

Intervention of Diabetes Foot Care Practices on the Prevention of New Diabetic Foot Ulcers in Patients with Type 2 Diabetes Mellitus

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Abstract

Background: In Southern Punjab region, we see high prevalence of diabetic foot patients. The causes are peripheral neuropathy, peripheral vascular disease, foot deformities, lack of foot care awareness and use of faulty footwear. The patients approach physicians at an advanced stage of diabetic foot for which they have to undergo regular debridements and amputations. Lack of foot care, the use of desi medicines (containing heavy metals), walking bare foot practices, excess alcohol intake and local juti's (faulty footwear) further increase the risk of diabetic foot problems. If the patient is made aware about the benefits of controlled blood sugar levels and proper foot care practices at an early stage, there will be significant decrease in diabetes related foot complications.

Method: We divided patients into two groups in our diabetes foot care clinic; intensively educated and trained group A patients (provided customized footwear also) and group B patients, given standard oral and written information on diabetes foot care. The division was done on the basis of their availability and acceptance for foot checkup, attending group education and training sessions at first visit and at every 3 months period. The preliminary check-up of the foot of all patients were done by use of various analytical techniques like -10 gm mono filament perception, vibration sensation (biothesiometer), plantar foot pressures (podiascan), ABI Index to see lower limb blood flow (foot doppler).

This study was carried from 15th march 2013 to 14th march 2014 (1 year) at ASIAN Diabetes and Obesity Care Centre in Bathinda, Punjab. Diabetes foot clinic was started on 23rd June 2013. Total 550 diabetic patients with some foot problems were registered in diabetes foot clinic at the start of this study (15th March). Inclusion criteria was - Type 2DM patients, Duration of diabetes 10-12 yrs, VPT>25 on Biothesiometer (neuropathy present), AGE 40-80 yrs, either of three foot complications:- Pvd or Foot deformities or Abnormal plantar foot pressures.

Results: our preliminary data results states that out of 250 eligible patients, 131 agreed to participate. Out of 131 included patients, 74 were males 57 were females, 61 were in group A (males=34 and females=27) and rest 70 in group B (40 males and 30 females). After 12 months out of 131 patients, 23 patients were drop outs, 11 from group A (M=7 and F=4) and 12 from group B (M=7 and F=5) so 108 patients completed the study period. At the study period 34% out of 108 patients had abnormal plantar foot pressures on podiascan, 20% had foot deformities (calluses, bunions, claw toes, hammertoes etc) and 17% had peripheral vascular disease and rest had combination of these. After one year when observed in group A, new ulcer or diabetic foot was seen in only 18% patients, while in group B new ulcer or diabetic foot developed in 31% patients

Conclusion: Thus it significantly states that group A patients are better benefitted by intensive education, training and customized footwear. The main reasons for ulcer development were shoe bite, external trauma, burns, walking bare foot and no known cause in some patients. In our study, the patients in the group B 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 while the patients in group A were ready to attend regular foot checkup clinics, diabetes foot care group sessions, workshops, and trainings at first visit and at every 3rd month regularly. They were provided with customized footwear and insoles for both indoor and outdoor purposes. However the sample size was small along with other limitations, we can still infer that this outcome is significant. Also we need long term follow up of all these patients to see favorable outcome from intensive diabetes education.

Keywords: Vascular disease; Diabetes foot care; Neuropathy

Introduction

Diabetes is a serious chronic disease that needs attention. Approximately 15% of all people with diabetes will be affected by a foot ulcer during their lifetime [1]. Five-year recurrence rates of foot ulcers are 70% [2]. Up to 85% of all amputations in relation to people with diabetes are preceded by a foot ulcer [1,2]. People with diabetes with one lower limb amputation have a 50% risk of developing a serious lesion in the second limb within 2 years [3]. People with diabetes have a 50% mortality rate in the 5 years following the initial amputation [4].

