

Assessment of Diabetic Retinopathy by Fluorescein Angiography

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ABSTRACT

Introduction: Diabetic retinopathy is one of the leading causes of blindness. According to “Statistics on blindness in the Model Reporting Area 1969-70, diabetic retinopathy was responsible for 11.1% of new cases of legal blindness in all the age groups and 19.1% of those in 20-64 years age group. Study objectives were to study diabetic Retinopathy in the context of age of onset of diabetes, duration of diabetes, and metabolic control, to study the relation of diabetic retinopathy with age and sex of the patients, to observe the different stages of retinopathy and their analysis and to observe the advantages of fluorescein angiography

Material and methods: This analytical study was performed in Sree Siddhartha Medical College Hospital, Tumkur for a period of one year. The initial examination was started with fundus examination with direct ophthalmoscope after pupillary dilatation with a combination of phenylephrine and tropicamide eyed drops e.g. Tropicacyl plus eyedrops). Due care was taken to rule out hypertension in the patient before administration of this eyedrops to avoid cardiovascular complications.

Result: The material for the present study consists of 50 diabetic patients who attended the outpatient department of, or who were admitted to, Sri Siddhartha Medical College Hospital, Tumkur, during the one-year period from March 2003 to February 2004.

Conclusion: Fundus Fluorescein Angiography is a very useful ancillary diagnostic procedure. The procedure is useful in diagnosis, treatment, documentation and follow-up of patients and to maintain permanent record of the stages of retinopathy, which is useful in understanding the course of the disease in the patient, response to the treatment and follow up.

Keywords: Diabetic Retinopathy, FFA, Fluorescein, PDR, NPDR, Maculopathy, FAZ, CSME, Microaneurysms, NVD, NVE

INTRODUCTION

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%.^{1,2} There is prevalence of 6.7% of retinopathy in patients of NIDDM at the initial diagnosis of diabetes.

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.

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. In

NIDDM Yanko and others have reported NPDR prevalence of 23% 10-13 years after the diagnosis of diabetes and 60% 16 years after the diagnosis.³

In India retinopathy was detected in 52% of patients with NIDDM of over 25 years duration.⁴ Among this NPDR was seen in 41.7% and PDR in 10.3% of patients.

Types of diabetic retinopathy

Non Proliferative Diabetic Retinopathy (NPDR)

This is the effect of ischemia on the retina and refers to the changes taking place within the retina. These consist of microaneurysms, superficial and deep haemorrhages, hard and soft exudates. The NPDR stage with macular edema is an important cause of impairment of vision.

Proliferative Diabetic Retinopathy (PDR)

This is the response of retina to ischemia and is seen in the form of new vessels, which can be seen on the disc as New Vessels at Disc (NVD) and New Vessels Elsewhere (NVE) in the retina.

The Proliferative phase can be complicated by vitreous hemorrhage, retinal detachment, which are important causes of visual impairment and blindness.

The NPDR needs no local treatment, only regular follow-ups are advised for early detection and treatment of proliferative changes, and treatable maculopathies.

Proliferative diabetic retinopathy needs treatment by means of photocoagulation in which the hypoxic areas, which stimulate the neovascularization, are thoroughly destroyed.

Fundus fluorescein angiography (F.F.A.)

Although only 40 years old, fluorescein angiography has been firmly established as a crucial aid for detecting ocular pathophysiologic mechanism for a better diagnostic, therapeutic and prognostic purposes. It surpasses such techniques as direct and indirect ophthalmoscopy, slit lamp examination and gonioscopy.

Fluorescein angiography provides a baseline on which subsequent changes can be easily projected and documented. Fluorescein angiography acts as a guide for further evaluation of the condition and its management.

Fundus fluorescein angiography is a highly specialized form of ophthalmic photography that requires sophisticated

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equipments and specialized photographic techniques.

