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Assessment of Thickness of Macular Edema on Optical Coherence Tomography in Diabetic Patients Treated with Anti-Vascular Endothelial Growth Factor

Inam Majid Soomro[1*], Imran Ali[1], Ayaz Ali Khoso[2], Prince Aakash Gul Kandhro[2], Zakaullah Gopang[1] and Safdar Ali Abbasi[1]

[1]Department of Ophthalmology, Chandka Medical College Hospital, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana, Pakistan
[2]Layton Rahmatulla Benevolent Trust, Gambat, Pakistan

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***Corresponding Author:**
Inam Majid Soomro
Department of Ophthalmology, Chandka Medical College Hospital, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana, Pakistan
inammajids@yahoo.com

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ABSTRACT

Diabetes is becoming more commonplace worldwide with potential causes. Diabetic retinopathy is a serious ocular complication that affects working-age adults and causes moderate to severe vision loss. **Objective:** To determine the outcome of anti-VEGF by optical coherence tomography (OCT) in DME thickness. **Methods:** A prospective (interventional) study was carried out at the Chandka Medical College Hospital's Department of Ophthalmology at SMBB Medical University, Larkana. The study included all individuals over the age of 15 who had diabetes mellitus of any kind. SPSS version 26 was used for data analysis. **Result:** Patients were 64.8 ± 14.2 years old on average, had a BMI of 33.56 ± 7.85 kg/m2, and had been on DME for an average of 8.06 ± 4.23 years. There were 17 (34%) female patients and 33 (66%) male patients out of 50. The most common risk factor among 50 patients was hyperlipidemia, 45(90%) followed by hypertension 43 (86%), anemia 42 (84%), insulin dependent, 37 (74%), obesity31(62%), chronic renal failure, 28 (56%) and smoking, 26 (52%). **Conclusion:** OCT can be used to accurately measure retinal thickness brought on by DME. OCT can therefore be a helpful technique in predicting the functional outcome and assessing how well anti-VEGF medication works for individuals with DME. Anti-VEGF therapy results in rapid and sustained thickness reduction on OCT, generally correlating with improvements in visual acuity. The outcome of anti-VEGF therapy in diabetic macular edema (DME), as measured by OCT, typically shows a significant reduction in central retinal thickness (CRT) or central subfield thickness (CST).

INTRODUCTION

Diabetes is a public health crisis that is expanding at the fastest rate since it can have many serious health effects [1]. Diabetes is becoming more commonplace worldwide; potential causes include ageing, obesity, physical inactivity, urbanization, sedentary lifestyles, and unhealthy eating habits. As a developing nation, Diabetes prevalence is sharply increasing in Pakistan [2]. Diabetic retinopathy is a serious ocular complication that affects working-age adults and causes moderate to severe vision loss. Diabetic retinopathy patients often have visual loss due to diabetic macular oedema (DME), which affects around 21 million individuals globally [3, 4]. Currently, intravitreal injections of various anti-vascular endothelial growth factor (anti-VEGF) medicines must be administered repeatedly to treat macular edema [5]. Other management techniques for DME comprise intravitreal steroid injections & macular laser photocoagulation [6]. VEGF has been linked to enhanced Vascular Permeability through the disruption of blood-retina barriers and its function in angiogenesis, both of which are pathophysiological factors for numerous retinal complications [7]. Additionally, VEGF regulates proper angiogenesis and vasculogenesis, among other

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physiological processes, and during the formation of retinal blood vessels, it serves as a survival factor [8]. They have a neuroprotective function that lowers neuronal apoptosis and preserves the metabolism of choriocapillaris and photoreceptors. There have been questions raised about the safety of using these agents over an extended period since these physiological activities of VEGF may get disrupted through protracted management of retinal problems with frequent injections [9, 10]. Numerous investigations revealed harmful cellular consequences when VEGF was inhibited. Nevertheless, several previous investigations used fundus fluorescein angiography (FFA) and OCT to evaluate the effects on macular and retinal perfusion of repeated intravitreal injections of anti-VEGF drugs used for DME. When compared to FFA, the OCT offers high-resolution, three-dimensional pictures of each of the distinct retinal vascular layers, allowing for noninvasive, dye-free imaging of superficial and deep retinal vessels. OCT can reliably and precisely detect capillary drop-out zones and produce a picture of the foveal avascular zone (FAZ) without being obstructed by dyed leaking or macular xanthophyll pigmentation shadowing, unlike FFA [11, 12]. Retinal vascular density (VD) and fractional dimension (FD) may also be accurately measured quantitatively and automatically using OCT [13]. Numerous studies have reported the short-term efficacy of anti-VEGF agents in reducing central macular thickness and improving vision. Studies exist comparing different anti-VEGF agents regarding efficacy and safety.

