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Bikbov M.M., Kudoyarova K.İ., Gilmanşin T.R., Mavlieva V.F.

DİABETİK MAKULYAR ÖDEMİ OLAN PASİYENTLƏRDƏ DEKSAMETAZON İMPLANTININ İNTRAVİTREAL TƏTBİQİNDƏN SONRA GÖRMƏ FUNKSİYASI VƏ HƏYAT KEYFİYYƏTİNİN DƏYİŞMƏSİ

Ufa Göz Xəstəlikləri Elmi-Tədqiqat İnstitutu, Ufa, Rusiya

Korrespondensiya üçün:
Kudoyarova Kseniya İqorevna, t.ü.f.d., 4-cü oftalmologiya şöbəsinin müdiri, Ufa Göz Xəstəlikləri Elmi-Tədqiqat İnstitutu, Ufa, Rusiya
E-mail: pasinkowa2012@yandex.ru
https://orcid.org/0000-0002-2148-4708

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Tədqiqatın anlayışı və dizaynı: Bikbov M.M.
Materialın toplanması və işlənməsi: Kudoyarova K.İ.
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Müəlliflər münaqişələrin (maliyyə, şəxsi, peşəkar və digər maraqları) olmamasını təsdiqləyirlər

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XÜLASƏ

Məqsəd – diabetik makulyar ödemi (DMÖ) olan xəstələrdə intravitreal deksametazon implantının tətbiqindən sonra görmə funksiyası və həyat keyfiyyətinin dəyişikliklərini qiymətləndirmək.

Material və metodlar
Tədqiqata DMÖ diaqnozu qoyulmuş 154 xəstə (154 göz) daxil edilmişdir. Müşahidə dövrü 6 ay davam etmişdir.
Xəstələr dörd qrupa bölünmüşdür: 1-ci qrup ilk dəfə DMÖ diaqnozu qoyulmuş xəstələr, 2-ci qrup ranibizumabın yükləmə dozalarına qarşı rezistentliyi olan xəstələr, 3-cü qrup aflibersept əsaslı anti-VEGF terapiyasına qarşı davamlı olan xəstələr, 4-cü qrup isə brolusizumabın beş intravitreal inyeksiyasından sonra makulyar nahiyədə davamlı tor qişa ödemi olan xəstələrdən ibarət idi. Bütün xəstələrə intravitreal deksametazon implantı (İVDİ) yeridilmişdir.
Həyat keyfiyyəti İVDİ-dən əvvəl və müalicədən 6 ay sonra tətbiq edilən Ümumdünya Səhiyyə Təşkilatının qısa formalı Həyat Keyfiyyəti sorğusu (ÜST HK) vasitəsilə qiymətləndirilmişdir.

Nəticələr
Müalicədən sonra bütün qruplarda HK göstəricilərində əhəmiyyətli dərəcədə yaxşılaşma müşahidə olunmuşdur: 1-ci qrup fiziki və psixoloji rifah sahəsində yüksək HK göstəriciləri nümayiş etdirmiş; 2-ci qrupda özünüqavrama və mikrososial dəstək sahələrində yaxşılaşma qeydə alınmış; 3-cü qrup özünüqavrama, mikrososial dəstək və sosial rifah üzrə ən yüksək göstəriciləri əldə etmiş; 4-cü qrup isə qiymətləndirilən bütün sahələr üzrə yüksək HK səviyyəsi nümayiş etdirmişdir.

Yekun
Diabetik makulyar ödem zamanı tor qişadakı dəyişikliklərlə bağlı görmə funksiyasının pozulması həyat keyfiyyətinin bir çox aspektinə mənfi təsir göstərir. Effektiv müalicə təkcə görmə itiliyini artırmır, həm də ümumi həyat keyfiyyətinin əhəmiyyətli dərəcədə yüksəlməsinə səbəb olur.

