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Original Research Article

To study the relation between the clinical risk factors and age related macular degeneration

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Abstract

Background: Age related Macular Degeneration is a leading cause of irreversible vision loss in older adults with significant social and economic burden worldwide. We have discussed different types of ARMD- wet and dry, highlighting the modifiable risk factors that can significantly slow the disease progression and in some cases reverse early stage changes.
Aims and Objectives: To establish and understand the clinical risk factors associated with dry and wet ARMD.
Materials and Methods: A cross-sectional comparative study conducted at a tertiary care hospital. Total 202 subjects were recruited and categorized in two groups of 101 each, one group consisting of patients of ARMD and the other group had normal controls selected as per the inclusion and exclusion criteria. The risk factors studied were gender, hypertension, history of smoking, alcohol, body mass index(BMI), lipid levels, type of diet(vegetarian/ non vegetarian).
Result: we conclude that out 101 ARMD Cases, 98 were diagnosed as dry ARMD and 3 were diagnosed with wet ARMD. Smoking, alcohol drinking and nonvegetarian diet were interpreted as high risk factors while female sex, high blood pressure, high body mass index (BMI) and abnormal lipid levels were considered as moderate risk factors. No statistically significant difference in risk factors between wet and dry ARMD could be seen.
Conclusion: Smoking, alcohol drinking and nonvegetarian diet were significant risk factors associated with development of ARMD.

Keywords: ARMD, Risk factors, Smoking.

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1. Introduction

Age related macular degeneration (ARMD) is undoubtedly, amongst the major causes of permanent vision loss in elderly population globally.[1] It is defined as a disorder in which there is imbalance in the lipid, complement, inflammatory, angiogenic, and extracellular matrix pathways.[2] 8.7% of the global population suffers from ARMD. As illustrated by a systemic review and meta-analysis, the depicted number of people with the disease in 2020 is around 196 million that will reach up to 288 million in 2040.[3]

The retinal pigment epithelium (RPE) is a single cell layer. It plays a key part in ARMD pathogenesis.[4] It undergoes through fast metabolism and it is exposed to a lot of oxidative stress, continuous exposure to visible light and a large amount of polyunsaturated fatty acid content (PUFA).[5] As we age, the capacity to oxidize decreases which thus compromises the innate repair capacity of RPE.[6] Due to aberrancy of RPE cells there occurs autophagic degradation of photoreceptor outer segments,[7] which then causes accumulation of lipids in Bruch's membrane and further vandalization of its permeability.[8] The lipids generate drusen, as depicted in **Figure 1** and **Figure 4** and interferes in nutrition of RPE cells, inducing a gradual atrophic process.[9]

Early ARMD is mostly asymptomatic.[10] Clinically, retinal examinations reveal RPE mottling and the presence of extracellular drusen deposits in the posterior pole. Geographical atrophy is significantly predisposed to develop in cases with large and confluent drusen, characterized by well-defined areas of RPE cell loss leading to

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hypopigmentation.[11] The advanced level of ARMD are distinguished into two major forms: non neovascular or geographical and neovascular, wet or exudative ARMD.[12] In wet ARMD, the RPE generates significant quantities of vascular endothelial growth factor (VEGF). This leads to the degeneration of the blood-retinal barrier and the emergence of delicate and slender blood vessels originating from the choroid. This process, known as neovascularization, involves the vessels penetrating through Bruch's membrane into the retina. The leakage of blood from these abnormal, permeable vessels results in edema and sudden vision loss.[13] **Figure 2** depicts the formation of a choroidal neovascular membrane confirming a significant increase in retinal thickness on OCT as illustrated by **Figure 3**.

Numerous risk factors for ARMD have been studied, including demographic (e.g.- ethnicity and race), genetic (e.g. complement factors), nutritional (e.g.- antioxidant, vitamins and dietary), lifestyle (e.g. alcohol and smoking), environmental (exposure to sun) medical (e.g. diabetes mellitus, any cardiovascular ailment, hypertension), etc.[14]

Research indicates that females bear a greater burden of ARMD compared to males. Additionally, blindness attributed to ARMD is more prevalent among elderly women. This heightened susceptibility among women may be attributed to factors such as limited access to medical care worldwide, making them more vulnerable to diseases leading to blindness.[15] A biological explanation that why the female gender is more affected by ARMD is the established shielding effect of estrogen against vascular diseases. Estrogen provides protection against maculopathy by reducing the degeneration of both vascular and retinal tissue.[16] As age advances the estrogen reduces significantly after menopause.