Thus diabetes mellitus and foot ulcers in combination increase the risk for amputation due to peripheral neuropathy, ischemia 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 [5]. 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 [6]. Previous studies aiming at prevention of

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Received November 22, 2014; Accepted January 02, 2014; Published January 06, 2015

Citation: Kotru S, Kotru B, Joshi K (2015) Intervention of Diabetes Foot Care Practices on the Prevention of New Diabetic Foot Ulcers in Patients with Type 2 Diabetes Mellitus. J Diabetes Metab 6: 494. doi:10.4172/2155-6156.1000494

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ulceration of feet in diabetic patients through education have not been able to show sufficient effect of the interventions [7]. Description of 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 patient's behaviour. The designs of the evaluation were too disparate to enable any conclusion regarding effectiveness of the interventions. Inspired by problem based learning, participant-driven group education identifying patients perceived problems and past experience; they might thus apply the knowledge to similar situations, related to their chronic disease [8-17]. This study was designed to explore whether participant- driven group education had an impact on ulceration during 1 year period 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) [18,19].

International guidelines for foot ulcer prevention includes strategies such as optimizing metabolic control, identification and screening of people at high risk for diabetic foot ulceration and patient education in order to promote foot self-care. Teaching diabetes to the patients along with the principles of self-examination of the feet and foot care, has since long been advocated as an essential attribute of prevention strategies and is widely implicated in clinical practice [20]. Recent population-based research suggests that now a day a meaningful reduction of the incidence of amputations caused by diabetes mellitus has been achieved [21]. This, however, may be attributable to improvements in ulcer treatment and therefore does not necessarily support cost effectiveness of preventive efforts. The importance of patient education is outlined by several review articles [22].

In this review of randomised controlled trials were therefore, evaluate the effect of education of people with diabetes aiming to promote foot self-care and to prevent the occurrence of foot lesions. Although this type of prevention is now a days widely advocated and implemented in standard practice, the evidence for the effectiveness is still scarce. Several review articles on the diabetic foot, which include education among the prevention strategies discussed, have been published [23,24]. However, only three of these reviews were systematic [25] and most of these reviews dealt primarily with uncontrolled studies. Furthermore, only two of these reviews assessed the methodological quality of the included studies. The overall conclusion of these review articles was that education is effective for the prevention of diabetic foot ulceration, but consequently this conclusion must be treated with care; especially since previous systematic reviews of patient education for adults with, for example, asthma and neck pain, have suggested that health outcomes were unlikely to be improved by limited patient education [26].

Thus, after reviewing the available evidence, we decided to perform a systematic review of the effectiveness of (components of) education programs targeted at people with diabetes with the aim of preventing foot problems.

Method

Design and setting

This is a randomised controlled study in which the effect of participant-driven patient foot care education, workshops, group sessions and use of customized footwear is compared to standard information on reduction of new foot ulceration in patients with neuropathy and either of pvd or foot deformities or abnormal plantar pressures or combination of these. The study took place in our clinic, to which patients were referred from primary or secondary care

centers from a catchment area of Malwa region inhabitants of Punjab. The patients were treated by the multidisciplinary team. All patients in group A at our centre were provided with adjusted shoes and individually fitted insoles for outdoor and indoor use and were provided regular foot care education and training. They were also advised to contact the foot clinic in the event of any severe foot symptoms. The patients continued to attend their regular health care services for diabetes treatment and other diseases; for type 2 patients this was given by general practitioners in primary care and for complicated type 2 patients health care was provided by hospital specialist clinics. Patients fulfilling the criteria for the study were invited to participate; they were in risk group 3 according to the risk classification in the International Consensus on the Diabetic Foot (Table 1) [5].

The inclusion criteria were previously known type 2 diabetes mellitus, duration of diabetes mellitus - 10-12 years, signs of peripheral neuropathy with peripheral vascular disease /abnormal foot pressures/ foot deformities, age 40–80 years.

Exclusion criteria were: advanced stage of CKD (stage IV and stage V), CAD with CHF, previous major amputation (transtibial or higher amputation) and reliance on an interpreter.