Açar sözlər: *həyat keyfiyyəti, diabetik makulyar ödem, intravitreal farmakoterapiya*

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CHANGES IN VISUAL FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH DIABETIC MACULAR EDEMA AFTER INTRAVITREAL ADMINISTRATION OF A DEXAMETHASONE IMPLANT

Ufa Eye Research Institute, Ufa, Russia

For correspondence:
Kudoyarova Ksenia Igorevna, PhD, Head of the 4th Ophthalmology Department, Ufa Eye Research Institute, Ufa, Russia
E-mail: pasinkowa2012@yandex.ru
https://orcid.org/0000-0002-2148-4708

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Concept and design of investigation: Bikbov M.M.
Material collection and processing: Kudoyarova K.I.
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SUMMARY

Purpose – to evaluate changes in visual functions and quality of life in patients with diabetic macular edema (DME) after intravitreal dexamethasone implant therapy.

Material and methods

The study included 154 patients (154 eyes) diagnosed with DME. The observation period was 6 months. Participants were divided into four groups: Group 1 included patients with newly diagnosed DME. Group 2: patients resistant to loading doses of ranibizumab. Group 3: patients resistant to aflibercept-based anti-VEGF therapy. Group 4 consisted of patients with persistent retinal edema in the macular area after five intravitreal injections of brolucizumab. All patients underwent Intravitreal Vitreous Implant of Dexamethasone (IVVID).
Quality of life was assessed using the short-form World Health Organization Quality of Life questionnaire (WHOQOL) administered before IVVID and 6 months after treatment.

Results

Following treatment, significant improvements in QoL domains were observed across all groups: Group 1 showed high QoL indicators in physical and psychological well-being; Group 2 demonstrated improvements in self-perception and microsocial support; Group 3 achieved the highest scores in self-perception, microsocial support and social well-being; Group 4 exhibited high QoL levels across all assessed domains.

Conclusion

Impaired visual function due to retinal changes in DME adversely affects multiple dimensions of quality of life. Effective treatment not only improves visual acuity but also leads to substantial enhancements in overall quality of life.

Key words: *quality of life, diabetic macular edema, intravitreal pharmacotherapy*

Diabetic macular edema is one of the most frequent and severe ocular complications of diabetes mellitus, often resulting in significant vision loss [1 – 3]. In developed countries, DME prevalence reaches up to 38%, depending on diabetes type and duration [4].

Currently, intravitreal anti-VEGF agents are the standard of care for DME, with efficacy and safety confirmed in large multicenter trials (RISE, RIDE, etc) [5]. In recent years, the dexamethasone intravitreal implant has emerged as an effective alternative.

In contemporary medicine, patient-reported outcomes – especially quality of life – have become essential indicators of treatment success Growing attention is being paid to patients' subjective satisfaction with their quality of life [6].

Quality of life encompasses physical aspects (health status, level of physical activity, access to medical care, and nutritious diet), emotional well-being (happiness, life satisfaction, availability of support from family and friends, and ability to cope with stress), social factors (quality and quantity of social interactions, sense of belonging to a community), economic conditions (financial stability, access to education and employment opportunities, standard of living), and cultural influences. QoL represents a person's overall sense of comfort and well-being – both in self-perception and in relation to the surrounding world [7].

To date, only a limited number of studies have demonstrated the significant impact of ocular pathology on patients' QoL [8]. Research specifically addressing QoL in retinal diseases remains scarce.

Quality of life assessment is commonly performed using the WHOQOL questionnaire, which evaluates multiple domains. Physical and psychological well-being, including the impact of physical pain on QoL, daily functioning, levels of activity and energy in everyday life, and sleep quality; self-perception, encompassing satisfaction with one's life and appearance; microsocial support, based on personal relationships and support from family and close friends; social well-being, which assesses perceived physical safety and security, adequacy of material resources, access to medical and social services, opportunities to acquire necessary information and skills, and availability of leisure and recreational activities [9].

