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Effect of Photodynamic Therapy with Verteporfin in Patients with Choroidal Neovascularisation Caused by Age Related Macular Degeneration- A Prospective Study

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KEYWORDS
Age-related macular degeneration, choroidal neovascularization, photodynamic therapy

ABSTRACT:

Aim: To see the Effect of Photodynamic therapy with verteporfin in patients with choroidal neovascularisation caused by age related macular degeneration

Materials and methods: The Study was prospective. 118 patients diagnosed with CNV secondary to AMD between February 2017 to March 2019, were including, study conducted in the department of ophthalmology in Shri Aurobindo Medical Research Centre Raipur Chhattisgarh, India.

Results: In current study, there was significant difference between the two group. Regarding to Height Group A mean 4.87 SD 1.65) and group B mean 5.463 SD .3931 are significant, mean (SD) of right intraocular pressure measured mean.30 SD .460 mmHg (10 mmHg– 32 mmHg) in the group A and mean 0.43 SD 0.499 mmHg (10 mmHg–28 mmHg) in the group B significant at $p<0.05$ level; and Hypertension- Group A 0.42 SD 0.497, and Group B mean 0.61 SD 0.497 are significant at <0.05 level.

Conclusion: ARMD patients had a mean age of 55.36 years most commonly affected. Females were found to have a higher prevalence of ARMD in our study. The 1-year result of Photodynamic Therapy (PDT) for AMD patients with predominantly classic and pure occult Choroidal Neovascularization (CNV) in eyes seems to be better than that of Photodynamic Therapy (PT) and Verteporfin in Photodynamic Therapy (VPT) studies.

1. Introduction

In India, Age-related macular degeneration (AMD) is the main purpose of irreversible blindness in adults older than >50 years. AMD is a clinical and socio-economic challenge because it has a similar effect on patient high-quality of existence to that suggested for acquired immunodeficiency syndrome, kidney failure, and stroke. [1,2] owing to the expanded life expectancy and exposure to environmental danger factors (e.g., atherosclerosis, weight problems, and smoking), the prevalence of AMD is anticipated to boom. [2,3]

In industrialized countries, ARMD is becoming one of the number one causes of visible impairment.[4] The range of people with ARMD is expected to boom from 3 to six million by means of the year 2020. That is due to a decrease in avoidable blindness, due to anterior segment pathologies and the growing life expectancy of the worldwide population. Global Fitness Corporation has protected ARMD in its movement plan, to deal with avoidable blindness in its imaginative and prescient 2020 program. [5]

The general incidence of AMD in India degrees from 1.4% to a few 1%. The prevalence changed to lowest in West India (1. 4%) and highest in South India (3.1%). We observed a better occurrence of early AMD than overdue AMD (2.3% vs. 0.6%). AMD turned more typical in rural regions than in urban (2.3% vs.2.1%) and in girls than in adult males (2.5% vs. 1.9%). The most crucial demographic aspect affecting the prevalence of AMD in India seems to be the age (> sixty-five years).[6] the superiority of ARMD varies from 1.2% to 29.3%.[7] From numerous research, it's miles nicely mounted that ARMD is frequent in coloured races and the superiority varies from 1.1% in South India 4 to 17. Four in Africa. [8] the superiority charge was discovered to be four 7% in a have a look at achieved in North India. [9]

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Frame mass index (BMI) as a threat aspect for ARMD has been the focus of few research; full-size chance component for accelerated intraocular blood pressure [10,11] hence we examined the affiliation among BMI as a modifiable hazard factor and improvement of ARMD. Waist-to-hip ratio as compared to BMI is more notably related to the risk of developing ARMD in women.[12] high occurrence of ARMD changed into additionally related to the prevailing and past history of systemic sicknesses like cardiovascular disease, high blood pressure, arteriosclerosis, and lung contamination.[13] it's been postulated that Asians are susceptible to visceral fat accumulation, which might be the cause of the finest prosperity to expand sicknesses which include diabetes at rather low BMI values.[14]

Among modifiable risk factors, weight loss programs and smoking are crucial chance factors for ARMD. Smoking is one of the most continuously documented modifiable danger factors in the majority of people. Preceding studies [15,16,17,18,19] confirmed smoking to be a famous chance component for AMD progression. Smoking is thought to have an effect on the flow of antioxidants. Aim- To see the Effect of Photodynamic therapy with verteporfin in patients with choroidal neovascularisation caused by age related macular degeneration.

