Section: Miscellaneous

Original Research Article

CLINICAL EVALUATION OF DIABETIC RETINOPATHY USING FUNDUS FLUORESCEIN ANGIOGRAPHY: A HOSPITAL-BASED OBSERVATIONAL STUDY

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ABSTRACT

Background: Diabetic maculopathy is a major cause of visual impairment in patients with diabetic retinopathy (DR). Fundus fluorescein angiography (FFA) remains an important imaging modality for identifying macular pathology, retinal ischemia, and neovascularization, thereby facilitating timely management. The objective is to evaluate the role of FFA in staging diabetic retinopathy, characterizing diabetic maculopathy, and determining its association with visual acuity and the severity of diabetic retinopathy.

Materials and Methods: This prospective observational study included 50 patients (100 eyes) with suspected diabetic retinopathy attending a tertiary care hospital. All patients underwent comprehensive ophthalmic examination and FFA. Diabetic retinopathy was graded according to the Early Treatment Diabetic Retinopathy Study (ETDRS) classification. Maculopathy was categorized as focal, diffuse, ischemic, or mixed based on angiographic findings.

Results: Of the 100 eyes examined, 71 eyes had diabetic maculopathy. Severe non-proliferative diabetic retinopathy (NPDR) was the commonest stage (36.6%), followed by very severe NPDR (25.4%). Focal maculopathy (39.4%) was the predominant angiographic pattern, followed by diffuse (36.6%), mixed (16.9%), and ischemic maculopathy (7.0%). Focal and diffuse maculopathy together constituted 76.0% of cases. A significant association was observed between BCVA and the type of maculopathy (χ^2=55.89, df=21, p<0.001), with focal maculopathy associated with better visual acuity and diffuse, ischemic, and mixed maculopathy associated with poorer vision. No significant association was found between the severity of diabetic retinopathy and maculopathy type (χ^2=18.12, df=12, p=0.112).

Conclusion: FFA effectively characterizes diabetic maculopathy and provides valuable information regarding visual prognosis. Although maculopathy type was strongly associated with visual acuity, it was not significantly associated with the severity of diabetic retinopathy. FFA remains an indispensable adjunct for diagnosis, prognostication, and treatment planning in patients with diabetic retinopathy.

Keywords: Diabetic retinopathy; Diabetic maculopathy; Fundus fluorescein angiography; Best-corrected visual acuity; Macular edema

INTRODUCTION

Diabetes mellitus is one of the most common chronic metabolic disorders worldwide and represents a major public health challenge because of its rapidly increasing prevalence and associated microvascular complications. Among these, diabetic retinopathy (DR) remains the leading cause of preventable visual impairment and blindness in the working-age population. With the global burden of diabetes continuing to rise, the incidence of DR and vision-threatening diabetic eye disease is expected to

increase substantially, particularly in developing countries such as India, which has one of the largest populations of individuals with diabetes worldwide.[1]

The principal causes of visual loss in DR include diabetic macular edema (DME), macular ischemia, and retinal neovascularization. Diabetic macular edema is the most frequent cause of vision loss, affecting nearly one-fourth of patients with diabetes.[2-5] The underlying mechanism involves breakdown of the blood–retinal barrier, resulting in increased vascular permeability, fluid leakage, and retinal thickening.[6] Early identification of these changes is crucial, as timely intervention can prevent irreversible retinal damage and preserve visual function.

Clinical examination with slit-lamp biomicroscopy and fundus evaluation remains the cornerstone for diagnosing diabetic retinopathy. However, these techniques are limited in detecting subtle retinal thickening, accurately assessing retinal ischemia, and objectively quantifying the extent of macular involvement.[7-10] Furthermore, clinical examination alone may not reliably identify the precise location and severity of vascular leakage or alterations in the perifoveal capillary network, which are essential for treatment planning.

Fundus Fluorescein Angiography (FFA) has been an established imaging modality for more than four decades in the evaluation of retinal vascular diseases. It provides dynamic visualization of the retinal circulation, allowing detailed assessment of vascular integrity, capillary non-perfusion, microaneurysms, neovascularization, and patterns of dye leakage. FFA plays an important role in confirming the severity of diabetic retinopathy, identifying clinically significant macular edema, evaluating enlargement of the foveal avascular zone, and differentiating focal, diffuse, ischemic, mixed, and cystoid forms of diabetic maculopathy. These findings are invaluable in determining the appropriate management strategy and monitoring therapeutic response.

