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Original Article

Ophthalmology Section

Understanding the Paradigm of Treatment Dropouts in Diabetic Retinopathy Care: A Prospective Cohort Study

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ABSTRACT

Introduction: Diabetes Mellitus is a lifelong condition that demands continuous management. Inadequate glycaemic control raises the risk of complications such as cardiovascular and cerebrovascular diseases, nephropathy, retinopathy and neuropathy. Diabetic Retinopathy (DR) if left untreated can pose a serious risk to one's vision and treatment dropouts pose a significant challenge. Adherence to prescribed treatment regimens is crucial in preventing the progression of these complications. Therefore, addressing this issue of treatment dropouts is the need of the hour.

Aim: To explore the factors associated with compliance among DR patients receiving Intra Vitreal Injections (IVI) (Anti-VEGF injections) and multiple laser sittings.

Materials and Methods: A prospective cohort study was conducted at a tertiary healthcare hospital, Kolar, Karnataka, India which involved 112 diabetic patients and factors associated with Loss To Follow-Up (LTFU) were assessed using questionnaires from July 2022 to October 2023 in a tertiary care hospital in Kolar, Karnataka. Data was analysed using Statistical Package for the Social Sciences (SPSS) 22.0 version software. Categorical data was represented as frequencies and proportions. The Chi-square test or Fischer's exact test (for 2×2 tables only) was used as a significance test for qualitative data with a p-value of <0.05, which was considered statistically significant.

Results: Age ranged from 22-81 years with a mean of 57.4±11.3 years. Out of the 112 patients, 34 (30.4%) were LTFU, and 78 (69.6%) were followed-up as recommended or had delays of less than six months. Significant difference was found between LTFU and the type of treatment given (p-value=0.012). Specifically, 17 (21.8%) Pan Retinal Photocoagulation (PRP) laser patients were LTFU as compared to 11 (50%) patients who received IVI Anti-VEGF injections and 6 (50%) patients who received both PRP laser and IVI (Anti-VEGF injections). The cardinal causes of LTFU were limited affordability (35.3%), lack of satisfaction with treatment (14.7%), and job obligations (23.5%).

Conclusion: Present study emphasised the socio-economic burden on the patient in terms of affordability and loss of daily income, which in turn affects their compliance with frequent follow-ups, demanding the need for newer strategies to improve compliance.

Keywords: Follow-up, Intravitreal injection, Laser, Preventive medicine, Socio-economic factors

INTRODUCTION

India's cultural and demographic diversity extends to socio-economic factors, disease prevalence and health outcomes. Notably, India has a high incidence of diabetes, with 77 million people affected, projected to rise to 125 million by 2045 [1]. In the context of diabetic complications, a "domino effect" is a prominent feature, with DR serving as an early warning sign of disrupted molecular and visual communication. Managing DR is significantly influenced by the state of mitochondrial health. In terms of specific statistics, DR affects 77.3% of Type 1 Diabetes (T1D) patients and 25.1% of those with Type 2 Diabetes (T2D). Of these cases, approximately 25 to 30% progress to vision-threatening diabetic macular oedema [1,2]. DR, a diabetes-related microvascular complication, can progress silently to Vision-Threatening Diabetic Retinopathy (VTDR), risking permanent vision loss without early detection and prompt intervention. Thus, regular fundoscopic exams are highly advised for individuals with diabetes to detect and treat DR early and to start them on IVI {Anti-VEGF injections (Anti Vascular Endothelial Growth Factor injection)} [2]. Pan Retinal Photocoagulation (PRP LASER) treatment has shown a 50% to 60% decrease in severe visual impairment risk within three months by halting abnormal blood vessel growth. Nonetheless, it is crucial to acknowledge that this treatment approach has various adverse effects, including an increased risk of macular oedema, peripheral vision loss and night vision impairment. Moreover, even after successful PRP LASER, some patients may require additional laser therapy [3,4].