Smoking is directly linked to increased levels of oxidative stress, increased platelet aggregation, elevated fibrinogen levels, reduced antioxidants in the blood, and diminished levels of high-density lipoprotein.[17]

There is increased evidence that suggests cataract surgery as a prominent predictor, with a four and threefold increase in the chances of neovascular ARMD and geographic atrophy respectively.[18] Cataract surgery itself induces an inflammatory response that disrupts or further stimulate delicate leaking new vessels characteristic of wet ARMD. Also, surgery might stimulate progression of geographic atrophy, evolution of choroidal neovascularization (CNV) or lead to a weaker anti-VEGF treatment response. In conclusion, multiple studies have demonstrated an increased risk as well as higher stage of ARMD in pseudophakic patients.[19]

The association of high serum lipid levels with ARMD has also been studied by many authors. Dyslipidemia, as a risk factor is often associated with the formation of drusen, which are likely to develop into early ARMD. Elevated levels of high-density lipoprotein cholesterol (HDL-C) improves the endothelial function and reduces the risk of atherosclerosis. A positive association between the HDL-C level and ARMD risk have been reported by numerous studies, while some of the studies have also shown an inverse relationship.[20]

A higher intake of red meat as compared to white meat has been correlated with higher levels of nitrosamines (*N*-nitroso compounds), heme iron, and advanced glycation end products. These extremely reactive species behave on their own or in conjunction with other inflammatory pathways to initiate ARMD.[21]

Studies have also illustrated a positive connection between AMD and Hypertension. Angiotensin II also known as Ang II, which is the major culprit of hypertension, induces inflammatory responses, injury to tissues and endothelial dysfunction in the eye and thus plays a bigger part in AMD pathogenesis.[22]

In the Age-Related Eye Disease Study,[23] a notable correlation exists between the history of diabetes mellitus and the incidence of neovascular ARMD when compared to individuals without diabetes. Diabetic conditions contribute to the accumulation of steady advanced glycation end products (AGEs) in various tissues, including the RPE cell layers and photoreceptors. This observation underscores the implication of AGE deposition in diabetic conditions in the pathophysiology of ARMD.[24]

The possible link between ARMD and body weight has also been extensively studied. Excess body fat affects the deposition and transport process of carotenoids from blood to macula. This leads to decrease in the number of macular pigments at the fovea causing reduced vision and finally blindness. [25]

Various writers have undergone research to look into the possible connection between drinking alcohol and the likelihood of developing AMD. The Reykjavik Eye Study (RES)[26] suggests a protective role of alcohol, but specifically when consumed in moderate amounts. Conversely, a different study has revealed an increased risk of ARMD in individuals who consume higher quantities of both alcohol and beer.[27]

There have been very few studies on ARMD and its risk factors on Indian populations and our study aims to co relate the risk factors linked with the various stages of age related macular degeneration and therefore to be able to recognize the population at risk and to aid in early diagnosis and treatment of ARMD.

2. Aims and Objectives

The aim of our study is to evaluate the major risk factors related to ARMD and to compare the risk factors between dry and wet ARMD.

3. Material and Methods

The research was undertaken with the approval of the Institutional Ethical Committee, aligning with the principles set forth in the Declaration of Helsinki for human subjects' research and in accordance with the guidelines of the ophthalmology department. Prior to their involvement in the study, all patients provided informed consent. The study design was prospective, observational, and centred within a single hospital setting, providing a focused examination of ARMD within this specific context.

This prospective study involved 102 participants, consisting of 101 cases with ARMD and 101 controls. The research was conducted at a single tertiary care centre.

In the control group, each eye exhibited an absence of drusen or had only non-extensive small drusen. For the case group, inclusion criteria were met if at least one eye displayed one or more intermediate drusen, extensive small drusen, or pigment abnormalities associated with ARMD. Alternatively, inclusion criteria were also met if at least one eye had one or more large drusen or extensive intermediate drusen. Additionally, individuals with at least one eye showing signs of geographic atrophy or neovascular ARMD were considered within the case group. All patients, male and female 45 years and above diagnosed with ARMD (dry and wet) were included in the study.