Fluorescein angiography is the technique of injecting a yellowish dye into a patient's antecubital vein, then photographically stimulating this dye with a blue green light at certain wavelengths to induce fluorescence, in the retinal vascular system of the human eye, and recording this fluorescence on photographic film using a fundus camera. Unlike, fundus photography, which is purely documentary, fluorescein angiography is a diagnostic test yielding information about the patient's ocular health otherwise unavailable to the ophthalmologist.

Role of fluorescein angiography in diabetic patients

F.F.A. can be used for:

- As a screening means for detection of diabetic retinopathy.
- Detection of presence and extent of retinal edema
- To differentiate between aneurysm and hemorrhage.
- To detect maculopathies – Focal, diffuse, ischemic.
- To assess the retinal blood flow (Arm retinal circulation and arteriovenous passage time, retinal circulation time.
- To detect area of capillary non-perfusion.
- To detect presence of new vessels (NVD, N.V.E.) and their extent.
- To assess the progression of diabetic retinopathy in a patient.
- To assess the effect of treatment on the patient. E.g., Laser photocoagulation.

The detection of preproliferative and proliferative diabetic retinopathy can prevent the complications if these patients are appropriately treated by photocoagulation of the ischemic retina.

This study was meant to determine the role of F.F.A. in detection of diabetic retinopathy changes in diabetic patients especially when these changes are not appreciated ophthalmoscopically or in doubtful cases, with emphasis on detection of early Proliferative diabetic retinopathy cases, their extent, follow up and response to treatment.

MATERIAL AND METHODS

This analytical study was performed in Sree Siddhartha Medical College Hospital, Tumkur for a period of one year. The cases included in the study were diabetic patients of both sexes and various age groups. These included were selected from the patients attending the department of medicine, Sree Siddhartha Medical College Hospital, Tumkur for the treatment of diabetes mellitus, who were referred to department of ophthalmology for evaluation. Known diabetic patients who attended the ophthalmology outpatient department directly for the ophthalmic evaluation were also included in the study.

Among the patients of diabetic retinopathy, only some patients were selected for further evaluation. The inclusion criteria for the selection of patients for the study are:

- All the patients with the history of diabetes confirmed by investigations and among those who have ophthalmoscopically detectable diabetic retinopathy changes.

- Some patients fulfilling the criteria were excluded from the study. The exclusion criteria were
- Patients of diabetic retinopathy who have media opacities or hazy media due to cataract or other causes.
- Patients of diabetic retinopathy who have undergone treatment for diabetic retinopathy by photocoagulation or other surgeries
- The duration of this study is one year.
- The total number of patients included in the study is fifty (50)
- All these patients were examined as per the protocol (Proforma).

Visual acuity was recorded and retinoscopy was done in all the cases. Blood glucose and urine examination for albumin and sugar was done in all cases and recorded.

The initial examination was started with fundus examination with direct ophthalmoscope after pupillary dilatation with a combination of phenylephrine and tropicamide eye drops e.g. Tropicacyl plus eyedrops). Due care was taken to rule out hypertension in the patient before administration of this eyedrops to avoid cardiovascular complications.

The study of diabetic changes in the fundus was performed by non-invasive techniques like direct ophthalmoscopy, indirect ophthalmoscopy and slit lamp biomicroscopy using +90D Volk lens. Heine Beta 200 direct ophthalmoscope, Heine indirect ophthalmoscope with +20D Volk lens and Haag-Streit model slit lamp along with +90D Volk lens were used throughout the study.

After getting the opinion from the physician regarding the fitness for the fundus fluorescein angiography, the patient was taken up for the procedure.

The patient was informed in vernacular about the procedure in detail. He was explained about the purpose, the procedure, and the possible adverse reactions, which are likely to occur during or immediately after the procedure. He was explained about the management of the likely adverse effect also.

Informed consent was taken from the patient.

All the emergency drugs were kept to treat the adverse reactions, which may occur during the procedure.

On the day of appointment, the patient was examined and his pupils were dilated with eyedrops of a combination of tropicamide and phenylephrine (e.g. tropicacyl plus). The procedure was carried out during the outpatient department working hours of Sree Siddhartha Medical College Hospital, Tumkur so that we could get the medical assistance of other specialists in the event of any untoward effects during the procedure.