The introduction of IVI of anti-VEGF has had a transformative impact on managing DR. Several studies involving IVIs of anti-VEGF have demonstrated comparable and, in some cases, potentially superior results compared to PRP LASER [5-10]. This shift in treatment methodology signifies a significant development in DR management. It is essential to highlight that anti-VEGF therapy for DR is administered through IVIs, which require frequent administrations, often every month [4,5]. Though DR is mainly treatable, complications arise when patients fail to follow-up consistently. There may be several untold factors that may lead patients not to follow-up. Some studies done showed factors such as limited affordability and the need for multiple sittings/injections [6-8]. To the best of the authors' knowledge, no studies validate or support the above studies in Southern India. Therefore, the aim of the present study was to determine the treatment discontinuation rate among DR patients undergoing anti-VEGF therapy and multiple laser sessions within a year and to investigate these factors in depth linked to treatment discontinuation in a different socio-economic and geographic setting. The goal was to develop effective strategies for enhancing follow-up care for these patients.

MATERIALS AND METHODS

This prospective cohort follow-up study involved 112 established T2DM patients who attended the ophthalmology outpatient department, affiliated tertiary healthcare hospital of a medical college in the Kolar district of Karnataka, India for DR screening and treatment from July 2022 to October 2023 after obtaining ethical

clearance from Institutional Ethical Committee (No. SDUMC/KLR/IEC/516/2023-24) and written informed consent from the subjects.

Inclusion criteria: All diabetic retinopathy patient undergoing treatment with anti VEGF and lasers were included in the study.

Exclusion criteria: All diabetic retinopathy patient undergoing/need surgical management were excluded from the study.

Sample size: The sample size was calculated using the proportion of LTFU in subjects, which was 16.3%, based on the study by Abdelmotaal H et al., using the formula $Z_{1-\alpha/2}^2$ P (1-P), where $Z_{1-\alpha/2}$=is standard normal variate (at 5% type 1 error (p-value <0.05) it is 1.96 P=Expected proportion in population based on previous studies or pilot studies, d= Absolute error or precision (7.5%) [6]. Using the above values at 95% Confidence level, a sample size of 94 subjects was obtained. Considering 10% non response, a sample size of 94+9.4≈105 subjects was considered for the study.

Study Procedure

Patient demographic characteristics, including age and sex, were collected. Detailed history and fundoscopic examinations for initial visit and each follow-up visit were recorded in the hospital database. Patients who were undergoing treatment for DR with PRP LASER or IVI (Anti-VEGF injections) or combination therapy were recruited to the study. The number of PRP LASER sessions and IVI (Anti-VEGF injections) were noted, and monthly follow-ups over six months were assessed. LTFU is defined as missing any follow-up visit for any interval exceeding six months, provided that patients eventually resumed care before the end of the study period [6]. These patients were followed-up by telephonic interview/direct interview using a questionnaire to assess the various factors and then differences in the rates of these factors for LTFU. Patients in the LTFU group were requested to complete an 8-factor questionnaire through the telephone method regarding the reasons for missing their follow-up appointments. These questionnaire items were chosen based on preliminary discussions with around 22 subjects who had faced similar situations before the study. The questionnaire covered various potential causes for LTFU such as:

(1) Lack of information provided by medical care providers on follow-up need or date;
(2) Lack of concern and/or compliance;
(3) Lack of trust in and/or satisfaction with treatment;
(4) Lack of treatment affordability;
(5) Difficulty with transportation;
(6) Other disabling conditions (comorbidity) that hindered appointment attendance;
(7) Lack of a social support system;
(8) Employment obligations.
(9) Others reasons

Patients were instructed to respond to the questionnaire with “yes” or “no.”

STATISTICAL ANALYSIS

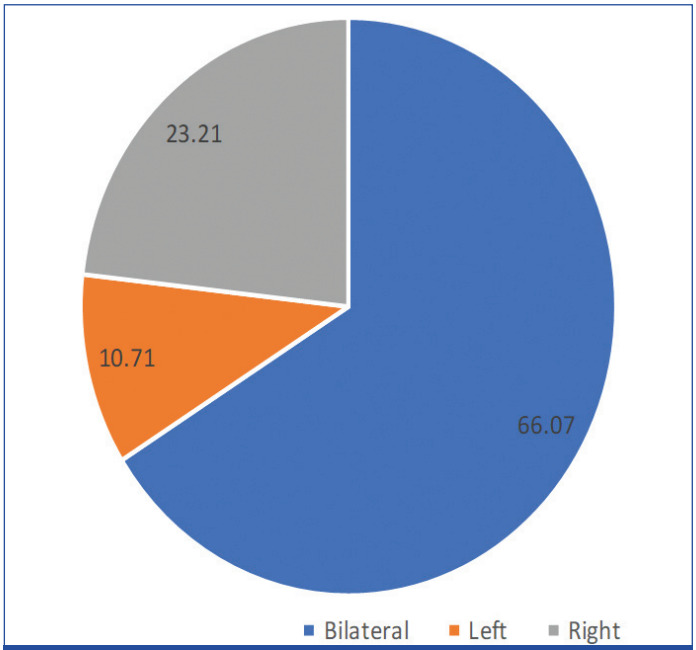
The data was recorded in a Microsoft Excel spreadsheet and analysed using SPSS version 22.0 software. Categorical variables were summarised using frequencies and proportions. The Chi-square test or Fischer’s exact test (for 2×2 tables only) was used as a significance test for qualitative data (causes for treatment dropouts). Continuous data was represented as mean and standard deviation. An Independent t-test was used as a significance test to identify the mean difference between two quantitative variables. The p-value of <0.05 was considered statistically significant.