Subjects < 45 years of age, patients with dense corneal, lenticular opacities like dense cataract or vitreous opacities; any active ocular inflammation, obstructing the view of retina in which fundus examination cannot be performed, patients with other retinal disorders, such as central serous retinopathy, retinal detachment, diabetic retinopathy, hypertensive retinopathy and any previous vitreoretinal surgeries, previous laser photocoagulation or any ocular surgery in past six months, conditions such as polypoidal choroidal vasculopathy, retinal angiomatous proliferation ,myopic chorioretinal degeneration and any macular dystrophies were excluded from the study. Furthermore, patients on steroids and NSAIDS were also excluded and subjects not giving valid consent for the study were also not included in the study.

Detailed history of patients was taken to know about the risk factors related to ARMD. The risk factors studied are gender, hypertension, history of smoking, (If the duration of smoking was less than one year, individuals were classified as non-smokers), alcohol, body mass index(BMI), lipid levels, type of diet(vegetarian/ non vegetarian).

Body mass index (BMI); for this height and weight were measured and BMI calculated using the standard formula Obesity in Asian population was defined as BMI >25 kg/m^2.

Blood pressure measurements were conducted in the sitting position using a mercury sphygmomanometer on the right arm. Two readings were obtained, with each reading taken 5 minutes apart. The mean of these two readings was calculated and considered as the final blood pressure (BP) for each individual. Participants with a blood pressure exceeding 140/90 mmHg, in accordance with the 2020 International Society of Hypertension global hypertension practice guidelines, and those who were already taking medications to manage blood pressure were categorized as hypertensive patients.

History of diabetes mellitus: Included as known diabetes if they were using any hypoglycemic drugs, either oral, insulin or both. Newly diagnosed diabetes is defined as fasting blood sugar levels (>125mg/dl). Random blood sugar (>200 mg/dl), post meal sugar (>200 mg/dl) and HbAIc of >6.5 mg/dl (American Diabetes Association)

Dyslipidemia was defined as either a known case of dyslipidemia who were on lipid lowering drugs or LDL (low density lipoprotein)> 100 mg/dl, HDL (high density lipoprotein) < 40 mg/dl, total cholesterol more than 200 mg/dl or triglycerides > 150 mg/dl. (American Heart Association).

Patients underwent ophthalmological examination including uncorrected visual acuity, best corrected visual acuity, refraction, measurement of intraocular pressure (using Goldman applanation tonometer) and slit lamp examination of anterior segment and posterior segment. The lens status was defined as immature cataract, aphakia, pseudophakia and clearlens. The fundus examination was conducted using both direct and indirect ophthalmoscopes, as well as slit lamp biomicroscopy, employing a plus power convex 90D lens. Prior to the examination, pupil dilation was achieved using tropicamide and phenylephrine.

The patients were further investigated by blood tests that included blood sugar – Fasting and post prandial, HbA1C and lipid profile. OCT macula and fundus photo images of patients were taken.

Data analysis was done using licensed SPSS software version 21.0 (Chicago, Illinois). Univariate analyses were done initially. Descriptive statistics were used to calculate frequencies of categorical variables, and measures of central tendencies and dispersion were used to describe continuous variables. Chi-square test was used to compare between categorical variable and for continuous variable unpaired t test was used.

A p-value <0.05 was considered as statistically significant.

4. Results

Out of the total 202 patients included in the study, the case group exhibited a gender distribution of 54.5% females and 45.5% males, while the control group displayed 47.5% females and 52.5% males. No statistically significant gender

disparities were discerned. The mean age of cases and controls was 59.9±8.5 years and 60.1±8.6 years respectively.

The mean systolic blood pressure (SBP) for cases was 131.1±8.4 mmHg, statistically significantly higher than the control group's 124.9±5.7 mmHg. (**Table 1**). Similarly, the mean diastolic blood pressure (DBP) for cases (84.4±6.8 mmHg) was statistically higher than that of controls (82.6±4.7 mmHg) (**Table 2**).

A noteworthy discrepancy emerged in smoking history, with 69.3% of cases reporting a history of smoking compared to a mere 13.9% in the control group (**Table 3**)

A statistically significant result surfaced in alcohol consumption history, with 41.6% of cases reporting a history of alcohol intake, in stark contrast to the 6.9% observed in the control group (**Table 4**).

The mean BMI for cases stood at 32.5±2.4 kg/m², indicating a statistically significant difference from the control group's mean BMI of 25.2±2.7 kg/m².

