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Research Article

STUDY ON QUALITY OF LIFE ASSESSMENT IN DIABETIC RETINOPATHY AMONG PATIENTS WITH TYPE 2 DIABETIC PATIENTS

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ABSTRACT

Objective: The aim was to study the vision-related quality of life (QOL) for diabetic retinopathy (DR) among patients with Type 2 diabetes and to assess the direct medical cost of different treatment modalities.

Methods: It was based on an individual-based analysis of QOL before and after the treatment for DR. The main objective of the study was to compare QOL between patients based on the different treatment modalities using vision function questionnaire (VFQ)-25, to evaluate the direct medical cost for DR patients undergoing different treatment modalities and to compare the cost and QOL of different treatment modalities in samples with non-proliferative DR (NPDR)/proliferative diabetic retinopathy (PDR) macular edema. The population included were patients with Type 2 diabetes with NPDR, with clinically significant macular edema and PDR, patients diagnosed to have diabetes above 5-year duration, adult patients, ocular pain those who are on regular follow-up and those who are willing to be a part of study. A total of 256 patients were selected out, of which 141 patients were satisfied the study criteria and participated in the study. Data relevant to the voice-related QOL study were obtained and recorded using VFQ-25 questionnaire. Other data relevant to the study were obtained and recorded in a semistructured data collection form by interviewing the patient or their caregivers and by direct examination of patient's medical record. Expenditure was calculated in Indian Rupees.

Results: After comparing the baseline QOL with QOL after treatment, it was found that the overall QOL of the study samples in accordance with the treatment undergone was found to be improved. The overall QOL had improved after the treatment for all samples and major improvement was seen on dependency, social functioning (SF), and mental health (MH).

Conclusion: The overall QOL had improved after the treatment for all samples and major improvement were seen on dependency, SF, and MH. In conclusion, the study analyzed that intravitreal bevacizumab therapy is the cheapest one and with the comparatively same clinical outcome when compared with intravitreal ranibizumab therapy for macular edema cases in patients with NPDR and PDR.

Keywords: Non-proliferative diabetic retinopathy, Proliferative diabetic retinopathy, Retinopathy.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic disorder with estimated prevalence rate of 6.4% in total population [1]. DM is a group of metabolic disorders characterized by hyperglycemia. It is associated with abnormalities in carbohydrate, fat, and protein metabolism. Type 1 is insulin-dependent diabetes which is an autoimmune disorder developing in childhood or early adulthood. Type 2 which is non-insulin dependent is characterized by insulin resistance and a relative lack of insulin secretion. Patients with Type 2 diabetes are more prone to develop micro- and macro-vascular complications that lead to damage of end organs such as kidneys, brain, and eyes, affect the direct and indirect cost and quality of life (QOL) [2]. Lack of education of the disease and its comorbidities is the leading cause for complications in any disease [3]. A study was conducted on QOL assessment in diabetic retinopathy (DR) among the patients with Type 2 diabetes before and after treatment. There is evidence that retinopathy begins to develop at least 7 years before being clinically diagnosed [4,5]. DR is a sight-threatening and chronic ocular disorder that eventually develops to some degree in nearly all people with diabetes. DR is an ocular manifestation of systemic disease which affects up to 80% of all patients who have had diabetes for 10 years or more [6]. Despite these intimidating statistics, research indicates that at least 90% of these new cases could be reduced if there was proper and vigilant treatment and monitoring of eyes [7]. After 10 years of DM, blindness was 1.8, 4.0, and 4.8% in Type 1, insulin-treated Type 2, and non-insulin treated Type 2 patients [8]. The main objective of the study was to compare QOL between patients based on the different treatment modalities using vision function questionnaire (VFQ). The patients visiting the Ophthalmology Department of Amrita Institute of Medical Science were selected depending on the inclusion and exclusion criteria. Data relevant to the voice-related QOL (VRQOL) study were obtained and recorded using VFQ 25 questionnaire. Other data relevant to the study were obtained and recorded in a semistructured data collection form by interviewing the patient or their caregivers and by direct examination of patient's medical record.

METHODS

Design of study

This was a non-experimental (observational), prospective study.

Settings

This study was carried out at the Outpatient Department of Ophthalmology of Amrita Institute of Medical Sciences (AIMS), Kochi. It is a 1450-bedded tertiary care, teaching, and super specialty referral hospital located in a huge campus at Elamakkara in Cochin. Facilities at AIMS include 210 outfitted intensive care beds and 25 operating theaters.