RESULTS

Age-wise distribution is shown in [Table/Fig-1]. Age ranged from 22-81 years with a mean of 57.4±11.3 years. Among these patients’ males were 65 (58%) and females were 47 (42%). A 74 (66.07%) patients underwent treatment for both eyes, 12 (10.71%) for left eye and 26 (23.21%) for right eye [Table/Fig-2].

Age (years)	n (%)
<50	30 (26.8)
51-60	41 (36.6)
>60	41 (36.6)

[Table/Fig-1]: Distribution of subjects according to age group (n=112).



[Table/Fig-2]: Pie diagram showing the distribution of subjects according to the laterality of treatment.

Distribution according to treatment is shown in [Table/Fig-3].

Out of the 112 patients, 59 (52.68%) were unemployed, 29 (25%) were self-employed and 24 (21.43%) were employed as show in [Table/Fig-4].

Treatment	n (%)
Laser	78 (69.6)
Anti VEGF	22 (19.6)
Both	12 (10.7)

[Table/Fig-3]: Distribution of subjects according to treatment with percentages.

Age (years)	Employed	Self employed	Unemployed
<50	8	10	12
51-60	11	12	18
>60	5	7	29
Total	24 (21.43%)	29 (25.89)	59 (52.68%)

[Table/Fig-4]: Distribution of subjects according to employment status for different age groups.

Among the 112 patients who were diabetic, 15 of them were hypertensives as well. A total of 37 patients had poor glycaemic control (HbA1c more than 8%) while the rest had fair glycaemic control (HbA1c 7-8%).

In this study, 112 cases of DR were evaluated, classifying them into two primary categories- Non Proliferative Diabetic Retinopathy (NPDR) and Proliferative Diabetic Retinopathy (PDR). Among the total cases, 68 individuals (60.7%) were diagnosed with NPDR, while 44 individuals (39.3%) had progressed to PDR.

Out of the 112 patients, 34 (30.4%) were LTFU, and 78 (69.6%) were followed-up as recommended or had delays of less than six months shown in [Table/Fig-5]. In the present study, it was noted that as age increased, rates of LTFU increased: 16.7% of patients aged

≤50 years were LTFU, 31.7% of patients aged 51-60 years were LTFU, and 39% of patients aged ≥61 years were LTFU as shown in [Table/Fig-6]. There were no significant differences between rates of LTFU and sex (27.7% in men and 34% in women). There was a significant difference (0.012) between LTFU and the type of intervention used. Specifically, 17 (21.8%) PRP laser patients were LTFU as compared to 11 (50%) patients who received IVI Anti-VEGF injections and 6 (50%) patients who received both PRP Laser and IVI (Anti-VEGF injections) [Table/Fig-6].

Follow-up	n (%)	Mean±SD	p-value
Followed-up	78 (69.6)	56.63±11.460	0.243
LTFU	34 (30.4)	59.35±10.924	

[Table/Fig-5]: Distribution of subjects according to follow-up and comparison of mean age according to follow-up.
*p-value <0.05; Clinically significant; Independent t-test

Variables	Followed-up (78) n (%)	LTFU (34) n (%)	p-value
Age group (years)			
<50	25 (83.3)	5 (16.7)	0.125
51-60	28 (68.3)	13 (31.7)	
>60	25 (61.0)	16 (39.0)	
Sex			
Female	31 (66.0)	16 (34.0)	0.471
Male	47 (72.3)	18 (27.7)	
Treatment			
Laser	61 (78.2)	17 (21.8)	0.012*
Anti VEGF	11 (50.0)	11 (50.0)	
Both	6 (50.0)	6 (50.0)	

[Table/Fig-6]: Association between demographic factors, treatment modalities and follow-up.
*p-value <0.05; Clinically significant; Chi-square test

Among those who were lost to follow-up, 17 patients were advised laser but following two session they were lost to follow-up and 11 others were subjected to IVI Anti-VEGF injections out of which 5 of them were lost to follow-up after one injection whereas 4 of the patients were lost to follow-up after taking two injections and out of the six patients who were advised combination of both, they had undergone three sessions of laser and one injection.