Despite the emergence of newer retinal imaging modalities, FFA continues to be an indispensable investigation for selected patients with diabetic retinopathy, particularly when evaluating retinal ischemia, occult neovascularization, and lesions requiring laser photocoagulation. It remains an important adjunct in treatment planning, including focal or panretinal laser photocoagulation and vitreoretinal surgical intervention when indicated.

The present study was undertaken to evaluate the role of Fundus Fluorescein Angiography in the staging of diabetic retinopathy, detection of diabetic maculopathy and neovascularization, assessment of visual impairment, and correlation of angiographic findings with the severity of diabetic retinopathy. The study also aimed to assess the utility of FFA in guiding appropriate management of patients with diabetic retinopathy.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Ophthalmology at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrolment.

Consecutive patients attending the ophthalmology outpatient department were screened for diabetic retinopathy, and those fulfilling the eligibility criteria were included in the study. A total of 50 patients (100 eyes) with diabetic retinopathy underwent Fundus Fluorescein Angiography (FFA), of whom 71 eyes demonstrated diabetic maculopathy.

Eligibility Criteria:

Patients with any of the following were included in the study:

- Diabetic retinopathy with clinically significant macular edema (CSME).
- Diabetic retinopathy with suspected macular ischemia in the absence of clinically significant macular edema
- Moderate non-proliferative diabetic retinopathy (NPDR) or more advanced stages of diabetic retinopathy.

Patients were excluded if they had uncontrolled diabetes with ketoacidosis, juvenile diabetes mellitus, impaired renal function, known hypersensitivity to sodium fluorescein, acute respiratory illness, or haematological disorders such as severe anaemia, sickle cell disease, or polycythaemia. Ocular exclusion criteria included corneal opacity, dense cataract, vitreous haemorrhage, retinal detachment, retinal telangiectasia, ocular tumors, pregnancy, and any previous treatment for diabetic retinopathy, including laser photocoagulation, intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections, or intravitreal corticosteroid therapy.

Clinical Evaluation: A detailed medical and ophthalmic history was obtained from all participants. Comprehensive ophthalmic examination included assessment of uncorrected and best-corrected distance and near visual acuity, slit-lamp biomicroscopy of the anterior segment, and measurement of intraocular pressure using a Schiotz tonometer. Pupillary dilatation was achieved using tropicamide and phenylephrine eye drops, with phenylephrine avoided in patients with uncontrolled hypertension. Fundus examination was performed using direct ophthalmoscopy, indirect ophthalmoscopy, and slit-lamp biomicroscopy with a 90-diopter lens.

Prior to FFA, all patients underwent pre-anaesthetic evaluation, and the procedure was performed with appropriate anaesthetic support. Emergency resuscitation equipment and oxygen supply were readily available throughout the procedure.

Fundus Fluorescein Angiography: Fundus Fluorescein Angiography was performed using a fundus camera following standard imaging protocols.

After explaining the procedure and possible adverse effects, 2 mL of 25% sodium fluorescein was administered rapidly through an intravenous cannula. Baseline colour and red-free fundus photographs were obtained before dye injection.

Serial angiographic images were captured from the early choroidal filling phase through the arterial, arteriovenous, venous, and late phases. Early images were acquired at one-second intervals during the initial transit phase, followed by sequential imaging over the subsequent minutes. Late-phase photographs were obtained approximately 15–20 minutes after dye injection. Seven-field retinal photographs were obtained according to the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol.

Following the procedure, patients were counselled regarding the transient yellow discoloration of the skin and urine that may persist for 36–72 hours.

Image Analysis: Fluorescein angiograms were evaluated according to ETDRS guidelines. The severity of diabetic retinopathy was confirmed, and angiographic features including microaneurysms, capillary non-perfusion, foveal avascular zone enlargement, retinal neovascularization, and leakage patterns were assessed. Diabetic maculopathy was classified as focal, diffuse, ischemic, mixed, or cystoid based on angiographic findings. The presence of clinically significant macular edema, retinal ischemia, and neovascularization was documented and correlated with visual acuity and the clinical stage of diabetic retinopathy.

Outcome Measures: The primary outcome measures were the role of Fundus Fluorescein Angiography in confirming the clinical stage of diabetic retinopathy, detecting diabetic macular edema and neovascularization, determining the prevalence and patterns of diabetic maculopathy, and correlating angiographic findings with visual impairment and disease severity. The secondary outcome measure was the utility of FFA in guiding the management of diabetic retinopathy, including laser photocoagulation and pars plana vitrectomy where indicated.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using SPSS software (Version 16.0). Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were analysed using the Chi-square test or contingency coefficient analysis where appropriate. Cross-tabulation was used to evaluate relationships between diabetic retinopathy stage, maculopathy type, and visual impairment. A p-value of <0.05 was considered statistically significant.

