



A SINGLE CENTER OBSERVATIONAL STUDY ON THE ASSOCIATION BETWEEN HYPERLIPIDEMIA AND DIABETIC RETINOPATHY AND PSYCHOSOCIAL IMPACT OF DIABETES IN THESE PATIENTS

¹Chirag Parmar, ^{*2}Chaitali Patel, ¹Upama Trivedi and ³Naitik D. Trivedi

¹Shivam Pharmaceutical Studies and Research Center, Valasan, Gujarat

²Department of Ophthalmology Shree Krishna Hospital, Karamsad, Gujarat

³A. R. College of Pharmacy & G. H. Patel Institute of Pharmacy, Vallabh Vidyanagar, Gujarat

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ABSTRACT

Introduction: The main objectives of this study was to find out the association between hyperlipidemia and diabetic retinopathy and the psychosocial impact in diabetic patients. **Method:** In a single center observational study, we had recruited 70 patients. Out of them, 35 patients had diabetes but no evidence of retinopathy and 35 patients had diabetic retinopathy. We correlated the findings with the age, sex and duration of DM along with its severity. We also tried to find an association, of serum lipids and the psychosocial impact of diabetes in these diabetic patients. **Results:** During the study, we found that with increase in the duration of diabetes the risk of diabetic retinopathy was also on the rise. TC, TG, LDL were also found to be higher in patients with diabetic retinopathy as compared to patients with no diabetic retinopathy. Psychosocial analysis of these patients showed no significant impact in either group. **Conclusion:** Our conclusion from the study was that that poor glycemic control, increase duration of diabetes and high levels of serum lipids are high risk factors for the development of diabetic retinopathy.

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INTRODUCTION

Diabetes mellitus is group of metabolic disorders characterized by hyperglycemia and is associated with abnormalities in carbohydrate, fat and protein metabolism as a result of defect in insulin secretion, insulin sensitivity or both. DM (Diabetes Mellitus) is characterized by increase in blood sugar level by variable interactions between hereditary and environmental factors.^[1]

According to WHO about 62 million people in the world are suffering from diabetes mellitus. Out of these, according to international diabetes federation 50% of the patients belong to India, China and USA and India is considered to be a diabetic hub. In India, particularly Gujarat there is high rate of the diabetic population and hence considered as the diabetic capital.

There are many complications of diabetes and all complications are divided in two groups micro vascular and macro vascular.^[2] These complications can lead to an increase in the rates of co-morbidity and mortality and thus reduce the life expectancy. Diabetic nephropathy, diabetic retinopathy, diabetic myopathy, diabetic neuropathy are the most common complications seen in diabetic patients. And if these complications are left untreated or undetected, it may have a direct impact on the quality of life.^[3] Diabetic retinopathy is an asymptomatic disease to start with. All the changes start in the

retina. Retina is the innermost coat of the eyeball and is located at the back side of the eye.^[7,1]

As the disease progresses and proliferative diabetic retinopathy sets in, neo vascularization occurs. There are formation of new vessels. It has been estimated that over one quarter of the retina must be non-perused before PDR (proliferative diabetic retinopathy) develops. Although pre-retinal new vessels may be arising anywhere in retina, they are most commonly seen at posterior pole. Fibrous tissues are initially fine, gradually the vessels increase in size. Diabetic macular edema is the most common cause of visual impairment and is caused by extensive capillary leakage from microaneurysms and dilated capillary segments.^[4]

Diabetic retinopathy is the most common problem seen in the last two decades and it affects the social and economical life of patients. Diabetic retinopathy may occur in both type 1 and type 2 diabetes mellitus. 75% of type 2 diabetic patients will develop diabetic retinopathy after 15 years of developing diabetes.^[6] Diabetic retinopathy is the most common cause of blindness in the working age group, affecting both the genders equally. A diabetic patient is 25 times more prone to blindness than people without Diabetes. Diabetic retinopathy is responsible for 4.8% of the 37 million cases of blindness due to eye disease. The prevalence of DR (diabetic retinopathy) in India is approximately 5.6 million. There are a number of risk

*Corresponding author: Chaitali Patel

Department of Ophthalmology Shree Krishna Hospital, Karamsad, Gujarat

factors for DR, out of which degree of glycemic level in the blood, blood pressure, duration of diabetes, presence of nephropathy and raised lipid level are more important. Elevated lipid in blood is the additional risk factor for diabetic macular edema due to the disposition of hard exudates in retina. This complication can lead to blindness in DM patients.^[2]

In recent years the incidence of diabetic retinopathy and its psychosocial impact on the diabetic patients are on an increase. This may be because of sedentary lifestyle and poor dietary intake. Other causes are alcohol consumption, smoking habits, pregnancy, etc.