2.Materials and Methods

The Study was prospective. 118 patients diagnosed with CNV secondary to AMD between February 2017 to March 2019, were including, study conducted in the department of ophthalmology in Shri Aurobindo Medical Research Centre Raipur Chhattisgarh, India. Patients of age-related macular degeneration > 50 years who attended the outpatient department (OPD) for treatment.

Study was performed after getting clearance from Institute Ethical Committee. Patients having corneal, lenticular or vitreous opacity in which fundus examination was not possible were excluded from study. Conditions such as polypoidal, choroidalvasculopathy, retinal angiomatous proliferation, myopic chorioretinal degeneration, any macular dystrophies were also excluded. Written, informed consent was obtained from all patients.

Patients identified with ARMD with the aid of an ophthalmologist cooperating with the study has been included. Ophthalmologists confirmed the diagnosis of ARMD through the use of a stereoscopic slit lamp and biomicroscopic exam with a unique contact lens. Manage topics have been also tested to rule out retinal changes. The type of ARMD changed into determined and entered in records collection paperwork. The subjects' weight and top were measured by a single technician using a setup Secca scale and a calibrated meter Photodynamic therapy (PT)e.

The Current study divided into two group – Group A photodynamic therapy (PT) and Group B- Verteporfin in photodynamic therapy (VPT), collected blood pressure were additionally measured and recorded in step with the standard protocol. History of smoking, antihypertensive and/or antidiabetic medicine, and duration of high blood pressure and/or diabetes have been taken and recorded in records series paperwork. Manage topics were selected amongst regular people and were matched for age, socio-demographic factors, intercourse, and chance factors. Manage group information has been additionally received through the use of data collection forms.

Records were analyzed using computer IBM- SPSS model 26 software program for additional statistical analysis. The descriptive evaluation was achieved using frequency and proportion, suggest, variance, paired t-take a look at, and frequency tables and graphs used for providing the records. The locating determined to use crude and altered or with a 95% confidence c programming language. Were used to test for factors associated with Age related macular desgeneration and a P-value < .05 was considered statistically significant.

3. Results

Table 1- Demographic factors and ARMD risk factors in group A and group B.

Variables	Categories	n	Percentage	Group A	Group B
Sex	Male	44	37.28%	24 (54.54%)	20 (45.45%)
	Female	74	62.71%	32 (43.24)	42 (56.75%)
Mean Age	Mean 55.36 (SD 4.650)				

		Mean	SD	STD Error Mean	95% Confidence Interval of the Difference		T value	Sig. (2-tailed)
Age Mean	Group A Male	39.85	25.059	4.362	-24.874	-7.732	-3.874	.000
	Group B Male	56.15	11.099	1.932				
	Group A Female	25.05	27.374	4.174	-36.608	-19.718	-6.730	.000
	Group B Female	53.21	9.193	1.402				
Height	Group A	4.8760	1.65142	.20973 .0499	-1.01816	-.15571	-2.722	.008
	Group B	5.463	.3931					
Weight	Group A	63.23	23.290	2.958 1.332	-11.657	2.947	-1.193	.238
	Group B	67.58	10.492					
Pressure Mesured	Group A	.30	.460	.059 .064	-.218	-.044	-3.009	.004
	Group B	.43	.499					

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Diabetes	Group A	.19	.398	.051 .056	-.127	-.002	-2.051	.045
	Group B	.26	.441					
Hypertension	Group A	.42	.497	.063 .062	-.295	-.092	-3.826	.000
	Group B	.61	.491					
Smoking	Group A	.21	.410	.052	-.077	.013	-1.426	.159
	Group B	.24	.432					