Study population

The study included patients visiting the ophthalmology ocular pain (OP) Department with DR and who satisfy the inclusion and exclusion criteria.

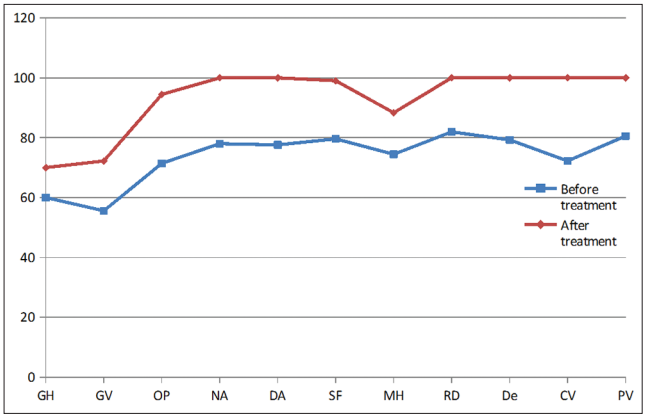

Fig. 1: Graphical representation of overall quality of life scoring of samples before and after treatment

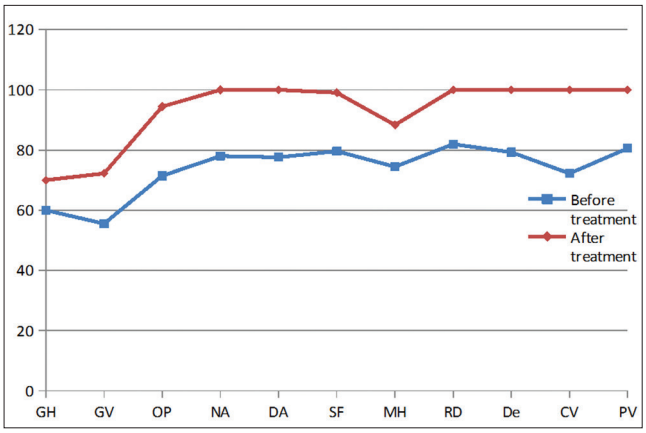

Fig. 2: Comparison of quality of life before and after treatment based on intravitreal ranibizumab therapy

Inclusion criteria (Figs. 1-7)

- Patients with Type 2 diabetes with non-proliferative DR (NPDR) with clinically significant macular edema (CSME) and proliferative DR (PDR) (Tables 1 and 2)
- Patients diagnosed to have diabetes above 5 years duration
- Adult patients
- OP those who are on regular follow-up
- Those who are willing to be a part of study.

Exclusion criteria (Figs. 1-7)

- Patients with Type 1 diabetes, gestational diabetes, and drug-induced diabetes (Tables 1 and 2)
- NPDR without CSME
- PDR patients with vitreous hemorrhage
- Migrating patients, those who cannot be contacted by means of phone
- Patients who are not willing to be part of the study
- Patients who are getting insurance and reimbursement.

Sample size

A total of 256 patients were diagnosed to have Type 2 DR who visited the ophthalmology department during the study period. From that, 141 patients were satisfied the study criteria and participated in the study.

Date collection

Data relevant to the VRQOL study were obtained and recorded using VFQ 25 questionnaire. Other data relevant to the study were obtained and recorded in a semistructured data collection form by interviewing the patient or their caregivers and by direct examination of patient's medical record.

Fig. 3: Comparison of quality of life before and after treatment based on intravitreal bevacizumab therapy

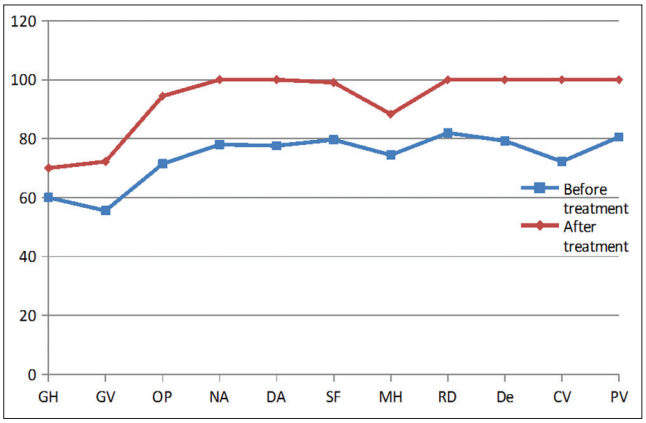

Fig. 4: Comparison of quality of life before and after treatment based on focal laser therapy

