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"To Study the Sensory Nerve Conduction Velocity in Initial Stages of Diabetic Neuropathy in Type 2 Diabetes Mellitus."

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Abstract: *Diabetes mellitus is characterized by "chronic hyperglycemia with disturbance of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action or both." India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the "Diabetes capital of the world". The primary objective of the study would be to diagnose the changes taking place in Sural nerve in Diabetic persons in initial stages of Diabetic Neuropathy. The secondary objective will be to establish NCV study as preventive diagnostic tool for prevention and treatment of Diabetic Neuropathy.*
Materials and Methods:*the study was observational. It consisted 90 participants. The participants were divided into three groups consisting of 30 participants each. The sample included participants who fulfilled the inclusion and exclusion criteria and were willing to participate in the study.Sampling design for the study was Convenientsampling.*
Results: *Descriptive statistics for all outcome measures were expressed as mean, standard deviations (SD) and test of significance such as unpaired "t" test used for comparing the data between the two groups. Demographic variables between the three groups were analyzed by Tukey- Kramer multiple comparison test, ANOVA for comparing the data in all the three groups. The results were concluded to be statistically highly significant and significant.*
Conclusion: *Sensory Nerve Conduction Velocity (SNCV) can be used as a diagnostic tool to detect early changes taking place in sensory nerves of Diabetes Mellitus patients in initial stages of Diabetic Neuropathy.*
Keywords: *Diabetic Neuropathy, SNCV, Sural Nerve*

I. Introduction

An old Chinese proverb says "The inferior physician treats the disease once it occurs. The mediocre physician prevents the disease from coming back. The superior physician prevents the disease from ever occurring."

Diabetes Mellitus (DM) is characterized by "Chronic hyperglycemia with disturbance of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action or both."[1]The National Institute of Health Sciences states that 95% of all Diabetes in all India are type II Diabetes due to sedentary lifestyle, obesity, lack of exercise, poor diet, family history and history of metabolic syndrome.[2] India leads the world with largest number of Diabetic subjects earning the dubious distinction of being termed the "Diabetes capital of the world". According to the Diabetes Atlas 2006 published by the International Diabetes Federation, individuals with Diabetes in India are around 40.9 million and are expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken. [3]

In developing countries, the majority of people with Diabetes are in 45 to 64 year age range.[4] Diabetes is one of the most common and serious problem which affects all the systems of the body, among which its impact over peripheral nerve is severe leading to Diabetic Neuropathy (DN). Neuropathic pain, sensory loss, weakness and functional deficit are some of the signs of DN. [5] Positive symptoms may be hypersensitivity to touch, electric shock like feelings, burning, pricking, pain; tingling and negative sensory symptoms are feeling of numbness and painless injuries due to loss of sensation.[2, 6] Peripheral neuropathy, foot ulceration, peripheral arterial disease and lower extremity amputation is twice as common in diabetic persons compared with non-diabetic persons and it affects 30 per cent of diabetic persons who are older than 40 yrs.[7, 8]Usually the lesions are symmetrically present in the lower limbs.[7,9]Neuroelectrophysiological examinations have been used as a gold standard for DSPN diagnosis. Various other scoring scales for asymptomatic patients include Neuropathy Impairment Score in the Lower Limbs, Diabetic Neuropathy Examination score, and Toronto Clinical Scoring System (CSS) score, which are mostly carried out based on patient's clinical signs and symptoms, usually have a poor sensitivity for disease screening. The more comprehensive scoring systems, such as the Neuropathy Deficit Score (NDS) and Michigan Neuropathy Screening Instrument (MNSI), are time-consuming. [10]
A common staging scale is given below. [11, 12]
N0— No neuropathy
N1a— Signs but no symptoms of neuropathy

N2a— Symptomatic mild diabetic polyneuropathy
N2b— Severe symptomatic diabetic polyneuropathy (as in N2a but patient unable to heel walk)
N3— Disabling diabetic polyneuropathy