Cases exhibited elevated triglyceride levels (204.1±39.6 mg/dL) compared to controls (139.2±19.1 mg/dL), a statistically significant difference. Additionally, cases demonstrated lower HDL levels (45.9±12.9 mg/dL) and higher LDL levels (154.8±25.3 mg/dL) than controls (HDL: 54.5±4.3 mg/dL, LDL: 117.7±17.1 mg/dL), both statistically significant. A statistically significant distinction was noted in dietary habits, with 87.1% of cases adhering to a non-vegetarian diet compared to 50.5% in the control group (**Table 5**).

No statistically significant differences were identified in sociodemographic and clinical parameters between wet and dry ARMD cases. (**Table 6**)

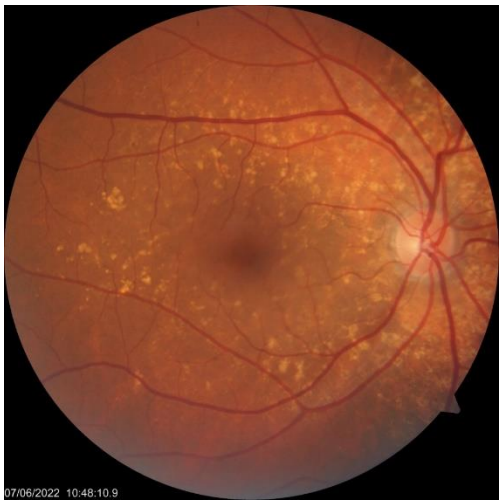

Figure 1: Right eye fundus with multiple well defined yellow hypopigmented lesions on and around the fovea depicting drusens

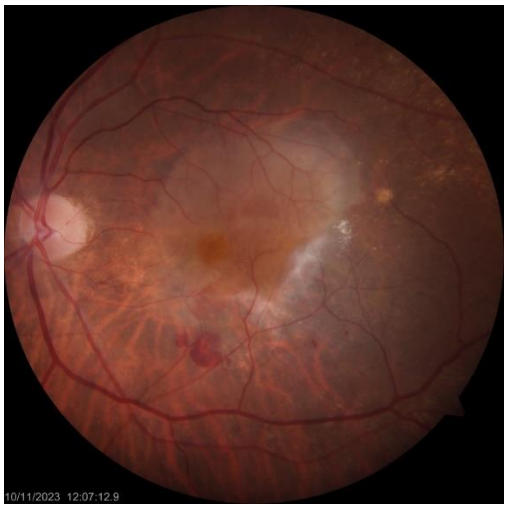

Figure 2: Left eye multiple hypopigmented lesions present on and around the fovea with absent foveal reflex with yellowish choroidal neovascular membrane with raised area of subretinal fluid and subretinal haemorrhage inferior to fovea.

Table 1: Comparison of systolic BP between both groups

Group	Mean	SD	Median	Minimum	Maximum	p-value
Case	131.10	8.372	130.00	110	160	0.0001
Control	124.87	5.693	124.00	110	140	
Total	127.99	7.794	129.00	110	160	

Table 2: Comparison of diastolic BP between both groups

Group	Mean	SD	Median	Minimum	Maximum	p-value
Case	84.39	6.748	86.00	60	100	0.032
Control	82.62	4.671	82.00	70	98	
Total	83.50	5.856	82.00	60	100	

Table 3: Comparison of smoking between the two groups

History of smoking	**Group**				**p-value**
	Case		Control		
	Count	%	Count	%	
NO	31	30.7%	87	86.1%	0.0001
YES	70	69.3%	14	13.9%	
Total	101	100.0%	101	100.0%	

Table 4: Comparison of alcohol consumption between two groups

History of alcohol drinking	**Group**				**p-value**
	Case		Control		
	Count	%	Count	%	
NO	59	58.4%	94	93.1%	0.0001
YES	42	41.6%	7	6.9%	
Total	101	100.0%	101	100.0%	

Table 5: Comparison of diet among both groups

Diet	**Group**				**p-value**
	Case		Control		
	Count	%	Count	%	
Non veg	88	87.1%	51	50.5%	0.0001
Veg	13	12.9%	50	49.5%	
Total	101	100.0%	101	100.0%	

