

Original Research Article

Patient education for the prevention of diabetic foot ulcers: Government Medical College, Suryapet**Sakru Mudavath¹, Kiran Kumar Bollepaka^{2*}, Yarra Sudhakar³**¹Assistant Professor, Department of general surgery, Government Medical College, Suryapet, Telangana, India.²Associate Professor, Department of general surgery, Government Medical College, Suryapet, Telangana, India.³Assistant Professor, Department of general surgery, Government Medical College, Suryapet, Telangana, India

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Abstract

Background: This study was designed to explore whether participant-driven patient education in group sessions, compared to the provision of standard information, will contribute to a statistically significant reduction in new ulceration during 20 months in patients with diabetes and high risk of ulceration. **Methods and Material:** This is a six-month interim assessment. The CONSORT guidelines were used to construct a randomized controlled trial. Age 34–78 years old, diabetes mellitus, sensory neuropathy, and a healed foot ulcer below the ankle were the inclusion criteria; 526 individuals (both male and female) were screened in order. **Results:** The research involved a total of 125 patients. Because of concerns regarding the patients' capacity to complete the trial according to protocol, an interim analysis of 85 participants was conducted after six months. After six months, 44.70 percent of the participants had acquired a new foot ulcer, with no statistical difference between the two groups. The number of patients was insufficient to draw any statistical conclusions about the intervention's effectiveness. Plantar stress ulcers and external trauma were the most common causes of ulcer formation. **Conclusions:** It was concluded that patients with diabetes and a healed foot ulcer develop foot ulcers despite 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 a lower risk of ulceration.

Key Words: diabetic foot ulcers, diabetes mellitus, randomized, neuropathy

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Introduction

It is estimated that on average 7% of the world population are diabetics now and this number is estimated to increase to 8.3% by 2030. It is also estimated that 80% of diabetics patients live in developing countries [1]. On average every 30 s an extremity is amputated due to complications of diabetes mellitus (DM) and the majority of these amputations are secondary to foot ulcers [2]. Diabetic foot ulcers (DFU) are a serious healthcare concern across the world. One of the most common and severe consequences in diabetes individuals is a diabetic foot ulcer. Infection in a diabetic ulcer is difficult and expensive to treat. Patients frequently need to take long-term medicines or be admitted to the hospital for a lengthy stay. It is predicted that 15 to 25% of diabetic people may acquire DFU over their lifetime [3]. More than 70% of patients with DFU, on the other hand, will have an aggravation of the condition in the next 5 years [4]. The ulcer frequently develops in the same or opposite extremity, and at least a quarter of these ulcers do not heal [5, 6]. Unfortunately, if an ulcer develops, therapy can be difficult and time-consuming. To care for the wound, a team of orthopedic surgeons, endocrinologists, infectious disease physicians, and a skilled nurse in dressing is required. If one is available, a podiatrist should also be added to the team. The cost of DFU therapy is high. If the wound develops serious and needs to be amputated, the cost will practically double to \$107900 [7]. As a result, based on the famous adage in the healthcare industry that "prevention is better than cure," Diabetic patients and their health care professionals should get familiar with

the principles of diabetic foot ulcer prevention. Diabetic patients should be taught in a way that makes it easy for them to understand and practice proper foot care. Now the goal should be based on decreasing the amputation rate in diabetic patients, in addition to adequate training of the patients and the team providing care to the patients. The periodic close monitoring of the patient by the health care providers should also be considered. It is important to note the increased prevalence of type two DM in children and adolescences, which by itself is a worldwide health problem. As a result, we, unfortunately, should expect a higher rate of micro and macrovascular complications of diabetes and an increased rate of DFU in younger ages [8].

This study was designed to explore whether participant-driven group education had an impact on ulceration during 20 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). The design of the study and interim analysis at six months follow-up are presented.

Materials and Methods

A prospective observational study was carried out in the Department of general surgery; Government Medical College, Suryapet, for 20 months (September 2019 to May 2021), after obtaining the institutional ethical permission.

