IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 22, Issue 3 Ser.1 (March. 2023), PP 54-60
www.iosrjournals.org

Neuropathy detection with tuning fork and monofilaments in obese inactive, prediabetes and type 2 diabetes individuals

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Abstract:
Background: *Diabetes can also be caused by a combination of these two inabilities. Diabetes is characterized by elevated levels of glucose in the blood. Diabetes can be caused either by the body's inability to produce insulin or by the body's inability to effectively utilize insulin when it is present.* ***Aim:*** *The present study aim is to determine to what extent, the128-HztuningforkdetectearlyDPNinanOO andT2DMpopulation? the 1-g and 10-g monofilaments detect early DPN in an OO and T2DMpopulation? and will the three instruments differ in their ability to detect DPN in OO and T2D populations?* ***Material & methods:*** *After debate, the institutional Human ethics committee approved the study protocol. Quantitative, observational, and correlational methodologies are used in this study. This study's population was OO—overweight, obese, and inactive. Glycated hemoglobin (HbA1C) levels and previous diagnoses were used to classify people into several groups for future examination.* ***Results:*** *A multiple regression was run to attempt to predict the right SNAP criterion with a regression model that accounted for HbA1C, age, and BMI as predictors. The multiple regression model significantly predicted the right SNAP value, F, p <.001; Age (p =.000) and Total QOL (p = .021) significantly added to the prediction. Regression coefficients and standard errors.* ***Conclusion:*** *Subacute and acutely hyperglycemic populations have distinct SNAP value distributions, as demonstrated by the NCS. This is because NCS findings indicate that populations with chronic and acutely elevated blood sugar levels have distinct SNAP value distribution patterns.*

Date of Submission: 20-02-2023 Date of Acceptance: 03-03-2023

I. Introduction:

Diabetes is a metabolic illness that can be caused by either an inability to produce insulin or an inability to use insulin correctly, or both [1,2]. Diabetes can also be caused by a combination of these two inabilities. Diabetes is characterized by elevated levels of glucose in the blood. Diabetes can be caused either by the body's inability to produce insulin or by the body's inability to effectively utilize insulin when it is present [3]. The abnormal functioning of many kinds of cells throughout the body, including the cells that are involved in fundamental physiological processes in the brain, organs, and muscles, can be disrupted by hyperglycemia, which occurs when blood glucose levels remain consistently high. [1] Hyperglycemia can also occur when blood glucose levels drop suddenly after being elevated for a period. Maintaining blood glucose levels that are within the normal range is one of the most effective ways to ward off hyperglycemia [4,5].

Different research populations, such as those who are overweight, obese, and inactive (OO), prediabetes and in addition to those who have T2DM, gave valuable insight into the optimal application of fundamental screening procedures for detecting early stages of diabetes peripheral neuropathy [6,7]. This information was helpful in determining how to best detect early stages of diabetes peripheral neuropathy [8,9]. It is estimated that one out of every four people who have diabetes are unaware that they have the condition until they experience severe symptoms; however, by this point, it is likely that irreversible damage or a catastrophic event has already taken place [2].The present study aim is to determine to what extent, the128-HztuningforkdetectearlyDPNinanOO andT2DMpopulation?, the 1-g and 10-g monofilaments detect early DPN in an OO and T2DMpopulation? and will the three instruments differ in their ability to detect DPN in OO and T2D populations?

II. Materials & Methods:

After debate, the institutional Human ethics committee approved the study protocol. Quantitative, observational, and correlational methodologies are used in this study. This study's population was OO—overweight, obese, and inactive. Glycated hemoglobin (HbA1C) levels and previous diagnoses were used to classify people into several groups for future examination. This study's participants had pre-diabetes and T2DM after additional analysis. Investigation findings were released. Hence, adults of both sexes were separated into three groups: overweight or obese and inactive normoglycemic (OO), prediabetes, and T2DM.