Table 1: Types of DR

Classification of DR	Frequency (%)		Total (%)
	Female	Male	
NPDR with CSME	12 (7.7)	16 (10.3)	28 (18)
PDR without CSME	37 (23.8)	67 (43.4)	104 (67.0)
PDR with CSME	3 (1.9)	6 (3.8)	9 (5.8)

NPDR: Non-proliferative diabetic retinopathy, CSME: Clinically significant macular edema, PDR: Proliferative diabetic retinopathy

Data collection tools

- VFQ 25 questionnaire
- Semistructured data collection form.

Methodology

An observational, prospective study was carried out on patients who were diagnosed to have DR under the Department of Ophthalmology of AIMS, Kochi, from March 1st 2011 to August 31st 2011. The aim was to assess the outcome of the treatment. The aim was to assess the outcome of the treatment that the patients have undergone according to the severity of the disease so as to study to what extend it had an impact on their QOL and to calculate the direct medical cost involved in the treatment process. It was based on an individual-based analysis of QOL before and after treatment for DR. Data were collected using a VFQ 25 questionnaire and a semistructured data collection forms and all information relevant to the study was entered by interviewing the patient and analyzing the case record. Direct medical cost was collected includes practitioner consultation fees, acquisition cost of medicines, different types of procedure costs, and the cost of different laboratory investigations. Expenditure in this study was calculated in accordance with Indian rupees.

Table 2: Treatment undergone

Types of DR	Treatment undergone	Overall QOL score			p value
		Before treatment	After treatment	Change in QOL	
NPDR with CSME	Intravitreal bevacizumab therapy+focal laser	73.69	93.19	19.50	0.001
	Intravitreal ranibizumab therapy+focal therapy	70.92	93.70	22.78	0.001
	Focal laser therapy	73.83	93.04	19.21	0.001
PDR without CSME	PRP	71.13	85.98	14.85	0.001
PDR with CSME	PRP laser+bevacizumab therapy	68.79	86.68	17.89	0.001
	PRP laser+ranibizumab therapy	67.47	87.03	19.56	0.001

NPDR: Non-proliferative diabetic retinopathy, QOL: Quality of life, CSME: Clinically significant macular edema, PDR: Proliferative diabetic retinopathy, PRP: Pan retinal photocoagulation

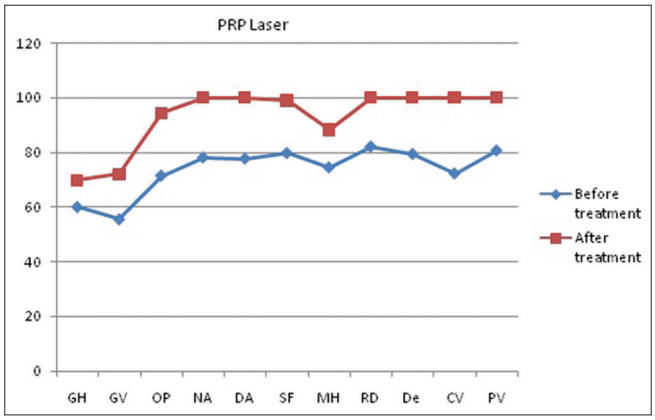

Fig. 5: Comparison of quality of life before and after treatment based on photocoagulation laser therapy

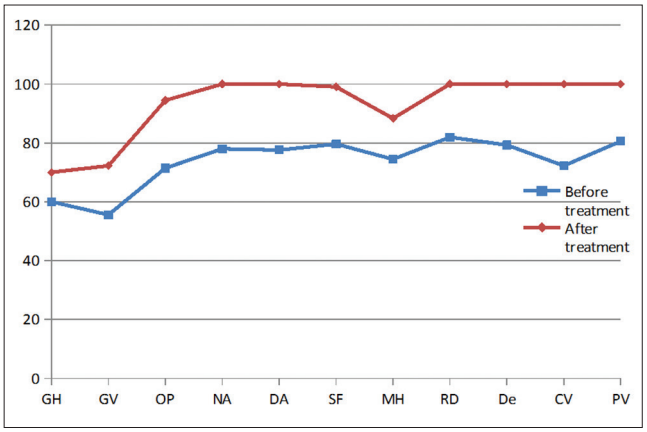

Fig. 6: Comparison of quality of life before and after treatment based on photocoagulation laser therapy laser+bevacizumab therapy [6]

RESULTS

Age distribution of the patients in the study group

Majority of the patients were in the age group of 60-64. The youngest patient in the study population was 35-year-old and oldest was 80-year-old.

