

Comparing the Effects of Two Teaching Methods on Healing of Diabetic Foot Ulcer

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ARTICLE INFO	ABSTRACT
<p><i>Article type:</i> Original Article</p> <hr/> <p><i>Article History:</i> Received: 17 Dec. 2011 Accepted: 23 Apr. 2012 ePublished: 26May 2012</p> <hr/> <p><i>Keywords:</i> Diabetic foot Patient education Self-care</p>	<p>Introduction: Some studies have reported that diabetic patients do not adhere well to the foot care recommendations. Reasons for non-adherence are less evident and the methods used in education programs may have an effect. Therefore, the aim of the present study was to compare the effects of lecture method and combined method of education on foot care of patients and healing rates of diabetic foot ulcers. Methods: A matched controlled trial study was conducted on a sample of 45 diabetic patients with foot ulcers. The two intervention groups were taught with similar content but different methods. Patients' foot care and healing rates of diabetic foot ulcers were assessed at the beginning of study and after 3 months in the two training groups as well as the control group. Results: Ulcer surface was decreased by 46%, 61% and 81.6% in the control, lecture group and combined group, respectively. The ulcer depth was also decreased by 66.7%, 97.5% and 69.1% in the three groups respectively. A significant relationship was observed between the group adherence of the self-care program and the amount of decrease in the ulcer surface area ($r = 0.36, p = 0.04$). Conclusion: The foot care education could significantly affect the healing of diabetic foot ulcer, especially in terms of the ulcers' surface area. Therefore, a self-care education program should be integrated in the health system to empower those living with diabetes to manage their own foot appropriately.</p>

Introduction

Diabetic foot ulcers are of the most serious causes of morbidity among diabetic people and often require a long hospital stay. These ulcers are of costly complications of diabetes and in many cases will require a lower-extremity amputation.¹ Studies in the United States estimated that 1 out of 5 patients who develop diabetic foot ulcers will eventually have to undergo amputation. It is estimated that 150 million people live with diabetes worldwide and 15% of them will finally suffer diabetic foot ulcers.² These ulcers are the result of damages to the vascular and nervous sys-

tems occur in diabetes. Neuropathy will lead to loss of the feet sensation, and vascular damage will result in a diminished blood supply which finally makes the feet more susceptible to damage, ulceration and infection. They are often characterized by poor healing rates that in turn increase the burden on patients in terms of morbidity, distress, impaired physical functioning; and on the health system in terms of the costs of medical and nursing care.²⁻⁴ A research indicated that 67% of diabetic foot ulcers remain unhealed after 20 weeks of care.⁵

Some studies have shown that diabetic foot ulcers have negative impacts on the patients

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and their caregivers' lifestyle, social activities, general health, quality of life and the ability to psychosocial adjustment to the illness.⁶⁻⁸ It has also been shown that the patients' foot care behavior predict foot lesions.⁹ Several researchers have emphasized that patient education is the cornerstone of diabetes management. These researchers have indicated that patient education can enhance self-care and would increase the patients' adherence with the health care team recommendations.¹⁰⁻¹² However, some studies have shown that patients do not adhere well to the self-care regimens for diabetes and foot care recommendations.^{6,13,14} A few studies with conflicting results were also conducted on the self-care adherence of Iranian diabetic patients. In one investigation, the patients' knowledge of foot care was significantly increased after training.¹⁵ However, the prevalence of poor diabetes control was about 85% in another study.¹⁶ One investigation also reported appropriate knowledge on overall self-care but inappropriate performance on overall and foot care.¹⁷ In two similar reports, 76-85% of diabetic patients had poor knowledge and 33.3% had poor performance on self-care and foot care despite of the routine patient education programs that were delivered in diabetes centers.^{18, 19} Reasons for noncompliance with self-care recommendations are less evident and the methods used in education programs may have an effect.²⁰ Consequently, the need for improved patient education programs and identifying ways to empower patients in diabetic foot care has been emphasized.²¹ However, this area has been neglected in Iran and some Middle East countries.²²

It is important to clarify how patients with diabetic foot ulcers who passed different training programs adhere the foot care recommendations and how this adherence affects the healing rates of diabetic foot ulcers. Therefore, the aim of the present study was to compare the effects of two training methods on patients' foot care and healing rates of diabetic foot ulcers.