So the main objectives of this study was to find an association between hyperlipidemia and DR and its psychosocial impact of diabetes in these patients.

MATERIAL AND METHOD

Study design was observational. This was a single center observational study carried out at Department of Ophthalmology Shree Krishna Hospital Karamsad and its IEC approval number is ECR/331/Ins/GJ/2013. We have followed the study with obtaining the informed consent form from the 70 patients who voluntarily participated and out of them 35 patients with diabetes without retinopathy and 35 patients with diabetic retinopathy respectively for the period of 6 months. We also obtained the case report form as well as psychosocial questionnaire which were filled up by respective patients included in the study. After the study, the data was collected from the CRF and questionnaires and the result was statistically analyzed.

Inclusion Criteria Were

- Patient with diagnosed diabetes type 2.
- Retinopathy as categorized by fundus examination under mydriasis of both eyes using indirect ophthalmoscopy and slit lamp bio microscopy with 90 D lens

Exclusion Criteria Were

- Patients with type 2 diabetes having history of heart disease such as angina pectoris or myocardial infarction, established nephropathy and or severe acute illness.
- Patient with other eye diseases except cataract.

International diabetic retinopathy severity scale was used in the diagnosis of diabetic retinopathy according to its clinical manifestation.

It is divided into Non-Proliferative Diabetic Retinopathy (NPDR) and Proliferative Diabetic Retinopathy (PDR). NPDR is further divided into Mild, Moderate, Severe and very severe. PDR is again divided as Early, High risk and Severe^(a)

Mild NPDR= One micro aneurysm on retinal examination

Moderate NPDR =multiple aneurysms, dot and blot hemorrhages, cotton wool spots

Severe NPDR= more than 20 intra retinal hemorrhages in **four** quadrant, venous beading in **two** or more quadrants, intra retinal micro vascular abnormalities in **one** quadrant but with no development of new vessels
(any one of the 4-2-1 rule)

Very Severe = any two of (4-2-1 rule)

Visual Loss in NPDR is due to Macular edema^(b)

PDR – To counter act the ischemic changes in the retina, new blood vessels start

growing in the vitreoretinal interphase. This neovascularisation on the Optic Disc (NVD) or elsewhere (NVE) are fragile and may rupture, leading to preretinal and vitreous hemorrhage

The diabetes distress screening scale was used to assess the psychological impact of diabetes on the life style of diabetic patients

Living with diabetes can be sometimes tough. There can be many problems which may vary greatly in severity. Problems may range from minor hassles to major discomforts.

- ✓ Listed in this scale were 2 potential areas that people with diabetes may experience problems.
- ✓ The patients were requested to go through the scale, consider the degree to which each of the 2 items may have distressed or bothered them during the past month and circle the appropriate number.
- ✓ The DDS17 yields a total diabetes distress scale score plus 4 subscale scores each addresses a different kind of distress.
- ✓ This scale includes 4 subscales- emotional burdens, physician related burden, regimen related distress, interpersonal disorder
- ✓ To score simply sum the patients responses to the appropriate items and divide that score by number of items in that scale.

This scale consider a mean item score of 3 or higher (moderate distress) as a level of distress worthy.

Statistical analysis was done. Statistical methodology was used in accordance with scoring manual. SPSS version 16 was used to enter and analyze data. Descriptive data obtained from 70 patients were analyzed by calculating percentages, mean, and frequencies.

For statistical analysis, independent T-test was applied for comparing the readings of lipid profile of the two groups'- diabetic retinopathy and diabetic non-retinopathy. For statistical significance the alpha level was considered at 0.05. For psychosocial analysis the score of DDS of diabetic retinopathy and diabetic non-retinopathy, independent T-tests was applied at alpha level 0.05 and according to alpha level statistical significance was stated.

70 patients of diabetes mellitus were included in this study. For diabetic patients general lipid components were recorded (HDL, LDL, total serum cholesterol, HDL/LDL, TC/HDL, triglyceride) for evaluation of lipid profile.

For psychosocial analysis DDS (diabetes distress scale) was used which had a total of 17 question related to the diabetic distress of patients.