Gender distribution

Out of 256 patients with DR, 141 patients were satisfied the study criteria. Among that, 63.12% were male and 36.87% were female.

Direct medical cost

Drugs used to cure macular edema were bevacizumab and ranibizumab and it cost Rs. 6800/- and Rs. 75,000/-. The drugs given for symptomatic relief were nepafenac (nevanac) which cost Rs. 175/-, moxifloxacin eye drops (milflox) Rs. 70/-, vigamox Rs. 195/-, prednisolone acetate eye drops Rs. 95/-, paracetamol (Dolo 650 mg) Rs. 2/tablet. The diagnosis is done by slit-lamp biomicroscopy which cost Rs. 75/-, optical coherence which cost Rs. 1250/-, and fundus fluorescein angiography which cost Rs.1000/-. Pan retinal photocoagulation laser therapy (PRP) and focal laser therapy cost Rs. 1000/- and Rs. 2000/-, respectively. Consultation fee costs Rs. 130/- and Rs. 180/- without and with appointment, respectively.

By evaluating the average of total direct medical cost, Rs. 79,040.00 and Rs. 10,804.92 cost for PRP laser+ranibizumab therapy and PRP laser+bivacizumab therapy, respectively. The average direct medical cost for focal laser+intravitreal ranibizumab therapy and focal laser+intravitreal bivacizumab therapy was estimated as Rs. 80,031.75 and Rs. 11,383.18, respectively.

QOL

A total of 141 patients were interviewed using National Eye Institute VFQ-25 (with subscales) before and after treatment. After comparing the baseline QOL with QOL after treatment, it was found that the overall QOL of the study samples in accordance with the treatment undergone was found to be improved.

The VFQ 25 contains different domains such as general health, general vision, OP, near activities, distance activities, social functioning, mental health, role difficulties, de-dependence, color vision, peripheral vision, and driving.

DISCUSSION

DR is a sight-threatening and chronic ocular disorder that eventually develops to some degree in nearly all people with diabetes. An observational, prospective study was carried out on patients who were diagnosed to have DR. The study conducted by Ossama and El Haddad *et al.* reported that higher percentage of samples was having NPDR than PDR. According to the study, 30% of samples were within the age group of (60-64), 16% within (55-59), 14% within (50-54), 13% within (65-69), and 12% within (45-49). A study conducted by Rasmieh *et al.* in 1000 DR patients with Type 2 DM. About 40% of the patients were within the age group of 56-65 years of age [9]. When the samples were categorized based on the treatment undergone according to their grade of DR, it was found that 67% undergone PRP laser, 10.3% undergone intravitreal bevacizumab therapy, 3.8% undergone intravitreal ranibizumab therapy, and 9.6%undergone focal laser therapy. The present study shows change in QOL after the treatment which indicates that there was an improvement in the overall QOL among samples in accordance with the treatment modalities. When compared the cost of treatment with the representative QOL, it showed that there is high variation in terms of money value between the intravitreal injections of bevacizumab and ranibizumab. Though the efficacy was comparatively similar ranibizumab is much safer than bevacizumab, because later one is an off - label drug and required reconstitution since 0.05 ml is required for the treatment of macular edema form the 4 ml vials. A study conducted by rich, Simó *et al.* (2009) [10] on the safety and efficacy of intravitreal bevacizumab reported that intravitreal bevacizumab is

