



E-ISSN: 2663-8274
P-ISSN: 2663-8266
www.ophthalmoljournal.com
IJMO 2019; 1(2): 45-47
Received: 11-03-2019
Accepted: 15-04-2019

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A comparative effect of Intravitreal Ranibizumab and Triamcinolone in patients with diabetic macular edema

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DOI: <https://doi.org/10.33545/26638266.2019.v1.i2a.53>

Abstract

Background: Diabetic Mellitus (DM), a chronic metabolic disorder is a major public health problem due to its associated complications. The present study compared the effect of intravitreal Ranibizumab and Triamcinolone in patients with diabetic macular edema.

Materials and methods: 64 patients diagnosed with diabetic retinopathy of both genders were randomly divided into 2 groups of 32 each. Group I patients received either intravitreal Ranibizumab (0.3mg) and group II patients received Triamcinolone acetonide (4mg). Spectral Domain OCT was done as well as best corrected Log MAR visual acuity.

Results: The mean intraocular pressure pre-operatively in group I was 16.4 at 1 month was 16.5 and at 3 months was 17.2. In group II was 15.8 at 1 month was 20.4 and at 3 months was 23.5. OCT was 520, 430.6 at 1 month and 395.2 at 3 months in group I and 560.4, 236.4 and 214.6 in group II, Visual acuity was 0.68 pre-operatively, 0.59 at 1 month and 0.54 at 3 months in group I and 0.72, 0.35 and 0.32 in group II respectively. The difference was significant ($P < 0.05$).

Conclusion: Both drugs found to be equally effective in the management of cases of diabetic retinopathy.

Keywords: Diabetic mellitus, diabetic retinopathy, Triamcinolone Acetonide

Introduction

Diabetic Mellitus (DM), a chronic metabolic disorder, is a major public health problem due to its associated complications^[1]. The prevalence of diabetes among the population is varied and different in different parts of the world. In India it has been reported from 4-28%. There is prevalence of 6.7% of retinopathy in patients of NIDDM at the initial diagnosis of diabetes^[2].

One of the major complications of DM is diabetic retinopathy (DR), which is an important cause of preventable blindness. DR is characterized by the progressive damage in the retinal microvasculature. It can be classified into non proliferative DR (NPDR) and proliferation DR (PDR)^[3]. In most cases, DR is featured with increased vascular permeability, leading to fluid accumulation and retinal hemorrhages in the macula, all of which referred to DME. The two most important causes of visual impairment secondary to DR are diabetic macular edema (DME) and proliferative DR (PDR). The prevalence of DME is 3% in mild non proliferative retinopathy and rises to 38% in eyes with moderate-to-severe non proliferative retinopathy, eventually reaching 71% in eyes with proliferative retinopathy^[4].

Structural modification of diabetic vitreous occurs secondary to enzymatic and non-enzymatic collagen glycation. Accumulation of advanced glycation end products (AGEs) in the vitreous of hyperglycemic patients promotes collagen crosslinking and may be the cause of VMT in diabetic eyes^[5]. The present study compared the effect of intravitreal Ranibizumab and Triamcinolone in patients with diabetic macular edema.

Materials and Methods

The present study was conducted among 64 patients diagnosed with diabetic retinopathy of both genders. The enrolment of patients was after obtaining their written consent.

Demographic profile such as name, age, gender etc. was recorded. Patients underwent a complete ophthalmic examination, with determination of Best Corrected Visual Acuity (BCVA), anterior segment examination, indirect ophthalmoscopy & 90-D lens

biomicroscopy. Patients were randomly divided into 2 groups of 32 each. Group I patients received either intravitreal Ranibizumab (0.3mg) and group II patients received Triamcinolone acetonide (4mg). Spectral Domain OCT was done as well as best corrected Log MAR visual acuity. Results were subjected to statistical analysis. P value less than 0.05 was considered significant.

Results

Table 1: Distribution of patients

Groups	Group I	Group II
Drug	0.3 mg Ranibizumab	4 mg Triamcinolone acetonide
M:F	20:12	18:14

Table 1 shows that group I had 20 males and 12 females and group II had 18 males and 14 females.

Table 2: Comparison of parameters

Parameters	Groups	Pre-operative	At 1 month	At 3 months	P value
IOP	Group I	16.4	16.5	17.2	0.01
	Group II	15.8	20.4	23.5	
OCT	Group I	520	430.6	395.2	0.02
	Group II	560.4	236.4	214.6	
VA	Group I	0.68	0.59	0.54	0.05
	Group II	0.72	0.35	0.32	

Table 2, Figure I shows that mean intraocular pressure pre-operatively in group I was 16.4, at 1 month was 16.5 and at 3 months was 17.2, In group II was 15.8, at 1 month was 20.4 and at 3 months was 23.5. OCT was 520, 430.6 at 1 month and 395.2 at 3 months in group I and 560.4, 236.4 and 214.6 in group II, Visual acuity was 0.68 pre-operatively, 0.59 at 1 month and 0.54 at 3 months in group I and 0.72, 0.35 and 0.32 in group II respectively. The difference was significant ($P < 0.05$).