Study Design

A hospital-based study.

Study Setting

Government Medical College, Suryapet.

Study Period

September 2019 to May 2021

Design and setting. This is a randomized controlled study in which the effect of participant-driven patient education in group sessions is compared to standard information on the reduction of ulceration in

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patients with neuropathy and a previous foot ulcer. The CONSORT guidelines [9] were used to construct the study. It took place in a multidisciplinary foot clinic to which patients were referred from primary and secondary care in a one-million-person catchment area. The patients were cared for by a multidisciplinary team until they healed, either with or without amputation [10]. Following the healing of the ulcer, all patients at the center were given modified shoes and custom-fitted insoles for outdoor and indoor usage, as well as a recommendation for regular chiropody. They were also told to see the foot clinic if they had any problems with their feet. For diabetes treatment and other diseases, the patients continued to see their regular health care provider; for type 2 patients, this was provided by general practitioners in primary care, and for type 1 patients and

complicated type 2 patients, health care was provided by the 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). The inclusion criteria were previously known as diabetes mellitus, signs of sensory neuropathy, age 35–79 years, and healed index ulcer (Wagner grade 1 or more) [11] 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.

Table 1. Risk categorization system according to the International Consensus on the Diabetic Foot [10]

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

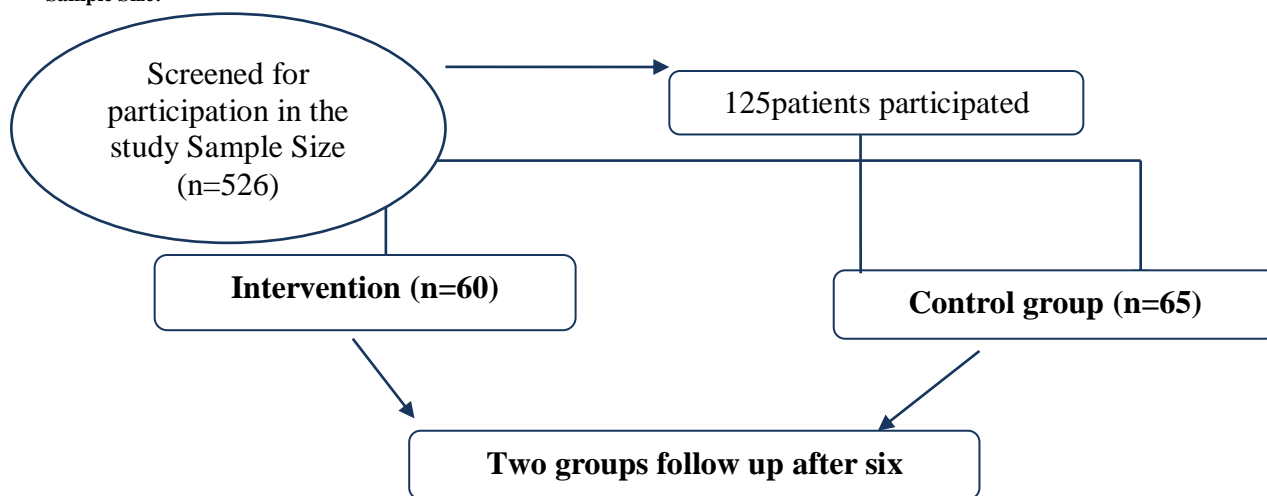
Participants: Patients aged 34 to 78 years old (n=526; 350 male and 176 female) were assessed for participation in the research 2019-2021 at the time of healing. 301 people were eliminated from further screening due to co-morbidity, severe amputation, regional considerations, or reliance on an interpreter. A total of 225 patients were eligible for the study, and they were contacted by mail, phone, or in-person at the foot clinic. A total of 100 patients opted out of the study. Patients who met the inclusion/exclusion criteria but declined to participate did so for a variety of reasons, including a lack of time, a lack of belief in the intervention, living too far away, perceived co-morbidity, or no reason at all. A total of 125 patients accepted the invitation and were randomized to either intervention or standard information. Patients receiving the intervention sometimes had to wait several weeks before a group of a minimum of one male and one female could be formed. During this period, eight patients were lost for participation, one 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. This was repeated to the patients in the control group immediately after randomization. Each patient participated once in the group sessions. The sessions were led by a diabetes specialist nurse, were held in the clinic's conference room, lasted about 60 minutes each, and were taped. Following the findings of Hjelm *et al.*, [12] we chose to organize 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: In comparison to conventional information, participant-driven patient education in group sessions will contribute to a statistically significant reduction in new ulcers over six months.