Materials and methods

A matched controlled trial study was conducted on a sample of diabetic patients with foot ulcers, referred to the Shahid Beheshti hospital and the diabetes center of Golabchi outpatient clinic, Kashan, Iran. This study was granted Institutional Review Board (IRB) approval by Kashan University of Medical Sciences (KAUMS) and received ethics approval from the ethic committee of KAUMS. All subjects were provided with a copy of the written informed consent and assured of their anonymity and confidentiality of data obtained.

Setting, sample and inclusion criteria

Kashan is a large city in Isfahan province Shahid Beheshti hospital is the largest hospital in Kashan with 400 beds and had various medical and surgical wards and is governed by KAUMS; the same is true regarding diabetes clinic in Golabchi health center. 2000 people with diabetes were registered in this center. Some irregular services and training programs were delivered to diabetic patients in this center.

Diabetic patients aging between 20 and 60 with no history of amputation were selected to participate in the study. Being under medical treatment, having an active diabetic foot ulcer with no need to surgical debridement (based on the physician's diagnosis), having no previous history of formal education on foot-care, and being able and willing to participate in the study were considered as the other inclusion criteria.

Sample size was calculated based on data obtained from a pilot study on 15 diabetic patients (5 in each group) who met the inclusion criteria. After the wound-assessment the patients were allocated into three groups and the procedures were conducted similar to the main study. Then the patients were followed for four weeks. Their ulcers re-evaluated and the mean differences in wound surface area was calculated (that was 99.00 ± 37.48 for controls, 245.60 ± 161.71 for the lecture group and 448.60 ± 125.96 for combined method group).

Sample size was calculated to be 7 subjects in each group ($\alpha = 0.01$, $1-\beta = 0.96$). However 15 subjects were recruited in each group based on the request of the Institutional Review Board.

We contacted the patients from the list of diabetic patients who were registered either in the Shahid Beheshti hospital or in the diabetes center of Golabchi outpatient clinic and patients who met the inclusion criteria were selected consecutively till 45 diabetic patients accepted to participate in the study. These 45 patients were then invited (by phone) to attend a primary meeting for initial evaluation of their ulcers. In this session, all participants signed a written informed consent form to enter the study and completed the personal characteristic form. The wound-assessment checklists were completed and photographs were taken from ulcers to be used in comparison after training (a transparent, millimeter scaled ruler was placed near the ulcer while a photograph was being taken). The participants were allocated into three groups (intervention A, intervention B, and control). Efforts were made for the three groups to be matched in terms of the wound surface area, medical regimen (insulin/oral drugs), literacy (illiterate/ elementary/ higher education) and age (± 5 y). Nonetheless, there were some limitations for full matching due to the patients' life location and transportation problems.

Measurement tools

Measurement tools included an entry questionnaire, a wound assessment checklist and a self-directed self-care (foot-care) checklist. All the measurement tools were prepared after an extensive literature review and their content validity was confirmed by 10 nursing faculty members. Reliability of the entry questionnaire and the self-directed self-care checklist were obtained through test-retest on 10 patients with one week interval ($r = 0.92$ and 0.89). Reliability of the wound assessment checklist was also checked by inter-rater agreement ($r = 0.96$).

The entry questionnaire had two parts: personal information and questions related to the patient's knowledge of the disease and self-care. The personal information form included 15 questions [name, age, sex, job, marital status, weight, height, level of education, number of years living with diabetes, the type of diabetes, the type of medical treatment, the last fasting blood sugar (FBS), and a telephone number]. The second part of the entry questionnaire included 24 yes/no questions to measure the participants' knowledge on diabetes, diabetic foot and their usual self-care.

The wound-assessment checklist included items on wound's attributes such as its location, diameters and depth (in millimeters). The wound diameters were measured using a transparent ruler (in millimeters). The real size digital wound photographs were also used for re-check of measurements at data entry stage. The wound depth was measured with a transparent narrow millimeters scaled ruler. The researcher placed the ruler at the bottom of wound and measured the wound depth while his eyes were at the horizontal level of the wound. The self-directed self-care checklist included a detailed list of 22 self-care activities related to daily foot care and was tabled for 7 days. The patients were asked to do a daily review on the checklist and mark self-care activities they followed.

Interventions

The two intervention groups were taught with similar content but with different methods. Separate education sessions were held for each intervention group. Illiterate participants were requested to attend education sessions along with a literate family member (to be trained about helping the patient to complete the self-care checklists). The group A ($n=15$) was taught in a one hour lecture (by the first researcher), and the group B ($n=15$) was taught by using the integrated method [lecture + watching PowerPoint slides (included related

pictures) + role playing (exhibition) + implementation of self care practices in the presence of the instructor]. Training included self-care and foot care (control of foot risk factors).