A total of 44 (37.28%) of subjects in the case group were male and 74 (62.71%) were female. Table 1 represents a comparison of demographic characteristics and ARMD risk factors between the two groups. In current study, there was significant difference between the two group. Regarding to Height Group A mean 4.87 SD 1.65) and group B mean 5.463 SD .3931 are significant, Weight group A mean 63.23 SD 23.290, Group B mean 67.58 SD10.492 are not significant. In this study, mean (SD) of right intraocular pressure measured mean.30 SD .460 mmHg (10 mmHg– 32 mmHg) in the group A and mean 0.43 SD 0.499 mmHg (10 mmHg–28 mmHg) in the group B significant at p<0.05 level; 89 (75.42%) of subjects are dry type and 29 (24.57%) were wet type of ARMD. Diabetes Group A mean 0.19 SD 0.398, and Group B mean 0.26 SD 0.441, and history of smoking group A mean 0.21 SD 0.410, and Group B mean 0.24 SD 0.432 are not significant and Hypertension Group A 0.42 SD 0.497, and Group B mean 0.61 SD 0.497 are significant at <o.o5 level. Over BMI regarding history of smoking and duration of hypertension and/or diabetes.

Table 2- Body mass index (BMI) in in group A and group B.

Variables		Mean	SD	STD Error Mean	95% Confidence Interval of the Difference		T value	Sig. (2-tailed)
					Lower	Upper		
Lean BMI<20	Group A	.10	.298	.038	-.016	.048	1.000	.321
	Group B	.08	.275	.035				
Normal 20<BMI<25	Group A	.32	.471	.063	-.114	.007	-1.764	.083
	Group B	.38	.489	.065				
Overweight 25<BMI <30	Group A	.39	.491	.062	-.172	-.021	-2.557	.013
	Group B	.48	.504	.064				
Obese BMI >30	Group A	.13	.338	.043	-.013	.077	1.426	.159
	Group B	.10	.298	.038				

On fluorescein angiogram, 11 eyes were classified as predominantly classic type of Choroidal Neovascularization (CNV) and 35 eyes were classified as pure occult type of Choroidal Neovascularization (CNV). The size of the lesion ranged from 1.03 to 5.4mm. The mean lesion size for predominantly classic and pure occult Choroidal Neovascularization (CNV) was 2.9 and 3.9mm, respectively. The mean number of PDT performed for each patient was 2.9 (ranged from 1 to 4) at the first year.

The changes in visual acuity throughout the study are summarized. Of the 11 patients with predominantly classic Choroidal Neovascularization (CNV), 7 patients (64%) showed visual improvement of which 5 improved from 1 to 3 lines and 2 improved from 3 to 6 lines. On the contrary, 4 patients (36%) showed loss in vision that included 1 loss from 1 to 3 lines and 3 losses from 3 to 6 lines.

As for the 35 patients with pure occult Choroidal Neovascularization (CNV), 10 patients (29%) showed visual improvement that included 8 improved from 1 to 3 lines and 2 improved from 3 to 6 lines. Of the 14 patients (40%) had the same vision as before, while 11 patients (31%) lost their vision that included 8 deteriorating from 1 to 3 lines and three deteriorating from 3 to 6 lines.

4. DISCUSSION

Age-related macular degeneration is a complex multifactorial disease with increased age being the strongest risk factor associated with AMD.[20] As Group A by BMI, 24 (42.85%) of the cases in this study were overweight and 8 (14.28%) were obese. Similarly, 30 (48.38%) of Group B subjects were overweight and 6 (9.6%) were obese. A study by Qian Yu Zhang et al of 1613 cases of BMI showed a linear dose-response relation with AMD risk (Pnonlinearity = 0.17), and the AMD risk increased by 2% (RR = 1.02, 95% CI: 1.01-1.04) for each 1 kg/m2 increase in BMI within the overweight and obese BMI ranges. [21]

In the current study, obesity was considered a risk factor for ARMD, yet lean individuals also seemed to be at risk. Similar to our study, few case–control and cross-sectional studies had reported that there was no significant association between obesity and AMD. [22,23,24] However, many case–control or longitudinal studies [25,26] and few cross-sectional studies [22,23,27] have shown a significant association between AMD and either one of the obesity indices. The Mean (SD) of BMI in Group A and Group B are respectively, showing no significant difference between the two groups.The Current study found a significant association of AMD with systemic diseases such as diabetes mellitus and hypertension. An increase in the risk of AMD progression with the presence of diabetes mellitus and hypertension in the obesity category was reported in previous studies. [28,29,30]