Each patient in both groups was examined by a licensed physician in the hospital's medicine department. 68 volunteers joined the study after first expressing interest. The patient's American Diabetes Association diagnosis was type 2 diabetes. Type 2 diabetes was diagnosed using American Diabetes Association criteria. The study's control group consisted of people the same age and gender with normal glycemic status. A medical practitioner examined each test participant according to protocols and procedures. This test followed standards. The patient's American Diabetes Association diagnosis was T2DM. T2DM was diagnosed using American Diabetes Association criteria. Both groups' height and weight were measured in meters (m) and kilograms (kg). We calculated each subject's height and weight in metric units. We calculated each subject's BMI. Millimeters and kilograms measured height and weight, respectively (by dividing their total body weight in kgs by the square of their height in m). After BMI calculation, everyone was assigned to a group based on the criterion. Divide each group into three subgroups using the WHO's BMI-based obesity diagnosis criteria for Asian people. To study Asian obesity, the WHO created these criteria. To study Asian obesity, the WHO developed these criteria. Obesity is above 30 kg/m2, while a healthy BMI is 18.5-24.9 kg/m2. Meet these prerequisites. Exclusion criteria: T1D, active cigarette use, hepatitis B, C, HIV, pregnancy, lower extremity injuries, nerve illness (other than neuropathy), peripheral artery disease, lower limb amputations, and foot ulcers were excluded. A major medical condition that jeopardized subject safety or study integrity was also excluded.A 128-hertz tuning fork was used to study how humans experience vibrations. This provided accurate results measuring. The "On/Off" approach followed standardized guidelines throughout. Familiarization, testing place, and procedures were provided. "Rapid Screening for Diabetic Neuropathy utilizing the 128-Hz Turning Fork" [16,17] describes these techniques. Tuning fork tests to diagnose peripheral neuropathy need participants to close their eyes and lie supine for the whole exam. Both sets of tuning fork testing will follow the method.

For sensation perception testing, a lab testing table was employed with commercial monofilaments weighing one to ten grammes. Monofilaments weighed 1–10 grammes. Monofilament was stored and tested in a controlled temperature environment according to previous research [18,19]. According to previous official guidelines, sensory testing was performed using monofilaments. The Canadian Diabetes Association's Quick Screening of Diabetic Neuropathy procedure was followed for 10-g monofilament testing on the great toe dorsum proximal to the nail bed [3,8,19]. These recommendations were followed for familiarization and testing. The 4.17/1-g and 5.07/10-g monofilaments were examined using standardized familiarization, subject response patterns, sites tested, stimuli, and score assignment based on earlier literature. The number of stimuli tested varies. Monofilament testing followed these stages.

NC-Stat DPN Check processes followed [24] techniques (DPN-Check, NeuroMetrix Inc., Waltham, MA). The POCD test measured sural nerve amplitude potential (SNAP) and conduction velocity (SNCV) [21-24]. Bilateral lower extremity evaluations did this. The equipment allows non-clinical people to examine SNCV and SNAP, detecting DPN earlier than bedside testing [22,23]. Two biosensor probes were placed directly on the skin behind the lateral malleolus. The probes measured skin electrical activity. One button press discharged a 100 mA current, which was detected by a disposable biosensor. An inside thermometer alerted the operator if the subject's skin reached a level unsuitable for testing between 23 and 30 degrees Celsius. Three SNCV and SNAP data were collected for each leg, making a total of five tries. The device registered zero values, but each person was allowed five retries. The NC-Stat DPN Check method was validated and effective in previous research. [21-24] supported this finding. The study's gold standard, this test was compared to all other assessments then reviewed and debated.

Statistical analysis:

The most recent version of SPSS will be used for the statistical analyses (SPSS, Chicago, IL). The results of the tuning fork, the 1-g and 10-g monofilaments, the QL-DN and the NC-Stat DPN Check will be analyzed for correlations, and age, HbA1c, and waist measurement will be taken into account (in cm). In order to ascertain whether or not there are distinctions to be made between the three groups, pairwise comparisons will be subjected to Kruskal-Wallis H tests. In all of the analyses, alpha was determined to be 0.05.