Participants

Out of 550 pts registered in diabetes foot clinic, 250 patients aged 40–80 years, who have type 2 diabetes mellitus with Peripheral neuropathy (Vpt>25 on biothesiometer) and PVD / Foot deformities / Abnormal plantar pressures or combination of these were included for participation in the study. Due to age<40 or >80 yrs, severe co-morbidities, major amputation, duration of diabetes <10 yrs, Type1 DM, etc, 300 were excluded from study. In all, 250 patients were eligible for participation and these were contacted by letter or by telephone, or while visiting the foot clinic for this study. A total of 131 patients agreed to participate. Reasons for patients meeting the inclusion 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. All patients who accepted the invitation were randomised to either intervention group A or standard information group B.

All 131 agreed patient had peripheral neuropathy and peripheral vascular disease / foot deformities /abnormal plantar foot pressures or combination of these and were divided into 2 groups:-

Group A included intensively educated and trained participants, n=61 provided with customized footwear. Those patients who consented for this group had to attend diabetes foot clinic at the start of the study and at every 3rd month for group diabetes foot care education sessions and diabetes foot care workshops. They were ready to use customized footwear and insoles for both indoor and outdoor purposes. The sessions were led by a diabetes specialist nurse, were held in the clinic's conference room and lasted about 60 minutes each. In accordance with the findings of Hjelm [27] we chose to organise separate groups sessions for men and women due to observations that

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

Table 1: Risk categorization system according to the International Consensus on the Diabetic Foot.

men and women have different attitudes towards health perception, choice of shoes and self-care of the feet. 11 patients were drop outs during this study in this group.

Group B n=70 these patients refused to get enrolled in group A category. These patients were provided with oral and written standard information on diabetes foot care and proper footwear on the basis of International Consensus on the Diabetic Foot at first consultation in diabetes foot clinic at start of the study and called back after 6 months and 1 year. 12 patients were drop outs.

Hypothesis

Participant-driven patient education in group sessions will contribute to a statistically significant reduction in new ulceration during 1 year in group A patients, compared to standard information provided to group B patients.

Primary outcome

This was the number of new foot ulcers and amputations during a 1 year observation period after the introduction of preventive participant-driven patient education foot care intervention and use of customized footwear.

Sample size

It was estimated that a reduction in 1 year incidence of new foot ulcers in the group A was 18% and in study group B was up to 31%. Randomization 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 chi² 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, and type 2 diabetes. Ulcer location, cause of ulcer, visits to a chiropodist and use of prescribed shoes were recorded at the 1 year follow-up visit. In addition, a Kaplan-Meier analysis was performed.

Follow up

During one year, the feet of all participating patients, regardless of intervention, were evaluated, history of any foot ulcer during this period was recorded. 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 preference. At the follow-up visits, all patients were encouraged to continue with adequate self-care behavior. The feet were visually inspected, touched and photographed from the dorsal, plantar and heel perspectives. Any ulcer was assessed according to Wagner 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 podiatrist with long experience in the assessment of foot ulcers in patients with diabetes. Patients who developed foot ulcers and were not using prescribed shoes or who did not attend foot clinic were told where to obtain these services. All patients with a new ulcer were told to attend or inform the foot clinic as soon as the ulcer was identified, regardless of whether it was before or at the 1 year evaluation [28,29].

Definitions

- **Diabetes mellitus:** defined arbitrarily as type 2 diabetes if age at diagnosis was 30 years or more.

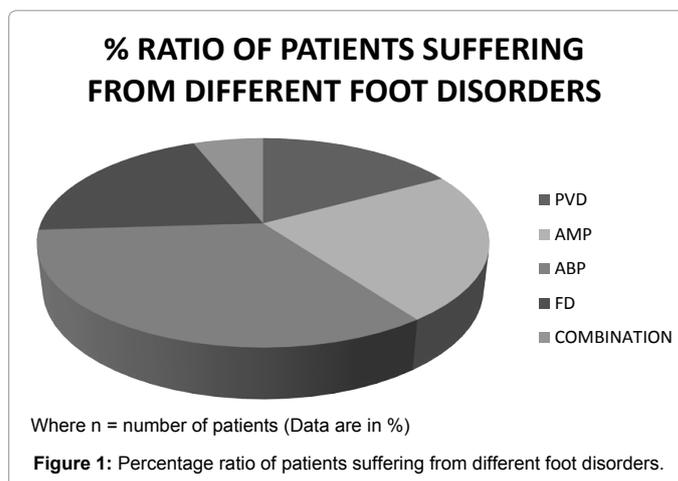
- **HbA1c:** was measured using IFCC values /NGSEP values [30].
- **Neuropathy:** signs of sensory polyneuropathy were tested using a biothesiometer and defined as present at biothesiometer values of 25V or more on any foot [31].
- **Duration of previous ulcer:** defined as the estimated number of weeks from ulcer development until healed as defined by Wagner grade 0.18 [31].
- **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 [32].
- **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 [32].