Canon CF-60UD fundus camera and ILFORD PAN 400 black and white film rolls were used throughout the study.

The patient was seated comfortably in front of the fundus camera. The antecubital vein was secured and scalp vein set was fixed. His chin was placed on the chin rest and the forehead on the head bar. Patient was asked not to move his head, which would lead to loss of focus eventually leading to poor quality photographic frames. Sometimes an assistant was requested to fix the patient's head in order to prevent the involuntary movements of patient's head.

On aiming and focussing the camera on the area of primary interest the patient was asked to fix the gaze by looking at the target. (A red fixation light which is the part of fundus camera system)

First patient's identification (name, IP/OP number) photograph was taken. Then red free photographs were taken using green filter. Then pre injection photographs were taken with exciter and barrier filters, if it was found necessary in the fundoscopic examination through fundus camera unit.

The fluorescein dye was injected into the antecubital vein and serial pictures were taken. All through the procedure, the patient's pulse and general condition was monitored and any reaction was attended to and noted.

After the procedure the patient was made to lie down and relax for 15 to 30 minutes. He was also explained about the change in the color of urine and skin. The patient was asked to attend the out patient department later on a specific date for the report.

The findings were recorded in the case sheet of the patient The features, which were observed, were

- Presence of microaneurysms
- Presence of retinal edema
- Presence of capillary dropouts
- Presence of IRMA
- Presence of new vessels, Presence of maculopathies.-focal, diffuse or/and exudative

RESULTS

The material for the present study consists of 50 diabetic patients who attended the outpatient department of, or who were admitted to, Sri Siddhartha Medical College Hospital, Tumkur, during the one-year period from March 2003 to February 2004.

Age and sex

The mean age of the study subjects was 55.65 years with standard deviation (SD) of 11.13 years. The youngest was 21 years old and the oldest, 80 years old.

There were 37 male and 13 female patients. The sex ratio is 37:13 or 2.9:1. There were almost three times as many male as female patients.

The 51-60 age group contained the majority of patients (48%). This was followed by the 61-70 group that accounted for 22% of the diabetics.

On an average the female patient was 1 year younger than the male counterpart.

Family history of diabetes

11 patients (22%) gave the family history of diabetes; 8 of these were males and 3 females. About equal proportion of male and female patients gave the family history of diabetes.

History of alcohol/tobacco consumption

5 patients (10%) gave the history of alcohol consumption. All these were males. 6 patients (12%) were abusing tobacco. All these, again, were males.

Comorbidity

In 44 patients (88%), there was no associated systemic

disease. Two of these, a 67 year old female and a 60 year old male, had pseudophakia in both eyes.

In 6 patients (12%) diabetes was associated with hypertension.

Duration

At the time of enrolment into the study, the patients had a mean duration of illness of 9.32 years with a SD of 4.63 years. The shortest duration was 2 years, and the longest, 20 years. The majority of patients (48% to be exact) were suffering from diabetes for between 6 and 10 years (table-1).

As expected, with increasing age of the patients, the duration of illness too increases. Under 50 years, all the patients have diabetes for less than 10 years. After 50 years, 16 out of 37 (43.24%) have illness of 10 years or more.

Treatment modality

45 patients (90%) were on oral hypoglycemic agents (OHAs). Four patients (8%) were on insulin therapy. A 72-year-old male diabetic was on both insulin and OHA therapy.

Treatment regularity

Treatment in as many as 41 patients (82%) was regular. Therapy in the case of the rest 18% was irregular.

Visual acuity

Right Eye: In the right eye of 16 diabetic patients (32%) the vision was normal (6/6). In 4 patients the right eye was economically blind (3/60 or worse). The remaining right eyes had loss of vision of various intermediary degrees.

Left Eye: Vision in left eye was normal (6/6) in 16 patients (32%). In 4 patients the left eye was economically blind (3/60 or worse). The remaining left eyes had loss of vision of various intermediary degrees.

