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Assessment of Diabetic Polyneuropathy and Plantar Pressure in Patients with Diabetes Mellitus in Prevention of Diabetic Foot

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ABSTRACT

Introduction: Risk assessment for development foot ulcer in diabetics is a key aspect in any plan and program for prevention of non-traumatic amputation of lower extremities. **Material and methods:** In the prospective research to assessed diabetic neuropathy in diabetic patients, to determined the dynamic function of the foot (plantar pressure), by using pedobarography (Group I), and after the use of orthopedic insoles with help of pedobarography, to determined the connection between the risk factors: deformity of the foot, limited joint movements, diabetic polyneuropathy, plantar pressure in effort preventing changes in the diabetic foot. **Results:** Out of 1806 patients, who are registered in one Team of family medicine examined 100 patients with diabetes mellitus Type 2. The average age of subjects was 59.4, SD11.38. The average HbA1c was 7.78% SD1.58.Combining monofilament and tuning fork tests, the diagnosis of polyneuropathy have 65% of patients. Comparing Test Symptom Score individual parameters between the first and second measurement, using pedobarography, in Group I, statistically significant difference was found for all of the assessed parameters: pain, burning sensation, paresthesia and insensitivity ($p<0,05$). The measurements of peak pressure, both first and the second measurement, for all of the subjects in Group I(45) show values above 200kPa. That's a level of pressure that needs to be corrected. The study finds correlation between the foot deformation, diabetic polyneuropathy and plantar pressure ($p>0,05$). **Conclusion:** A detail clinical exam of diabetic food in a family doctor office equipped with pedobarography (plantar pressure measurements), use of orthopedic insoles, significantly reduces clinical symptoms of diabetic polyneuropathy in patients with diabetes.

Key words: Diabetic foot, Assessment, Diabetic polyneuropathy, Plantar pressure,

1. INTRODUCTION

Worldwide increase in prevalence of diabetes mellitus and the consequent severe complications are increasingly larger medical and socioeconomic problem as well as one of the largest challenges of modern medicine. Being widespread and having especially undesirable consequences, diabetes has attracted a strong interest from the scientific community since its discovery until now (1). Pathological changes on the feet of the patients with diabetes are the most frequent cause of hospitalization in the western world and the problem is the number one in consumption of the healthcare resources worldwide (2). In patients with diabetes there is no a normal foot, but physicians would rather classify it as a risky or high risk foot (3).

Early assessment, such as assessment of sensory disorder and/or corresponding symptoms of polyneuropathy, are of importance for diabetes patients. Recognizing two stages of diabetes polyneuropathy -reversible and chronic–is important. Thus the need for an early assessment and treatment of the disorder. Diabetic foot is an interdisciplinary medical condition, requiring interdisciplinary approach to its treatment. According to statistics from WHO one in four diabetics gets diabetic foot condition during his life. 10% of diabetic patients end up with an amputation. In 50% of amputations the underlying cause is diabetic foot or the related complications.

Medical team has an important role in providing help with neutralizing the injury and care for diabetic foot. Diagnosis of diabetic foot is typically established in a family medicine care setting. Diagnosis of polyneuropathy is based on assessment of sensory function, temperature measurement, and examination with 10-gram monofila-

ment and/or a tuning fork. Conducted together, these exams result in sensitivity for detecting symmetrical distal polyneuropathy of 87%.

Plantar foot surface has been already recognized as the most likely place for foot ulcer development. The studies about the prevalence of the risk factors for ulcer foot development have found that a variety of deformities can result in increased plantar pressure. The most frequent deformities, the hammer and claw toes type deformities are also found to be a significant factor in the structural foot changes that often result in increase in pressure in certain areas of plantar side of foot (4,5). Presence of sensory neuropathy is indicated as the most significant risk factor (6).

