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TO COMPARE OCT CHANGES AND VISUAL ACUITY IMPROVEMENT IN PATIENTS WITH DIABETIC MACULAR EDEMA BASED ON INTERNATIONAL CLINICAL CLASSIFICATION AFTER LASER PHOTOCOAGULATION.

Ophthalmology

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ABSTRACT

CONTEXT: Diabetic macular edema is the leading cause of vision deterioration and the most effective treatment is laser photocoagulation. However , grading macular edema based on the ETDRS classification is difficult by general ophthalmologists. Hence in this study we classified macular edema based on the international clinical classification.

AIMS:

- To study macular thickness changes by OCT examination and Visual Acuity improvement in patients with diabetic macular edema based on international clinical classification after laser photocoagulation.
- To find out the need for repeat laser photocoagulation or intravitreal injection Anti-VEGF in various grades of diabetic macular edema.

METHODS AND MATERIAL: The study was conducted on all diabetic patients with diagnosed diabetic macular edema from the eye out patient department. General ophthalmic examination like visual acuity and best corrected visual acuity for distance and near, intraocular pressure and anterior segment examination, dilated fundus examination and OCT examination were done. Macular edema was classified based on the international classification of diabetic macular edema. Laser photocoagulation was performed and the patients were called for regular follow up visits. On each follow up: the visual acuity, best corrected visual acuity, dilated fundus examination and OCT examination were performed. The findings at 1 week, 1 month and 6 month were recorded and statistical analysis was performed.

RESULTS: A significant improvement in visual acuity and decrease in macular thickness which suggests reduction in diabetic macular edema after laser photocoagulation was noted over a period of 6 months in patients of all grades of macular edema.

CONCLUSIONS: Grading macular edema based on the international classification proves to be easier for general ophthalmologists to treat patients with diabetic macular edema and to note the progression of the disease.

KEYWORDS

Diabetic Macular Edema , Laser Photocoagulation ,visual Acuity , OCT Changes.

INTRODUCTION

Diabetic retinopathy remains the leading cause of blindness among working age adults in Western society. A recent study of patients with type I diabetes demonstrates that after 14 years of diabetes over 70% demonstrate some level of diabetic retinopathy and 10% have moderate to severe diabetic retinopathy. Diabetic retinopathy causes progressive vision loss associated with breakdown of the BRB.[1] Macular edema occurs when there is abnormal leakage and accumulation of fluid in the macula from damaged blood vessels in the nearby retina. Most people with macular edema will have symptoms that range from slightly blurry vision to noticeable vision loss. Histopathologic reports indicate that intraretinal cystoid spaces in macular edema may vary in their location and size according to the underlying disease etiology. This can now be corroborated in situ by OCT imaging[2]

Diabetic macular edema treatment studies are based on ETDRS classification. In view of new international classification this study will formulate treatment criteria and response of laser photocoagulation in treating various grades of macular edema along with OCT changes. It will also give insight into long term effect (6 month) of laser photocoagulation on diabetic macular edema.

MATERIALS AND METHODS

Study design & area

This is a prospective observational study undertaken at ophthalmology out patient department of tertiary health care centre in western province of India, affiliated with a medical college after approval of the ethics committee of the hospital.

Inclusion criteria

All diabetic patients of known as well as freshly diagnosed macular edema of all age and gender , irrespective of their duration & type of diabetes, presenting to the out patient department and undergoing laser photocoagulation would be included in the study.

Exclusion criteria

1) Patients not giving consent
2) All patients with proliferative diabetic retinopathy
3) All patients with macular ischemia
4) All patients with retinal arterial/venous occlusion diseases

Data collection

Total 30 subjects were included in the study after taking informed and written consent.

Total 56 eyes were included in the study. The study was conducted on all diabetic patients with diagnosed diabetic macular edema, irrespective of their duration of the disease, type of diabetes, age and sex. Participants were selected from the eye out patient department. They were briefed regarding the importance of fundus examination and laser photocoagulation and it's side effects.