Table 6: Comparison between wet and dry ARMD

Age group	**ARMD**				**p-value**
	Dry (n=98)		Wet (n=3)		
	Count	%	Count	%	
Gender					
Female	55	56.1%	0	0.0%	0.055
Male	43	43.9%	3	100.0%	
Smoking history	67	68.4%	3	100.0%	0.242
Alcohol drinking	39	39.8%	3	100.0%	0.052
Diet					
Non Veg	85	86.7%	3	100.0%	0.499
Veg	13	13.3%	0	0.0%	

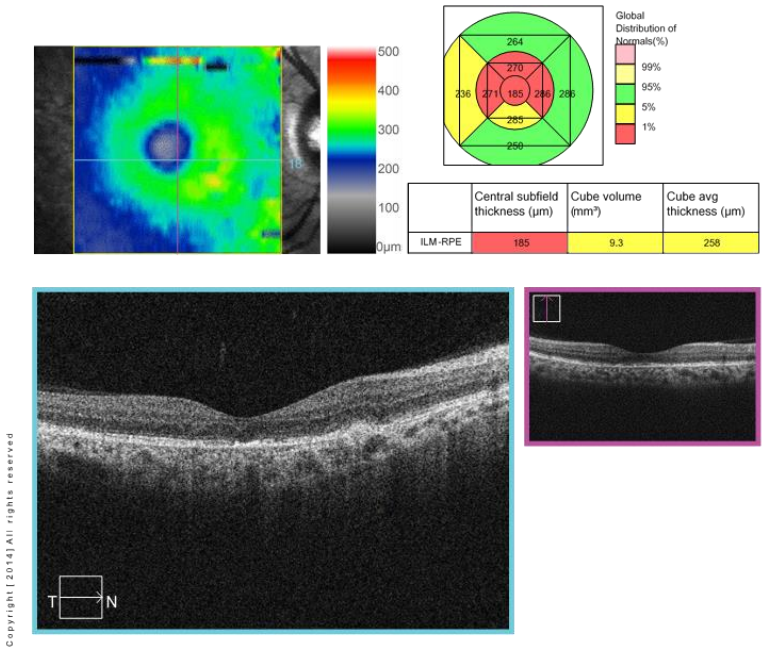

Figure 3: Left eye OCT macula depicting discrete hyper reflective elevation in the retinal pigment epithelium layer involving fovea and parafoveal drusenoid PED

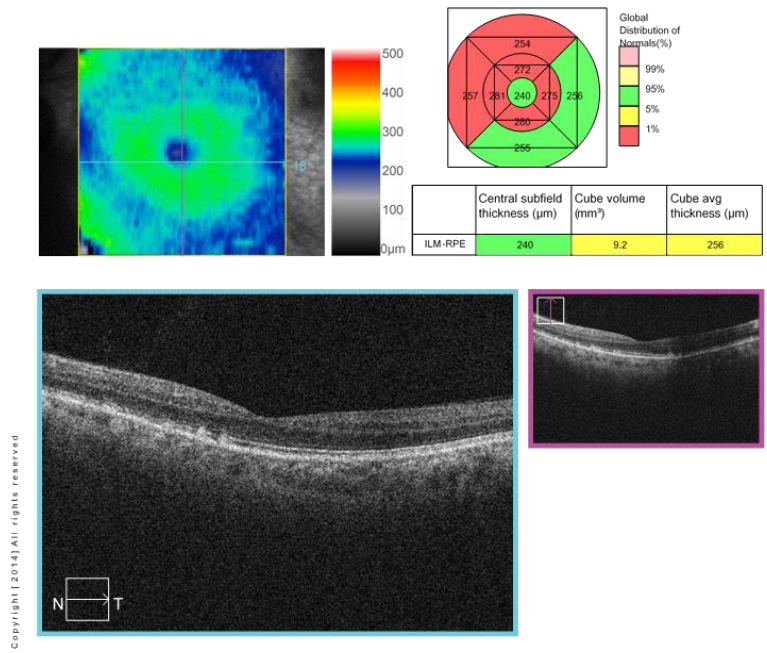

Figure 4: Left eye OCT macula depicting discrete hyper reflective elevation in the retinal pigment epithelium layer involving fovea and parafoveal drusenoid PED

5. Discussion

In our present study, out of the 101 participants in case group, 55 (54.5%) were female and 46 (45.5%) were male which supports the findings from other studies. The mean ages of cases and controls were 59.9±8.5 and 60.1±8.6 years, respectively, with no statistically significant difference