Given the multifactorial etiology of ARMD, the main physiopathology of ARMD was seen less often in patients with lower BMI, although a comparison of BMI did not show a significant difference between Group A

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and Group B. ARMD patients had more risk factors. Although no significant difference was observed, the difference can thus be explained. The mean (SD) of right intraocular pressure in Group A and Group B measured mean of 0.30 SD 0.460 mmHg and 0.32 SD 0.471, respectively. Left intraocular pressure in Group A and Group B measured a mean of 0.43 SD 0.499 mmHg, and a mean of 0.48 SD 0.504 respectively, showing a significant difference between the two groups. Recent studies of patients with open-angle acute glaucoma have highlighted BMI as an independent and significant risk factor for increased intraocular blood pressure.25 26 Studies of the association of BMI and intraocular pressure have yielded results consistent with these findings.

The baseline demographic characteristics of our patients including mean age and lesion size are similar to that of Group A and Group B studies. The average treatment session is also comparable to the recommendation from Group A and Group B studies (2.9 vs 3.4/1st year). Of the 11 predominantly classic Choroidal Neovascularization (CNV) in our study, 3 (27%) suffered a loss of more than three lines and seven (64%) had visual improvement after treatment at 12 months. Photodynamic therapy (PDT) is another treatment for CNV where the photosensitizing drug verteporfin is injected intravenously, and a low-intensity laser light treats the CNV tissue through a photochemical reaction that damages vascular endothelial cells, causing thrombosis.[31]

In further subgroup analysis, when looking at patients with predominantly classic Choroidal Neovascularization (CNV), there was a statistically significant benefit in the prevention of visual acuity loss in the verteporfin-treated group as compared with the placebo group (67 vs 39%). When we compared our result with that of Photodynamic Therapy (PT) report 1 for predominantly classic lesions, a smaller number of our patients had visual deterioration in terms of visual acuity loss of more than three lines than that of Photodynamic Therapy (PT) report 1 subgroup analysis (27 vs 33%). As for the pure occult Choroidal Neovascularization (CNV) group, three (9%) out of 35 patients had visual acuity loss of more than three lines while 10 (29%) had visual improvement after the treatment at 12 months. A similar study conducted by Azab .M et al. their study of subfoveal minimally classic choroidal neovascularization revealed that reduced fluence (300 mW/cm2 for 83 seconds at 25 J/cm3) PDT was a safe and more efficacious option for the treatment of AMD in comparison to standard fluence. At 12 months, a loss of at least 3 lines of visual acuity was observed in 14% of the reduced fluence group compared to 28% in the standard fluence group and 47% in the placebo group. Results were similar in the 2-year follow-up. Progression to classic CNV was seen in 28% of the placebo group 5% of the reduced fluence (p=0.007) and 3% of the standard fluence group (p=0.002).[32] When we compared our results with that of Verteporfin In Photodynamic Therapy (VPT) report 2, a smaller number of our patients had visual deterioration in terms of visual acuity loss of more than three lines than that of Verteporfin In Photodynamic Therapy (VPT) report 2 (9 vs 51%).

5. CONCLUSION

ARMD patients had a mean age of 55.36 years most commonly affected. Females were found to have a higher prevalence of ARMD in our study. Smoking and obesity, history of cardiovascular disease, cataract surgery, and sunlight exposure were not found to have a significant association with the risk of developing ARMD in our study. Age group, height, hypertension, intraocular pressure, and Family history of ARMD was significant risk factor found in the current study. Many such studies need to be done in the future to establish more risk factors associated with the development of ARMD.

The 1-year result of Photodynamic Therapy (PDT) for AMD patients with predominantly classic and pure occult Choroidal Neovascularization (CNV) in eyes seems to be better than that of Photodynamic Therapy (PT) and Verteporfin in Photodynamic Therapy (VPT) studies. Further observation and follow-up will be necessary for documentation.

6. LIMITATIONS

There are a number of limitations in our study. Firstly, our study is retrospective while Photodynamic Therapy (PT)/Verteporfin in Photodynamic Therapy (VPT) studies are prospective in nature. Secondly, our sample size.

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