A total of 34 LTFU subjects were asked to complete the questionnaire. Financial constraints, job obligations, and treatment ineffectiveness were the three main factors, and they were noted in 12 (35.3%), 8 (23.5%), and 5 (14.7%) patients, respectively [Table/Fig-7].

Reasons for loss to follow-up	Lack of information	Lack of concern/ compliance	Lack of trust in and/or satisfaction with treatment	Financial/treatment affordability	Difficultly with transportation	Employment/ Job obligations	Lack of social support	Others/disabling conditions
N	4	0	5	12	1	8	3	1
%	11.8	0	14.7	35.3	2.9	23.5	8.8	2.9

[Table/Fig-7]: Various causes for LTFU with frequencies (N=34).

DISCUSSION

All patients with risk factors for DR presenting to the ophthalmology outpatient department should be made aware of the debilitating effect of DR on one's life and should be evaluated in detail if one presents with associated risk factors. Given the myriad of challenges in diabetic treatment, LTFU shows a significant threat in preventing vision-threatening diseases [5,6].

All 112 patients included in the study were diabetic and 15 of them were hypertensives as well. A total of 37 patients had poor glycaemic control (HbA1c more than 8%) while the rest had fair glycaemic control (HbA1c 7-8%). The predominance of NPDR cases highlights the importance of early detection and intervention in DR. NPDR, as the earlier stage of the disease, presents an opportunity for timely management to prevent progression to PDR, which is associated with a higher risk of vision-threatening complications. However, the significant proportion of PDR cases (39.3%) underscores the need for enhanced screening and follow-up strategies, particularly in individuals with long-standing diabetes or poor glycaemic control.

The study included subjects across different age groups, with a notable concentration of participants aged 51-60 and over 60, comprising 36.6% of the total sample. A higher proportion of male participants (58%) were observed than females (42%). This shows that the working age group numbers are higher, and males account for the higher number. This demographic trend shows that predominantly men of the older age group are prone to miss their follow-up. This may be because they may be unable to reach the healthcare facilities due to physical health issues or job liabilities. However, another study showed that the younger age group was prone to LTFU [6]. When examining age as a factor in follow-up adherence, the study found no statistically significant difference in mean age between followed-up and LTFU groups (p-value=0.243). Similarly, no significant associations were observed between follow-up adherence and age group or sex, indicating that these demographic factors did not substantially influence follow-up patterns in this sample.

In this study, 30.4% of patients who received PRP Laser and IVI (Anti-VEGF injections) to treat DR were LTFU. Other studies done in Egypt found that the overall LTFU rate was 16.3% over approximately five years [6-8]. Another randomised clinical trial noted an average LTFU rate of 16.7%, 19%, and 20% at 2, 4, and 5 years, respectively [9]. Sivaprasad S et al., noted an LTFU rate of 4% in one year [10]; whereas, Subash M et al., reported an LTFU rate of 12% at six months [11]. Obeid A et al., in their study found an LTFU rate exceeding 20% in a retrospective cohort study [8]. The authors that a selection bias could have caused the high LTFU rate because more concerned and compliant patients may have chosen to participate in prospective trials.

In present study, patients with persistently active DR routinely underwent various PRP Laser and IVI (Anti-VEGF injections) procedures, all administered by the same treating specialist. This approach ensured consistent management and allowed for the adaptation of treatment strategies based on individual patient responses. The distribution of treatment modalities showed a preference for laser treatment, administered to 69.6% of participants, whereas anti-VEGF treatment was used in 19.6%, and both treatments in 10.7%. However, treatment type was associated with follow-up adherence: patients receiving laser treatment had higher adherence rates than those receiving anti-VEGF or combined treatments (p-value=0.012). Follow-up rates revealed that 69.6% of participants continued follow-up, while 30.4% were LTFU. A higher rate of LTFU was observed in subjects who underwent IVI (Anti-VEGF injections) (50%) or a combination of pan-retinal photocoagulation (PRP Laser) and IVI (Anti-VEGF injections) (50%) compared to those who underwent PRP Laser alone (21.8%). This may be due to the high cost of anti-VEGF injections and the need for multiple injections compared to Laser treatment. These findings were found to be in contradiction with another study where a higher LTFU rate was noted in the PRP LASER-only group [6].