The Sural nerve is a distal sensory nerve that reliably exhibits nerve conduction changes in Diabetic Peripheral Neuropathy (DPN). [13-17] It is a branch of the Tibial nerve in the popliteal fossa. It descends between the two heads of the gastrocnemius and pierces the deep fascia in the middle of the leg. It is joined by the peroneal communicating nerve about 5 cm above the heel. After passing behind the lateral malleolus, the nerve runs forwards along the lateral border of the foot, and ends at the lateral side of the little toe. It supplies the skin of the lower half of the central area and the lower one third of the lateral area of the calf; and also over the lateral border of the foot up to the tip of the little toe. [18]

Sural nerve conduction is highly correlated to the morphological severity of DPN as assessed by biopsy. Diagnosis of DPN is made on the basis of the patient's history, physical examination, and objective test results. Sural nerve conduction is a quantitative biomarker that helps: [13]Identify DPN in the absence of signs and symptoms, Confirm clinically evident DPN and Stage DPN severity.

Sensory NCSs are performed by applying electrical stimulation near a nerve and recording the response from a distant site along the nerve. Response parameters include amplitude, latency, configuration, and sensory nerve conduction velocity. Normal sensory NCV ranges between 40 and 75 m/sec. amplitude, measured with surface electrodes, may be 10 to 120 µV, and duration should be short, less than 2 msec. [19]

II. Materials And Methodology

The research design used for the study was Observational Study. The data collected was primary. The study was conducted in Biofeedback lab, in Neurophysiotherapy Department. It was conducted from February 2015- November 2015. Male and Female individuals clinically diagnosed with Type II Diabetes Mellitus were included. The sample included participants who fulfilled the inclusion and exclusion criteria and were willing to participate in the study.The sample size was 90.Sampling design for the study was Convenient sampling. The equipment used for the study was EMGNCV.

Inclusion Criteria:

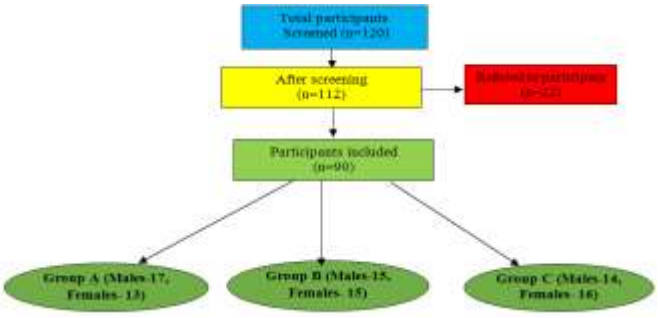
Participants with Age above 40 years to 65 yrs.
Patients having clinical diagnosis of Type II Diabetes Mellitus for atleast 10 years.
Both male and female participants.

Exclusion Criteria:

Individuals who were Chronic Alcoholic.
History of familial neural, muscular or neuromuscular disorders.
Individuals diagnosed with any other cause, signs or symptoms, or history of Peripheral neuropathy.
Following were the outcome measure used in this study:

- **Sensory Nerve Conduction Velocity (SNCV) (m/s):**The Sensory Nerve Action Potential (SNAP), is a compound potential that represents the summation of all the individual sensory fibre action potentials. A Sensory Conduction Velocity can be calculated with one stimulation site alone, by taking the measured distance between the stimulator and active recording electrode and dividing by the onset latency.
- **Latency (ms):**There are onset latency and peak latency that we get during the study. Sensory onset latency represents nerve conduction time from the stimulus site to the recording electrodes for the largest cutaneous sensory fibres in the nerve being study.
- **Amplitude (µV):**The SNAP amplitude is most commonly measured from baseline to negative peak. The amplitude reflects the sum of all the individual sensory fibres that depolarize. Low SNAP amplitudes indicate a definite disorder of peripheral nerve. It is measured from the first negative peak to the next positive peak.

III. Procedure



Flow chart representing the procedure of selection of participants

The study received ethical approval from the Institutional Ethical Committee (Ref. no. COPT/2015/1561/4). The participants were briefed about the nature of study, the time required and informed written consent was obtained from the participants. A brief history and physical examination was done. During examination they were assessed for muscle atrophy, tone, weakness, reflexes and for any loss of sensations like vibration, temperature and pain. Surface electrodes were used to deliver and detect the electrical impulses. The test was safe and well tolerated with only minor discomfort and no long term side effects. Patients were asked to avoid prior application of topical creams as these may increase skin resistance to the applied current, and therefore require stronger levels of electrical stimulation. No fasting was required and patients returned to normal activities such as driving immediately afterwards.[20]Patient's limb was placed in relaxed position as any movement of limb would hamper the results. Electrode impedance was reduced by applying electrode gel under the electrode and by affixing the electrode with adhesive tape to the skin.

