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Compare P100 latency of VEP between type II diabetes mellitus patient and age and sex matched healthy controls

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I. Introduction

Visual dysfunction in DM is multifactorial and depends on predominant pathophysiologic factors in various stages of the disease. One of the primary goals of management in diabetic patients is to avoid the risk of diabetic retinopathy by maintaining blood glucose levels close to the normal range. Before the onset of microvascular lesions, the neural retina of diabetic eyes undergoes subtle functional changes that are not detectable by fundus photography. Analysis of VEP responses may provide early diagnosis of such diabetic changes and determine prognosis during treatment. Pattern VEP (PVEP) can detect any defect from the optic nerve to the occipital cortex[1].

DM with its long asymptomatic stage has a propensity to cause long-term microvascular &/or macro vascular complications. It affects retina causing diabetic retinopathy which may result in irreversible blindness. DR, characterized as a neurovascular disease entity, results from hyperglycemia-induced changes to the blood–retinal barrier and retinal vasculature. Increasing damage to the retinal vasculature results in vessel leakage and diabetic macular oedema, and subsequent vascular sclerosis results in ischemia, angiogenesis, and, eventually, retinal neo- vascularization, or proliferative diabetic retinopathy.

Visual evoked potential (VEP) is a non -invasive, sensitive tool to measure the P100 latency which reflects the functional abnormalities of optic pathway even in early stages.[2] The latency depends on an intact, myelinated nerve as myelin and the saltatory conduction are essential for fast action potential propagation in normal subjects. In contrast, the amplitude of the waveform depends primarily on number of axons functioning within the nerve. Slowing of conduction velocity or prolongation of latency usually implies demyelinating injury, while loss of amplitude usually correlates with axonal loss or dysfunction.

Hence, it is aimed to compare the visual evoked potentials in type-2 diabetes mellitus patients with that of healthy controls and to find out if there is any correlation with duration of DM or glycemic control of diabetes patients with P100 latency.

II. Aims & Objectives

General: Evaluation of central neuropathy in patients with type 2 diabetes mellitus

Specific:

1) To compare P100 latency of VEP (both Right and Left eye) between type II diabetesmellitus patient and age and sex matched healthy controls.
2) To see the relationship between P100 latency and duration of diabetic, glycaemic control.

III. Materials & Methods

Study setting:

Department of Physiology and Diabetic clinic, Dept. of General Medicine,Calcutta National Medical College, 32 Gorachand Road, Kolkata 700014

Timelines: February 2020 to January 2021 (Approx. one year)

Definition of problem:

Visual dysfunction in DM is multifactorial and contributed by both vasculopathy and neuropathy. According to previously cited literature, damage of retinal ganglion cells may occur even before vascular lesions become clinically visible[3]. Visual evoked potential (VEP) is a non - invasive, sensitive tool to measure the P100 latency which reflects the functional abnormalities of optic pathway even in early stages . Hence analysis of VEP responses may provide early diagnosis of such diabetic changes and determine prognosis during treatment . Although there were few similar studies in past, most of them were reported in western literature[2]. Hence the

author intended to compare P100 latency of VEP between type II diabetes mellitus patient and age and sex matched healthy controls.

Definition of population:
Patients attending Diabetic clinic, Department of General Medicine, Calcutta NationalMedical College.

Study variables:
Latency of P100 waves of VEP in 60 healthy subjects and 60 patients with diabetes mellitus of age group 20 to 40 years were enrolled in the study. All patients were undergo fundoscopic examination at Department of Ophthalmology, CNMC before the VEP test. The Control group was age and gender matched healthy subjects with normal fasting and postprandial blood sugar.

Inclusion criteria:
- Age group 40 - 50 years, of both gender
- Type II diabetic patients with or without symptoms of neuropathy
- Both recently diagnosed and chronic diabetic patients
- Patients on oral hypoglycemic agents or insulin or both
- Visual acuity checked with Snellen‘s chart and ophthalmological examination were done to ruleout any visual disorder.