The research of Duffin A. C. shows that one in four of young diabetics (age 11-24) has increased plantar pressure and/or plantar blister (lump, tissue thickening – lat. plantar callus). The impacted areas are high risk areas for development of some kind of foot condition in adulthood. Biomechanical changes increase occurrence of development of blisters, fissures and deformities. Limited range of motion in joints is frequent seen in diabetes patients. About 30% of diabetics has some level of the range of motion issue in the major or minor joints. Limited range of motion in ankle joint and the first metatarsophalangeal joint (MTPH) is caused by the thickening and shortening of ligaments. The condition results in an increased plantar pressure at the front side of foot (7).

To prevent diabetes complications it is necessary to maintain normal level of blood sugar, have proper and adequate medical care, participate in therapy, have proper diet, be physically active, wear clean cloth and shoes that are adequate and provide comfort, for foot to be able to carry different levels of resistance.

It's a significant success to improve control of diabetes and consequently improve quality of life for diabetics, prevent complications associated with the disease and extend life expectancy.

Pedobarography is a technique that allows to measure pressure between a foot and a surface during dynamic resistance test. Pedobarographic analysis shows the distribution of plantar foot pressure. The data collection must be standardized in such a way that it allows for progression/trend analysis for the follow up visits as well as to be able to compare it with and establish a standard/norm. In combination with the clinical examination of a patient, we obtain various useful information about a foot condition as well as about the level of resistance through different parts of the walk cycle. All of that is enabled by development of electronic sensors built into special platforms and surfaces for walking (Emed platforms). The sensors are connected with a computerized foot function analysis system (8,9). A software analysis provides 3D view of a foot and zones of higher and lover pressure. Based on pedobarographic assisted diagnosis, using a CAD (computer assisted design) system and a robotic machine, with the corresponding CAM program (computer assisted machine), a shoe insert is made. The firmness and the type of material used for an orthopedic insoles is selected based on the clinical exam result, result of pedobariography and the medical requirement on relieving a specific part of a foot (10).

A team effort in prevention and treatment of the indicated risk factors decreases the occurrence of ulceration by 40-80% (11).

2. GOAL

The goal is to assess the level of diabetic neuropathy and the overall symptoms of polyneuropathy (total TSS), to determine the dynamic function of the foot in patients with diabetes mellitus, by using pedobarography, at the start and at the end of the study after using the robotic made personalized orthopedic insoles and to determine the connection between the risk factors: deformity of the foot, limited joint movements, diabetic polyneuropathy and plantar pressure, all with goal of preventing the transition into the diabetic foot.

3. MATERIAL AND METHODS

A prospective research has been conducted in a family practice. The participating patients are all from the pool of patients from the clinic, diagnosed with diabetes mellitus type 2. Out of 1806 patients, who are registered in one Team of family medicine, 107 patients were previously diagnosed with type 2 diabetes and recorded in the Register of diabetics. All of the patients with the diagnosis of diabetes type 2 were carefully examined and consequently included in the study. 45 subjects, satisfying the qualifying conditions, was selected from the register to participate in pedobarography (Group I). 55 subjects were placed in Group II, which didn't participate in pedobarography. In total, 100 subjects participated in the study (N=100). The inclusion criteria for participating in pedobarography consisted of: requirements for the subject to be 50-65 year old, to have both lower extremities, and to be able to independently make decisions. The exclusion criteria consisted of: patients with feet ulcers, gangrene impacted, strong peripheral vascular condition, patients unable to follow the program of the study. The exclusion criteria for pedobarography consisted of: the subjects were excluded if they developed ulcer and/or gangrene's changes on feet during the course of the study; and if patient became bedridden during the study due to a medical condition.

100 patients of the Health Centre Ilidza, Sarajevo Canton, with diabetes mellitus Type 2 from the Register for diabetics were examined. The test parameters were HbA1c, duration of diabetes, type of therapy, BMI, Test Symptom Score (TSS), clinical examination of the foot-testing sensory polyneuropathy with 10g monofilament and vibrations of a tuning fork of 128Hz and test plantar pressure-pedobarography (Group I).