Patients were in Side lying/Supine lying position. Surface electrodes were used with the active electrode placed between the lateral malleolus and the Achilles tendon at the malleolar level with the reference electrode 3cm distal to active electrode. Ground electrode was placed between the stimulating and recording electrode. Antidromic surface stimulation of the nerve was performed slightly distal to the lower border of the bellies of the Gastrocnemius, approximately at the junction of the middle and lower third of the leg,just lateral to the midline. The patient felt shocks radiating to the heel and foot. Sites 10cm, 14 cm, or 17 cm from the active electrode were stimulated antidromically. Since Antidromic potential is larger to Orthodromic potential, it is less subject to noise and other artifacts.The patients were divided into three Groups. In which:

Group A: Had patients with "No neuropathy signs".

Group B: Had patients with "Signs but no symptoms of neuropathy".

Group C: Had patients with "Symptomatic mild diabetic polyneuropathy"**.**

Descriptive statistics for all outcome measures were expressed as mean, Standard Deviations (SD) and test of significance such as unpaired "t" test used for comparing the data between the two Groups. Demographic variables between the three Groups were analysed by Tukey- Kramer Multiple Comparison Test, ANOVA for comparing the data in all the three Groups.

IV. Demographics And Results

Table 4.1: Demographics of Sex distribution in three Groups.

SEX/GROUP	Group A	Group B	Group C
MALES	17	15	14
FEMALES	13	15	16

Group A, B and C had 30 individuals respectively. Age of all individuals in this study was between 40 to 65 years. Group A had 17 males and 13 females, Group B had 15 males and 15 females and Group C had 14 males and 16 females **(Table 4.1)**

Table 4.2: Intra Group comparison of SNCV, Latency and Amplitude of Right lower limb of Group A and Group B.

Right Lower Limb	Group A Mean (SD)	Group B Mean (SD)	Unpaired 't' Test with (df)	'p' value
Sensory Nerve Conduction Velocity (m/S)	45.94 (±7.8)	36.96(±7.1)	4.62 (58)	< 0.001
Latencies (ms)	2.94 (± 0.56)	3.67 (± 0.66)	4.62 (58)	< 0.001
Amplitude (µV)	16.32 (± 3.1)	15.05 (± 1.5)	2.0 (58)	0.04

The mean value in Right lower limb for Group A was 45.94 (± 7.8) m/s and Group B was 36.96 (± 7.1) m/s. The differences in the baseline parameters for SNCV in both Groups were highly statistically significant. The mean value of Latencies in Right lower limb for Group A and Group B was 2.94 (± 0.56) ms and 3.67 (± 0.66) ms respectively. The differences in the baseline parameters for Latencies in both the Groups were highly significant statistically. The mean value for Amplitudes in Right lower limb for Group A and Group B was 16.32 (± 3.1) µV and 15.05 (± 1.5) µV respectively. The differences in the baseline parameters for Amplitude in both the Groups were significant statistically. **(Table 4.2).**

Table 4.3: Intra Group comparison of SNCV, Latency and Amplitude of Left lower limb of Group A and Group B.

Left Lower Limb	Group A Mean (SD)	Group B Mean (SD)	Unpaired 't' Test with (df)	'p' value
SNCV (m/s)	46.57 (± 8.6)	36.08 (± 6.3)	5.35 (58)	< 0.001
Latencies (ms)	2.91 (± 0.54)	3.74 (± 0.60)	5.57 (58)	< 0.001
Amplitude (µV)	16.32 (±3.1)	16.15 (±2.20)	0.25 (58)	0.80

The mean value of SNCV in Left lower limb for Group A and Group B was 46.57 (± 8.6) m/s and 36.08 (± 6.3) m/s respectively. The differences in the baseline parameters for SNCV in both Groups were highly statistically significant. The mean value of Latencies in Left lower limb for Group A and Group B was 2.91 (± 0.54) ms and 3.74 (± 0.60) ms respectively. The differences in the baseline parameters for Latencies in both the Groups were highly significant statistically. The mean value of Amplitude in Left lower limb for Group A and Group B was 16.32 (± 3.1) µV and 16.15 (±2.20) µV respectively. The differences in the baseline parameters for Amplitude in both the Groups were not significant statistically. **(Table 4.3).**

Table 4.4: Intra Group comparison of SNCV, Latency and Amplitude of Right lower limb of Group A and Group C.