Exclusion criteria:
- Corneal opacity, squint, cataract, glaucoma, maculopathy
- Use of miotic or mydriatic drugs
- Systemic diseases like hypothyroidism, hypertension, chronic associated disorders such as cardiac decompensation, renal disorders, other demyelinating neuromuscular disorders
- Drugs acting on central nervous system Patients on drugs leading to neuropathy
- Patients with cochlear implant / cardiac pacemakers
- Habitual history of smoking and alcohol drinking,
- History of head injury
- diabetic retinopathy
- glaucoma or opacification
- visual acuity

Sampling design:
Systemic random sampling method was applied when collecting diabetic patient from diabetic clinic (every Friday 12 pm to 2 pm). To get 60 diabetic patients in a year, they need to collect 1 patient per week.(As in CNMC there is average 60 diabetic patient per week & 40 working weeks in a year is taken, So: 60patients /40weeks = 1.5, approx.2 patients per week). A random number table was used to assign the samples satisfying inclusion and exclusion criteria. Average 50 patients visit diabetic clinic every Friday, so every (50*40/60) 33rd patient was chosen and matched with the criteria.

Case, control required or not:

Case: Sixty (60) adult patients with diabetes mellitus of age group 20 to 40 years
Control: Sixty (60) healthy adults

Methods of data collection:
1) Subjects are to be collected from Diabetic clinic
2) All patients had undergone fundoscopic examination before the VEP test.
3) A detailed clinical history about Type II diabetes mellitus (duration) was collected and thoroughphysical examination was performed.
4) The basic parameters such as height, weight, pulse rate including body temperature was recorded. The relevant blood investigations (fasting, post prandial blood sugar level, HbA1c) andother reports were noted in a pre-structured proforma.
5) The subjects were properly instructed and motivated to provide full cooperation and selected bysimple random sampling method.
6) The detailed procedure and purpose of the study was explained in the regional language.

7) The written informed consent was taken from each subject in regional language before theyentered the study.
8) The participants were made to relax and comfortable prior to the test.

Experimental design:
Analytical observational Study, Cross-sectional Outcome definition: Delay in P100 latency of VEP before development of overt Retinopathy in Type II Diabetes Mellitus patients
Schedule of data collection: Diabetic patient was enrolled from Diabetic clinic, CNMC (every Friday of a week)
The fundoscopic examination had done on the same day at Dept of Ophthalmology to confirm absence or presence of Retinopathy VEP had done at dept. of Physiology. All the activities had done with permission and knowledge of the Head of the department (Physiology), without disturbing my work schedule in physiology department.

Statistical Analysis Plan: Statistical methods to be adopted are as follows:

- Unpaired t test
- Correlation test

A p-value of < 0.05 was taken as significant finding

Additional resources (if required) &sources: No other human resource, material or funding would be needed from any other institute or organization for this study.

IV. Result And Analysis

Continuous variables are expressed as Mean, Median and Standard Deviation and compared across the groups using Mann-Whitney U test/Kruskal Wallis Test as appropriate.

Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate.

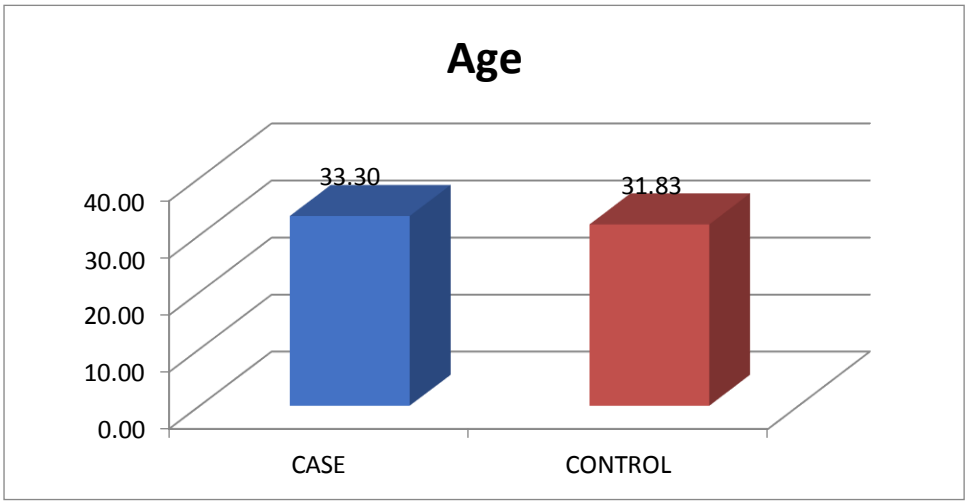
Association between continuous variables was captured by Spearman's Rank Correlation Coefficient. The statistical software SPSS version 22 has been used for the analysis. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