III. Results:

Table 1: Present study subject general characteristics

Variables		Frequency	Percentage
Gender	**Male**	20	30
	Female	48	70
Diabetes diagnosis	**None**	30	45
	Prediabetes	16	24
	T2DM	22	31
Neuropathy diagnosis	**No prior diagnosis**	56	82
	Prior diagnosis	12	18
Medication	**No medication**	44	22
	T2DM specific	20	42
	T2DM & neuropathy	4	36
HbA1c	**OO**	20	30
	PD	26	38
	T2DM	22	32
BMI Category	**Normal**	2	3
	Overweight	18	27
	Obese	48	70

There were 20 males and 48 females in our sample, and the HbA1C ranged from 4.4 to 14.0% for all of the subjects (Table1). Thirty people out of 68 said they had no prior diagnosis or knowledge of type 2 diabetes or prediabetes (PD). Ten out of thirty people had PD HbA1C values, and they were divided into appropriate groups as a result. Sixty-six people out of a total of 68 were classified as overweight or obese. 56 people said they had never been diagnosed with neuropathy or knew anything about it. Twenty of the 68 participants reported using T2DM-specific medication as part of their individual medical plan, indicating a wide range of medication use. Four people with type 2 diabetes reported taking neuropathy medication in addition to their diabetes medication.

Table 2: Spearman correlations

		SNAP-R (n=68)	SNAP-L (n=68)	SNCV-R (n=68)	SNCV-L (n=68)
Tuning fork	**On/off**	0.222	0.138	0.321	-0.91
	Sig.	0.122	0.324	0.213	0.421
	Timed-R	-0.071	-0.018	-0.018	-0.098
	Sig.	0.366	0.462	0.460	0.304
	Timed-L	-0.064	-0.053	-0.019	-0.082
	Sig.	0.372	0.394	0.466	0.366
Monofilaments	**Tot 1-g**	**0.365**	**0.312**	-0.060	-0.141
	Sig.	**0.025**	**0.043**	0.388	0.331
	1-g R	0.228	0.208	0.027	0.088
	Sig.	0.117	0.143	0.443	0.356
	1-g L	**0.398**	**0.401**	-0.242	-0.324
	Sig.	**0.015**	**0.041**	0.166	0.048
	Tot 10-g	0.099	0.161	0.008	-0.088
	Sig.	0.309	0.299	0.491	0.365
	10-g R	0.093	0.161	0.009	-0/78
	Sig.	0.413	0.66	0.989	0.043
	10-g L	0145	0.121	0.482	0.482
	Sig.	0.45	0.98	0.65	0.66

The on/off test with the tuning fork did not correlate with any of our criterion variables. Despite this, the tuning fork was able to achieve a sensitivity of 53.8% and a specificity of 75.0%. Testing with a timed tuning fork did not turn up any statistically significant correlations or relationships within the scope of the study. The 1-g total scores demonstrated a moderate relationship to both SNAPs [R, p 0.016; L, p =.053] of the NC-Stat DPN Check, and the left 1-g scores also demonstrated a moderate relationship to both SNAPs [R, p => 0.05; L, p .047]. [R, p => 0.05; L, p .047] The sensitivity of the test with the monofilament weighing 1 gramme was 73.1%, but the specificity was only 25%. There was no significant correlation found between the 10-g monofilament and any of our criterion variables. The 10-g sample had a sensitivity of 46.2% while the specificity was at 62.5%.