Right Lower Limb	Group A Mean (SD)	Group C Mean (SD)	Unpaired 't' Test with (df)	'p' value
SNCV (m/s)	45.94 (±7.8)	33.48 (± 4.6)	7.48 (58)	< 0.001
Latencies (ms)	2.94 (±0.56)	3.96 (±0.55)	7.09 (58)	<0.001
Amplitude (µV)	16.32 (± 3.13)	14.61 (± 3.17)	2.10 (58)	0.03

The mean value of SNCV in Right lower limb for Group A and Group C was 45.94 (± 7.8) m/s and 33.48 (± 4.6) m/s respectively. The differences in the baseline parameters for SNCV in both Groups were highly statistically significant. The mean value of Latencies in Right lower limb for Group A and Group C was 2.94 (± 0.56) ms and 3.96 (± 0.55) ms respectively.The differences in the baseline parameters for Latencies in both the Groups were highly significant statistically. The mean value of Amplitude in Right lower limb for Group A and Group C was 16.32 (± 3.13) µV and 14.61 (± 3.17) µV respectively.The differences in the baseline parameters for Amplitude in both the Groups were significant statistically. **(Table 4.4).**

Table 4.5: Intra Group comparison of SNCV, Latency and Amplitude of Left lower limb of Group A and Group C.

Left Lower Limb	Group A Mean (SD)	Group C Mean (SD)	Unpaired 't' Test with (df)	'p' value
SNCV (m/s)	46.57 (± 8.64)	33.74 (± 5.03)	7.02 (58)	<0.001
Latencies (ms)	2.91 (± 0.54)	3.92 (± 0.54)	7.20 (58)	<0.001
Amplitude (µV)	16.32 (± 3.13)	15.05 (± 1.51)	2.00 (58)	0.49

The mean value of SNCV in Left lower limb for Group A was 46.57 (± 8.6) m/s and Group C was 33.74 (± 5.03) m/s respectively. The differences in the baseline parameters for SNCV in both Groups were highly statistically significant. The mean value of Latencies in Left lower limb for Group A and Group C was 2.91 (± 0.54) ms and 3.92 (± 0.54) ms respectively.The differences in the baseline parameters for Latencies in both the Groups were highly significant statistically.The mean value of Amplitude in Left lower limb for Group A and Group C was 14.61 (± 3.17) µV and 15.05 (± 1.51) µV respectively. The differences in the baseline parameters for Amplitude in both the Groups were not significant statistically. **(Table 4.5).**

Table 4.6: Intra Group comparison of SNCV, Latency and Amplitude of Right lower limb of Group B and Group C.

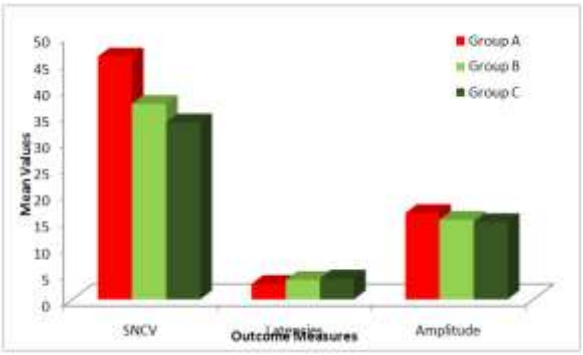
Right Lower Limb	Group B Mean (SD)	Group C Mean (SD)	Unpaired 't' Test with (df)	'p' value
SNCV (m/s)	36.96 (± 7.16)	33.48 (± 4.65)	2.23 (58)	0.02
Latencies (ms)	3.67 (± 0.66)	3.96 (± 0.55)	1.7 (58)	0.07
Amplitude (µV)	15.05 (± 1.5)	14.61 (± 3.17)	0.68 (58)	0.49

