

# Determining the Use of Complementary and Alternative Medicine to Prevent Diabetic Foot Ulcer Levels in Patients with Type 2 Diabetes “Prevent Diabetic Foot Ulcers”

Tip 2 Diyabetli Hastaların Diyabetik Ayak Ülserini Önlemek için Tamamlayıcı ve Alternatif Tıp Kullanımının Düzeylerinin Belirlenmesi “Diyabetik Ayak Ülserini Önleme”

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## ABSTRACT

**Objective:** The aim of this article is to determine the use of complementary and alternative medicine (CAM) in patients with type 2 diabetes to prevent the formation of diabetic foot ulcer and to evaluate their level of knowledge and behavior about the diabetic foot.

**Material and Methods:** A descriptive and cross-sectional study was performed in a research hospital in Istanbul with type 2 diabetes patients who used CAM and those who did not use. Diabetic foot care knowledge and behavior levels were assessed with Diabetes Foot Knowledge Questionnaire (DFKQ) and Foot Self-care Behavior Scale (FSCBS) questionnaire.

**Results:** Of the 180 patients included in the study, 51.7% (n = 93) stated that they used CAM and 48.3% did not use CAM. Massage (21.5%), ozone oil (17.2%), hypericum perforatum oil (12.9%) and honey (10.8%) were the most preferred CAM in diabetic patients. The DFKQ and FSCBS scores were found significantly lower in CAM using group (p <0.05).

**Conclusion:** Diabetic patients who use CAM should be informed about the complications of such approaches that applied to diabetic foot. Therefore, evidence-based studies are necessary to investigate the benefits and possible adverse effects of these methods and to inform medical staff adequately.

**Keywords:** Diabetic foot, foot care, complementary and alternative medicine.

## ÖZET

**Amaç:** Bu makalenin amacı, diyabetik ayak ülseri oluşumunu önlemek için tip 2 diyabetli hastalarda tamamlayıcı ve alternatif tıp (TAT) kullanımını belirlemek ve diyabetik ayakla ilgili bilgi ve davranış düzeylerini değerlendirmektir.

**Gereç ve Yöntem:** Tanımlayıcı ve kesitsel çalışma, İstanbul'da bir araştırma ve kesitsel bir çalışma yapıldı. Diyabetik ayak bakımı bilgi ve davranış düzeyleri Diyabetik Ayak Bilgi Ölçeği (DABÖ) ve Ayak Bakımı Davranış Ölçeği (ABDÖ) ile değerlendirildi.

**Bulgular:** Çalışmaya dahil edilen 180 hastanın % 51.7'si (n = 93) TAT kullandığını ve % 48.3'ü TAT kullanmadığını belirtti. Diyabetik hastalarda masaj (% 21,5), ozon yağı (% 17,2), hypericum perforatum yağı (% 12,9) ve bal (% 10,8) en çok tercih edilen tamamlayıcı ve alternatif tedavidir. DABÖ ve ABDÖ skorları TAT kullanan grupta anlamlı olarak düşük bulundu (p <0.05).

**Sonuç:** TAT kullanan diyabetik hastalar, diyabetik ayağa uygulanan bu tür yaklaşımların komplikasyonları hakkında bilgilendirilmelidir. Bu nedenle, bu yöntemlerin yararlarını ve olası olumsuz etkilerini araştırmak ve sağlık personelinin yeterince bilgilendirmek için kanıt dayalı çalışmalar gereklidir.