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.



Statistical analysis: Descriptive statistics in Origin Pro 8.5 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 the ulcer, visits to a chiropodist, smoking, and use of prescribed shoes were recorded at the six-month follow-up visit.

Follow up: The feet of all participants, regardless of treatments, were examined after six months. The same nurse who conducted the intervention also did the assessment. Depending on the patient's desire, the visits were made at the foot clinic or the patient's house. All patients were urged to maintain sufficient self-care behavior during follow-up visits. From the dorsal, plantar, and heel viewpoints, the feet were visually inspected, handled, and photographed. According to Wagner *et al.*, [11], any ulcer was evaluated, and in addition to its position on the foot and etiology, the

ulcer was documented according to the patient's statement. The photographs were later assessed by a diabetes specialist physician 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 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.

Results

Only 225 (42.77 percent) of the 526 healed patients satisfied the inclusion/exclusion criteria. Only 125 (55.55 percent) of the 225 eligible patients consented to participate. Females made up 28.80% of the patients, with 36 percent having type 1 diabetes, 88 percent having retinopathy, 20.80% having peripheral vascular disease, and 15.20 percent being current smokers. Table 2 shows the baseline patient characteristics.

Table 2. Baseline characteristics of included patients (n=125)

	Intervention (n=60)	Control group (n=65)	Total (n=125)
Age (years)	36-76 (Median 63.5)	34-78 (Median 63.5)	35-78 (Median 63.5)
Male/female (n)	44/16	45/20	89/36
Living alone/with a partner (n)	18/42	15/50	33/92
Current smoker (n)	6	13	19
Type 1/2 diabetes (n)	25/35	20/45	45/80
HbA1c (mmol/mol)	64.5± 12	72.5 ± 15.6	68.5 ± 13.2
Coronary insufficiency (n)	6	11	17
Coronary heart disease (n)	10	13	23
Hypertension (n)	40	31	71
Nephropathy (n)	13	15	28
Retinopathy (n)	51	59	110
Peripheral vascular disease (n)	11	15	26
Minor amputation (n)	13	15	28

The most significant concerns to cover during the intervention included living with reduced eyesight, proprioceptive disturbance owing to neuropathy, access to chiropody, and shoe selection and pricing. 11 (8.33%) of the 125 patients assigned to the intervention did not engage in the patient-driven group education (10 withdrew and one died). Two patients (one from each group) died before the six-month follow-up, while four others declined to continue. A total of 13 patients (six in the intervention group and seven in the control group) did not complete the six-month follow-up. Lack of time, a misunderstanding of the study's perceived usefulness, or a claim of significant impairment owing to comorbidity were all reasons for dropping out. Follow up on 85 patients (40 intervention patients and 45 control patients, respectively). In terms of new ulcers, 55.30 percent of the 85 patients examined at six months had not acquired a new foot ulcer (22 in the intervention group and 25 in the control group) (Figure 3.) Plantar stress ulcers and external trauma were the most common causes of ulcer formation. In the stepwise regression analysis, the previous amputation was related to the probability of new ulceration.