Assessment done as below

- ✓ Demographic factor
- ✓ Clinicopathological factor
- ✓ Psychosocial analysis

RESULT

Out of 35 patients of diabetic retinopathy 8.5% patients were found between the age group 31-40, 20% patients are found between 41-50, 25.5% patients were found between 51-60, 28.5% patients were found between 61-70, and 16.6% patients were above in the age group 71.

Age distribution chart shows that the ratio of the diabetic retinopathy was high in the age group 61-70(28.5%). Results shows as age increases the incidence of diabetic retinopathy is also on the rise.

Total 70 patients were recruited out of them, 35 patients had diabetic retinopathy.. In diabetic retinopathy patients, 24 were male and 11 patients were female. In diabetic non-retinopathy patients 19 patients were male and 16 patients were female.

Gender distribution chart shows the ratio of diabetic retinopathy was higher in males as compared with females(69% males and 31% females).

Total 35 patients were recruited for diabetic retinopathy out of them 2 patients had diabetes with 2 years, 5 patients were between 6-10 diabetic years, 9 patients were in 11-15 years, 12 patients in 16-20 years, and 7 patients in 21-25 years. Above observation shows that the diabetic condition increases with the duration of diabetes.

In the above data more than 80% patients were suffering by diabetic retinopathy after 10 years duration of diabetes.

Total 35 patients were found to have diabetic retinopathy. Out of them 11 patients had mild NPDR, 7 patients were with moderate NPDR, 11 patients had stable PDR, and remaining 6 patients were found with severe Proliferative diabetic retinopathy.

Above data shows that maximum number of patients were found to have mild NPDR (31.42%) and stable PDR (31.42) compare to moderate NPDR and severe NPDR

Total 70 patients of diabetes type II were on various treatments modalities . 51 were on oral hypoglycemic drug therapy, and 19 patients were on insulin therapy.

In the present study the level of Triglycerides, total serum cholesterol, LDL, LDL/HDL ,TC/HDL was significantly increased in patients with diabetic retinopathy as compared to patients without diabetic retinopathy . The results showed that the risk of diabetic retinopathy increases with increasing serum lipid level.

Mean of the lipid profile in diabetic retinopathy patients was found to be 209.34, 39.34, 115.34, 182.2, 2.93, 5.40 for TC, HDL, LDL, TG, LDL/HDL, TC/HDL respectively. The TC, LDL, TG level were increased in DR as compared to patients without DR.

The mean of Glycosylated hemoglobin (HbA1c) level in diabetes non-retinopathy patients was found to be 8.14% as against 9.65%. in patients with DR. This shows than the average %HbA1c was higher in diabetic retinopathy patients. The blood pressure of diabetic retinopathy patients was significantly higher as compared to patients without diabetic non retinopathy.

The level of significance using independent t tests were as follows :1) cholesterol had a significance of 0.001 which is < 0.05, which means it was significantly increased in diabetic

retinopathy patients.2) LDL and TG level had a significance value of 0.007 and 0.0001 respectively. In this result we found that TG is highly significant in diabetic retinopathy patients. The level of %HbA1c was found significant in diabetic retinopathy patients (0.002<p).

In psychosocial analysis of diabetic non retinopathic patients score of emotional, physician related regimen related interpersonal was 3.2, 2.2, 3.5 and 3.0 respectively. Thus patients were found to be regimen related stressful. Total score was 3.15 which shows that the patients were distressed in diabetes. In psychosocial analysis of diabetic retinopathic patients score of emotional, physician related, regimen related interpersonal was 3.5,2.28,3.5 and 3.04 respectively. Thus patients were found to be regimen and interpersonal related stressful. Total score was 3.17 which shows that the patients are distressed in diabetes. We compared the mean of the DDS score with diabetic retinopathic and diabetic non retinopathic. There was not considerable difference in stress between these patients. Mean of diabetic non retinopathic patients was 3.15 and for diabetic retinopathic is 3.17 which was statistically not significant.

But in both groups the patients were found to be distressed because of diabetes.

DISCUSSION

There are a number of studies which have shown an association of various risk factors with macrovascular and microvascular complications in diabetes. Some have shown an association between dyslipidemia with microvascular complications of diabetes such as coronary artery disease^[10]. In this study diabetic retinopathy significantly correlates with demographic and clinic-pathological parameters such as age, gender, duration of diabetes, severity of DR, treatment, HBA1c, BP and lipid level i.e total cholesterol, triglyceride and LDL with diabetic retinopathy, as well as psychosocial impact of diabetes on the patients.

