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RISK FACTORS FOR CLINICALLY SIGNIFICANT MACULAR EDEMA IN NONPROLIFERATIVE DIABETIC RETINOPATHY PATIENTS

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ABSTRACT

Aim: To determine the risk factors for Clinically significant macular edema (CSME) in Non proliferative diabetic retinopathy patients(NPDR).

Methods: This study was an unmatched case control hospital based study containing 92samples , 46 cases NPDR patients with CSME and 46 controls NPDR patients . A detailed history taking, Visual acuity assesment,slit lamp examination by 90D , indirect ophthalmoscopy by 20D and confirmation of macular edema with OCT. Data collected were analysed for risk factors.

Observation: Most of the risk factors were found to be higher in CSME group except TLC and PLT. FBS,HbA1c,Total cholesterol,PCV,Serum urea and Urinary albumin have major role in developing CSME .Most of the patients were males, hypertensive, non smokers with moderate NPDR .Odds ratio was found to be higher for Hb,HbA1c,Serum urea and Urinary albumin.

Conclusions: Adequate control of risk factors and reduction of risk factors with greater odds ratio helps in reducing the prevalence of CSME.

KEYWORDS : CSME,NPDR,Risk Factors.

INTRODUCTION

Most common complication that can develop in diabetic patients is diabetic retinopathy. It is the leading cause of blindness in people aged 20-64 years .From Aravind eye disease survey in south India found 27% prevalence of diabetic retinopathy in people aged 50 years or older. Which was similar to a study conducted in an urban population from Hyderabad reported 22% prevalence[1]. Risk factors leading to diabetic retinopathy are duration of diabetes, hyperglycemia , hypertension, endogenous and exogenous insulin, proteinuria and nephropathy, cigarette smoking and alcohol consumption, obesity, exercise ,pregnancy and reproductive measures and inflammation[2].

Clinically significant macular edema is the most common cause of moderate visual loss in non proliferative diabetic retinopathy.CSME is defined as situation in which at least one of the following criterion is fulfilled 1)Retinal thickening with in 500micro metre of centre of macula 2)Hard exudates with in 500 micro metre of centre of macula with adjacent retinal thickening and 3)Retinal thickening one disc area (1500micro meter) or larger, any part of which is within one disc diameter of the centre of the macula[3].This study was to determine various risk factors for developing CSME in NPDR patients.

MATERIALS AND METHODS

This was an unmatched case control hospital based study including 92 samples with 46 NPDR patients with CSME and 46 NPDR patients with out CSME who were consulting in ophthalmology department at justice K S Hegde Medical Academy, Mangaluru during the study period January 2018 to June 2019.Ethical Clearance was obtained from Ethical committee.Universal sampling of cases done, taking consecutive cases Type 2DM NPDR patients with CSME and controls Type 2 DM patients with out CSME were included in the study.

Patients with other diseases of retina like BRVO,Arterial occlusion, Retinal detachment,Optic atrophy,Retinitis pigmentosa ,Cystoid macular edema and macular edema due to other causes were excluded from the study.

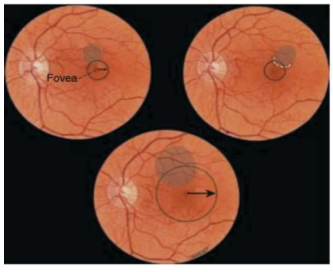

Fig 1 Clinically significant macular edema

An informed consent was obtained from every subject included in the study. After getting history from the patient a detailed anterior segment examination using slit lamp biomicroscopy by 90D followed by indirect ophthalmoscopy by 20D ,CSME was diagnosed using above mentioned diagnostic criteria.

Then confirmation of the findings by OCT. Risk factors selected for this study were Age at diagnosis,Sex,Duration of diabetes, Hypertension,Familyhistory,Smoking,Hb,TLC,FBS,HbA1C, PLT,PCV, Total cholesterol,Serum urea ,Serum creatinine and Urinary albumin.

Statistical analysis :

Quantitative variables such as duration of diabetes ,Hb,Fbs,Total cholesterol will be expressed in terms of mean and standard deviation.Qualitative variables such as NPDR grade , sex etc. expressed in terms of percentage and proportions.Odds ratio of the diseased calculated and regression analysis done to find out risk factors.