Table 3. Outcome after 6 months (n=85 patients)

		Intervention (n=40)	Control (n=45)	Total (n=85)
New ulceration	No ulcer(n)	22 (55%)	25 (55.55%)	47(55.30%)
	New ulcer (n)	18 (45%)	20 (44.44%)	38 (44.70%)
Cause of ulceration	Stress ulcer (n)	6 (33.33%)	5 (25%)	11 (29%)
	Trauma (n)	8 (44.44%)	5 (25%)	13 (34.20%)
	Other(n)	4(22.22%)	10 (50%)	14 (36.80%)
Location of ulcer	Big toe & other toes (n)	10 (55.55%)	7 (35%)	17 (44.73%)
	Plantar (n)	4 (22.22%)	6 (30%)	10 (26.32%)
	Other, including heels (n)	4 (22.22%)	7 (35%)	11 (28.94%)

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.

Discussion

In this randomized controlled trial, 44.70 percent of the patients with diabetes, neuropathy, and a healed foot ulcer developed a new foot ulcer within six months. In terms of the occurrence of a new ulcer, there was no difference between the intervention and control groups. Only 44% of the patients at a multidisciplinary foot clinic who were

healed were eligible for the educational intervention. Because the patients were to be followed for two years, those with severe comorbid illnesses were excluded. However, three of the participants in the trial had died after six months. This indicates the vulnerability of the diabetic foot ulcer patient group, as well as the fact that many of them have a short life expectancy [15-19]. The unusually high mortality rate in this patient group raises questions regarding the practicality of developing and conducting randomized trials in this cohort. At six months, Lincoln *et al.*[20] lost five out of 172 patients, whereas we lost five out of 98. Patients with the peripheral vascular

disease were included in the research, which may have influenced the death rate, although they make up a significant part of diabetic foot patients in a multidisciplinary clinic, [21, 22], and they, too, require education. Patients with co-morbidities, such as dementia, or language difficulties were omitted from the research since they require different instructional techniques not included in this one. Other co-morbidities that were eliminated were patients who were permanently confined to a wheelchair and those who had their legs amputated, as different loading on the feet is necessary as compared to patients who could walk on two feet. The ulceration rate in this patient group at high risk of developing new foot ulcers was 44 percent after six months, which was greater than the data given by Lincoln *et al.*, [20] with a comparable patient population; in their research, the rate was 41 percent after 12 months. 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 ulcers 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 [23]; this might constitute a contributing cause of external trauma. The need for improved patient education programs targeting both practical and psychosocial needs in patients with impaired vision has been stressed by Leksell *et al.*[24] That plantar stress ulcer 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 molded insoles and shoes provided by an orthopedic technician, but, as also described by Cavanagh *et al.*[25] there is evident bias in how many hours per day the individual patient is 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 behavior [12]. 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 the 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 the outcome of ulcers over short follow-up times [26].

In general, diabetes patient education has evolved over the previous few decades, to improve clinical results, health status, and quality of life [27]. However, pedagogical research-based studies on teaching concerning specific foot issues have been lacking. The prevalence of comorbidity inevitably led to a significant drop-out rate in this study including a high-risk group, a specified educational

intervention, and a lengthy follow-up (two years). All patients, on the other hand, were given individually fitted shoes and insoles, as well as self-care instruction and visits to a chiropodist; as a result, they were given best practice as stated in the International Consensus on the Diabetic Foot. This group of patients visited the multidisciplinary foot clinic regularly until they healed, and these visits might be used in the future for organized teaching based on the patients' queries as well as urgent issue resolution. It has been stressed that the incidence of new foot disease may be dominated by established physical factors and that educational input and surveillance may have only a limited impact [28]. It has also been questioned whether educational interventions for patients at the end of their lives are 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 a limited impact. 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 before ulceration, and reimbursed diabetes educated chiropodists.

Conclusion

Most patients with diabetes and a healed foot ulcer are not eligible for structured education with 20 months follow-up due to comorbidity. Participant-driven education in group sessions as an intervention is not necessarily insufficient as a pedagogical method; however, this high-risk patient group has external risk factors that are beyond this form of education, and the method should be evaluated in patients with a lower risk of ulceration.

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