RESULTS

The study included 50 patients with diabetic retinopathy. Most participants were aged 51–60 years (56%), followed by 61–70 years (32%), with an almost equal sex distribution (52% males and 48% females). More than half of the patients (52%) had diabetes mellitus for >10 years, 54% had associated systemic hypertension, and 72% were receiving oral hypoglycaemic agents, while 28% were on insulin therapy [Table 1]

Table 1: Distribution of Patients according to baseline characteristics.

Baseline characteristics	Subcategory	Number (No.)	Percentage (%)
Age (in years)	40-50	04	08
	51-60	28	56
	61-70	16	32
	71-80	02	04
Gender	Male	26	52
	Female	24	48
Duration of diabetic mellitus (years)	<10	24	48
	>10	26	52
Associated systemic hypertension	Present	27	54
	Absent	23	46
Treatment History	Oral Hypoglycaemic Agents	36	72
	Insulin	14	28
Total	--	50	100.00

A total of 71 eyes were evaluated. Severe NPDR was the most common stage (36.6%), followed by very severe NPDR (25.4%) and moderate NPDR (16.9%). Low-risk and high-risk PDR accounted for 11.3% and 9.9% of eyes, respectively, while no eyes had mild NPDR. Overall, 62.0% of eyes had advanced NPDR and 21.2% had proliferative diabetic retinopathy [Table 2].

Table 2: Distribution of type of diabetic retinopathy

Severity of retinopathy	No. of eyes	Percentage
Mild NPDR	00	00
Moderate NPDR	12	16.9
Severe NPDR	26	36.6
Very severe NPDR	18	25.4
Low Risk PDR	08	11.3
High Risk PDR	07	9.9
Total	71	100

Among the 71 eyes, focal maculopathy was the predominant type (39.4%), followed by diffuse maculopathy (36.6%), mixed maculopathy (16.9%), and ischemic maculopathy (7.0%). Collectively, focal and diffuse maculopathy accounted for 76.0% of all cases [Table 3].

Table 3: Classification of Maculopathy

Types of Maculopathies	No. of eyes	Percentage
Focal	28	39.4
Diffuse	26	36.6
Ischemic	05	7.0
Mixed	12	16.9
Total	71	100

A significant association was observed between best-corrected visual acuity (BCVA) and the type of maculopathy ($\chi^2 = 55.89$, df = 21, $p < 0.001$). Focal maculopathy predominated in eyes with better visual acuity (6/6–6/12), whereas diffuse, mixed, and ischemic maculopathy became increasingly common with worsening vision, particularly in eyes with BCVA of 6/36 or worse [Table 4].

Table 4: Co-relation of Vision with type of Maculopathy.

BCVA		Types of Maculopathies				
		Focal	Diffuse	Ischemic	Mixed	Total
6/6	No.	2	0	0	0	2
	%	100%	0	0	0	3%
6/9	No.	6	0	0	0	6
	%	100%	0	0	0	8%
6/12	No.	8	3	0	0	11
	%	72.2%	27.2%	0	0	15%
6/18	No.	6	7	0	1	14
	%	42.9%	50%	0	7.1%	20%
6/24	No.	6	3	2	2	13
	%	46.1%	23%	15.3%	15.3%	18%
6/36	No.	0	6	3	2	11
	%	0.1%	54.5%	27.2	18.2%	15%
6/60	No.	0	7	0	5	12
	%	0	58.3%	0	41.6%	17%
3/60	No.	0	0	0	2	2%
	%	0	0	0	100%	3%
Total	No.	28	26	5	12	71
	%	39.4%	36.6%	7%	16.9%	100%

[Chi-square (χ^2) = 55.89; Degrees of freedom (df) = 21; $P < 0.001$]

The association between the severity of diabetic retinopathy and the type of maculopathy was not statistically significant ($\chi^2 = 18.12$, df = 12, $p = 0.112$). Focal maculopathy predominated in moderate and severe NPDR, mixed maculopathy was most frequent in very severe NPDR, while diffuse maculopathy was the commonest pattern in low-risk PDR. High-risk PDR demonstrated a relatively even distribution of focal and diffuse maculopathy [Table 5].