The study has been conducted in an ambulatory family clinic of the Public medical facility Health Canton Sarajevo, in a unit of Health center Illidza, in the facilities for physical therapy and rehabilitation MHS d.o.o. Sarajevo, Orthoaria d.o.o. Sarajevo and Dr. Zubčević d.o.o.. Subjects of both genders were included in the study. The study parameters were: HbA1c (glycohemoglobin), time since diagnosis with diabetes mellitus, type of therapy for diabetes mellitus, body mass index (BMI), assessment of diabetes polyneuropathy (based on a combination of two exams: test with 10g monofilament and the test with vibration 128Hz sound fork), assessment of overall poly-

neuropathy symptoms (total symptom score – TSS; pain, burning, paresthesia, insensitivity), clinical assessment of foot deformity, test of mobility – mobility of metatarsophalangeal and ankle joint and pedobarography for Group I. The study was conducted in three phases. The study parameters were taken for all of the subjects in the first phase, at the beginning of the study. In the second phase an examination and pedobarographic analysis of dynamic foot function (measurement of plantar pressure) and robotic production of orthopedic insoles was conducted (N=45). In the third phase the final study measurements of dynamic foot function after six month of use of the orthopedic insoles and the other parameters was taken. Relationships and dependencies between the measurements were then analyzed.

For testing statistical significance Student t-test and Chi-square test were used. For testing the relationship between the studied parameters Pearson's test of linear correlation was applied.

4. RESULTS AND DISCUSSION

The average age of the study participants was 59,4; SD 11.38 (min 34 and max 87), with 53% being female and 47% male. The average duration since onset of their diabetes disease was 10.16 years; SC 8.87 (min 1 and max 40), with 64% of subjects being in the 0-10 years category, 24% in 11-20 years and 12% of subject with the disease for over 20 years. The largest number of subjects was on oral medications/therapy, 56, on insulin therapy 21 and a combination of the therapies 23 subjects. The average HbA1c in the whole study sample, at the start of the study (i.e. at first measurement) was 7.783% with SD of 1,58 (min 5, max 15.0).

HbA1c (%) – 1st measurement * Group					
			Group		Total
			Group I	Group II	
HbA1c (%) – 1st measurement	<6.5	N	9	11	20
		%	20.0	20.0	20.0
	6.5<7	N	7	6	13
		%	15.6	10.9	13.0
	7-8	N	11	14	25
		%	24.4	25.5	25.0
	>8	N	18	24	42
		%	40.0	43.6	42.0
Total		N	45	55	100
		%	45.0	55.0	100.0

Table 1. Distribution of the subjects according to HbA1c- first measurement point. $\chi 2$=0.499; p=0.919

Grouping the measured HbAc1c values in four buckets in analyzing the distribution at the first measurement and the corresponding comparison among the groups shows that there is no statistically significant difference among the groups (p>0.05). The analysis also shows that majority of the subjects in both groups had the HbA1c values above 8% (42 subjects). The target value of HbA1c < 7% had only 33 subject in the whole sample (Table 1).

During the course of the study after the first measurement of HbA1c five subjects from Group II with elevated values of glycohemoglobin, in consultation and recommendation from a diabetes specialist, was moved from oral to insulin therapy.

HbA1c (%) – 2nd measurement * Group					
			Group		Total
			Group I	Group II	
HbA1c (%) – 2nd measurement	<6.5	N	30	23	53
		%	66.7	41.8	53.0
	6.5<7	N	2	6	8
		%	4.4	10.9	8.0
	7-8	N	9	14	23
		%	20.0	25.5	23.0
	>8	N	4	12	16
		%	8.9	21.8	16.0
Total		N	45	55	100
		%	45.0	55.0	100.0

Table 2. Distribution of the subjects according to HbA1c- second measurement point. $\chi 2$=7,082; p=0,069