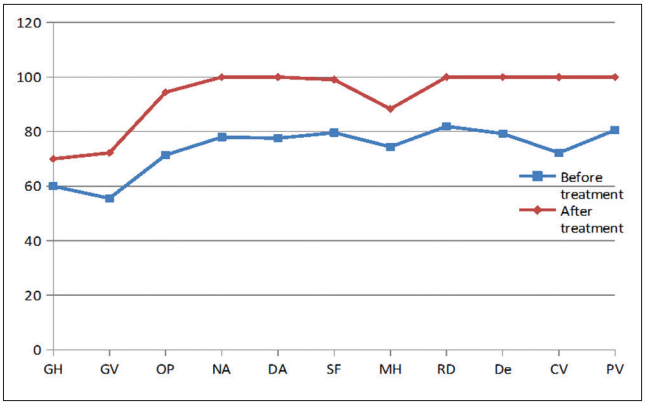

Fig. 7: Comparison of quality of life before and after treatment based on photocoagulation laser therapy laser+ranibizumab therapy

a cost-effective therapy for the treatment of neovascular age-related macular edema, but the long-term safety and efficacy remain unknown. The findings suggest that treatment regimen, level of glycemic control, and the presence of complications are associated with QOL [11].

CONCLUSION

The study was conducted on the vision-related QOL for DR among patients with Type 2 diabetes and to assess the direct medical cost of different treatment modalities. A total of 141 cases of Type 2 DM having DR were selected during the study period of which males were more when compared to females. Among the samples collected, it is shown that higher prevalence of disease was associated with PDR cases. Majority patients were with >60 years of age out of the total sample. Out of the 141 patients, 88.6% were having above 10 years duration of DM. Direct medical cost study showed a higher cost of therapy for intravitreal ranibizumab injection when compared to intravitreal bevacizumab therapy. There was an improvement in their QOL after the treatment and the change in QOL between the study samples who had undergone intravitreal injections were only 0.7. The overall QOL had improved after the treatment for all samples and major improvement was seen on dependency, social functioning, and mental health. In conclusion, the study analyzes that intravitreal bevacizumab therapy is the cheapest one and with the comparatively same clinical outcome when compared with intravitreal ranibizumab therapy for macular edema cases in patients with NPDR and PDR.

REFERENCES

1. Joseph TD, Robert LT, Gary CY. Pharmacotherapy a Pathophysiological Approach. 7th ed. New York, NY: McGraw-Hill Medical; 2008. p. 1205-8.
2. Balaiah S, Tirupa M, Narayana G, Mohanraj R, Reddy YP. Assessment of pharmaceutical care services on health related quality of life in patients with Type 2 diabetes mellitus. Int J Pharm Pharm Sci 2014;6(7):456-61.
3. Vijayan M, Nampoothiri V, Krishnan S, Vinod K, Vijayan N. Study on clinical pharmacists' initiated interventions in improving compliance among geriatrics patients. Int J Pharm Sci Rev Res 2016;36(1):17-21.
4. Klein R, Klein BE, Moss SE. Prevalence and risk of diabetic retinopathy where age at diagnosis is 30 or more years. Arch Ophthalmol 1984;102(4):527-32.
5. Hanna AK, Roy M, Zinman B, McCulloch JC, Mortimer C, Falk JA, *et al.* An evaluation of factors associated with proliferative diabetic retinopathy. Clin Invest Med 1985;8(2):109-16.
6. Kertes PJ, Johnson TM. Evidence Based Eye Care. 1st ed. Philadelphia, PA: Lipincott Williams; 2007. p. 403-41.
7. Tapp RJ, Shaw JE, Harper CA, de Courten MP, Balkau B, McCarty DJ, *et al.* The prevalence of and factors associated with diabetic retinopathy in the Australian population. Diabetes Care 2003;26(6):1731-7.
8. Singh R, Ramasamy K, Abraham C, Gupta V, Gupta A. Diabetic retinopathy: An update. Indian J Ophthalmol 2008;56(3):178-88.
9. Rasmieh M, Khader Y, Malas S, Abu-Yaghi N, Al-Bdour M, Ajlouni K, *et al.* Prevalence and risk factors of diabetic retinopathy among Jordanian patients with Type 2 diabetes mellitus. J Ophthalmol 2008;24(1):29-35.
10. Simó R, Hernández C. Advances in the medical treatment of diabetic retinopathy. Diabetes Care 2009;32(8):1556-62.
11. Andayani TM, Ibrahim MI, Asdie AH. The association of diabetes - Related factor and quality of life in Type 2 diabetes mellitus. Int J Pharm Pharm Sci 2010;2(1):139-45.