In this study we found that out of 35 patients of diabetic retinopathy, 60% patients were more than that of 50 years. So incidence of diabetic retinopathy increases with age. Mohamed Saad also reported that in Oman, mean age of diabetic patients was found to be 40 years. The level of significance in their study was (p<0.006) which is highly significant with age.^[11] In 2013 Dr. Smita Javdekar *et al* also proved that the diabetic retinopathy is highly significant with increasing age of patients.^[13] In 2010 Dr. Rimpal Patel *et al* also found that 77.5 % patients in their study were found to be suffering from diabetic retinopathy^[33]

In study we found that 68 % patients were males. This observation shows that the male female ratio of diabetic retinopathy was higher in males compared to females. This may be because of higher rate of diabetes found in males compared to females. As a result males have a greater tendency to develop diabetic retinopathy compared to females. In 2013 Smita javdekar also reported the same.^[13]

The duration of diabetes also strongly correlates with diabetic retinopathy. More than 10 years of diabetes increases the risk of diabetic retinopathy. In this study we found that 70% patients suffering from diabetes retinopathy had diabetes for more than ten years. This may be because of lack of awareness. People are not aware about the complications of diabetes, so they do not undergo regular screening for diabetic

retinopathy. In UKPDS (united kingdom prospective diabetes study) the duration of diabetes correlated with diabetic retinopathy. As the duration of diabetes increases, the risk of diabetic retinopathy is also on the rise.^[11] In 2003 Dornan *et al* also reported that the age and duration of diabetes is closely related with diabetic retinopathy.^[11] In 1998 Ossama A Haddad and Mohhamed Saad also reported that in Oman, diabetic retinopathy had a 8.7 fold increase after 10 years of diabetes. Level of significance of duration of diabetes and diabetic retinopathy was highly significant ($p < 0.0001$)^[12]. In 2013 Dr. Chaitali Patel *et al.* proved that duration of diabetes strongly correlates with the duration of diabetes ($p < 0.03$).^[7] In 2014 Dr. J Kuli and Dr. Deepanjan Ghosh also reported that duration of diabetes directly correlated with the duration of diabetes with significant value 0.03. Average duration of diabetes was found to be 11.13 years in diabetic patients.^[13] In 2003 Tapp *et al.* also concluded that duration of diabetes directly correlates with diabetic retinopathy.^[14]

The glycosylated hemoglobin (%HbA1c) was found to be highly significant with diabetic retinopathy ($p < 0.002$). Average mean %HbA1c in diabetics without retinopathy was 8.14 whereas in diabetic retinopathy patients it was 9.65, thus higher blood sugar level was significantly associated with diabetic retinopathy. In my result it was found that more than 60 % patients have higher HbA1c level. Blood sugar level is much significant because of polyol pathway which induces the sorbitol osmotic stress. Higher sugar level increases the glucose flux. In 2010 Patel Rimpal *et al* also found that the level of blood sugar is high in diabetic retinopathy patients. The p value of HbA1c in diabetic retinopathy patients was 0.001, which shows higher significance in diabetic retinopathy patients.^[15]

Total serum cholesterol, triglycerides, LDL were significantly associated with diabetic retinopathy. Triglyceride was highly significant (p value > 0.05). In comparison with triglyceride and total serum cholesterol, LDL was not much significant. Dornan *et al* in 2003 reported that dyslipidemia is a major risk factor for diabetic retinopathy. As lipid level is impaired, the risk of diabetic retinopathy also increases.^[10] In 2005 Van Heck *et al* also reported that higher lipid level triggers the endothelial and inflammatory mechanism. This mechanism induces diabetic retinopathy.^[17] In 2013 Smita Javdekar *et al* also reported the same. In cross sectional study by Smita Javdekar *et al.* total cholesterol level, triglyceride and LDL were found to be higher in diabetic retinopathy patients with type 2 diabetes. In 2013 Alpana Mathur *et al.* found that TG, TC, LDL level was higher in type 2 diabetic retinopathy patients ($p < 0.0001$). In 2001 Joussen *et al* also reported that higher TG level incorporate into cell membranes, which change the permeability of a cell membrane and induces edema of the vascular cells, leading to endothelial dysfunction. Higher lipid level is associated with diabetic retinopathy, because higher lipid level damages the tiny blood vessels by endothelial mechanism. Some study also support that the higher VEGF (vascular endothelial growth factor increases) in proliferative diabetic retinopathy.^[18]