Decrease in HbA1c was observed in both groups at the second measurement point (after six month). Majority of the subject had the values below 6.5%. The target values HbA1c < 7% or better had 61 of the subjects, 32 in Group I and 29 in Group II. The difference observed between the two groups in getting to the target HbA1c values is statistically significant (p<0.05). Somewhat larger number of subjects with HbA1c > 7 values was in Group II, but without statistically significant difference to Group I (p>0.05), Table 2. According to the results of a German study, Meisinger, 46.6% of their subjects achieved the target values of HbA1c (<7%). The study covered the subjects from younger and middle age group. Also the study have demonstrated a clear relationship between the decrease in level of HbA1c and the decrease in complications related to diabetes.

An explanation for the achieved results in glucoregulation in our study is due to the ongoing management of diabetes that was based on recipes "based on proof", clinical guides, introduction of new, more efficient medications on the list of the essential medications in Canton Sarajevo, adequate choice of therapy, constant education of the patients, long term monitoring of the patients as well as a quality collaboration of the medical team and the patients. It's worth mentioning that the previously more stringent target values HbA1c < 6.5% in management of hyperglycemia in patients with diabetes type 2 have been relaxed in July 2012 by American Diabetics Associations and European Association for Diabetes (ADA/EASD) to HbA1c < 7%. The new target values were used in our study as well.

Examining BMI as a potential risk factor, it was determined that an average value of BMI in the total study sample was 29.43±4.7. 65% of the subjects were in the overweight category, BMI of 25-30 kg/m2, 29% in obese category with BMI>30 kg/m2. 6% of the subjects had a normal BMI<25 kg/m2. There was no statistically significant difference between the two study groups from the point of BMI. In the Cea Calvo study in Spain, that involved 2339 subjects with diagnosis of diabetes and hypertension, 42.9% of the subjects had BMI>30 kg/m2.

Combined results of two exams, 10g monofilament test and 128Hz sounds fork test, have been used to establish diagnosis of polyneuropathy in 65% of the study participants. Polyneuropathy has been somewhat more prevalent in the group of subjects from Group I (71.1%) vs. Group II (60%). The difference is not statistically significant. In our study the analysis of the results of TSS total score, at first and second measurement point was conducted. At the first measurement point no statistically significant difference has been found between the two groups. After the six month of use of the individualized, robotic made, orthopedic insoles, at the second measurement point, statistically significant different with respect to significantly lower values of TSS in Group I($p<0.05$) have been found. Comparing individual parameters of TSS between the first and second measurement in Group I, it was found that there is a significant difference in all of the monitored parameters: pain, burning, paresthesia, insensitivity ($p<0.05$), (Figure 1).

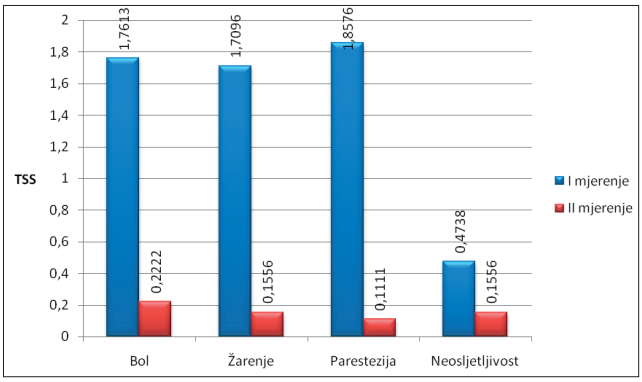

Figure 1. Comparison of the TSS parameters between the first and second measurement in Group I

Diabetes, as a disease category, represents a significant and a frequent challenge for the teams in family practice. According to the latest reports from Public Health Center Canton Sarajevo, in the first six month of 2012, in the age group of 19-64 year old (population of 252 928) diabetes is on the third place among the ten leading most prevalent diseases at 6 812 newly diagnosed, and on second place in the age group of over 65 year old (population group of 75 727), with the number of newly diagnosed 6 738. In the population group of 7-18 year old diabetes is not among the top ten prevalent diseases. The total population in Canton Sarajevo is 438 757 (12). The rate of prevalence for diabetes was at 36/1000 in 2011 for Canton Sarajevo, and 24/1000 for the Federation BiH. The number of newly diagnosed in the Federation BiH was at 56 185 in 2011 (13).