Group		Age	FBS	PPBS	Rt. P100 Latency	Lt. P100 Latency	Rt. P100 Amplitude	Lt. P100 Amplitude
Case	Mean	33.30	154.05	217.10	111.66	112.28	5.12	6.05
	Median	33.50	130.50	190.00	111.95	112.75	5.20	5.31
	SD	4.80	65.83	83.61	8.06	7.07	2.70	3.80
Control	Mean	31.83	92.80	133.67	101.69	103.39	5.20	4.65
	Median	32.00	89.50	134.00	102.45	103.70	5.39	4.86
	SD	4.68	13.13	13.34	3.93	3.70	0.92	0.92
	p Value	0.129	<0.001	<0.001	<0.001	<0.001	0.873	0.016
	Significance	Not Significant	Significant	Significant	Significant	Significant	Not Significant	Significant

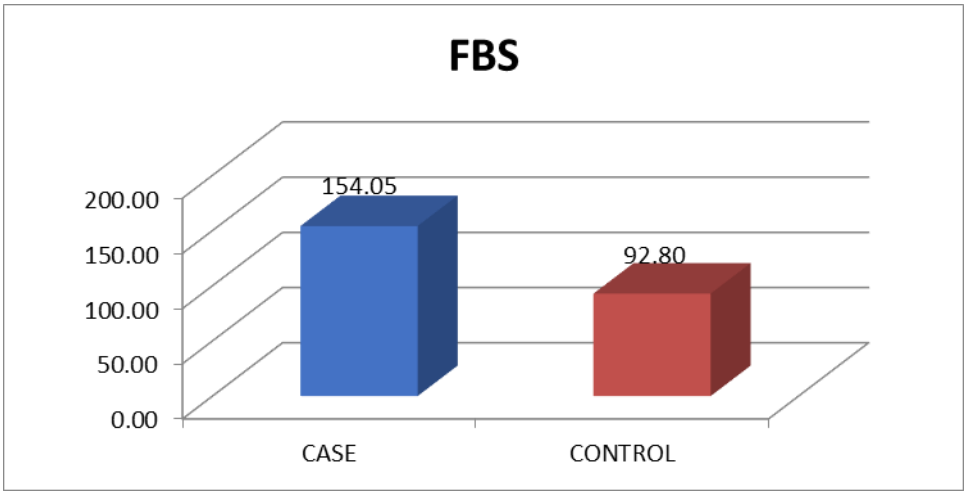
Age:
In Case, the mean Age (mean± s.d.) of patients was 33.30± 4.80.

In Control, the mean Age (mean± s.d.) of patients was 31.83± 4.68.

Distribution of mean Age with Group was not statistically significant (p=0.129).

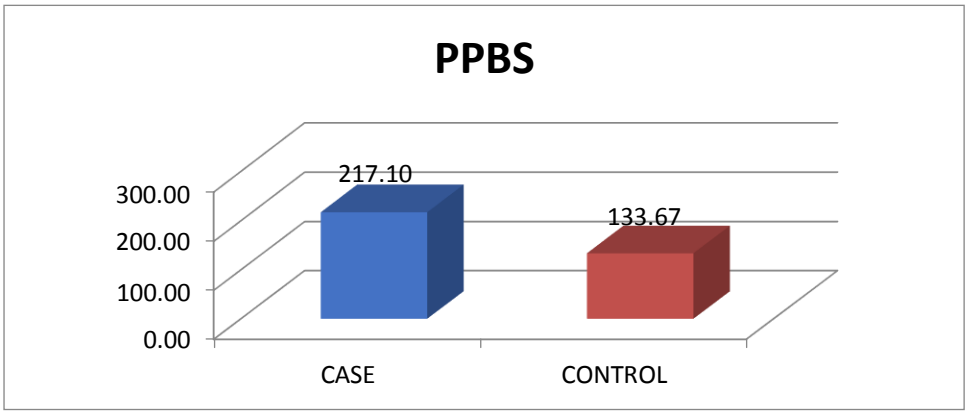


FBS:
In Case, the mean FBS (mean± s.d.) of patients was 154.05± 65.83. In Control, the mean FBS (mean± s.d.) of patients was 92.80± 13.13.
Distribution of mean FBS with Group was statistically significant (p<0.001).