According to study conducted by Ritu Sharma et al, a diastolic blood pressure of more than 80 mmhg was a significant risk factor for ARMD. In our study there was statistically significant increase in systolic BP and diastolic BP both among the cases which could prove the above theory to be correct.[28]

Smoking stands out as the most significant risk factor among various factors implicated in the development of ARMD. Study done by Richard A. Armstrong in 2015, concluded that smoking is the risk factor which was most consistently associated with ARMD. Smokers had three times higher risk of ARMD as compared to non-smokers.[29] In our study, out of the 101 participants in case group, 70 (69.3%) had history of smoking. Out of the 101 participants in control group, 14 (13.9%) had history of smoking.

Similar sentiments can be attributed to alcohol consumption. Studies offer genetic evidence suggesting that heightened alcohol intake may serve as a causal risk factor for geographic atrophy (GA).[27] In our study, among the 101 participants in the case group, 42 individuals (41.6%) reported a history of alcohol consumption.

Talking about triglycerides levels, HDL and LDL levels and BMI in our study, the results of both were statistically significant. Sharma et al. observed a connection between elevated lipid levels and a higher BMI with the progression of ARMD to late stages when compared to non-ARMD cases. These findings align with the results demonstrated by Seddon et al., who also highlighted the correlation between ARMD and higher BMI.[17]

According to Chong EW et al., greater consumption of red meat, as opposed to white meat, has been linked to elevated levels of nitrosamines. These compounds activate inflammatory pathways, potentially initiating ARMD.[21]

As illustrated by Amanda strombom et al. A plant-based diet reduces inflammation and lowers high sensitivity C-reactive protein (hsCRP).[30] These factors combine to give vegetarians a lower risk of dry ARMD. Epidemiological studies have shown that consuming meat raises the risk of dry ARMD while consuming plant foods lowers the risk. In the present study, out of the 101 participants in case group, 88 (87.1%) were non-vegetarian and 13 (12.9%) were vegetarian. Out of the 101 participants in control group, 51 (50.5%) were non-vegetarian and 50 (49.5%) were vegetarian. This difference was found to be statistically significant

Coming to the risk factors associated with wet ARMD, no significant difference in risk factors could be seen between dry versus wet ARMD in our study.

The distribution of participants based on gender, and clinical parameters showed no significant variations between cases and controls. However, significant differences were discovered in systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglyceride levels between cases and controls. Additionally, lifestyle factors such as smoking, alcohol consumption, and dietary habits showed statistically significant differences between the two groups. The findings underscore the importance of public health interventions aimed at mitigating modifiable risk factors, such as promoting healthier lifestyles, smoking cessation programs, dietary modifications, and regular eye screenings, to reduce the burden of ARMD.

Age-related macular degeneration remains a significant public health concern, particularly in aging populations worldwide. Our study has thoroughly investigated the various risk factors associated with ARMD, shedding light on both modifiable and non-modifiable elements that contribute to its development and progression. The summary concludes with the absence of significant differences in sociodemographic and clinical parameters between wet and dry ARMD cases, emphasizing the importance of these findings in understanding the risk factors and characteristics of ARMD. Through a comprehensive review of existing literature, it has become evident that age, genetics, smoking, diet, obesity and cardiovascular health are among the primary risk factors influencing the onset and severity of ARMD.

While considerable progress has been made in understanding ARMD risk factors, there are still gaps in knowledge that warrant further investigation. Longitudinal studies with larger sample size are need to validate associations and elucidate underlying mechanisms. Additionally, interventions targeting multiple risk factors simultaneously may offer greater efficacy in preventing ARMD onset or slowing its progression.

The limitation of our study is that we could include only three patients of wet ARMD. A study with more number of wet ARMD patients is required to comment further.

6. Conclusion

This study contributes valuable insights to the field of ARMD research, emphasizing the multifactorial nature of the disease and the importance of holistic approaches in its prevention and management. By addressing both modifiable and non-modifiable risk factors, public health efforts can strive towards reducing the global burden of ARMD and improving the quality of life for affected individuals.

It is recommended that early diagnosis, early initiation of treatment, good control of risk factors of ARMD and regular follow up of the patients is a must for prevention of complications and early diagnosis and appropriate treatment of ARMD.

7. Source of Funding

Not required.

8. Conflict of Interest

None.

9. Ethical

Ethical No.: HIMSR/IEC/0068/2022.

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