**Anahtar Sözcükler:** Diyabetik ayak, ayak bakımı, tamamlayıcı ve alternatif tıp.

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## INTRODUCTION

Diabetes Mellitus is an important health issue due to its steadily increasing frequency, the acute and chronic consequences of the disease when left untracked and uncontrolled, and the economic burden the disease places on the shoulders of individuals and the community. According to the data of the International Diabetes Federation (IDF), in 2017, about 425 million people between the ages of 20-79 had diabetes and this figure is expected to reach 629 million in 2045 (IDF,2017; ADA, 2017; TEMD, 2019)

Diabetic foot ulcers constitute one of the most serious and frequently encountered complications of diabetes. Diabetic foot ulceration, caused by diabetic neuropathy and/or vascular dysfunction, is one of the most serious and commonly observed complications of diabetes. Every patient with diabetes carries a 12%- 15% risk of developing diabetic foot during his/her lifetime. Diabetic foot ulcers account for 40%- 60% of non-traumatic foot amputations. It has been shown that the relative risk of death for diabetics newly found to have foot ulcers has increased 2.5-fold. Besides the risk of amputation, diabetic foot leads to increased morbidity, a deterioration in the quality of life, and elevated costs of treatment (TEMD, 2019; Oyibo et al., 2001; Valensi et al.,2005). Diet and lifestyle changes as well as oral antidiabetic agents, insulin and other modern evidence-based approaches are recommended for the treatment of diabetes. On the other hand, complementary and alternative therapies are also frequently preferred among diabetic patients. Complementary and alternative medicine (CAM) is generally categorized under two headings: pharmacological (such as herbal remedies, multivitamins) and non-pharmacological (yoga, massage, aromatherapy, hypnosis).<sup>6</sup> Many studies investigating the types of CAM used by diabetic patients and their rates of use are included in the literature (Candar et al., 2018; Villa-Caballero et al., 2010; Egede, 2004). However, there are no studies investigating diabetic foot information, behavior-attitudes of patients with CAM.

## MATERIAL AND METHODS

This descriptive and cross-sectional study was performed to determine the use of complementary and alternative medicine in patients with type 2 diabetes to prevent the formation of diabetic foot ulcer and to determine their level of knowledge and behavior about the diabetic foot.

### The sample of the research

The sample of the study consisted of people with diabetes who applied to the internal diseases outpatient clinic of a training and research hospital in Istanbul Province between 01.09.2018 and 28.12.2018. Every diabetic patient has a 12-15% risk of developing diabetic foot.<sup>3</sup> The sample size was calculated using the sample size calculator (Sample Size Calculator by Raosoft, Inc.). The calculations were based on an alpha error at 5%, a confidence level at 95%, and a response distribution of 12% sample. These parameters

generate a necessary sample size of at least 161 participants for this study. Considering a drop-out rate of 10%, a total of 180 volunteers were included in the study.

The patients who were diagnosed with type 2 diabetes according to ADA criteria at least six months ago and who were 18 years of age and older, were illiterate, had no diabetic foot injury and had no mental problems were included in the study.

### Data collection

**Information Form:** The information form that was drawn up by the researcher in the light of the literature (Biçer – Enç, 2016; Cevik – Tari, 2019). Questions such as age, gender, marital status, education, occupation, diabetes education, smoking, alcohol use, treatment compliance, and complementary and alternative approaches to prevent diabetic foot ulcers are included.

**The "Diabetes Foot Knowledge Questionnaire (DFKQ)"** and its subscale the "Diabetes Knowledge Questionnaire-24 (DKQ)" were developed by Garcia et al. (2001) as a 5-item instrument that assesses the level of knowledge patients have about foot care. The Turkish validity and reliability study of the instrument as adapted into Turkish was carried out by Bicer (Biçer – Enç, 2016). In Bicer's study, the instrument's Cronbach alpha value was .58; in this study, it was calculated as .906. The responses to the items in the questionnaire are "Yes," "No" and "I don't know." The questionnaire is evaluated on the basis of the total score. The lowest possible score on the scale is 0; the highest is 5. An increase in the score indicates that the diabetic individual has an increased level of knowledge about foot care (IDF, 2017).

**Foot Self-care Behavior Scale (FSCBS):** This instrument, developed by Borges (2008) and adapted into Turkish by Bicer<sup>9</sup>, assesses self-efficacy behavior in the context of foot care. It is a 15-item 5-point Likert-type of scale in which responses are assessed as "I do this: 1=Never, 2=Occasionally, 3=Sometimes, 4=Frequently, 5=Always." The lowest possible score on the scale is 15; the highest is 80. In Biçer's study, the instrument's Cronbach alpha value was .83; in this study, it was calculated as .905 (Biçer – Enç, 2016).