Evaluating QoL indicators in patients with DME and monitoring their changes following intravitreal pharmacotherapy may serve as an additional criterion for assessing treatment efficacy.

Purpose – to investigate changes in visual function and quality of life in patients with DME before and after intravitreal dexamethasone implant therapy.

Material and methods

The study enrolled 154 patients (154 eyes) with DME secondary to type 2 diabetes (mean duration: 11.5 ± 3.5 years; mean age: 64.3 ± 4.9 years; target HbA1c level ≤ 7.4 ± 1.17%). The cohort comprised 78 women (50.6%) and 76 men (49.4%). All had compensated glycemia on oral antidiabetic agents. The observation period was 6 months.

Group 1 consisted of 44 patients with newly diagnosed DME who received an intravitreal dexamethasone implant as initial monotherapy. Group 2 included 40 patients (40 eyes) whose loading doses of the anti-angiogenic agent (Ranibizumab) produced no significant effect on retinal structure (central retinal thickness decreased by no more than 10% from baseline); these patients were subsequently switched to the dexamethasone implant. Group 3 comprised 42 patients (42 eyes) resistant to Aflibercept-based anti-VEGF therapy, who were also transitioned to the dexamethasone implant. Group 4 included 28 patients who continued to exhibit persistent macular edema after five intravitreal injections of Brolucizumab and subsequently received the dexamethasone implant. The control group (Group 5) consisted of individuals without visual impairment.

Quality of life was assessed using the WHOQOL questionnaire before treatment

and 6 months afterward. This instrument evaluates QoL across multiple domains, ensuring comprehensive coverage of the construct under study and capturing respondents' subjective experiences and active engagement in shaping their personal well-being [8, 9]. QoL scores were interpreted according to the WHO criteria: 0–20% - low; 21-40% - below average; 41-60% - average; 61-80% - elevated; 81-100% - high.

Statistical analysis was performed using descriptive statistics, one-way analysis of variance, and Duncan's post hoc test for multiple comparisons. Differences were significant at $p < 0.05$.

Results

Prior to treatment, Groups 1, 2, 3, 4 demonstrated reduced QoL scores, which correlated with their low baseline visual acuity, 0.25 ± 0.08, 0.04 ± 0.1, 0.38 ± 0.1, 0.1 ± 0.1, respectively **(Table 1)**.

At baseline QoL scores for physical and psychological well-being in Groups 1-4 were within the average range (**Figure 1**).

Six months after treatment, QoL scores for physical and psychological well-being reached high levels in Groups 1 and 4 (83.5% ± 7.4 and 82.5% ± 6.2, respectively). In Groups 2 and 3, QoL scores improved to 66.9% ± 8.4 and 78.9% ± 3.6, respectively.

Table 1. *Changes in visual acuity and QoL in patients with diabetic macular edema after intravitreal pharmacotherapy*

	Group I		*Group II*		*Group III*		*Group IV*	
	Before	After	Before	After	Before	After	Before	After
Physical and psycological well-being, %	52.1±3.0	83.5±7.4*	50.4±3.3	66.9±8.4*	54.3±9.1	78.9±3.6*	51.9±7.1	82.5±6.2*
Self-perception, %	56.2±5.8	77.5±6.7*	49.3±6.6	88.7±9.9*	53.4±6.1	89.3±3.8*	56.5±6.1	90.6±3.4*
Microsocial support, %	54.5±3.9	78.8±4.5*	53.5±3.9	82.7±8.7*	51.7±4.0	89.2±4.6*	57.1±8.4	89.9±5.4*
Social well-being, %	54.4±5.0	75.7±5.5*	52.8±5.6	77.8±6.2*	51.4±7.1	87.2±7.4*	51.6±6.0	89.1±6.1*
Visual acuity	0.25±0.08	0.65±0.1	0.04±0.1	0.3±0.1	0.38±0.1	0.46±0.1	0.1±0.1	0.5±0.1