Ophthalmoscopic findings

Right Eye: 35 right eyes (70%) showed non-proliferative diabetic retinopathy (NPDR). Of these mild and moderate cases were 21 and 14 respectively. In 4 patients (8%), ophthalmoscopy revealed NPDR associated with clinically significant macular edema (CSME). In another 9 patients (18%), NPDR was combined with focal exudative maculopathy (FEM).

In 2 cases (4%) proliferative diabetic retinopathy (PDR) was detected.

Left eye:

32 eyes (64%) showed NPDR. Of these 19 were mild, 12 were moderate and 1 was severe NPDR.

Ophthalmoscopy revealed NPDR+CSME In 3 patients (6%),

Age group (years)	Duration of diabetes (years)				Total
	11-5	6-10	11-15	16-20	
21-30				-	2
31-40	2	1	-	-	3
41-50	3	5	-	-	8
51-60	3	13	5	3	24
61-70	-	5	4	2	11
71 and above	-	-	-	2	2
Total	10	24	9	7	50

Table-1: Age and duration of illness in 50 diabetic patients

NPDR+FEM in 12 (24%), and in 1 NPDR plus ischemic maculopathy (IM) in 1.

In 2 cases (4%) PDR was detected. These were the same patients whose right eye also showed PDR (graph-1).

Role of age, sex, duration of illness on fundus findings

To elucidate the role of the above predisposing factors on the retinal complication of diabetes, the ophthalmoscopic changes of both eyes are totaled (100 eyes), and grouped into two tentative categories: (a) mild NPDR category and (b) other severer categories. The latter is made up of moderate NPDR, severe NPDR, NPDR+CSME, NPDR+FEM, NPDR+IM and PDR.

Role of age

With the increase in age of the patient up to 50 years, the proportion of severer categories decreases. This proportion is the lowest in the 41-50 years group. After 51 years, this proportion goes on increasing till it is 100% in patients over 71 years. This relationship is statistically significant (p = 0.0011).

Role of sex

A greater proportion of male diabetic eyes as against female ones is showing other severer categories. This difference, however, is statistically not significant (p = 0.1080).

Role of illness duration

The impact of duration of illness on ophthalmoscopic findings is depicted in Table 3.

The severity of retinopathy as revealed by ophthalmoscopic examination rises with the increase in the duration of illness.

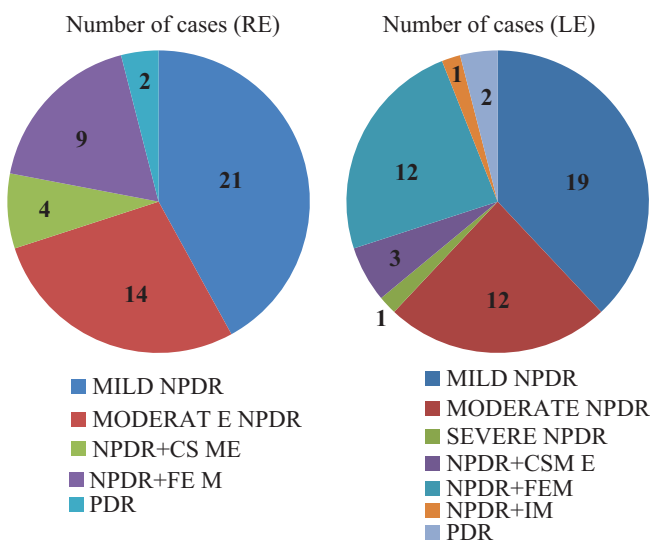
Diagnosis	No. of cases (RE)	Percent	No. of cases (LE)	Percent
Mild NPDR	21	42	19	38
Moderate NPDR	14	28	12	24
Severe NPDR	-	-	1	2
NPDR+CSME	4*	8	3*	6
NPDR+FEM	9**	18	12**	24
PDR	2	4	2	4
NPDR+IM	--	--	1***	2