Table 3: Quality of life-Diabetic Neuropathy Regression Results

	B	Std Error	B	T	Sig.	LB	UB
Constant	**28.01**	**7.31**		**3.91**	**0.001**	**13.2**	**43.1**
Age	**-.38**	**.07**	**.7**	**-4.8**	**.000**	**-.45**	**-.18**
HbA1c	**.27**	**.61**	**.1**	**.5**	**.723**	**.944**	**1.54**

BMI	**-.122**	**.152**	**.2**	**.89**	**.912**	**.842**	**.199**

A multiple regression was run to attempt to predict the right SNAP criterion with a regression model that accounted for HbA1C, age, and BMI as predictors. The multiple regression model significantly predicted the right SNAP value, F, p <.001; Age (p =.000) and Total QOL (p = .021) significantly added to the prediction. Regression coefficients and standard errors can be found in table 3.

There was not a significant difference between HbA1C levels, and the overall group means for SNAP and SNCV characteristics. Testing with Kruskal-Wallis H revealed that there were no significant differences in SNAP or SNCV values between the OO, PD, and T2DM groups (SNAP: R, p > 0.05; L, p > 0.05; SNCV: R, p > 0.05, L, p > 0.05); The presentation includes the raw data's means as well as standard deviations. There were fifty-four people who received confirmed, individualized, abnormal NCS results; of these, fifty were bilateral and symmetrical.Seven cases presented with normal NCS findings, but in the presence of reported symptoms and reduced bilateral distal sensation.

Table 4: Nerve conduction studies results by group.

		N	Min	Max	Mean	Std. Dev
SNAP-R (µV)	**OO**	20	2	14.4	1.48	4.6
	PD	26	2	24.8	1.7	6.1
	T2DM	22	2	25.1	2.2	7.1
SNAP-L (µV)	**OO**	20	2.4	21.8	7.2	5.8
	PD	26	3.1	21.8	7.3	4.3
	T2DM	22	3.1	21.8	10.6	6.9
SNCV-R (µV)	**OO**	20	35.4	55.8	46.3	6.1
	PD	26	31	57.1	48.3	6.8
	T2DM	22	35.4	57.1	45.6	6.1
SNCV-L (µV)	**OO**	20	41.4	55.1	47.3	4.9
	PD	26	43.1	55.1	49.3	3.9
	T2DM	22	37.4	57.1	46.9	6.5

Table 5: Sural nerve conduction studies signs & studies

			Group		
	Variable	**Total**	**OO**	**PD**	**T2DM**
Sural NCS (n= 68)	**Normal**	14	2	8	6
	Abnormal	54	20	18	16
Tuning fork signs (n=68)	**Normal**	26	6	10	10
	Abnormal	22	14	14	12
MF (1-g) signs (n=68)	**Normal**	6	2	0	4
	Abnormal	62	18	24	18
MF (10-g) signs (n=68)	**Normal**	6	2	0	4
	Abnormal	62	18	26	18
NCS, Sign & symptom combination	**AbNCS, Signs & Symptom**	34	6	18	10
	AbNCS, Signs or Symptom	18	10	2	6
	AbNCS, No Signs & Symptom	2	2	0	0
	NNCS, Signs & Symptom	14	2	6	6

IV. Discussion:

The integration of these testing methods provided an excellent framework to develop abetter understanding of the onset of dysfunctional physiological processes within PD and OOindividuals during the beginning of disease onset and examination of relationships betweensymptoms and disease.This study compared the effectiveness of the 128-Hz tuning fork, 1-gand 10-g monofilaments as screening measures for early DPN detection toestablished NCS criterion values as measured by the NC-Stat DPN Check.Our evaluationutilized the NC-Stat DPN Check and associated NC-Stat software to account for the age, height and weight of the subjects in conjunction with 3 bilateral sural NCS readings to assess thefunction of large, myelinated nerve fibers, and thus we did not directly assess small fiberneuropathy associated deficits.This study offers a nonclinical analysis based off the criteriarequired by a study [10] aiming to achieve minimal definition requirements forconfirmed and subclinical DSPN classification, with the intent of developing early screeningmeasures for DPN prone populations [10].