Two days after the participants were allocated into the groups, the participants of intervention group A were invited to attend in two training sessions which were held in consecutive days. The day after the training of the group A, the education sessions were held for the group B in consecutive days. Content of the training sessions was similar for the two groups. The first session of education included etiology, clinical manifestations, diagnosis, management and complications. The second session of education focused on diabetic foot ulcer etiology, risk factors, foot care strategies, and how to complete the self-care checklist.

At the end of the second education session, all participants in intervention groups were given two daily foot-care checklists (each for one week) and they were instructed how to complete it. The participants were asked to do a daily review on the checklist and mark self-care activities they followed. They were also instructed to return the completed checklists to the researcher at the end of each two weeks and new self-care checklists were given to them for the next two weeks. The completed checklists were gathered by the second researcher in a biweekly home visits and new checklists were given to the patients for the next two weeks and this continued for three months. All the three groups were then reevaluated (for their ulcers) after the third month. The control group was also given the educational materials at the end of the third month to observe ethics principles.

The wound characteristics (the wound surface area in squared millimeters and its depth in millimeters) were used as the criteria for healing and effectiveness of the program. The rate of adherence to the self-care program was also calculated based on the days that the patient followed the recommendations and

marked them in the checklists. The score for each item in the checklist ranged between 0 and 90 for 90 days.

Statistical analysis

Data analysis was performed by SPSS ver. 11.5. Descriptive statistics were computed for all variables. Student's t-test, ANOVA, ANCOVA, chi-square and the Fisher exact test were employed to check the statistically significant differences between the groups of study.

Results

A total of 45 patients enrolled in the study but two subjects (one in each intervention group) did not follow the program and were excluded. Finally the data from 43 patients (28 males and 15 females) with a mean age of 57.9 ± 12.3 years were analyzed. Table 1 shows the sociodemographic characteristics of the sample. A majority of the sample in this study had elementary education (48.8%) or was illiterate (44.2%). Most of our subjects were retired (41.9%), 81.4% were married and 88.4% had a non-insulin dependent diabetes mellitus with a mean duration of 14.3 ± 7.9 years. No significant differences were observed between the three groups in terms of sex, age, weight, height, type of diabetes and duration of disease, current employment status and education.

Mean score of the self-care knowledge was 12.0 ± 3.8 , 10.2 ± 2.8 and 12.0 ± 2.01 in the control, lecture and combined method groups, respectively ($p = 0.22$).

Table 2 shows that the ulcer surface area was 366.6, 650.7 and 536.0 squared millimeters in the control, lecture and combined method groups ($p = 0.12$) and were decreased by 46%, 61% and 81.6% in these groups, respectively. Result shows that the ulcer depth was also 2.80, 4.07 and 1.85 millimeters in the control, lecture and combined method groups that were decreased by 66.7%, 97.5% and 69.1% in the three groups, respectively. The mean score of adherence of the self-care program was 67.3 ± 10.2 and 78.8 ± 8.2 for the lecture and

combined method groups, respectively ($p = 0.009$). A significant relationship was also observed between the group adherence of the

self-care program and the amount of decrease in the ulcer surface area ($r = 0.36$, $p = 0.04$).

Table 1. **Sociodemographic characteristics of participants**

Variable	Group			P-value
	Control (n = 15)*	Lecture (n = 14) *	Combined method (n = 14) *	
Age (years), Mean (SD)	58.3 (11.8)	58.4 (8.8)	56.9 (16.1)	0.94
Sex				
Male	10 (66.7)	8 (57.1)	10 (71.4)	0.72
Female	5 (33.3)	6 (42.9)	4 (28.6)	
Marital status				
Married	9 (60.0)	13 (92.9)	14 (100)	0.01
Widowed	6 (40.0)	1 (7.1)	0 (0)	
Weight (Kg), Mean (SD)	84.8 (9.1)	82.0 (15.5)	75.5 (18.8)	0.24
Height (Cm), Mean (SD)	170.4 (9.8)	168.3 (11.4)	170.5 (9.0)	0.82
Type of diabetes				
IDDM	3 (20.0)	0 (0)	2 (14.3)	0.34
NIDDM	12 (80.0)	14 (100)	12 (85.3)	
Duration of disease, Mean (SD)	16.6 (8.1)	13.7 (8.8)	12.3 (6.8)	0.34
Fast blood sugar, Mean (SD)	191.4 (56.6)	285.0 (102.5)	156.9 (110.8)	0.009
Current job				
Retired	5 (33.3)	6 (42.9)	7 (50.0)	0.35
Household	5 (33.3)	6 (42.9)	4 (28.6)	
Manual worker	2 (13.4)	2 (14.2)	2 (14.3)	
Clerk	3 (20.0)	0 (0)	1 (7.1)	
Education				
Illiterate	8 (53.4)	5 (35.7)	6 (42.9)	0.303
Elementary	5 (33.3)	9 (64.3)	7 (50.0)	
Intermediate/High school	2 (13.3)	0 (0)	1 (7.1)	