Diabetic macular edema (DME) is a major cause of visual impairment among patients with diabetic retinopathy, particularly in developing countries where the burden of diabetes is rapidly increasing. Anti-vascular endothelial growth factor (anti-VEGF) therapy has emerged as a key treatment modality for reducing macular edema and improving visual outcomes. However, the effectiveness of this therapy and its anatomical response assessed through optical coherence tomography (OCT) has not been extensively studied in the local population. Moreover, limited regional data exist regarding changes in central subfield thickness following anti-VEGF treatment, highlighting the need for further clinical evaluation. This study aims to find out how anti-VEGF treatment using OCT affects the thickness of diabetic macular edema (DME). Owing to a lack of data, research on this topic would be beneficial as well.

METHODS

A prospective (interventional) study, using a random sampling approach was carried out at the Chandka Medical College Hospital Department of Ophthalmology at Shaheed Mohtarma Benazir Bhutto (SMBB) Medical University, Larkana (1-9-2024 to 28-2-2025). Data were collected after getting approval from the research ethics committee of SMBBMU Larkana (NO.SMBBMU/IRB/06). To calculate sample size, an equation was used: Effect size (Δ): 40 µm. Standard deviation (σ): 90 µm. $\alpha = 0.05$, Power = 0.80. $n=(Z\alpha/2+Z\beta)\cdot\sigma/\Delta)2$. $n=(1.96+0.84)\cdot 90/40)2$. n=40 patients. To account for dropouts, the study has increased it to around 50 patients. Inclusion criteria was consisted on patients of any type of DME, having age above15years to 70 years, either gender, no history of Retinal by treatment by (focal/grid/scatter) laser or by intravitreal injections of anti-VEGF agents or steroids were included and patients of DME with intraocular inflammation or infection, uncontrolled glaucoma, previous retinal laser photocoagulation, Grid, Focal and Scatter, history of stroke and un controlled hypertension, intravitreal injections of anti VEGF/steroids were excluded from the study. Patients who satisfied the selection criteria were chosen from the ophthalmology department's retina clinic and given a thorough examination that included measurements of intraocular pressure, anterior and posterior segment investigations, and best-corrected visual acuity measurements (BCVA). All patients signed consent forms to confirm their enrollment in the study. Baseline data like age, gender, duration, type of DM, grading of DME, type of diabetes, diabetic retinopathy stage (Both proliferative and non-proliferative diabetic retinopathy are possible), risk factors of DME and central subfield thickness were recorded from patients' history on a pre-designed approved Performa. All patients underwent treatment with one injection of bevacizumab (1.25 mg/ 0.05 ml) for 3 months consecutively, as a similar drug was studied by Elnahry *et al.*, [14]. The protocol of using optical coherence tomography was based on informed consent obtained from the patient. The procedure was explained for non-invasive imaging using light waves to take cross-sectional pictures of the retina. Remove contact lenses/glasses. Turn on the OCT machine and allow it to calibrate. Select appropriate scan protocol: (e.g., macular cube, optic disc cube, anterior segment). Check lens cleanliness and optical components. Adjust the chair and chin rest for proper alignment. Seat the patient comfortably at the machine. Instruct the patient to place the chin on the rest and the forehead against the bar. Select the eye to scan (right or left). Use auto-focus or manual focus to get a sharp image. Ensure the eye is centred in the scan window. Capture the scan: Confirm image quality: signal strength ≥ 6–7/10 is generally acceptable. Check for segmentation errors or artefacts. Save images to the patient's electronic record. The patients were assessed for CST on an OCT investigation basis (Before and after 3 injections). The outcome variable, i.e. change in CST on OCT, was measured at 3 months. OCT made in Poland with model REVO 60 was used. SPSS software, version 26.0, was used to enter and analyze the data that were gathered. Mean ± SD was calculated for

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quantitative data regarding the age, gender, duration/ type of DM, and CST before and after injections. Frequency and percentage were calculated for gender, diabetic retinopathy stage, grading, and risk factors of DME.T-tests were also applied, pie chart was constructed. Normality of data was checked by Shapiro-Wilk's test. A p-value<0.050 was considered significant.