The current study revealed that limited affordability was the predominant cause of LTFU (35.3% of LTFU cases). Despite anti-VEGF agents being included in the World Health Organisation's (WHO)

list of essential medicines, their inconsistent access, availability, and administration may render them financially unsustainable in developing countries with low- or intermediate-resource settings [12]. This access disparity could explain the elevated LTFU rates observed in the IVI (Anti-VEGF injections) and PRP LASER + IVI (Anti-VEGF injections) groups. The second major cause of LTFU (23.5% of LTFU cases) was job obligations, particularly prominent in the younger age group (Upto 60 years of age). Notably, a significant portion of patients in the older age category (>60 years of age) were either unemployed or self-employed. Therefore, their reasons for lost to follow-up were owing to other factors apart from job obligations. Out of the 112 patients in present study, 59 (52.68%) were unemployed, 29 (25.89%) were self-employed and 24 (21.43%) were employed. This employment status played an important role in their treatment follow-up as this in turn contributes to their financial situation and these job obligations which lead to poor compliance.

Achieving the desired results necessitates multiple treatment sessions. The identification of "ineffective treatment" as the third major cause of concern was reported by 14.7% of the patients. Notably, patients in the older age group are prone to categorise the treatment as ineffective, especially after a single session. This tendency may elucidate the observed trend toward an increased LTFU with advancing age, with the highest LTFU rate observed in subjects aged 61 years and older (39%). Conversely, an alternate study highlighted a diminishing rate of LTFU as age increased [6].

Approximately, 60% of patients with DR exhibit a positive response to PRP laser, specifically in retinal neovascularisation regression, within three months following the completion of their treatment [13]. However, it is important to note that the development of new retinal blood vessels may continue for about one-third of these patients despite having undergone the initial PRP laser session [14]. This persistence of neovascular growth highlights the variability in treatment outcomes and underscores the need for ongoing monitoring and potential additional interventions for a significant subset of patients.

Consequently, vitreous haemorrhage poses a significant risk of vision loss and may impede the continuation of further PRP Laser sessions in these individuals. In contrast, IVIs of anti-VEGF agents can rapidly reverse retinal neovascularisation after just a single injection [15]. However, the efficacy of IVI (Anti-VEGF injections) tends to be relatively short-lived, with new vessel growth recurring in 93% of eyes within 12 weeks. While the effects of PRP LASER are generally more durable, a notable portion of patients ultimately require alternative therapies [16-19].

Patients expressing dissatisfaction exhibit a lack of trust in their treating doctors, thereby contributing to higher LTFU rates. Consequently, there is a pressing need for comprehensive, straightforward and thorough patient education beyond procedural consent forms. This education should enhance patient awareness regarding the nature of their condition and how it is effectively managed.

Limitation(s)

Present study had several limitations. First, there was no ideal time interval for treatment duration because PRP Laser and IVI (Anti-VEGF injections) follow-up schedules can vary widely between the various stages of DR patients. Second, this study did not had randomised treatment decisions, which may have introduced a selection bias. Third, since present study was not a funded study, the role of financial factors affecting LTFU was obvious and biased; hence, the other factors could not be assessed to their full potential. Lastly, it was essential to note that the outcomes of present research may not be universally applicable on an international scale as several of these factors are more applicable to this socio-economic background. The varied nature of healthcare practices, patient demographics, and treatment accessibility across different regions may limit the generalisability of present study results beyond the specific context in which the study was conducted.

CONCLUSION(S)

This study emphasises the need to address modifiable factors contributing to the loss of follow-up among DR patients receiving anti-VEGF therapy and laser treatments. Geographic and socio-economic challenges are major causes, with dropouts often linked to affordability, treatment dissatisfaction and work commitments. Targeted interventions like improved patient education, better communication, telemedicine and affordable treatment options through insurance or support schemes could enhance compliance and reduce the risk of vision loss.

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