokers. Baseline patient characteristics are presented in Table 2. As the male/female ratio was not evenly distributed, one woman who was allocated to intervention received standard information because there were no more women waiting for a group to be formed. Two men randomised to the intervention refused to participate in a group session. One man received standard information because the other three members of his group did not show up due to various reasons.

During the intervention, problems regarding living with impaired vision, proprioceptive disturbance due to neuropathy, access to chiropody, and choice and cost of shoes were mentioned as the most important issues to discuss. Out of the 61 patients randomised to intervention, 11 (18%) did not participate in the patient-driven group education

(10 withdrew and one died). Four patients (two in each group) died before six-month follow up while three had declined further participation. A further 15 patients (seven and eight in the intervention and control groups, respectively) did not reach six-month follow up.

Reasons for drop out were lack of time, did not understand the perceived value of the study or claimed severe disability due to co-morbidity.

Regarding new ulcers at six months' follow up, 58% of the 98 patients evaluated had not developed a new foot ulcer (21 in the intervention group and 36 in the control group [NS]). (Table 3.) The main reasons for ulcer development were plantar stress ulcer and external trauma. In the stepwise regression analysis, previous amputation was related to probability of new ulceration. Kaplan-Meier analysis of ulcer free days did not show a significant difference between the two groups.

Two patients (one in each group) had stopped smoking during the six-month follow up, while one patient in the control group had started smoking. Sixty-one percent (n=60) had visited a chiropodist and 67% (n=66) were wearing prescribed shoes at the follow-up visit.

Discussion

In this randomised controlled study of patients with diabetes, neuropathy and a healed foot ulcer, 42% of the participating patients developed a new foot ulcer within six months. There was no difference with regard to occurrence of a new ulcer between the intervention and control groups.

Only 38% of the entire population of patients healed at a multi-disciplinary foot clinic were eligible for the educational intervention. Patients with severe concomitant diseases were excluded as the intention was to follow the patients during two full years. However, by six months, five of the patients included in the



study had died. This reveals the fragility of the population of patients with diabetic foot ulcers, and that many of them have a short life expectancy.^{31–35} Mortality in this selected patient group was unexpectedly high and it raises concerns about the feasibility of designing and performing randomised studies in this cohort. In comparison, Lincoln *et al.*⁷ lost five patients out of 172 at six months, while we lost five out of 98. Patients with peripheral vascular disease were included in the study which might have affected the mortality rate, but they constitute a large proportion of the diabetes foot patients at a multidisciplinary clinic,^{28,36} and they also need the education. Patients with co-morbidity, such as dementia, or with language barriers were excluded as they require other educational methods that were not part of this study. Other co-morbidities which were excluded related to patients permanently in a wheelchair and leg amputated patients, as different loading on the feet is required compared to patients walking on two feet.

An ulceration rate of 42% after six months in this patient group at high risk of developing new foot ulcers was higher compared to results presented by Lincoln *et al.*, with a similar patient group; in their study they reached 41% after 12 months.⁷ However, the methods of assessment are not comparable: in their study, medical records were assessed together with patient questionnaires, while in our study the patients' feet were seen and photographed, and the pictures were evaluated by a person blinded to the intervention. In this way, ulcers of which patients were unaware were discovered, recorded and referred to the multidisciplinary foot clinic for treatment.

In the present study, the reasons for ulceration were plantar stress ulcer in 32% of the patients who developed an ulcer and external trauma in 32%.

Accidental injuries, causing trauma on the feet, are difficult to avoid even for healthy people and, as it is well known that impaired vision is common among foot ulcer patients;^{28,32,37} this might constitute a contributing cause of external trauma. The need for improved patient education programmes targeting both practical and psychosocial needs in patients with impaired vision has been stressed by Leksell *et al.*³⁸

That plantar stress ulcers were common ulcerating causes may be due to difficulties in providing the patients with perfectly adjusted shoes. The patients in this study all had access to individually moulded insoles and shoes provided by an orthopaedic technician, but, as also described by Cavanagh *et al.*,³⁹ there is evident bias in how many hours per day the individual patient is actually wearing the prescribed shoes, and how many hours a day he/she is walking. This needs further exploration.

At six months' follow up, only 61% of the participants in both groups stated that they had visited a chiropodist, but there was no statistical significance between those who developed a new foot ulcer and those who remained healed. Access to chiropodists with competency in the treatment of patients with diabetes was also an item for discussion in the intervention group as these were not a part of the public health care reimbursement system at the time of the study. It cannot be excluded that financial reasons prevented visits to chiropodists as the patients had to pay full price out of their own pockets.

Different beliefs and attitudes have shown an impact on self-care of the feet, with men more passive than women in their attitude towards help-seeking behaviour.¹⁹ It is difficult to distinguish between neglect, lack of awareness and lack of communication in the educational situation. This needs to be explored further.