Sural nerve conduction and amplitude values are validated quantitative physiologicalmarkers that assist in the assessment and confirmation of DPN status with, or without thepresence of signs or symptoms.Fifty-two of 68 individuals had abnormal NCS, 48 of whomreported symptoms and bilateral

symmetrical signs upon examination (1-g, 10-g monofilaments,128-Hz tuningfork),meetingtherequirementsfor confirmed DSPNaccordingtosome literature[10]; however, we find that this is a significant percentage of study participantsin comparison to other research conducted with this device [11].In addition,sixindividualswithabnormalNCSreportedsymptomsandunilateralpresentation of signs, potentially indicating pathology that is not the focus of this study, while two individuals withabnormal NCS reported no symptoms or signs, confirming the likelihood of subclinicalneuropathy.Twelve individuals obtained normal NCS studies, but had the presence of signs and reportedsymptoms, while two individuals had normal NCS, but the presence of signs and noreportedsymptoms.

Studies [11-14] experienced significant findings, yet their study only evaluatedindividuals withdiagnoseddiabetes(T1DandT2DM), whereasourstudyexamineda widerangeofindividuals,including"healthy"individualsthatwererecruitedforourOOpopulationthatwe believed might be prone to DPN, as well as PD and T2DM individuals.The fact that we reportbilateral, abnormal findings in 71% of the individuals we tested, leaves room for questions.Weappliedrigoroustestingpreparationandmethods,andwhileit ispossiblethatthereisan error weare unawareof,ourfindingsmaybequestionedasvalid.ItisalsopossiblethattheNC-StatDPN Check's current software components and algorithms are too sensitive for the subjectpopulation.For clarification, we compared our SNAPs to Perkins et al. and found that, overall,our SNAP values for our groups contained values ranging from 2–25μV, withmeans ranging from 6.6 to 10.5μV, compared to Perkins et al., who contained means of 5.6μV.Many of their participants (32) had undetectable levels, whereas we were able to achieve threereadings on all but 4 individuals to whom LOCF was applied.At present, we interpret ourreadings as valid given that we acquired three readings on each leg, across a diverse collection ofindividuals, all of whom were likely to develop DPN.In support of our findings, the individualswith abnormal findings self-reported symptoms via QOL-DN and had documented distalsensation loss via 128-Hz tuning fork, and 1-g or 10-g monofilaments.It is, however, possiblethatourreadings arealteredin somewaythat we areunawareof atpresent.

To offer specific recommendations of normal or abnormal findings based onapplied individual characteristics, our assessment differed from previous research by evaluatingeach individual participant according to age, height and weight and determining appropriatecutoffs for normal and abnormal findings, thereby individualizing results to each participant withthebuilt-inNC-Statsoftware.Thismethodof analysesseemedparticularlyappropriate giventhe role of the potential impact of overweight, obese status within our population.Having noteddiscrepancies between the two in the study performed that analyzed both measures, notes that the SNCV values tend to be lower with a traditional NCS when compared to theNC-Stat DPN Check [15,16-20].This would prove to an interesting point to consider, ifthe same type of error were true, as it would likely boost the number of individuals who hadabnormalitieseven higher.

Detecting such diabetes complications is an unfolding evolution that involves multipledynamics.DPN may present in a completely silent manner, without pain, burning or symptomsof annoyance.In such cases, individuals will not disclose physical symptoms that they aren't currently experiencing.Individuals with early DPN may experience the disease in a variedmanner, with some individuals experiencing asymptomatic disease patterns, ultimately requiringhandsonscreeningtoidentifythe silentprogressionofthe disease.Futureresearchshould likelycontinue to examine the present study methods for early DPN detection, as several subscales indicatecorrelations.