The mean value of SNCV in Right lower limb for Group B was 36.96 (± 7.16) m/s and Group C was 33.48 (± 4.65) m/s. The differences in the baseline parameters for SNCV in both Groups were statistically significant.The mean value of Latencies in Right lower limb for Group B and Group C was 3.67 (± 0.66) ms and 3.96 (± 0.55) ms respectively. The differences in the baseline parameters for Latencies in both the Groups were not quite significant statistically.The mean value of Amplitude in Right lower limb for Group B and Group C was 15.05 (± 1.5) µV and 14.61 (± 3.17) µV respectively. The differences in the baseline parameters forAmplitude in both the Groups were not significant statistically.**(Table 4.6).**

Table 4.7: Intra Group comparison of SNCV, Latency and Amplitude of Left lower limb of Group B and Group C.

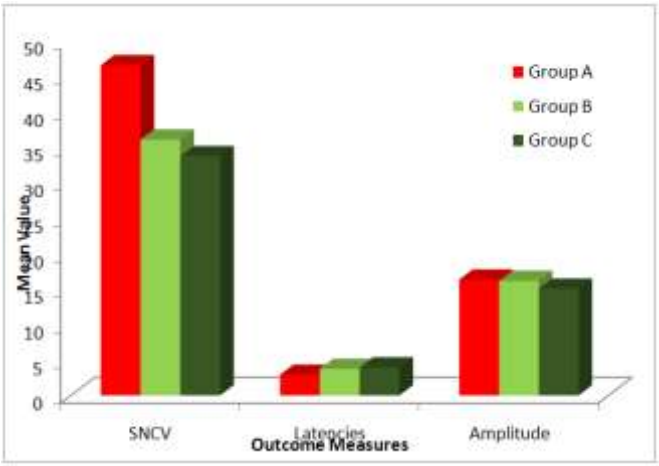
Left Lower Limb	Group B Mean (SD)	Group C Mean (SD)	Unpaired 't' Test with (df)	'p' value
Sensory Nerve Conduction Velocity (m/s)	36.08 (± 6.35)	33.74 (± 5.03)	1.57 (58)	0.11
Latencies (ms)	3.74 (± 0.60)	3.92 (± 0.54)	1.23 (58)	0.22
Amplitude (µV)	16.15 (± 2.20)	15.05 (± 1.51)	2.24 (58)	0.02

The mean value of SNCV in Left lower limb for Group B and Group C was 36.08 (± 6.35) m/s and 33.74 (± 5.03) m/s respectively. The differences in the baseline parameters for SNCV in both Groups were statistically significant. (p = <0.11). The mean value of Latencies in Left lower limb for Group B and Group C was 3.74 (± 0.60) ms and 3.92 (± 0.54) ms respectively.The differences in the baseline parameters for Latencies in both the Groups were not significant statistically. (p = <0.22)**.** The mean value of Amplitude in Left lower limb for Group B and Group C was 16.32 (± 3.13) µV and 15.05 (± 1.51) µV respectively.The differences in the baseline parameters for Amplitude in both the Groups were significant statistically. (p = 0.02). **(Table 4.7).**



Graph 4.8: Inter Group comparison of SNCV, Latency and Amplitude of Right lower limb of Group A, Group B and Group C.

The mean value of SNCV in Right lower limb for Group A, Group B and Group C were 45.94 (± 7.8) m/s, 36.96 (± 7.1) m/s and 33.48 (± 4.6) m/s respectively. The differences in baseline parameters of SNCV when calculated using Tukey- Kramer Multiple Comparison Test was statistically highly significant. (p= < 0.001, F= 27.64) The mean value of Latencies for Right lower limb for Group A, Group B and Group C were 2.94 (± 0.56) ms, 3.67 (± 0.66) ms and 3.96(± 0.55) ms respectively. The differences in the baseline parameters for Latencies in all three Groups in right lower limb when calculated using Tukey- Kramer Multiple Comparison Test were highly significant statistically. (p = <0.001, F= 23.44)**.** The mean value of Amplitude in Right lower limb for Group A, Group B and Group C was 16.32 (± 3.13) µV, 15.05 (± 1.51) µV and 14.61 (± 3.17) µV respectively. The differences in the baseline parameters for Amplitude in all three Groups in right lower limb when calculated using Tukey- Kramer Multiple Comparison Test were considered significant statistically. (p = 0.04, F= 3.22). **(Graph 4.8).**



Graph 4.9: Inter Group comparison of SNCV, Latency and Amplitude of Left lower limb of Group A, Group B and Group C.