OBSERVATIONS

This study included 92 samples, 46 cases NPDR patients with CSME and 46 controls NPDR patients without CSME.

Table 1 Comparison of continuous variables using independent t test

	Group	N	Mean	Std. Deviation	T	Df	P-Value
Age at diagnosis	NPDR with out CSME	46	57.020	9.346	-1.182	89	0.24
	NPDR+CSME	46	59.220	8.377			
Durationof diabetes(Years)	NPDR with out CSME	46	9.674	4.432	-1.189	90	0.238
	NPDR+CSME	46	10.804	4.684			

Hb(g/dl)	NPDR with out CSME	46	10.907	1.436	-1.425	90	0.158
	NPDR +CSME	46	11.322	1.358			
TLC(Cells/mm3)	NPDR with out CSME	46	7502.174	996.993	0.563	90	0.575
	NPDR +CSME	46	7384.783	1004.206			
PLT(Cells/mm3)	NPDR with out CSME	46	1.764	0.635	1.478	76.564	0.143
	NPDR +CSME	46	1.600	0.406			
PCV(Cells/mm3)	NPDR with out CSME	46	40.420	3.547	-2.24	90	**0.028**
	NPDR +CSME	46	41.994	3.183			
FBS(mg/dl)	NPDR with out CSME	46	118.630	28.423	-9.098	90	**<0.001**
	NPDR +CSME	46	162.739	16.533			
HbA1c(mmol/mol)	NPDR with out CSME	46	6.724	1.876	-3.586	90	**0.001**
	NPDR +CSME	46	7.990	1.489			
Total cholestrol(mg/dl)	NPDR with out CSME	46	190.848	18.381	-8.519	80.822	**<0.001**
	NPDR +CSME	46	219.087	12.944			
Serum urea(mg/dl)	NPDR with out CSME	46	39.817	6.231	-2.619	90	**0.01**
	NPDR +CSME	46	43.365	6.751			
Serum creatinine(mg/dl)	NPDR with out CSME	46	1.202	0.322	-1.466	90	0.146
	NPDR +CSME	46	1.290	0.250			

From this study all risk factors were found to be higher in CSME group except TLC and PLT which were higher in NPDR group.

Statistically significant p value (<0.05) was noted for PCV, FBS, HbA1c,Total cholesterol and serum urea.

Comparison of categorical variables using chi square test Males were higher in CSME group which was not statistically significant (p=0.519).Hypertensive patients were higher in CSME group which was not statistically significant. Family history was absent in all patients in the CSME group so p-value cannot be calculated.Smokers were less compare to nonsmokers in the CSME group and was not found to be statistically significant(p=0.283).Moderate NPDR was present in the majority of patients in both the groups and was not found to be statistically significant (p= 0.289).Urinary albumin was present in all cases of CSME as compared to only 56.5% of NPDR without CSME. With a statistically significant with a p-value of <0.001.

Risk factors with significant odds ratio was calculated .For Hb,TLC,PLT,PCV,FBS,HbA1c ,Total cholesterol,Serum urea,Serum creatinine,Hypertension,Smoking and Urinary albumin. Odds ratio was found to be2.696, 0.672,0.701,2. 095,2.150,2. 643, 2.533, 2.721, 2.078,1.240,1.590 and 2.769. Which indicate the chance of developing CSME in NPDR patients.

DISCUSSION

In this study, while comparing risk factors for CSME in NPDR patients between cases and controls age at diagnosis was higher in cases than controls where as in a case-control study conducted by Ong ming J et al there was no significant difference in age between two groups[4] . CSME found to be higher in older individualsin a study conducted by Asensio-sanchez V M et al, Hirai FE et aland Wong TY et al[5,7,10].