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 Helsinki and was approved by the Institutional Research Board [32] (Figures 1-3 and Table 2).

Results

Our preliminary data results states that out of 250 eligible patients 131 (52.4%) agreed to participate. Out of 131 included patient 34% patients have abnormal foot pressures and 17% had peripheral vascular disease (Table 2). After one year out of 131 patients 75% patients had no ulcer while 25% had developed new ulcer. When observed in group A no ulcer was found in 82% patients and new ulcer was seen in only 18% patients, while in group B there was 69% patients in which no ulcer was seen and new ulcer was developed in 31% patients which significantly states that group A patients are better benefitted by intensive education, training and customized footwear. The main reasons for ulcer development were plantar stress ulcer and external trauma. Thus in our study, the patients in the group B were presented with a set of



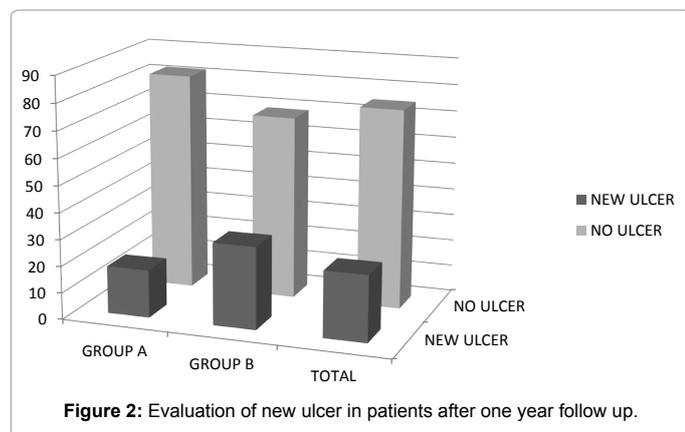


Figure 2: Evaluation of new ulcer in patients after one year follow up.

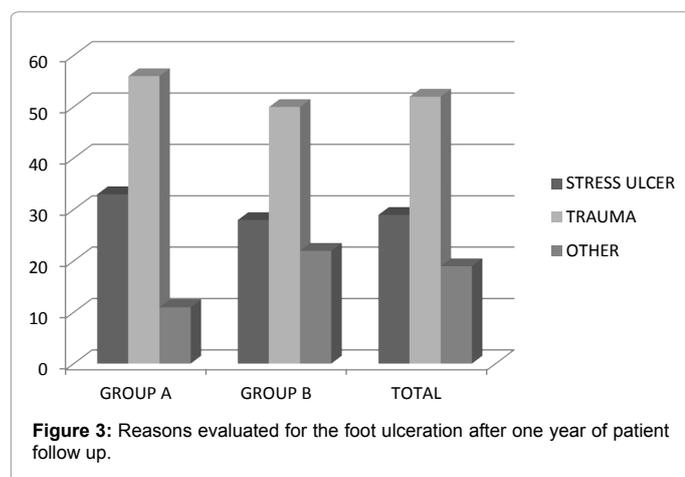


Figure 3: Reasons evaluated for the foot ulceration after one year of patient follow up.

predefined actions/goals and they were able to choose as to whether or not they wished to adapt to these objectives while the patients in group A were ready to follow group sessions, workshops, trainings held after every 3 months regularly and were provided with customized footwear and insoles for both indoor and outdoor purposes. The main reasons for ulcer development were shoe bite, 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.