*The data are given as n (%)
SD = standard deviation

Table 2. **Comparison of wound surface area before and after the intervention**

	Wound surface area		Changes in wound surface area*	P-value (before - after)
	before the intervention*	after the intervention*		
Control,	366.6 (329.1)	198.0 (180.4)	168.6 (182.6)	0.003
Lecture	650.7 (275.6)	253.2 (213.7)	397.4 (219.7)	< 0.001
Combined	536.0 (480.7)	98.4 (139.2)	437.6 (364.1)	0.001
P-value (ANOVA)	0.12	0.08	0.01	
P-value (ANCOVA)	0.26	0.02	0.04	

*The data are given as Mean (SD)

Discussion

The present study was conducted to evaluate the effect of two educational methods on patients' foot care and healing rates of diabetic foot ulcer. Our result was encouraging as the mean decrease in ulcers' surface area was drastically more in the intervention groups, which signifies a higher level of healing especially in the combined method group. Tests of Between-group differences was non-significant using ANOVA test that may be attributed to the small sample size, however,

the ANCOVA analysis showed significant findings when the associations were controlled for covariates such as age, sex, job, marital status, weight, height and level of education as (R squared = 0.441).

Valk et al.²³ suggested that although education seems to have a short-term positive effect on foot self-care knowledge and behaviors, whether it can prevent foot ulceration and amputations has remained uncertain. Malone et al.²⁴ randomized patients presenting with severe diabetic foot complications into those receiving foot care education and

those with no education. After 2 years' follow-up, the ulceration and amputation rates were three times lower in the intervention than the control group. However, Jeffcoate et al.²⁵ conducted a similar study design, failed to verify these findings.

In the present study the mean score of adherence of the self-care program was significantly higher for the combined method group than the lecture group. A significant relationship was also observed between the groups' adherence of the self-care program and the amount of decrease in the ulcer surface area. Litzelman et al.²⁶ also reported that patients received foot care education were more likely to report appropriate foot self-care behaviors and were in reducing risk for lower extremity amputations than control patients. Therefore, we can conclude that the higher decrease in the ulcers' surface area in our study may be the result of the better adherence of the self-care program.

Our analysis showed that although the depth of ulcer was decreased in all groups, the mean decrease was nearly the same in the control and the combined method groups (66.7% versus 69.1%) while the most reduction in the depth of ulcer occurred in the lecture method group. The tests of between-group effects were statistically non-significant that signifies the need to more investigations though it may also be attributed to the small sample size.

Foot ulcer is a common and costly complication of diabetes that may take weeks or months to heal. Non-healing ulcers may result in infection, gangrene, and amputation of the affected limb and are the main reason for hospitalization of diabetic patients.²⁷ The capacity of health system for responding properly to this public health issue depends on the system's power to identify ways to improve healing rate of diabetic foot ulcers. There is evidence that diabetes self-care behaviors influence prevention and healing of foot ulcers.^{28, 29} Nurses are in a unique position to identify problems, educate patients,

positively influence self-care practices, and refer higher risk individuals for expert care.²⁹

Limitations

The small sample size may limit the generalization of findings. Therefore a large scale study can be suggested. Wound healing is a multi-factorial process and factors such as patients' nutrition, the level of activity and pressure on the affected limb as well as the level of HbA_{1c} may have effects on the process of wound healing and we did not controlled these factors. Randomized clinical trials with control of these factors are suggested. Although we tried to match the three groups, however, there were some limitations for full matching in terms of the patients' life location and transportation.

Conclusion

The present study showed that self-care education and particularly the combined method could significantly affect on healing of diabetic foot ulcer especially in terms of the ulcers' surface area. Therefore, a number of structured self-care education programs should be integrated in the health system to educate patients and empower those living with diabetes to help them independently managing their own diabetes and foot care. The impact of the interventions on the depth of ulcer remained unclear that may be attributed to the small sample size and signifies the need to more investigations.

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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