RE: *3 mild NPDR and 1 moderate NPDR, RE: ** 1 mild NPDR and 8 moderate NPDR, LE: *2 mild NPDR, 1 severe NPDR, LE: ** 3 mild NPDR, 9 moderate NPDR, LE: *** moderate NPDR

Table-2: Ophthalmoscopic findings of right eye in 50 patients

Duration (years)	NPDR mild category		Other severer categories		Total	
	Number	Percent	Number	Percent	Number	Percent
2-5	17	85.00	3	15.00	20	100
6-10	20	41.67	28	58.33	48	100
11-15	3	16.67	15	83.33	18	100
16-20	0	0.00	14	100.00	14	100

Table-3: Duration



Graph-1: Chart showing ophthalmoscopic findings in 50 patients

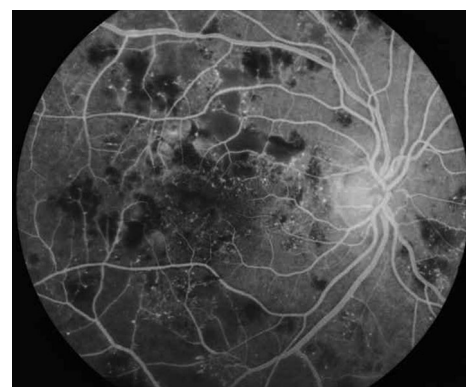


Figure-1: (RE) FFA showing microaneurysm and IRMA.

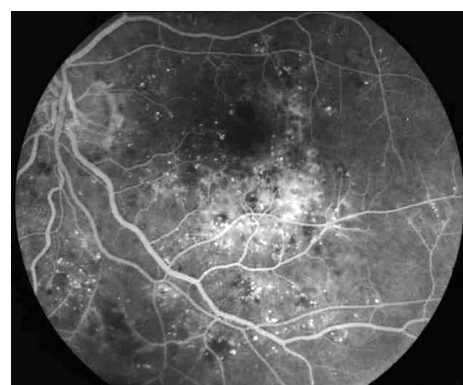


Figure-2: (LE) FFA showing diffuse leak around macula.

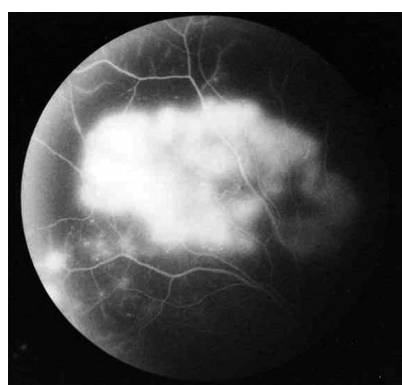


Figure-3: late FFA film showing extensive leak.

The changes noted in the above table are statistically very significant ($p < 0.0001$).

Role of alcohol, tobacco, hypertension and regularity of treatment

While only 55.56% of those abstaining from alcohol had severe categories of retinopathy, 100% of alcohol addicts had the said categories.

Again, while only 54.55% of those abstaining from tobacco had other severer categories of retinopathy, 100% of tobacco abusers had them.

While 91.67% of the diabetics with hypertension showed severer level of retinopathy changes, only 55.68% of non-hypertensive patients had such changes.

Regularity of treatment has reduced the other severer categories by about half, i.e., from 100% to 51.22%

Dissimilarities in the eyes on FFA

Of the 3 patients with PDR in the right eye, only 1 left eye showed the condition. Among the remaining, one left eye had NPDR+FEM and the other left eye, severe NPDR.

16 diabetics patients showed mild NPDR in both eyes. In one patient mild NPDR in the left eye was paired with moderate NPDR in the right, and in another, mild NPDR in the right eye was associated with NPDR+FEM in the left. Finally, there was a case with mild NPDR in the left and NPDR+CSME in the right eye.

12 cases showed moderate NPDR in both eyes. In one patient moderate NPDR in the right eye was associated with NPDR+FEM in the left, and in the other, moderate NPDR in the left eye was paired with NPDR+FEM in the right.