Note: *differences are statistically significant compared to baseline data before intravitreal pharmacotherapy with the Ozurdex implant ($p < 0.05$).*

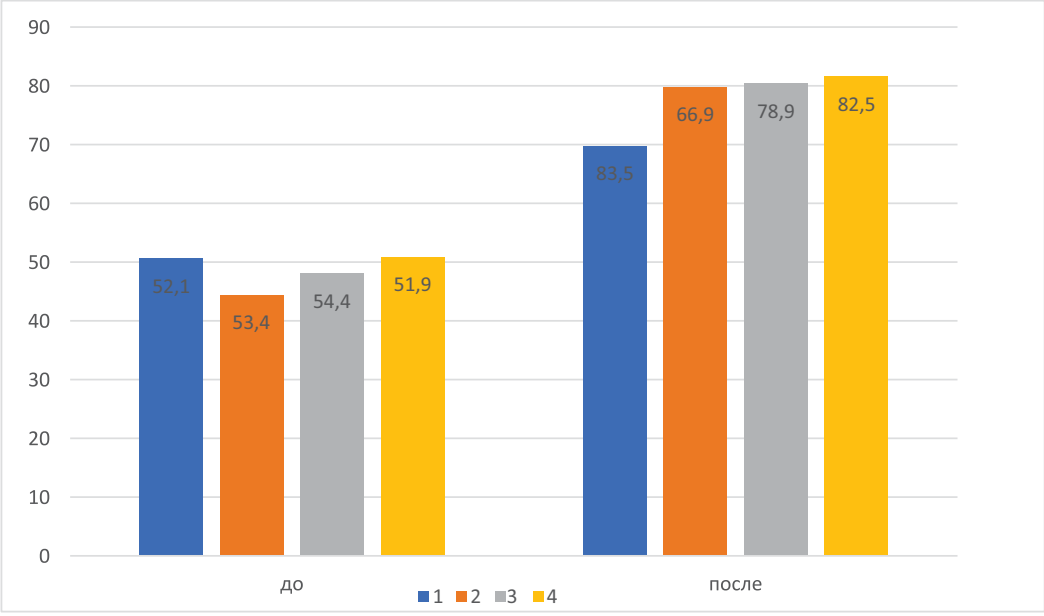

Figure 1. *Changes in physical and psychological well-being.*

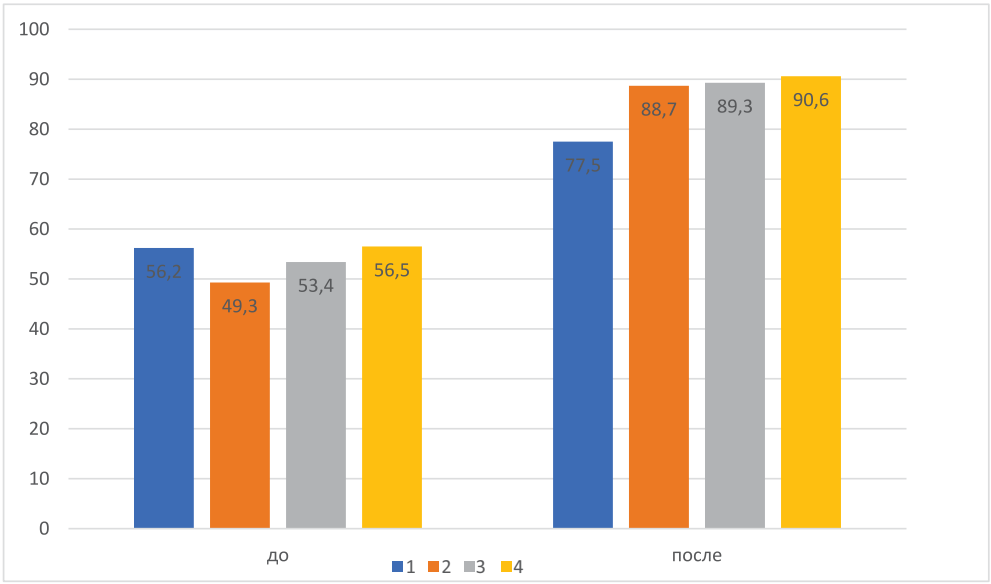

Figure 2. *Changes in self-perception.*

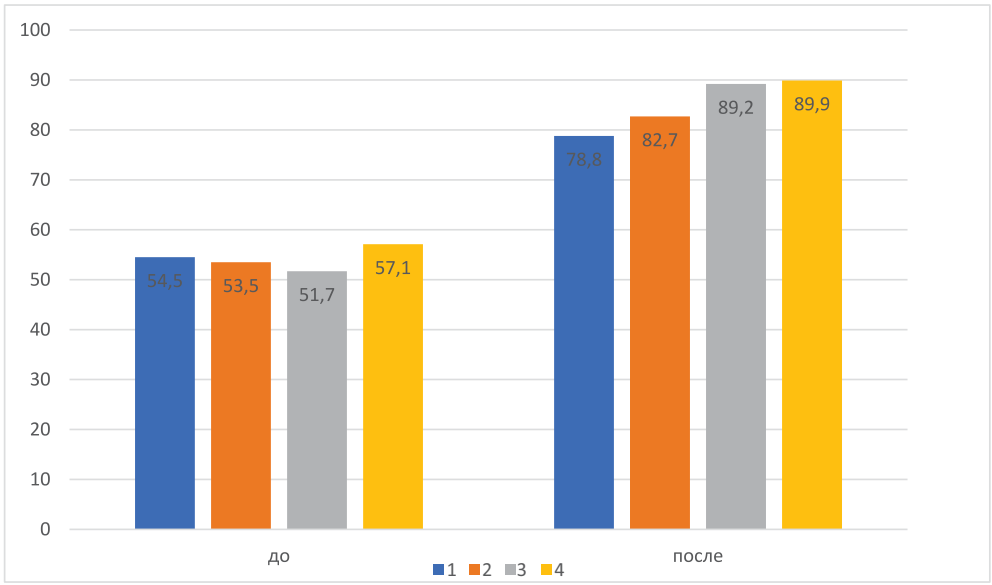

Figure 3. *Changes in microsocial support.*

At baseline, self-perception scores in Groups 1-4 were within the average range according to WHO QoL assessment criteria. Six months after treatment, self-perception scores rose markedly: in Groups 2, 3, 4, they reached 88.7% ± 9.9, 89.3% ± 3.8, and 90.6% ± 3.4, respectively, while in Group 1, the score increased to 77.5% ± 6.7 (**Figure 2**).

At baseline QoL scores for both microsocial support and social well-being were within the average range across all study groups.

Six months after intravitreal pharmacotherapy, microsocial support scores reached their highest levels in Groups 2, 3, 4, with values of 82.7% ± 8.7, 89.2% ± 4.6, and 89.9% ± 5.4, respectively. In Group 1, microsocial support scores improved to the "elevated" range according to WHO criteria (**Figure 3**).

With regard to social well-being, post-treatment scores in Groups 1 and 2 reached 75.7% ± 5.5 and 77.8% ± 6.2, respectively, while in Groups 3 and 4 they reached 87.2% ± 7.4 and 89.1% ± 6.1, respectively (**Figure 4**).