RESULTS

Fifty people participated in the current study. Findings display the patients' mean age, BMI and DME (64.8 ± 14.2 years), (33.56 ± 7.85 kg/m2), (8.06 ± 4.23 years), respectively. According to gender distribution,33 (66%) of the 50 patients were men and 17 (34%) were female. Regarding diabetes type status, most of the patients were type-II DM 42 (84%), and 8(16%) were Type-I DM (Table 1).

Table 1: Demographic Information Related to Age, Gender, DME and Diabetes Status of Patients

Variables	Mean ± SD, Frequency (%)
Age	64.8 ± 14.2
BMI	33.56 ± 7.85
DME (Years)	8.06 ± 4.23
Gender	
Male	33 (66%)
Female	17 (34%)
Type of Diabetes	
Type I	8 (16%)
Type II	42 (84%)

Results demonstrate the risk factors of diabetic macular edema. The most common risk factor was hyperlipidemia 45 (90%), followed by hypertension 43(86%), anemia 42(84%), insulin dependent 37(74%), obesity 31 (62%), chronic renal failure 28 (56%) and smoking 26 (52%) (Table 2).

Table 2: Risk Factors Associated with Progression of Diabetic Macular Edema

Risk Factors	Frequency (%)
Smoking	26 (52%)
Obesity	31 (62%)
Hyperlipidemia	45(90%)
Insulin dependent	37 (74%)
Anemia	42 (84%)
Chronic Renal Failure	28 (56%)
Hypertension	43 (86%)

This study demonstrates that baseline CST was compared post-intervention of ANTI-VEGF at the 1st month,2nd month, and 3rd months; a significant difference was observed (Table 3).

Table 3: Patients with Diabetes with Anti-Vascular Endothelial Growth Factor (ANTI-VEGF) Treatment Showed CST on OCT

Central Subfield Thickness				
Before Treatment	CST after 1st Anti-VEGF (1st Month)	CST after the 2nd Anti-VEGF (2nd Month)	CST After 3rd Anti-VEGF (3rd Month)	p-value
442.6 ± 117.0	375.2 ± 57.4	337.3 ± 62.9	323.0 ± 65.4	0.001

DISCUSSION

Clinical research has shown that a decline in visual acuity corresponds with an increase in central macular thickness in DME, and that vision is improved by treatments that lessen retinal thickening. Macular edema that is not clinically obvious can be detected by OCT, and number of biomarkers acquired from OCT can be used to predict the severity, course, and visual prognosis of the condition. In this work, we examined new measures to assess change in the Central subfield thickness on OCT in DME eyes receiving intravitreal treatment during 3 months. There was a considerable change in visual acuity related to any given central macular thickness. While eyes with moderate edema showed considerable reduction in vision, several eyes with severe macular edema had extremely strong visual acuity. It has also been observed that there is not always a consistent increase in central macular spot thickness accompanied by an improvement in visual acuity, nor is there a consistent decrease in central retina thickness accompanied by a decrease in visual acuity. This suggests that in cases with macular edema associated with diabetes, OCT assessment may serve as a reliable proxy for visual acuity. OCT measures DME, the main clinical factor affecting visual acuity in DR, to evaluate and assess therapeutic response. There exists a somewhat negative relationship between retinal thickness and visual acuity [15]. In comparison to baseline, our study found a statistically significant gain in visual acuity and a statistically significant decrease in CST at the end of a 3-month follow-up period. Following anti-VEGF medication therapy, our results were in line with earlier studies that showed a reduction in Central subfield thickness [16]. In their research, Zhang *et al.*, studied variables influencing how individuals with DME responded to intravitreal anti-VEGF injections [17]. After three and six months of therapy, they saw improvements in BCVA from 4.78 and 5.52 letters and a decrease in central retinal thickness from 80.25 and 106.12 microns. Their response to the reduction in core retinal thickness led them to conclude that the most promising candidates for anti-VEGF therapy might be identified. This data could then be utilized to forecast a post-treatment improvement in BCVA. The effectiveness of bevacizumab as a single anti-VEGF injection as the main therapy for DME was established by Santos J et al., [18]. The study examined the effects of bevacizumab administered alone, in conjunction with intravitreal triamcinolone acetonide, and concerning macular laser photocoagulation. The outcome demonstrated that there