Comparison of ophthalmoscopic with FFA findings

Right Eye: Ophthalmoscopy is very sensitive in diagnosing NPDR+CSME and mild NPDR in the right eye. It is least sensitive in diagnosing NPDR+FEM and NPDR+IM.

Left Eye: Ophthalmoscopy is very sensitive in diagnosing mild NPDR and NPDR +FEM. It is least sensitive in detecting severe NPDR.

On the average the sensitivity of ophthalmoscopy in detecting right grades of retinopathy in both eyes of diabetic patients is 80%.

DISCUSSION

The material for the present study consists of 50 diabetic patients who attended the outpatient department or who were admitted to Sree Siddhartha Medical College Hospital, Tumkur during the period of March 2003 to February 2004.

The mean age of the present study subjects was 55.65 years with a standard deviation of (SD) of 11.13 years.

In a similar study conducted by Ramsevak V. et al³ who have studied 775 cases, the mean age was 72.1 years.

In another study conducted by Sumi S. et al⁴ who studied 242 patients, the mean age of their patients was 52.9 years. (Range-13-84 years) and the mean duration of diabetes was 10.7 years.

Another study conducted by Gonzalez Villalpando C. et al⁵

where 231 patients were examined. The mean age was 62.4 years.

Sl No	Name	Mean age
1	Ramsevak V. et al ³	72.1 years
2	Sumi S, et al ⁴	52.9 years
3	Gonzalez Villalpando C. et al ⁵	62.4 years
4	Present study	55.65 years

The mean age in the first study is more when compared to the remaining three studies due to the reason that the patients selected for the study are only of type 2 diabetes mellitus when compared to the patients of the other three studies where in the patients are of both type 1 and type 2 diabetes mellitus.

Male: Female ratio

Male: Female ratio in our study is 37:13 i.e. 2.9: 1 when compared to the study conducted by Gonzalez Villalpando C et al⁵ where male to female ratio is 0.91: 1.

Duration of the disease

The mean duration of diabetics in the present study is 9.32 years whereas is the study conducted by Ramsevak V. et al³ the mean duration of the disease was 13 years.

In another study conducted by Sumi S, et al⁴ who studied 242 patients, the mean duration of diabetes was 10.7 years.

Another study conducted by Gonzalez Villalpando C et al⁵ where 231 patients were examined. The mean duration of diabetes was 11 years.

Study	Duration of the disease
Ramsevak V. et al ³	11 Years
Sumi S, et al ⁴	10.7 years
Gonzalez Villalpando C et al ⁵	12.3 years
Present study	9.32 years

Role of irregular treatment and poor glycemic control

In our study we had 9 patients who were irregular in their treatment. This can be considered a factor, which lead to poor glycemic control. The grade of retinopathy of these patients are tabulated according to the duration of diabetes as follows.

Grade	No of Patients	Duration of diabetes
Mild/Moderate NPDR	5	2-7 years
Sev NPDR	1	15 years
PDR	3	16-18years

In a study conducted by Voutilainen-Kaunisto RM, et al who studied progress of retinopathy with respect to poor glycemic control in 133 patients observed of retinopathy changes in 55% of patients after 5 years

They concluded, in the diabetic patients, poor glycemic control was the most important predictive factor for the development of retinopathy. It was directly associated with HbA1C values in their by their study.

Another study conducted by Kingsley LA et.al⁶ showed significant differences in glycosilated hemoglobin values in patients with and without retinopathy changes. The number of microaneurysms was positively associated with individual mean glycosilated hemoglobin (HbA1c)

Comparison of ophthalmoscopic and fluorescein angiography findings

Detailed study of dilated ophthalmoscopy, biomicroscopy where ever needed, was followed by fluorescein angiography. The different grades of retinopathy noticed in our study of 50 patients are compared with the following studies.

The study conducted by Bertram et al⁷ who studied 130 patients of diabetic retinopathy, the different grades of retinopathy in their study was compared with our study. The study conducted by Sumi S, et al⁴ and Ramsevak V. et al³ were also compared.