The 1-g monofilament proved to be useful within our study, with (60) individualsexperiencing abnormal findings.This measure indicated high sensitivity (73.1%) and poorspecificity (25.0%), yielding concerns.However, validation of 1-g physical findings was seenthrough moderate correlations back to our criterion SNAP variables.Our results relate toprevious research efforts that reported high sensitivity and low specificity, as is the case of [21] andreviewsperformedby [21,22].

The 10-g monofilament testing lacked significant correlational relationships, yet theusefulnessofthistool hasbeenwellestablishedinT2DMandlimitedPDpopulationsinother research.Our correlational findings did not add support for its use in normoglycemic obesepopulations, but insensate feet relate to neuropathy in later stages and this research focusedinsteadonearlydetection.Incontrast,Ylitaloetal. examinedcardiometabolicandneuropathyfactors in obese individuals and found that the 10-g monofilament was a useful tool for suchresearch[23].

Our criterion measure, the NC-Stat DPN Check wastargetedtowardsscreeningforlarge fiber,andthusmaynotcorrelateaswellwitha well-roundedscreeningmeasurethattargets multipleareasof neuropathy,suchas theQOL-DN. Finally, our results reflect a strong indication of neuropathy in this population,suggesting that careful screening of individuals at earlier stages may be quite beneficial in theearly detection of DPN, even prior to hyperglycemia diagnosis.A study [24] foundelevated HbA1C status in such populations to be a concern for the development of large fiber-relatedneuropathycomplications, as was foundinour cohort [24].

Diabetes-related complications,suchas decreasedmotorandsensorynerveconduction velocities, may arise out of acute bouts of hyperglycemia experienced though postprandialexcursions,which maybebest

reflected byHbA1C values[25]. Ourstudy certainlyhassomelimitations.In thisstudy,generalizationsoffindings may not be made to large populations.Lack of random assignment and use ofvolunteersforsubjectscreatedpotentialselectionbias,withclinicalpopulationresearchtargetingandlowavailablefunding heavilyinfluencing thismethod.TheHbA1Ctesting machinethatwas used within the study is a validated machine, yet oral glucose tolerance testing is preferredby some researchers, particularly for individuals with cardiac autonomic neuropathy (CAN)[26].We did not test for CAN and, therefore, cannot account for unknowndiscrepancies.Temperature and humidity have been found to affect monofilament results, byaffecting the potential validity of the instrument in extremely high temperatures as well as hightestingvolumes in shortperiods oftime [27,28].

Temperature was accounted for by limiting monofilament storage and use to normal climate-controlled room temperatures and monitored these values.Humidity was monitored, but notcontrolled beyond what the laboratory air-conditioning and heating systems accounted for.Preparationformonofilamentusagefollowedpreviouslystatedguidelines andrecommendations,with testing amounting to far less than 100 compressions per day per instrument [28].TheNC-StatDPNCheckdevicewasusedsolelytotestthesuralnerve;therefore, deficits in nerve function relating to other nerves of the lower leg were not confirmedthrough this device and two nerves were not evaluated, as some literature advises.

V. Conclusion:

This study's objective was to identify signs and symptoms of diabetic peripheral neuropathy (DPN) in adults who were overweight, obese, and inactive (OO) prior to the diagnosis of pre-diabetes by utilizing well-established, low-cost tools and comparing them to a validated nerve conduction test (PD). This was accomplished by comparing both sets of test results. In addition to being overweight, these individuals were also obese, and they led sedentary lifestyles. For the purposes of this study, participants had to be at least 18 years old to be considered adults. When it came to detection in this population, the monofilament with a weight of 1 g was more effective than the one with a weight of 10 g. Even if the on-and-off test with the tuning fork did not match our criterion standard, the fact that it indicated that this population utilized the instrument in an equitable manner remains unaffected.Subacute and acutely hyperglycemic populations have distinct SNAP value distributions, as demonstrated by the NCS. This is because NCS findings indicate that populations with chronic and acutely elevated blood sugar levels have distinct SNAP value distribution patterns.

Conflict of interest:

None declared.

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