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was no discernible difference between these two treatments in terms of improving visual acuity while lowering central macular thickness. In clinical studies and clinical practice, central subfield thickness is frequently used to evaluate the effectiveness of intravitreal treatment in patients with DME. Nevertheless, prior research has shown that in DME eyes, CST and BCVA may not exhibit a linear association. Specifically, a decrease in CST below normative healthy values does not always translate into an increase in BCVA [19]. These results appear to support the idea that visual improvement is linked to an initial drop in retinal thickness caused by fluid absorption, but visual deterioration relates to further retinal thinning caused by retinal neurodegeneration. According to recent research, anti-VEGF medications are astonishingly successful at treating macular edema owing to diabetes, are safe, affordable, and easily accepted in clinical settings. Patients also seem to handle these medications well. Researchers have shown that bevacizumab(1.25mg) is effective in treating DME patients [20]. When intravitreal bevacizumab (1.25 mg) was used as a single dosage to treat proliferative DR, the area of leaky vessels significantly decreased. It was linked to a notable increase in average visual acuity. According to these studies, bevacizumab frequently reduces the thickness of macular tissue in the non-injected partner eye in bilateral DME, and 40% of injected eyes show improved visual acuity. Prior research indicates that when bevacizumab is coupled with dexamethasone for DME, visual acuity is significantly improved compared to bevacizumab monotherapy [21]. The effectiveness of using injectable bevacizumab (anti-VEGF) to treat diabetic macular disease in people with diabetes was reported in this study. The established effectiveness metrics on OCT were the central subfield thickness. According to recent research, initiating anti-VEGF medication early in the course of the disease greatly improves visual results. [21, 22]. Six months following therapy, patients who had presented sooner and had a shorter history of symptoms showed higher improvement in visual acuity and persistent decrease in central retinal thickness. In individuals with an extended medical history, however, there would be little difference between baseline values at the start of therapy and core retinal thickness and visual acuity three and six months later [23]. Based on these findings, early macular edoema therapy is recommended for better and longer-lasting morphological and visual outcomes. Therefore, early identification of decreased visual acuity is crucial for the management of recurrent ME. Further research demonstrated the relationship between baseline visual acuity and central subfield thickness following bevacizumab therapy. Younger individuals with DME were linked to considerably better visual acuities and decreased central retinal thickness after every six weeks of therapy, which is consistent with other research [24, 14]. Recurring intravitreal bevacizumab would not, however, result in discernible improvement in vision if the course of therapy is postponed for longer than six weeks.

This study had several limitations, including a relatively small sample size and short follow-up duration, which may limit the generalizability of the findings. Additionally, the study was conducted at a single center and evaluated only one anti-VEGF agent, which may not reflect outcomes with other treatment regimens. Future studies with larger multicenter populations and longer follow-up periods are recommended to better understand long-term treatment efficacy and visual outcomes. Further research comparing different anti-VEGF agents and combination therapies may also provide more comprehensive insights into optimal management strategies for diabetic macular edema.

CONCLUSIONS

It was concluded that anti-VEGF therapy significantly reduces central macular thickness in patients with diabetic macular edema (DME), as assessed by OCT. This indicates a positive anatomical response to treatment, reinforcing the efficacy of anti-VEGF agents in managing DME. Continued monitoring with OCT remains essential for evaluating therapeutic outcomes and guiding treatment regimens. The reduction in CST after anti-VEGF (vascular endothelial growth factor) treatment plays a critical role in improving outcomes for patients with retinal vascular diseases such as diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD), and retinal vein occlusion (RVO) and the reduction in CST helps patients in improved visual acuity, decreased retinal swelling, reduced risk of vision loss and better quality of life.

Authors' Contribution

Conceptualization: IMS
Methodology: IMS, IA, SAA
Formal analysis: IMS
Writing and Drafting: AAK, PAGK, ZG, SAA
Review and Editing: AAK, PAGK, ZG, SAA, IMS, IA

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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