Study	Mild / Mod NPDR		Sev NPDR		PDR		CSME	
	No.	%	No	%	No	%	No	%
Bertram et.al	93	19	23	4.7	14	2.9	41	8
Sumi S, et al	113	71	-	-	17	7	5	3
Ramsevak V. et al	166	21.4	-	-		2.8		6.1
Present study	35	70	2	4	2	4	3	6

In our study we found more cases of mild/ moderate NPDR than the other studies. This may be due to the fact that we had an exclusion criteria of not including the patients having hazy media and the patients who had already undergone photocoagulation.

In the study conducted by Bertram et.al⁷ 48 patients (9.8%) had already undergone laser photocoagulation, 13 panretinal scatter, 18 with focal photocoagulation and 17 with both.

The NPDR category in the study conducted by Ramsevak V. et al³ is 21.4% which is also less when compared to the present study. This is because they have screened the patients of diabetes mellitus patients who attended the ophthalmic clinic for the first time for the evaluation.

The microaneurysms were appreciated better both in the number, position and in relation to vasculature.

This was in consensus with the study conducted by Friberg TR and others.⁸ who studied 101 patients, about twice as many microaneurysms were detected on the FFA as on the colour photography. Also FFA showed microaneurysms in 57% of the eyes that had no detectable microaneurysms on colour photography.

However the study conducted by Niesel P. et al⁹ states that the described method of quantitative evaluation of diabetic retinopathy quantifies the progression of retinopathy. The difficulty of quantification are due to interpretation problems of the photographic documentation. Accurate quantitative analysis of the comparison between the ophthalmoscopic quantification and angiographic quantification was difficult because of the cumbersome nature of counting especially by ophthalmoscopy, lack of accuracy and interpretation problems.

In a study conducted by Helstedt, et.al¹⁰ it is concluded that although microaneurysms in fluorescein angiography and red spots in color or red free photographs all reflect the degree of retinopathy, about half of the red dots in photography don't represent open micro aneurysms in fluorescein angiography. Ischaemic maculopathy was better appreciated by fluorescein angiography than by ophthalmoscopy. Widening of FAZ was

also better delineated with fluorescein angiography than by ophthalmoscopy.

In a study conducted by Smith RT et. al¹¹ they studied 34 diabetic patients with clinically significant macular edema (CSME) by fundus photography, fluorescein angiography and vitreous fluorophotometry observed that all the three investigations together best predicted visual acuity. They also concluded that by performing fluorescein angiography it is possible to quantitate macular ischaemia.

Clinically significant macular edema (CSME) was observed better by fluorescein angiography than by ophthalmoscopy. The study conducted by Kylstra JA et al¹² where 100 patients were studied by six retina specialists also concluded that the use of FA improves the accuracy of treatment planning of CSME.

Fluorescein angiography was also more accurate is exact localization and extent of neovascularization. This finding was in concurrence with the one observed by Jain BS, et al.¹³ Who studied 25 patients of diabetic retinopathy by ophthalmoscopy and fundus fluorescein angiography.

CONCLUSION

Fundus Fluorescein Angiography is a very useful ancillary diagnostic procedure. It is helpful in diabetic retinopathy in characterization and quantification of microaneurysms. It is also useful to differentiate 'red dots' observed by ophthalmoscopy or fundus colour photography. It is also useful in assessing the severity of characteristics like the extent of capillary loss (ischaemia).

It helps in the exact localisation of neovascularisation and extent of neovascularisation. Although fundus fluorescein angiography is not mandatory before the treatment of macular edema, the use of FFA improves the accuracy of treatment planning of CSME. It is also useful in classification of diabetic retinopathy from fluorescein angiograms (ETDRS Report No. 11).

The procedure is useful in diagnosis, treatment, follow-up of patients and to maintain permanent record of the stage of retinopathy, which is useful in understanding the course of the disease in the patient, response to the treatment and follow up.

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