Discussion

Ulceration of the foot is one of the major health problems for

people with diabetes mellitus. It is estimated to affect 15% to 25% of people with diabetes at some time in their lives [20]. Foot ulceration can result in marked physical disability and reduction of quality of life [21], not to mention limb loss and even death. Diabetic foot ulcers precede 25% to 90% of all amputations [33-36]. The risk of a lower extremity amputation in people with diabetes is therefore much higher than in people without diabetes [24].

Several factors are involved in the development of foot ulcers, including peripheral neuropathy, PVD, limited joint mobility and repeated trauma from abnormal load distribution on the foot [22]. The underlying causes of foot ulcers are usually irreversible and chronically progressive. Therefore, 70% of healed foot ulcers recur within five years [24]. Moreover, treatment itself is very challenging and often needs to be long lasting. It requires not only expert interference, orthopaedic appliances and antimicrobial drugs but also costly topical dressings and inpatient care [22]. Not surprisingly, this leads to substantial economic burden. Healing of a single ulcer costs approximately USD17, 500 (1998 US dollars) [37]. In cases where lower extremity amputation is required, health care is even more expensive: USD 30,000 to USD 33,500 [37]. These costs do not even represent the total economic burden, since costs related to loss of productivity, preventive efforts, rehabilitation and home care should also be considered.

In the present study, the reasons for ulceration were plantar stress ulcer in 29% of the patients who developed an ulcer and external trauma in 52%. The need for improved patient education programmes targeting both practical and psychosocial needs in patients with impaired vision has been stressed by Leksell [38]. In the plantar stress ulcers 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 [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 1 year 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 behavior. It is difficult to distinguish

Total	GROUP-A n=61 (Intensively educated, Trained & customized footwear group)	GROUP-B n=70 (oral and written standard information)	Total
Age (years)	42-79	40-80	40-80
Male/female (n)	40/10	43/15	83/25
Type 2 diabetes (n)	50	58	108
HbA1c (mmol/mol)	65 (±19)	70 (±18)	67 (±19)
Hypertension (n)	31	20	51
Peripheral vascular disease PVD (n)	12(19.6%)	10 (14.2%)	22(17%)
Previous minor amputation (n)	12(19.6%)	18(25.74%)	30(23%)
Abnormal foot pressure ABP	20(32.7%)	24(34.2%)	44(34%)
Foot deformities FD	14 (22.9%)	12(17.1%)	26(20%)
Combination of foot complications	3 (5%)	6(8%)	9 (6%)

Data are in % or means ± SE with P<0.001

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

		Group A (n=50)	Group B (n=58)	Total (n=108)
New ulceration:	No ulcer (n)	41 (82%)	40 (69%)	81 (75%)
	New ulcer (n)	9(18%)	18 (31%)	27 (25%)
Cause of ulceration	Stress ulcer (n)	3 (33%)	5 (28%)	8 (29%):
	Trauma (n)	5 (56%)	9 (50%)	14 (52%)
	Other (n)	1 (11%)	4 (22%)	5 (19%)
Location of ulcer:	Forefoot (n)	6 (67%)	8 (44%)	14 (52%)
	Midfoot(n)	1 (11%)	4 (22%)	5 (19%)
	Heel region (n)	2 (22%)	6 (33%)	8 (29%)

Table 3: Outcome after 1 year (n=108 patients).

between neglect, lack of awareness and lack of communication in the educational situation. This needs to be explored further (Table 3).

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.

Conclusion

It was estimated that 1 year incidence of new foot ulcers in group A patients was upto 18% after proper foot education and training in comparison to patients of group B where the incidence was 31%, provided with standard information. Thus in our work we observed the significant reduction of 13% in diabetic foot patients with new ulcers. However the sample size was small along with other limitations, we can infer that this outcome is significant in our diabetic foot clinic.

Acknowledgements

With due respect and deep warmth feeling I thank my parents, my wife and family with whose support I completed my study. I would also thank Dr. S. Kotru who helped me in foot analysis and education.

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