Table 5: Correlation of type of diabetic retinopathy with type of Maculopathy

Type of diabetic retinopathy		Types of Maculopathies				
		Focal	Diffuse	Ischemic	Mixed	Total
Moderate NPDR	No.	7	4	0	1	12
	%	25%	15.3	0	8.3	16.9
Severe NPDR	No.	12	10	1	3	26
	%	42.9	38.4	20	25	36.6
Very Severe NPDR	No.	4	6	1	7	18
	%	14.3	23.1	20	58.3	25.4
Low Risk PDR	No.	2	4	2	0	8
	%	7.1	15.3	40	0	11.3
High Risk PDR	No.	3	2	1	1	7
	%	28	26	5	12	9.9%
Total	No.	28	26	5	12	71
	%	28	26	5	12	100

[Chi-square (χ^2) = 18.12; Degrees of freedom (df) = 12; P = 0.112]

DISCUSSION

The present study included patients aged 40–80 years, with the majority belonging to the 51–60-year age group, consistent with previous studies reporting a mean age between 57 and 62 years, reflecting the higher prevalence of diabetic retinopathy and maculopathy in middle-aged and older adults.[11-12]

Similar to the observations of Shetty et al.[13] and Lawson et al,[14] most participants had type 2 diabetes mellitus, emphasizing its strong association with diabetic macular disease. The sex distribution was nearly equal, which is in agreement with the findings of Wani et al,[14] and Golubovic-Arsovska,[15] who also reported no significant gender predilection.

More than half of the patients had diabetes for over 10 years, supporting earlier reports that the risk of diabetic maculopathy increases with longer disease duration.[13,14,16] Although 54% of patients had coexisting hypertension, this variable was not significantly associated with maculopathy, consistent with the findings of Espiritu et al.[17] Most patients were treated with oral hypoglycaemic agents, similar to previous Indian studies.[14]

Fluorescein angiography demonstrated that focal (39.4%) and diffuse maculopathy (36.6%) were the predominant patterns, together accounting for over three-fourths of affected eyes. This distribution is comparable to reports by Jian Wanchen et al,[10] and Ma et al,[18] who also found focal and diffuse edema to be the commonest angiographic patterns, although the relative proportions varied across studies. In contrast, Golubovic-Arsovska et al,[15] reported mixed maculopathy as the predominant subtype, highlighting possible differences in patient characteristics and disease severity.

A significant association was observed between BCVA and the type of maculopathy ($p < 0.001$). Better visual acuity was predominantly associated with focal maculopathy, whereas diffuse, mixed, and ischemic maculopathy were increasingly associated with poorer vision. These findings are consistent with previous studies demonstrating worse visual outcomes in diffuse and ischemic macular edema and a significant correlation between macular morphology and visual impairment.[11,12,17,19,20]

Most eyes in the present study had advanced NPDR, and focal maculopathy predominated in moderate and severe NPDR, whereas diffuse and mixed patterns were more common in advanced disease. However, no significant association was found between the severity of diabetic retinopathy and the type of maculopathy ($p = 0.112$). Similar observations have been reported by Wani et al. regarding the predominance of focal maculopathy in NPDR and diffuse maculopathy in PDR, although they demonstrated a significant association for ischemic maculopathy in proliferative disease.[14] In contrast, Espiritu et al. and Kojima et al. reported a significant correlation between retinopathy severity and maculopathy, suggesting that differences in study population, sample size, and disease spectrum may account for the observed variation.[15,17]

CONCLUSION

Diabetic maculopathy was observed predominantly in patients with type 2 diabetes mellitus, with focal and diffuse maculopathy representing the most common angiographic patterns. Best-corrected visual acuity showed a significant association with the type of maculopathy, with focal maculopathy generally associated with better visual acuity, whereas diffuse, ischemic, and mixed maculopathy were associated with greater visual impairment. Advanced diabetic retinopathy was common in the study population; however, the type of maculopathy did not demonstrate a significant association with the severity of diabetic retinopathy.

These findings highlight the importance of comprehensive fundus evaluation in all patients with diabetic retinopathy, as diabetic maculopathy may be present even in eyes with relatively preserved visual acuity. Fundus fluorescein angiography (FFA) remains a valuable tool for accurately characterizing macular involvement, assessing disease severity and visual prognosis, and guiding timely therapeutic interventions, including focal or grid laser photocoagulation and follow-up assessment. Early identification and appropriate management of diabetic maculopathy are essential to preserve vision and reduce the risk of irreversible visual loss.

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