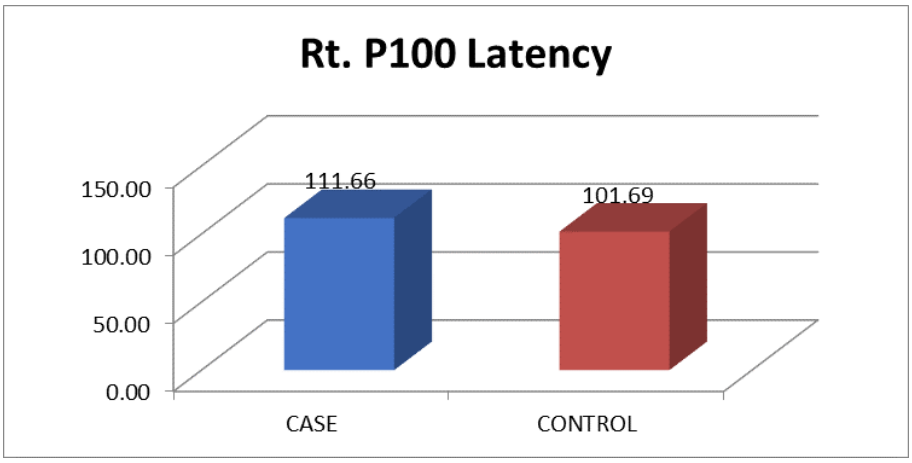


PPBS:
In Case, the mean PPBS (mean± s.d.) of patients was217.10± 83.61.

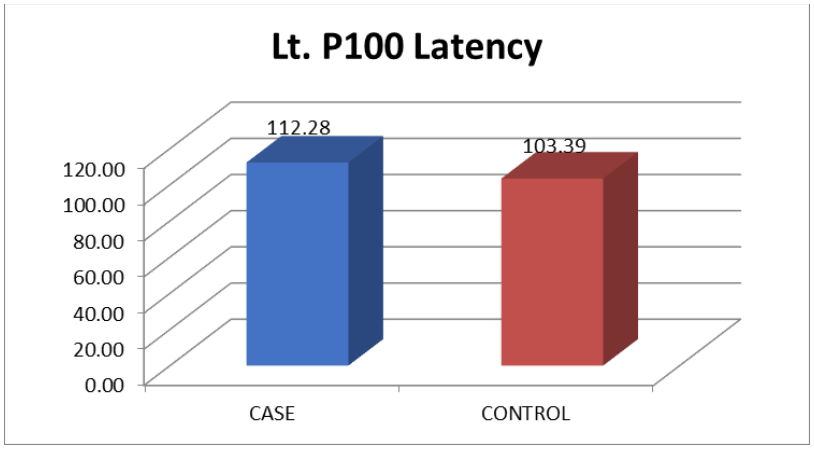
In Control, the mean PPBS (mean± s.d.) of patients was133.67± 13.34. Distribution of mean PPBS with Group was statistically significant (p<0.001).



Rt. P100 Latency:
In Case, the mean Rt. P100 Latency (mean± s.d.) of patients was 111.66± 8.06.
In Control, the mean Rt. P100 Latency (mean± s.d.) of patients was 101.69± 3.93. Distribution of mean Rt. P100 Latency with Group was statistically significant (p<0.001).