### Data Analysis

SPSS® (Statistical Package for Social Sciences) 18 software was used for data evaluation. The Shapiro Wilks test was used to assess whether the data had a normal distribution. It was determined that the data did not show a normal distribution and therefore nonparametric tests were used in the analysis. In the statistical evaluation of the data, averages, percentages, frequencies, and mean values (min-max) were calculated, and the Wilcoxon signed-rank test was also used. All results were considered meaningful at  $p < .05$  and a confidence interval of 95%.

### Ethical Considerations

The study was approved by the Clinical Studies Ethics Committee of the University, (Approval No: 2018/0094,



Date: 21.03.2018), and written permission was obtained from the institution to conduct the study. Written informed consent was obtained from participants prior to participation as well. The study was carried out according to the guidelines presented in the Declaration of Helsinki.

## RESULTS

Of the 180 patients included in the study, 51.7% (n = 93) stated that they used complementary and alternative medicine (CAM) and 48.3% did not use CAM. The subjects included in the study were divided into two groups as CAM users and non-users. The socio - demographic and clinical characteristics of patients and their comparison as CAM and non - using groups are shown in Table 1.

There was no significant difference between the two groups in terms of socio-demographic data such as education level, gender, age, and smoking and alcohol use. This shows that both groups are homogeneously distributed. In terms of clinical features, there was no statistically significant difference between the two groups in terms of HbA1c level, however, there was a significant difference between the two groups in terms of clinical features such as the frequency of diabetes control and the duration of diabetes diagnosis (years). Diabetic patients used CAM had an average of  $9.71 \pm 7.05$  years of diabetes and the mean duration of diabetes mellitus was  $13.67 \pm 8.02$  years. 8,6% of diabetic patients who used CAM and 49% of diabetic patients who did not use CAM had previously received diabetes education. At the same time, 30.1% of diabetic patients using CAM go to the health facility for diabetes control only once a year, while 50.6% of diabetic patients who do not use CAM go to the health institution regularly for diabetes control every 3 months.

Alternative types of treatment that are preferred by diabetic patients using CAM are shown in Table 2. Massage (21.5%), ozone oil (17.2%), hypericum perforatum oil (12.9%) and honey (10.8%) were the most preferred CAM in diabetic patients.

Table 3 shows the comparison of the level of knowledge of diabetic foot and foot care in patients with and without use of CAM. There was statistically significant difference between the two groups in terms of knowledge about diabetic foot ( $p < 0.05$ ). The "Diabetes Foot Knowledge Questionnaire (DFKQ) and Foot Self-care Behavior Scale (FSCBS) scores were significantly lower in diabetic patients who used CAM compared to the patients who did not use CAM ( $p < 0.05$ ) (Table 3).

## DISCUSSION

In our study, we aimed to determine the alternative approaches used by patients with type 2 diabetes to prevent the formation of diabetic foot injury and to evaluate the levels of their knowledge and behavior about the diabetic foot. 51.7% of the participants in the study were using complementary and alternative treatment methods (CAM)

and massage, ozone oil and honey were the most preferred methods. According to the studies in the literature are stated that foot massage can stimulate meridian of foot, improve circulation of blood and nerve tissue feeding and thus relieve neurological symptoms and symptoms (Yue et al., 2018) but it has not been proved that massage is an effective method in preventing diabetic foot ulcer (Lozano-Montoya I et al., 2016). One of the most commonly used alternative methods in our study is ozone oil. Ozone oil is used for diabetic foot ulcer due to antiseptic effects and it is preferred an alternative treatment method to prevent fungus formation especially in foot ulcer (Izadi et al., 2017). The use of ozone oil in diabetic foot ulcers is typically safe without adverse reactions, but if it is administered outside its therapeutic window, toxic effects may occur.<sup>16</sup> Uzun et al. reported that the rate of infection and necrosis increased after intralesional ozone application in a case with diabetic foot ulcer (Uzun et al., 2012). Ozone oil application is not recommended for deep, heavily infected or necrotic wounds (Kushmakov et al., 2018).