In this interim analysis, the number of patients is too small to draw any statistical conclusions regarding the effect of the intervention. However, the exclusion of patients who have had a previous minor amputation is reasonable because those with amputation of toe(s) or forefoot have a different walking pattern. The direct causes of ulceration cannot be affected by patient education, but might have their roots in the general co-morbidity of the patients. The fact that foot ulcer patients suffer from multi-organ disease and that their general health is diminished has been a neglected area in previous studies focusing on ulcers and outcome of ulcers over short follow-up times.⁴⁰

Patient education in diabetes in general has developed during the last few decades, aiming at improved clinical outcomes, health status and quality of life.¹⁶ However, studies regarding education about specific problems of the feet, based on pedagogical research, have been insufficient.⁴ In this study involving a high risk population, a defined educational intervention and long follow up (two years), the presence of co-morbidity inevitably contributed to a high drop-out rate. However, all patients have been offered individually adjusted shoes and insoles, information about self-care and visits to a chiropodist; consequently, they have been offered best practice as described in the International Consensus on the Diabetic Foot.¹

This cohort of patients have come to the multidisciplinary foot clinic regularly during many visits until healing,²⁸ and in the future these visits could be used for structured education based on the patients' questions alongside acute problem solving.

It can be questioned whether educational interventions for patients at the end of their life is meaningful or if they require other



preventive measures; in addition, it has been stressed that it is possible that the incidence of new foot disease is dominated by established physical factors and that educational input and surveillance may have only limited impact.⁴¹ Educating health care professionals involved in the patient's daily life and also educating the patient's next of kin may constitute a more effective intervention, in combination with improved footwear, education during or even prior to ulceration, and reimbursed diabetes educated chiropodists.

Methodology. In the present study, recruitment of the number needed to treat turned out to be a challenge since the patient group is heterogeneous and with substantial co-morbidities. However, all patients visiting the foot clinic were screened for eligibility and clear inclusion and exclusion criteria were used to select appropriate patients. There may be a risk of bias in the fact that only allocation to the intervention was blinded but not the intervention itself, due to its nature.

A further limitation might lie in the fact that the same person provided the intervention and performed the follow-up visits, constituting a potential bias. However, as it was not possible to blind the intervention due to its nature, there was no purpose in blinding the follow up; the patients are aware whether they have participated in group education or not. To overcome this, the primary outcome – new ulceration – was assessed by checking the photographs that were taken at the follow-up visits. The person assessing these photographs was blinded to the allocation and intervention of each patient. One other limitation was that the intervention group only met once. Taking into consideration the high mortality and co-morbidity in the cohort, one group session is realistic

and the educational style focused on patients' concerns regarding risk for foot ulcers. The solutions discussed were those which could be taught in one session.

It was considered that the value of the intervention lay in the fact that it was participant driven and that patients took a more active role than those in the standard information group. Participants in the intervention group could acquire information based on questions which they had raised themselves, such as practical problem solving regarding daily living. This has proven beneficial in other studies.^{16,42} In our study, the patients in the control group were presented with a set of predefined actions/goals and they were able to choose as to whether or not they wished to adapt to these objectives. Previous studies based on behaviouristic pedagogical methods have failed to show evidence that the targeted educational programme was associated with clinical benefit in this population of patients with high risk of developing foot ulcers, when compared to usual care.^{5,7}

Segregating groups by gender seems to be relevant as men and women differed in their perception of issues and potential problems; this was in line with the results presented by Hjelm *et al.*,¹⁹ although, as it turned out, it was difficult to create female groups due to lack of female patients. In future studies of patient education for those with lower risk for ulceration, we suggest that men and women should be kept separate in foot education due to differences in attitudes towards feet, self-care and choice of shoes.

The great number of patients excluded from eligibility mirrors the composition of this heterogeneous fragile patient group. A majority of patients who have undergone a period of ulceration of the foot without major amputation are not likely to be able to participate in a study

with two-year follow up. As there are not many patients who are healed during a given week at a specialist clinic, arranging group sessions is cumbersome. Some patients drop out due to ulceration while waiting for a group, some lose interest and some of them pass away.

Another selection bias could be that many patients who volunteer to participate in studies have better health compared to those patients declining participation.

Conclusion

Most patients with diabetes and a healed foot ulcer are not eligible for structured education with a two-year follow up due to co-morbidity. Participant-driven education in group sessions as an intervention is not necessarily insufficient as a pedagogical method; however, this high risk patient group have external risk factors that are beyond this form of education, and the method should be evaluated in patients with a lower risk of ulceration.⁴³

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Declaration of interests

There are no conflicts of interest declared.

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