Before retinal evaluation, basic work up like visual acuity and best corrected visual acuity on Snellen's chart, intraocular pressure on Goldmann's applanation tonometer, anterior segment examination on slit lamp was noted. After dilatation of pupils with Tropicamide 0.8 % + Phenylephrine 5 % eye drops, fundus evaluation was done with help of indirect ophthalmoscope with 20 D convex lens. Further examination was done on slit lamp with 90 D convex lens (slit lamp biomicroscopy). The patients underwent OCT examination.

The diagnosis based on these examinations and findings was noted down. Macular edema was classified based on the international classification of diabetic macular edema. Diagnosis and the available treatment options were explained to the patients. Informed consent in English & vernacular language was taken after duly explaining the patients regarding laser photocoagulation and its side effects. Laser photocoagulation was performed and the patients were called for regular follow up visits. On each follow up: the visual acuity, best corrected visual acuity, dilated fundus examination and OCT examination were performed.

The findings at 1 week, 1 month and 6 month were recorded and statistical analysis was performed.

Ethical issues: none

Informed consent

Informed consent in English & vernacular language was taken after duly explaining the participants about the study and answering all the questions the participants may have had regarding the study.

Statistical analysis: Done using STATA 14.2 software.

RESULTS & INTERPRETATIONS

TABLE 1 : Number of observations as per ETDRS classification

Grade of diabetic retinopathy	Grade of macular edema based on international classification (no of observations and it's %)		
	Mild	Moderate	Severe
Moderate NPDR	0 (0%)	20 (95.24%)	1 (4.76%)
Severe NPDR	1 (11.11%)	6 (66.67%)	2 (22.22%)
Very severe NPDR	0 (0%)	14 (53.85%)	12 (48.28%)

As per the above table :

- 95.24% patients with moderate NPDR had moderate macular edema, 4.76% patients with moderate NPDR had severe macular edema.
- 11.11% patients with severe NPDR had mild macular edema, 66.67% patients with severe NPDR had moderate macular edema and 22.22% patients with severe NPDR had severe macular edema.
- 53.85% patients with very severe NPDR had moderate macular edema and 48.28% patients with severe NPDR had severe macular edema.
- Hence , maximum number of patients had moderate macular edema.

TABLE 2: Type of macular edema and the type of laser photocoagulation done

Grade of macular edema	Type of laser given (no of observations and it's %)	
	Grid	Focal + grid
Mild	0 (0%)	1 (100%)
Moderate	7 (17.5%)	33 (82.50%)
Severe	3 (20%)	12 (80%)

- 17.5% patients with moderate macular edema and 20% patients with severe macular edema were given grid laser.
- 82.50% patients with moderate macular edema and 80% patients with severe macular edema were given focal + grid laser.

TABLE 3: % CHANGE IN DISTANT VISUAL ACUITY AFTER LASER PHOTOCOAGULATION.

Distant visual acuity	Improve (n, %)	Deteriorate (n, %)	No change (n, %)
At 1 week after laser photocoagulation	6 (10.71%)	18 (32.14%)	32 (57.14%)
At 1 month after laser photocoagulation	18 (32.14%)	26 (46.43%)	12 (21.43%)
At 6 month after laser photocoagulation	25 (44.64%)	18 (32.14%)	13 (23.21%)

- At the end of 1 week, 10.71% patients showed improvement, 32.14% patients showed decrease where as 57.14% patients showed no change in distant visual acuity.
- At the end of 1 month, 32.14% patients showed improvement, 46.43% patients showed decrease where as 21.43% patients showed no change in distant visual acuity.
- At the end of 6 months, 44.64% patients showed improvement, 32.14% patients showed decrease where as 23.21% patients showed no change in distant visual acuity.