St. John's Wort (*Hypericum perforatum* L.) oil was determined the third most preferred type of CAM in the study. *Hypericum perforatum* oil has anti-inflammatory effects (Cevik- Tari, 2019; Yue et al., 2018) and it is also indicated by experimental animal studies that it has a repairing effect on wound healing (Lozano-Montoya I, 2016; Izadi et al., 2017). The use of *hypericum perforatum* oil in the diabetic foot ulcer was first shown in a case-report study with the use of neem oil. In addition, it is stated that this inexpensive method can be effective in patients with diabetic foot ulcers, if it is confirmed by a randomized controlled studies, it can provide patients with wound care at home (Yue et al., 2018).

In our study, the fourth most preferred type of CAM was determined as honey. Glucose oxidase enzyme in honey content produces low amounts of hydrogen peroxide. In addition to having antiseptic effects of hydrogen peroxide, it has also an important role in wound healing by stimulating epithelial cells and fibroblasts. For this reason, honey is a preferred type of CAM in diabetic foot ulcers (Çürük – Savsar, 2016). In addition to its broad spectrum bactericidal effect, honey also promotes debridement and reduces inflammation. Activation of immune cells and reduction of malodour are also attributed to honey dressing (Carville, 2013). One of the studies about honey found that honey-impregnated dressing significantly reduced the duration of wound healing in diabetic foot ulcer patients (Imran et al, 20115). On the other hand Siavash et al found that 5% topical royal jelly did not show any superiority over placebo group (Siavash et al., 2015). There is insufficient good quality data to realistically conclude on the efficacy of honey on diabetic foot ulcers. Honey is safe and can be an alternate dressing for diabetic foot ulcer. To prove its superiority over conventional dressing, properly designed randomized controlled clinical trials with adequate sample size, uniform inclusion criteria and outcome measures are necessary (Kateel et al., 2016).

According to data of epidemiological studies conducted in Turkey, 20 years and older of Turkey's population is



approximately 13.7% suffering from diabetes (Karakurt et al., 2017). Every person with diabetes has a 12-15% risk of developing diabetic foot. Non-traumatic foot amputations were performed in 50% -70% because of diabetic foot ulcer (ADA, 2017). In the literature it is stated that diabetic patients should have regular health checks and information about foot care to reduce the incidence of diabetic foot ulcer and preventing (Dorresteijn et al., 2012) Diabetes education generally includes general diabetes information, acute and chronic complications of diabetes, use of insulin and oral anti-diabetic drugs, nutrition, physical activity, foot care, self-care and problem-solving skills (TEMD, 2019). In our study, we compared diabetes education status between CAM users and participants who did not use CAM. The number of those who received diabetes education from CAM users was significantly lower than diabetes patients who did not use CAM. In this study, Diabetes Foot Knowledge Questionnaire (DFKQ) was used to evaluate the knowledge of diabetic foot, and the Foot Self-care Behavior Scale (FSCBS) was used to assess the level of behavior about diabetic foot care. Scores of DFKQ and FSCBS from CAM users were significantly lower than participants who did not use CAM. This result shows that the level of knowledge about diabetes and diabetic foot care among CAM users is lower than participants who did not use CAM. Meng Ren et al. found that the incidence of diabetic foot ulcers decreased with the help of diabetic foot care training given to prevent formation of diabetic foot ulcer (Ren et al., 2014). From this point of view, the importance of diabetes and foot care education is important in preventing the formation of diabetic foot ulcers. One of the issues we discussed in our study was to assess the level of knowledge about diabetic foot care in patients who preferred CAM. In the literature, the causes of using CAM among diabetic patients were investigated but the knowledge levels of diabetic foot in patients who prefer CAM are not investigated (Küçükgüçlü et al., 2012; Surucu et al., 2013). In this study, we investigated whether the level of knowledge about diabetic foot care can affect the use of CAM, according to our results, low level of knowledge about diabetic foot care increases use of CAM. Reasons of using CAM were investigated in literature and these reasons are listed as follows: easy and cheap access to CAM, the desire for psychological relaxation, the close environment, suggestion of friends and the influence of media (Küçükgüçlü et al., 2012; Surucu et al., 2013). In our study, while there was no significant difference about age, gender and education level between CAM user and participants who did not use CAM, there was a significant difference about the level of knowledge about diabetic foot and diabetes education. In the literature, no difference was found about age, gender and educational status between CAM users and patients who did not prefer CAM (Küçükgüçlü et al., 2012; Surucu et al., 2013). We think that one of the most important issues in preferring complementary and alternative medicine in diabetic patients is the lack of knowledge about diabetes and diabetic foot care.