There was no any significant relation found regarding psychosocial stress in patients with diabetes having retinopathy as compared to patients without diabetic non-retinopathy. But in both diabetic retinopathy and diabetic retinopathy patients are found to be under stress. Chinmay jani *et al* also reported that patients with diabetic retinopathy have

psychosocial effects which has an adverse effect on the quality of life of patients with diabetes.^[5]

CONCLUSION

From results and discussion of our study we can conclude that poor glycemic control and unbalanced values of serum lipids have risk of development of retinopathy in diabetic patients. TC and TGs blood level were significantly associated with occurrence of retinopathy. And the diabetic patients who had controlled serum sugar and lipid had no or minimum risk of retinal damage. So we can hypothesize that high serum lipids specifically TGs, TC and LDL with in physiological range decrease the risk of retinal damage in diabetic patients.

The psychosocial impact of diabetic retinopathy varies in each individual. partly according to the diabetes status as well as duration of diabetes and particularly due to retinal or other complications involved. In this study we observed some degree of psychosocial impact on DR patients but it was not that much significant.

Therefore estimation of serum lipid and psychosocial impact are very important tools, which helps clinicians in controlling and preventing complications like retinopathy as well as psychosocial problems which may increase complications in diabetic patients.

References

1. <http://guidelines.diabetes.ca/browse/chapter3>
2. <http://www.idf.org/about-diabetes/facts-figures>
3. Sheikh Mohammed Shariful Islam "Social and economical impact of diabetes in bangladesh" BMC public health, 2013, 17, 23-26.
4. Michael J. fowler, "The evaluation of micro vascular and macro vascular complications in diabetes" Journal of clinical diabetes 2008, 26, 77-82.
5. Jani Chinmay, Desai Tejas, Parikh Sonal "Correlation between types of diabetic retinopathy and its psychosocial impact" peers p prints 2015.
6. Royal college of ophthalmology "Diabetic retinopathy guideline" 2012, 5-6
7. Patel Chaitali, Haridas N, Chauhan Kiran "A study of serum magnesium level in diabetic retinopathy patients" Indian journal of applied research 2013 vol 3, 5, 482-484.
8. International council of ophthalmology "ICO guideline for eye care" 2015 <http://emedicine.medscape.com/article/1225122-overview>
9. Dornan TL, Carter RD, Bronn A J, Turner RC "Low density lipoprotein cholesterol an association with the severity of diabetic retinopathy. Diabetologia, 22,167-170, 1982.
10. UK Prospective Diabetes Study (UKPDS) Group "Intensive blood-glucose control with sulphonyl urea or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33)" Lancet 1998; 352: 837-53
11. El Haddad OA, Saad MK. "Prevalence and risk factors for diabetic retinopathy among Omani diabetics." *Journal of ophthalmology*, 1998 Aug;82(8):901-6
12. Smita Dileep Javdekar "Correlation of Diabetic Retinopathy with Serum Lipids" *International Journal of Recent Trends in Science And Technology*, ISSN

- 2277-2812 E-ISSN 2249-8109, Volume 8, Issue 1, 2013 pp 22-26.
13. Dr. J.J.Kuli, Dr. Deepanjan Ghosh “Comparison and Measurement of Serum Levels of Magnesium (Mg) & Zinc (Zn) In Patients with Non- Proliferative Diabetic Retinopathy (NPDR) & Proliferative Diabetic Retinopathy (PDR).” *Journal of Dental and Medical Sciences*, p-ISSN: 2279-0861. Volume 13, Issue 12 (Dec. 2014), 63-66.
 14. Tapp *et al.* “The prevalence of and factors associated with diabetic retinopathy in the Australian population.” *Journal of diabetes care* 2003 Jun;26(6):1731-7.
 15. Patel Rimpal *et al.* “Co-Relation Of Serum Lipids and Glycosylated Haemoglobin With Changes In Retina In Type -2 Diabetes.” *International Journal of Basic and Applied Physiology* Vol. 2 Issue 1, 16-21.
 16. M.V Van hack *et al* “ Inflammation and endothelial dysfunction are associated with retinopathy: the Hoorn Study” *Diabetologia* (2005) 48: 1300–1306
 17. Jousen *et al* “A central role for inflammation in the pathogenesis of diabetic retinopathy.” 2004 Sep;18 (12):1450-2. Epub 2004 Jul 1.

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