TABLE 4 : % CHANGE IN NEAR VISUAL ACUITY AFTER LASER PHOTOCOAGULATION

Near visual acuity	Improve (n, %)	Deteriorate (n, %)	No change (n, %)
At 1 week after laser photocoagulation	5 (8.93%)	16 (28.57%)	35 (62.50%)
At 1 month after laser photocoagulation	17 (30.36%)	26 (46.43%)	13 (23.21%)
At 6 month after laser photocoagulation	25 (44.64%)	15 (26.79%)	16 (28.57%)

- At the end of one week, 8.93% patients showed improvement, 28.57% showed decrease where as 62.50% showed no change in near visual acuity.
- At the end of one month, 30.36% patients showed improvement, 46.43% showed decrease where as 23.21% showed no change in near visual acuity.
- At the end of six months, 44.64% patients showed improvement, 26.79% showed decrease where as 28.57% showed no change in near visual acuity.

TABLE 5 : % CHANGE IN MACULAR THICKNESS AFTER LASER PHOTOCOAGULATION

Macular thickness	Increase (n, %)	Decrease (n, %)	No change (n, %)
At 1 week after laser photocoagulation	35 (62.50%)	14 (25%)	7 (12.50%)
At 1 month after laser photocoagulation	28 (50%)	26 (46.43%)	2 (3.57%)
At 6 month after laser photocoagulation	13 (23.21%)	39 (69.64%)	4 (7.14%)

- At the end of one week, 62.50% patients showed increase, 25% showed decrease where as 12.50% showed no change in macular thickness on OCT examination.
- At the end of one month, 50% patients showed increase, 46.43% showed decrease where as 3.57% showed no change in macular thickness on OCT examination.
- At the end of six months, 23.21% patients showed increase, 69.64% showed decrease whereas 7.14% showed no change in macular thickness on OCT examination.

TABLE 6 : Types of laser and requirement of intravitreal anti – VEGF

Type of laser photocoagulation	Intravitreal injection anti – VEGF (n , %)		
	Not required	Pre laser injection given	Post laser injection given
Grid laser	6 (10.71%)	3 (5.35%)	0 (0%)
Focal + grid laser	30 (53.57%)	9 (16.07%)	8 (14.28%)

- 64.28% of the patients did not require intravitreal injection Anti-VEGF & only 14.28% patients required the injection after laser photocoagulation

TABLE 7 : Types of macular edema and requirement of intravitreal anti – VEGF

TYPE OF MACULAR EDEMA	No. of observations which required intravitreal injection anti – VEGF after laser photocoagulation
MILD	0
MODERATE	6
SEVERE	2

- It was observed that out of 40 patients with moderate macular edema , only 6 patients i.e 15% patients of moderate macular edema required intravitreal injection after laser photocoagulation.
- Out of 15 patients with severe macular edema , only 2 patients i.e 13.33% patients of severe macular edema required laser photocoagulation.

Table 8 - Types of diabetic retinopathy and requirement of intravitreal anti – VEGF

TYPE OF DIABETIC RETINOPATHY	No. of observations which required intravitreal injection anti – VEGF after laser photocoagulation
MODERATE NPDR	7
SEVERE NPDR	0
VERY SEVERE NPDR	1

- It was observed that out of 21 patients with moderate NPDR , only 7 patients i.e 33.33% patients of moderate NPDR required intravitreal injection after laser photocoagulation.
- Out of 26 patients with very severe NPDR , only 1 patient i.e 3.84% patients of very severe NPDR required laser photocoagulation.