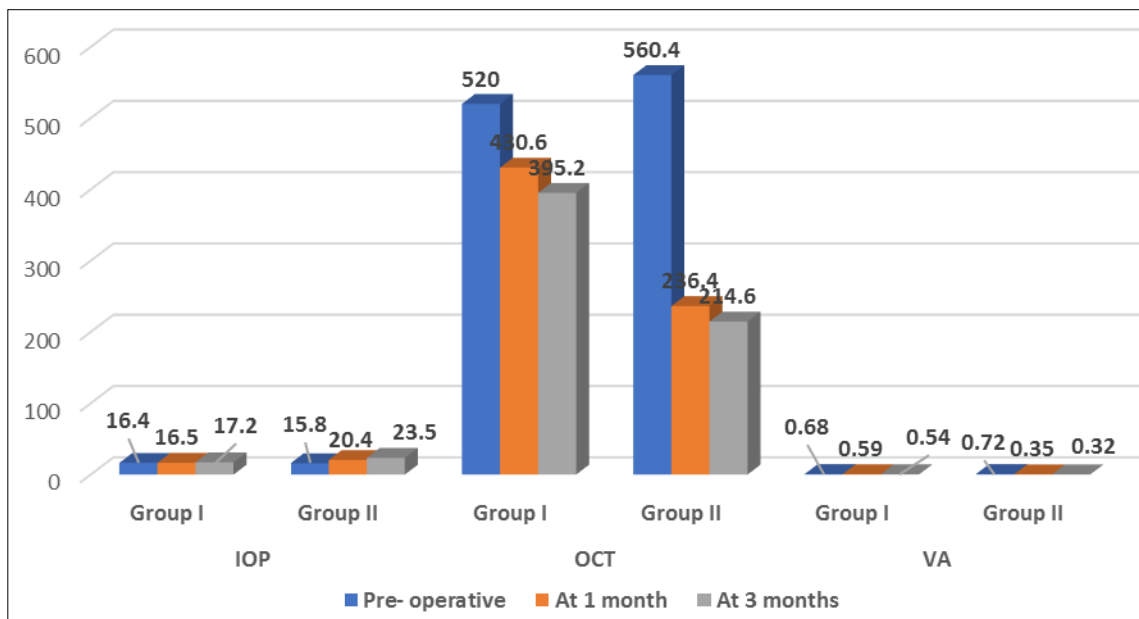


Fig 1: Shows that mean intraocular pressure pre-operatively

Discussion

The World Health Organization (WHO) has estimated that, the number of adults with Fundus disorders in the world would increase alarmingly [6]. Globally, it is estimated that there are 38 million people who are blind. In India: 9 million people are blind which comes to one fifth of the total in the world. The prevalence of blindness in India, as determined by the three major population based surveys and one rapid assessment of avoidable blindness are as follows 1.38% in ICMR (1971 - 74), 1.49% in WHO-NPCB (1986-89), 1.1% in NPCB (2001-2002), 1% in RAAB (2006-2007) [7]. The prevalence of blindness due to posterior segment diseases in India was 4.7% of total blindness according to national survey (NPCB) of 2001-2002 and 3% of total blindness as per the rapid assessment of avoidable blindness (RAAB) 2006-07 survey. The trend of retinal blindness has changed its pattern over the years in developing countries. Diabetic retinopathy and ARMD are becoming one of the major causes of blindness [8]. Both longitudinal and cross-sectional studies show that the best predictor of diabetic retinopathy is the duration of

diabetes. For insulin dependent diabetes mellitus (IDDM) virtually there is no clinically apparent retinopathy for 4-5 years after the initial diagnosis of diabetes mellitus [9]. After 5-10 years, 25-30% develop some retinopathy while after 10-15 years it will be observed in 75-95% of patients. After 20-25 years proliferative diabetic retinopathy is observed in 18-40% of patients. PDR is rare before 10 years and is unknown before 5 years duration of diabetes [10]. The present study compared the effect of intravitreal Ranibizumab and Triamcinolone in patients with diabetic macular edema. In present study, Group I patients received either intravitreal Ranibizumab (0.3mg) and group II patients received Triamcinolone acetonide (4 mg). Group I had 20 males and 12 females and group II had 18 males and 14 females. Ahmed *et al.* [11] compared the effect of intravitreal Ranibizumab (0.3 mg) and Triamcinolone (4mg) on different parameters in spectral domain OCT and their relation to visual acuity of patients with diabetic macular edema. Patients were randomly divided into 2 groups receiving either Pro re nata intravitreal Ranibizumab

(0.3mg) or Triamcinolone acetonide (4mg), to whom Spectral Domain OCT was done as well as best corrected Log MAR visual acuity. Comparison and correlation of mean BCVA and mean CMT among and within treatment groups revealed strong and significant relationship between both parameters and showing equal effect of both treatment types regarding them with the consideration that Triamcinolone acetonide treated group (Group B) showed statistically significant lower CMT compared to Ranibizumab treated group (Group A) at three and six months. Also both showed equal effectivity regarding improvement of the photoreceptors integrity and in turn the improvement of the BCVA.

We found that mean intraocular pressure pre-operatively in group I was 16.4, at 1 month was 16.5 and at 3 months was 17.2. In group II was 15.8 at 1 month was 20.4 and at 3 months was 23.5. OCT was 520, 430.6 at 1 month and 395.2 at 3 months in group I and 560.4, 236.4 and 214.6 in group II, Visual acuity was 0.68 pre-operatively, 0.59 at 1 month and 0.54 at 3 months in group I and 0.72, 0.35 and 0.32 in group II respectively. Maheshwary *et al.*^[12] claimed a strong trend suggesting a relationship between macular volume and visual acuity, although borderline significance was found ($P=0.07$). They used macular volume instead of central retinal thickness as an indicator of edema severity. The Diabetic Retinopathy Clinical Research Network (DRCR.net) showed that total macular volume may be used when macular edema is more diffuse and represents a more global measurement of macular edema. A statistically significant correlation between percentage disruption of the IS/OS junction and visual acuity was found ($P=0.0312$).

Conclusion

Authors found that both drugs found to be equally effective in the management of cases of diabetic retinopathy.

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