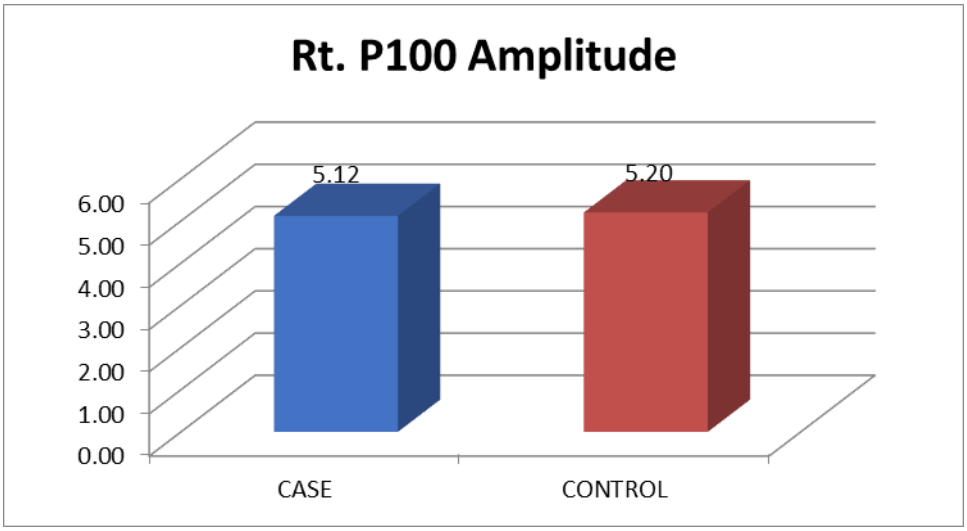
Lt. P100 Latency:
In Case, the mean Lt. P100 Latency (mean± s.d.) Of patients was 112.28± 7.07.
In Control, the mean Lt. P100 Latency (mean± s.d.) Of patients was 103.39± 3.70. Distribution of mean Lt. P100 Latency with Group was statistically significant (p<0.001).



Rt. P100 Amplitude:
In Case, the mean Rt. P100 Amplitude (mean± s.d.) Of patients was 5.12± 2.70.

In Control, the mean Rt. P100 Amplitude (mean± s.d.) Of patients was 5.20± 0.92.

Distribution of mean Rt. P100 Amplitude with Group was not statistically significant(p=0.873).

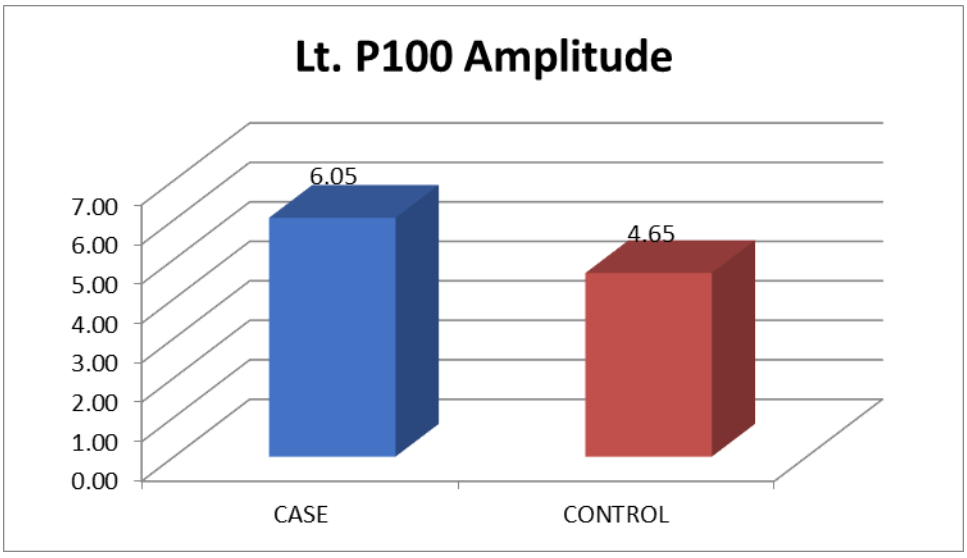


Lt. P100 Amplitude:

In Case, the mean Lt. P100 Amplitude (mean± s.d.) Of patients was 6.05± 3.80.

In Control, the mean Lt. P100 Amplitude (mean± s.d.) Of patients was 4.65± 0.92.