DISCUSSION

Diabetic retinopathy is a vascular disorder affecting the microvasculature of the retina. It is estimated that diabetes mellitus affects 4% of the world's population, almost half of whom have some degree of DR at any given time [3]. DR occurs both in type 1 and type 2 diabetes mellitus and has been shown that nearly all type 1 and 75% of type 2 diabetes will develop DR after 15 year duration of diabetes as shown in earlier epidemiological studies [4,5]. In the western population, DR has been shown to be the cause of visual impairment in 86% of type 1 diabetic patients and in 33% of type 2 diabetic patients [6]. In India with the epidemic increase in type 2 diabetes mellitus as reported by the World Health Organization (WHO) [7], diabetic retinopathy is becoming an important cause of visual disability. Diabetic macular edema is the leading cause of decreased vision from diabetic retinopathy. Diabetic macular edema tends to be a chronic disorder. Although spontaneous

recovery is not an uncommon occurrence, over one-half of diabetics with macular edema will lose two or more lines of visual acuity within two years.[8]

There have been various studies comparing the role of intravitreal injection Anti-VEGF and laser photocoagulation in cases of diabetic macular edema. There has been a need to repeat the intravitreal injection Anti-VEGF over short durations which is not only non-compliant to the patients but is also an economic burden to the patients. Hence the most promising treatment for diabetic macular edema has been photocoagulation. However it has been noted that rarely , few patients require intravitreal injection Anti – VEGF even after laser photocoagulation . In our study, only 14.28% of the patients who had undergone laser photocoagulation (focal + grid laser) required to be treated with intravitreal injection Anti – VEGF.

The ETDRS provides definitive information as to whether photocoagulation is effective in various subgroups of patients with diabetic macular edema. The ETDRS staging system is recognized as the gold standard for grading in clinical trials. However in everyday clinical practice, it has not proven to be easy or practical to use. There are too many levels, required correlations with standard photographs and additional complicated grading rules for the different stages, and these are difficult to remember. Contemporary studies have documented that the ETDRS grading system is not employed by the vast majority of ophthalmologists managing patients with diabetes. Hence it is useful to have a common disease severity scale for DME. Thus, a system that can be used globally is needed to facilitate communication between retina sub specialists and general ophthalmologists.[9] As per the findings of our study, patients with moderate NPDR with maculopathy should be referred to an ophthalmologist. And all patients with severe NPDR & very severe NPDR with or without maculopathy should be referred to the retina specialists based on the INTERNATIONAL CLASSIFICATION.

In our study, we used the INTERNATIONAL CLASSIFICATION of diabetic macular edema and the patients underwent laser photocoagulation. Changes in visual acuity for distance and near and also the changes in macular thickness on OCT examination were studied. Macular edema was classified into various types based on the OCT classification for macular edema also and it was noted that diffuse cystoid macular edema is the most common type followed by non – cystoid macular edema . The result of the study is that over the time duration of 6 months , there was a gradual significant decrease in the macular thickness and the visual acuity improved gradually in significant number of patients, which suggests a decrease in macular edema.

Overall 44.64% patients had improved distant visual acuity at 6 months in our study. Maximum improvement in distant visual acuity was noted in patients with moderate macular edema (50%) and maximum decrease in macular edema was noted in patients with moderate macular edema (72.5%). 69.64% patients showed decrease in macular thickness on OCT examination at 6 months, suggesting decrease in macular edema. Hence laser photocoagulation has a longer lasting effect on reducing the macular edema.

This study would be useful to monitor the progression of diabetic macular edema and it would be easier for general ophthalmologists to use the clinically more feasible INTERNATIONAL CLASSIFICATION of diabetic macular edema which would improve patient management and would define the criteria when to refer the patient to retina specialist for further management.

CONCLUSIONS

Diabetic macular edema is a significant cause for visual deterioration and timely diagnosis and intervention can prevent the visual loss in patients. As per our study , it would be easier to grade diabetic macular edema based on the international classification and it would aid in the treatment of the patient. Also it is found that due to laser photocoagulation, the visual acuity improves and the macular edema reduces over a period of 6 months. Hence it has a longer duration of effect to decrease macular edema . Laser photocoagulation has a better patient compliance and also lesser economic burden to the patient.

LIMITATIONS OF THE STUDY

- Single centre study
- Limited sample size
- Shorter study period.

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