The conditions that risk to lead to amputation of a diabetics foot are peripheral polyneuropathy, foot deformity and callus, limited mobility in the ankle joint, history of foot ulcer or amputation, obesity, poor sugar level control and inappropriate footwear (14). In their studies Bus et al. and Ledoux et al. conclude that assessing of the presence of sensory neuropathy is crucial in conducting pathology of diabetic foot (15).

Analyzing foot deformity, as one of the risk factors that can lead to ulceration, it has been found that the average number of foot deformities in the study sample was 2,84. Even though the subjects from the group with pedobariography, Group I, on average had more deformities, 3.02±0.9, than the subjects from Group II, 2.7±1.1 (min 1, max 5, $t=2.592$, $p=0.111$) the difference between the groups is not statistically significant ($p>0.05$). The most prevalent conditions among the study subjects are flat feet condition at 66%, hallus valgus feet condition at 57% and foot callus 60%. The hammer toes condition had 24% of the subjects. In the whole sample 63 (63%) of the participants had three or more foot deformities. A detail analysis of the number of foot deformities shows that the three or more deformities condition was significantly more prevalent in the group with pedobariography Group I ($p<0.05$) at 73.3%, compared to 54.5% in Group II. The study on presence of foot deformities conducted by Bokan V. finds the highest prevalence of hallus valgus at 40%. The study finds the other type of deformity about equally prevalent (16).

In our study, the Test of mobility – metatarsophalangeal mobility and mobility of ankle joint indicates reductions of mobility present in 39% of surveyed in both Groups. Normal result of the Test of mobility was somewhat more prevalent in Group I (64.4%), relative to the Group II (59.2%) but the difference was not statistically significant ($p>0.05$).

For the subjects from Group I, who underwent the Pedobarographic exam (dynamic function of foot) the parameters of plantar pressure (Peak pressure in kPa, Force in Ns and Area in cm) were recorded. The average value of the peak pressure at the first measurement was 473,38kPa. At the second measurement, after 6 month of use of the individualized orthopedic insoles made based on pedobarography, the value was 577.6kPa. The average measurement of the Force was 128.87Ns and 662.13Ns at the first and the second measurement respectively. The average size of the zone (area) was 128.87cm and 124cm, at the first and the second measurement respectively. It has been noted that there is a statistically significant difference in the Peak pressure (kPa) and the Area (cm) but not in the Force (Ns), between the first and the second measurement. The results of our study show that all of the subjects from Group I (45) at the first and the second measurement have Peak pressure values above 200kPa, and that they are in the range of the Peak pressures requiring attention.

In the research study by Burns J. et al., the results have shown a statistically significant connection between the pain sensation and plantar pressure in patients with foot

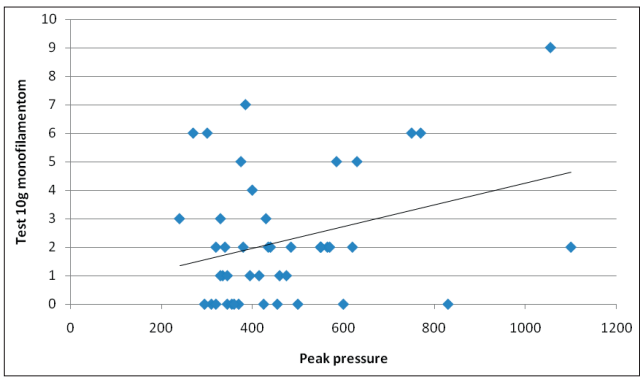

Figure 2. Correlation of Test 10g monofilament with Peak pressure.

deformity. Specifically, the patients with foot deformity who complained about a stronger and more intense pain in an area of a foot, had higher values of peak pressure, duration of pressure and pressure time integral (17). In this study, statistically significant correlation between Peak pressure and the Test with 10g monofilament has been found at r=0.317 and p=0.034 (p<0.05). The patients with more significant sensibility abnormality had an increased value of plantar pressure (Figure 2).