The mean value of SNCV in Left lower limb for Group A, Group B and Group C were 46.57 (± 8.6) m/s, 36.08 (± 6.3) m/s and 33.74 (± 5.03) m/s respectively. The differences in baseline parameters when calculated using Tukey- Kramer Multiple Comparison Test was statistically highly significant. (p= < 0.001, F= 29.88). The mean value of Latencies for Left lower limb for Group A, Group B and Group C were 2.91 (± 0.54) ms, 3.74 (± 0.60) ms, 3.92(± 0.54) ms respectively. The differences in the baseline parameters for Latencies in all three Groups in Left lower limb when calculated using Tukey- Kramer Multiple Comparison Test were highly significant statistically. (p = <0.001, F= 27.24). The mean value of Amplitude in Left lower limb for Group A, Group B and Group C was 16.32 (± 3.13) µV, 16.15 (± 2.20) µV and 15.05 (± 1.51) µVrespectively. The differences in the baseline parameters for Amplitude in all three Groups in Left lower limb when calculated using Tukey- Kramer Multiple Comparison Test were considered not quite significant statistically. (p = 0.08, F= 2.52). **(Graph 4.9).**

V. Discussion

The results of the present study showed highly significant decrease in Nerve Conduction Velocity between all three Groups. The study also showed significant increase in Latencies and significant decrease in Amplitude when compared with normal values.

- **Nerve Conduction Velocity (m/s):**The Nerve Conduction Velocity was significantly reduced in Group C as compared to Group B and in Group B as compared to Group A. When all three Groups were compared the 'p' value was <0.001 for Right lower limb and < 0.001 for Left lower limb, which is said to be statistically highly significant.The results of present study are supported by a study conducted by Al. Kakrani et al in which symptoms and signs of neuropathy were correlated with Nerve Conduction Velocity. They found out that nerve conduction detects neuropathy changes before signs develop. The study also stated that sensory neuropathy are better appreciated by Nerve Conduction Studies than vibrational test.[1] Alev LEVENTOGLU et al in their study concluded that dorsal Sural nerve conduction may improve the diagnostic yield, and thus should be included in routine evaluation of diabetic patients with normal nerve conduction studies.[21]
- **Latencies (ms):**In the present study Latencies of Group C were significantly increased as compared to Group B and that of Group B were significantly increased as that of Group A. When all three groups were compared the 'p' value for Right lower limb was < 0.001 and for Left lower limb was <0.001, which is considered highly significant. The following studies show the possible reasons and support the findings of this study.Nerve Conduction Studies done by William Huguh et al interpreted that as axonal degeneration progresses, latencies can be mildly prolonged and conduction velocity slightly slowed because of loss of larger, fast conducting fibers.[22] Kimura J et al also found increased latency and decreased conduction velocity in lower limb nerves in diabetics as compared to normal subjects.[23]
- **Amplitude (µV):**When all three groups were compared the 'p' value for Right lower limb was 0.04 considered significant and for Left lower limb was 0.08, which was considered not quite significant. The results show significant decrease in the Amplitude of the three Groups. Bansal et al suggested that the slowing of NCV indicated the ongoing damage to the myelin sheaths and also the amplitude decreases with the rising HbA1c levels, thus suggesting the onset of axonopathy.[24]

V. Conclusion

On the basis of present study it can be concluded that Sensory Nerve Conduction Velocity studies can detect Diabetic Neuropathy in its early stages. And hence can be used as a diagnostic tool to detect early changes taking place in sensory nerves of Diabetes Mellitus patients in initial stages of Diabetic Neuropathy.

Limitations Of The Study

The study had small sample size.The study did not take into consideration Height, Weight, and BMI of the patients.Follow up of the patients was not done after the study.There was no equal distribution of males and females.

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