## CONCLUSION

Diabetes patients preferring CAM often hide their preferences from health professionals. However, there are studies reporting that hyperglycemia and other complications developed due to the use of CAM in diabetic patients (Argaez-Lopez et al., 2003; Egede, 2004). Therefore, diabetes patients who use CAM should be informed about the approaches they apply to diabetic foot and its complications. Evidence-based studies should be conducted, the benefits and possible adverse effects of these methods should be investigated and also health personnel should be informed.

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## Tables

**Table 1. Comparison of socio-demographic and clinical features of diabetic patients with and without use of CAM**

Descriptive Characteristics variables		Using CAM (n=93)		Non-using CAM (n=87)		Differential analysis between groups
		n	%	n	%	p
Gender	Female	44	47.3	48	55.2	0.292*
	Male	49	52.7	39	44.8	
Level of education	Primary school	56	60.2	54	62.1	0.888*
	Secondary school	20	21.5	20	23	
	High school	12	12.9	8	9.2	
	University	5	5.4	5	5.7	
Tobacco use	Yes	21	22.6	18	20.7	0.758*
	No	72	77.4	69	79.3	
Alcohol use	Yes	1	1.1	0	0	0.332*
	No	92	98.9	87	100	
Diabetes education	Yes	8	8.6	49	56.3	<b>0.001*</b>
	No	85	91.4	38	43.7	
Diabetes control frequency	Once in a month	8	8.6	4	4.6	<b>0.011*</b>
	Twice in a month	11	11.8	5	5.7	
	Once in 3 months	26	28	44	50.6	
	Once in 6 months	15	1	18	20.7	
	Once a year	28	6.1	15	17.2	
	None	5	30.1	1	1.1	
Age (years)	Avg ± Sd	54.48±1.09		54.73±1.14		0.929**
HbA1c	Avg± Sd	8.01±2.09		8.27±2.14		0.424**
Diabetes Year	Avg ± Sd	9.71±7.05		13.67±8.02		<b>0.001**</b>

Avg: average Sd: Standard deviation \*: Chi-square test \*\*: Mann-Whitney U

**Table 2. Types of Complementary and Alternative Medicine used by diabetic patients**

Alternative Treatment Types	n	%
Ozone oil	16	17.2
Apple Cider Vinegar	9	9.7
Almond oil	3	3.2
Massage	20	21.5
Honey	10	10.8
St. John's Wort (Hypericum perforatum L.) oil	12	12.9
Salt water	6	6.5
Carbonated water	7	7.5
Mint oil	4	4.3
Lavender oil	6	6.5
Total	<b>93</b>	<b>100</b>

**Table 3. Comparison of Knowledge and Behavioral Levels of Diabetic Patients with and without Alternative Therapy on Diabetic Foot**

Ölçekler	Variables	Using Complementary and Alternative Therapy (n=93)	No Complementary and Alternative Therapy (n=87)	p
FSCBS	Avg ± Sd	40±1.72	44.62±1.44	<b>0.01*</b>
	Median (Min-Max)	38 (15-94)	46 (15-94)	
DFKQ	Avg ± Sd	2.59±1.88	3.55±1.53	<b>0.001*</b>
	Median (Min-Max)	3 (0-5)	4 (0-5)	

Avg: average Sd: Standard deviation \*: Mann-Whitney U