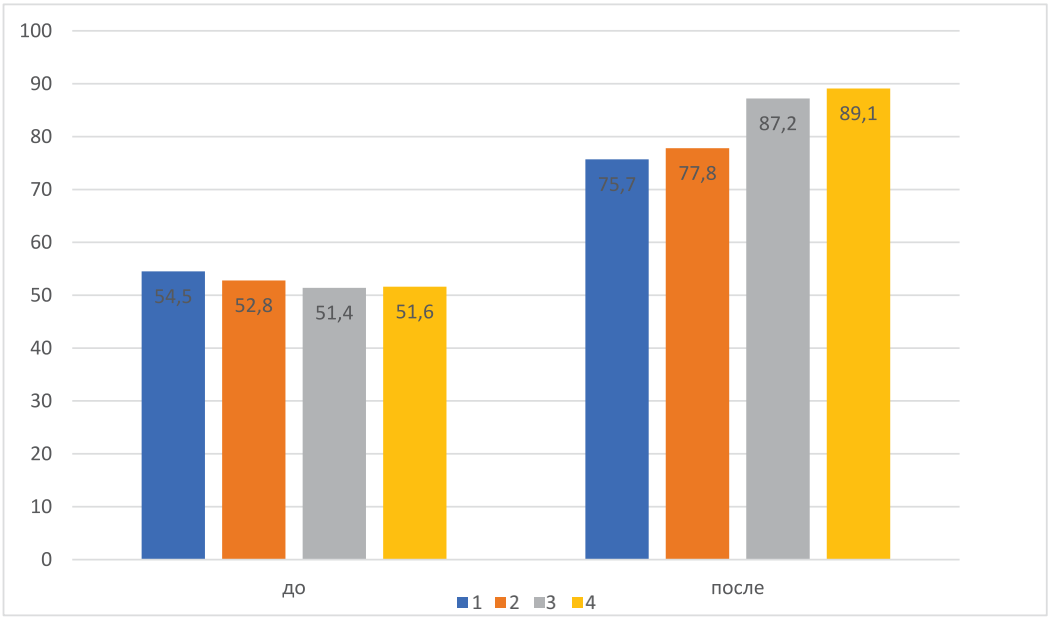

Figure 4. *Changes in social well-being.*

Discussion

Our findings on the improvement in patients' quality of life following intravitreal pharmacotherapy are consistent with results reported by other researchers [10, 11]. For instance, in a study comparing quality of life in patients with DME with native vitreous versus those who had undergone vitrectomy (avitria), quality of life scores after intravitreal Ozurdex injection were higher in the vitrectomized group than in those with an intact vitreous body [11].

In our comparative analysis of QoL indicators between DME patients (Groups 1-4) prior to treatment and those in the control group (Group 5), we observed that QoL scores in the DME groups were approximately twice as low as those in the control group (**Table 1**).

Following the course of intravitreal pharmacotherapy, improvements in QoL scores in the studied Groups 1-4 correlated with increases in visual acuity to 0.65 ± 0.10, 0.30 ± 0.10, 0.46 ± 0.10, and 0.50 ± 0.10, respectively.

It is known that glucocorticosteroid drugs can contribute to an increase in IOP and influence the development of lens opacity [12, 13]. Studies have shown that in the group of early switching from an anti-VEGF drug to an implant with dexamethasone, IOP increased in 9.7% of cases, in the late switching group - in 26.3% [14]. In our study, a similar picture was observed: the IOP level increased in 6.8% of patients in group 1, 12.9% in patients in group 2, 11.1% in patients in group 3, and 8.5% in patients in group 4 of the study. After instillation of hypotensive drops, IOP stabilized in all cases. In patients of group 1, IOP remained stable throughout the entire observation period

Conclusion

The development of DME and the consequent decline in visual acuity in patients with diabetes mellitus negatively impacts quality of life across all domains, reducing key indicators to the "average" range according to the WHO classification (49.3-57.1%). After treatment with the dexamethasone implant, QoL scores in all groups improved significantly ($p < 0.05$), reaching WHO-defined "elevated" and "high" levels across all measured domains: physical and psychological well-being – 66.9%–83.5%; self-perception – 77.5%–90.6%; microsocial support –79.8%–89.9%; social well-being – 75.7%–89.1%.

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