Distribution of mean Lt. P100 Amplitude with Group was statistically significant (p=0.016).



V. Discussion

This Analytical observational, Cross-sectional Study was conducted at the Department of Physiology and Diabetic clinic, Dept of General Medicine, Calcutta National Medical College, 32 Gorach and Road, Kolkata 700014 from February 2020 to January 2021.

60 healthy subjects and 60 patients with diabetes mellitus of age group 20 to 40 years were enrolled in the study. All patients had to undergo fundoscopic examination at Department of Ophthalmology, CNMC before the VEP test. The Control group was age and gender matched healthy subjects with normal fasting and postprandial blood sugar.

Patients with Age group 40 - 50 years of both genders, Type II diabetic patients with or without symptoms of neuropathy, both recently diagnosed and chronic diabetic patients, patients on oral hypoglycemic agents or on insulin or both and Visual acuity checked with Snellen‘s chart and ophthalmological examination were done to rule out any visual disorder were included in this study.

Total 120 patients participated in this study.

We found that in 'Case', the mean Age (mean± s.d.) of patients was 33.30± 4.80 and in 'Control', the mean Age (mean± s.d.) of patients was 31.83± 4.68 which was not statistically significant (p=0.129).

It was found that in 'Case', the mean FBS (mean± s.d.) of patients was 154.05± 65.83 and in 'Control', the mean FBS (mean± s.d.) of patients was 92.80± 13.13 which was statistically significant (p<0.001). **We also found that i**n 'Case', the mean PPBS (mean± s.d.) of patients was 217.10± 83.61 and in 'Control', the mean PPBS (mean± s.d.) of patients was 133.67± 13.34 which was statistically significant (p<0.001).

Heravian J et al [4](2011) found that the P100 latency in PVEP was increased in both groups of patients but the P100 amplitude was reduced only in anisometropic group. In PERG, the amplitude of P50 was reduced in all patients with no significant change in latency. Beside reduced PVEP responses in strabismic and anisometropic amblyopia, the activity of retina reduced too. It is likely that retinal impulses can affect the development of visual system.

Our study showed that in 'Case', the mean Rt. P100 Latency (mean± s.d.) of patients was 111.66± 8.06 and in 'Control', the mean Rt. P100 Latency (mean± s.d.) of patients was 101.69± 3.93 which was statistically significant (p<0.001). It was found that in 'Case', the mean Lt. P100 Latency (mean± s.d.) of patients was 112.28± 7.07 and in 'Control', the mean Lt. P100 Latency (mean± s.d.) of patients was 103.39± 3.70 which was statistically significant (p<0.001). **We observed that i**n 'Case', the mean Rt. P100 Amplitude (mean± s.d.) of patients was 5.12± 2.70 and in 'Control', the mean Rt. P100 Amplitude (mean± s.d.) of patients was 5.20± 0.92 which was not statistically significant (p=0.873). It was found that in 'Case', the mean Lt. P100 Amplitude (mean± s.d.) of patients was 6.05± 3.80 and in 'Control', the mean Lt. P100 Amplitude (mean± s.d.) of patients was 4.65± 0.92 which was statistically significant(p=0.016).

VI. Summary

We found that FBS and PPBS were significantly higher in patients with diabetes mellitus compared to control group .

In our study Rt. P100 Latency, Lt. P100 Latency and Lt. P100 Amplitude were significantly increased in patients with diabetes mellitus compared to control group . We also found that Rt. P100 Amplitude was decreased in patients with diabetes mellitus compared to control group .

We concluded that VEP responses are deranged in diabetic patients before the development of retinopathy. VEP measurements can be used for the early diagnosis of visual dysfunctions in diabetes for a better prognosis of the condition.

We also concluded that changes in VEP may be detected in diabetics before the onset of retinopathy. Thus, a routine VEP assessment should be recommended to all diabetic patients for early identification of visual defects and for early and proper management of the disease.

LIMITATIONS OF THE STUDY :

In spite of every sincere effort my study has some lacunae.The notable short comings of this study are:

1. The study has been done in a single centre.
2. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruledout.
3. On-going COVID 19 pandemic and lockdown have further hampered the study.

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