In this study duration of diabetes was found to be higher in cases with a p value of 0.238. Duration of diabetes was significantly associated with CSME in a study conducted by Ong ming J et al, Knudsen LL et al, Hirai FE et al and Nithyanandam S et al with p< or = 0.001 [4,6,7,8]. In this study hemoglobin values were higher in cases than control and were not found to be statistically significant, while hemoglobin values were found to be significant in a study done by Ong ming J et al[4] .For cases, TLC and PLT were lower in this study and no significant association was noted ,in a study done by Ong ming J et al[4].Packed cell volume was higher and significant in this study which was found to be significant in the CSME group in a study done by Ong ming J et al[4]. In this study the risk factors PCV,FBS, HbA1c, total cholesterol and serum urea were significant with p value of 0.028 for PCV,p <0.001 for FBS, HbA1c , total cholesterol and p = 0.01 for serum urea which was similar to a case-control study by Ong ming J et al with a significant P value of 0.001 for FBS ,HbA1c and total cholestrol[3]. A study done by Asensio-sanchez V M et al and in another study done by Knudsen LL et al (p-value 0.036) level of HbA1c was significantly associated with CSME[5,6].Then hyperglycemia was a consistent risk factor in a study done by Wong TY et al[10].

Serum creatinine was found to be higher in this study similar to Ong ming J et al study[4]. Serum urea and creatinine which determining renal function was found to be higher in the CSME group. Then comparing other variables males were higher in both the groups 65.2% and 58.7% respectively, no significant difference found in gender in a study conducted by Ong ming J et al[4].

In another study by Asensio-sanchez V M et al 60% of women were having CSME and 40% of men were having CSME also in another study by Wong TY et al women were greater in number[5,10].

Hypertension was found to be present in both the groups with slight higher percentage of patients detected in CSME group whereas in a study by Knudsen LL et alsystolic BP was associated with CSME with a p-value of 0.063[6]. In another study by Wong TY , BP pressure was higher for patients detected with CSME[10].In this study family history was not a significant factor causing CSME. Family history was not a risk factor in any of other studies. Smokers were present in both groups, less compare to non smokers but not statistically significant in CSME group. A study conducted by Kamoi K et al smokers were higher in the CSME group than those without CSME[9] .

In this study, while classifying NPDR into different grades more patients found to be higher in moderate NPDR grade, almost half of the patients from both groups similar result was attained in a study done by Wong TY et al where as in a study by Hirai FE CSME with severe grade was higher[10,7]. In another study by Nithyanandam S et al greater number of patients with diabetic retinopathy were having mild-moderate NPDR[8] .In this study, urinary albumin was present in all patients with CSME with a statistically significant p-value <0.001. Serum albumin was statistically significant in the Ong ming J et al study with a p-value of 0.001, hypoalbuminemia occurring secondary to renal loss of albumin postulated to be a factor involved in the formation of macular edema[4]. A similar association was found in a study conducted by Knudsen LL et al with proteinuria significantly higher in the CSME group with a p-value of 0.004[6]. From this study PCV, FBS, HbA1c, Total Cholesterol, Serum Urea and Urinary albumin were found to be important risk factors leading to CSME. Among different variables risk factors having significantly high odds ratios were Hb, PCV, FBS, HbA1c, Total Cholesterol, Urea, Creatinine and Urinary Albumin (>2).With greatest odds ratio for Hb,HbA1c, Serum urea and Urinary Albumin were 2.696,2.643,2.721,2.769 respectively.This means for each unit increase in Hb odds of having CSME is 2.696 times higher. The risk factor having the least odds ratio is TLC (0.672). Which is comparable to a study conducted by Ong ming J et al in which total cholesterol and HbA1c having a high odds ratio of 3.054 and 2.955 respectively[4]. Whereas in a study done by Asensio-sanchez V M et al

greatest odds ratio was for HbA1c(2.4)[5].

CONCLUSION

Among the risk factors, most of them were found to be higher in the CSME group except TLC and PLT. Risk factors with significant p-value were found to be FBS(<0.001), HbA1c(<0.001), PCV(P=0.028),Total Cholesterol (<0.001) and Serum Urea(P=0.01). Urinary albumin was present in all patients with CSME with a significant p-value of <0.001. The odds ratio was calculated for significant risk factors. The odds ratio found to be higher for Hb (2.696), HbA1c(2.643), Serum Urea (2.721) and Urinary Albumin (2.769). Which determine the chance of having CSME with an increase in value of those risk factors. Hence it is concluded from this study that adequate control of risk factors helps in reducing the prevalence of CSME. The reduction of risk factors having a greater odds ratio further helps in decreasing the prevalence of CSME.

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