Boulton and the association for studies of diabetic foot and risk of development of ulcer report that 51% of diabetics and polyneuropathy have abnormal plantar foot pressure (18,19). Our study of correlation between diabetes polyneuropathy and Peak pressure has found higher Peak pressure in patients with stronger polyneuropathy. However, that relationship is not statistically significant at r=0.56 and p=0.713 (p>0.05), Figure 3.

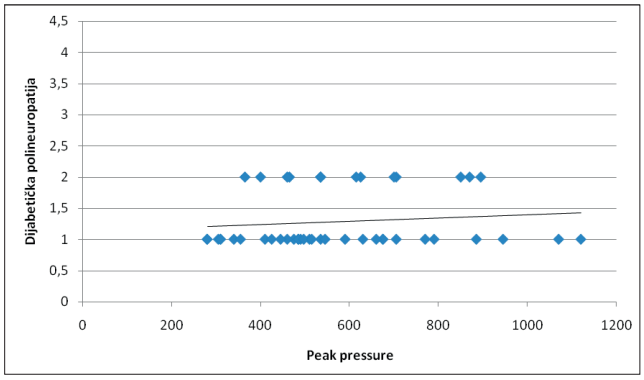

Figure 3. Correlation of diabetic polyneuropathy with Peak pressure

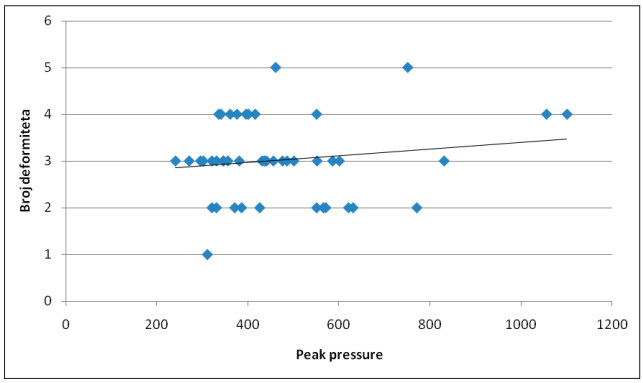

Figure 4. Correlation of the number of deformities with Peak pressure.

Lavery reported about the trend of increase in plantar pressure with the increase in the number of foot deformities. Bus et al. indicate on significant correlation between distribution of plantar pressure and ulceration (20,21). Analyzing correlation of plantar pressure and deformity of foot, our work also finds an increase in Peak pressure with increase in foot deformities. However, the finding is not statistically significant at r=0.155 and p=0.308 (p>0.05), Figure 1.

Our study finds an increase in Peak pressure (kPa) in patients with higher mobility of joints, but the relationship is not statistically significant at r=0.126 and p=0.410 (p>0.05).

The results of the study demonstrate connection between foot deformity, diabetic polyneuropathy and plantar pressure. A role of a family doctor in prevention of the disease has been noted.

The assessment of the dynamic function of foot, by conducting pedobarographic exam, and use of individualized orthopedic insoles, can assist family medical care offices to help patients with reduction in the pain sensation in the feet, enable better mobility and other activities as well as improvement in life quality of the patients.

5. CONCLUSION

A detail clinical exam of diabetic feet in a family doctor office equipped with pedobarography and the use of individualized robotic made orthopedic insoles significantly reduces clinical symptoms of diabetic polyneuropathy in patients with diabetes. The approach provides preventive foot care against deformities on diabetic foot.

CONFLICT OF INTEREST: NONE DECLARED.

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